# UNITED STATES FEDERAL COURT DISTRICT OF PUERTO RICO

BERKEY INTERNATIONAL, LLC,	§	
Plaintiffs,	§	
	§	CIVIL CAUSE NO.
v.	§ _	
	§ –	
ENVIRONMENTAL PROTECTION AGENCY,	§	
MICHAEL S. REGAN, Administrator, CHRISTINE	§	
TOKARZ, and DAVID COBB, in their official capacities	§	JURY TRIAL
Defendants.	§	DEMANDED

# PLAINTIFF'S ORIGINAL COMPLAINT AND APPLICATION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION AGAINST THE ENVIRONMENTAL PROTECTION AGENCY

Plaintiff Berkey International, LLC files its *Original Complaint* against the Environmental Protection agency ("EPA") for its violations of the Administrative Procedures Act ("APA") and due process involving Berkey water filters. Plaintiff also simultaneously files *Plaintiff's Memorandum in Support of Application for Temporary Restraining Order, Preliminary Injunction, and Permanent Injunction* incorporates it by reference.

To summarize, the public has relied on Berkey mechanical water filters without incident or regulation by the EPA for twenty-five years. Suddenly and without notice in 2022, the EPA demanded Plaintiff register its mechanical filter products, first as "pesticide devices" and then as "pesticides" without authority and without complying with the APA's rulemaking process.

The EPA's failure to operate using plain language and in compliance with the APA notice rule has caused Plaintiff devastating damage. Plaintiff asks this Court to enjoin the EPA from enforcing pesticide registration requirements against Plaintiff's mechanical filtration systems by issuing a restraining order preventing enforcement of the EPA's determination that Berkey filters are pesticides and barring issuance of further SSUROs to Plaintiff and its allied Berkey network, dealers, and vendors. Plaintiffs further seek a declaration that the classification of Berkey filters as a pesticide is arbitrary, capricious, an abuse of discretion, and constitutes a clear error.

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#### III. PARTIES

- 1. Plaintiff Berkey International, LLC, ("Berkey Int'l" or "Berkey") is a Puerto Rican limited liability company doing business in Puerto Rico. The members of Berkey Int'l are the beneficiaries of the JMDBC Trust. James "Jim" Shepherd is the president of Berkey Int'l. Parties may serve Berkey Int'l through its counsel of record, the undersigned.
- 2. Defendant Michael S. Regan is the administrator of the Environmental Protection Agency ("EPA") and is sued in his official capacity. Regan may be served at the EPA headquarters at 1200 Pennsylvania Avenue, N.W. Washington, DC 20460 or wherever he may be found.
- 3. Defendant Environmental Protection Agency is an agency of the United States Government which may be served at 1200 Pennsylvania Avenue, N.W. Washington, DC 20460.
- 4. Defendants Christine Tokarz and David Cobb are all EPA personnel to be enjoined in their official capacities for their individual *ultra vires* actions taken outside of their statutory authority and, in the alternative, for abusing their Constitutional authority as federal officers. They may be contacted through the EPA at the address above, or wherever they may be found. *See Larson v. Dom. & For. Com. Corp.*, 337 U.S. 682, 716 (1949); *Ex parte Young*, 209 U.S. 123, 155–56 (1908).

#### IV. JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), which provides subject matter jurisdiction based on federal questions. This Court's review of Defendants' unlawful actions arises under the Administrative Procedures Act ("APA"), which gives this Court jurisdiction to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or that is "contrary to constitutional right, power, privilege, or immunity," and specifically allows reviewing courts to provide injunctive relief. 5 U.S.C. §§ 553, 701–06.

- 6. This Court has jurisdiction to grant declaratory relief, pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, 5 U.S.C. §§ 705–06, Federal Rule of Civil Procedure 57, and the Court's inherent equitable powers.
- 7. This Court has jurisdiction to review Defendants' unlawful actions and enter relief under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), at 7 U.S.C. § 136n.
- 8. This District Court has authority to award attorney fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.
- 9. Venue is proper in the United States District of Puerto Rico pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events giving rise to the claims occurred in the district, a substantial part of property that is the subject of the action is situated in the district, and Plaintiff has been damaged in this district.

#### V. CONDITIONS PRECEDENT

10. The Plaintiff in the above-captioned matter hereby affirms that, as of the filing date of this Original Complaint, all conditions precedent required by the Federal Rules of Civil Procedure ("FRCP") have been duly satisfied to initiate legal proceedings in this jurisdiction.

#### VI. FACTS

#### A. History of Water Filters.

11. Humans have been using various techniques to filter water since antiquity. As recorded in the New Testament, the apostle Paul made what the EPA would call pesticidal claims about the addition of a little wine to water in his first letter to Timothy "for the sake of his stomach and frequent ailments."

<sup>&</sup>lt;sup>1</sup> See 1 Tim. 5:23, "No longer drink only water, but use a little wine for the sake of your stomach and your frequent ailments." ESV.

- 12. The Sushruta Samhita (3rd century CE, or earlier) detailed various methods to purify water, including boiling and filtering water through sand, coarse gravel, and charcoal filters (Baker & Taras, 1981). These writings suggest that these ancient people sought better tasting water, with the assumption that better tasting water was also cleaner water. Those filtering techniques paved the way for later understandings about water sanitation.
- 13. The Greek scientist Hippocrates invented the first early water filter, known as the 'Hippocratic sleeve', which used a cloth bag to filter out the impurities from the Greek aqueducts. The water was boiled and poured through the cloth, which trapped the sediments that were causing the bad taste and smell, creating cleaner, better tasting drinking water.
- 14. Luc Antonio Porzio published the first known illustrated description of sand filters in 1685, which proposed multiple-filtration through sand, preceded by straining and sedimentation, a device that used gravity-fed mechanical filtering.<sup>2</sup>
- 15. In 1746, Joseph Amy of France received the first patent for a water filter, placed on the market in 1750, using wool, sponge, and charcoal to perform mechanical filtering.
- 16. In 1804 the first actual municipal water treatment plant designed by Robert Thom, was built in Scotland, where water was treated by a sand filtration process; potable water was available to every household in Scotland within a few years.
- 17. In 1827, John Doulton invented the ceramic water filter to remove bacteria from drinking water, and then the Doulton Manganous Carbon Filter in 1862, which tied in with the French chemist, Louis Pasteur's research into bacteria, and was one of the first carbon cartridge type filters. By 1835, Henry Doulton's cartridges could remove bacteria with 99% efficiency using porous ceramic bowls and diatomaceous earth to filter water, resulting in a commission from Queen Victoria for Doulton to provide a filter for her royal household.

<sup>&</sup>lt;sup>2</sup> Mays, Larry, A brief history of water filtration/sedimentation, Water Science & Tech: Water Supply, V.13.3, 2013.

- 18. The difference between those filters and Berkey filters is qualitatively no different, except that Berkey filters use a far more efficient and robust construction, and no manufacturer or resident of the early United States had to receive permission to use these devices from the federal or state government. Certainly, those early citizens would claim the right to filter their own water using mechanical filter processes employed since antiquity.
- B. Background Berkey is a famous American brand known for its quality water filters created and sold by Plaintiff, protected by patents and trademarks.
- 19. Plaintiff Berkey International, LLC ("Berkey Int'l") is a Puerto Rico based manufacturer of Berkey filtration systems, which holds a license to manufacture Berkey filtration systems which include Berkey filter elements, the subject of the EPA's concerns. Exh. A, B, & D.
- 20. Berkey's signature product is its Black Berkey Filter. Black Berkey filters employ proprietary, trade-secret technology in gravity-fed filters which employ microscopic pores that mechanically trap and remove contaminants from water. Berkey distributes its filters to authorized retailers. Exh. A. The mechanical water filters use a registered pesticide as a treated article. The registered pesticide only protects the mechanical filter and has no pesticidal purpose. Exh. A.
- 21. New Millennium Concepts, LTD, ("NMCL") is a distribution company working with Berkey International, holding intellectual property rights to the Berkey water filters. James Enterprises sold Berkey products while doing business as Berkey Filters for decades before these events transpired.
- 22. During Berkey's quarter-century existence, the EPA never sought to enforce FIFRA regulations against Berkey products as pesticides until 2022. Exh. A. As explained below, Congress created FIFRA to regulate pesticides used in agricultural products. Exh. C-1. EPA guidelines state that mechanical filter construction warrants regulation only as a device, and not a pesticide. Exh. C-2 & C-6.

- 23. In May of 2022 Cristine Tokarz confirmed to NMCL both verbally and in a closeout letter that Black Berkey filter elements were a Pesticidal Device writing "it appears that you are marketing a pesticide device" and asserted verbally during a phone call "I can assure you though, these are pesticide device claims, I have no doubt about that in my mind." Exh. A, B-2.
- 24. Unfortunately, unauthorized retailers and knockoffs of Berkey's products abound; all attempting to benefit from Berkey's reputation for excellent, reliable products. Berkey struggles with knockoff filters because a knockoff competitor can market mundane carbon filters constructed to fit into the Berkey filter system as a form-and-fit physical replacement, but not a "functional" replacement. The knockoffs are made with low quality materials that lack Berkey's proprietary structural filtration maze and consequently are unable to perform as Berkey filters do. The knockoff filters are designed to imitate the appearance of Black Berkey filters but the cheap and ineffective materials are not readily discernable to the average consumer when compared to the components of authentic Berkey filters. Compounding matters, water filtration is often not observable to naked human senses. Lab tests are generally necessary to ascertain the degree of filtration provided by any given product. As a result, consumers are totally dependent on reputation built on proven empirical reliability and proven performance over the decades. Imitation filters masquerading as Berkey products, traffic off Berkey's reputation for scientifically demonstrated excellence, while potentially endangering consumers via application of unreliable methods of filtration. In this way, purveyors of knockoff and imitation Black Berkey filters can market them at a fraction of the cost of genuine Berkey filters. Consumers cannot easily distinguish between genuine Berkey filters and inferior knockoff filters, yet they are left to bear the burden of adverse health consequences. Exh. A & B.
- 25. Berkey struggles with counterfeit look-alike filter elements because a counterfeiter can market mundane carbon filter elements as genuine Black Berkey replacement filter elements,

though these elements do not function as Berkey filters do, though they have a similar or even identical appearance and mechanically fit into Berkey systems. Currently, NMCL is suing four foreign companies that are fraudulently selling counterfeit filters in the US and abroad. Exh. A.

- 26. To Plaintiff's knowledge, the EPA has not engaged in enforcement actions against any unauthorized sellers of Berkey knockoff or counterfeit filters but is singling out genuine Berkey products for enforcement.
- 27. The EPA is applying its regulations and enforcement actions unevenly. It targets Berkey while neglecting unauthorized knockoff sellers and counterfeit manufacturers. The EPA's actions are destructive to Berkey and create a void that is currently rewarding low-value knockoffs and counterfeit filters, jeopardizing public health. These low-quality filters do not perform as well as Berkey products and are typically made by overseas manufacturers, often outside of any proper regulatory apparatus, and sold by entities cloaked in anonymity. Thus, they can operate without fear of being sued in the United States or being held accountable by the EPA.
- 28. By targeting Berkey, a long-time American brand known for quality and a manufacturer of scientifically-validated filtration systems, the EPA is frustrating its purpose. By crushing Berkey's market share and ensuring that customers are diverted to unregulated, untested, unsafe, counterfeit filters sold to unsuspecting customers, by fraudulent water filter element sellers who are illicitly trading on Berkey's reputation,<sup>3</sup> the EPA is making the market less safe for American consumers and rewarding international intellectual property theft. Exh. A & B.

#### C. Regulatory Background - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

29. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. Ch. 6 § 136) was passed in 1947, amended in 1972 by the Federal Environmental Pesticide Control Act

<sup>&</sup>lt;sup>3</sup> Indeed, one knockoff filtration system deliberately brands itself as "Berkey Black" a name deliberately designed to be confused with Berkey's signature "Black Berkey" filtration system.

(FEPCA) and again by the FIFRA Amendments of 1988. FIFRA requires that all pesticides be licensed by the Environmental Protection Agency before they may be sold or distributed in commerce. 7 U.S.C. § 135j(a). By contrast, manufacturers of pesticidal devices need only register the manufacturing facility, not the devices themselves. § 135e. Exh. C-1.

- 30. According to the EPA, since 1975, the EPA has interpreted "devices" to include "water filters (*except those containing substances or mixtures of substances which are pesticides*)." Part 162—Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, 40 Fed. Reg. 28242, 28266 (July 3, 1975) (emphasis added).
- 31. As the EPA explained in a 1976 guidance document, if an "article incorporates a substance or mixture of substances *intended to prevent, destroy, repeal, or mitigate any pest*, it is considered to be a pesticide." Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976) (emphasis added). Exh. C-2.
- 32. Under the heading "Products Commonly Mistaken as Devices," EPA notes that:

Where a product that would otherwise be a device also incorporates a pesticidal substance, it may be considered a pesticide product. For example, a filter that physically traps microbial pests (generally a device) would be an antimicrobial pesticide product if it also incorporated a pesticidal substance that kills those pests to improve the efficacy of the entire system. (emphasis added)

- U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides, (last updated Dec. 29, 2022).<sup>4</sup>
- 33. The same website also explains that if a water filter "contains any substance <u>intended to</u> <u>disinfect the water</u>, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed." (emphasis added).
- 34. Berkey filters were not considered a *pesticide* until 2022, but rather *pesticide devices*, because *they do not use a pesticidal substanc*e to kill waterborne pests in the effluent water, nor utilize a pesticide to improve the efficacy of the entire system. Instead, they trap microbiological

<sup>&</sup>lt;sup>4</sup> https://www.epa.gov/pesticides/pesticide-devices-guide-consumers (last visited August 22, 2023).

contaminates within the filter element by utilizing a tortuous maze of micropores to separate pests from the effluent water.

- 35. In 2000, the EPA adopted a "Treated Articles Exemption to Antimicrobial Pesticides" policy, announced by Pesticide Registration Notice 2000-1, dated March 6, 2000. This policy exempts EPA registration articles that are treated with already registered pesticides, the purpose of which is solely to protect the articles themselves (and not to support health claims). Exh. B-20. 36. The EPA lists 127 registered pesticides that utilize silver on its website. This list comprises such items as plastics and cloth as well as various media utilized in the manufacture of water filter elements. However, this list does not include manufacturers of products that utilize the listed registered pesticides to protect the products themselves. The media registered as pesticides on this website are primarily utilizing the media to clean the water. There are no water filters that utilize the various media listed to only protect the filter elements themselves on the entire list, demonstrating that the EPA has not previously regulated water filters as it now suddenly asserts.
- 37. The media containing silver utilized in the Black Berkey formulation is registered to protect the media itself and is utilized to protect the Black Berkey element. Exh. A. Testing conducted on Black Berkey elements has verified that the minuscule amount of silver in the filter element formulation does not kill pathogens in the water but merely protects the filter itself. Exh. A.
- 38. The EPA is applying its regulations capriciously and unevenly. It targets Berkey filters as pesticides because they use a registered form of silver to protect the elements of the filter but ignoring other outdoor, camping and emergency filter elements that make similar pesticidal claims that also utilize a similar registered pesticide to protect the filter element itself from bacterial growth. Exh. A.

<sup>&</sup>lt;sup>5</sup> See https://ordspub.epa.gov/ords/pesticides/f?p=113:6::::P6 XCHEMICAL ID:3769.

- 39. The EPA ignores the distinction between registered pesticides and treated articles. Registered pesticides are products that are designed as pesticides, to kill microbes, insects, or other pests, to support human, animal, or plant health. Treated articles, by contrast, are products that contain parts or objects that are treated with pesticides or contain pesticides for the express purpose of protecting the product itself (such as mosquito nets or seeds pretreated with registered pesticides). Berkey filters containing silver are properly classified as treated articles because the silver is part of a registered pesticide that is used to preserve the mechanical filtration maze itself. The silver does not act a pesticide for purposes of killing waterborne pathogens within the water, nor does Berkey make any such claim.
- 40. Berkey filters were considered treated articles until 2022, because they are treated by a registered pesticidal product designed to protect the filter itself but contain no product that acts as a pesticide to kill pathogens in the effluent water traveling through the filter. Exh. A, B, & D.
- 41. In 2010 the 111<sup>th</sup> Congress created Public Law 111-274, known as the "Plain Writing Act of 2010". While the Act does not cover regulations, three separate Executive Orders emphasize the need for plain language: E.O. 12866, E.O. 12988, and E.O. 13563. This law requires that Government documents explain to the public how to comply with a requirement the federal government administers or enforces. Such documents must be written clearly and explain to the public how to comply with a requirement that the federal government administers or enforces. The term "plain writing" means writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience. While the EPA states that it writes new documents in plain language, it has substantially failed to update its communications and guidance that were issued prior to 2010.

- D. After disregarding Berkey filters for decades, the EPA suddenly reinterpreted its prior rules without notice or opportunity to hear stakeholder input, to Plaintiff's detriment.
- 42. Around April 28, 2022, the Environmental Protection Agency stopped an inbound NMCL container at customs to conduct an EPA inspection. An NMCL shipper, Charles Shayer, set up a call on for May 3, 2022, with Christine Tokarz, a Region 8 EPA inspector.
- 43. On May 1, 2022, EPA agent Tokarz confirmed the upcoming call by email, writing, "This is a virtual compliance call to discuss devices and compliance with FIFRA regulations." She also included links to EPA Guidance for pesticide devices. Exh. B-1.
- 44. On or about May 3, 2022, Tokarz stated during the phone call that Berkey products may be in violation of 7 U.S.C. § 136j(a)(1)(F) for distributing a device that is misbranded for allegedly "potentially false or misleading pesticidal claims." Referring to her review of the website and packaging, she further stated, "I can assure you, though, these are pesticide device claims, I have no doubt about that in my mind". She concluded the call saying "My goal here is to help American companies stay in business and get them into compliance, not to enforce a bunch of, you know, record keeping rules. That's not really my goal". Exh. B.
- 45. On or about May 4, 2022, Berkey Int'l President James Shepherd learned that the EPA considers that the inclusion of a pesticidal device (Black Berkey filters) within the same packaging of the water filtration system makes the entire system a pesticidal device that requires registration of the Berkey manufacturing facilities. Exh. A. Shepherd's EPA consultant informed him that since the COVID-19 era, the EPA was considering reinterpreting its regulations on exempt devices, removing the device exemption for any water filters that claimed to remove viruses, while giving no guidance to stakeholders in affected companies or taking their input. Exh. A.
- 46. Around this same time, Shepherd learned that the EPA may be reinterpreting its regulations and begin targeting water filter manufacturers making virus removal claims and perhaps pathogenic bacteria removal claims as well. Neither he nor other Berkey manufacturers were aware

of any formal change to the relevant laws or regulations. Further, Shepherd learned that the EPA might now consider mechanical outdoor water filters that can filter raw untreated water and remove virus and other waterborne pathogens to be pesticides. Exh. A.

47. About May 5, 2022, Tokarz issued a letter<sup>6</sup> concluding an investigation of a shipment by NMCL which included the following conclusion:

Under FIFRA section 7, all pesticide devices sold or distributed in the United States must be produced in a registered establishment. 7 U.S.C. §§ 136e(a), 136j(a)(2)(L). A pesticide device is defined as any instrument or contrivance that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life...

Exh. B-2 (Tokarz Close Out Letter), Exh. C-1.7

- 48. For the last 25 years, Berkey has not needed to register its manufacturing facilities. Berkey has used original equipment manufacturers ("OEM") which had to be registered. The EPA considered Berkey to be manufacturing a pesticide device because the filter box, which had the establishment number, was placed inside the system box. The EPA requested that, because Berkey had the manufacturer's filter box with the establishment number inside the system box, Berkey get an establishment number and print that number outside of the system boxes. Exh. A.
- 49. In May and June of 2022, in an effort to mollify Tokarz and the EPA, NMCL requested EPA establishment registration numbers for its manufacturing facilities.<sup>8</sup> The EPA issued Establishment Nos. 101921-CO-1 and 102008-PR-1, respectively, shortly thereafter and Plaintiff communicated that development to Tokarz in support of Berkey's position that it was compliant

<sup>&</sup>lt;sup>6</sup> While Vendor B no longer is under a SSURO, Plaintiff asks the Court to note that Vendor B's SSURO regarded the same subject matter as the SSURO for Plaintiff Berkey Int'l. Even though Vendor B's SSURO was ended, which regarded the same subject matter as Plaintiff's SSURO, the SSURO for Plaintiff still remains.

<sup>&</sup>lt;sup>7</sup> The laws cited by Tokarz do not show that a pesticide device must be produced in a registered establishment. §136e(a) requires registration of establishments that produce *pesticides*, but nowhere requires registration of establishments producing devices; § 136j(a)(2)(L) requires producers to refrain from violating § 136e.

<sup>&</sup>lt;sup>8</sup> "The EPA Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) company number is a unique identification number assigned to each company which applies for product registration, supplemental distribution or establishment registration." (from <a href="https://usepa.servicenowservices.com/ecss?id=kb">https://usepa.servicenowservices.com/ecss?id=kb</a> article <a href="https://usepa.servicenowservices.com/ecss?id=kb</a> article <a href="https://usepa.servicenowservices.com/ecss?id=kb</a> article <a hre

with the new demand for Berkey filters to be treated as a pesticide device, because the establishment numbers were now being shown on the outside of the packaging for each Berkey filtration system. Tokarz denied that those actions satisfied FIFRA. Exh. A, B-3.

- 50. About June 8, 2022, NMCL filed a 30-day report making NMCL compliant with the EPA's requirements for Pesticide Devices. Exh. A, B-3 (Email Thread on NMCL 30-day Report, Texado Establishment Number).
- 51. After the EPA's demands for pesticide device compliance, Berkey verified that all its claims were accurate according to the test data for removing waterborne pathogens. Exh. A.

#### E. The EPA changed course and began issuing SSUROs for pesticides.

- 52. From 2006 until the time that the EPA began targeting Berkey, James Enterprises sold Berkey products while doing business as Berkey Filters. During an EPA inspection on November 22, 2022, the staff of James Enterprises witnessed EPA inspectors take note of language on products that suggested pesticide claims. EPA Region 8 contact Tokarz informed James Enterprises personnel that she knew that Berkey filters were sold with virus claims, and the EPA was cracking down on such claims. Because of the inspection, NMCL again checked its virus removal claims and testing to verify they contained no misleading contaminant-removal claims and found that all claims could be verified by independent third-party lab tests. Exh. A.
- 53. On or about December 2, 2022, Tokarz wrote to James Enterprises,

EPA believes that the products listed below may be subject to FIFRA regulations: *Black Berkey Filters, Sport Berkey Replacement Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey* Water *Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, the Berkey Light Water Filters, and the Sport Berkey Water Bottle.* Please provide the requested documentation on each of the 9 separate products identified above.

Exhibit B-5 (Tokarz Email, December 2, 2022).

<sup>&</sup>lt;sup>9</sup> "Initial Reports: An initial report is due to EPA 30 days after the company is notified of their pesticide-producing or device-producing establishment number." (<a href="https://www.epa.gov/compliance/pesticide-establishment-registration-and-reporting">https://www.epa.gov/compliance/pesticide-establishment-registration-and-reporting</a>. Last visited, 11/21/2023.)

- 54. On or about December 27, 2022, EPA agent David Cobb signed an EPA Stop Sale, Use or Removal Order (SSURO) to James Enterprises, in Docket Number: FIFRA-08-2023-0011. This SSURO requires James Enterprises to respond within 30 days and then on a monthly basis thereafter to Christine Tokarz. Exh. B-4. This was the first SSURO alleging that Berkey water filter systems were unregistered and misbranded pesticides. Exh. A.
- 55. This SSURO to James Enterprises was an unwarranted surprise, as the EPA did not provide any sort of explanation, notice, or guidance, before issuing the order. Exh. A. The SSURO stated that it is based in part on a statement found on a foreign European website claiming that Black Berkey elements utilized silver *to protect the filter*, as well as filter labeling that stated, "Black Berkey Purification Elements: VIRUSES: >99.999% PATHOGENIC BACTERIA (AND SURROGATES) >99.9999% -Exceeds Purification Standard (Log 6): *Bacillius atrophaeus* (Anthrax Surrogate)." Exh. B-4.
- At no point has any Berkey-authorized entity claimed that the silver in its products is intended to be used for any purpose other than to protect the filter itself. Berky has never claimed pesticidal applications for silver in its products. Exh. A & B. The EPA's SSUROs rely on a statement made by a foreign retailer of Berkey products which made claims that may be acceptable in the European Union but are not claims made by Berkey in the United States. Nevertheless, inexplicably, Berkey is now being held to account for claims made about its products by international actors over whom it has no control. Exh. A. The EPA has not shown that Plaintiff or SSURO recipients have had ownership, control, or custody over any products using or claiming to use silver as a pesticide, or any products from the foreign retailers.
- 57. Though the SSURO to James Enterprises recognized that the mention of silver is in the context of protecting the filter at para. 26, para. 27 concludes "[t]hese claims indicate that **Berkey**

Black<sup>10</sup> Filter Products are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u)." This conclusory statement does not identify the "substance or mixture of substances" in Berkey's filter which allegedly constitute the regulatable pesticides. The drafter of the SSURO seems to have latched onto the mere presence of silver and shoehorned it into the definition of "pesticide", ignoring the silver's stated purpose, even though the SSURO repeats the language of the European website: "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water." Exh. B-4, para. 26. This statement is not a pesticidal claim warranting regulation, even if Plaintiff had ownership, custody, or control over the European website when it made the above claim. Further, Plaintiff believes the name "Berkey Black" which is a knockoff product whereas the real name of the product is "Black Berkey", utilized in the SSURO indicates that Defendant Tokarz utilized a lawsuit that used that same incorrect term, to draft the SSUROs. See Exh. A & B6-11.

- 58. Prior to the SSURO to James Enterprises, all NMCL and Berkey's discussions and correspondence with the EPA were based upon a long-time joint understanding that Black Berkey elements were treated articles or "pesticide devices" and never "pesticides," making them exempt from registration as a pesticide. Exh. A.<sup>11</sup> The SSURO turns that understanding on its head.
- 59. In mid-January of 2023, Berkey and James Enterprises agreed that, rather than fighting with the EPA about whether Black Berkey products were a pesticide or pesticide device, which could take years to determine, they would work with the EPA in good faith by agreeing to be

<sup>&</sup>lt;sup>10</sup> As noted supra, the term "Berkey Black" is a name used by knockoff filter marketers to sell fake Black Berkey filters. Troublingly, "Berkey Black" was used a dozen times in the SSURO.

<sup>&</sup>lt;sup>11</sup> Treated articles are not registered or identified; pesticidal devices must be made in a EPA-registered establishment; pesticides must be individually registered. Exh. A.

classified as merely a treated article and would remove all testing references and statements that could be construed to indicate that the filters could remove waterborne pathogens from their literature, advertising, websites, and packaging. Exh. A.

- 60. Undeterred by such communications with Berkey and James Enterprises, Tokarz in bad faith continued to target Berkey, its dealers and vendors and issuing multiple SSUROs, all of them based on allegations that Berkey products are unregistered and misbranded pesticides. Exh. A.
- 61. On or about February 3, 2023, Keriema Newman digitally signed for Carol L. Kemker when issuing an SSURO, Docket Number: FIFRA-04-2023-0700, to Vendor B, an OEM manufacturer for NMCL. Exh. B-6 ("Vendor B SSURO"). The Vendor B SSURO alleged that Vendor B violated FIFRA by selling the Black Berkey Filter Products, which the EPA considered to be unregistered, misbranded pesticides. Vendor B also agreed to adopt the "treated article" approach and remove all references to testing and statements that could be construed to indicate that the filters removed waterborne pathogens. Exh. A, B-6.
- On March 3, 2023, David Cobb issued an SSURO, Docket Number: FIFRA-08-2023-0015, to Fritz Wellness, a Berkey dealer, requiring a monthly response to Tokarz. It alleged Fritz Wellness violated FIFRA by selling the Black Berkey Filter Products, which the EPA considered to be unregistered and misbranded pesticides. Exh. B-7. Again, the knockoff filter name "Berkey Black" was used in the SSURO. Exh. A, B-7.
- 63. On March 6, 2023, David Cobb issued a SSURO, Docket Number: FIFRA-08-2023-0014, to Eden Valley Farms LLC, a Berkey dealer. Exh. B-8 ("Eden Valley Farms SSURO") requiring a monthly report to Tokarz. The SSURO followed the now-established pattern and alleged that Eden Valley Farms LLC violated FIFRA by selling Black Berkey Filter Products, which the EPA considered to be unregistered and misbranded pesticides. Exh. A, B-8.

- 64. On March 7, 2023, David Cobb issued an SSURO, FIFRA-08-2023-0017, on Mountain Mama Natural Foods, Inc., a Berkey dealer, again alleging that Black Berkey filters are unregistered and misbranded pesticides and required a monthly report to Sherrie Kinard. Exh. B-9. Again, the knockoff filter name "Berkey Black" was used in the SSURO.
- 65. On May 2, 2023, David Cobb issued an SSURO, Docket Number: FIFRA-08-2023-0037, to Good Earth Natural Foods Co. South Dakota ("Good Earth"), a Berkey dealer, alleging that Good Earth violated FIFRA by selling the Black Berkey Filter Products, which the EPA considered to be unregistered and misbranded pesticides. Exh. B-10. Again, the knockoff filter name "Berkey Black" was used in the SSURO a dozen times and the Good Earth SSURO required it to respond to Tokarz with a monthly report.
- On May 8, 2023, David Cobb issued an SSURO, Docket No. FIFRA-08-2023-0038, to Plaintiff Berkey International, LLC, which alleged that Berkey Int'l violated FIFRA by selling Black Berkey Filter Products, which the EPA considered to be unregistered, misbranded pesticides. Exh. A, B-11, & D. Berkey Int'l is in region 2, and not region 8; Berkey Intl. has never been contacted by EPA region 2. Prior to issuing the SSURO there was no inspection of the products. Additionally, on the Regional Hearing Clerk Filing Coversheet Ms. Tokarz and Shaula Eakins in another show of bad faith rushed to get the SSURO closed immediately after docking requesting a final order. They erroneously stated that Berkey had no legal counsel, that no public notice was required and that there were no comments received. Again, the SSURO uses the knockoff filter name "Berkey Black" and required Berkey Int'l to send monthly reports to Tokarz. Exh. B-11. On May 9th, 2023, the SSURO was closed, preventing any comments from Berkey or its attorneys. See Exhibit B-24.
- 67. Starting in late January of 2023, NMCL began sending James Enterprises ("JE") new packaging designs, which were consistent with Berkey products being treated articles, for

submission in good faith to the EPA for approval. Exh. A. Thereafter, JE submitted multiple iterations of these designs to the EPA. Each was rejected for minor changes that could have been communicated to JE during the EPA phone discussions that occurred during January and February of 2023, the EPA inspection on November 22, 2022, or any number of other email communications thereafter. Exh. A, B-13 ("Rejected Packaging Proposals").

- 68. During discussions with the EPA on packaging, Tokarz told JE that the image of a lake, which has been on the packaging for two decades, must be removed because it conveys an idea that the filter can be used to remove pests from lake water. Exh. A, B-13.
- 69. In June of 2020, in response to new products offered to the public regarding COVID-19, the EPA had ordered Amazon and eBay to stop the sale of certain pesticide products that were identified on a list attached to the order. Exh. B-12 ("EPA Order to Amazon and eBay"). Berkey products were not included in the original list of offending products in 2020, nor were they listed in a 2021 update. Exh. B-12. However, in an apparent reaction to the SSUROs issued in the first half of 2023, Amazon restricted sales of Berkey products on June 24, 2023, without identifying the reasons it believed Berkey products violated FIFRA. Exh. A, B-12.<sup>12</sup>
- 70. At all times during these events, EPA agent Tokarz has been an inspector in Region 8.
- 71. Berkey has been in business for more than twenty-five years and has always rigorously complied with the EPA's environmental regulations. Berkey has periodically hired EPA consultants to review its websites and claims and to ensure that Berkey complied with EPA regulations. Exh. A.

<sup>&</sup>lt;sup>12</sup> In a news story about the EPA Order, EPA Administrator Andrew Wheeler was quoted as saying, "These stop sale orders to Amazon and eBay demonstrate the Trump Administration's continued commitment to protecting the health and safety of Americans...We remain vigilant against the claims of producers that falsely assert their efficacy and safety. Of particular concern are products that falsely claim to be effective against COVID-19. It is our duty to continue transparent communication with the public on unregistered products that may cause injury to consumers, and immediately remove them from commerce." <a href="https://allongeorgia.com/georgia-public-safety/epa-orders-amazon-and-ebay-to-stop-sale-of-certain-pesticide-products/">https://allongeorgia.com/georgia-public-safety/epa-orders-amazon-and-ebay-to-stop-sale-of-certain-pesticide-products/</a> (last assessed July 27, 2023).

- 72. Since May of 2022, Berkey has consistently complied with EPA regulations in making treated articles that mechanically removed waterborne pathogens, but the EPA suddenly decided to require Berkey to re-label products as pesticides. Berkey has completed its reporting requirements and verified its advertising claims for accuracy. Berkey has been and remains in compliance as manufacturing treated articles. Exh. A.
- 73. During early 2023, Berkey and JE modified their websites to change the status of Berkey water filter products from pesticide devices to treated articles. Berkey repackaged the Black Berkey products with packaging that did not make any waterborne pathogen removal claims for U.S. sales, and all filters in the original packaging were marked for international export. Exh. A.
- On or about July 12, 2023, Berkey agents conferred with EPA Inspector Tokarz. Tokarz stated that Berkey continues to make pesticide claims about Berkey products. Berkey has slowly come to realize, based on the numerous rejections of proposed designs in the Rejected Packaging Proposals and the phone conversations rejecting even an image of a lake that Berkey has used for many years, that Tokarz and her allies at the EPA will never allow Berkey to sell its filters without being registered as pesticides, even if Berkey just sold a boxed filter and provided no specification to consumers. Exh. A. Consumers know that Berkey is a water filter that has a reputation for reducing contaminants in water, and Berkey will never escape that reputation.
- 75. Not content with its direct attack, the EPA's SSUROs issued against vendors has caused additional damage to the Berkey network. One contract manufacturer (Vendor B) was even forced by the EPA to agree not to work with NMCL and the Berkey sales network as long as the packaging included any pesticidal claim. Exh. B-6.
- 76. Thus, the EPA has enforced SSUROs across the Berkey vendor and distributor network, though these products have been a mainstay in the water filter world for more than two decades

without incident, forcing vendors to cease doing business with the Berkey network lest the EPA force the vendor to shut down completely. Exh. A.

Berkey Int'l has \$38,800,000 in wholesale inventory that it is unable to manufacture and

77.

- sell. Storage costs are approximately \$86,000 per month. More than 500 jobs have been lost at least temporarily and more are imperiled by the irrational decision to creatively re-interpret a rule so that the mere presence of silver is enough to warrant registration as a pesticide, though the EPA is aware that the referenced silver is used to protect the filters and has no pesticidal function. Even when the EPA was informed that the silver present in the filter is part of the registered pesticide used to protect the filter, and the EPA registration for the pesticide specifically states that the pesticide is used for that purpose, the EPA still in bad faith wants to force registration as a pesticide. 78. As discussed supra, the EPA's website that lists all pesticides utilizing silver is easily viewed online by the public. 13. There are no outdoor, camping or emergency water filtration systems listed because this list is composed of registered silver pesticides that can be utilized in the manufacture of Treated Articles. Black Berkey filters utilize one of the listed pesticides to protect the filter itself. Exh. A. Tokarz should have been aware of this before issuing any of the SSUROs. None of the customers of the media products listed are required to also be registered as a pesticide when they use the products to protect the articles themselves. Instead, only the media products that are used for manufacturing Treated Articles are registered as pesticides.
- 79. On July 13th, 2023, Christine Tokarz informed NMCL during a phone call with its counsel that because of a posted response to a private lawsuit that "NMCL continues to make pesticide statements in the public record reflects its intent and will make it difficult for EPA to make the finding necessary to allow the products to be sold." However, that post made no pesticidal claims. *See* Exhibit A and B-19.

<sup>&</sup>lt;sup>13</sup> See https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6 XCHEMICAL ID:3769.

- 80. As previously stated, the SSUROs utilized the same knock-off term "Berkey Black" as those found in the lawsuit. The EPA has not been granted the authority to pick winners and losers in private industry nor to select winners and losers in private lawsuits. More importantly, given that she utilized the same knock-off term in her SSUROs as those found in the lawsuit, Plaintiff believes that Tokarz interest in re-interpreting EPA regulations was to influence the outcome of a private lawsuit rather than to follow EPA regulations.
- 81. During that call she instructed NMCL's counsel to confirm that the SSURO issued to Berkey International was also applicable to NMCL. *See* Exhibit A.
- 82. Berkey cannot be colorably accused of endangering any life but has made water cleaner for millions of people for decades. This vendetta on the part of Tokarz and the EPA endangers Berkey's continued operation while also encouraging low-grade knockoffs and counterfeit filters to proliferate and fill the market gap left by Berkey's demise with cut-rate products. To the extent the purpose of the EPA's pesticide rules is to *protect* the public, its unreasonable application and enforcement, in this instance, defeats that objective, and counter-intuitively, makes the public *less safe*. When a member of the public is harmed by counterfeit filters, redress will be more difficult or impossible since the sourcing for knockoff filters is rarely obvious, the filters are often deceptively presented as exact replacements for Berkey filters, in spite of their differing low-quality construction, and are almost always produced outside the US, where seeking redress for damage is almost impossible. Exh. A & B.

#### VII. AUTHORITIES

#### A. General

83. The Fifth Amendment to the United States Constitution states:

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

#### B. Administrative Procedures Act (5 U.S.C. 553)

- 84. The foundational statute of the administrative state is the Administrative Procedure Act ("APA"), which outlines procedures an agency must follow to execute final agency action. Unless the agency's enabling statute requires formal rulemaking, the APA provides that an agency must conduct notice-and-comment rulemaking to promulgate rules that bind the public. 5 U.S.C. § 553.
- 85. To change the rights and duties of interested parties, an agency must promulgate rules by notice-and-comment rulemaking. 5 U.S.C. § 553 provides for certain exceptions to notice-and-comment rulemaking, for example, when the rules are merely interpretive. Use of this exception is limited to rules that do not change the rights and duties of interested parties that would be subject to the rule, or use mandatory language. An agency cannot significantly modify its regulations without notice by merely labeling the change as an interpretation when in reality the change is one in policy. *Torch Operating Co. v. Babbitt*, 172 F. Supp. 2d 113 (D.D.C. 2001).

#### C. FIFRA (7 U.S.C. Ch. 6 § 135–136y)

86. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was passed by Congress in 1947 to regulate agricultural pesticides. Products of interest to the EPA under FIFRA can be loosely categorized as pesticides, pesticidal devices, and treated articles.

#### 87. FIFRA defines "pesticide" as:

(u) Pesticide. The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(w)), that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. § 321(x)) bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321).

7 U.S.C. chap. 6 § 136u.

88. FIFRA defines "device" in the context of pesticide regulations as:

The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

7 U.S.C. Ch. 6 § 136h. FIFRA requires pesticide manufacturing facilities to register their location, including contract manufacturers.

89. The EPA recognizes "treated articles or substances" as follows:

An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

40 C.F.R. § 152.25.

90. The above categories are often discussed and explained in case opinions, such as *Anderson* v. *McCarthy*, No. C 16-00068 WHA, 2016 U.S. Dist. LEXIS 63671 (N.D. Cal. 2016) (clarifying that pesticide-coated seeds are "pesticidal devices" and not "pesticides").

#### VIII. CAUSES OF ACTION

- 91. Through this suit, Plaintiff brings against Defendants three counts for breaching the restrictions that the Constitution and Congress have placed upon the Defendants.
- 92. For Plaintiff, vacatur of the SSUROs and new substantive rule that "any silver in a filter it a pesticide, irrespective of the purpose of the silver's inclusion in the product" would remedy the harms that flow therefrom. Indeed, for APA violations that are unlawful, the default—and appropriate—remedy is vacatur. *See Sierra Club v. Marsh*, 976 F.2d 763, 773 (1st Cir. 1992)(quoting *Environmental Defense Fund, Inc. v. Costle*, 657 F.2d 275, 285 (D.C. Cir. 1981)). For example, "nearly every logical outgrowth violation leads to vacatur." Nicholas Bagley, *Remedial Restraint in Administrative Law*, 117 COLUM. L. REV. 253, 275 (2017).
- 93. Alternatively, if the EPA's reinterpretation of FIFRA were to stand, declaratory and injunctive relief declaring the reinterpretation of the mechanical filter as a pesticide under the FIFRA unconstitutional and enjoining the EPA from enforcing the same would remedy the harms that flow from the EPA's enforcement action predicated on its reinterpretation.
- 94. In the claims below, Plaintiff first asserts more traditional claims that: a) the EPA failed to follow its rule-making procedures; and b) irrespective of the procedures, the EPA's new rules are contrary to FIFRA. Plaintiff also makes constitutional claims, including and due process claims under the 5<sup>th</sup> Amendment. Lastly, the Rule of Lenity should prevent enforcement of an everchanging regulation that cavalierly attempts to give a business death penalty punishment without notice or an opportunity to respond before simply prevented from operating.
- A. Count 1: Violation of the APA; 5 U.S.C. § 706 Plaintiff seeks vacatur of the EPA's SSURO and unnoticed new regulation for failure to follow the rule-making procedures.
- 95. The EPA provided no notice and comment procedures, no notice of proposed rulemaking, nothing in the EPA's application or guidance of FIFRA to water filters or its explanation thereof "gave [any] indication that [the agency] was contemplating a potential change" as drastic as

reinterpreting substances that protect the filter without a pesticidal effect as pesticides. *See Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1376 (Fed. Cir. 2017). Exh. A, B, & D.

- 96. As the reviewing court in this case, under 5 U.S.C. § 706(2)(D), it should hold unlawful and set aside any action, findings, and conclusions found to be without observance of procedure required by law. The APA's rulemaking requirements include a mandate for the EPA to provide the public with a meaningful opportunity to comment on the elements of a rule and the materials that form its basis. *See*, *e.g.*, 5 U.S.C. § 553(c); "I begin by recognizing that the purpose of notice is, in large measure, to inform the public of what the agency intends to change and to provide the public a meaningful opportunity to comment." *Ms. S. v. Reg'l Sch. Unit* 72, No. 2:13-cv-453-JDL, 2017 U.S. Dist. LEXIS 191257, at \*23 (D. Me. 2017)
- 97. The Administrative Procedure Act ("APA") provides that, whenever an agency undertakes to promulgate, amend, or repeal a regulation, it must first issue a "notice of proposed rule-making . . . in the Federal Register"—which must include, among other information, "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). A corollary of this requirement is that "the final rule the agency adopts must be a logical outgrowth of the rule proposed. The object, in short, is one of fair notice." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (cleaned up).
- 98. Even if a "final rule d[oes] not amount to a complete turnaround from the [proposed rule]," the notice of proposed rulemaking is inadequate if it does not "indicate[] that the [agency] was contemplating a particular change" that appears in the final rule. *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081–82 (D.C. Cir. 2009); *see also Medics, Inc. v. Sullivan*, 766 F. Supp. 47, 53-55 (D.P.R. 1991) (granting mandamus to force notice and comment rulemaking even when the court concluded that the Secretary of Health and Human Services interpreted a statute correctly because the rule was substantive).

- 99. Berkey products have been sold for more than two decades without any opposition from the EPA, which issued no regulation to suggest that sale of a water filter which uses a registered pesticide to protect its media will be considered a pesticide if the filter if the filter is sold with pesticidal claims. Plaintiffs contend that neither the statute nor anything issued by the EPA would give a warning to any filter manufacturer such that this change could be anticipated, violating the APA. A *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021) (concluding that an agency's notice must adequately frame the subjects for discussion such that the affected party should have anticipated the agency's final course in light of the initial notice.).
- 100. The EPA gave no notice of the impending change, though the APA requires the EPA, to (1) give general notice of proposed rulemaking in the Federal Register and thereafter (2) "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(c).
- 101. In the present case, Berkey has explained that removal of its filters from the market has created greater demand for counterfeit filters which do not provide the same filtering as Berkey filters, potentially creating a greater market for dangerous products, ironically damaging the prospects for vulnerable populations who need quality water filtering. This lack of consideration makes the EPA's position in this case unreasonable. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (an agency's action is not reasonable if the agency "entirely failed to consider an important aspect of the problem.").
- 102. The issues of which Berkey complains would have been heard by the EPA during a public comment section and given the EPA an opportunity to devise rules without doing actual damage by its clumsy lack of notice. The lack of following the APA's process resulted in a denial of EPA's ability to "consider and respond to significant comments received during the period for public comment." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

- 103. Additionally, the failure to follow the public comment process prevented the EPA to respond to comments at all, preventing the EPA from failing to respond "in a reasoned manner to the comments received." *Action on Smoking & Health v. C.A.B.*, 699 F.2d 1209, 1216 (D.C. Cir.), supplemented, 713 F.2d 795 (D.C. Cir. 1983) (internal quotations omitted).
- 104. Because the EPA failed to gather all relevant factors or respond to them, the EPA's actions should be considered "arbitrary or capricious", as an agency must take into account all relevant factors in making its determination. *Hanly v. Mitchell*, 460 F.2d 640, 648 (2d Cir. 1972); see also United States v. Irizarry, 98 F. Supp. 2d 160, 164 (D.P.R. 2000).
- 105. Courts have recognized the importance of the public comment process, which is designed to prevent a person from being required to resort to, or be adversely affected by, significant rulemaking without having the opportunity to participate in that rulemaking. *See Kollett v. Harris*, 619 F.2d 134, 140 n.5 (1st Cir. 1980). In the present case, Berkey and its business partners have been denied the opportunity to participate in the process.
- 106. Here, the EPA's application and guidance of FIFRA to water filters gave no "indication that [the EPA] was contemplating a potential change" as drastic as reinterpreting substances that protect the filter without a pesticidal effect as pesticides. *See Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1376 (Fed. Cir. 2017). Exh. A, B, & D.
- 107. The 1975 Rule and 1976 guidance documents uses vague phraseology, specifically stating if an "article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide." Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976). Moreover, the US congress mandated that the EPA provide communications such that Government documents explain to the public how to comply with a requirement the federal government administers or enforces. Such documents must be written clearly so that the public can understand,

use, and explain to the public how to comply with a requirement that the federal government administers or enforces. The EPA continues to enforce based upon the old vague documents written prior 2010. Here, the EPA impermissibly is continuing to use an ever-changing inaccurate and vague definition of pesticide that no rational person would adopt, in contravention of the Rule of Lenity, to prosecute Berkey filters. *See v. Cargill Garland*, 57 F.4th 447, 450 (5th Cir. 2023). 108. The EPA also relies on its guidance document, "U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides", explaining that if a water filter "contains any substance *intended* to disinfect the water, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed," (emphasis added). 14 *See id.* There is nothing in the 1975, 1976, or in the Guide for Consumers that shows that substances *not intended* to prevent, destroy, repeal, or mitigate pests or *not intended* to disinfect the water are pesticides.

109. As referenced above and reiterated here, the substantial discrepancy between the inconsistent decisions to label a mechanical filter as a pesticide, and its recent reinterpretation and application of the rule against Plaintiff, the public was denied the chance to comment on the substance of the latter. That denial violates the APA and warrants vacatur of the SSUROs. *See CSX Transp.*, 584 F.3d at 1083; *Ass'n of Priv. Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 462 63 (D.C. Cir. 2012). EPA's actions are not a logical outgrowth of any notice and comment or proposed rules. *Victim Rights Law Ctr. v. Cardona*, 552 F. Supp. 3d 104, 134 (D. Mass. 2021). These rules are not a logical outgrowth of any previous notice and comment process. *See id.* 

110. On information and belief, a full review of the record in this case will evidence that the EPA failed to adequately consider the ramifications of its novel interpretation of the Final Rule in their SSURO as applied to inert silver on the public and the filter industry writ large and failed to

<sup>&</sup>lt;sup>14</sup> Available at https://www.epa.gov/pesticides/pesticide-devices-guide-consumers (last visited March 4, 2024).

adequately consider the financial impact on businesses because the industry lacked requisite notice to comment on the rule as recently interpreted. Exh. A, B, C, & D.

- B. Count 2: Irrespective of whether the EPA created a formal "Final Rule", Plaintiff seeks vacatur of the EPA's new practice of treating devices protected by silver as a pesticide because it is arbitrary, capricious, and not in accordance with law.
- 111. While there is no "Final Rule" that has undergone proper APA vetting, Plaintiff asserts that the EPA in its SSUROs have adopted two de facto substantive irrational rules: a) the use of a registered pesticide to protect the filter turns the filter into a pesticide; and b) use of silver for any purpose in a filter inexorably leads to a requirement that the filter must be registered as a pesticide.
- 112. Under 5 U.S.C. § 706(2)(A), "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" Any "final rules" arising from the application of the SSUROs by the EPA is arbitrary, capricious, and not in accordance with law.
- 113. Without both of these new rules, the SSUROs could not have been issued, and both are irrational substantial departures from EPA rules since the 1970s.
- 114. Under FIFRA, a water filter is a device, as it is an instrument or contrivance intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life; by contrast a pesticide is generally any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. *See* 7 U.S.C. Chapter 6 § 136 (definitions); *see also* Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976); *see also* U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides.
- 115. Based on these definitions, a device is not a pesticide unless it also utilizes a substance *intended* for destroying pests. The new rules employed by the EPA in issuing the subject SSUROs ignore the "intent" aspect, contrary to the governing statute. Exh. A, B, C, & D. Both of these rules

were not identified, described, otherwise included in any proposed or final rule and did not undergo proper notice and comment. *See Medics, Inc.*, 766 F. Supp. at 54. These rules are not a logical outgrowth of any notice and comment. *See id*.

116. Thus, irrespective of the procedure that should have been followed by the EPA before adopting these rules, the rules that the EPA are attempting to employ are thus invalid as contrary to FIFRA, and thus should not be enforced.

# C. Count 3: Plaintiff seeks vacatur for violation of the APA 5 U.S.C. § 706 and for violation of the U.S. Constitution U.S. Const. Amend. V as void for vagueness.

- 117. Shown by EPA's application of the statute, FIFRA's vague definition of "pesticide" is so uncertain that that persons of average intelligence have no choice but to guess at its meaning and modes of application. Exh. A-D. 7 U.S.C. § 136 (u) violates the void-for-vagueness doctrine.
- 118. "No person shall . . . be deprived of life, liberty, or property, without due process of law." U.S. CONST. AMEND. V.
- 119. Agency regulations bear the "force and effect of law." *Perez*, 575 U.S. at 96.
- 120. Thus, agency regulations are subject to the same constitutional limits on vagueness as is legislation. *See FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253, 254–55 (2012) (indicating that the void-for-vagueness doctrine applies to agency regulations).
- 121. But a statute is unconstitutionally vague only if it "prohibits . . . an act in terms so uncertain that persons of average intelligence would have no choice but to guess at its meaning and modes of application." *United States v. Councilman*, 418 F.3d 67, 84 (1<sup>st</sup> Cir. 2005) (quoting *United States v. Hussein*, 351 F.3d 9, 14-16 (1st Cir. 2003).
- 122. The "doctrine prohibiting the enforcement of vague laws rests on the twin constitutional pillars of due process and separation of powers." *United States v. Davis*, 139 S. Ct. 2319, 2325 (2019); *accord Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018).

- 123. A law must provide "fair notice' of the conduct a statute proscribes," in order to "guard[] against arbitrary or discriminatory law enforcement[.]" *Sessions*, 138 S. Ct. at 1212; *see Fox Television Stations, Inc.*, 567 U.S. at 253 (judicial vagueness inquiries ensure that regulated parties know what is required of them and that enforcement of the law will not be arbitrary and discriminatory). To do otherwise is to violate the well-established Rule of Lenity, which prevents punishment of vague laws for which no fair notice has been given. *See Wooden v. United States*, 595 U.S. 360, 142 S. Ct. 1063, 1085-86 (2022).
- 124. As already noted, FIFRA vaguely defines "pesticide" to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u). The key phrase "substance" gives no notice that a carbon-activated water filter would be considered a "substance or mixture", irrespective of any pesticidal claims made during the sale.
- 125. To attempt to explain the vague definition, the 1975 Rule and 1976 guidance documents uses more vague phraseology, specifically stating that an "article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide." Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976). The EPA also relies on its U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides, explaining that if a water filter "contains any substance intended to disinfect the water, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed." (emphasis added) See id.
- 126. As discussed above, this definition is unduly vague for the manufacturers who are attempting in good faith to comply with the law, if this statement covers both a) substances intending to destroy pests and disinfect water and b) those substances that do not intend to destroy pests or not intended to disinfect water. Given that the EPA's enforcement action conflicts with this statute, it is not remotely clear what devices fall within the ambit of the pesticide definition.

One cannot tell whether substances not intended to prevent, destroy, repeal, or mitigate pests are included, compared to substances not intending to disinfect the water. Exh. A, B, C, & D.

127. 7 U.S.C. § 136(u) is thus unduly vague, at least as applied in this case, and violates the void-for-vagueness doctrine, necessitating vacatur.

#### D. Count 4: Plaintiff seeks declaratory judgment and damages for the EPA's violations.

- 128. Plaintiff claims here that the EPA violated the APA by arbitrarily and capriciously issuing an SSURO against Plaintiff and designating Black Berkey water filters as pesticides with no basis in any record of facts. Plaintiff claims here that the EPA violated the APA by exceeding its statutory authority under FIFRA to require pesticide registration by attempting to regulate water filters which do not qualify as pesticides.
  - i. The EPA arbitrarily and capriciously designated Plaintiffs' filters as pesticides.
- 129. Plaintiff claims here that the EPA violated the APA by arbitrarily and capriciously issuing an SSURO against Plaintiff and designating Black Berkey water filters as pesticides with no basis in any record of facts.
- 130. As discussed *supra*, the APA allows for this Court to review final agency actions. Final agency actions under 5 U.S.C. § 704 include orders of the agency, which are anything relating to interested parties that are not rules. Here, the decision to classify Black Berkey Filters as pesticides applies to one interested party, Berkey, and its allied sales channels. This decision did not undergo notice and comment rule making procedures, nor was it a statement of general applicability to numerous or all interested parties to FIFRA. Thus, the EPA's decision, expressed here as Stop Sale, Use, or Removal Orders were orders constituting a final agency action.
- 131. The EPA's SSUROs (orders) resulted from informal adjudication because there was no public hearing on the record as described in 5 U.S.C. §§ 556 and 557. *See Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971) (holding that the substantial-evidence standard of

review for agency actions did not apply to informal orders). As a result, the standard for review of the order is arbitrariness and capriciousness based on the record the agency considered while creating the order. *See generally, id.* However, if the agency cannot describe its basis for why it reversed its adjudication of the issue in the record of available data it considered, courts view that decision as arbitrary and capricious. *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515–16 (2009). EPA's actions are not a logical outgrowth of any notice and comment or proposed rules. These rules are not a logical outgrowth of any notice and comment.

- 132. Here, the EPA provided no record of data, nor did it explain its reasoning on any such data for why it suddenly considered Black Berkey Filters as pesticides. The EPA's actions mirrors the FCC's arbitrary and capricious order in *Fox TV* where the agency could not explain on a record of data why it suddenly changed order on what words were television appropriate and which were prohibited. *See generally*, *id.* In the same way, the EPA originally viewed the filters as pesticide devices, but inexplicably changed its mind, and declared the filters as pesticides, in part by referencing its 1975 and 1976 guidance documents. Exh. A-D. Thus, the EPA's determination that Berkey filters are pesticides is arbitrary and capricious and shows the EPA is violating 5 U.S.C. § 704–706, damaging Plaintiff, necessitating damages, declaratory judgment, and injunctive relief to restore Plaintiff to the rightful position. Exh. A, B, C, & D.
  - ii. The EPA exceeded its authority with a rule that does not comport with FIFRA.
- 133. Plaintiff claims here that the EPA violated the APA by exceeding its statutory authority under FIFRA to require pesticide registration by attempting to regulate water filters which do not qualify as pesticides.
- 134. As discussed at 5 U.S.C. § 701, et. seq., the APA allows an interested party to challenge final agency actions which exceed congressionally granted, statutory authority. Final agency actions under § 704 include orders of the agency, which are anything relating to interested parties

that are not rules. Here, the decision to classify Berkey Filters as pesticides applies to interested parties: Berkey, and its distribution channel partners. The decision did not undergo notice and comment rule making procedures, nor was there a statement of general applicability to all interested parties to FIFRA. Therefore, the EPA's decision was an order and final agency action subject to review under 5 U.S.C. § 704–06.

- 135. For the EPA to have authority to require product registration under FIFRA, the targeted product must be a pesticide. 7 U.S.C. § 136a. FIFRA defines pesticides in § 136(u) as chemical products intended to destroy pests. The EPA further defined "pesticides" to exclude animal drugs and feed. 40 C.F.R. § 152.3. Relevant here, the EPA promulgated 40 C.F.R. § 152.10 to clarify that products not <u>intended</u> to destroy pests are not pesticides.
- 136. The legislative history of FIFRA and the regulations promulgated by the EPA all indicate that FIFRA is designed to regulate chemical compounds, particularly for use in agriculture, and not devices. For example, in the last major overhaul of FIFRA in 1978, the Senate Committee on Agriculture, Nutrition, and Forestry conducted a bill analysis and published a report on the proposed changes. Staff of S. Comm. on Agric., Nutrition, and Forestry, 95th Cong., Comm. Rep. on Fed. Pesticide Act of 1978 (Comm. Pr. 1979). In the section on the history of FIFRA, the Committee noted that Congress passed FIFRA originally to deal with an explosion in the use of chemical agricultural pesticides in the United States. Id. at 189–90. The particular pesticides that Congress wanted to target were DDT and herbicides. Id. at 190. Continued concern over the use of pesticides on agricultural products that ended with human consumption drove further amendments. Id. at 190–91. Notably absent from consideration were any physical devices that Congress considered to be "pesticides." See generally, id. Instead, Congress was concerned with chemical cocktails.

- 137. Further, the EPA has promulgated regulations to define certain innocuous products that would otherwise be pesticides that are exempt from registration. 40 C.F.R. § 152.25. Some examples include embalming fluids, castor oil, pheromone traps, and peppermint oil. *Id.* None of these exempt pesticides even remotely resemble a water filter.
- 138. Regardless, none of the EPA's legislative history clarifies why substances not intended to repel pests are now considered to be actual pesticides, rather than pesticidal devices (devices that trap or eliminate pests mechanically, such as Berkey filters) or treated articles (which includes items treated with a pesticide to protect the item from pesticides).
- 139. Thus, the EPA's attempt to force Berkey to register its water filters as actual pesticides exceeds the bounds of the congressionally granted authority found in FIFRA. Exh. A, B, C, & D. EPA's actions are not a logical outgrowth of any notice and comment or proposed rules. *Victim Rights Law Ctr.*, 552 F. Supp. 3d at 134. These rules are not a logical outgrowth of any notice and comment. *See id.* Water filters are not chemical compounds used to eliminate pests. Use of a silver treatment to protect a mechanical filter does not change a filter into a chemical substance to destroy pests for purposes of FIFRA and the EPA.
- 140. Berkey filters are mechanical products designed to make water more palatable for human consumption. Hence, they do not fall within the scope of FIFRA and the EPA may not require registration as pesticides. Therefore, the EPA is in violation of 5 U.S.C. § 704–06.
- 141. The EPA's violations have substantially injured Plaintiff and require damages, declaratory judgment, and injunctive relief to restore Plaintiff to its rightful position.

# E. Count 5: Procedural Due Process claim against the EPA for its violation of Plaintiff's APA rights notice and comment rights and 5<sup>th</sup> Amendment Procedural Due Process.

142. The EPA violated Plaintiff's procedural due process by failing to provide notice or opportunity to be heard when arbitrarily and capriciously issuing the SSURO and relabeling Berkey products from "pesticide devices" to "pesticides" without any discussion, explanation, or

guidance. *See* Exhibit A & B-11. Berkey Products' and Plaintiff's good name and reputation were damaged by EPA's lack of explanation and cooperation with Plaintiff in issuing a stop order for Berkey Products with no rational explanation. *Id*.

- 143. The arbitrary and capricious procedures of the EPA involved no notice or opportunity for Plaintiff to be heard and resulted in a 50% decrease in market share of Black Berkey elements and a 90% decrease in market share of Big Berkey filtration systems since February 2023 due to the resulting harm to Berkey Products' good name, reputation, and perceived integrity. *Id*.
  - i. The EPA failed to follow the APA rule-making notice and comment process before issuing SSUROs based on new unnoticed rules, concluding Berkey filters are not pesticide devices, but actual pesticides themselves.
- 144. As noted above, the EPA provided no notice or opportunity to be heard when in May 2022 issued a SSURO against Plaintiff and labeled Berkey Products as "pesticide devices", then seven months later without explanation or published guidance issued SSUROs, again relabeling Berkey Products, this time as "pesticides." Plaintiff received no explanation of the EPA's reinterpretation of Berkey Products, nor even a notice, let alone an opportunity to be heard. Exh. A, B, & D. Because of EPA's relabeling, the EPA issued multiple stop orders for Berkey Products in December 2022, which during 2023 resulted in a 50% decrease in market share of Black Berkey elements and a 90% decrease in market share of Big Berkey filtration systems. Exh. A & B.
- 145. The EPA shut Plaintiff out of any opportunity to participate in the reinterpretation of its rules, gave no public notice or guidance, and afforded no opportunity to be heard or solicit public comments; Plaintiff suffered harm to its product's reputation and good name, resulting in 2023 more than a 50% decrease in market share of Black Berkey elements and 90% decrease in market share of Big Berkey filtration systems since February 2023, while also encouraging parasitic knockoff and counterfeit filters which are abundantly available and completely ignored by the EPA. Exh. A & B.

- 146. The EPA did not satisfy notice and comment rulemaking requirements and violated Plaintiff's procedural due process rights by issuing the SSURO while not providing notice or an opportunity to be heard. *Victim Rights Law Ctr.*, 552 F. Supp. 3d at 134. Plaintiff will continue to suffer extreme hardship in having to spend valuable time and money to both clear its good name and comply with whatever irrational requirements the EPA arbitrarily adopts next. EPA's actions are not a logical outgrowth of any notice and comment or proposed rules. These rules are not a logical outgrowth of any notice and comment. *See id*.
  - ii. The EPA violated Plaintiff's procedural due process rights arbitrarily and capriciously, and while abusing its discretion, when issuing SSUROs alleging Berkey Products were pesticides that must be registered without proper notice and comment based on foreign non-pesticidal claim statements.
- 147. The EPA shut Berkey's operations down and reclassified Berkey Products as a pesticide without notice, opportunity to be heard, guidance, or properly followed notice and comment rulemaking, resulting in harm to Plaintiff's good name and reputation. This violates Plaintiff's procedural due process rights. *See Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); *Victim Rights Law Ctr.*, 552 F. Supp. 3d at 134.
- 148. There was no rational basis for the EPA's reclassification, nor is there any public record or guidance regarding what evidence was considered when the EPA made the decision to reclassify Berkey products. No reasonable person can be expected to abide by rules that may be arbitrarily and capriciously reinterpreted without notice or published guidance.
- 149. Due process requires consideration of the private interest at stake, the risk of erroneous deprivation of that interest, and the government's interest in using the particular procedures. *See id.* Plaintiff's private interest to be free of wrongful interference in the operations of its business and needless damage to its professional reputation is at stake and was erroneously deprived thereof by the EPA's stop order. The government can have no interest in using arbitrary and capricious

actions that violate notice and comment rulemaking and procedural due process. No rational person can justify a governmental interest in the procedures that gave rise to this suit.

150. After over 25 years of production without EPA interest, the EPA has reinterpreted or created an obscure rule had been reinterpreted by the EPA to apply to Plaintiff and that Plaintiff have thus been rendered non-compliant with rules of which they were previously unaware. Exh. A-D. The Court should declare that the EPA in issuing the SSURO acted arbitrarily and capriciously, did not satisfy notice and comment rulemaking requirements under the APA, and violated Plaintiff's procedural due process rights.

# F. Count 6: The EPA's actions implicate well-established rights to filter water which violate the 9<sup>th</sup> and 10<sup>th</sup> Amendments.

- 151. Plaintiff asserts that the EPA's attempt to regulate water filters which have no "substance" in them violates both of the Ninth Amendment and Tenth Amendments to the United States Constitution, recognizing that federal courts generally show no respect to these venerable and important amendments.
- 152. As described above, water filter devices were well-known in the 18<sup>th</sup> century. The idea that a federal government could regulate a carbon-based water filter would have been laughable to early American citizens. The Ninth Amendment was designed to ensure that no government agent would go beyond the enumerated powers of the Constitution and regulate such products. Even if a court wants to take the vogue position that the Ninth Amendment is a mere construction tool, the Ninth Amendment should certainly guide every court away from regulating actions that were unregulated during the Founding of this country, at least without a clear enabling law that does not require a court to squint its eyes and turn its head a certain way in order to "find" a power where none was clearly provided. At the very least, the Ninth Amendment requires lenity in this case.

Additionally, the Tenth Amendment should guide the Court, as every state can regulate

153.

substance water filters employing technology that existed centuries ago, a federal court should require a federal bureaucracy to find constitutional support for a regulation in the enumerated powers. And even if the Court is content with finding such support in penumbras and emanations between the lines of the Constitution's enumerated powers, the Court must strictly restrain the EPA with the statutory rules requiring a notice and public comment process before its minions are released into an industry that has not needed its regulation and historically been left alone.

# IX. APPLICATION FOR TEMPORARY RESTRAINING ORDRE, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION

- 154. Pursuant to Fed. R. Civ. P. 65(a), Plaintiff moves this Court for a temporary restraining order and equally a preliminary injunction directing Defendant EPA and all those in concert with them, directly or indirectly, from enforcing the SSUROs, or any other statute, ordinance, or policy that entirely prohibits or chills the constitutional rights of Plaintiff Berkey. *See also, Plaintiff's Memorandum, concurrently filed.*
- 155. Further, Plaintiff asks that the Court make the injunction nationwide and vacate all associated SSUROs and any attendant agreements based thereon, as the EPA's SSUROs have been used against vendors, causing additional damage to the Berkey network, e.g., one contract manufacturer was forced by the EPA to agree not to work with NMCL and the Berkey sales network as long as the packaging included any pesticidal claim.
- 156. Reiterating, the Court should enjoin the EPA from enforcing stop orders based on sale of the Berkey filter vendors and distributors which have been on sale now for more than two decades without incident, unless the EPA can find a rational basis for the action which is more persuasive than, "We just noticed that Berkey filters use a registered pesticide, so now we want to put Berkey out of business, even though it is not a substance and the use of the pesticide is to protect the filters, which is explicitly listed as an exception to a registration requirement.

157. Pursuant to Rule 65 (b), Plaintiff moves this Court for immediate equitable relief restraining Defendant from enforcement of its Berkey-related SSUROs as unconstitutional. *See Plaintiff's Memorandum*. As detailed therein, the Plaintiff has suffered irreparable injury, monetary damages are inadequate, equity demands this remedy, and the public interest will not suffer by enforcement of a permanent injunction. The EPA will suffer no hardship by being compelled to refrain from enforcing the SSUROs, and thereby respect the constitutional rights of the Plaintiff.

### X. PRAYER

In addition to the temporary restraining order and preliminary injunction described above, upon trial and final judgment of this Court, Plaintiff prays this Court award the following:

- a. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA exceeded its statutory authority under FIFRA when issuing the SSURO and require Plaintiff to register its Black Berkey Water Filters as pesticides;
- b. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA violated Plaintiff's 5<sup>th</sup> Amendment due process rights by failing to meet APA and constitutional requirements when changing the rights of the Plaintiff as to its Berkey filters when issuing the SSURO;
- c. preliminary and permanent injunctive relief pursuant to 28 U.S.C. § 2202, enjoining the EPA from enforcing FIFRA pesticide registration requirements against Berkey filters and set aside the relevant SSUROs and eliminate any attendant agreements between the EPA and Berkey-associated businesses, as supported in the *Application for Preliminary and Permanent Injunction*, concurrently filed;
- d. a declaratory judgment pursuant to 28 U.S.C. § 2201 that 7 U.S.C. § 136(u) is void for vagueness;
- e. general damages, special damages for lost market share and sales revenues, lost employee and vendor employee expertise, lost new customers, massive irrecoverable business expense losses and damage to the good Berkey Brand name directly attributable to Defendants, or in the alternative, nominal damages should other damages be unavailable;
- f. attorney's fees and costs of court because of this action; and
- g. such other and further relief that the Court deems just and proper.

# Respectfully submitted,

/s/Warren V. Norred Warren V. Norred, Texas Bar Number: 24045094 Norred Law, PLLC; 515 E. Border St.; Arlington, TX 76010 O: (817) 704-3984 warren@norredlaw.com Counsel for Plaintiff /s/ Juan J. Charana Agudo
Juan J. Charana Agudo
USDC-PR No. 300914
Puerto Rico Business Group, LLC
P.O. Box 361547
San Juan, PR 00936
787-234-6575
Juan.charana@prbusinessgroup.com
Local Counsel for Plaintiff

## ATTACHMENT IN PLAINTIFF'S ORIGINAL COMPLAINT:

- Exhibit A: First Declaration of James "Jim" Shepherd
  - A-1: Report on Pesticide Information
  - A-2: Coalition Letter to Messina
  - A-3: Statement Regarding Berkey Water Filter Lawsuit
  - A-4: Berkey Response to Wirecutter
  - A-5: Berkey Positive Review Samples
  - A-6: Impact to Black Berkey Sales
  - A-7: Manufacturer EPA Pesticide Records
  - A-8: Berkey COVID-19 Test
  - A-9: EPA's Plane Language Statement
  - A-10: EWG's PFAS Contamination Crisis
  - A-11: EWG's Story on PFAS Filters

## Exhibit B: Declaration of Susan Spaar

- B-1: Tokarz Email Thread (May 1, 2022)
- B-2: Tokarz EPA Close Out Letter (May 5, 2022)
- B-3: Texado Establishment Number, 30-Day Report Email Thread (May 2022)
- B-4: SSURO to James Enterprises, FIFRA-08-2023-0011 (December 27, 2022)
- B-5: Tokarz Email Seeking Documents (December 2, 2022)
- B-6: SSURO to Vendor B (FIFRA-04-2023-0700 (February 3, 2023)
- B-7: SSURO to Fritz Wellness, FIFRA-08-2023-0015 (February 27, 2023)
- B-8: SSURO to Eden Valley Farms LLC, FIFRA-08-2023-0014 (March 6, 2023)
- B-9: SSURO to Mountain Mama Natural Foods, Inc., FIFRA-08-2023-0017 (March 7, 2023)
- B-10: SSURO to Good Earth Natural Foods Co., FIFRA-08-2023-0037 (May 2, 2023)
- B-11: SSURO to Berkey Int'l, FIFRA-08-2023-0038 (May 8, 2023)
- B-12: EPA Order to Amazon and eBay, including Updated List
- B-13: Rejected Packaging, including Lake Image
- B-14: Communications Regarding Damage to Reputation
- B-15: Amazon Counterfeit Documentation
- B-16: Counterfeit Examples
- B-17: Big Berkey Amazon sales decrease from SSUROs
- B-18: Reputation damage example in global marketplace from wrongful EPA actions
- B-19: Berkey Statement Regarding Berkey Water Filter Lawsuit
- B-20: March 6, 2000, Pesticide Registration (PR) Notice 2000 1\*
- B-21: Pesticide Registration Notice (PR Notice) 2023-01
- B-22: Best Water Filters for PFAS chemicals CBS Philadelphia
- B-23: Clerk Cover Sheet
- B-24: Berkey Int'l SSURO Closed

### Exhibit C: Authorities

- C-1: FIFRA, 7 U.S.C. Ch. 6 § 136
- C-2: Notice 51061 1976 Guidance document
- C-3: EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers
- C-4: PR 2023-1, Lists of Pests of Significant Public Health Importance Revised 2023
- C-5: Pesticide Registration Manual, Chapter 13 (updated March 1, 2023), maintained online at <a href="https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices">https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices</a>
- C-6: Pesticide Device: A Guide to Consumers

#### CERTIFICATE OF SERVICE

I certify that on March 6, 2024, I filed this proceeding with the Clerk of the Court through the ECF system, which will send notification of such filing to the following by email to Andrew Coghlan, Shari Howard, and Mark Walters, at the addresses shown below, or the documents will be sent by direct emails as indicated below. This email service is not intended to replace formal service under the Civil Rules, but is to ensure that the EPA's agents are aware of the concurrent request for injunctive relief.

### **TODD KIM**

Assistant Attorney General Environment & Natural Resources Division Andrew Coghlan (CA Bar. No. 313332)
Shari Howard (IL Bar No. 6289779)
Mark Walters (TX Bar No. 00788611)
United States Department of Justice
Environment & Natural Resources Division
Environmental Defense Section
P.O. Box 7611; Washington, D.C. 20002

Tel: (202) 598-9407 Fax: (202) 514-8865 andrew.coghlan@usdoj.gov shari.howard@usdoj.gov mark.walters@usdoj.gov Attorneys for Federal Defendants

I will also send this document to the individual defendants through their email:

Christine Tokarz, FIFRA Inspector, EPA, Region 8, tokarz.christine@epa.gov David Cobb, Section Supervisor, Region 8, cobb.david@epa.gov Carol Kemker, Region 4, kemker.carol@epa.gov Keriema Newman, newman.keriema@epa.gov

/s/Warren V. Norred

Warren V. Norred

# UNITED STATES FEDERAL COURT DISTRICT COURT OF PUERTO RICO

BERKEY INTERNATIONAL, LLC.,	§	
Plaintiff,	§	
	§	CIVIL CAUSE NO.
v.	§	
	§	
ENVIRONMENTAL PROTECTION AGENCY,	§	
MICHAEL S. REGAN, Administrator, CHRISTINE	§	
TOKARZ, and DAVID COBB, in their personal	§	
capacities	§	
Defendants.	§	JURY TRIAL DEMANDED

# PLAINTIFF'S MEMORANDUM IN SUPPORT OF APPLICATION FOR TEMPORARY RESTRAINT, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION

Plaintiff requests a temporary restraining order, preliminary injunction, and permanent injunction pursuant to Fed. R. Civ. Pro. 65(a). Plaintiff incorporates its *Original Complaint* ("Complaint") and its exhibits by reference.

As initially discussed in its Complaint Plaintiff has suffered irreparable injury, monetary damages alone are not adequate, and an injunction is necessary to prevent future harm. Plaintiff seeks immediate equitable relief preventing enforcement of the EPA's determination that Berkey filters are pesticides and the SSUROs subject of this suit.

Plaintiff believes that temporary restraint and a preliminary injunction are appropriate to stop enforcement of the SSUROs, or in the alternative, an injunction to stop the EPA from issuing further SSUROs on this issue until the matter can be decided on the merits.

As herein described, Plaintiff requests a temporary restraining order, preliminary injunction, and permanent injunction.

### I. ARGUMENT AND AUTHORITY

In deciding a motion for temporary restraint, preliminary injunction, a court weighs the following factors: 1) the probability that plaintiffs will succeed on the merits; 2) the possibility that the movant will experience an irreparable injury if the injunction is not granted; 3) whether the potential injury to the plaintiff outweighs any potential injury to defendants; and 4) whether the public interest will be adversely affected by granting the injunction. *See Morales-Narvaez v. Rossello*, 852 F. Supp. 104, 107 (D.P.R. 1994). *See also* Fed. Rul. Civ. Pro. 65.

1. Plaintiff will likely succeed on the merits, showing the EPA acted arbitrarily and capriciously in requiring Berkey to register its water filter elements as pesticides, a substantial change in Plaintiff's duties asserted without notice and public comment.

Plaintiffs emphasize that the EPA acted arbitrarily and capriciously in clear error of judgment because: a) Berkey Products are mechanical filters and not pesticides, and b) the EPA has not followed the Administrative Procedures Act and failed to follow the notice and public comment process. Original Complaint, Exh. A & B.

### A. Berkey water filter elements are not pesticides requiring registration.

As explained in its Complaint, Berkey Products are treated articles or pesticidal devices because they use a registered pesticide to protect the mechanical filter, and not for a pesticidal purpose. *See* Exhibit A.

In spite of Berkey's decades-old business during which Berkey products have operated without incident, the EPA has relied on foreign websites that made no pesticidal claims to justify business-killing stop sale orders ("SSURO") to Berkey-allied recipients. The EPA has not explained why something not intended to have a pesticidal effect but is meant to protect the filter is now a pesticide. Exh. A, B, & D.

Further, the EPA provided no record of data, nor did it explain its reasoning on any such data for why it suddenly considered Black Berkey Filters as pesticides.

For the EPA to have authority to require product registration under FIFRA, the targeted product must be a pesticide. 7 U.S.C. § 136a. FIFRA defines pesticides in § 136(u) as chemical products intended to destroy pests. The EPA further defined "pesticides" to exclude animal drugs and feed. 40 C.F.R. § 152.3. Relevant here, the EPA promulgated 40 C.F.R. § 152.10 to clarify that products not <u>intended</u> to destroy pests are not pesticides.

The 1975 Rule and 1976 guidance documents uses vague phraseology, specifically the 1967 if an "article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide." Exh. C-2. The EPA also relies on U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides, explaining that if a water filter "contains any substance intended to disinfect the water, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed." (emphasis added) Exh. C-6. The guidance is clear that substances *not intended* to prevent, destroy, repeal, or mitigate any pest, and substances that are *not intended* to disinfect the water are not pesticides. Yet, the issued SSUROs rely on statements that show substances not intended to prevent, destroy, repeal, or mitigate any pests and substances that are *not intended* to disinfect the water. Exh. A & B. The issued SSUROs were issued against bases arbitrarily, capriciously, and in clear error of judgment. 5 U.S.C. § 706(2)(A).

The EPA has justified its actions based on a foreign website that states "[y]es, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water." Exh. B-4, para. 26. Neither Plaintiff nor the SSURO recipients have ever had ownership, custody, or control over the European website when it wrongly made the above claim. Exh. A & B. Further, the statement shows that silver is not used to disinfect the water but to protect

the filter. Berkey Filters are mechanical filters that include a registered pesticide, Berkery filters may be a treated article, or pesticide device, but not a pesticide. *See* Exh. A. Certainly, the EPA cannot rely on non-pesticidal statements made by foreign parties not controlled by SSURO recipients. The EPA cannot point to any pesticidal claim made by the SSURO recipients when issuing their SSUROs. Exh. A, B, & D. The EPA acted arbitrarily, capriciously, and in clear error of judgment when issuing their SSUROs and labeling Berkey products as a pesticide.

None of the cited statutory authorities in the EPA's SSURO's nor legislative history clarify why substances not intended to repel pests are now magically pesticides, rather than devices or treated articles. Use of a silver treatment to protect a mechanical filter does not change a filter into a substance to destroy pests for purposes of FIFRA and the EPA. Exh. C-2 & C-6. Substances not intended to disinfect the water or not intended to prevent, destroy, repeal, or mitigate any pest are not pesticides. Exh. C-2 & C-6.

Additionally, the EPA cannot base their SSUROs on statements relating to such devices not under the control of the recipients. The EPA cannot base their SSUROs on non-pesticidal claims. The EPA cannot take a foreign website that does not make a pesticidal claim to stop all the SSURO recipients' operations for pesticide registration.

# B. The EPA's functional change in definition without a notice and public comment period violates the Administrative Procedures Act.

The EPA's determination that Berkey filters are pesticides is a new conclusion, and taken by the EPA in the previous decades of operation. Plaintiff claims here that the EPA violated the APA by exceeding its statutory authority under FIFRA in a clear error of judgment by reinterpreting their rules to require pesticide registration for Berkey filters without proper notice and comment procedures.

The EPA reinterpreted its rules to regulate Berkey, after more than 25 years of operation, during which time it has never been treated as a pesticide. The EPA gave no notice that mechanical filters would be subject to pesticide registrations before issuing a SSURO against Berkey Int'l.

The EPA is required to provide notice of agency action that could adversely affect parties with economic interests so that such parties have an opportunity to submit comments regarding the potential action that may adversely affect the interests. *See Summers v. Earth Island Institute*, 555 U.S. 488, 497, 129 S. Ct. 1142, 173 L. Ed. 2d 1 (2009); *Citizens for Better Forestry v. U.S. Dep't of Agriculture*, 341 F.3d 961, 969 (9th Cir. 2003); *Ctr. for Biological Diversity v. United States EPA*, 847 F.3d 1075, 1088 n.15 (9th Cir. 2017); *Torch Operating Co. v. Babbitt*, 172 F. Supp. 2d 113, 159 Oil & Gas Rep. 896, 2001 U.S. Dist. LEXIS 18417 (D.D.C. 2001); *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007); 5 U.S.C. § 553.

Here, the decision to classify Berkey filter elements as pesticides applies to interested parties Berkey Int'l, and its distribution channel partners. Exh. A & B. The decision did not undergo notice and comment rule making procedures, there was no public hearing, no public notice, nor was there a statement of general applicability to numerous or all interested parties to FIFRA. *Id.* The final rule adopted was not a logical outgrowth of the rule proposed. *Id.* There was no fair notice. *Id.* Therefore, the EPA's decision did not follow APA notice and comment requirements.

Because the EPA's decision and subsequent SSURO's did not undergo notice and comment rule making procedures, there was no public hearing, no public notice, and no statement of general applicability to interested parties, the EPA's SSUROs are arbitrary and capricious under the APA. *Id*.

The EPA is in violation of the APA reviewable under 5 U.S.C. § 704–706 and 7 U.S.C. § 136n(a). Exh. A, B, & D. The EPA's violations have substantially injured Plaintiff and require damages, declaratory judgment, and injunctive relief to restore Plaintiff to the rightful position. Exh. A & B, see Plaintiff's Original Complaint.

Further, the statements relied on in the SSUROs are from foreign websites that neither Plaintiff nor SSURO recipients have any control over. Exh. A & B. Additionally, the statements relied on in the SSURO show no pesticidal claim, but only mechanical filters using a treated article to protect the filter and not to have a pesticidal effect on the water. Exh. A; B6-11, & D. The EPA cannot show any pesticidal claim by the SSURO recipients or Plaintiff. Exh. A, B, & D. The EPA provided no guidance or notice and comment opportunities for their enforcement of labeling substances intended to protect the devices as pesticides rather than treated articles or pesticide devices. Exh. A & B.

The EPA violates the APA by acting arbitrarily, capriciously, and in error of judgment, reviewable under 5 U.S.C. § 704–06. Plaintiff shows the EPA provided no opportunity for notice and comment or public hearing before declaring something that contains a substance to protect the filter rather than intending to destroy pests as being relabeled as pesticides. Exh. A, B, & D. The SSUROs were issued arbitrarily, capriciously, and in clear error of judgment; Plaintiff should not be required to register their products as pesticides. The EPA's actions have significantly hurt Plaintiff. Exh. A & B. Plaintiff will suffer more irreparable harm if the SSUROs are continued, and EPA continues to arbitrarily require pesticide registration of Berkey Products.

<sup>&</sup>lt;sup>1</sup> Region 8 issued the SSURO to Plaintiff's in Puerto Rico. Region 8 governs Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming and 28 Tribal Nations and has no jurisdiction of Puerto Rico. Region 2 has jurisdiction and governs New Jersey, New York, Puerto Rico, the U.S. Virgin Islands and eight Indian Nations. *See https://www.epa.gov/aboutepa/epa-region-2;* and https://www.epa.gov/aboutepa/epa-region-8-mountains-and-plains.

FIFRA and the APA allow this Court to review final agency actions under FIFRA. Final agency actions under 5 U.S.C. §§ 704, 706(2)(A) include orders of the agency, which are anything relating to interested parties that are not rules. 7 U.S.C. § 136n(a) provides that "Other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States." Here, the decision to classify Black Berkey Filters as pesticides applies to one interested party, Berkey, and its allied sales channels, this decision did not undergo notice and comment rule making procedures, nor was it a statement of general applicability to numerous or all interested parties to FIFRA. Thus, the EPA's decision, expressed here as Stop Sale, Use, or Removal Orders ("SURROs") were orders constituting a final agency action.

The EPA's SSUROs ("orders") resulted from informal adjudication because there was no public hearing on the record as described in 5 U.S.C. §§ 556 and 557. See Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 414 (1971) (holding that the substantial-evidence standard of review for agency actions did not apply to informal orders). Exh. A, B, & D. As a result, the standard for review of the order is arbitrariness and capriciousness based on the record the agency considered while creating the order. See generally, id. However, if the agency cannot describe its basis for why it flipped its adjudication of the issue in the record of available data it considered, courts view that decision as arbitrary and capricious. FCC v. Fox TV Stations, Inc., 556 U.S. 502, 515–16 (2009); see also Rural & Migrant Ministry v. United States EPA, 510 F. Supp. 3d 138, 159 (S.D.N.Y. 2020).

# 2. Plaintiff will suffer irreparable harm to Plaintiffs if the injunction is not granted.

To demonstrate an injury in fact, a plaintiff "must show that 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical." *Spokeo. Inc.*, 578 U.S. at 339 (quoting *Lujan*, 504 U.S. at 560). An injury is "particularized" when it "affect[s] the plaintiff in a personal and individual way." *Id.* A "concrete" injury must "actually exist... [the injury must be] real, and not abstract." *Id.* at 340. (cleaned up). Further, the injury must be traceable to the defendant's actions. *See California v. Texas*, 141 S. Ct. 2104, 2113 (2021). Finally, the plaintiff must show that the court can redress the injury.

Plaintiff suffered a real injury when the EPA issued a stop sale order to Berkey International. Each day the SSUROs are in place Berkey is harmed by not being able to operate their business. Exh. A. The losses in the regular course of business causes Plaintiff to suffer irreparable injury, which will only worsen substantially over time as expenses accumulate during the SSUROs. Exh. A & B. Further, Plaintiff's distributors have questioned, with some merit, whether Berkey has long term stability and viability given the EPA's campaign to make it jump through ever more ridiculous hoops. *Id.* The SSURO literally stops Berkey from operations while violating its constitutional rights. *Id.* 

The SSUROs have caused a massive loss in market share to competitor filtration systems since the EPA began issuing SSURO's against Berkey products. According to Amazon's statistics in February of 2023, NMCL's flagship Big Berkey system alone was clearly the market leader with sales on Amazon approximately 2.5 times that of the closest competitor. Since then, sales have suffered a decrease in sales of approximately 90%. Big Berkey systems have fallen below two competitors, which are now selling nearly three times the volume that Big Berkey systems are selling. Upon information and belief, Berkey filtration systems have had the same attrition on other platforms such as Walmart.com, Ebay.com, etc. Exh. A & B. Plaintiff will supplement further

expert testimony on the market share loss. President of Berkey, Jim Shepherd, understands that Berkey filtration systems have had the same attrition on other platforms such as Walmart.com, Ebay.com, etc. *Id*.

To date, Plaintiff has lost more than 90% of their market share in their flagship Big Berkey systems, massive damage to reputation and brand in both the eyes of customers and distributors that will take years to repair and have lost untold opportunities to gain new distributors and customers. *Id.* Each of these injuries is a real, significant injury that threatens Berkey's existence without this Court's intervention to prevent the EPA from continuing to exceed its statutory authority by declaring Berkey Black Water Filters to be pesticides. *Id.* 

Because of the EPA's SSUROs, Berkey Int'l has been forced to release ALL of its employees. Further, every day this Court does not issue an injunction adds to the substantial resources Berkey Int'l will have to invest to hire and train new employees. Every day of delay is another former employee finding work elsewhere, increasing the resource cost on Berkey. Such an expense is real but cannot be adequately measured for a legal remedy to place the Plaintiffs back in the rightful position. *Id*.

Further, Berkey Int'l has a contract with the government of Puerto Rico which requires maintenance of a certain number local employees in Puerto Rico, and these jobs have been lost, placing Berkey Int'l in jeopardy with defaulting on its agreement with Puerto Rico. *Id.* Unless the Court issues restraint on the EPA's enforcement, these job losses will likely be permanent, as even a later injunction may be too late to save these jobs. *Id.* 

Because of the SSUROs, Berkey Int'l is unable to supply products to its vendors, which threatens decades of professional relationships. One vendor alone was forced to lay off over 425 skilled workers, which it cannot replace without long-term training. If the vendors are not able to

rehire such workers before they find new jobs, the vendors will suffer irreparable damage to their operations. *Id*.

Because of the EPA's SSUROs, Berkey Int'l has \$38,500,000 in wholesale inventory that it is unable to manufacture or sell. Storage costs exceed \$68,000 per month. *Id*.

Because of the EPA's SSUROs, Black Berkey filters have experienced a massive loss in market share to knock-off replacement filters. The imitation Black Berkey elements are simply look-alike filters that have no testing or performance data. Their only claim is that they fit Berkey filtration systems or that they are replacement filters for Berkey elements. American consumers' health may be harmed when they use such filters that fail to provide Berkey filtration performance as the customers expected. *Id*.

During the first six months of 2022, genuine Berkey products were the market leader. Since the first SSURO was issued in December of 2022, knockoff replacement filters are now the market leaders with twice the market share as the original and genuine Berkey elements. *Id*.

Because of the EPA's SSUROs, Black Berkey filters have experienced a massive loss in market share to counterfeit Black Berkey filters. The imitation Black Berkey elements are fraudulently being marketed as genuine Black Berkey filters. The counterfeit elements have no testing or performance data. NMCL, one of Berkey International's customers has filed four lawsuits against foreign actors that are fraudulently marketing the fake counterfeit filters in the US and abroad. These bad actors imitate Black Berkey packaging and fraudulently market their filters as genuine Black Berkey elements when they are not. Because of the EPA's SSUROs a void has been created for Black Berkey elements enabling counterfeiters to meet the pent up demand. American consumers' health may be harmed when they use such filters that fail to provide Berkey filtration performance as the customers expected. *Id*.

To date, Berkey has been hamstrung by the EPA issues preventing it from educating the public on the dangers of using untested knock-off and counterfeit filters that could endanger their health and safety, as EPA agents refuse to give approval to Berkey new websites. Nor has the EPA informed them specifically of what they can and cannot say, therefore Berkey cannot make comments without any certainty that they are not committing additional violations. For example, Region 8 has stated that Berkey is making pesticide statements in the public record in response to a lawsuit. However, when analyzed by Berkey, its agents could not find any pesticide claims. *Id*.

Because of the EPA's SSUROs, Berkey has been prevented from supplying its international Dealers even though the EPA has no regulatory authority outside of the United States. *Id.* The SSUROs damage Berkey and the Berkey brand's good name and reputation in the global marketplace. *Id.* 

The EPA's SSUROs have left Berkey in a state of confusion. As previously mentioned on or about February 3<sup>rd</sup>, 2023, the EPA issued an SSURO to Vendor B, an OEM manufacturer for NMCL and on or about May 8, 2023, Tokarz (Region 8) issued an SSURO in a different region (Region 2) on Plaintiff Berkey Int'l. Exh. A, B-6, & C. On or about May 26, 2023, Region 4 of the EPA terminated the Stop Sale order on Vendor B allowing it to manufacture and sell Berkey filter products as treated articles, including the Travel Berkey, Big Berkey, Light Berkey, Royal Berkey, Imperial Berkey, Crown Berkey and Black Berkey elements. However, the SSURO on Berkey Int'l remains in effect, preventing it from manufacturing and selling those same products as treated articles. Exh. A & B.

Further, "where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, "any loss of income suffered by [the] plaintiff is irreparable *per se*."" *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008); *see also Smoking Everywhere*,

*Inc.* v. United States FDA, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010). Plaintiff's incoming generating operations have been stopped by the EPA, constitution irreparable harm *pre se. See id.* 

No adequate legal remedy exists to make Plaintiff whole. The EPA's SSUROs have stopped Berkey's operations and violated its constitutional rights. *Id.* Therefore, the legal remedy of traditional compensatory damages is inadequate to remedy Plaintiff's injuries, requiring this Court to grant equitable relief in the form of a temporary injunction to prevent irreparable harm before this Court holds an evidentiary hearing on Plaintiff's petition for a preliminary injunction. In summary, Berkey has suffered several distinct property injuries. Plaintiff is unable to alienate its property, Black Berkey Filters. Instead, the stock languishes in warehouses, unable to be shipped or sold. Further, the beneficiaries of the trusts have been deprived of the benefit of their property because Berkey Int'l is unable to operate and provide any benefits like profits and royalty payments to which they are entitled. Therefore, Plaintiff has suffered concrete injuries. Furthermore, Plaintiff's property injury is traceable back to the EPA's actions. It is only because the EPA classified Black Berkey Filters as pesticides that the Plaintiff is unable to manufacture or sell any products because of the changed rights and duties as well as the SSUROs. Further, the EPA's decision deprived the beneficiaries of the trusts of the benefit of their property because the businesses held in trust are unable to operate. Therefore, the injuries are traceable to the EPA's actions.

# 3. The equities in this favor Plaintiff, which is suffering, against the U.S., which will suffer no damage if this Court grants an injunction.

Defendants suffer no hardship from immediate equitable relief. Berkey has sold its filter elements on the market for two decades without an issue. Defendants considered Plaintiff to be a manufacturer of pesticide devices, not pesticides, up until late 2022, when, without adequate explanation, it suddenly reversed course. When this Court grants the temporary restraining order

and then preliminary injunction, the EPA will suffer no prejudice in its investigation and its enforcement efforts against legitimate pesticides will continue unabated as FIFRA mandates.

As described above, the public is currently being harmed by the militant stance of the EPA as it prosecutes Berkey products, making Berkey filters difficult to obtain while knock-offs and counterfeit filters proliferate in the vacuum left by the lack of genuine product.

The EPA is not capable of stopping the knockoffs and counterfeits, which are available on multiple global sources. The choice before the EPA and this Court is whether the EPA can shut down Berkey and prevent quality tested products from being offered for sale leaving the marketplace to untested knockoffs and counterfeits.<sup>2</sup>

By contrast, Plaintiff will suffer extreme hardship if this Court refuses to grant an injunction. Plaintiff faces irreparable harm, market share loss, sales revenue loss, brand and reputational loss, and loss of new customers while being drowned with massive irrecoverable legal and business expenses. Exh. A & B.

Ongoing enforcement efforts against Berkey filters, if left unchecked, will continue to cause these injuries. As the EPA can show no damage that Berkey filters have caused in 25 years, Berkey filters should be allowed to continue to be sold while the dispute is resolved. Conversely, the EPA should not be allowed to starve Berkey with stop orders designed to bring its sellers to their economic knees and force capitulation that is unwarranted based on the merits of the orders, but in practical terms are tantamount to victory. Exh. A & B.

Even now, the EPA has forced at least one of Berkey's contract manufacturers to cease doing business with Berkey Int'l as long as Berkey Int'l makes pesticidal claims, which Berkey Int'l has been doing for decades. An injunction must therefore not only prevent the SSUROs from

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<sup>&</sup>lt;sup>2</sup> See, e.g., <a href="https://www.alibaba.com/product-detail/BB9-2-Black-Purification-Element-Water\_1600431948291.html?spm=a2700.galleryofferlist.normal\_offer.d\_title.1d8a114eJp7Mbk">https://www.alibaba.com/product-detail/BB9-2-Black-Purification-Element-Water\_1600431948291.html?spm=a2700.galleryofferlist.normal\_offer.d\_title.1d8a114eJp7Mbk</a> (July 27, 2023).

having any effect, but also vacate all agreements with the EPA which are based on these enforcement actions.

# 4. The public interest supports the requested immediate equitable relief.

The First Circuit has recognized, "the public has an interest in the enforcement of federal statutes." *Coxcom, Inc. v. Chaffee*, 536 F.3d 101, 112 (1st Cir. 2008).

Public interest demands that administrative states all over the country properly comply with constitutional and statutory bounds. *See id.* Public interest does not support arbitrary, capricious, or abusive agency actions taken without notice, comment, guidance, or explanation. *See id*; 5 U.S.C. § 706(2)(A). No reasonable person wants government agencies to have carte blanche authority to change their own interpretations of the rules without warning or notice to affected parties against Congresses express wishes. *See id.* 

Citizens in a purportedly free country are supposed to have a restrained, transparent, and respectful government, not a leviathan working in the shadows. Producers' and entrepreneurs' incentives to provide products and new goods cannot survive in an economy where they may be subject to arbitrary and ever-changing regulations that will destroy any hope for profit and survival. A regulatory agency run amok with power raises the cost of business for everyone.

Because the public will find imitation filters, which are available even if Berkey's filters are made unavailable by dictatorial fiat, the EPA should consider the real-world impact to the public that is occurring when it acts without addressing the entirety of the market.

Further, Berkey Products have been in service for over twenty-five years and there has been no notable harm to the environment through the sales of official Berkey Products subject to the SSUROs. The success of Berkey Products has shown the public interest in supporting viable and successful safe mechanical water filters for over twenty-five years. Exh. A & B.

### **BOND**

Because the temporary restraining order and a preliminary injunction would place so little burden on the Defendants and provide such great relief to the Plaintiff, Plaintiff requests this court set the bond at \$100, if at all.

### **CONCLUSION & PRAYER**

Because of the irreparable injury that Plaintiff will suffer before trial and the inadequacy of legal remedies, Plaintiff seeks a temporary restraining order and preliminary injunction as argued supra. Additionally, Plaintiff pray for a permanent injunction after trial to enjoin the EPA's illegal action.

If the Court chooses not to issue the injunction requested, Plaintiff asks that the Court issue an injunction at least preventing any additional SSUROs from the EPA on this matter, to allow Berkey to have a chance of surviving these new regulations while working through them, or to replead. Thus, upon trial and final judgment of this Court, Plaintiffs pray this Court award the following:

- a. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA exceeded its statutory authority under FIFRA when it attempted to require Plaintiffs to register their Black Berkey Water Filters as pesticides;
- b. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA violated Plaintiffs 5<sup>th</sup> Amendment due process rights by failing to meet APA and constitutional requirements when changing the rights and duties of the Plaintiffs as to their Berkey Water Filters;
- c. temporary restraining order pursuant to 28 U.S.C. § 2202 enjoining the EPA from enforcing FIFRA pesticide registration requirements against Berkey Water Filters and set aside the relevant SSUROs,
- d. preliminary, and permanent injunctive relief pursuant to 28 U.S.C. § 2202 enjoining the EPA from enforcing FIFRA pesticide registration requirements against Berkey Water Filters and set aside the relevant SSUROs,
- e. general damages, special damages for lost market share and sales revenues, lost employee and vendor employee expertise, lost new customers, massive irrecoverable business expense losses and damage to the good Berkey Brand name directly attributable to Defendants, or in the alternative, nominal damages should other damages be unavailable;
- f. attorney's fees and costs of court because of this action; and
- g. such other and further relief that the Court deems just and proper.

Respectfully submitted,

## /s/Warren V. Norred

Warren V. Norred, warren@norredlaw.com, Texas Bar Number: 24045094 Norred Law, PLLC; 515 E. Border St.; Arlington, TX 76010 (817) 704-3984 (Office); (817) 524-6686 (Fax) Counsel for Plaintiffs

Juan J. Charana Agudo, juan.charana@prbusinessgroup.com Local Counsel, Attorney at Law (787) 234-6575 Puerto Rico Business Group, LLC

# FED. RULE CIV. PRO. 65 CERTIFICATE of CONFERENCE

Without the Court's protection, the Defendant has shown it will continue requiring Berkey Int'l to comply with the SSURO.

In this case, Plaintiff also requested (through the undersigned) that the Defendants stop issuing SSURO against Berkey products because they are not pesticides, and the EPA did not undergo proper notice and comment procedures. Defendants refuse to concede.

As Defendant has determined to go forward with the SSURO, it is presented to the Court for determination of a temporary restraining order, followed by a preliminary injunction.

Formal notice should not be required because, even with the demand by Plaintiffs, the Defendants have continued to hold Plaintiffs to the SSURO. Defendants still refuse acknowledge their decision has no basis in any public record and did not follow proper notice and comment procedures. *See Plaintiff's Original Complaint*. Further, Region 8 does not have jurisdiction over Berkey International, LLC in Region 2, but EPA agent Christine Tokarz has threatened criminal punishment for noncompliance of the SSURO.

The Defendant's actions have put significant burdens on Plaintiff and no notice should be required to issue a restraining order on the Defendants during the pendency of the civil suit. The restraining order should be issued as necessary in aid of this Court's jurisdiction, and to protect or effectuate its judgments.

Plaintiffs assert that \$5000 is a reasonable bond in this case, as the Defendant is not imperiled with any economic loss should Plaintiff fail.

If the Court chooses not to issue a temporary restraining order, Plaintiff still requests a hearing on the matter as soon as possible on the requested preliminary injunction.

I swear under penalty of perjury that this Certificate of Conference is true and correct, and based on my personal knowledge, made February 23, 2024.

s/Warren V. Norred Warren V. Norred

## APPENDIX FILED WITH PLAINTIFF'S ORIGINAL COMPLAINT:

- Exhibit A: First Declaration of James "Jim" Shepherd
  - A-1: Report on Pesticide Information
  - A-2: Coalition Letter to Messina
  - A-3: Statement Regarding Berkey Water Filter Lawsuit
  - A-4: Berkey Response to Wirecutter
  - A-5: Berkey Positive Review Samples
  - A-6: Impact to Black Berkey Sales
  - A-7: Manufacturer EPA Pesticide Records
  - A-8: Berkey COVID-19 Test
  - A-9: EPA's Plane Language Statement
  - A-10: EWG's PFAS Contamination Crisis
  - A-11: EWG's Story on PFAS Filters

# Exhibit B: Declaration of Susan Spaar

- B-1: Tokarz Email Thread (May 1, 2022)
- B-2: Tokarz EPA Close Out Letter (May 5, 2022)
- B-3: Texado Establishment Number, 30-Day Report Email Thread (May 2022)
- B-4: SSURO to James Enterprises, FIFRA-08-2023-0011 (December 27, 2022)
- B-5: Tokarz Email Seeking Documents (December 2, 2022)
- B-6: SSURO to Vendor B (FIFRA-04-2023-0700 (February 3, 2023)
- B-7: SSURO to Fritz Wellness, FIFRA-08-2023-0015 (February 27, 2023)
- B-8: SSURO to Eden Valley Farms LLC, FIFRA-08-2023-0014 (March 6, 2023)
- B-9: SSURO to Mountain Mama Natural Foods, Inc., FIFRA-08-2023-0017 (March 7, 2023)
- B-10: SSURO to Good Earth Natural Foods Co., FIFRA-08-2023-0037 (May 2, 2023)
- B-11: SSURO to Berkey Int'l, FIFRA-08-2023-0038 (May 8, 2023)
- B-12: EPA Order to Amazon and eBay, including Updated List
- B-13: Rejected Packaging, including Lake Image
- B-14: Communications Regarding Damage to Reputation
- B-15: Amazon Counterfeit Documentation
- B-16: Counterfeit Examples
- B-17: Big Berkey Amazon sales decrease from SSUROs
- B-18: Reputation damage example in global marketplace from wrongful EPA actions
- B-19: Berkey Statement Regarding Berkey Water Filter Lawsuit
- B-20: March 6, 2000, Pesticide Registration (PR) Notice 2000 1\*
- B-21: Pesticide Registration Notice (PR Notice) 2023-01
- B-22: Best Water Filters for PFAS chemicals CBS Philadelphia
- B-23: Clerk Cover Sheet
- B-24: Berkey Int'l SSURO Closed

### Exhibit C: Authorities

- C-1: FIFRA, 7 U.S.C. Ch. 6 § 136
- C-2: Notice 51061 1976 Guidance document
- C-3: EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers
- C-4: PR 2023-1, Lists of Pests of Significant Public Health Importance Revised 2023
- C-5: Pesticide Registration Manual, Chapter 13 (updated March 1, 2023), maintained online at <a href="https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices">https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices</a>
- C-6: Pesticide Device: A Guide to Consumers

### CERTIFICATE OF SERVICE

I certify that on March 6, 2024, I filed this proceeding with the Clerk of the Court through the ECF system, which will send notification of such filing to the following by email to Andrew Coghlan, Shari Howard, and Mark Walters, at the addresses shown below:

### **TODD KIM**

Assistant Attorney General Environment & Natural Resources Division Andrew Coghlan (CA Bar. No. 313332)
Shari Howard (IL Bar No. 6289779)
Mark Walters (TX Bar No. 00788611)
United States Department of Justice
Environment & Natural Resources Division
Environmental Defense Section

P.O. Box 7611; Washington, D.C. 20002 Tel: (202) 598-9407 Fax: (202) 514-8865 andrew.coghlan@usdoj.gov shari.howard@usdoj.gov mark.walters@usdoj.gov Attorneys for Federal Defendants

I will send this document to the individual defendants through their email: Christine Tokarz, FIFRA Inspector, EPA, Region 8, tokarz.christine@epa.gov David Cobb, Section Supervisor, Region 8, cobb.david@epa.gov Carol Kemker, Region 4, kemker.carol@epa.gov Keriema Newman, newman.keriema@epa.gov

<u>/s/Warren V. Norred</u> Warren V. Norred

# DECLARATION OF JAMES "JIM" B. SHEPHERD

I declare under penalty of perjury that the proceeding statements are true and correct. My name is James "Jim" B. Shepherd. I have written this Declaration to support the complaint to which it is attached, filed against the Environmental Protection Agency ("Complaint").

- 1. I am the trustee for the James B. Shepherd Trust ("JBS Trust"). I hold legal title to the majority partnership interest in New Millennium Concepts, Ltd. ("NMCL") and hold legal title to Berkey International, LLC's ("Berkey Int'l") intellectual property. The JBS Trusts' beneficiaries hold equitable title to the majority partnership interest and Berkey Int'l's intellectual property. Berkey Int'l pays royalty fees to me as legal title holder to distribute according to the trust's terms.
- 2. I am also the President for Berkey International, LLC. ("Berkey Int'l") and trustee for the JMDBC Trust that owns 100% of Berkey International, LLC.
- 3. Berkey International, LLC is a Puerto Rico manufacturer of Berkey filtration systems. The JBS Trust has licensed Berkey Int'l to manufacture Berkey filtration systems. These systems include Berkey filters, the subject of the EPA's concerns. JBS Trust has licensed NMCL to manufacture and sell Berkey filters since 1998.
- 4. Berkey water filtration systems mechanically remove waterborne pathogens such as pathogenic bacteria, virus and cysts and also remove or reduce chemical contaminates such as volatile organic chemicals, forever chemicals, pharmaceuticals and heavy metals from water. Additionally, Berkey filters are able to filter these contaminates from raw untreated lake, river, or pond water. For that reason Berkey filters have been used worldwide for over a quarter of a century during crisis and emergencies to provide potable water when potable water sources are not available. Thus, over the decades Berkey water filters have saved countless lives during crisis and emergencies.
- 5. During and after hurricane Maria struck Puerto Rico in 2017, municipal water systems were damaged throughout Puerto Rico. Over a 1,250 Berkey water filtration systems were donated

to communities across Puerto Rico by Berkey International, Foundation for Puerto Rico and Oxfam. Berkey serves all members of the public by providing them with access to filtered water. Millions of Berky filters bearing the Berkey marks have been sold all around the world.

- 6. On or about April 28, 2022, the Environmental Protection Agency stopped an inbound NMCL container at customs to conduct an EPA inspection. The first time in Berkey's 25-year existence that the EPA has developed an interest in Berkey filters that led to administrative action.<sup>1</sup>
- 7. Berkey has records regarding comments made around May 3, 2022, when EPA agent Christine Tokarz said that Berkey products are violating 7 U.S.C. § 136j(a)(1)(F) by distributing a device that is misbranded for allegedly "potentially false or misleading pesticidal claims."
- 8. Referring to her review of Berkey's website and packaging, Tokarz further stated:

  I can assure you though, these are pesticide device claims, I have no doubt about that in my mind. . . . My goal here is to help American companies stay in business and get them into compliance, not to enforce a bunch of, you know, record keeping rules. That's not really my goal.
- 9. On or about May 5, 2022, Tokarz issued an EPA Close Out letter to NMCL which stated, "Under FIFRA section 7, all pesticide devices sold or distributed in the United States must be produced in a registered establishment. 7 U.S.C. §§ 136e(a), 136j(a)(2)(L). A pesticide device is defined as any instrument or contrivance that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life." The letter is attached as Exh. B-2.
- 10. For the last 25 years, Berkey has not needed to register its manufacturing facilities. Berkey has used OEM manufacturers which had to be registered. The EPA considered Berkey to be

Berkey Int'l v. EPA, Declaration of James "Jim" Shepherd

<sup>&</sup>lt;sup>1</sup> After May 4, 2022, EPA enforcement actions against companies with which I do business indicated to me that water filter manufacturers making virus removal and pathogenic bacteria removal claims may lose the exemption as a pesticide device for their water filters under the new reinterpretation of the regulations. EPA Enforcement actions publicly viewable on its website indicate that the EPA may now consider outdoor water filters that can filter raw untreated water and remove waterborne pathogens to be pesticides, though the EPA has not given any guidance with respect to their enforcement of pesticide registration requirements against such water filters.

manufacturing a pesticide device because the filter element box, which had an establishment number, was placed within the water filter system box. The EPA requested that, because Berkey included the Black Berkey filter element box, with its establishment number, inside the system box, Berkey needed to get an establishment number and print that number outside of the water filter system boxes.

- 11. After the EPA's demands for pesticide device compliance, Berkey verified that its claims were accurate according to the test data for removing waterborne pathogens. Around May 11, 2022, Berkey requested an EPA establishment number for Texado, Ltd., its third-party distribution center, and received it around May 19, 2022, as discussed with Tokarz by email in Ex. B-3.
- 12. On June 7, 2022, NMCL consultant Kevin Kutzel, wrote to Tokarz:

Even though your letter implies that this action is closed out, I wanted to provide an update to your office and inform you that Texado, the Colorado manufacturer and packager for Berkey Products, has obtained an EPA Establishment No. 101921-CO-1 and this number is now being posted on the outside of the box for each Berkey filtration system that they manufacture. I believe that the acquisition of this EPA Est. No. for Texado, Ltd., meets the legal requirements for a distributor of a device and no false and misleading claims are being made on the packaging.

### Exhibit B-3.

13. On June 8, 2022, Tokarz responded to Kutcel's June 7<sup>th</sup> email:

Appreciate the follow up, but would like to note that simply adding the EPA Establishment number to the pesticide device label does not meet all the FIFRA requirements. Also note that there seems to be quite a few new establishments that are not submitting their Initial 30-day report, rendering them 'delinquent.'

# Exhibit B-3.

14. Kutcel responded to Tokarz's June 8 email, "KRK Consulting LLC will work closely with New Millennium Concepts, Ltd. to ensure all pesticide device requirements are in compliance and no false and misleading claims are made. We will also be sure to file the initial 30-day report for Texado, Ltd." A true and correct copy of this email thread is attached to the Complaint as Exhibit

- B-3. About that same day, NMCL filed the 30-day report making NMCL compliant with the EPA's requests pertaining to pesticide devices.
- 15. On or about November 22, 2022, the EPA inspected James Enterprises facilities. The EPA Inspectors reported to the staff that they observed that Black Berkey Filter, Berkey's signature product, labeling included pesticidal claims, e.g., "Black Berkey Purification Elements: VIRUSES: >99.999% PATHOGENIC BACTERIA (AND SURROGATES) >99.9999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)."
- 16. Black Berkey employs proprietary, patented, trade-secret technology to ensure its water filters are both safer and more effective than competing filters on the market and distributes its filters to authorized retailers. The virus claims are accurate, based on third-party tests, which are available to any lawful authority.
- 17. Because of the inspection of James Enterprises, I instructed NMCL and Berkey to again check its virus removal claims and testing and verify that no misleading treatment claims were being made.
- 18. On or about December 2, 2022, Tokarz wrote to James Enterprises:

EPA believes that the products listed below may be subject to FIFRA regulations: *Black Berkey Filters, Sport Berkey Replacement Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, the Berkey Light Water Filters, and the Sport Berkey Water Bottle.* Please provide the requested documentation on each of the 9 separate products identified above.

Exhibit B-5.

19. On or about December 27, 2022, Tokarz issued an unwarranted surprise EPA Stop Sale, Use or Removal Order (SSURO) to James Enterprises, a Berkey dealer, in Docket Number: FIFRA-08-2023-0011. A true and correct copy of this order is attached to the Complaint as Exhibit B-4. This was the first SSURO alleging that Berkey water filter systems were unregistered misbranded pesticides.

- 20. The EPA did not provide any sort of explanation, notice, or guidance before issuing the order. It is my understanding that the EPA based its SSURO on the fact that Black Berkey elements effectively removed waterborne pathogens and a statement found on a foreign European website claiming that Black Berkey elements utilized silver to protect the filter. Prior to this order, all NMCL and Berkey's discussions and correspondence with the EPA were based upon a joint understanding that Black Berkey elements were "pesticide devices" exempt from registration and were not "pesticides." Even more peculiar was the term "Berkey Black", which knockoff producers use to sell fake Berkey products, was used a dozen times in the SSURO.
- 21. In mid-January of 2023, Berkey and James Enterprises agreed that, rather than fighting with the EPA about whether Black Berkey products were a pesticide or pesticide device, which could take years to determine, they would work with the EPA in good faith by agreeing to be classified as merely a treated article and would remove all testing references and statements that could be construed to indicate that the filters could remove waterborne pathogens from their literature, advertising, websites, and packaging.
- 22. On or about January 27, 2023, NMCL through Sean Elliot and James Shephard began sending Parker and Todd Emerson at James Enterprises new packaging designs, including new bar codes and new wording, which were consistent with Berkey products being treated articles. They were instructed to submit the new materials to the EPA for approval. Thereafter, James Enterprises submitted multiple iterations of the materials to the EPA, which rejected them and required minor changes without actionable guidance for changes that could have been communicated to James Enterprises on the first iteration.
- 23. As examples, on the first submission sent for approval on January 26, 2023, all pathogenic organism removal claims had been removed. That submission was rejected for the phrase "Purified the natural way" because the EPA didn't like the word "purified". Another iteration was rejected

for the phrase "Filtered the natural way" because the EPA didn't like the word "natural". Another iteration was rejected because the EPA objected to the word "extreme". Another iteration was rejected because the EPA didn't like the phrase "Great Outdoors". Another iteration was rejected because it had a picture of a lake, a picture that NMCL has utilized on its packaging for water filters for 25 years. Another iteration was rejected because of a picture of a Berkey system on the inside of a cabin. True and correct copies of rejected packaging and communications are attached to the Complaint as Exhibit B-13, including the lake image which the EPA prohibited.

- 24. While Berkey and JE were working in good faith with the EPA, in terms of changing their websites and packaging to be in compliance with Treated Article status, the EPA in bad faith stepped up its attack on Berkey-related companies, issuing several SSUROs to Berkey dealers and manufacturers, including Berkey Int'l. Each SSURO concluded the recipient violated FIFRA by selling Black Berkey Filter Products, which the EPA considers to be unregistered and misbranded pesticides, and each required reports to an EPA agent.
  - a) February 3, 2023, FIFRA-04-2023-0700 (Exh. B-6), to Vendor B, a Berkey OEM manufacturer located in Alabama and classified by Berkey as a trade secret;<sup>2</sup>
  - b) March 3, 2023, FIFRA-08-2023-0015 (Exh. B-7), to Fritz Wellness; a Berkey dealer located in Colorado.
  - c) March 6, 2023, FIFRA-08-2023-0014 (Exh. B-8), to Eden Valley Farms LLC, a Berkey dealer located in Utah.
  - d) March 7, 2023, FIFRA-08-2023-0017 (Exh. B-9) to Mountain Mama Natural Foods, Inc., a Berkey dealer located in Colorado.
  - e) May 2, 2023, FIFRA-08-2023-0037 (Exh. B-10), to Good Earth Natural Foods Co. South Dakota, a Berkey dealer located in South Dakota.

<sup>&</sup>lt;sup>2</sup> As part of the injunction sought, Plaintiffs seek vacatur of the restrictions by which this vendor is obligated to operate; the EPA lifted its SSURO on this vendor with the caveat that it would not sell filter products to Berkey Int'l and NMCL unless NMCL, Berkey Int'l, and their affiliates make no pathogenic removal claims regarding these products.

- 25. Finally, about May 8, 2023, David Cobb issued an SSURO, Docket No. FIFRA-08-2023-0038, on Berkey International, LLC (Exhibit B-11). The order alleged that Berkey International, LLC violated FIFRA by selling the Black Berkey Filter Products, which the EPA considered to be unregistered and misbranded pesticides. Tokarz has jurisdiction in Region 8 but leapt over region 2, where BI is located, to issue the SSURO to Berkey International. Again, the knock off filter name "Berkey Black" was used in the SSURO and it required response to Tokarz.
- 26. On the same day, May 8, 2023, Tokarz issued a Regional Hearing Clerk Filing recommending that the EPA close the SSURO "immediately after docketing", requesting a final order within one week and indicated that Berkey Int'l was "not represented by legal counsel" and that no public notice was required. The following day the EPA closed the SSURO. A true and correct copy of the docket and order is attached to the Complaint as Exhibit B-23 and B-24.
- 27. On or about May 26, 2023, I became aware that Vendor B received notice of the Termination of its SSURO. The Termination was predicated upon the condition that Vendor B would not be able to manufacture products for Berkey unless Berkey agreed to make no pesticidal (pathogenic removal) claims. A true and correct copy of the docket status is attached to the Complaint as Exhibits #B-6.
- 28. In or about June 24, 2023 Amazon restricted sales of Berkey products without any clear guidance as to what the offending statements or language was that led them to believe Berkey products violated FIFRA.
- 29. Berkey has been in business for more than twenty-five years and has always attempted to comply with EPA environmental and public health regulations. Berkey has periodically hired EPA consultants to review its websites and claims and to ensure compliance with EPA regulations.
- 30. In May of 2022 NMCL's EPA consultant informed me that because of COVID-19 the EPA was considering re-interpreting their rules such that water filters that were capable of removing

virus would be re-classified as pesticides. I asked the consultant what guidance the EPA was giving. The consultant replied, "The EPA was giving no guidance and that they were being very tight lipped about the issue." Months later when Ms. Tokarz began issuing SSUROs to Berkey dealers she stated that the EPA had stepped up compliance because of COVID-19.

- 31. Prior to the COVID-19 pandemic, neither NMCL nor Berkey Int'l had ever had any issues with the EPA. To the best of my knowledge, the EPA has never published any guidance that would provide adequate notice to Berkey regarding reclassification to pesticides due to the Black Berkey filters capability of removing viruses from water.
- 32. By May of 2022, Berkey came into compliance with exempt device regulations as the EPA required at the time. Berkey complied by obtaining and then attaching establishment numbers to its products, completed its reporting requirements and verifying its advertising claims for accuracy.
- 33. During early 2023, I became aware that NMCL, Berkey, Vendor B, and James Enterprises modified their websites to change the status of Berkey water filter products to treated articles. Berkey repackaged the Black Berkey Filters with packaging that did not make any waterborne pathogen removal claims for U.S. sales, and all un-repackaged filters were marked for international export.
- 34. Berkey Int'l has \$38,800,000 in wholesale inventory that it is unable to manufacture. Storage costs are \$86,000 month. More than 500 jobs have been lost by the EPA's actions, at least temporarily, as Berkey Int'l has had to release all of its employees. Unless the Court issues restraint on the EPA's enforcement, these job losses will likely be permanent, as even a later injunction may be too late to save these jobs.
- 35. Berkey Int'l has a contract with the government of Puerto Rico which requires maintenance of a certain number local employees in Puerto Rico, and these jobs have been lost, placing Berkey Int'l in jeopardy with defaulting on its agreement with Puerto Rico.

- 36. The SSUROs on Berkey Int'l and other Berkey-related businesses have seriously damaged the reputation of Berkey filtration systems. We have received multiple emails from allied businesses indicating the extent of the damage of EPA's prosecution, a true sample of which are attached to the Complaint as Exhibit B-14.
- 37. There are millions of Berkey filters and filtration systems around the world whose owners are in jeopardy of not being able to replace their Berkey filter elements because of the SSURO.
- 38. The SSURO has caused Berkey to suffer a massive loss in market share to knockoff replacement filters since the EPA issued it. During the first six months of 2022, genuine Black Berkey elements were clearly the market leader. Since the first SSURO was issued in December of 2022, knockoff replacement filters are now the market leaders with twice the market share as the original and genuine Black Berkey elements. It is my understanding that Berkey systems have had the same attrition on other platforms such as Walmart.com, Ebay.com, etc. A true copy of the report showing market share loss is attached to the Complaint as Exhibit B-15, which I created using Amazon's sales tools.
- 39. Additionally, the SSURO has allowed a massive and incalculable loss in market share to counterfeit Berkey product sales. To date Berkey Int'l has been unable to stop the contamination of counterfeit filters marketed on Amazon and other platforms such as Ebay and Wallmart.com. Currently rampant counterfeiting is accelerating on all platforms. NMCL has filed lawsuits against four Ukrainian organizations importing counterfeit filters into the US. The supply void of legitimate Berkey elements has limited legitimate sellers of Berkey filters to ship product, which in turn has allowed unregistered and untested knockoff and counterfeit filters to fill market demand.
- 40. The counterfeit and knockoff Black Berkey elements are simply look-alike filters that have no testing or performance data. To my understanding, knockoffs are made to fit and replace Berkey

Filters, but do not function like genuine Black Berkey filters and do not necessarily market themselves as Berkey products, rather just compatible. Their only claim is that they physically fit Berkey filtration systems or that they are replacement filters for Black Berkey elements. A true and correct copy of an example lookalike Black Berkey is attached to the Complaint as Exhibit B-16. Counterfeit on the other hand attempt to market their fake products as genuine Berkey products. In my opinion, this is tantamount to an unknown person selling an untested drug claiming that the fake pills he is selling look just like a particular critical medication that a patient needs, for a fraction of the price. Berkey's American customers' health may be harmed or be in jeopardy when they use filters that don't provide Black Berkey filtration performance that the customers expected. Moreover, the Berkey brand is harmed when customers complain online about the performance of knockoff or counterfeit Black Berkey elements, believing they have purchased the genuine article. Yet, because of the SSUROs, counterfeit and knockoff filter sales have flourished and overtaken much of the Berkey filter market.

- 41. The SSUROs have also caused a massive loss in market share to competitor filtration systems since the EPA began issuing SSUROs against Berkey products. According to Amazon's statistics, in February of 2023 our flagship Big Berkey system alone was clearly the market leader with sales on Amazon approximately 2.5 times that of the closest competitor. I created a chart of these statistics using Amazon's sales tracking tools and included it as Exhibit B-17 to the Complaint to which this Declaration is attached. Since these SSUROs have been issued, sales have decreased by more than 90%, and now are below two of Berkey's competitors.
- 42. Because of the SSURO, Berkey is unable to purchase products from its vendors, which is destroying decade-old commercial relationships. One vendor alone was forced to lay off over 425 skilled workers, which it cannot replace without long-term training. If the vendors are not able to rehire such workers before they find new jobs, the vendors will suffer irreparable damage to their

operations. More importantly, it will take years for Berkey Intl and its vendors to re-train new

employees and recover from the damage that has been done.

43. As stated above, the SSURO to Berkey Int'l has forced Berkey Int'l to lay off **ALL** its

employees, which it cannot replace without long-term training. If Berkey Int'l is not able to rehire

such workers before they find new jobs, Berkey Int'l and its vendors will suffer irreparable damage

to their operations.

44. The SSURO prevents Berkey Int'l from supplying its international Dealers even though

the EPA has no regulatory authority outside of the United States. The SSURO damages the Berkey

brand's good name and reputation in the global marketplace. For example, one French website<sup>3</sup>

asserts "Berkey filtration cartridges are prohibited from export sales. This prohibition is the result

of the conviction by the environmental agency of the United States, the FIFRA. The Berkey

cartridges, unlike the British Berkefeld cartridges are far from providing the promised filtration

which is simple deception on the goods they sell to you...Justice has decided !!.. Below is the

detail of the judgment." A true and correct copy of the website and English translation provided

by Google Translate is attached as Exhibit B-18.

45. The British Berkefeld cartridges mentioned above are also marketed in the US and plainly

state on their packaging that they utilize silver to protect the filter and they also make pesticidal

claims. To my knowledge the EPA has taken no actions against them but rather has re-interpreted

their rules specifically for Berkey products alone.

46. On July 13, 2023, the EPA informed NMCL during a phone call with counsel that it was

giving Berkey Int'l only three options to release the SSUROs on Berkey Products:

3https://eaudoulton.com/berkey-condamnation/?fbclid=IwAR3pMdVvqS8cgx-

fTZzR7n9Qyg4ySbRmnF6SzbOAXxT9QC5xz2fvsg19lNY

- 1. The SSUROs will remain in effect until the Berkey products are registered as pesticides even though Black Berkey products are treated devices. This option could take two to three years and will take time and money. In the meantime, Berkey products would be off the market until they get the approval for registration. This option would have the effect of putting Berkey products and dealers out of business.
- 2. Sell a "new" filter product/system that does not make claims that implicate pesticide issues and that they suggested that they would likely not allow the "Berkey" trademark to be used on any products. Additionally, under this option, if the market recognized that the new product was a repackaged and rebranded Berkey product, the EPA would swing back into punishment mode and issue another SSURO. Berkey has over a quarter of a century of goodwill behind its brand and this option would have the effect of putting Berkey products and dealers out of business.
- 3. The SSUROs will remain in effect until a successful cleanup of the world wide web and marketplace for Berkey products takes place, to the maximum extent possible, of all waterborne pathogen removal claims. This would require not only elimination of all waterborne pathogen removal claims on the web but also affirmative statements disclaiming pesticide intent as "corrective action." Tokarz expressed doubt that we would be able to clean up all the communications of claims in the marketplace to their satisfaction since some appear in places over which Berkey cannot control or remove. This option would have the effect of putting Berkey products and dealers out of business.

Accordingly, all three options offered would have the effect of putting Berkey products and dealers out of business.

43. On the same phone call, Tokarz informed NMCL because of a posted response to a private lawsuit that "NMCL continues to make pesticide statements in the public record reflects its intent

and will make it difficult for EPA to make the finding necessary to allow the products to be sold." Even more alarming, in our review of the public statements the EPA referenced as making pesticide claims, we could find no pesticide claims whatsoever. *See* Exhibit B-19.

- 44. I suspected from the first SSURO that Tokarz issued that she was inserting herself into a private matter by using the regulatory power of the EPA to influence the outcome in that private lawsuit. I came to that conclusion because she made the same mistake that the Plaintiffs made in that lawsuit when she specified the name "Berkey Black" filters in her SSUROs instead of their proper name, which is "Black Berkey". For the record 'Berkey Black" elements are untested knock off filters that are not genuine Berkey products and over which Berkey has no control. These knock-off elements are harming the good name of Berkey because they do not have the performance of genuine Black Berkey elements. The good name of Berkey is harmed when it is blamed for the poor performance of the knock off elements.
- 45. Tokarz informed my counsel that she will not allow NMCL to defend itself in the lawsuit publicly or in the court against these and other fallacious claims. Cristen Rose, attorney for NMCL in this action, emphasized to Tokarz that NMCL has the right to defend itself in the class action, which necessarily requires that it address the claims at issue. However, Tokarz stated that if NMCL continues to defend itself that it would make it difficult for EPA to make the finding necessary to allow the products to be sold.
- 46. As previously stated, the SSURO's utilized the same Knock-off term "Berkey Black" as those found in the lawsuit. The EPA has not been granted the authority to pick winners and losers in private industry nor to select winners and losers in private law suits. More importantly, given that Tokarz utilized the same knock-off term in her SSURO's as those found in the lawsuit, I believe that Tokarz interest in re-interpreting EPA regulations was to influence the outcome of a

private lawsuit rather than to follow EPA regulations. During this call, Tokarz instructed NMCL's counsel to confirm that the SSURO issued to Berkey International was also applicable to NMCL.

- 47. Berkey cannot be colorably accused of endangering any life, rather they have saved many lives over the decades by producing cleaner water for millions of people worldwide. This vendetta on the part of Tokarz and the EPA endangers Berkey's continued operation while also encouraging low-grade knockoffs and counterfeit filters to proliferate and fill the market gap left by Berkey's demise with cut-rate products. To the extent the purpose of the EPA's pesticide rules is to *protect* the public, its unreasonable application and enforcement, in this instance, defeats that objective, and counter-intuitively, makes the public *less safe*. When a member of the public is harmed by counterfeit filters, redress will be more difficult or impossible since the sourcing for knockoff filters is rarely obvious, the filters are often deceptively presented as exact replacements for Berkey filters, in spite of their differing low-quality construction, and are almost always produced outside the US, where seeking redress for damage is almost impossible.
- 48. Berkey Int'l has offered its customers the option of utilizing third party ceramic filters, in lieu of Black Berkey filters, for over two decades in the following systems: *Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, and Crown Berkey Water Filters*. Yet, the EPA has indicated that going forward they would likely not allow the use of the Berkey trademark in association with the modified filters, which would include such ceramic filters that are not as issue.
- 49. Black Berkey filters and Products are not pesticides. In the light most favorable to the EPA's position they are at best "pesticide devices" or are at least "treated articles" and have never had any public health issues. They do not utilize substances to kill the pathogens in the water. Instead, they use mechanical means to remove waterborne pathogens, specifically, water is filtered through a maze of micro pores that trap pathogens and remove them from the water.

- 50. The EPA published its Guide Standard and Protocol for Microbiological Water Purifiers in 1986, which established standards for filtration systems to be considered a microbiological purifier. It is my understanding that the standard was established for backpackers, floods and natural disasters, foreign travel, motor homes etc. and requires that virus, among other pathogens, be removed to meet that standard. The document mentions registration as a pesticide for microbiological purifiers using chemicals (to kill waterborne pathogens) but also mentions non-registerable devices (that mechanically remove viruses). This Standard also requires that units containing silver to protect the filter element itself be stress-leach tested to assure that excess levels of silver will not be leached into the drinking water. A true and correct copy of this EPA standard is attached as Exhibit C-5.
- 51. Black Berkey filters have met the EPA's standard as outlined in the Guide Standard and Protocol and have demonstrated that silver used to protect the filter itself does not leech into the water. The EPA document does not state that any filter that meets this standard will be considered to be a pesticide. Black Berkey filters are not pesticides but rather are a treated device that does not require registration as a pesticide. The EPA exempts devices that remove microbial pests by physical or mechanical means from registration as a pesticide but requires registration when a device contains any substance intended to disinfect the water.
- 52. To reiterate, Black Berkey elements remove microbial pests by physical and mechanical means and do not contain any substance intended to disinfect the water and therefore should be exempt from registration as a pesticide.
- 53. On March 6, 2000, the EPA issued a Pesticide Registration (PR) NOTICE 2000–1. The notice clarifies current EPA policy with respect to the scope of the "treated articles exemption" in 40 CFR 152.25(a). This notice has never been revoked or revised. This exemption covers qualifying treated articles and substances bearing claims to protect the article or substance itself.

And "provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if: (1) the incorporated pesticide is registered for use in or on the article or substance, and; (2) the sole purpose of the treatment is to protect the article or substance itself." A true and correct copy of the document is attached as Exhibit B-20. Black Berkey elements incorporate a trade secret pesticide registered for use in the formulation and the manufacture of bacteriostatic water filter units and is designed to inhibit the growth of bacteria in the filter to prolong the life of the filter. Use of this registered pesticide is for the sole purpose of protecting the filter itself and therefore is exempt according to the notice.

- 54. The EPA lists 127 registered Pesticides that utilize silver on their website: <a href="https://ordspub.epa.gov/ords/pesticides/f?p=113:6::::P6 XCHEMICAL ID:3769">https://ordspub.epa.gov/ords/pesticides/f?p=113:6::::P6 XCHEMICAL ID:3769</a>. This list comprises such items as plastics, cloth as well as various media utilized in the manufacture of water filter elements. However, this list does not include manufacturers of products that utilize the listed registered pesticides that protect the products themselves. The media registered as pesticides on this website are primarily utilized in the manufacture of filters that are Treated Articles utilizing the media in order protect the filters themselves.
- 55. One of the many media utilized in the Black Berkey proprietary formulation is a registered pesticide that utilizes silver to protect the media itself. The Black Berkey formulation incorporates this media in its proprietary formulation to protect the filter element itself. Testing conducted on Black Berkey elements has verified that the minuscule amount silver in the filter element formulation does not kill pathogens in the water but merely protects the filter itself. There are no water filters that utilize the various media listed to protect the filter elements themselves, on the entire list. The EPA is applying its regulations and enforcement actions unevenly. It targets Berkey filters as Pesticides because they use a registered form of silver to protect the element itself, while neglecting other outdoor, camping and emergency filter elements that make similar pesticidal

claims that also utilize a similar registered pesticide to protect the filter element itself from bacteriological overgrowth.

- 56. The EPA's SSUROs rely on statements found on a European website to claim that Black Berkey elements are pesticides. Black Berkey elements are sold globally, and each foreign country has its own standards that typically differ from EPA standards applicable within the US. Therefore, international Berkey sales are not bound by EPA standards. Even so, the European website the EPA specifically referenced clearly states that the silver is utilized to protect the filter itself and is not utilized to disinfect the water: "Yes, silver is used as an antimicrobial to self-sterilize the BlackBerkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."
- I have diligently searched as have multiple of my EPA consultants for any official EPA public announcement that because of Covid-19, there is a prohibition against mechanically removing virus or that mechanically removing virus constitutes a pesticide. To date, the only public notice that we have found in terms of virus removal is **Pesticide Registration Notice** (**PR Notice**) 2023-01. In that document it states, "Microorganisms and acellular particles... listed in this category cause diseases such as COVID-19, cholera, meningitis, Legionnaire's Disease and many others." And specifically states "**IV. WHAT REGISTRANTS SHOULD DO:** Registrants do not need to do anything in response to this notice." A true and correct copy is attached as Exhibit B-21. Moreover, the EPA's claims that Berkey products are pesticides, are general in nature and do not state what specific regulation has been violated.
- 58. Berkey Int'l is domiciled in EPA Region 2 and has never been contacted by Region 2. The only communications to BI have been an SSURO issued from EPA Region 8. Since Region 8 leapt

<sup>&</sup>lt;sup>4</sup> Online at https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html (accessed July 28, 2023).

over region 2 to issue an improper surprise SSURO, the business of more than a dozen companies have been critically impacted imperiling their survival, more than 500 individuals have lost their jobs, and the market share for Berkey systems has been virtually decimated.

- 59. When I reflect back on Tokarz assurance on the first conference call that "My goal here is to help American companies stay in business and get them into compliance, not to enforce a bunch of, you know, record keeping rules. That's not really my goal," I cannot reconcile that statement with the damage that has been done to individual employees, to multiple companies, to the Berkey brand, to the American people and people worldwide who are purchasing counterfeit Berkey products believing them to be genuine. For example, on July 11th, 2023, CBS recommended the Travel Berkey system, both in print and in their broadcast news, based upon the Environmental Working Group's testing that found Travel Berkey systems removed toxic PFAS to below detectable limits. And on June 7th, 2023, popular consumer health advocate Mike Adams recommended Big Berkey® systems reporting that they removed an impressive 99.99% of radioactive cesium-137. However, Region 8 is actively working to make these systems unavailable to the American people and to people worldwide.
- 60. Berkey Int'l (a.k.a. "BI") has contractual commitments that require it to employ a certain number of employees. Berkey Int'l is now in danger of defaulting on that contract because of the EPA's SSURO. Without an injunction, BI will default on its contract and will be unable to renew it and therefore will likely be forced out of business by the time this case has been tried.
- Additionally, Berkey Int'l has storage expenses that are running approximately \$2,250 per day and it has no other source of income. This case will likely not be decided for at least a year, which will cost Berkey Int'l more than a million dollars in storage fees alone. Again, by that time Berkey Int'l will already be in default on its contract and be out of business. In the absence of an injunction, the default will cause irreparable harm to Plaintiffs, who will not be able to sustain the

damage to reputation, its disappearing supply chain and the loss of its market leadership. Because the EPA is on this warpath and issued the SSUROs not only to Berkey Intl. and its dealers but also to its vendor, no new vendor can expect to operate without the same harassment.

- 62. To make matters worse, the EPA's unjustifiable enforcement actions have led one of Berkey International's primary dealers to breach their contract with Berkey, selling counterfeit goods which infringe on Berkey's brand, all in an effort to remain in business. James Enterprises, one of Berkey's primary domestic dealers that received the first SSURO, has breached its contract with Berkey by selling non-Berkey Boroux water filters on berkeyfilters.com, which James Enterprises controls and has registered Berkey trademarks in China and potentially other countries, without permission from NMCL or Berkey Int'l. Their implications that their knock-off filter is a Berkey product is creating even more alarming confusion in the Berkey marketplace. See Exhibit "Great News for Berkey! Berkey and Boroux have teamed up with a carbon filter solution!"
- 63. Over a quarter of a century ago, I was personally involved with Berkey pioneering the outdoor, camping and emergency water filtration market. As such, I have an exhaustive knowledge of the industry and Berkey's competitors. Any filter that filters raw untreated lake, river, or pond water must be bacteriostatic otherwise pathogenic growth will occur within and on the filter which, will then be overgrown with pathogenic bacteria. When this happens, the filtered water becomes more contaminated with bacteria than the source water. To protect the filter, it must be a treated article.
- 64. Berkey is not alone in our opinion that there are serious problems at the EPA. In 2020, a former EPA committee member sued the agency in cause no. 1:21-cv-02623, claiming EPA advisory bodies improperly eliminated business sector representation under the present administration. He claimed in his Amended Complaint, "[i]n its haste to eliminate all traces of industry from its advisory committees, EPA ran roughshod over FACA and its obligation to engage

in reasoned decision-making." *Young v. EPA*, 1:21-cv-02623-TJK (D.D.C., 2021) (Doc. 17, p. 2.). In that case, the court granted partial summary judgment and forced the EPA to revise committees to be more balanced and include industry-affiliated members.

65. Moreover, major leaders in the water filtration industry including the Water Quality Association (WQA), International Asso. of Plumbing and Mechanical Officials (IAPMO), and more than 30 Coalition Partners have asserted that the EPA's regulations are ambiguous and inconsistent with respect to FIFRA enforcement. On September 30, 2022, this industry group wrote to Edward Messina Director EPA's Office of Pesticide Programs to discuss modernization of the enforcement of regulations pertaining to certain water filtration systems under FIFRA, and included the following recommendations:

Since 1976, the EPA Office of Pesticide, under FIFRA, has treated water filtration systems that inhibit bacteria, viruses, and other microorganisms in drinking water as pesticides and pesticidal devices. Although the EPA has good intentions, the agency's ambiguity, and inconsistent enforcement of FIFRA on water filtration systems in recent years have caused significant delays and detrimental impacts on the water filtration industry. Ultimately, this has a cascading effect on consumers, safety, and the economy. Additionally, EPA has continued to require manufacturers to comply with rigorous mandates including labeling, registration, and other requirements that often have little bearing on human health and environmental safety. This can be costly, time-consuming, and with little guidance from EPA, confusing.

. . .

The coalition recommends that EPA consider modernizing its interpretation of the regulation to instead rely on third-party certification since the current enforcement guidelines can prevent the deployment and increase costs of water filtration systems that are being used to protect Americans, including many from disadvantaged and underserved communities, from a host of new, and emerging threats impacting drinking water quality.

The letter contains a specific proposal regarding residential drinking water filters that fall under the term "pesticidal devices" and water treatment devices that contain a bacteriostat to protect the device itself, and addresses the issue head on. I have attached the coalition letter to Messina as Exhibit A-2. To date the EPA has been unresponsive to this attempt to modernize its regulations.

### Case 3:24-cv-01106 Document 1-2 Filed 03/06/24 Page 21 of 93

Exhibit A, Declaration of James "Jim" Shepherd

66. The emails and other documents to which I have referred in this declaration were collected by me personally at or near the time they were created or collected by an employee or agent. These are documents kept in the ordinary course of business in all Berky-related companies, and I can attest to these documents as a custodian of records for Plaintiffs:

A-1: Report on Pesticide Information

A-2: Coalition Letter to Messina

A-3: Statement Re: Berkey Water Filter Lawsuit

A-4: Berkey Response to Wirecutter A-5: Berkey Positive Review Samples

A-6: Impact to Black Berkey Sales

A-7: Manufacturer EPA Pesticide Records

A-8: Berkey COVID-19 Test

A-9: EPA's Plane Language Statement A-10: EWG's PFAS Contamination Crisis

A-11: EWG's Story on PFAS Filters

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on March 6, 2024,

JAMES "JIM" B. SHEPHERD

Microbiological Testing, Research and Consulting

01 October 2009

Adam W. Lock, Sr. Berkey Water PO Box 201411 Arlington, TX 76006

Subject: Microbiological Challenge Study; ASI Report 36463RAbr

Dear Adam,

This report pertains to microbiological challenge testing of your Black Berkey filter elements, performed as initially described in ASI proposal 2009-0817-01P (dated 18 Aug 2009).

<u>Executive Summary</u> - Challenge organisms were MS2 and fr coliphage (viruses) and *Raoultella terrigena* (bacteria) under clean water conditions. Under the test conditions described herein, the Black Berkey filters exceeded the target log reduction criteria (4 log viruses, 6 log bacteria).

We appreciate your selection of ASI as a microbiological testing/consulting resource. If you have any questions about the testing described herein, please contact me at anytime.

Sincerely, ANALYTICAL SERVICES, INC. (ASI)

Paul S. Warden Vice President v: 800.723.4432 x15

e: pwarden@analyticalservices.com

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Microbiological Testing, Research and Consulting

### **Project Description**

The objective of this testing was to establish preliminary data regarding the efficacy of viral removal / inactivation from clean water, in preparation for a full challenge study using NSF P248 Emergency Military Operations Microbiological Water Purifiers (Dec. 2008). Berkey Water provided one Travel Berkey drinking water treatment unit and four (4) Black Berkey filter cartridges for testing. It is understood the unit contains a complex, proprietary filter matrix that treats water from the 1.5 gallon (5.7L) reservoir, and that no true integrity test procedure is currently available to verify the condition of the filter media and proper installation.

The Travel Berkey unit was operated as per manufacturer's instructions. This initial testing was performed using viral (MS2 and fr coliphages) and bacterial (*Raoultella terrigena*) challenge organisms as per P248 to demonstrate 4 log and 6 log reduction, respectively. (*Cryptosporidium*, also specified in P248, was not be used in these initial trials as per Berkey Water's instructions). Organisms were propagated as per ASI's standard procedures and stock samples collected prior to use as positive control samples.

The challenge water for the initial trial was municipal supply water (dechlorinated by carbon filtration, filtered to 1 µm nominal and disinfected by UV light, which approximates General Test water).

Prior to testing, each filter element was conditioned with approximately 10 gallons (38 L) of unseeded water. During conditioning, one negative control sample was collected from the unit effluent, and was analyzed for all three test organisms. After conditioning, the reservoir was partially filled with four liters (4 L) and seeded to achieve a pretreatment concentration of approximately 10e6 PFU/mL (coliphage) and 10e7 CFU/mL (bacteria). One influent sample was collected immediately from the unit reservoir. The results form the analysis of this sample established the pretreatment concentrations and were used to calculation log reductions of each organism type.

After approximately 50% of the seeded reservoir volume had been processed, effluent samples were collected. Data from these analyses were used to determine the log reduction achieved. The above testing was performed with a single filter element in place; MS2 and Raoultella were tested first, then the unit was emptied, rinsed, disinfected and a second conditioned filter installed for testing with fr coliphage.

At the end of the MS2 and *Raoultella* trials, an effluent sample was collected a spiked to serve as a control sample to determine whether anti-microbial agents leach into the effluent water. This is critical in terms of claims of treatment within a specific timeframe. This sample was spiked with a known concentration of MS2 (10e3 PFU/mL) and *Raoultella* (10e3 CFU/mL). Two samples were collected from this seeded control; one sample was analyzed immediately and the other sample was analyzed after approximately three hours contact time. If no anti-microbial agents are present in the treated water, the results for each organism type at different time points are expected to be similar; if analysis of the second sample indicates a substantially lower concentration, it suggests anti-microbial compounds are present in the effluent water. In this case, the compound(s) would need to be identified and neutralized upon sample collection to generate valid microbiological reduction data as the water leaves the unit.

All samples were analyzed quantitatively as per ASI's standard procedures. Log reductions for each organism type, with and without iodine, were calculated as follows:

Log Reduction = 
$$Log_{10}$$
 ( Influent concentration Effluent concentration )

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Microbiological Testing, Research and Consulting

### **Results**

The results of the testing described above are presented in Tables 1 - 4, below.

Table 1. Summary of log reductions of MS2, fr and *R. terrigena* in General Test Water achieved by the Black Berkey filters compared to 248 requirements.

	Log	P248	
Sample ID	Reduction	Requirement	
	(Minimum)		
MS2	6.24	4.00	
fr coliphage	>5.21	4.00	
R. terrigena	>6.36	6.00	

Table 2. Concentrations of stock microorganisms (MS2, fr and R. terrigena).

	AVg. PFU/mL or	
Sample ID	CFU/mL	LOG
MS2 Stock	6.40E+09	9.81
fr Stock	8.23E+07	7.92
R. terrigena Stock	3.67E+08	8.56
R. terrigena Stock (Day 2)	9.00E+08	8.95

Table 3. Results of MS2, fr and *R. terrigena* in General Test Water, filtered with one Black Berkey element.

	Avg.		Log
Sample ID	PFU/mL	LOG	Reduction
MS2 Influent	5.27E+06	6.72	N/A
MS2 Effluent	3.00E+00	0.48	6.24
fr Influent	1.64E+05	5.21	
fr Effluent	<1	< 0.00	>5.21
R. terrigena Influent	4.57E+06	6.66	
R. terrigena Effluent	<2	< 0.3	>6.36

Table 4. Summary of leaching test results; MS2 and R. terrigena spiked into product effluent.

	Avg.		Log
Sample ID	PFU/mL	LOG	Reduction
			_
MS2, T0	6.60E+03	3.82	
MS2, T+3 hrs	1.22E+04	4.09	-0.27
R. terrigena, T0	3.73E+01	1.57	_
R. terrigena, T+3 hrs	2.07E+01	1.32	0.26

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Microbiological Testing, Research and Consulting

#### **Discussion**

Flow rate was indicated to be 2.75 gallons per hour (10.4 LPH) with two filter elements installed. The flow rate observed by ASI was approximately 2 LPH. The initial priming was performed as described in the instructions, using the "sport bottle" approach. Although "sweating" was observed over the entire surface of the filters, this did not appear to be completely effective at forcing the air out of the pores of the filter and allowing the expected flow rate. The two filters initially received were re-primed using "priming button" and ASI pressurized reagent water system. This was more effective at priming the filters. The fastest flow rate measured was 200 mL/min or 3.17 GPH.

All controls samples, including stock samples, analytical positive and negative controls, and the negative control collected prior to seeding yielded appropriate results and were accepted.

The results of the leaching control samples (effluent sample spiked with MS2 and *R. terrigena* and analyzed at two time points) were quite similar, suggesting that no active antimicrobial agent is leaching into the treated water. Please note that the *Raoultella* concentration was lower than expected due to a low stock concentration, but did not affect the leaching test.

Under the test conditions described, the Black Berkey filters exceeded the minimum log reduction requirements specified in NSF P248 for all three types of microorganisms (Table 1). It was noted that MS2 and *R. terrigena* were detected in the treated water samples at very low concentrations.

Overall, the unit is well designed and simple to operate, and yielded results that exceeded the target log reduction criteria (4 log viruses, 6 log bacteria) under the clean water test conditions described above. Further testing to determine the performance of the Black Berkey filters under "challenge water" conditions (elevated turbidity, organic carbon, etc.) is recommended as the next step.

Ref.: ASI #36463RAbr Page 4 of 4

September 30, 2022

Edward Messina Director EPA's Office of Pesticide Programs William J. Clinton Bldg. 1200 Pennsylvania Ave, NW Washington DC, 20460

### **RE: Modernizing FIFRA Compliance for Water Filtration Systems**

Dear Director Messina,

On behalf of the Water Quality Association (WQA), International Association of Plumbing and Mechanical Officials (IAPMO), and more than 30 Coalition Partners, we would like to discuss an effort to modernize the enforcement of regulations pertaining to certain water filtration systems under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). We respectfully request a meeting to further review the EPA's interpretation of the statute and discuss a proposal for creating an alternative compliance pathway for manufacturers to adhere to this regulation.

Since 1976, the EPA Office of Pesticide, under FIFRA, has treated water filtration systems that inhibit bacteria, viruses, and other microorganisms in drinking water as pesticides and pesticidal devices. Although the EPA has good intentions, the agency's ambiguity, and inconsistent enforcement of FIFRA on water filtration systems in recent years have caused significant delays and detrimental impacts on the water filtration industry. Ultimately, this has a cascading effect on consumers, safety, and the economy. Additionally, EPA has continued to require manufacturers to comply with rigorous mandates including labeling, registration, and other requirements that often have little bearing on human health and environmental safety. This can be costly, time-consuming, and with little guidance from EPA, confusing. In response to these concerns, a coalition came together to review the regulation with the purpose of crafting a revised compliance pathway that better aligns with the original intent of FIFRA to protect human health and the environment.

When the agency first began to regulate water filtration systems as pesticides and pesticidal devices, third-party certification standards did not exist. Over the last half-century, national consensus-based standards, such as those developed by ANSI process, have far surpassed the scope of what the EPA requires and are at the forefront of meeting emerging water quality issues. These standards already cover performance in addition to having strict requirements for material safety, structural integrity, and literature. The coalition recommends that EPA consider modernizing its interpretation of the regulation to instead rely on third-party certification since the current enforcement guidelines can prevent the deployment and increase costs of water filtration systems that are being used to protect Americans, including many from disadvantaged and underserved communities, from a host of new, and emerging threats impacting drinking

water quality (e.g., Lead, PFOA/PFOS, legionella, disinfection by-products (DBPs), chromium-6, etc.).

Proposal for Compliance: Considering advancements made over the last 45 years, WQA, IAPMO, and our Coalition Partners propose that water treatment devices would comply with FIFRA if they meet the requirements of an alternative path of compliance which consists of these devices being independently certified to meet national standards associated with the claims being made for performance. These national standards, such as those created through the ANSI consensus-based process, have been developed with the participation of all interested and affected stakeholders. This includes manufacturers, non-profits, advocacy organizations, representatives of government (such as the EPA), and academia. These national standards are regularly updated to address emerging threats and to incorporate the latest science. This alternative path of compliance would also require the certification of such products by an independent Certifying Body (CB) accredited to ISO/IEC 17065 by a signatory to the International Accreditation Forum Multilateral Recognition Arrangement (IAF MLA) such as the American National Accreditation Board (ANAB). Compliance with FIFRA under the current EPA regime would still be an option for products that have not obtained certification to national standards.

This proposal addresses specific residential drinking water filters that fall under the term "pesticidal devices" and water treatment devices that contain a bacteriostat to protect the device itself:

Pesticidal Devices: Applicable standards would include ANSI standards (e.g., NSF/ANSI 53, 55, 58, 62, 244), other consensus-based standards as determined by the EPA Administrator, and the U.S. EPA Purifier Guide Standard<sup>2</sup> that covers performance for the anti-microbial claims provided the device was also certified to a consensus standard that covers material safety, structural integrity, and literature. Devices certified to NSF P231 would technically meet these requirements by default, even though it's not a consensus standard, since it is a combination of the U.S. EPA Purifier Guide Standard and the NSF/ANSI standards referenced above.

Pesticides: Currently under FIFRA, bacteriostatic agents that are used to protect the product itself from fouling are considered exempt under treated articles. However, that has not been consistently applied by regulators in the field. The exemption is described under FIFRA as an article or substance treated with or containing a pesticide to protect the article itself. It is worth noting that, any bacteriostatic agents which are used to protect the product itself from fouling (such as silver-impregnated carbon, media, and copper-zinc media.) are evaluated for material safety under the existing standards listed above. This would include products that make a bacteriostatic claim under NSF/ANSI 42. Any product which makes anti-microbial claims for protection of the end user based on

<sup>&</sup>lt;sup>1</sup> As defined in FIFRA Section 2(h) (CFR 152.5000)

<sup>&</sup>lt;sup>2</sup> Guide Standard and Protocol for Testing Microbiological Water Purifiers, U.S. Environmental Protection Agency, 1987.

an active anti-microbial agent would not fall under this exemption and would still require FIFRA registration.

In summary, to more effectively protect consumers, increase safety, and remove regulatory burdens, the Coalition recommends an alternative compliance pathway under FIFRA for drinking water filtration systems if they meet national standards that require nationally recognized third-party testing and certification requirements for the claims being made. This alternate compliance pathway is similarly used to protect water quality in plumbing components in model plumbing codes, as well as in EPA's enforcement of water-related products (e.g., the WaterSense program and rule on lead-free plumbing components). Making this change to FIFRA registration requirements for water filtration systems would remove an unnecessary burden on manufacturers, importers, and the EPA.

We applaud the EPA and its efforts to ensure the health and safety of Americans and we hope to work with you to modernize the enforcement of FIFRA as it pertains to water filtration systems. Additionally, enclosed with this letter is a technical analysis that provides additional information on current FIFRA requirements vs. third-party certification. Thank you in advance for your consideration of this proposal, and we request the opportunity to meet with you to discuss these recommendations in greater detail.

Sincerely,

Jeremy Pollack

Director of Government Affairs

Water Quality Association (WQA)

JPollack@wqa.org

Christopher A. Lindsay

Vice President of Government Relations

**IAPMO** 

Christopher.Lindsay@iapmo.org

CC: EPA's Office of Policy, EPA's Office of Water

### **Technical Analysis**

### FIFRA Requirements vs. Certification to National Standards

The overall aim of certifying products, processes, or services is to give confidence to all interested parties that a product, process, or service fulfills specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfillment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to:

- consumers who rely on products to meet safety and efficiency standards;
- water treatment technology manufacturers;
- government regulators;
- water authorities; and
- non-governmental organizations.

Certification of products, processes, or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents. In the case of residential drinking water filters, an accredited Certification Body (CB) has developed certification schemes that include initial product testing, initial factory inspection, and compliance with the applicable health and safety product standards, including marking and labeling requirements. CBs also require annual surveillance inspections that take into account the quality management system, retesting requirements and frequency, modifications to certified products, and revisions to product standards.

### Table 1: Analysis of FIFRA Requirements vs. National Standards

The table outlines the comparison of FIFRA requirements for pesticidal devices to third-party testing and certification to NSF/ANSI-accredited product standards for proposed use as an alternative compliance pathway under FIFRA.

### Table Notes

- <u>Category Column</u>: Focuses on overarching themes present in both FIFRA & the NSF/ANSI Standards. Additional background can be found in the Appendix.
- <u>FIFRA Requirements for Pesticidal Devices Column</u>: Addresses the various categories and needs involved with FIFRA compliance.
- <u>Third-Party Product Testing & Certification Requirements Column</u>: Analyzes the requirements specified in NSF/ANSI standards for an independent CB accredited to ISO/IEC 17065.
- *Rating* Column: Considers the requirements of *FIFRA* as compared to Product Certification and NSF/ANSI Standards and assigns an assessment.

Category	FIFRA Requirements for Pesticidal Devices	Third-Party Product Testing & Certification Requirements	Rating (Certification to Standards vs. FIFRA Requirements)
<b>Product Safety</b> - Certified products undergo rigorous testing to ensure product safety and compliance with specific NSF/ANSI standards.	<ul> <li>Directions &amp; Cautionary Statements</li> <li>Child Resistant Packaging</li> </ul>	<ul> <li>Independent review of materials in contact with water</li> <li>Toxicological assessment</li> <li>Material safety testing</li> </ul>	Exceeds
Performance - To certify a product, it must undergo verification testing specifically related to claims and/or intent of the product's use.	N/A	<ul> <li>Review of health effects claims</li> <li>Test microbiological performance</li> <li>Test to ensure active agents (silver) do not impact water quality</li> </ul>	Exceeds
<b>Structural Integrity</b> - The purpose of testing structural integrity performance is to evaluate the materials, design, and fabrication quality of the complete water treatment system.	N/A	<ul> <li>Elevated water pressure testing</li> <li>Life cycle pressure testing</li> </ul>	Exceeds
<b>Product Literature</b> – Defines user instructions for labeling, installation, maintenance, and disclosures of product limitations.	<ul> <li>General Product info:</li> <li>Labeling Requirements (40 CFR Part 156)</li> <li>Misbranding</li> <li>Exporting Labeling Requirements</li> </ul>	<ul> <li>Product         Literature             requirements     </li> <li>Performance         Data Sheet that is             independently             verified     </li> <li>Data Plate (label             on the product             itself)</li> </ul>	Exceeds
Surveillance – Each laboratory that certifies products shall operate a formal QA program.	• Pesticide Establishment Requirements (Annual Reporting)	Initial product testing, retested every several years or if changes are	Exceeds

Facility Registration — Administrative requirements	<ul> <li>Facility register by EPA</li> <li>EPA Specific Documents</li> <li>Importing; NOA (EPA Form 3540-1)</li> <li>Establishment Number (EPA form 3540-8)</li> </ul>	made to product or standard.  Manufacturer facility inspection (annual)  Facility registered through Certification Body  Manufacturer Facility Inspection (annual)  Certification Body is required to publicly list all certified companies and products  U.S. CBP able to verify compliant products with a Certification Body	Exceeds
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### **Testing Required Under National Standards and Third-Party Testing**

NSF/ANSI-accredited product standards for water filters are developed through a consumerdriven process that includes industry experts from around the world. These standards are continually being refined to account for new water quality challenges and technologies. Whereas FIFRA requirements are largely based on a manufacturer's own statement of compliance (selfdeclaration). Third-party testing and certification provide an independent non-biased way to verify product claims utilizing knowledgeable staff with proven expertise in water filtration technologies.

# Examples of tests required on Third-party certified water filters, but are not required for EPA registration:

Material Safety Test: (Extraction Test, Evaluation of materials in contact with water): A toxicologist reviews the materials used in the water filter to determine the appropriate test battery. These tests involve soaking the product to ensure that there are no harmful contaminants introduced through simple contact with the water filter. If any harmful contaminants leach from the product, it is also confirmed that they come out at safe levels.

- Structural Integrity Test: This test helps to ensure that the products will maintain their integrity when subjected to water line pressure. The test inflates the actual pressure to simulate 20 years of the life of the product. This helps to ensure that the product will not leak under normal usage and will continue to perform over time.
- Elective Performance Test (based on health effects claims): If a device makes a health claim from one of the categories below, it triggers a performance test in order to qualify for certification. The test verifies that the product reduces the contaminants to requirements set forth by the NSF/ANSI standard or better. These requirements are continually being evaluated and updated to include new science and technological capabilities. Health effects performance tests are conducted with a safety factor. When a system has a performance indication device that warns a user to replace the cartridge, testing is done to 120% of water filter capacity or 200% of capacity if a performance indication device does not exist. Performance tests are completed to verify health effects claims related to the following categories:
  - Microbes (bacteria, virus, and protozoan cysts)
  - Volatile organic compounds (benzene, 1,2,3 TCP, 24D, atrazine, lindane, etc.)
  - Disinfection byproducts (bromate, trihalomethanes (THMs), etc.)
  - PFAS (PFOA, PFOS)
  - Heavy metals (lead, arsenic, hexavalent chromium, etc.)
  - Inorganic compounds (nitrates, perchlorate, etc.)
  - Emerging contaminants and compounds (pharmaceuticals, etc.)
- o **Flow Verification Test**: This test helps to ensure the water filter flows at a reasonable rate too slow and it impacts consumer satisfaction, too fast and it could impact filtration performance. Rated service flow test ensures the product does not flow at a rate greater than where the contaminant reduction testing was performed.
- o There are a number of other tests depending on the nature of the product including pressure drop testing, active agent, and performance indication device testing.

# Table 2: Water Treatment Device Registration Process: EPA Pesticidal Device Registration vs. Third-Party Product Testing & Certification

This table is meant to delineate the process for pesticidal device registration under FIFRA through the EPA and the third-party certification requirements for water treatment devices. This is not meant to be a comparison of each step, however, exhibits the process participants must undergo to comply with FIFRA and CBs.

EPA PESTICIDAL DEVICE	THIRD-PARTY CERTIFICATION
REGISTRATION PROCESS	PROCESS
Company applies for an EPA company number	Application: Includes a list of all products the manufacturer intends to certify. The list includes detailed components, supplier information, detailed information on the production facility, and product literature (installation/operation manual, data plate, performance data sheet).
Company applies for an EPA	Technical Review: The Certification Body
establishment number and prints this	review the application information and assign
number on the pesticidal device.	specific performance testing in accordance
	with the performance standard.
Product labeling must comply with FIFRA section 2(q)(1) and 40 CFR Part 156 and EPA regulations on child-resistant	Manufacturing facility initial inspection: The manufacturer provides a list of all manufacturing locations. The Certification
packaging40 CFR 157.20 – 157.36:	Body schedules initial inspections at all
FIFRA does not require device producers to	locations to ensure a minimum quality
submit any data concerning either safety or	assurance plan is in place.
efficacy of a device prior to distribution or sale.	
Importer submits to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1) for each shipment.	Laboratory Testing: Testing laboratories conduct product testing per the technical review and provide test reports to the Certification Body.
Manufacturer reports annual sales of	Final technical review / Initial Listing:
pesticidal devices (filters) to the EPA.	Certifying Body reviews lab testing reports, factory inspection reports, and product literature to verify compliance with the performance standard and certification policies. If everything is found compliant with the certifier authorizing the use of its registered product certification mark future product production.
	Continuous compliance – ISO 17065
	requires the Certification Body to perform
	surveillance activities to ensure the ongoing validity of the certifications. This is
	accomplished through periodic inspection of
	marked products and factory inspections to
	ensure the products remain compliant with the
	requirements in the standards. Retesting can

be triggered through updates to the standards, product modifications, or new product claims.

### **CONCLUSION**

The process that an independent CB accredited to ISO/IEC 17065 undertakes to address consumer protection, public health, and transparent business operations demonstrate the higher protection offered to consumers through third-party certification. Specifically for water treatment devices, the testing, examination, and data reporting that are required to meet national standards are robust and are more stringent than the requirements specified under FIFRA by EPA. Third-party certification should be accepted as an alternative compliance pathway for FIFRA.

# NMCL—Statement Regarding Berkey Water Filter Lawsuit

Attorneys typically advise clients not to discuss ongoing litigation, and New Millennium Concepts, Ltd. (NMCL), provider of Berkey® water filters, has remained silent until now. However, NMCL believes that our loyal customers deserve a public response to the false and erroneous misinformation appearing online regarding a lawsuit filed against NMCL.

There are many problematic issues in the lawsuit that we cannot address here, but below are some brief highlights:

- One of the named plaintiffs previously filed a lawsuit, but later withdrew after NMCL responded to the suit and showed that the plaintiff's claims were so weak that she would obviously lose. Now the plaintiffs have filed a second lawsuit, apparently attempting to engineer around the arguments that NMCL made during the first lawsuit. This current lawsuit seems to be just another attempt to "do-over" the first suit in order to force NMCL to settle.
- We also believe that much of the information that the plaintiff collected for the lawsuit came from Berkey knock-off filter websites because of their <u>carbon block descriptions</u> (Black Berkey® Elements are <u>not</u> carbon block filters), and the plaintiff repeatedly uses the term "Berkey Black" in their lawsuit, which is a term utilized by knock-off filter websites in order to engineer around our trademark "Black Berkey®".
- While the plaintiffs claim Black Berkey® Elements do not perform as advertised, the plaintiffs do not claim that they have suffered any physical or health-related harm in any way by their Berkey® systems. Instead, plaintiffs claim that they are representing everyone that has ever purchased a Berkey® system, claiming that Berkey® systems are "nothing more than an empty can or plastic bottle".
- We strongly believe the plaintiffs' allegations are not based on valid testing of authentic Black Berkey® Elements, but are based on counterfeits which are deceptively similar in appearance, but are mere carbon block filters which look like Berkey® filter elements. The plaintiffs' testing results in no way comport with the factual results of other independent accredited third-party labs that have tested genuine Black Berkey® Elements.

# NMCL vigorously denies the plaintiff's allegations and we believe that the plaintiff is utilizing counterfeit product to exact a settlement.

## History of Black Berkey® Elements and Counterfeit Products

• Over two decades ago, NMCL developed the proprietary formulation for our Black Berkey® Elements, and during their history they have undergone what we believe to be the most rigorous testing of any other gravity-fed filter elements. Berkey® water systems have been utilized in off-grid applications by relief groups for disaster recovery, charities, and people worldwide without access to clean water for over two decades without a complaint of which we are aware as to their ability to remove contaminants from unpotable water sources. More importantly, to our knowledge there has never been a successful suit filed against the Black Berkey® Elements because they have historically provided customers with exceptional performance and value—a perception that has been challenged only because Chinese and other foreign counterfeit filters entered the market failing to meet consumers' performance expectations and appear so similar to genuine Black Berkey® Elements that consumers are being misled by not

being able to determine the difference between the authentic Black Berkey® Elements and the counterfeit carbon block filters.

• Worse, NMCL discovered that major online retail marketplaces were commingling at their warehouses counterfeit elements supplied by unauthorized sellers with authentic Black Berkey® Elements supplied by our authorized Berkey® dealers. The marketplaces then shipped product from the commingled inventory to consumers who purchased authentic Black Berkey® Elements. Since that discovery, NMCL has required its authorized dealers to opt out of all commingling programs, and keep separate inventories at Amazon and other platforms to prevent comingling from occurring in the future. However, it is important to note that the majority of plaintiffs claim to have purchased their products on Amazon prior to NMCL discovering the commingling issue.

NMCL believes that the plaintiffs likely tested <u>counterfeit</u> Berkey® elements, and that NMCL is being required to defend itself against the performance of Chinese and other foreign counterfeit carbon block filters rather than the proven performance of authentic Black Berkey® Elements. Moreover, NMCL is also being required to defend itself against various websites, social media and video-sharing platforms that presume the likely imitation carbon block filters tested in the lawsuit are authentic Black Berkey® Elements, when they are not. If the plaintiff tested counterfeit or knock-off filters, then obviously any testing they conducted is irrelevant to the performance of authentic Black Berkey® Elements.

### Regarding Black Berkey® Elements Test Results

- Multiple accredited third-party laboratories have tested Black Berkey® Elements and those independent results validate that they meet exceptional standards of quality. NMCL's claims are based upon test reports from these laboratories, which are available on our website at:
  - http://berkeywaterkb.com/black-berkey-purification-elements-test-results/
- NMCL has had an extremely difficult time in getting cooperation from major online retail platforms in removing the counterfeit filters. This only allows the counterfeit problem to continue metastasizing. In fact, of 57 test buys of Black Berkey® Elements purchased from <u>unauthorized</u> sellers on two major platforms, 51 test buys (89%) were confirmed as being counterfeit—meaning that 89% of sales from unauthorized sellers were just generic, untested Chinese or foreign carbon block filters packaged to imitate the appearance of authentic Black Berkey® Elements. The problem has become so pervasive that the estimated sales of verified counterfeit filters have exceeded more than two and a quarter million dollars during the first nine months of 2022 on just one major U.S. online retail marketplace alone.

We also ask that Berkey® customers assist NMCL in purging the market of counterfeit filters by always buying Berkey® systems and Black Berkey® Elements from authorized Berkey® dealers. Customers can verify authorized dealers by calling our customer service department at 888-803-4438.

If you suspect your online marketplace purchase (from Amazon, eBay, etc.) may contain counterfeit elements, please check this page (<a href="https://support.berkeywater.com/buyer-beware/">https://support.berkeywater.com/buyer-beware/</a>) for a guide to identifying counterfeit elements. Then, after reviewing those examples, if you believe you have received counterfeit filters, we suggest the following course of action:

1. Demand a full refund from the dealer or marketplace.

- 2. Return the product stating the specific seller from whom you purchased, shipped you counterfeit filters.
- 3. Leave a review on the specific seller's storefront stating that the seller sold and shipped you counterfeit filters, rather than authentic Black Berkey® Elements.
- 4. Contact NMCL to report the marketplace and seller that sold you the counterfeit product (this helps us identify and take action against unauthorized sellers). We also urge customers who have been fooled into purchasing untested knock-off carbon block filters advertised as replacements to follow the same procedure.
- 5. Replace the counterfeit filters by purchasing genuine Black Berkey® Elements from an authorized Berkey® dealer.

We appreciate the countless Berkey® Water System users around the world and want to assure you that we fully stand by the quality of Berkey® products and intend to defend and defeat this baseless lawsuit.

**CLICK HERE TO SEE SAMPLES OF COUNTERFEIT FILTERS** 

# NMCL Responds: Wirecutter.com's Misleading Big Berkey® System Review

Wirecutter.com recently published a review of the Big Berkey® System that contains misleading, incomplete information and uninformed personal opinions. It fails to accurately portray the product or the brand. As the leader in gravity-fed water purification systems, NMCL must address several major shortcomings of this review for the benefit of our customers.

### **OVERVIEW**

- Fails to tell the whole story, or share the empirical truth that Berkey systems are relied on throughout the world in the harshest of conditions every single day
- **2. Does not understand Berkey**® **customers**, and that they are a powerful endorsement of the product
- 3. Potential financial interests are unclear
- 4. Downplays America's serious water infrastructure issues
- Does not appear to understand emergency / disaster preparedness, and does not seem to extend it beyond 72-hours
- **6. Fails to clearly distinguish apples from oranges**, Black Berkey<sup>®</sup> Purification Elements are *purifiers*, not filters, and are vastly different in terms of performance, uses-cases and lifespan- yet the article is completely based on comparing them to filters
- 7. Presents a shallow, misleading objection to recommending Berkey® Systems based on NSF testing and apples-to-oranges comparisons

- 8. Relies on a very questionable and much less-strict contaminant testing protocol than the independent, rigorous testing protocol utilized by New Millennium Concepts, Ltd.
- 9. Uses hard-to-follow language and points, often lacks context

### Misses the Mark At a Basic Level

### Fails to Tell the Whole Story

The review fails to point out the empirical truth that Berkey® systems have been relied upon by people around the world in the *harshest of conditions*. Real world experience is a powerful proof of effectiveness. Families facing natural disasters, missionary organizations working in unforgiving parts of the world, relief agencies battling the elements, and everyday families rely on Berkey® Systems to do what they say they can do, and continue to choose Black Berkey® Purification Elements time and time again.

## **Does Not Understand Berkey® Customers**

The author acknowledges that Berkey® Systems have "a significant following among the disaster-preparedness community and government skeptics." We suspect he does not understand that this statement is a powerful endorsement of Berkey® products. It also reveals much about the brand's focus. **Berkey® customers test their preps**. They are proof-oriented individuals who do their own homework. Mainstream testing is not something they necessarily rely upon. Knowing this, NMCL has pursued extensive, independent testing. We believe their trust is the best, and most authentic kind of proof there is. Bottom line: trust Berkey® customers- more than us or any single review.

### **Potential Financial Interests are Unclear**

Wirecutter.com appears to make money when you click on a link and buy a product. We believe this should be strongly highlighted from the start, and also clarified throughout the article.

### **Downplays America's Serious Water Infrastructure Issues**

The article states, "No matter your reason for interest in Berkey or any other water filters, we should emphasize that most US municipal water is clean to begin with." Yes, the sentence includes the word "most," but the flippancy of the statement downplays the very serious state of America's water infrastructure. The US currently averages 240,000 water main break per year. **Boil orders and accidental sewer discharges affect the wellbeing of communities every single day.** Many families are facing the consequences of serious contaminant issues, from lead to PFCs to pharmaceuticals- the list goes on. And many are interested in Berkey® Systems for reasons of emergency preparedness- which often involves treating raw, harsh water sources. Access to clean water is a *very real and growing concern in the US*, and Berkey® customers are well aware of this reality. NMCL finds the author's framing of the situation very concerning.

### **Does not Appear to Understand Emergency / Disaster Preparedness**

The author suggests, "If you are concerned with disaster preparedness and wish to ensure a supply of clean water during an emergency, we recommend the water storage products from our emergency preparedness guide." This should be a red flag for readers. Water storage solutions and chemical treatment options for biologicals are indeed good ideas. However, disaster preparedness goes far beyond a 72-hour plan, and also far beyond one potential class of contaminant. Berkey® Systems are a long-term, off-grid solution to continually produce water that's not just potable, but purified and refreshing. And here again, people are presently, actively relying on them every single day.

Let us be clear: Berkey® Systems equipped with Black Berkey® Purification Elements remove up to 99.999% of viruses and 99.9999% of pathogenic bacteria, while also removing or dramatically reducing protozoa, trihalomethanes, inorganic minerals, heavy metals, pharmaceuticals, pesticides, VOCs, petroleum products, perfluorinated chemicals, rust, silt, sediment and even radiologicals.

# **Fails to Clearly Distinguish Apples from Oranges**

The author repeatedly uses the phrase apples-to-apples, yet fails to distinguish between filtration and purification level performance, or consider lifespan as a factor (among other features). Black Berkey® Purification Elements are not filters- they are *purifiers*. Comparing *filters* with an average lifespan between 50-100 gallons or so, and *purifiers* with a lifespan of 6,000 is apples-to-oranges.

### Shallow, Misleading Objection Based on NSF Testing

Keep in mind the failure to distinguish between apples and oranges. We perceive his main objection to the Big Berkey® System to be a lack of NSF testing. He laments that Berkey® elements were "not independently certified to NSF/ANSI standards like [the author's] other filter picks". And he says, "Specifically, NSF/ANSI requires that filters of the type Berkey employs pass twice their rated capacity of contaminated water through the filter before measurements are taken."

But the truth is that NSF certifications are limited in their application with respect to our elements. In the case of apples, or the filter picks, testing would involve passing roughly 100-200 gallons of contaminated water through before taking measurements. In the case of oranges, or Black Berkey® Purification Elements, this would mean passing roughly 12,000 gallons of contaminated water through before taking measurements.

The efficacy of Black Berkey® Purification Elements has been tested for hundreds of contaminants. They have been submitted to rigorous independent, third-party tests that often exceed the protocol required for NSF Standard 42 (aesthetic effects) and Standard 53 (health effects). NMCL documents, and discusses test results routinely, explaining how running challenge solutions (often spiked to extreme levels) and taking multiple effluent samples provides a % rate of decline in contaminant-reduction efficacy over time. This data is used to determine the lifespan of the elements.

Yes, NSF testing *is* cost-prohibitive. The author acknowledges this, "We spoke with a representative from NSF while reporting this guide, and learned that it would cost well over \$1,000,000 to conduct certification testing for all of the substances New Millennium Concepts claims that the Black Berkey filters remove." NSF testing is not a good fit for this particular case, no matter how the author might wish otherwise.

### Yes, the System is Larger, also Actually More Economical

Again the author attempts to compare apples to oranges, "In addition, because the Berkey® System is larger, more expensive, and harder to use than many water filtration options—which also have the benefit of independent NSF/ANSI certification—we wouldn't recommend it to most people looking for a water filtration solution."

Because we have already addressed the question of NSF testing, let us focus on the other points. Berkey® Systems are *designed* to provide higher daily outputs, and have a higher capacity than smaller filter pitchers. A person needs about a gallon of water per day during an emergency. Daily use may entail more than just drinking- preparing food, cooking, etc. In addition, a pair of Black Berkey® Purification Elements treats up to 6,000 gallons of municipal tap water, reducing or removing over one hundred contaminants for about two cents a gallon. Small \$50 pitcher-type filters handle a fraction of the contaminants and

require frequent (and expensive) filter replacements. The system may indeed be "more expensive" upfront, but it is also the long-term economical win- it is overall much less expensive.

### And the System Is, In Fact, Easy to Use

In terms of ease of use- it appears the author does not understand the product's benefits properly. Once again, Black Berkey® Purification Elements are *purifiers*; they are not filters. Yes, they require priming, which we assume is the issue at hand, but priming is a strategic advantage when it comes to emergency planning. It allows the elements to be stored for long periods of time and then reprimed. Additionally, we believe priming is worth the effort for purification-level performance.

We are uncertain how simply pouring water into the top of the system amounts to anything but easy. Moreover, when you consider maintenance and the frequency of replacing a typical filter element, Berkey® Systems are, we believe, far more convenient to use.

# **Uses Hard-to-Follow Language and Points**

### **Tested Just Two Contaminants**

Black Berkey® Purification Elements remove up to 99.999% of viruses and 99.9999% of pathogenic bacteria, while also removing or dramatically reducing protozoa, trihalomethanes, inorganic minerals, heavy metals, pharmaceuticals, pesticides, VOCs and more. However, the author tests only lead and chloroform—admittedly on a "limited scale." This decision forces the reader to focus on an extremely narrow scope. The author then moves to a problematic discussion of testing.

### **Discussion of Testing Sows Confusion**

The author acknowledges NMCL's testing as "thorough and professional," but lumps this acknowledgement in with their own "tests." They should not have suggested NMCL's testing and their testing are similar in quality or methodology- again, there is an issue here with apples and oranges.

Consider the apple- the author says, "To test these claims, as with our filter-pitcher testing, John Holecek prepared so-called challenge solutions, ran them through the Big Berkey system (fitted with the Black Berkey filters), and sent samples of the solutions and the filtered water to an independent lab (EnviroMatrix Analytical) accredited by the state of California for analysis." The language the author uses to describe their testing aims to impress. But here's the bottom line: EnviroMatrix Analytical (their lab) did not spike the challenge water, or run it through the system—they did. The lab tested the samples

after receiving them in the mail. As stated, "John Holecek, a former NOAA researcher, has conducted air and water quality testing for us since 2014." It is he who "mixed the chloroform into the contaminant solution immediately prior to filtering." They relied on very questionable and much less-strict contaminant testing.

Now consider the orange- NMCL has had three professional, independent labs **run multiple tests from** *start to finish* **using rigorous testing protocols**.

### **Lacks Full Context and Clarity**

The author goes on to use a conversation with lab technician Jamie Young to presumably suggest his "review" has authority, "We shared our lab's results with Jaime Young, a chemist and New Jersey state-licensed owner/operator of the water analysis lab (then known as Envirotek) commissioned in 2014 by New Millennium Concepts (manufacturer of the Big Berkey system) for its own testing of its Black Berkey filters. Young corroborated our findings on both chloroform and lead." But this statement lacks context. As Envirotek has never conducted chloroform testing for the elements, we can only assume this statement ought to communicate "he looked at" the author's testing.

The author goes on to share, "He [Young] reported that the filters gave exceptional performance on lead in his test, too, corroborating our own finding. However, he said that they stopped meeting the NSF removal standard after approximately 1,100 gallons of filtering—barely more than a third of the 3,000-gallon lifespan New Millennium claims for the Black Berkey filters." As explained previously, testing for the elements is calculated by multiple samples and the % reduction in efficacy over time. The author simply does not provide a complete and balanced picture here.

### Questions the Composition of Our Elements, But Not of the "Top Picks"

As a side note, the author states that NMCL does not disclose the exact composition of our elements, but then leaves out that his "top picks" *do not either*. The exact composition of our elements is a trade secret—and shall remain so—for obvious reasons.

## **Questions?**

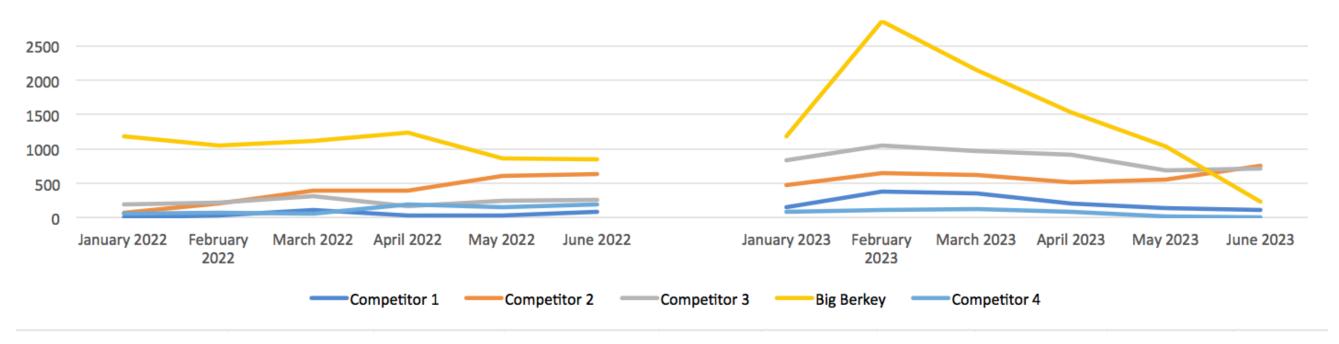
Overall we believe this "review" has numerous issues, and cannot be relied upon as a balanced source of information. We recommend interested customers dig deeper and reach out to the Berkey® by NMCL Support and Service Team with any additional questions.

Website Name / contributor	Video (Y or N)	Article (Y or N)		Affiliate (Y or N)	Date Posted	Number of views /followers if available	Title	Overview summary	Link
Blog: Martha Stewart	N	Υ	N	N	6-Jul-18	N/A	Purifying Water with Berkey	Martha's first hand experience using a Berkey System	https://www.themarthablog.com/2018/07/purifying-water-with-berkey.html
Blog: Martha Stewart	N	Y	N	N	6-Apr-22	N/A	Maintaining Our Berkey® Water	4 Years Later - Maintaining her Berkey System	https://www.themarthablog.com/2022/04/maintaining-our-berkey-purification-water- systems.html
Environmental Working Group	N	Υ	N	N	11-Jul-23	4.4k Share	Purification Systems	Product comparison site that reviews and ranks similar products	systems.ntml https://www.ewg.org/research/getting-forever-chemicals-out-drinking-water-ewgs- guide-pfas-water-filters
CBS NEWS	Υ	Υ	N	N	11-Jul-23		Environmental group tests to find	PHILADELPHIA (CBS) Water filters have become more popular following studies that show nearly half of the	https://www.cbsnews.com/amp/philadelphia/news/best-water-filters-for-pfas-chemicals-
							the best water filters for removing	country's tap water could be contaminated with potentially toxic compounds. But which are the best water filters? The	environmental-working-group-test/
							PFAS	Environmental Working Group testing showed three of the filters tested stood above the rest. "They actually reduced	
								PFAS down to non-detectable levels, which is really great," said Sydney Evans, with the Environmental Working Group.  In the study, pitchers from "Clearly Filtered" and "Zero Water" blocked 100% of PFAS tested. So did the standing travel	
								Berkey filter system.	
Chris Beat Cancer	Υ	Y	N	N & Y		166,000	5 reasons why I love my Berkey	started using a Berkey Water Filter in 2012, switched from using a water distiller and loves his family using Berkey. Clean	https://www.chrisbeatcancer.com/berkey/
							water filter	water is critical for healthy living. Chris's family used Berkey for years before becoming an affiliate	
Brighteon Broadcast News	Y	Y	N		7-Jun-23	27,020	Water filter CESIUM removal test	Mike Adams with Brighteon (& Natural News) recently completed test on a big range of water filters for CESIUM (a	https://www.brighteon.com/a13ab11c-123b-45a6-819c-aa44322a7024
							results released	radioactive contaminant that would be present after a nuclear bomb detonation or dirty bomb). Berkey® came in the top 6 at #4, and was #1 of the larger units. The report about water filters is in the first 30 minutes of his show. Keep in mind that	
								iust because a filter (or water pitcher) removes 99.9+% of Cesium, does not mean it will filter other contaminants	
								(especially microbiological) to the same levels. In conclusion, the good news is, if a person found themselves in a survival	
								situation, they would want the biggest volume water filter possible to remove Cesium (radioactive fallout) to sustain life	
								long-term and Berkey was #1 of the larger volume systems!!!	
Natural News					7-Sep-14	43,000	Big Berkey, ProPur and gravity	Update to previous test conducted on Big Berkey, ProPur, Doulton, Zen Water Systems and others. The results are all over	
							water filters: A lab testing update	the map. Some of these filters work extremely well to remove heavy metals, and others hardly work at all.	g.html
Natural News - Mike Adams	v			v	12-Feb-19	29.000	from the Health Ranger Water filter glyphosate removal	Video for Water filter glyphosate (toxic broad-spectrum systemic herbicide) removal lab test results released by Natural	https://www.naturalnews.com/2019-02-12-glyphosate-water-filter-lab-test-results-released-
Natural News - Mike Additis	ľ			ľ	12-reu-19	29,000	lab test results released by Natural News		by-natural-news.html
Water Filter Labs: Mike Adams	N	Y	N	Υ			Gravity Filter Heavy Metal Test	Big Berkey was by far the best-performing gravity water filter we tested	https://waterfilterlabs.com/Big-Berkey-gravity-water-filter-heavy-metals-lab-results.html
Water Filter Labs: Mike Adams							Introduction to ICP-MS testing of	Explanation about testing that Berkey came out the top filter	https://waterfilterlabs.com/introduction-gravity-water-filter-heavy-metals-lab-results.html
							gravity water filters conducted by		
							Mike Adams, the Health Ranger		
THE LYONS' SHARE	N	Y	N	N			Is your water actually good for	Hi! I'm Megan Lyons,	https://www.thelyonsshare.org/2019/10/14/is-your-water-actually-good-for-you-a-berkey-
The Survival Mom	N	v	N	N	26-Sep-17	376 SHARES	you? A Berkey Water Filter Review	the voice behind The Lyons' Share. I love all things health, wellness, and fitness-related, and I hope to share some of my passion with you. Berkey is the best water filter. Article on the assembly and benefits of Berkey from a Family survival perspective	water-filter-review-and-giveaway/ https://thesurvivalmom.com/review-berkev-water-filters/
THE SULVIVAL WOLL	l l	ľ	l l	IN .	20-3ер-17	370 SHARES	Review of Berkey Water Filters	At the off the assertion and benefits of between from a nathing survival perspective	IICLSS.// (triesus vivalinoini.com/) review-dei key-water-intersy
Daily Filters	Υ	Y	N	N			How Fast Does Berkey Filter	General informational website about water filters. "In conclusion, Berkey water filters effectively provide clean and safe	https://dailyfilters.com/how-fast-does-berkey-filter-water/
							Water? 4 Benefits of Using a	drinking water. Berkey filters stand out from other filtration systems with their ability to remove contaminants while	
							Berkey Water Filter	retaining essential minerals, their versatility for various settings, and their cost-effectiveness. Whether for everyday use,	
								camping trips, or emergencies, Berkey water filters offer a dependable solution for obtaining purified water. Invest in a	
Food Network	N	v	N	v	19-Jul-23		Our Honest Review of the Big	Berkey water filter today and enjoy the advantages of clean and safe drinking water.  Here's what I learned after testing the Big Berkey filter for more than two years. I'm a water snob. There, I said it.	https://www.foodnetwork.com/how-to/packages/shopping/product-reviews/berkey-water-
TOOU NEEWOLK	"	ľ	ľ	ľ	15-301-23		Berkey Water Filter System	(Seriously though, I would ace a bottled water blind taste test with a head cold.) So when it came to investing in an at-	filter-review
								home water filter system two years ago, I did tons of research and ended up purchasing the holy grail of filtration systems	
								(according to the Internet): the Big Berkey Water Filter.	
A Healthy Slice of Life	N	Y	N	Y	9-Jul-18		Berkey Water Filter: What It Is and Why I Bought One	Blog of products used by writter and recommended based on preformance. I'm a former health coach turned homeschooling, work-at-home mom to two energetic girls. She explains "What I Love About Having a Berkey Water Filter"	https://www.ahealthysliceoflife.com/berkey-water-filter-what-it-is-and-why-i-bought-one/
A Radiantly Healthy Life	N	v	N	v			Berkey Water Filter Review: Pros.	Are you researching water filters so you can have clean, pure drinking water? Let me help! Here's a helpful Berkey water	https://aradiantlyhealthylife.com/berkey-water-filter-review/
A Radiantly Fleatury Life	ľ	ľ		ľ			Cons & FAQ's	filter review where you'll find the benefits, pros & cons so you have all the info you need to make the best choice for you and your family.	https://alabiahtyriealtryme.com/berkey-water-inter-review/
A Traditional Life	N	Y	N	Υ			WHY I USE A BERKEY WATER	Choosing a good water filter system for the kitchen can be overwhelming. There are so many options on the market! So	https://atraditionallife.com/why-i-use-a-berkey-water-filter-in-the-kitchen/
							FILTER IN THE KITCHEN	I'm going tell you about the water filter I chose for our home and also why I use a Berkey water filter in the kitchen!	
Accidental Hippies	N	Y	N	Υ	10-Mar-22			HOMESTEAD blog with products and advice for sustainability. Berkey water Filter Review 2023: is Berkey Worth the Hype?	https://www.accidentalhippies.com/berkey-water-filter-review/
Autoimmune Wellness	N	l,	l <sub>N</sub>	V	10-Feb-17		Berkey Worth the Hype? BERKEY WATER FILTER REVIEW	One Year off the Grid With five autoimmune diseases between them, Mickey and Angie found their path to better health with the Autoimmune	https://autoimmunewellness.com/berkey-water-filter-review/
Autominium Arcilliess	1"	[	Ι''	ľ	20-1 60-17		DESIGNED TWATENTIETEN NEVIEW	Protocol. Now it's their mission to share that approach with nourishing recipes, practical resources, and community	Traps, // documented in the second of the se
					1			connections. Their recoemndations include strong testimony about the benefits of owning and using a Berkey for all their	
								drinking water needs.	
B O S Gene Fitzgerald	N	Y	N	Υ	4-Aug-23		Review: Berkey Water Filter	The Big Berkey is best for people who want a countertop water filtration system that's easy to assemble and use, low in	https://www.best-osmosis-systems.com/berkey-water-filter-reviews/
					1		Systems – Pros, Problems &	maintenance, and very effective at removing impurities to provide drinking water of superb quality. Not a surprise that	
	N	l	N.	v	9-Mar-23	Not listed	Complaints	the Big Berkey is highly popular – that's 4.5 stars from us!  Lifestyle blog to educate people with trusted and verified information. We believed with the right knowledge	https://brizfeel.com/best-water-filter/
BrizFeel	"	[	["	[	5-Iviai-23	INUL IISLEU		Jufestyle blog to educate people with trusted and verified information. We believed with the right knowledge you make the best decision to improve your life.	nttps://onzieei.com/pest-water-inter/
Bumblebee Apothecary	N	Y	N	Υ	10-Apr-20		Berkey Water Filter Review	In my Berkey water filter review, I'm going to share why we love our Berkey water filter.	https://bumblebeeapothecary.com/berkey-water-filter-review/
Common Sense Home	Υ	Υ	N	N	15-May-22	6 Comments		Article on the assembly and benefits	https://commonsensehome.com/big-berkey-review/
Cooking Gods Way	N	Υ	N	Υ	2015		Big Berkey Water Filter System	Healthy living articles; Our Review of The Big Berkey Water Filter System	https://www.cookinggodsway.com/big-berkey-water-filter-system-review/
CRAZY FAMILY ADVENTURE	Y	Y	N	Y	5-May-23		BERKEY WATER FILTER - OUR	We have been using the Berkey Water Filter for over 9 years! We took it in our RV when we traveled full time and now	https://www.crazyfamilyadventure.com/berkey-water-filter/
Dani on the loose	N.	V	N.	V	30-Sep-18		REVIEW AFTER 9 YEARS OF USE WHY YOU NEED THE BERKEY	have it in our house and use it daily. I've researched options for probably over a whole year now and I always came back to the same one by the same	https://daniontheloose.com/why-you-need-the-berkey-water-filter/
Dani on the loose	IN.		IN .		20-26b-19		WATER FILTER	I've researched options for probably over a wnoie year now and I always came back to the same one by the same company. Enter, BERKEY! This is by far the most easily accessible and raved about water filter I came across during my research the last year or so.	intups.// uamontulerouse.com/wny-you-need-tne-berkey-water-inter/
Don't Mess With Mama Wellness	N	Y	N	Y	<b>-</b>		Berkey Water Filter Review – After	research the last year or so.  In this Berkey water filter review, I discuss why it has become an essential part of our kitchen kit and everyday lives. I also	https://dontmesswithmama.com/berkey-water-filter-review/
Blog	"	ľ		ľ			8+ Years of Use	share what makes the Berkey water filter special in comparison to others on the market and where you can buy one of your own.	manufacture with the remaining of the state
Drink Filtered	N	Υ	N	Υ	17-Dec-21		The Reason(s) You Need A Big	This Berkey Water Filter review will take you through the features and levels of performance that you can expect from	https://www.drinkfiltered.com/posts/big-berkey-water-filter-review
	$\perp$						Berkey Water Filter	these high performance water purifiers, in turn helping you to come to an informed buying decision through our research as well as decide whether this is the best gravity water filter for your filtered water needs.	
Emergency Food Essentials	N	Y	N	Υ			Big Berkey Water Filter: 5 Reasons	The Big Berkey Water Filter has been consistently ranked as one of the top water filtration systems by consumers, and	http://emergencyfoodessentials.com/big-berkey-water-filter-5-reasons-one/
	1				1		You Should Own One	with very good reason. Built to last, ideal for camping and a perfect emergency water filter.	
armhouse on Boone	ĮΥ	ĮΥ	N	Υ	Jul-23	628 SHARES	1	Blog of products used by writter and recommended based on preformance	https://www.farmhouseonboone.com/berkey-water-filter-review

Food & Wine	In:	Tv.	In Iv	7 3-Aug-23		The 8 Best Water Filters for your	We independently evaluate all recommended products and services. This freestanding filtration system is one of the few	https://www.foodandwine.com/best-water-filters-6979537
rood & wille	IN .	ľ	IN I	3-Aug-23		Home in 2023	that can be considered a water purifier, thanks to its ability to remove over 200 contaminants and filter out 99.9 percent. That makes it ideal not only for household use but also for taking on the road or camping, where you may come across a	intps://www.toudanuwine.com/pest-water-inters-0373337
							more questionable water source than a kitchen tap.	
orkin' Plants	N	Y	N	12-Apr-18		5 Reasons You Need a Berkey Water Filter in Your Life	Testimony of why health & wellness plant-based chef Melissa loves being a Berkey user and recomends others to use them as well.	https://www.forkinplants.com/post/5-reasons-you-need-a-berkey-water-filter-in-your-life
iessell Frisbee	N	Υ	N Y	/ 16-May-19	187 Shares		Blog of products used by writter and recommended based on preformance	https://www.gessellfrisbee.com/berkey-water-filter-review/
Ground water governance	N	Y	N Y	20-Oct-22		The Benefits Of Berkey Water	A Berkey water filter can remove impurities from well water, making it safer and more pleasant to drink. The filter can	https://www.groundwatergovernance.org/the-benefits-of-berkey-water-filters/
						Filters	also improve the taste and smell of well water, making it more palatable. Berkey water filters are easy to use and can be a great way to ensure that your family has access to clean, safe water	
Happy Mothering	N	Y	N N	N Septembe 2022	r 30, 41 Shares		Article on the assembly and benefits	https://www.happy-mothering.com/berkey-water-filter-review/
Head-water	N	Υ	N N	N 26-May-23		What Is a Berkey Water Filter?	Drinking water advocate website: Clean water is essential for our well-being, and finding the right water filter is crucial. In	https://head-water.com/filters/water-filter/berkey-water-filter.html
							this article, we will unravel the Berkey Water Filter, explore its features, benefits, and why it has garnered a loyal following, in conclusion The Berkey Water Filter offers effective filtration, versatility, and durability, though it may be pricier.	
udge Me	N	Υ	N N	N ??	Not listed		Review website - Based on 1,724 reviews - Score 4.93 out of 5	https://judge.me/reviews/berkeyfilters.myshopify.com
CETO IN PEARLS	N	Y	N Y	14-Dec-22		Berkey Water Filter Review: Is is right for you?	Safe and clean drinking water is something many Americans take for granted, myself included. After the devastating events in Texas in early 2021, my husband and I realized we needed an emergency plan in the event we did not have access to water for an extended period of time. We have been using our Berkey Filter for a little over a month now. This Berkey Water Filter review will help you make a more informed decision on if a Berkey is right for your family. No clue what a Berkey Filter is? This review will help with that too!	https://ketoinpearls.com/berkey-water-filter- review/?fbclid=lwAR1nX_rfFulPtziKRn7TE1qOv8gkXMTxiKTYK2PYuwi6OIOIOTVEXvAoEQ
Kitchen Stewardship	N	Y	N N	Published: 01/25/201 Updated:	89 Comments 2 /		what a enterprine is 1 his review with near that too: Article on the assembly and benefits	https://www.kitchenstewardship.com/berkey-water-filter-review/
Laura London Fitness, wellness &	N	V	N V	01/21/202	2	Health Benefits Of The Berkey	Why I love my Berkey Water Filter System	https://lauralondonfitness.com/benefits-berkey-water-filter/
Podcast	<u> </u>	Ľ	<u> </u>	<u> </u>		Water Filter		
Little House Living	N	Y	N Y	Posted November 2018 Updated 1/30/2023	851 SHARES		Blog of products used by writter and recommended based on preformance	https://www.littlehouseliving.com/the-berkey-must-have-water-filter.html
Lora Lynn Fanning	N	Υ	N Y	22-May-13	22 COMMENTS		Blog of products used by writter and recommended based on preformance	http://loralynnfanning.com/a-berkey-water-filter-review-for-water-purists-like-me/
Mommy's Memorandum	N	Υ	N Y	??	246 Views		Article on the assembly and benefits	https://mommysmemorandum.com/big-berkey-water-filter/#google_vignette
Moon and Spoon and Yum	N	Y	N Y	Mar 19, 20 Modified: 8, 2023			Article on the assembly and benefits - May contain affiliate links	https://moonandspoonandyum.com/berkey-water-filter-review/
Natural Health Resources	N	Y	N N	N		Health Benefits of Berkey Water Filter	Dr. Melissa Gallagher recomends using Berkey for health benefits: Improved Digestion, Maintain a Healthy Weight, Better Brain Function & Healthier Nervous System, Detoxification, and Stronger Immune System.	https://www.naturalhealthresources.com/blog/benefits-of-drinking-cleaner-better-filtered-
Nomads With a purpose	N	Υ	N Y	19-Feb-23	3 Comments	The co	Article on the assembly and benefits	https://www.nomadswithapurpose.com/berkey-water-filter-review/
Off Grid Life	N	Y	N	Published: 17, 2021 · Modified: 15, 2023	Aug 1 Comment		Article on the assembly and benefits of using Berkey Water Filters living OFF-Grid	https://www.anoffgridlife.com/berkey-water-filter-review/
Oh Sweet Mercy	N	Υ	N Y	/ 28-Aug-14	Not listed		Article on the assembly and benefits - May contain affiliate links	https://www.ohsweetmercy.com/berkey-water-filter-system-review/
Olive You Whole	N	Y	N N	N ??	Not recorded		Blog of products used by writter and recommended based on preformance	$\frac{\text{https://www.oliveyouwhole.com/clean-lifestyle/the-best-home-water-filter-whats-actually-in-your-tap-water}{} \\$
Organic Life Tips	N	Υ	N Y	/ 3/5/19	Not listed		Blog of products used by writter and recommended based on preformance	https://www.organiclifetips.com/big-berkey-water-filter-review/
Pretty Opinionated	Y	Υ	N N	N 16-Dec-19	Not listed		Article on the assembly and benefits - Imbedded video from Affiliate	https://www.prettyopinionated.com/2019/12/the-royal-berkey-water-filter-system-
Pure Water Ions	N	Y	N Y	Published 10-21 Mod 2023-08-09			Dedicated to providing independent and unbiased reviews of the best water ionizer machines on the market	it-a-good-buy/ https://purewaterions.com/big-berkey-water-filter-review
Pure Wow Dara Katz	N	Y	N Y	23-Nov-22	NA	The Big Berkey Is the Water Filter You Can Take with You When the World Ends	So, when I spotted a statuesque stainless steelvat (?)drum (?)keg (?) in my friend's kitchen, I implored, "What is that thing?" He response? The Big Berkey. Unbeknownst to me, I'd stumbled upon a cult-favorite brand among both off grid survivalists and urban dwellers alike. A couple weeks later, I was in possession of my very own Big Berkey, Here's my	https://www.purewow.com/home/big-berkey-water-filter- review?fbclid=lwAR2KovKKCdRHJ0dcYJMF9eIn429YKrTMI76Ek7Y5us2hWvLS8iNI8e_4ZdA
D. C 20	<u>.                                    </u>	ļ.,	ļ.		2.0		review.	Nu - 11
Refinery29 RV Texas Yall	N	l Y	N N	N 25-Feb-22 N Not listed	3 Comments Not listed	1	Article on the assembly and benefits	https://www.refinery29.com/en-us/berkey-water-filter-review
Safe Healthy Home	N	v v	N P	N Not listed 16-Jan-23	Plus 20 Comments	1	11:45 video and complete write up of the design and usage and benefits  Blog with mission to help make your home a safer and healthier place to live.	https://rvtexasyall.com/rv-tips/product-reviews/travel-berkey https://thesafehealthyhome.com/about-us/
Safe Healthy Home	N	Y	N Y	22-Jan-21	i ius 20 Comments	Big Berkey Water Filter Review:	Review by consumer that has used Berkey for amny years and loves it!	https://thesafehealthyhome.com/big-berkey-water-filter-system-review/
Seed to Pantry School	N	Y	N Y	22-Sep-14	443 Facebook share	Your Questions Answered!	Article on the assembly and benefits - Imbedded video from Affiliate	https://seedtopantryschool.com/berkey-review/
Stack Your Dollars	N	Υ	N Y	24-May-23	Not listed	0. 10	Financial Coach and budget-savvy military wife blog	https://stackyourdollars.com/big-berkey-water-filter-system-review/
The Everyday Farmhouse	Y	ľ	N Y	′		Benefits and Reasons to Use a Berkey Water Filter System	Explains why a Berkey is essential for any kitchen and provides information and videos on setup, maintenance and use.	https://theeverydayfarmhouse.com/reasons-to-use-a-berkey-water-filter-system/
The Goldilocks Kitchen	N	Υ	N Y	7 5-Aug-19	14 comments		Blog of products used by writter and recommended based on preformance	https://goldilockskitchen.com/2019/08/travel-berkey-water-purifier-review/
he Home Intent	N	Y	N Y	7 17-Oct-21		THE BIG BERKEY WATER FILTER REVIEW	Is the Berkey water filter all it's cracked up to be? I give an honest, full review of the pros and cons of this popular water filtration system.	https://thehomeintent.com/berkey-water-filter-review/
THIS LOVELY LITTLE FARMHOUSE	Y	Y	N Y	27-Jan-20		BERKEY WATER FILTER REVIEW	Blog of products used by writter and recommended based on preformance. I saw my first Berkey water filter many years ago as a kid at a friend's house. It wasn't until my adult years that I learned why water filters are so important. I'm	https://thislovelylittlefarmhouse.com/berkey-water-filter-pros-and-cons-berkey-filter-review
Tidbits & Company	Υ	Y	N Y	/ 18-Jan-22			sharing all about our Berkey, it's pros and cons, and a few helpful tips.  Article "Berkey Water Filter Review plus Reasons to Buy One!"	https://www.tidbits-cami.com/berkey-water-filter-review/
Tidbits & Company	Ÿ	Y	N Y	13-Jan-22			Berkey user had water tested with good results and becomes an affiliate for the water testing company and a Berkey Dealer. Also made video posted on Youtube	https://www.ndubis-cami.com/perkey-water-revew/ https://www.tdubis-cami.com/perkey-water- test/#:-text=1%20can%20see%20that%20tt,drinking%20more%20appealing%20and%20cor
Tiny Living	N	Y	N Y	Published 2 04-28 Modified 2 06-08	2022- Not listed 023-		Blog of products used by writter and recommended based on preformance	nient. https://tinylivinglife.com/comprehensive-big-berkey-water-filter-review/
Trustworthy Fitness	N	Y	N Y	/ Not listed	Not listed		Blog of products used by writter and recommended based on preformance	https://trustworthyfitness.com/big-berkey-water-filter-review/

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Ultimate Meal Plans	N	Υ	N	N	10-Jan-23	Not listed		Article on the assembly and benefits	https://ultimatemealplans.com/articles/berkey-water-filter-review/
Water Geek	Υ	Υ	N	Υ	16-Mar-23	Not listed		Article on the assembly and benefits - Imbedded video from Affiliate	https://thewatergeeks.com/berkey-water-filters/
WaterSeer	N	Υ	N	N	3/2/23	Not listed		Blog of products used by writter and recommended based on preformance	https://waterseer.org/big-berkey-filter-review/
wellness with linds	N	Y	N	Υ			Berkey Water Filter Review: Is It	One of the most common questions I get on social media (Tiktok in particular): is your Berkey water filter worth it? Yes,	https://lindsayfuce.com/berkey-water-filter-review/
							Worth It?	yes, yes, and yes! I recommend the Berkey purification system to just about all of my friends. So much so, they're	
								probably sick of hearing about it by now.	
Whole World Water	N	Y	N	N			Big Berkey Water Filter Review:	Consumer advocate site. Their mission is "Our core objective is to help everyone have easy access to clean, fresh, and	https://wholeworldwater.co/big-berkey-water-filter-reviews/
							Worth the Money in 2023?	healthy water!" Gives fair objective review of Berkey Water Filters	
World of Water Falls	Υ	Υ	N	Υ	??	Not listed		Sponsored post - Article on the assembly and benefits - Must be login in to see comments	https://www.world-of-waterfalls.com/travel-berkey-review/
World Water Reserve	N	Υ	N	Υ	25-Jul-23		My Big Berkey Water Review - 2	The Big Berkey is a popular gravity-fed water purification system with excellent filtration capabilities. This article gives an	https://worldwaterreserve.com/big-berkey-water-filter-
							Years of Steady Use	in-depth review of its use. There are many reasons why the Berkey is one of the most practical water purification devices	review/?fbclid=IwAR0a76TcvqZAA1qi_aEpdH63EJO6wzwUHYwPDX1BfwyJIsw81s_M_Cgrvco
								available, especially for self-sufficiency and off-grid settings. But what I like most about my Berkey is its simplicity and	
								reliability.	

### Big Berkey Equivilant Unit Sales on Amazon Jan to June 22' vs 23'



Case 3:24-cv-01106 Document 1-2 Filed 03/06/24 Page 48 of 93 US ENVIRONMENTAL PROTECTION AGENCY 37589-2 OFFICE OF PESTICIDES PROGRAMS TERM OF ISSUANCE REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460 NAME OF PESTICIDE PRODUCT NOTICE OF PESTICIDE: REGISTRATION REREGISTRATION X-262 Pacteriostatic Silver (Under the Federal Insecticide, Fungicide, Impregnated Activated Carbon and Rodenticide Act, as amended) NAME AND ADDRESS OF REGISTRANT (Include ZIP code) Pestech, Inc. 442 South Dixie Pighway Fast Peripara Feach, FI, 33060 NGTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number. On the basis of information furnished by the registrant, the above named posticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodencicide Act. A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith. Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is conditionally registered in accordance with FIFPA sec. 3(c)(7)(A) provided that you: 1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Adency requires all registrants of similar products to submit such data. 2. Make the labeling changes listed below before you release the product for shipment: Add the phrase "FPA Registration No. 37580-2." On the Mechnical Data Sheet, move the heading Directions For Use so that it appears immediately above the statement "It is a violation of Federal . . . labeling." Also delete the colon. Include a reference statement somewhat as follows on the label: enclosed "echnical Data Sheet for directions for use." 3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling. 90658: J. Lee: RD: 85/19: KENCO: 12/11/85: Del. 12/20/85: eq: VO ATTACHMENT IS APPLICABLE SIGNATURE OF APPROVING OFFICIAL DATE

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

John H. Lee

Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

#### A-7, pg. 3

## BACTERIOSTATIC SILVER IMPREGNATED ACTIVATED CARBON

ACTIVE INGREDIENT Silver (as elemental)

0.20%

INERT INGREDIENTS

99.80%

100:00%

### CAUTION: KEEP OUT OF REACH OF CHILDREN

### STORAGE AND DISPOSAL

STORAGE DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL, STORE CONTAINER IN DRY PLACE, IF SPILLAGE OCCURS, SWEEP UP, PLACE IN PLASTIC BAG AND FOLLOW DISPOSAL INSTRUCTIONS.

DISPOSAL: WASTES RESULTING FROM USE OF THIS PRODUCT MAY BE DISPOSED OF ON SITE OR AT AN APPROVED WASTE DISPOSAL FACILITY. COMPLETELY EMPTY BAG INTO APPLICATION EQUIPMENT, DO NOT REUSE BAG OR BOX. THEN DISPOSE OR EMPTY BAG IN A SANITARY LANDIFILL OR BY INCINERATION, OR, IF ALLOWED BY STATE AND LOCAL AUTHORITIES, BY BURNING, IF BURNED STAY OUT OF SMOKE.

Silver inhibits the growth of bacteria within this filter media bed. This product is only to be used for manufacturing or fabricating bacteriostatic water filters, which are used to remove objectionable tastes, odors, color and suspended particles from municipally-treated tap water. Manufacturers or formulators who use this media are responsible for providing data to the U.S. Finite-innern. I Protection Agency to support the registration of their products. If media is repackaged, relabeled or put in a device for resale, EPA registration of that product is required.

EPA REG. NO. EPA EST. NO. 37589-FL-1

Net Contents: \_\_\_\_\_ cu. ft.

BESTECH, INC. 442 South Dixie Highway East Pompano Beach, Florida 33060 U.S.A. ACCEPTED

with COMMENTS

to EPA Letter Date in

DEC 19 1985



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442 S. Dixie Highway, East M. Pompano Beach, Florida 33060 R. Phone (305) 785-4550

### X-262 SILVER IMPREGNAT D ACTIVATED CARBON TECHNICAL DATA

DIRECTION FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

X-262 Inhibits the growth of bacteria within the media bed.

ACCEPTED
with COMMENTS
in TPA Letter Details

X-262 Removes objectionable tastes, odors and color from municipally-treated water supplies.

EPA Registration No.

DEC 1 9 1985

EPA Establishment No. 37589-FL-1

Under the Percut his Parabolic the Rodent as concated, for the registered under EPA I

Active Ingredient: 0.20% Silver

X-262 media should be rinsed before use. It should be rinsed for 15 minutes at the flow rate you specify for your equipment. Cycling the outlet valve on and off will help clear the media of carbon fines.

The bacteriostatic properties of X-262 will have a maximum range of 4,500 to 6,000 gallons per pound. Specific gallonage may vary with ph and temperature of the influent.

Todine Number, minimum.....825

Mesh size, U.S. sieve.....20 x 50

If media is repackaged, relabeled or put in a device for resale, EPA registration of that product is required.

Shipping and repackaging may greatly reduce the mesh size of a small portion of this material. For treatment of potable water, a suitable filter (50 microns or smaller) is suggested for removal of particulates.

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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 5, 2020

David R. McAdams Environmental Engineer c/o Heather F. Collins Regulatory Consultant Calgon Carbon Corporation 3000 GSK Drive Moon Township, PA 15108

Subject: PRIA Label and CSF Amendment – Registration of New Product Name, Addition

of ABN, New Source of Unregistered AI,

and Label Language Update

Product Name: Calgon Carbon Corporation Type CE Bacteriostatic Water Filter

Media

EPA Registration Number: 58295-2 Application Date: 05/13/2020 Decision Number: 562949

#### Dear Ms. Collins:

The amended label and CSF(s) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 08/08/1995
- Alternate CSF 1 dated 05/13/2020

Page 2 of 2 EPA Reg. No. 58295-2 Decision No. 562949

Please note that the alternate brand name Barnebey & Sutcliffe Type CE Bacteriostatic Water Filter Media has been added to the product record, and the new registered product name is Calgon Carbon Corporation Type CE Bacteriostatic Water Filter Media.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, you may contact Perri Moeller at 703-347-8618 or via email at Moeller.Perri@epa.gov.

Sincerely,

Joseph Varco

Acting Product Manager, Team 33 Regulatory Management Branch I Antimicrobials Division Office of Pesticide Programs

Enclosure

### CALGON CARBON CORPORATION TYPE CE BACTERIOSTATIC WATER FILTER MEDIA

## CAUTION CAUTION

EPA REG. NO.: 58295-2 EPA EST. NO.: 58295-OH-001

### **ACTIVE INGREDIENT**

 METALLIC SILVER\*:
 1.05%

 INERT INGREDIENT(S):
 98.95%

 TOTAL
 100.00%

**ACCEPTED** 10/05/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 58295-2

THIS PRODUCT IS DESIGNED TO REMOVE OBJECTIONABLE TASTES, ODORS, AND COLOR FROM MUNICIPALLY-TREATED TAP WATER.

### PRECAUTIONARY STATEMENTS

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE: IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. THIS PRODUCT INHIBITS THE GROWTH OF NON-PUBLIC HEALTH BACTERIA IN THE FILTER TO PROLONG THE LIFE OF THE FILTER. DRINKING WATER FILTERS ARE FOR USE WITH COLD WATER ONLY.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: STORE IN CLOSED CONTAINER WHICH EXCLUDES MOISTURE AND FLIMES

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

#### CONTAINER HANDLING:

Drum: Nonrefillable container. Do not reuse or refill this container. Completely empty drum by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

Supersack: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty supersack in a sanitary landfill or by incineration.

MANUFACTURED BY: CALGON CARBON CORPORATION P.O.BOX 2526 COLUMBUS, OH 43216-2526

<sup>\*</sup> from silver nitrate

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### U.S. ENVIRONMENTAL PROTECTION **AGENCY**

Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

### NOTICE OF PESTICIDE:

x Registration Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

Date of Issuance:

71332-5

SEP 28 2007

Term of Issuance:

### Conditional

Name of Pesticide Product:

EPL 0.25 Silver/Ceramic Filter Material

Name and Address of Registrant (include ZIP Code): Thomas Palkton WQA Laboratory Agent for Envirogard Products Limited 4151 Naperville Rd, Lisle IL 60532

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
- 2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the "EPA Registration Number to read, "EPA Reg. No. 71332-5".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (Control of the Marshall Summer States)

Antimicrobials Division (7510P)

SEP 2 8 2007

EPA Form 8570-6

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Page 2 EPA Reg. No. 71332-L

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely

Marshall Swindell

Product Manager Team-33

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

### EPL 0.25 Silver Ceramic Filter Material

Directions for Use: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This silver/ceramic filter material is intended for use only with water filter units designated for use with cold water. Maximum temperature 100°F.

EPA Reg. No.: 71332-U

EPA Est. No.: 071332-CAN-001

Active Ingredient:

Metallic Silver...... 00.25% Inert Ingredients...... 99.75%

# Keep Out of Reach of Children Caution

This silver/ceramic filter material is intended for assembly into water filter units. Use with cold water only. This product inhibits the growth of bacteria in the filter to prolong the life of the filter. This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water.

Storage and Disposal: When not in use, store in a dry location. To dispose, wrap used silver/ceramic filter material in newspaper and discard with trash.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 28 2007

Under the Rederal Insecticide, Rungicide, and Rodenticide Act essmended, for the pesticide, registered under EPA Reg. No.

7/332-5

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



### **SEPA** United States Environmental Protection Office of Pesticide Programs Agency

K-2 Concepts, Inc. 114 North Prince Street, 3rd Floor Lancaster, PA 17603

FEB 2 3 2012

AGENT: Lewis and Harrison

122 C Street, N.W., Suite 740 Washington, D. C. 20001

Attention: Karen E. Warkentien

Subject: Aquastat XR

EPA Registration No. 79630-2 Notification Dated February 3, 2012

This will acknowledge receipt of your notification of a new inert ingredient supplier, submitted under the provisions of FIFRA Section 3(c)(9).

### **Proposed Noatifiction**

- Adding an Indoor, Nonfood Site to the Label

### **General Comments**

Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell

**Product Manager 33** 

Regulatory Management Branch 1 Antimicrobials Division (7510P)

2/6

Please read instructions on r		ting fo.		Z	Form Ap		1			A-7, pg. 12 <b>0. Approval expires 2-28-9</b>	
<b>≎EPA</b>		nited States  Protection Agency gton, DC 20460			Registri Amend V Other		trati idme	on	OPP Identifier Number		
		Application	on for	Pesticio	le - Sec	tion	l				
1. Company/Product Number 79630-2	,			ł .	roduct Man III Swinde	•			3. Proposed Classification  ✓ None Restricted		
4. Company/Product (Name) Aquastat(R)-XR				PM# 33							
5. Name and Address of App K2 Concepts Inc. 114 North Prince Street Lancaster PA 17603	de)	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.									
Check ii ans	13 4 110 10 40 410 410 410		Sec	tion - II	t Name				·		
Amendment - Explain  Resubmission in resp.  Notification - Explain  Explanation: Use addition  Notification of Label Change regulations at 40 CFR § 156. that it is a violation of 18 USC  PR Notice 98-10 and 40 CFR and 14 of FIFRA.	below.  al page(s) if necessar per PR Notice 98-10: T 46, and no other chang	y. (For section this notification es have been the any false state the state of the section in the section is the section in the section in the section is the section in the section in the section is the section in the section in the section in the section is the section in t	is consiste made to th atement to	ent with the e labeling o EPA. I furth	or the Confid er understa	ter date Applica  lain be PR No lential S nd that	tice 98-1	0 and t	he requ mula for	r this product. I understand consistent with the terms of	
			Sec	tion - II		·					
1. Material This Product Will	Be Packaged In:										
Child-Resistant Packaging Yes No * Certification must	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per	No Plas Glas Glas Pap					Metal Plastic Glass Paper	Specify)		
be submitted  3. Location of Net Contents I Label C	stail Container 5. Location of Label Directions										
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stend	graph glued ciled		Othe	r					
			Sect	ion - IV	1						
1. Contact Point <i>(Complete</i>	items directly below t	or identification	on of indiv	idual to be	contacted,	if nece	ssary, t	proce	ss this	application.]:	
Name Karen E. Warkentien	1					1	Telephone No. (Include Area Code) (202) 393-390\$ x22c c				
I certify that the stater I acknowledge that an both under applicable I	y knowlinglly false or		all attach							6. Date Application Received  (Stamped)	
2. Signature			3. Title  Consultant to K2 Concepts Inc.								

5. Date

4. Typed Name

Karen E. Warkentien

3 February 2012

# LEWIS & HARRISON

122 C Street, N.W., Suite 740 Washington, D.C. 20001 telephone 202.393.3903 fax 202.393.3906

Consultants in Government Affairs

3 February 2012

Via Hand Delivery

Mr. Marshall Swindell, PM #33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 Crystal Drive
Arlington VA 22202

SUBJECT: Aquastat XR, EPA Reg. No. 79630-2

**Application for Pesticide Notification** 

Addition of Additional Substrate per PRN 98-10

Dear Ms. Noble:

On behalf of our client, K2 Concepts Inc. (K2), Lewis & Harrison, LLC, submits herewith the following documents in support of amended registration for Aquastat XR, EPA Reg. No. 79630-2:

Volume I: Administrative Materials

- Application for Pesticide Notification (EPA Form 8570-1)
- Draft label (two copies, one with highlighted changes)

This submission is made pursuant to PR Notice 98-10, ¶II.C: <u>Adding an Indoor, Nonfood Site for an Antimicrobial Product</u>, by including air filters as an additional substrate for this manufacturing use product (MUP).

### Notification of Label Change per PR Notice 98-10

This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR § 156.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 USC § 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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Mr. Marshall Swindell, PM #33

Page 2 of 2

This submission is NOT subject to processing under the Pesticide Registration Improvement Act (PRIA) and should be categorized as a notification.

Should you have any questions concerning this submission, please contact me by phone at (202) 393-3903 x22 or via email at <a href="mailto:kwarkentien@lewisharrison.com">kwarkentien@lewisharrison.com</a>.

Sincerely,

LEWIS & HARRISON, LLC Consultant to K2 Concepts Inc.

Karen E. Warkentien

Enclosures

cc: Bryan Kepner, K2 Concepts Inc.

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[] denotes alternate and/or language Proposed changes are underlined and highlighted

# AQUASTAT®-XR

An antimicrobial agent for manufacturing or fabricating [bacteriostatic] [and] [or] [fungistatic] [water] [and] [or] [air] filters

Active ingredient:	
Silver (as elemental)	
Other ingredients	98.6%
Total	

### KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID: roduct container or label with you when calling a poison control center or doctor, or going for treatment.
<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye</li> <li>Call a poison control center or doctor for treatment advice</li> </ul>
<ul> <li>Move person to fresh air</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth, if possible</li> <li>Call a poison control center or doctor for further treatment advice</li> </ul>
<ul> <li>Immediately call a poison control center or doctor</li> <li>Do not induct vomiting unless told to do so by a poison control center or doctor</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person</li> </ul>
<ul> <li>Take off contaminated clothing</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes</li> <li>Call a poison control center or doctor for treatment advice</li> </ul>

EPA Reg. No. 79630-2	EPA Establishment No. 79630-GA-001
Net Contents:	Lot No.:



K2 CONCEPTS INC. 2625 Piedmont Rd. NE Atlanta GA 30324 (404) 452-9010

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

**CAUTION**. Causes eye irritation. May be harmful if swallowed. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

- AQUASTAT -XR is to be used only for manufacturing or fabricating bacteriostatic [and] [or] fungistatic [water] [and] [or] [air] filters. Filter manufacturers or formulators who use this product are responsible for providing data to US EPA to support any necessary registrations.
- AQUASTAT-XR is to be used to protect the [water] [and] [or] [air] filter itself against the growth of bacteria [mold] [and] [or] [mildew] and to prevent odors [and unpleasant tastes] or discoloration.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

- Pesticide Storage: Do not store in areas accessible to children. Keep product dry and containers covered during storage.
- ☐ Pesticide Disposal: Wastes from the use of this product may disposed of on site or at an approved waste disposal facility
- ☐ Container Disposal: [only one will appear, based on the container type]

Plastic containers: Triple rinse (or equivalent). Then offer for recycling or recondition, or puncture and dispose of in a sanitary landfill or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Fiber drums with liners: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residues into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for the liner.

Notification 2012-01-31



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 1 6 2010

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Bio-Gate, AG Fahrenheitstrasse 11 German 28359 Germany

AGENT: Technology Sciences Group, Inc. 1150 18<sup>th</sup> Street, NW

Suite 1000

Washington, DC 20036

Attention: Erin M. Tesch

Subject: MicroSilver BG-R

> EPA Registration No: 84146-1 Notification Dated April 21, 2010

This will acknowledge receipt of your notification for the following additional alternate bran names, submitted under the provisions of FIFRA Section 3©(9). Based on a review of the submitted material, the following comments apply.

### ADDITONAL BRAND NAME

MicroSilver BG-Tec

### **General Comments**

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please feel free to contact Zebora Johnson at (703) 308-7080.

Sincerel<sup>1</sup>

Product Manger (33)

Regulatory Management Branch 1 Antimicrobial's Division (7501P)

Case 3:24-cv-01106 Document 1-2 Filed 03/06/24 Page 65 of 93
A-7, pg. 18

Please read instructions on I	everse before comple	ting form.	<del>, , , , , , , , , , , , , , , , , , , </del>	Form Apr	proved	<u>I. OMB N</u>	<u>lo. 207</u>	0-0060	Approvel expires 2-28-9
<b>\$EPA</b>	Inited States  I Protectio ington, DC 204	ion Agency			Amer	Registration Amendment Other		OPP Identifier Number	
		<b>Applicatio</b>	n for Pestici	de - Sec	tion	<b>l</b> .			
1. Company/Product Numbe 84146-1	r		l l	Product Man all Swindel	-				posed Classification  None Restricted
4. Company/Product (Name) MicroSilver BG-R			PM# 33						· · · · · · · · · · · · · · · · · · ·
5. Name and Address of App Bio-Gate AG Fahrenheitstrasse 11 Bremen 28359 Germany	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.								
Check if this	is a new address		Produ	ct Name					
			Section -	II					
Amendment - Explain  Resubmission in resp  Notification - Explain	Final printed labels in repsonse to Agency letter dated "Me Too" Application.  Other - Explain below.								
An alternate brand name, "Micros 872-0745.  This notification is consistent with statement of formulation for this p is not consistent with the terms of sections 12 and 14 of FIFRA.	the provisions of PR Notice	ce 98-10 and EPA t is a violation of 18	regulations at 40 CFR 3 U.S.C. Sec. 1001 to	152.46, and no villfully make ar	other o	changes hav	ve been r to EPA. I	nade to ti further u	he labeling or the confidential nderstand that if this notification
			Section - I	11					
1. Material This Product Will	Be Packaged In:								
Child-Resistant Packaging Yes No	Unit Packaging Yes No		Water Soluble Packaging Yes No			2. Type of Container  Metal Plastic Glass			
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per . container	If "Yes" No. per Paper						pecify)
3. Location of Net Contents	Information	4. Size(s) Reta	etail Container 5. Location of Label Directions						ns
Label C	ontainer	10, 3	), 300, 500, and 2000 g						· · · · · · · · · · · · · · · · · · ·
6. Manner in Which Label is	Affixed to Product	Lithogr Paper   Stencil	ograph Other						
	······································		Section - I	V				•	
1. Contact Point (Complete	items directly below t	for identification	n of individual to b	e contected,	if nec	essary, to	o proce	ss this	application.)
Name Erin M. Tesch,Technolog	Title Regulatory Cons	itle				Telephone No. (Include Area Code) (202) 828-8966			
•	and the second s	ichments thereto are true, accurate and complete. may be punishable by fine or imprisonment or					6. Date Application Received (Stamped)		
2. Signature	MEGHA EVE		3. Title Regulatory Consultant to Bio-Gate AG						
4. Typed Name	r	5	5. Date					}	
Erin M. Tesch		4/21/10							



April 21, 2010

#### WASHINGTON

1150 18th Street, N.W.

**Suite 1000** 

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Mr. Marshall Swindell

Office of Pesticide Programs Antimicrobial Division (7504P)

Office of Pesticide Products

U.S. Environmental Protection Agency Room S-4900, One Potomac Yard

2777 South Crystal Drive Arlington, VA 22202-4501

RE: MicroSilver BG-R

(EPA Reg. No. 84146-1)

Notification for Label Changes per PR Notice 98-10

Suite A

Davis, CA 95616

**SACRAMENTO** 

712 Fifth Street

Telephone 530 757-1298

Fax 530 757-1299

Dear Mr. Swindell:

Technology Sciences Group Inc., on behalf of Bio-Gate AG, is submitting the enclosed notification to add an alternate brand name, "MicroSilver BG-Tec", to the master label. The enclosed label includes the change identified above.

You will find the following included with this submission:

- 1) EPA Application Form:
- 2) One redline version of the revised label:
- 3) Three clean copies of the revised label; and
- 4) Letter authorizing TSG to act on behalf of Bio-Gate AG.

concerns at (202) 828-8966 or via e-mail: etesch@tsgusa.com.

Please do not hesitate to contact me directly with any questions and/ or

CANADA 275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Sincerely

Tesch

Regulatory Agent for Bio-Gate AG

E-mail tsg@tsgusa.com

http://www.tsgusa.com

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### MicroSilver BG-Tec

# For Use in the Manufacture of Commercial and Consumer Products to Impart Antimicrobial Properties

MicroSilver BG-Tec is an antimicrobial additive that safely and effectively inhibits the growth of stain and odor causing bacteria, mold, and mildew on the product in which it is added or applied.

<u>Active</u>	Ingredient:	
Silver		<u>100%</u>

TOTAL: 100%

# KEEP OUT OF REACH OF CHILDREN CAUTION

EPA REG. No. 84146-1 EPA EST. No. 084146-DEU-001

Manufactured by

Bio-Gate AG

Fahrenheitstrasse 11 28359 Bremen GERMANY

### SEE SIDE PANEL FOR PRECAUTIONARY STATEMENTS

Please refer to the Technical Bulletin for information concerning uses.

### DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labeling. MicroSilver BG-Tec is a bacteriostatic agent for processing or manufacturing use only. Formulators are responsible for obtaining registrations for their own end use products.

# PRECAUTIONARY STATEMENT. CAUTION

4-7, pg. 21

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed, inhaled, or absorbed through the skin. May cause eye irritation. Prolonged skin contact may cause skin irritation and/or dermatitis. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

	FIRST AID					
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if applicable, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>					
If swallowed	<ul> <li>Call a poison control center or doctor immediately.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not give anything to an unconscious person.</li> </ul>					
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>					
If on skin or clothing	<ul> <li>Take off contaminate clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>					
<ul> <li>HOT LINE NUMBER: 1-800-873-1138</li> </ul>						
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.						

### **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a national Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### STORAGE AND DISPOSAL

Storage	Keep tightly closed in a dry, cool and well-ventilated place. Avoid dust formation Dust may form explosive mixture in air. Keep container closed to prevent contact with moist air. Do not store in area where food or feed may come in contact with the product. Keep away from direct sunlight.
Disposal	<u>Pesticide Disposal:</u> Unused material should be disposed of in accordance with federal, state and local environmental control regulations. <u>Container Disposal:</u> Emptied container retains product residue. Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities

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## MicroSilver BG-Tec

## For Use in the Manufacture of Commercial and Consumer Products to Impart Antimicrobial Properties

### TECHNICAL BULLETIN

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

MicroSilver BG-Tec is intended for use in the manufacture of the products listed below to impart antimicrobial properties. MicroSilver BG-Tec inhibits the growth of stain and odor causing bacteria, mold, and mildew on the product to which it is applied. Products containing MicroSilver BG-Tec may not make claims of antimicrobial activity other than protection of the article itself against growth of bacteria, mold, and mildew.

This product is <u>not</u> approved for any food contact or food packaging uses. This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water.

MAXIMUM CONCENTRATION: MicroSilver BG-Tec may be incorporated into the types of products listed below at maximum concentration of no more than one (1) percent on a weight basis of the finished products.

1). <u>Ceramics, ceramic glazes, porcelain enamels, and other glasses.</u>

Specific materials: vitreous china, ceramics, glazes, earthenware, stoneware, dental glasses, borosilicate glasses, lead glasses, soda lime glasses, special glasses, porcelains, porcelain enamels, clays, concretes, and grouts.

Applications: Applications include toilets, sinks, urinals, bidets, lavatories, bathtubs, tile, flooring, windows, shower doors, shower walls, shower trays, bath and kitchen accessories, countertops, handles and knobs.

This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water.

2). Plastics and plastic composite materials.

Specific materials: Resins including alkyds, amino resins, (melamine formaldehyde and urea formaldehyde), polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethyl-pentene (PMP), polysiloxane, polyvinyl alcohol, (PVOH), polyvinyl acetate (PVA), ethylene vinyl acetate (EVA), polyethylene copolymer, polyvinyl chloride (PVC), epoxies, phenolic, polycarbonate, celluosics, cellulose acetate, polystyrene, polyeurethane, acrylic, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile-styrene-acrylic copolymer (ASA), acetals, polyketones, polyphelylene, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymer and fluoropolymers, amino resins, thermoplastic elastomer, rubber (including styrene, butadiene, common acrylonitrile rubber, CR) polyacetal (polyoxymethyleneP, and blends and copolymers thereof.

Applications include toilet seats, toilets, sinks, urinals, bidets, lavalues, bathtubs, spas, tile, flooring, shower doors, shower walls, shower trays, bath and kitchen accessories, plumbing supplies and fixtures, countertops, handles, knobs, automobile parts, shower curtains, mats, protective covers, waste containers, general purpose containers, shower heads, ops, brooms, tapes, packaging, gaskets, pipes, tubing, pipe fittings, whirlpool tub and spa components, structural reinforcement composites (e.g., fiber reinforced resin backings), furniture, HVAC parts and equipment, window blinds, tools, keyboards, personal grooming equipment, footwear including boots, sports equipment, telephones, and computer equipment.

This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water.

### 3) <u>Fibers.</u>

Specific materials: Resins including polyester ("Dacron" PET, and PTT), acetate, polyolefins, polyamides (Nylon), polypropylene (PP), polyethylene (PE), acrylics, viscose, polyurethane, "Rayon", polyvinyl alcohol (PVOH), polyvinyl chloride PVC), polyvinylidene chloride, polysaccharides, and blends and copolymers thereof.

Applications include fabrics for household applications, components of aircraft interiors, home furnishings, automotive fabrics, and apparel.

This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water.

### 4) Coatings

Types of coatings: All application methods including water borne, nonaqueous solvent borne, 100% solids, physical vapor deposition, radiation cure, thermal cure, liquid, slurry, and powder coatings.

Specific materials: Resins including alkyds, amino resins, (melamine formaldehyde and urea formaldehyde), polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol, (PVOH), polyvinyl acetate (PVA), ethylene vinyl acetate (EVA), polyethylene copolymer, polyvinyl chloride (PVC), epoxies, phenolic, polycarbonate, celluosics, cellulose acetate, polystyrene, polyeurethane, acrylic, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile-styrene-acrylic copolymer (ASA), acetals, polyketones, polyphelylene, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymer and fluoropolymers, amino resins, thermoplastic elastomer, rubber (including styrene, butadiene, common acrylonitrile rubber, CR) polyacetal (polyoxymethyleneP, and blends and copolymers thereof.

Applications include toilet seats, toilets, sinks, urinals, bidets, lavatories, bathtubs, spas, tile, interior paint, flooring, shower doors, shower walls, shower trays, bath and kitchen accessories, plumbing supplies and fixtures, countertops, handles, knobs, automobile parts, shower curtains, mats, protective covers, waste containers, general purpose containers, shower heads, mops, brooms, tapes, packaging, gaskets, pipes, tubing, pipe fittings, whirlpool tub and spa components, structural reinforcement composites (e.g., fiber reinforced resin backings), furniture, HVAC parts and equipment, window blinds, tools, keyboards, personal grooming equipment, footwear including boots, sports equipment, telephones, and computer equipment.

This product may not be used for any applications involving food contact, A-7, pg. 24

food packaging, or storage of human detailed.

#### Adhesives and Sealants. 5).

Specific materials: Resins including alkyds, amino resins, (melamine formaldehyde and urea formaldehyde), polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol, (PVOH), polyvinyl acetate (PVA), ethylene vinyl acetate (EVA), polyethylene copolymer, polyvinyl chloride (PVC), epoxies, phenolic, polycarbonate, celluosics, cellulose acetate, polystyrene, polyeurethane, acrylic, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrilestyrene-acrylic copolymer (ASA), acetals, polyketones, polyphelylene, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymer and fluoropolymers, amino resins, thermoplastic elastomer, rubber (including styrene, butadiene, common acrylonitrile rubber, CR) polyacetal (polyoxymethyleneP, and blends and copolymers thereof.

Applications include toilet seats, toilets, sinks, urinals, bidets, lavatories, bathtubs, spas, tile, flooring, shower doors, shower walls, shower trays, bath and kitchen accessories, plumbing supplies and fixtures, countertops, components of aircraft interiors, handles, knobs, automobile parts, shower curtains, mats, protective covers, waste containers, general purpose containers, shower heads, mops, brooms, tapes, packaging, gaskets, pipes, tubing, pipe fittings, whirlpool tub and spa components, structural reinforcement composites (e.g., fiber reinforced resin backings), furniture, HVAC parts and equipment, window blinds, tools, keyboards, personal grooming equipment, footwear including boots, sports equipment, telephones, and computer equipment.

This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water.



### **Berkey Water Filtration Verification**

Report#: E1526E-121820 Date Report Prepared: 12/18/2020

Author: Angela Carlson

### Part 1 Purpose

The purpose of this verification is to evaluate the filtration performance fo the Berkey Light Filtration System (2.75gal) Water filter to remove viral particles. The performance will be evaluated by artificially spiking Houston City water with a virus and comparing the levels of pre and post filtration.

### Part 2 References and Test Methodology

Wastewater Concentration by Adsorption and Direct Extraction for SARS-CoV-2 RNA Detection and Quantification by RT-ddPCR V.1

### Part 3 Data, Results and Interpretation

**Point of Use Device (POU):** Berkey Light (2.75 gal) Filter #23 (provided by manufacturer)

Image 1: Berkey Light fully assembled Image 2: Top View of filters installed





### **Water Preparation:**

Houston City Water from laboratory City Water from laboratory was used in this study. 10.5 Gallons was collected from laboratory spigot for use throughout study. A 250ml aliquot of water was set aside, unspiked for use as analysis blank (Water-Blank). An additional 50ml aliquot of water was analyzed for general composition as outlined below.

Table 1: Composition day of use:

Lab Analytes	Results
Free Chlorine	0.2
Conductivity	0.1
pH	7.8
Temperature	22.1

Water was spiked with Bovine Respiratory Syncytical Virus (BRSV) from a commercially available source<sup>1</sup> at a rate of approximately 10,000 viral copies / L (Water+BRSV).

### **Filtration:**

One 250ml container of unfiltered water, spiked with BRSV to be analyzed as the prefiltration level. POU was setup based on manufacturers instructions by priming with unspiked water. Spiked water was passed through the POU and 250ml containers of water collected after 3 time points: 1 gallon (Water+BRSV-1), 5 gallon (Water+BRSV-5), 10 gallon (Water+BRSV-10). All other excess water was disinfected to remove BRSV and disposed.

### **Filtrate Analysis:**

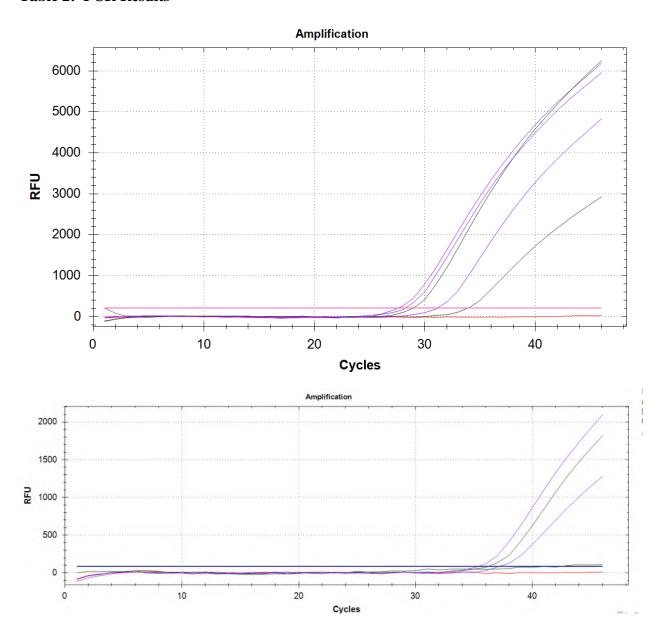
The four (4) filtrates alongside the blank unspiked, unfiltered water were analyzed using RT-PCR for detection and quantitation of BRSV.

### **Part 4 Summary**

	<b>BRSV Found</b>	Concentration if found (copies/L)	Percent decrease*
Water-Blank	Not detected		NA
Water+BRSV		10,000	NA
Water+BRSV-1	Detected	569.2	94.3%
Water+BRSV-5	Detected	654.3	93.5%
Water+BRSV-10	Detected	50.15	99.5%

\*Percentage (%) decrease =  $\frac{\text{[Water+BRSV concentration]-[concentration found]}}{\text{[Water+BRSV concentration]}}x\ 100$ 

**Table 2: PCR Results** 



**Red: Non-Template Control Purple: Calibration Standards** 

**Green: Samples** 

### Part 5 Footnotes

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Clear air... clear water... it all depends on **clear writing**.

The Plain Writing Act of 2010 (pdf) <a href="https://www.gpo.gov/fdsys/pkg/plaw-111publ274/pdf/plaw-111publ274.pdf">https://www.gpo.gov/fdsys/pkg/plaw-111publ274/pdf/plaw-111publ274.pdf</a> requires federal agencies to write "clear Government communication that the public can understand and use." Former President Obama emphasized the importance of establishing "a system of transparency, public participation, and collaboration" in his January 21, 2009 Memorandum on Transparency and Open Government <a href="https://obamawhitehouse.archives.gov/the-press-office/transparency-and-open-government">https://obamawhitehouse.archives.gov/the-press-office/transparency-and-open-government</a>.

We are committed to writing new documents in plain language, using the Federal Plain Language Guidelines <a href="https://www.plainlanguage.gov/guidelines/">https://www.plainlanguage.gov/guidelines/</a>.

We have assigned staff to oversee our plain language efforts. Eric Wachter is the Senior Agency Official for Plain Writing.

We're training our employees and have strengthened our oversight process. We must use plain language in any document that:

- is necessary for obtaining any federal government benefit or service or filing taxes;
- provides information about any federal government benefit or service; or
- explains to the public how to comply with a requirement that the federal government administers or enforces.

We have to report our progress and compliance. This site includes the initial report, issued in 2011, and subsequent annual reports that the Plain Writing Act requires.

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- 2021 Annual Report <a href="https://epa.gov/web-policies-and-procedures/plain-writing-act-2021-annual-report">https://epa.gov/web-policies-and-procedures/plain-writing-act-2021-annual-report</a>
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### PFAS contamination in the U.S. (August 18, 2023)







# Mapping the PFAS contamination crisis: New data show 3,186 sites in 50 states, the District of Columbia and two territories

Update: August 18, 2023: The Environmental Protection Agency has released the first round of public water system testing data for the "forever chemicals" known as PFAS, as required by its Fifth Unregulated Contaminant Monitoring Rule, or UCMR 5. The data reveal <u>431 sites</u> have detectable levels of PFAS. The results highlight the sheer scale of the PFAS problem in the U.S. They build on EWG's landmark PFAS contamination map.

### WHY IS THIS MAP IMPORTANT?

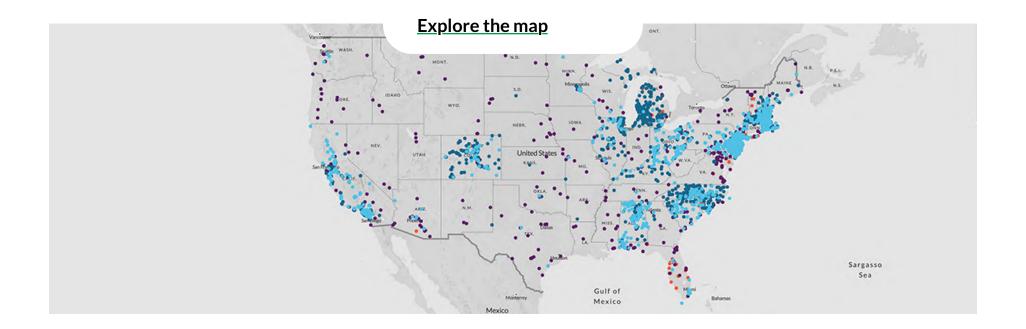
The number of U.S. communities confirmed to be contaminated with the highly toxic fluorinated compounds known as PFAS

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continues to grow at an alarming rate. As of August 2023 and the latest data shows 3,186 locations in 50 states, the District of Columbia and two territories are known to be contaminated.

The latest update of this interactive map shows PFAS pollution in public and private water systems. Details about our sources and methodology are <a href="here">here</a>.

Information about sites newly added to the map comes from various PFAS detections reported to the EPA under UCMR 5, which requires monitoring of public water systems for 29 PFAS between 2023 and 2025. More data will be released on a rolling basis over the next two years.



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#### WHAT IS THE GOVERNMENT DOING?

The Environmental Protection Agency has known about the health hazards of PFAS <u>for decades</u> but has failed to limit PFAS discharges into the air and water or set cleanup standards.

The agency released a <u>woefully inadequate PFAS action plan</u> in 2019, which failed to include deadlines for action, and the EPA has made little progress.

The Department of Defense has been testing for PFAS at military installations but made <u>little to no progress</u> cleaning up any contaminated bases.

President Joe Biden has promised to tackle PFAS contamination by regulating the chemicals in drinking water, designating PFAS as hazardous substances under the federal Superfund law, stopping government purchasing of some products containing PFAS, and funding additional research into the chemicals.

In March 2021, <u>the EPA announced</u> it would regulate two PFAS – PFOA and PFOS, the two most notorious PFAS chemicals – in drinking water. But it could take years before these regulations are final.

The EPA has <u>added 189 PFAS</u> to the Toxics Release Inventory, or TRI, in response to a congressional mandate. A listing in the TRI requires facilities to report releases of those PFAS into the environment. But many manufacturers appear to be <u>taking</u> <u>advantage of a loophole</u> in the TRI that allows them to evade reporting requirements. The EPA has proposed but not finalized a rule to close this and other reporting loopholes.

In October 2021, the EPA released a PFAS Strategic Roadmap, which includes accelerating efforts to set a national drinking water standard for PFOA and PFOS by 2023.

As part of that work, in March 2023 the agency proposed new drinking water contamination limits for six notorious PFAS:

PFOA, PFOS, PFNA, PFHxS, PFBS and GenX.

The limits, known as maximum contaminant levels, or MCLs, are the highest level of a contaminant allowed in drinking water. The MCLs announced are 4 parts per trillion, or ppt, for PFOA and 4 ppt for PFOS. For the other four PFAS, the agency proposes using a "hazard index," a tool for addressing cumulative risks of mixtures of chemicals.

The agency also proposed designating PFOA and PFOS as hazardous substances under the Superfund law <u>in September 2022</u>. Some public water systems will have to continue monitoring for PFAS, as required by the UCMR 5. The EPA is expected to release more data from these systems in 2024 and 2025.

<u>Congress has introduced dozens of bills</u> to monitor the scope of PFAS contamination, ban non-essential uses of PFAS, address ongoing PFAS contamination, and clean up legacy PFAS pollution.

A number of <u>states</u> are also taking steps to address PFAS pollution by banning some uses of the substances and setting cleanup standards.

\_

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### **Get Your FREE Copy of EWG's Guide To Avoiding PFAS Chemicals**

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#### About the Map

For all water systems with a detection of PFOS, PFOA or another PFAS, a maximum concentration for each PFAS and a maximum total PFAS concentration is displayed. The maximum levels listed are from a single point in time and do not reflect whether a water system has changed sources or is treating the water to reduce PFAS levels.

All locations represented on the map are approximate and intended to portray the general area of a contamination site or a community water system. Locations were mapped using the best data available from official records, including data provided by

tests of public drinking water systems, the <u>Unregulated Contaminant Monitoring Rule</u>, the <u>Safe Drinking Water Information</u>
<u>System</u>, the Department of Defense report "<u>Addressing Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)</u>," among others.

Levels listed are for the range of the total of all PFAS detected at the time of the tests and do not reflect whether a water system is treating the water to reduce levels.

Data on contaminated water system, industrial and military sites was current as of August 2023.

Disclaimer: EWG has worked to ensure the accuracy of the information provided in this map. The map is dynamic. This contaminant site, results, suspected sources and other information in the database may change based on evolving science, new information or other factors. Please be advised that this information frequently relies on data obtained from many sources, and accordingly, EWG cannot guarantee the accuracy of the information provided or any analysis based thereon.



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HEALTH

# Environmental group tests to find the best water filters for removing PFAS



BY STEPHANIE STAHL
JULY 11, 2023 / 5:51 PM / CBS PHILADELPHIA



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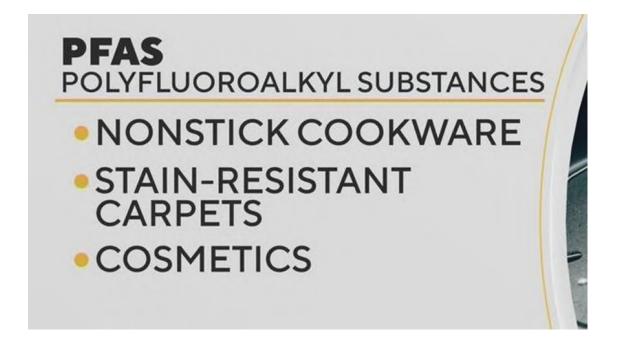
PHILADELPHIA (CBS) -- Water filters have become more popular following studies that show nearly half of the country's <u>tap water</u> could be contaminated with potentially toxic compounds. But which are the best water filters?

There are different ways to filter your water at home, according to a recent study focused on specialized pitchers that are designed to block <u>PFAS</u>, also known as <u>forever chemicals</u>.

The Environmental Working Group tested 10 water pitchers and found some of the most well-known are "not" effective at fully filtering out PFAS.

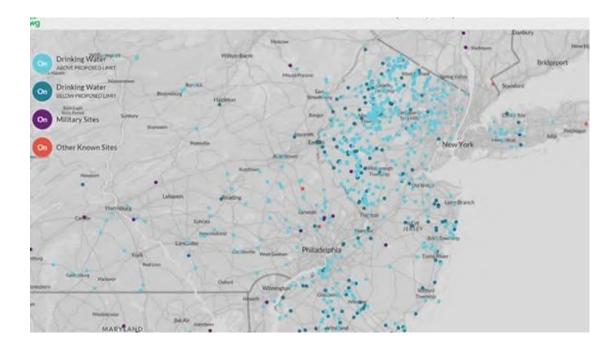
## ALSO SEE: West Deptford chemical manufacturing company agrees to \$392.7M settlement for PFAS pollution

The so-called forever chemicals -- used in products like nonstick cookware, stain-resistant carpets and cosmetics -- have been linked to an increased risk for a number of health problems, including certain cancers, high cholesterol and pregnancy complications.



"We've since discovered that all these PFAS are immune suppressants, so they suppress your immune system and that means any opportunistic disease, including some types of cancer, could take over," said Graham Peaslee, who is a biochemist.

PFAS have also been found in drinking water. A map from the Environmental Working Group shows contamination in the Phila region, as well as north into New York.



Now, there's growing interest in water filtration systems.

# ALSO SEE: Pennsylvania sets limit on "forever chemicals" in drinking water

The <u>Environmental Working Group testing</u> showed three of the filters tested stood above the rest.

"They actually reduced PFAS down to non-detectable levels, which is really great," said Sydney Evans, with the Environmental Working Group.

In the study, pitchers from "Clearly Filtered" and "Zero Water" blocked 100% of PFAS tested. So did the standing travel Berkey filter system.





The Epic Pure pitcher was close, blocking 98% of PFAS.

However, for them to work properly, filters need to be changed, which can be costly.

The travel Berkey sells for \$327, but the filter lasts eight years.

The other recommended pitchers have a lower up-front price but changing the filters can cost hundreds of dollars a year.

For a full year's use, Epic has the lowest price.

ALSO SEE: Toxic "forever chemicals" found in U.S. farmland soil

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#### DECLARATION OF SUSAN SPAAR

My name is Susan Spaar. I declare under penalty of perjury that the proceeding statements are true and correct, and based on my personal knowledge and documents collected as the records custodian for Transglobal Management, LLC. I have written this declaration to support the complaint to which it is attached, filed against the Environmental Protection Agency ("Complaint").

- I am a manager at Transglobal Management, the General Partner for New Millennium Concepts, and sometimes act as Jim Shepherd's agent on business concerning New Millennium Concepts, Ltd. ("NMCL"), which has sold Berkey water filters with a license issued by the JBS Trust for many years. This declaration uses "Berkey" to jointly refer to NMCL and Berkey Int'l.
- 2. In late April of 2022, the EPA stopped an inbound NMCL container at customs in Denver to conduct an EPA inspection. NMCL's shipping agent set up a phone call with EPA Region 8 Inspector Christine Tokarz to resolve the issue. On May 1, 2022, Tokarz confirmed the upcoming call by email, writing to me and others, "This is a virtual compliance call to discuss devices and compliance with FIFRA regulations." She also included links to EPA Guidance for pesticide devices. A true copy of this email thread is attached to the Complaint as Ex. B-1.
- 3. On or about May 3, 2022, I participated in a phone call with EPA Region 8 Inspector Christine Tokarz on Jim Shepherd's behalf. Tokarz mentioned that Berkey products may be in violation of 7 U.S.C. § 136j(a)(1)(F) for distributing a device that is misbranded for allegedly "potentially false or misleading pesticidal claims." Tokarz also stated that, after reviewing NMCL's website and packaging, she stated, "I can assure you though, these are pesticide device claims, I have no doubt about that in my mind". Lastly, Tokarz concluded the call by saying "My goal here is to help American companies stay in business and get them into compliance, not to enforce a bunch of, you know, record keeping rules. That's not really my goal". A recording of the conversation is available to the Court and all parties. As the custodian of these records, I am familiar with the manner in which they are created and maintained by virtue of my duties and responsibilities with NMCL.
- 4. I am the custodian of records for NMCL concerning this dispute, which includes emails and collection of communications and relevant documents, emails sent to me from NMCL agents, various people who are identified on these records, and documents concerning these meetings, of which I have personal knowledge by observing the document in question or receiving it from the apparent author.
- The records were made at or near the time of each act or event set forth in the record, which I created for my own records and for the benefit of NMCL management, or any other interested persons with whom NMCL is working.

- 7. Attached are 279 pages of records, which are exact duplicates of the records that I received, and are labeled and titled as follows:
  - B-1: Tokarz Email Thread (May 1, 2022)
  - B-2: Tokarz EPA Close Out Letter (May 5, 2022)
  - B-3: Texado Establishment Number, 30-Day Report Email Thread (May 2022)
  - B-4: SSURO to James Enterprises, FIFRA-08-2023-0011 (December 27, 2022)
  - B-5: Tokarz Email Seeking Documents (December 2, 2022)
  - B-6: SSURO to Vendor B (FIFRA-04-2023-0700 (February 3, 2023)
  - B-7: SSURO to Fritz Wellness, FIFRA-08-2023-0015 (February 27, 2023)
  - B-8: SSURO to Eden Valley Farms LLC, FIFRA-08-2023-0014 (March 6, 2023)
  - B-9: SSURO to Mountain Mama Natural Foods, Inc., FIFRA-08-2023-0017 (March 7, 2023)
  - B-10: SSURO to Good Earth Natural Foods Co., FIFRA-08-2023-0037 (May 2, 2023)
  - B-11: SSURO to Berkey Int'l, FIFRA-08-2023-0038 (May 8, 2023)
  - B-12: EPA Order to Amazon and eBay, including Updated List
  - B-13: Rejected Packaging, including Lake Image
  - B-14: Communications Regarding Damage to Reputation
  - B-15: Amazon Counterfeit Documentation
  - B-16: Counterfeit Examples
  - B-17: Big Berkey Amazon sales decrease from SSUROs
  - B-18: Reputation damage example in global marketplace from wrongful EPA actions
  - B-19: Berkey Statement Regarding Berkey Water Filter Lawsuit
  - B-20: March 6, 2000, Pesticide Registration (PR) Notice 2000 1\*
  - B-21: Pesticide Registration Notice (PR Notice) 2023-01
  - B-22: Best Water Filters for PFAS chemicals CBS Philadelphia
  - B-23: Clerk Cover Sheet
  - B-24: Berkey Int'l SSURO Closed

Executed on July 30, 20:

Susan Spaar

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 3 of 281 Exhibit B-1, pg. 1 of 4.

From: SUSAN sstransworld@startmail.com @Subject: Fwd: Pesticide Device Compliance Call - Imports

Date: May 2, 2022 at 8:48 AM To: JS-TW@startmail.com

S

--- Original message ---

Subject: Pesticide Device Compliance Call - Imports

From: tokarz.christine@epa.gov Date: Sunday, May 1, 2022 11:30 AM

To: SUSAN <<u>sstransworld@startmail.com</u>>, Scooter Ruskamp <<u>scooter.ruskamp@schayer.com</u>>

This is a virtual compliance call to discuss pesticide devices and compliance with FIFRA regulations. Please forward as you see fit.

Product Website: <a href="https://support.berkeywater.com/">https://support.berkeywater.com/</a>

EPA Guidance: https://www.epa.gov/pesticides/pesticide-devices-guide-consumers

Tips for filing FIFRA regulated products in ACE: https://www.cbp.gov/document/publications/ace-tips-filing-

epa-pesticides

Best-

### **Christine Tokarz**

FIFRA Inspector

EPA, Region 8

tokarz.christine@epa.gov

O:303-312-6147

C:518-416-8965

### Microsoft Teams meeting

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### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 4 of 281 Exhibit B-1, pg. 2 of 4.

sip:teams@video.epa.gov

Video Conference ID: 119 578 695 3

Alternate VTC instructions

#### Or call in (audio only)

+1 720-642-6536,,100357603# United States, Denver

Phone Conference ID: 100 357 603#

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Learn More | Meeting options

DEPARTMENT OF HOMELAND SECURITY Generated on 04-27-2022 U.S. Customs and Border Protection Entry and PGA data: 700-15582169 Entry Number 700-15582169 ACE Entry System 01 - Consumption: Free and Dutiable Released Entry Type Entry Status 3307 - DENVER, CO Release Date Port of Entry 04-22-2022 04-22-2022 15:27:54 10 - Vessel (Non-Containerized) File Date MOT Arrival Date 04-09-2022 00:00:00 Bill Number MEDUI7034438 8 - Continuous House Bill Bond Type Firms Code In-Bond Number Importer Consignee 75-278722200 NEW MILLENIUM CONCEPTS NEW MILLENIUM CONCEPTS 1848 NORWOOD PLZ HURST TX 76054-3751 US 1848 NORWOOD PLZ HURST TX 76054-3751 US Line Item Information Line Status PGA Data Une # HTS Code Country Manufacturer Consignee AETIOUS CORPORATION LLP A - 1701, KANAKIA AROHA DATTAPADA R MUMABAI MUMABAI, 400066 IN L1:51 8421990140 IN **NEW MILLENIUM CONCEPTS 1848** Closed **EPA** NORWOOD PLZ STE 100 HURST, TX 76054-3751 US **PGA Data** Line: L1:S1 HTS Code: 8421990140 OI (Cargo Desc): WATER FILTER PTS

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 5 of 281 Exhibit B-1, pg. 3 of 4.

PG01 - Agency Key Indicators			
PGA Line Number	1		
Govt Agency Code	EPA	Program Code	PS1
Processing Code	NA.	Electronic Image Submitted	NA
Confidentiality Indicator	NA	Disclaimed Indicator	A





#### Case 3:24-cv-01106 Document 1-3, Filed 03/06/24 Page 7 of 281



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

1595 Wynkoop Street Denver, CO 80202-1129 Phone 800-227-8917 www.epa.gov/region08

Ref: 8ENF-AT-P; ICIS 3601409839

Ms. Susan Spaar New Millennium Concepts, Ltd 1848 Norwood Plaza Hurst, Texas 76054-3751 sstransworld@startmail.com

Re: Closeout of Federal Insecticide, Fungicide, and Rodenticide Act Investigation

Dear Ms. Spaar:

On May 4, 2022, the U.S. Environmental Protection Agency facilitated a virtual compliance call with representatives of Charles M. Schayer & Company brokerage and New Millennium Concepts, Ltd of Hurst, Texas. The purpose of this call was to discuss a shipment of Berkey Water Filter parts in the shipment with entry number 700-15582169. It was determined that these products in and of themselves were not FIFRA regulated and this shipment was released.

However, as part of this compliance investigation, information was discovered on your company's website (https://www.berkeyfilters.com/) related to the distribution of your company's water filter systems and claims regarding disinfection. Based on this information, it appears that you are marketing a pesticide device. You are advised to ensure your activities are compliant with FIFRA, 7 U.S.C. §§ 136 to 136y, and its implementing regulations, 40 C.F.R. parts 150-180, which together are the federal laws governing the production, sale, distribution, and use of pesticides in the United States.

#### Applicable Law

Under FIFRA section 7, all pesticide devices sold or distributed in the United States must be produced in a registered establishment. 7 U.S.C. §§ 136e(a), 136j(a)(2)(L). A pesticide device is defined as any instrument or contrivance that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life. 7 U.S.C. § 136(h). An establishment is any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale. 7 U.S.C. § 136(dd).

"To distribute or sell" is defined by FIFRA in section 2, to mean to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. 7 U.S.C. § 136(gg). In FIFRA section 2, the term "produce" is defined to mean to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. 7 U.S.C. § 136(w). Under FIFRA section 2(q)(1)(D) a device is considered misbranded and subject to enforcement action if the label fails to bear the establishment number of the establishment where it was produced. 7 U.S.C. § 136(q)(1)(D). It is a violation of FIFRA section 12(a)(1)(F), 7 U.S.C. § 136j (a)(1)(F), to distribute a device that is misbranded.

A device is considered intended for a pesticidal purpose, and thus must be produced in a registered establishment under several circumstances including when the person who distributes or sells the substance claims, states, or implies, by labeling or otherwise, that the substance can or should be used as a pesticide, 40 C.F.R. § 152.15(a), or when the person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose. 40 C.F.R. § 152.15(c).

#### Compliance Advisory

Production of a pesticide device in an establishment that has not been registered with the EPA is a violation of section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L). The following is a partial list of potential false or misleading pesticidal claims found on your website:

- "To be classified as a water purifier, a water treatment device must remove at least 99.9999% of pathogenic bacteria, reduce viruses by 99.99%, and reduce parasites and cysts by 99.9%." (https://www.berkeywater.com/exceeding-the-standard-for-water-purification/)
- "Berkey® Systems equipped with Black Berkey® Purification Elements remove up to 99.999% of viruses and 99.9999% of pathogenic bacteria, while also removing or dramatically reducing protozoa, trihalomethanes, inorganic minerals, heavy metals, pharmaceuticals, pesticides, VOCs, petroleum products, perfluorinated chemicals, rust, silt, sediment and even radiologicals." (https://www.berkeywater.com/travel-berkey-system-1-5-gal/)

New Millennium Concepts, Ltd may be in violation of FIFRA section 12(a)(1)(F), 7 U.S.C. § 136j(a)(1)(F), for distributing a device that is misbranded.

Nothing in this letter shall limit or preclude EPA from assessing penalties or taking any other action authorized under FIFRA. The EPA reserves the right to bring an action against New Millennium Concepts, Ltd assessing or seeking penalties or other relief for any FIFRA violations.

The EPA has agreed to notify small businesses of their rights pursuant to the Small Business Regulatory Enforcement Fairness Act, https://www.epa.gov/enforcement/small-businesses-and-enforcement. Please note that SBREFA neither eliminates your responsibility to comply with FIFRA nor creates any new rights or defenses under law.

If you have any questions concerning this advisory letter, please contact Christine Tokarz at (303) 312-6147 or by email at tokarz.christine@epa.gov. Thank you for your prompt attention to this matter.

Sincerely,

CHRISTINE TOKARZ Digitally signed by CHRISTINE

Date: 2022.05.04 15:36:22 -06'00'

Christine Tokarz, FIFRA Inspector Toxics and Pesticides Enforcement Section Enforcement and Compliance Assurance Division

cc: James Shepherd, New Millennium Concepts, Ltd., jshep@berkeywater.com

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 9 of 281

Scooter Ruskamp, Charles M. Schayer & Company, <a href="mailto:scooter.ruskamp@schayer.com">scooter.ruskamp@schayer.com</a>
Warren Norrad, Norred Law, PLLC, <a href="mailto:wnorred@norredlaw.com">wnorred@norredlaw.com</a>
Ruben Deleon, Deleon Law Group, <a href="mailto:rdeleon@deleonlawgroup.com">rdeleon@deleonlawgroup.com</a>

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 10 of 281 Exhibit B-3, pg. 1 of 5.

From: Brian Hogan brianhogan330@gmail.com

Subject: Re: 8ENF-AT-P; ICIS 3601409839

Date: June 8, 2022 at 9:40 AM

To: Kevin Kutcel kevinkutcel@gmail.com

Cc: Tokarz, Christine tokarz.christine@epa.gov, JIM JS-TW@startmail.com

Just so everyone is aware, the initial report for this EPA Est. No. was filed and accepted by EPA. Please see below.



wnload All Copy of Record

On Wed, Jun 8, 2022 at 11:15 AM <kevinkutcel@gmail.com> wrote:

Ms. Tokarz,

Thank you for the follow-up. KRK Consulting LLC will work closely with New Millenium Concepts, Ltd. to ensure all pesticide device requirements are in compliance and no false and misleading claims are made. We will also be sure to file the initial 30 day report for Texado, Ltd.

Warm Regards,

**Kevin Kutcel** 

KRK Consulting LLC

5807 Churchill Way Medina, OH 44256

440-263-7305

kevinkutcel@gmail.com

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Exhibit B, pg. 8 of 280

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### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 11 of 281 Exhibit B-3, pg. 2 of 5.

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From: Tokarz, Christine < tokarz.christine@epa.gov>

Sent: Wednesday, June 8, 2022 10:45 AM

To: kevinkutcel@gmail.com

Cc: 'JIM' <JS-TW@startmail.com>

Subject: RE: 8ENF-AT-P; ICIS 3601409839

Good Morning Mr. Kutcel,

I appreciate the follow up, but would like to note that simply adding the EPA Establishment number to the pesticide device label does not meet all the FIFRA requirements. Also note that there seems to be quite a few new establishments that are not submitting their Initial 30 day report, rendering them "delinquent".

Please ensure that your clients are in compliance with all the regulations:

https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices

Best-

### **Christine Tokarz**

FIFRA Inspector

EPA, Region 8

tokarz.christine@epa.gov

O:303-312-6147

C:518-416-8965

Tips for FIFRA Imports: https://www.cbp.gov/document/publications/ace-tips-filing-epa-pesticides

File a Tip or Complaint to EPA: <a href="https://echo.epa.gov/report-environmental-violations">https://echo.epa.gov/report-environmental-violations</a>

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From: <a href="mailto:kevinkutcel@gmail.com">kevinkutcel@gmail.com</a>>

Sent: Tuesday, June 7, 2022 3:43 PM

To: Tokarz, Christine < tokarz.christine@epa.gov>

Cc: 'JIM' <JS-TW@startmail.com>

Subject: Re: 8ENF-AT-P; ICIS 3601409839

Ms. Christine Tokarz

US Environmental Protection Agency, Region 8

Toxics and Pesticides Enforcement Section

Re: 8ENF-AT-P; ICIS 3601409839

Dear Ms. Tokarz,

KRK Consulting LLC is the authorized agent for New Millenium Concepts, Ltd. I am writing in response to your letter regarding the closeout of your Federal Insecticide, Fungicide and Rodenticide Act Investigation (Ref: 8ENF-AT-P; ICIS 3601409839). Even though your letter implies that this action is closed out, I wanted to provide an update to your office and inform you that Texado, the Colorado manufacturer and packager for Berkey Products, has obtained an EPA Establishment No. 101921-CO-1 and this number is now being posted on the outside of the box for each Berkey filtration system that they manufacture. I believe that the acquisition of this EPA Est. No. for Texado, Ltd., meets the legal requirements for a distributor of a device and no false and misleading claims are being made on the packaging. Please let me know if you have any questions.

Warm Regards,

#### Exhibit B-3, pg. 4 of 5.

Kevin Kutcel

**KRK Consulting LLC** 

5807 Churchill Way Medina, OH 44256

440-263-7305

kevinkutcel@gmail.com

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Brian

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 15 of 281 Exhibit B-4, pg. 1 of 10.

12/27/2022

7:00am

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Received by EPA Region VIII Hearing Clerk

	_ Hearing Cl
IN THE MATTER OF:	
	) Docket No. FIFRA-08-2023-0011
James Enterprise, Inc.	
DBA Berkey Filters	) FIFRA SECTION 13(a)
, and the second	
1976 Aspen Circle	STOP SALE, USE, or
Pueblo, Colorado 81006	) REMOVAL ORDER
Respondent.	)
	)

#### I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

#### II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
- 5. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), provides that it shall be unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by FIFRA.
- 6. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136j(a)(2)(S), provides that it shall be unlawful for any person to violate any regulation issued under sections 3(a) or 19 of FIFRA.

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 16 of 281 Exhibit B-4, pg. 2 of 10.

- 7. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 8. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."
- 9. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics . . . ." 40 C.F.R. § 152.5(d).
- 10. Section 2(h) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...."
- 11. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 12. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 13. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."
- 14. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:
  - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
  - (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered under the name of, another pesticide;
  - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 17 of 281 Exhibit B-4, pg. 3 of 10.

- (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]
- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]
- 15. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:
  - (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing—
    - (i) the name and address of the producer, registrant, or other person for whom produced;
    - (ii) the name, brand, or trademark under which the pesticide is sold;
    - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
    - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]
- 16. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

#### III. BASIS FOR THE ORDER

- 17. Respondent James Enterprise, Inc., doing business as Berkey Filters, is a corporation organized under the laws of the State of Colorado and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.
- 18. On November 22, 2022, a representative of the EPA inspected Respondent's facility located at 1976 Aspen Circle, Pueblo, Colorado 81006 (the Facility), to determine Respondent's compliance with FIFRA (the Inspection).
- 19. Upon review of the information collected at the Inspection and upon review of Respondent's website, <a href="www.berkeyfilters.com">www.berkeyfilters.com</a>, the EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell unregistered and misbranded pesticides, specifically **Black Berkey**

Filters, Sport Berkey Replacement Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, Berkey Light Water Filters, and Sport Berkey Water Bottles, in violation of FIFRA.

- A. Black Berkey Filters and Products Sold with Black Berkey Filters (Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, and Berkey Light Water Filters)
- 20. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.
- 21. Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters and Berkey Light Water Filters are sold with Berkey Black Filters inserted in the apparatus and will be referenced as "Berkey Black Filter Products".
- 22. Black Berkey Filter labeling includes the following language:

"Black Berkey Purification Elements:

VIRUSES: >99.999%
PATHOGENIC BACTERIA (AND SURROGATES)
>99.999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)".

- 23. The EPA observed that Respondent had **Berkey Black Filter Products** at its Facility being held for distribution or sale, and that it offers them for sale and distribution online through its website, <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>.
- 24. **Berkey Black Filter Products** are available for purchase online at: <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>.
- 25. The EPA observed the following statements regarding **Berkey Black Filter Products** on the site, <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>:
  - a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
  - b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
  - c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
  - d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."

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- e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
- f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction the requirement in order to be classified for pathogenic removal)."
- g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
- h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."
- 26. The EPA observed the following statements regarding **Berkey Black Filter Products** on the site, <a href="https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html">https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html</a>:
  - "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."
- 27. These claims indicate that **Berkey Black Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
- 28. None of the **Berkey Black Filter Products** are registered with the EPA.
- 29. None of the **Berkey Black Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 30. Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides, **Berkey Black Filter Products** in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 31. Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Berkey Black Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).
  - B. Sport Berkey Replacement Filter and Products Sold with Sport Berkey Replacement Filter (Sport Berkey Water Bottles)
- 32. The **Sport Berkey Replacement Filter** product is a water filtration unit that is used in the **Sport Berkey Water Bottles** and may be purchased as part of that product or on its own.

- 33. **Sport Berkey Replacement Filter** products are available to purchase online at https://www.berkeyfilters.com/products/berkey-sport-filter.
- 34. A brochure for the Sport Berkey Filter available at https://cdn.shopify.com/s/files/1/0167/5480/2788/files/The Sport Berkey.pdf?11355, states:

"The media within the filter element removes contaminants by a surface phenomenon known as 'adsorption' which results from the molecular attraction of substances to the surface of the media. As the bottle is pressed, the source water is forced through the filter. The quality and volume of media used, determine the rate of adsorption. The flow rate or time of exposure through the filter has been calculated to yield the greatest volume removal of toxic chemicals caused by pollution from industry and agriculture. This exclusive filter also incorporates proprietary absorbing media that are impregnated into the micro-porous filter for the IONIC absorption of pollutants into the filter such as aluminum, cadmium, chromium, copper, lead, mercury, and other dangerous heavy metals."

- 35. The **Sport Berkey Replacement Filter** website: <a href="https://www.berkeyfilters.com/products/berkey-sport-filter">https://www.berkeyfilters.com/products/berkey-sport-filter</a>, includes the following claims:
  - a. "This is the factory original replacement for the filter in the Sport Berkey Water Bottle and has the same filtration medium as the larger Black Berkey Filter element."
  - b. "The Sport Berkey® Portable Water Filter is the ideal personal protection traveling companion featuring the IONIC ADSORPTION MICRO FILTRATION SYSTEM. The theory behind this innovation is simple. The bottle's filter is designed to remove and/or dramatically reduce a vast array of health-threatening contaminants from questionable sources of water, including remote lakes and streams, stagnant ponds and water supplies in foreign countries where regulations may be sub standard, at best."
  - c. "The Sport Berkey® Portable Water Filter eliminates or reduces: Harmful microscopic pathogens."
- 36. The EPA observed that Respondent had **Sport Berkey Replacement Filter** products at its Facility being held for distribution or sale, and that it offers the product for sale and distribution online through its website <a href="https://www.berkeyfilters.com/products/berkey-sport-filter">https://www.berkeyfilters.com/products/berkey-sport-filter</a>.
- 37. These claims on the **Sport Berkey Replacement Filter** product's labeling indicate that **Sport Berkey Replacement Filter** is a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus a pesticide pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
- 38. The **Sport Berkey Replacement Filter** label does not contain an EPA Registration Number or any other information regarding registration of the **Sport Berkey Replacement Filter** as a pesticide with the EPA.
- 39. The EPA has not registered the **Sport Berkey Replacement Filter**.

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- 40. The **Sport Berkey Replacement Filter** label does not bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced.
- 41. Because of the lack of an EPA establishment registration number on the label, **Sport Berkey Replacement Filter** is misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 42. The **Sport Berkey Water Bottles** are sold with the **Sport Berkey Replacement Filters** inserted in the apparatus.
- 43. Because the **Sport Berkey Water Bottles** are sold with the **Sport Berkey Replacement Filters** inserted in the apparatus, and because the pesticidal claims associated with the **Sport Berkey Replacement Filters** accompany the **Sport Berkey Water Bottles**, the **Sport Berkey Water Bottles** is also a pesticide pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
- 44. The EPA has not registered the **Sport Berkey Water Bottle**.
- 45. The **Sport Berkey Water Bottle** label does not bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced.
- 46. Because of the lack of an EPA establishment registration number on the label, **Sport Berkey Water Bottle** is misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 47. Respondent distributed or sold, and continues to distribute or sell, the following unregistered pesticides, the **Sport Berkey Replacement Filters** and the **Sport Berkey Water Bottle**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 48. The Respondent distributed or sold, and continues to distribute or sell, the following misbranded pesticides, the **Sport Berkey Replacement Filters** and the **Sport Berkey Water Bottles**, in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

#### IV. ORDER

- 49. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all **Berkey Black Filter Products**, **Sport Berkey Replacement Filters**, and **Sport Berkey Water Bottle** units ("**Subject Products**") under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 50. The **Subject Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
- 51. Should Respondent seek an exception to this Order's prohibitions, Respondent may submit a request to EPA, in accordance with the following:

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- a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at <a href="mailto:tokarz.christine@epa.gov">tokarz.christine@epa.gov</a>.
- b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.
- c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
- d) Any movement or removal of any **Subject Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
- 52. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Subject Products** subject to this Order. The accounting must be submitted to Christine Tokarz, at the e-mail address above, and must include the following:
  - a) The complete list of media used in the composition of **Black Berkey Filters** and **Sport Berkey Replacement Filters**.
  - b) An accounting of all existing product inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;
  - c) A list of each shipment of the **Subject Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s); and
  - d) A list of each shipment of **Subject Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
- 53. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Subject Products** in its ownership, custody or control.
- 54. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such

information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

#### V. OTHER MATTERS

- 55. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 56. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 57. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 58. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 59. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 60. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

	DAVID	Digitally signed by DAVID COBB
Date:	By: COBB	Date: 2022.12.22 11:26:00 -07'00'
	David Cobb, Section Supe	ervisor
	Toxics and Pesticides Enf	Forcement Section
	Enforcement and Complia	ance Assurance Division

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 25 of 281 Exhibit B-5, pg. 1 of 2.

From: Todd Emerson todd@berkeyfilters.com

Subject: Inspection

Date: December 2, 2022 at 12:36 PM
To: JS js-tw@startmail.com

TE

**From:** Tokarz, Christine < tokarz.christine@epa.gov>

Sent: Friday, December 2, 2022 10:34 AM

To: Eddy, Ronald M. < reddy@shermanhoward.com>

Cc: Tegtmeier, Richard L. < <a href="mailto:rtegtmeier@shermanhoward.com">rtegtmeier@shermanhoward.com</a>; Kinard, Sherrie

< <u>Kinard.Sherrie@epa.gov</u>> **Subject:** RE: Berkey Filters

EXTERNAL EMAIL WARNING: Do not click links or open UNKNOWN attachments.

Good Morning,

Thank you for your email regarding the inspection follow up document request.

EPA believes that the products listed below may be subject to FIFRA regulations:

Black Berkey Filters, Sport Berkey Replacement Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, the Berkey Light Water Filters, and the Sport Berkey Water Bottle.

Please provide the requested documentation on each of the 9 separate products identified above.

For further information on the types of products that are subject to FIFRA regulations please see the following website, <a href="https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a>.

We look forward to your responses on or before January 6, 2023.

Best-

### **Christine Tokarz**

FIFRA Inspector

EPA, Region 8

tokarz.christine@epa.gov

O:303-312-6147

C:518-416-8965

Tips for FIFRA Imports: https://www.cbp.gov/document/publications/ace-tips-filing-epa-pesticides

File a Tip or Complaint to EPA: https://echo.epa.gov/report-environmental-violations

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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 4 ATLANTA, GEORGIA

IN THE MATTER OF:	)
	) TERMINATION OF
	) STOP SALE, USE OR
	) REMOVAL ORDER
Respondent.	)
	) FIFRA-04-2023-0700
	)

#### TERMINATION OF STOP SALE, USE OR REMOVAL ORDER

- 1. On February 3, 2023, the U.S. Environmental Protection Agency issued a Stop Sale, Use or Removal Order ("SSURO"), FIFRA-04-2023-0700, to the Respondent (hereinafte product), pursuant to Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The SSURO prohibited product from selling and distributing certain water filters and water treatment units which contained a registered pesticide and for which was making pesticidal claims on product labels and on their website that were not properly qualified to meet the requirements of the treated article exemption under 40 C.F.R. § 152.132. Therefore, these products were determined to be unregistered pesticides.
- 2. The unregistered pesticides products subject to the SSURO were listed in Attachment A to the SSURO. Ingredient statements on the pesticide product labels showed that the following products contained the pesticide active ingredient "Metallic Silver 1.05%" or "Silver Carbon 1.05%," including the Clearbrook Water Treatment Units, Woder ADVANCED WD-S-5K-REP, Woder ADVANCED WD-4K, Woder ADVANCED WD-10K, Woder ADVANCED WD-S-8K-REP, Woder HEAVY METAL WD-HM-REP, and Woder ADVANCED WD-HMADV-REP. Additionally, the label of at least one of the Water Treatment Units included the

products that had pesticidal claims indicating that the products were intended for a pesticidal purpose; however, the products were not registered as pesticides with the EPA.

- 3. In response to the SSURO, ceased sale and distribution of the aforementioned unregistered pesticide products, removed pesticidal claims from the labels and labeling and from its website pertaining to these products, and notified its primary customers and distributors of the products that no pesticidal claims should be made for these products as the products are not pesticides or pesticide devices, and are not intended to be used for pesticidal purposes. The notification to one of its customers/distributors also advised that the filter product being sold by to that customer/distributor is a treated article that has been treated with a pesticide to protect the filter from degradation but not to protect the user of any products containing the filter from microbial contamination.
- 4. Based on the actions taken by as noted above to comply with the SSURO and to return to compliance with FIFRA, the EPA hereby terminates the SSURO.
- 5. may distribute, sell and use the products listed in Attachment A to the SSURO, provided that the products are in compliance with FIFRA.
- 6. The issuance of this Termination shall not act as a waiver by the EPA of any enforcement action that may be brought agains for violations of FIFRA in connection with the import of these pesticide devices, as set forth in the SSURO and herein, or for any future enforcement actions or other authority available to the EPA under FIFRA.

7. This Termination is effective upon the date it is signed by the EPA official designated below.

Signing for

KERIEMA NEWMAN Digitally signed by KERIEMA NEWMAN Date: 2023.05.26 14:55:34 -04'00'

Carol L. Kemker
Director
Enforcement and Compliance Assurance Division

### Attachment A

Unregistered pesticides offered for sale on about March 24, 2022, to April 1, 2022)

ID	Brand	Model
1	Berkey	Travel Berkey (1.5 gallons)
2	Berkey	Big Berkey (2.25 gallons)
3	Berkey	Light Berkey (2.4 gallons)
4	Berkey	Royal Berkey (3.25 gallons)
5	Berkey	Imperial Berkey (4.5 gallons)
6	Berkey	Crown Berkey (6 gallons)
7	Berkey	Black Berkey Water Replacement Filter
8		Dual Quick connect cartridge system with 5K Fluoride + Gen III Filter and Direct connect hoses
9		Single Quick Connect Cartridge system with Gen III 8K filter and direct connect hoses
10		Quick Connect Gen. III 8k/ Replacement filter
11		Survival High Performance Water Filter Bottle – 32oz White
12		Survival High Performance Water Filter Bottle - 22oz Blue
13		Survival High Performance Water Filter Bottle - 22oz Yellow
14		Survival High Performance Water Filter Bottle - 24oz Blue
15		Sport High Flow Water Filter Bottle - 32oz White
16		Sport High Flow Water Filter Bottle - 22oz Blue
17		Sport High Flow Water Filter Bottle - 22oz Yellow
18		Sport High Flow Water Filter Bottle - 24oz Blue
19		Replacement Survival Filter for 22oz or 32oz Water Filter Bottle
20		Replacement Survival Filter for 24oz Water Filter Bottle with Straw
21		Replacement Sport Filter for 22oz and 32 oz Water Filter Bottles
22		Replacement Sport Filter for 24oz Water Filter Bottle with Straw
23		Well Water Sink Filter - Triplex Cartridge System
24		Well Water Sink Filter - Duplex Cartridge System
25		Well Water Sink Primary Sink Filter
26		Whole House Water Filter System

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03/06/2023

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Received by EPA Region VIII

Hearing Clerk

7:00am

IN THE MATTER OF:

Docket No. FIFRA-08-2023-0015

Fritz Wellness, Professional Company

DBA Fritz Wellness Center

FIFRA SECTION 13(a)

STOP SALE, USE, or

Longmont, Colorado 80501

Respondent.

Respondent.

### I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

### II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
- 5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 6. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."

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- 7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics . . . ." 40 C.F.R. § 152.5(d).
- 8. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...."
- 9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 10. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."
- 12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:
  - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
  - (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered under the name of, another pesticide;
  - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
  - (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

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- (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]
- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]
- 13. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:
  - (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing
    - (i) the name and address of the producer, registrant, or other person for whom produced;
    - (ii) the name, brand, or trademark under which the pesticide is sold;
    - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
    - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]
- 14. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

#### III. BASIS FOR THE ORDER

- 15. Respondent, Fritz Wellness, Professional Company DBA Fritz Wellness Center, is a limited liability company organized under the laws of the state of Colorado and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.
- 16. On January 12, 2023, a representative of the EPA inspected Respondent's facility located at 1749 Terry Street, Longmont, Colorado 80501 ("Facility"), to determine Respondent's compliance with FIFRA.
- 17. Upon review of the information collected at the inspection and upon review of Respondent's website, <a href="https://www.fritzwellness.com">https://www.fritzwellness.com</a>, the EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell unregistered and misbranded pesticides, specifically Black Berkey Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, in violation of FIFRA.

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- 18. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.
- 19. Berkey Black Filter labeling includes the following language:

"Black Berkey Purification Elements:

VIRUSES: >99.999% PATHOGENIC BACTERIA (AND SURROGATES)

>99.9999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus

(Anthrax Surrogate)".

- 20. Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, and Crown Berkey Water Filters, are sold with Black Berkey Filters inserted in the apparatus and will be referenced as "Black Berkey Filter Products."
- 21. At the Facility, the EPA observed that Respondent had **Black Berkey Filter Products** being held for distribution or sale and being offered for sale.
- 22. The EPA observed the following statements regarding **Black Berkey Filter Products** on the website https://www.fritzwellness.com/water:
  - a. "Berkey water filters offer amazing filtration capabilities at an affordable price, and the best part is that the filters do not remove the important minerals that your body needs. Stop in our office to see the different sizes available and determine which size would best fit your family."
  - b. "Black Berkey® Purification Elements are black filters that sit in the top chamber of a Berkey® System. Simply pour untreated water into the system's top chamber, and the water is purified as gravity pulls it through the Black Berkey® Purification Elements into the bottom chamber where it is easily dispensed through a handy spigot."
  - c. "THE GOLD STANDARD IN WATER PURIFICATION
  - Black Berkey® Purification Elements classified as water purifiers because they reduce or remove up to 99.999999% of pathogenic bacteria and up to 99.999% of viruses, which greatly exceeds the standard."
  - d. "They remove or greatly reduce contaminants like viruses, bacteria, pesticides, PFCs, pharmaceuticals, heavy metals like lead and even radiologicals."
  - e. "Berkey Systems. New Millennium Concepts Ltd. Authorized Dealer."
- 23. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>:
  - a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
  - b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
  - c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters

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- removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
- d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."
- e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
- f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction the requirement in order to be classified for pathogenic removal)."
- g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens." h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."
- 24. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site <a href="https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html">https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html</a>:
  - "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."
- 25. These claims indicate that **Black Berkey Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, are pesticides pursuant to section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- 26. None of the **Black Berkey Filter Products** are registered with the EPA.
- 27. None of the **Black Berkey Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q) of FIFRA, 7 U.S.C. § 136(q).
- 28. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides, **Black Berkey Filter Products**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 29. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Black Berkey Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

#### IV. ORDER

- 30. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all Black Berkey Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters units ("Subject Products") under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 31. The **Subject Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
- 32. Should Respondent seek an exception to this Order's prohibitions, Respondent may request authorization from EPA by submitting a request in accordance with the following:
  - a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at <a href="mailto:tokarz.christine@epa.gov">tokarz.christine@epa.gov</a>.
  - b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.
  - c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
  - d) Any movement or removal of any **Subject Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
- 33. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Subject Products** under its ownership, custody or control. The accounting must be submitted to Christine Tokarz, at the email address above, and must include the following:
  - a) An accounting of all existing **Subject Product** inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes.
  - b) A list of each shipment of the **Subject Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers,

- and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s).
- c) A list of each shipment of **Subject Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
- 34. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Subject Products** in its ownership, custody, or control.
- 35. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

#### V. OTHER MATTERS

- 36. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 37. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 38. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 39. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 40. Violation of this Order may result in the imposition of civil or criminal penalties as prescribed by Section 14 of FIFRA, 7 U.S.C. § 1361.
- 41. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 42. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Date:	DAVID  Digitally signed by DAVID COBB
	By: COBB Date: 2023.03.03 16:48:00 -07'00'
	David Cobb, Section Supervisor
	Toxics and Pesticides Enforcement Section
	Enforcement and Compliance Assurance Division

# Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 39 of 281 Exhibit B-8, pg. 1 of 9.

of 9. 3/6/2023

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Received by EPA Region VIII Hearing Clerk

7:00am

IN THE MATTER OF:	
	Docket No. FIFRA-08-2023-0014
	,
Eden Valley Farms LLC	) FIFRA SECTION 13(a)
-	
1145 North State Street	STOP SALE, USE, or
Orem, Utah 84057	) REMOVAL ORDER
Respondent.	

#### I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

#### II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
- 5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 6. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."
- 7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to

### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 40 of 281 Exhibit B-8, pg. 2 of 9.

- man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics . . . . " 40 C.F.R. § 152.5(d).
- 8. Section 2(h) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...."
- 9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 10. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."
- 12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:
  - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
  - (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered under the name of, another pesticide;
  - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
  - (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
  - (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]

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- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]
- 13. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:
  - (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing—
    - (i) the name and address of the producer, registrant, or other person for whom produced;
    - (ii) the name, brand, or trademark under which the pesticide is sold;
    - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
    - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]
- 14. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

### III. BASIS FOR THE ORDER

- 15. Respondent, Eden Valley Farms LLC, is a limited liability company organized under the laws of the State of Utah and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.
- 16. On January 30, 2023, a representative of the EPA investigated Respondent's website, https://edenvalleyfood.com/.
- 17. Upon review of the information on the website, the EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell unregistered and misbranded pesticides, specifically Black Berkey Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, and Berkey Light Water Filters in violation of FIFRA.
- 18. Upon review of the information on the website, the EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell unregistered pesticide, **Nano Silver Family Sized 16oz (57PPM)** in violation of FIFRA.
  - A. Black Berkey Filters and Products Sold with Black Berkey Filters (Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, and Berkey Light Water Filters)
- 19. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.

20. The Black Berkey Filter labeling includes the following language:

"Black Berkey Purification Elements:

VIRUSES: >99.999%
PATHOGENIC BACTERIA (AND SURROGATES)

>99.999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus

(Anthrax Surrogate)".

- 21. Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters and Berkey Light Water Filters are sold with Black Berkey Filters inserted in the apparatus and will be referenced as "Black Berkey Filter Products".
- 22. The EPA observed the **Black Berkey Filter Products** available for purchase online at: <a href="https://edenvalleyfood.com/water-purification-products/">https://edenvalleyfood.com/water-purification-products/</a>.
- 23. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site, https://edenvalleyfood.com/berkey-water-filter/:
  - a. "The last thing you need to be worrying about during an emergency is whether your bottled water is contaminated with chemicals or bacteria. Berkey Water Filters get rid of all those concerns for you."
  - b. "The Berkey Water filter system is simply the most efficient water filtration system available in the world right now. It is so powerful it is classified as a water purifier rather than a water filter."
  - c. "The filter has micropores through which the water passes, leaving any bacteria, sediment, or harmful chemicals trapped within the filter. The material it is made of has ion exchange and adsorption properties which keep that waste from passing on to your drinking water."
  - d. "Again, Berkey is classified as a water purifier, which means it removes 99.9999999% of pathogenic bacteria and 99.999% of viruses from water. It really doesn't get any cleaner than that."
- 24. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site, <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>:
  - a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
  - b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
  - c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
  - d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."

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- e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
- f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction the requirement in order to be classified for pathogenic removal)."
- g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
- h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."
- 25. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site, <a href="https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html">https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html</a>:
  - "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."
- 26. These claims indicate that **Black Berkey Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
- 27. None of the **Black Berkey Filter Products** are registered with the EPA.
- 28. None of the **Black Berkey Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 29. Based on the above, EPA has reason to believe Respondent distributed or sold, and intends to continue to distribute or sell, the unregistered pesticides, **Black Berkey Filter Products**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 30. Based on the above, EPA has reason to believe Respondent distributed or sold, and intends to continue to distribute or sell, the misbranded pesticides, **Black Berkey Filter Products**, in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

#### B. Nano Silver – Family Sized 16oz (57PPM)

- 31. The EPA observed the **Nano Silver Family Sized 16oz (57PPM)** products available to purchase online at <a href="https://edenvalleyfood.com/product/nano-silver-family-sized-16oz-57ppm/">https://edenvalleyfood.com/product/nano-silver-family-sized-16oz-57ppm/</a>.
- 32. The EPA observed the following statements regarding the **Nano Silver Family Sized 16oz** (57PPM) on the site, https://edenvalleyfood.com/product/nano-silver-family-sized-16oz-57ppm/:

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- a. "Eden Valley Farms Nano Silver is 6X more POWERFUL than any other Nano Silver you'll find. With our proprietary methods of infusing our solution with Silver, this is the most effective Nano Silver you've ever used."
- b. "Our Nano Silver will kill over 600 bacteria, viruses and fungi on contact."
- c. "Kills bacteria and fungi on all kinds of surfaces."
- d. "Use in the Kitchen, Bathroom, or anywhere that needs disinfecting."
- e. "Also for emergency water purification, just use 4-5 drops per quart of water, or 2.5oz per 50 gallons. Let stand for 20 minutes."
- 33. These claims indicate that **Nano Silver Family Sized 16oz (57PPM)** is a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus a pesticide pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
- 34. The Nano Silver Family Sized 16oz (57PPM) label does not contain an EPA Registration Number or any other information regarding registration of the Nano Silver Family Sized 16oz (57PPM) as a pesticide with the EPA.
- 35. The EPA has not registered the Nano Silver Family Sized 16oz (57PPM).
- 36. The Nano Silver Family Sized 16oz (57PPM) label does not bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced.
- 37. Because of the lack of an EPA establishment registration number on the label, **Nano Silver Family Sized 16oz (57PPM)** is misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 38. Based on the above, the EPA has reason to believe Respondent distributed or sold, and intends to continue to distribute or sell, the unregistered pesticide, **Nano Silver Family Sized 16oz** (57PPM), in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

#### IV. ORDER

- 39. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all **Black Berkey Filter Products**, and **Nano Silver Family Sized 16oz (57PPM)** products (**Subject Products**) under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 40. The **Subject Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
- 41. Should Respondent seek an exception to this Order's prohibitions, Respondent may request authorization from EPA by submitting a request in accordance with the following:
  - a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at <a href="mailto:tokarz.christine@epa.gov">tokarz.christine@epa.gov</a>.

## Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 45 of 281 Exhibit B-8, pg. 7 of 9.

- b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.
- c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
- d) Any movement or removal of any **Subject Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
- 42. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Subject Products** under Respondent's ownership, custody or control. The accounting must be submitted to Christine Tokarz, at the e-mail address above, and must include the following:
  - a) An accounting of all existing **Subject Product** inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;
  - b) A list of each shipment of the **Subject Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s); and
  - c) A list of each shipment of **Subject Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
- 43. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Subject Products** in its ownership, custody or control.
- 44. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

#### V. OTHER MATTERS

- 45. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 46. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 47. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 48. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 49. Violation of this Order may result in the imposition of civil or criminal penalties as prescribed by Section 14 of FIFRA, 7 U.S.C. § 136l.
- 50. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 51. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

Exhibit B-8, pg. 9 of 9.

### **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8**

Digitally signed

		DAVID	Digitally signed
Date:			by DAVID COBB
		COBB	Date: 2023.03.03
	By:	CODD	16:44:01 -07'00'
		David Cobb, Sect	tion Supervisor
		Toxics and Pestic	eides Enforcement Section
		Enforcement and	Compliance Assurance Division

3/7/2023

11:51 AM

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Received by EPA Region VIII Hearing Clerk

IN THE MATTER OF:	)
	) Docket No. FIFRA-08-2023-0017
Mountain Mama Natural Foods, Inc.	)
	) FIFRA SECTION 13(a)
	)
1625 West Uintah Suite A	) STOP SALE, USE, or
Colorado Springs, Colorado 80904	) REMOVAL ORDER
	)
Respondent.	)
	)
	)

#### I. <u>AUTHORITY</u>

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

### II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
- 5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 6. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."

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- 7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics . . . ." 40 C.F.R. § 152.5(d).
- 8. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...."
- 9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 10. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."
- 12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:
  - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
  - (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered under the name of, another pesticide;
  - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
  - (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

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- (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; or
- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment.
- 13. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if
  - (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing
    - (i) the name and address of the producer, registrant, or other person for whom produced;
    - (ii) the name, brand, or trademark under which the pesticide is sold;
    - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
    - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]
- 14. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

#### III. BASIS FOR THE ORDER

- 15. Respondent Mountain Mama Natural Foods, Inc. is a corporation organized under the laws of the state of Colorado and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.
- 16. On January 10, 2023, a representative of the EPA inspected Respondent's facility located at 1625 West Uintah Suite A, Colorado Springs, Colorado 80904 ("Facility"), to determine Respondent's compliance with FIFRA.
- 17. Upon review of the information collected at the inspection, the EPA has reason to believe Respondent distributed or sold and continues to distribute or sell unregistered and misbranded pesticides, specifically **Black Berkey Filters** and **Big Berkey Water Filters** in violation of FIFRA.
- 18. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.
- 19. **Berkey Black Filter** labeling includes the following language:

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"Black Berkey Purification Elements:

VIRUSES: >99.999%
PATHOGENIC BACTERIA (AND SURROGATES)
>99.9999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)".

- 20. At the inspection of Respondent's Facility, EPA observed **Big Berkey Water Filters** being sold with **Black Berkey Filters** taped to the top of the box and inserted in the apparatus and **Black Berkey Filters** sold separately. Together the **Big Berkey Water Filters** and the **Black Berkey Filters** will be referenced as "**Berkey Black Filter Products**".
- 21. At the Facility the EPA observed that Respondent had **Black Berkey Filter Products** being held for distribution or sale and being offered for sale.
- 22. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>:
  - a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
  - b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
  - c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
  - d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."
  - e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
  - f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction the requirement in order to be classified for pathogenic removal)."
  - g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
  - h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."
- 23. The EPA observed the following statements regarding **Black Berkey Filter Products** on the site <a href="https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html">https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html</a>:
  - a. "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements."

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- b. "Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."
- 24. These claims indicate that **Black Berkey Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, are pesticides pursuant to section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- 25. None of the **Black Berkey Filter Products** are registered with the EPA.
- 26. None of the **Black Berkey Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 27. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides **Black Berkey Filter Products** in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 28. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Black Berkey Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

#### IV. ORDER

- 29. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all **Black Berkey Filter Products** under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 30. The **Black Berkey Filter Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
- 31. Should Respondent seek an exception to this Order's prohibitions, Respondent may request authorization from EPA by submitting a request in accordance with the following:
  - a) Requests must be made in writing by electronic mail to Sherrie Kinard, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at kinard.sherrie@epa.gov.
  - b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.

- c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
- d) Any movement or removal of any **Black Berkey Filter Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
- 32. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Black Berkey Filter Products** under Respondent's ownership, custody or control. The accounting must be submitted to Sherrie Kinard, at the email address above, and must include the following information:
  - a) an accounting of all existing **Black Berkey Filter Products** inventory at any of respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;
  - b) a list of each shipment of the **Black Berkey Filter Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s); and
  - c) a list of each shipment of **Black Berkey Filter Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
- 33. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Black Berkey Filter Products** in its ownership, custody, or control.
- 34. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

#### V. <u>OTHER MATTERS</u>

- 35. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 36. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 37. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 38. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 39. Violation of this Order may result in the imposition of civil or criminal penalties as prescribed by Section 14 of FIFRA, 7 U.S.C. § 136l.This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 40. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY REGION 8

		DAVID	Digitally signed
			by DAVID COBB
Date:	By:	CORR	Date: 2023.03.03
	•	David Cobb, Secti	oh7\$Qh:34:97'00'
		Toxics and Pestici	des Enforcement Section
		Enforcement and (	Compliance Assurance Division

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5/2/2023

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Received by EPA Region VIII Hearing Clerk

IN THE MATTER OF:	
	) Docket No. FIFRA-08-2023-0037
Good Earth Natural Foods Co.	)
South Dakota	) FIFRA SECTION 13(a)
638 North Main Street	STOP SALE, USE, or
Spearfish, South Dakota 57783	) REMOVAL ORDER
Respondent.	)
	)

#### I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

#### II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
- 5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 6. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."
- 7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism,

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- except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs ... and cosmetics . . . . " 40 C.F.R. § 152.5(d).
- 8. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...."
- 9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 10. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."
- 12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if
  - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
  - (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered under the name of, another pesticide;
  - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
  - (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
  - (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]
  - (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]

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- 13. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:
  - (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing
    - (i) the name and address of the producer, registrant, or other person for whom produced;
    - (ii) the name, brand, or trademark under which the pesticide is sold;
  - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
  - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]
- 14. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

#### III. BASIS FOR THE ORDER

- 15. Respondent, Good Earth Natural Food Co. *South Dakota*, is a limited liability company organized under the laws of the state of South Dakota and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.
- 16. On February 1, 2023, a state representative of the South Dakota Department of Agriculture and Natural Resources (SDDANR) inspected Respondent's facility located at 638 North Main Street, Spearfish, South Dakota 57783, to determine Respondent's compliance with FIFRA.
- 17. Upon review of the information collected at the inspection, the EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, unregistered and misbranded pesticides, specifically Black Berkey Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, and Crown Berkey Water Filters, in violation of FIFRA.
- 18. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.
- 19. Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, and Crown Berkey Water Filters, are sold with Berkey Black Filters inserted in the apparatus and will be referenced as "Berkey Black Filter Products."
- 20. **Berkey Black Filter** labeling includes the following language:

"Black Berkey Purification Elements:

VIRUSES: >99.999%

PATHOGENIC BACTERIA (AND SURROGATES)

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- >99.999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)".
- 21. The SDDANR representative observed that Respondent had **Berkey Black Filter Products** at its Facility being held for distribution or sale, and that it offers them for sale and distribution.
- 22. The SDDANR representative observed that the Respondent had the following statements regarding **Berkey Black Filter Products** displayed
- a) "Berkey water filters keep the good minerals your body needs while removing: Pathogenic bacteria Parasites and cysts Chemicals such as chlorine, fluoride & Radon 22 Heavy metals (reduced up to 95%) We sell Berkey Water Filters in our household section"
- b) "Berkey vs. Brita Water Filters Educating yourself about the limits and benefits of each product is essential for beign able to make a well-informed purchase. Berkey wants to help by giving valuable product comparison information to assist you as you look at a variety of filters. Berkey water filters are superior in construction, design and filtering ability, but don't just take our word for it. Let's see how Berkey stacks up against the competition."
- c) "Maximum filtering capacity: The largest Berkey filter system, Crown Berkey, is capable of filtering six gallons of water at a time, while our travel model still is capable of filtering up to one and a half gallons of water at a time which means you will always be able to get a substantial amount of clean, fresh, water to drink no matter where you go."
- d) "Filter Replacement Cost Per Year: A good filtering system keeps costs down by maximizing the life of the filters so you don't have to keep replacing them. Even though Berkey systems have a higher initial cost to purchase the whole systems, you end up saving substantially throughout the life of the filters. A pair of Black Berkey Purification elements will last up to 6000 gallons. With the use of 3 gallons per day, you will be paying 2¢ per gallon over the lifespan.
- e) "Filtering Capabilities: The most important question to consider when shopping for a water filter is what exactly does the filter you are considering remove? At Berkey, we are proud to say that our filters are capable of removing 100% pathogens from regular drinking water. That's right, there were no pathogen found in water filtered by Berkey filter. These filters were rigorously tested by state and EPA laboratories to confirm these results which were phenomenal."
- f) "The Choice is Simple Brita water filter systems have been exceedingly popular for many years, but the numbers don't lie. Brita filters simply lack the quality and filtering capability necessary. Berkey filters are the winner hands down in quality, longevity, long term affordability, and filtering capability."
- 23. The EPA observed the following statements regarding **Berkey Black Filter Products** on the site <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>:
- a) "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
- b) "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
- c) "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a

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- long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
- d) "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."
- e) "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
- "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction the requirement in order to be classified for pathogenic removal)."
- g) "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
- h) "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."
- 24. The EPA observed the following statements regarding **Berkey Black Filter Products** on the site <a href="https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html">https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html</a>:
  - "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."
- 25. These claims indicate that **Berkey Black Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, are pesticides pursuant to section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- 26. None of the **Berkey Black Filter Products** are registered with the EPA.
- 27. None of the **Berkey Black Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q) of FIFRA, 7 U.S.C. § 136(q).
- 28. Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides, **Berkey Black Filter Products**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 29. Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Berkey Black Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

#### IV. ORDER

30. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all Black Berkey Filters, Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water

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Filters, Crown Berkey Water Filters units ("Subject Products") under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.

- 31. The **Subject Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
- 32. Should Respondent seek an exception to this Order's prohibitions, Respondent may submit a request to EPA, in accordance with the following:
- a) Requests must be made in writing by electronic mail to Devin Donaldson, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at <a href="mailto:donaldson.devin@epa.gov">donaldson.devin@epa.gov</a>.
- b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.
- c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
- d) Any movement or removal of any **Subject Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
- 33. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Subject Products** subject to this Order. The accounting must be submitted to Christine Tokarz, at the email address above, and must include the following:
- a) The complete list of media used in the composition of Black Berkey Filters.
- b) An accounting of all existing product inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes.
- c) A list of each shipment of the **Subject Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s).
- d) A list of each shipment of **Subject Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
- 34. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Subject Products** in its ownership, custody, or control.
- 35. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information

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at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

### V. OTHER MATTERS

- 36. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 37. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 38. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 39. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 40. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 41. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

	DAVID	Digitally signed by DAVID COBB
Date:	By: COBB	Date: 2023.04.26
	David Cobb, Section Superv	13:13:16 -06:00
	Toxics and Pesticides Enfor	
	Enforcement and Compliance	ce Assurance Division

4:42 PM

5/8/2023

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY **REGION 8**

Received by **EPA Region VIII** Hearing Clerk

IN THE MATTER OF:	)
	) Docket No. FIFRA-08-2023-0038
Berkey International LLC	)
	) FIFRA SECTION 13(a)
Royal Industrial Park, B-2	)
869 Km 1.5, Barrio Palmas	) STOP SALE, USE, or
Catano, Puerto Rico 00962	) REMOVAL ORDER
	)
PO Box 2206,	)
Orocovis, Puerto Rico 00720	)
	)
Respondent.	

#### I. **AUTHORITY**

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

#### II. **GOVERNING LAW**

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
- 5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 6. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."

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- 7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics . . . ." 40 C.F.R. § 152.5(d).
- 8. Section 2(h) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...."
- 9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 10. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."
- 12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:
  - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
  - (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered under the name of, another pesticide;
  - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
  - (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

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- (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]
- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]
- 13. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:
  - (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing—
    - (i) the name and address of the producer, registrant, or other person for whom produced;
    - (ii) the name, brand, or trademark under which the pesticide is sold;
    - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
    - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]
- 14. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

#### III. BASIS FOR THE ORDER

- 15. Respondent, Berkey International LLC, is a limited liability company organized under the laws of Puerto Rico and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.
- 16. On November 22, 2022, a representative of the EPA inspected the facility of James Enterprise Inc. doing business as Berkey Filters (JEI), located at 1976 Aspen Circle, Pueblo, Colorado 81006, to determine compliance with FIFRA.
- 17. At that November 2022 inspection, the EPA observed **Black Berkey Filters** and products containing **Black Berkey Filters** being held for distribution and sale.

a.

18. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.

- 19. Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters and Crown Berkey Water Filters (Black Berkey Filter Products) are sold with Black Berkey Filters inserted in the apparatus.
- 20. At the November 2022 inspection, EPA Inspectors observed that the **Black Berkey Filter** labeling included the following language:

"Black Berkey Purification Elements:

VIRUSES: >99.999%
PATHOGENIC BACTERIA (AND SURROGATES)
>99.9999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)".

- 21. At the time of the November 2022 inspection, the EPA observed the following statements regarding **Black Berkey Filter Products** on the website, <a href="https://www.berkeyfilters.com/products/black-berkey-filter">https://www.berkeyfilters.com/products/black-berkey-filter</a>:
  - a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
  - b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
  - c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
  - d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."
  - e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
  - f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction the requirement in order to be classified for pathogenic removal)."
  - g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
  - h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."
- 22. At the time of the November 2022 inspection, the EPA observed the following statements regarding **Black Berkey Filter Products** on the website, <a href="https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html">https://berkey-store.com/en/faq/faq-water-filter-black-berkey-water-filter.html</a>:

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"Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."

- 23. These claims indicate that **Black Berkey Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
- 24. None of the **Black Berkey Filter Products** are registered with the EPA.
- 25. None of the **Black Berkey Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).
- 26. As a result of that November 2022 inspection, the EPA issued a Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011, pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), and ordered JEI to immediately cease the sale, use, or removal of all **Berkey Black Filter Products**, **Sport Berkey Replacement Filters**, and **Sport Berkey Water Bottle** units under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of the Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011.
- 27. As part of the investigation related to the Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011, the EPA received information related to the products referenced in the FIFRA Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011.
- 28. EPA has information demonstrating the following:
  - a. Respondent sold or distributed **Big Berkey Water Filters**;
  - b. Respondent sold or distributed Travel Berkey Water Filters;
  - c. Respondent sold or distributed Crown Berkey Water Filters;
  - d. Respondent sold or distributed Imperial Berkey Water Filters;
  - e. Respondent sold or distributed Royal Berkey Water Filters; and
  - f. Respondent sold or distributed Travel Berkey Water Filters:
- 29. Accordingly, EPA has reason to believe that Respondent sold or distributed the following Berkey Black Filter Products: Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, and Crown Berkey Water Filters.
- 30. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides, **Black Berkey Filter Products** in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 31. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Black Berkey Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

#### IV. ORDER

- 32. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all **Black Berkey Filter Products**, under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 33. The **Black Berkey Filter Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
- 34. Should Respondent seek an exception to this Order's prohibitions, Respondent may submit a request to EPA, in accordance with the following:
  - a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at <a href="mailto:tokarz.christine@epa.gov">tokarz.christine@epa.gov</a>.
  - b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.
  - c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
  - d) Any movement or removal of any **Black Berkey Filter Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
- 35. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Black Berkey Filter Products** subject to this Order. The accounting must be submitted to Christine Tokarz, at the e-mail address above, and must include the following:
  - a) The complete list of media used in the composition of Black Berkey Filters.
  - b) An accounting of all existing product inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;
  - c) A list of each shipment of the **Black Berkey Filter Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or

- addresses from which the shipment was shipped and the destination establishment(s); and
- d) A list of each shipment of **Black Berkey Filter Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
- 36. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Black Berkey Filter Products** in its ownership, custody or control.
- 37. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

### V. <u>OTHER MATTERS</u>

- 38. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 39. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 40. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 41. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 42. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 43. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

	DAVID	Digitally signed by DAVID COBB
Date:	By: COBB	Date: 2023.05.04
	David Cobb, Section Su	18.07.03 -00 00 apervisor
	Toxics and Pesticides E	
	Enforcement and Comp	oliance Assurance Division

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION X 1200 6<sup>th</sup> AVENUE, Suite 155 SEATTLE, WASHINGTON 98101

In the Matter of:	) ORDER
-	) SECTION 13(a)
Amazon.com Services LLC,	)
	) FEDERAL INSECTICIDE, FUNGICIDE
	) AND RODENTICIDE ACT
	)
Respondent	) Docket No. FIFRA-10-2020-0102
	)
	)

#### I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order ("Order") is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency (EPA) by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. This authority has been delegated from the EPA Administrator to the Director of the Enforcement and Compliance Assurance Division for EPA Region 10 through the Regional Administrator for EPA Region 10.
- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136a.
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any State to distribute or sell to any person any pesticide which is adulterated or misbranded.
- 5. Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), provides that it shall be unlawful for any person in any State to distribute or sell to any person any device which is misbranded.

In the Matter of: AMAZON.COM SERVICES LLC Docket Number: FIFRA-10-2020-0102 Stop Sale, Use, or Removal Order Page 1 of pg. 70 of 280

- 6. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 7. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a "pesticide," in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." *See also* 40 C.F.R. § 152.15.
- 8. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a "pest" as "any insect, rodent, nematode, fungus, weed, or . . . any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section [25(c)(1) of FIFRA]."
- 9. Section 2(h) of FIFRA, 7 U.S.C. § 136(h) defines a "device" as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals).
- 10. The regulation at 40 C.F.R. § 152.500 provides that devices are subject to the requirements set forth in:
  - (a) FIFRA sec. 2(q)(1) and 40 C.F.R. Part 156, with respect to labeling;
  - (b) FIFRA sec. 7 and 40 C.F.R. Part 167, with respect to establishment registration and reporting;
  - (c) FIFRA sec. 8 and 40 C.F.R. Part 169, with respect to books and records;
  - (d) FIFRA sec. 9, with respect to inspection of establishments;
  - (e) FIFRA sec. 12, 13, and 14, with respect to violations, enforcement activities, and penalties;
  - (f) FIFRA sec. 17, with respect to import and export of devices;
  - (g) FIFRA sec. 25(c)(3), with respect to child-resistant packaging; and
  - (h) FIFRA sec. 25(c)(4), with respect to the Agency's authority to declare devices subject to certain provisions of the Act.
- 11. The regulation at 40 C.F.R. § 152.15 states that "a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if: (a) the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that the substance can or should be used as a pesticide; . . . (b) the substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than use for pesticidal purpose (by itself or in combination with any other substances); . . . or (c) the person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose."

In the Matter of: AMAZON.COM SERVICES LLC Docket Number: FIFRA-10-2020-0102 Stop Sale, Use, or Removal Order Page 2 of pg. 71 of 280

- 12. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." This section also defines "labeling" as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device . . . ."
- 13. Section 2(gg) of FIFRA, 7 U.S.C § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."
- 14. The regulation at 40 C.F.R. § 152.3 further defines "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State."
- 15. The regulation at 40 C.F.R. § 168.22(a) states: "FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to 'offer for sale' any pesticide if it is unregistered, or if claims made for it as part of its distribution of sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access."
- 16. The regulation at 40 C.F.R. § 168.22(b)(4) states: "EPA regards it as unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to place or sponsor advertisements which recommend or suggest the purchase or use of . . . [a]ny unregistered pesticide for any use unless the advertisement is one permitted by 40 C.F.R. § 168.22(b)(2) or (3)."
- 17. Under Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), "A pesticide is misbranded if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular."
- 18. In accordance with 40 C.F.R. § 156.10(a)(5), the following statements or representations in pesticide or device labeling constitute misbranding:
  - (a) A false or misleading statement concerning the composition of the product;
  - (b) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
  - (c) A true statement used in such a way as to give a false or misleading impression to the purchaser;
  - (d) A false or misleading comparison with other pesticides or devices;
  - (e) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless," or "nontoxic to

- humans and pets" with or without such a qualifying phrase as "when used as directed;" and
- (f) Non-numerical and/or comparative statements on the safety of the product, including but not limited to: "Contains all natural ingredients;" "Among the least toxic chemicals known;" or "Pollution approved."
- 19. Under Section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D), a pesticide is misbranded if its label does not bear the registration number assigned under section 7 to each establishment in which it was produced.

### II. BACKGROUND

- 20. Amazon.com Services LLC ("Amazon") is a corporation incorporated in the State of Delaware with its principle place of business located in the State of Washington. Therefore, Amazon is a "person" as defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- 21. This Order refers to Amazon and all its divisions, offices, and branches collectively as "Amazon."
- 22. Amazon is an indirect subsidiary of Amazon.com, Inc. and offers internet-based retail services to businesses and individuals via Amazon.com.
- 23. Amazon acquires and directly distributes products through Amazon.com, hereinafter referred to as "Amazon direct sales."
- 24. In addition to Amazon direct sales, Amazon provides third-party sellers two fee-based options to sell and distribute products via Amazon.com: the "Selling on Amazon Service" and the "Fulfillment by Amazon" (FBA) service.
- 25. For Amazon direct sales, Amazon purchases products in bulk quantities, offers the products for sale on Amazon.com, fulfills the orders and ships the products to customers. The Amazon.com product detail page for products shipped and sold through Amazon direct sales states, "Ships from and sold by Amazon.com."
- 26. The "Selling on Amazon Service" allows third-party sellers to advertise and sell products directly on Amazon.com. Third-party sellers, also known as Marketplace Fulfilled Network (MFN) sellers, participating in the Selling on Amazon Service use Amazon's account management tools, including multi-feature offer templates, to manage product inventory, listing, presentation, and pricing with the benefits of accessing Amazon's hundreds of millions of consumers. The third-party sellers work within Amazon's platform to establish a "detail page" on Amazon.com for each product offered for sale. Third-party sellers fulfill and ship products to customers once an order is placed on Amazon.com. The Amazon.com listing page for products shipped and sold by third-party vendors states, "Ships from and sold by [Amazon.com profile alias of seller]."

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- 27. According to Amazon.com, the "Fulfillment by Amazon" service, "is a service [Amazon] offer[s] sellers that lets them store products in Amazon's fulfillment centers, and [Amazon] directly pack[s], ship[s] and provide[s] customer services for these products." The Amazon.com listing page for products shipped and sold by the FBA service states, "Sold by [Amazon.com profile alias of seller] and Fulfilled by Amazon."
- 28. Amazon Standard Identification Numbers ("ASIN") are unique numbers Amazon assigns to each product sold through the Amazon.com marketplace. Products with the same ASIN are identical (or purportedly identical on Amazon.com) in all material respects.
- 29. All sellers on Amazon are required to assent to terms and conditions laid out in the document titled "Amazon Services Business Solutions Agreement" ("Agreement").
- 30. The Section of the Agreement entitled "Selling on Amazon Service Terms" states, "The Selling on Amazon Service . . . is a Service that allows you to offer certain products and services directly on Amazon Sites."
- 31. The Agreement defines Amazon Sites to include www.Amazon.com.

#### Selling on Amazon Service

- 32. The Agreement contains the following pertinent sections: General Terms, Selling on Amazon Service Terms, Fulfillment by Amazon Service Terms, Amazon Advertising Service Terms and Transaction Processing Service Terms.
- 33. General Terms, Section 3. "Term and Termination" of the Agreement grants Amazon the authority to terminate a third party's use of Amazon's services for convenience, provided Amazon provides advanced notice to the third party.
- 34. General Terms, Section 4. "License" of the Agreement grants Amazon a royalty-free, non-exclusive, worldwide right and license to any and all of a third-party seller's original or derivative intellectual property associated with the third-party seller's products. The Agreement also allows Amazon to sub-license the third-party seller's intellectual property to Amazon's affiliates, as defined in the Agreement.
- 35. General Terms, Section 18. "Miscellaneous" of the Agreement provides that Amazon retains the right to immediately halt any transactions, prevent or restrict a third-party seller's access to any of Amazon's services or take any other action to restrict access to or availability of any inaccurate listing, any inappropriately categorized items, any unlawful items, or any items otherwise prohibited by applicable Program Policies.
- 36. In accordance with Selling on Amazon Service Terms, Section 2.1 "Sale and Fulfillment" of the Agreement, third party sellers must source, offer, sell and fulfill products offered on Amazon.com in accordance with the Agreement as well as terms provided by the third-party seller or Amazon and displayed on the applicable site on Amazon.com.

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- 37. In accordance with Selling on Amazon Service Terms, Section 2.1 "Sale and Fulfillment" of the Agreement, sellers may only cancel transactions in accordance with the terms and conditions appearing on the applicable Amazon.com website as well as the Agreement.
- 38. In accordance with the Agreement, all sellers must assent to Amazon's "Program Policies," which include, but are not limited to:
  - (a) Amazon Seller Code of Conduct
  - (b) ASIN creation policy
  - (c) Category and Product Restrictions
  - (d) Product Detail Page Rules
  - (e) Product Guidelines
- 39. In accordance with the ASIN creation policy and Amazon's "Add a Product" tool, third party sellers seeking to list a product already on Amazon.com are prohibited from requesting a new ASIN or creating a new product detail page and must match to the existing product detail page. Using Amazon's "Add a Product" tool, third party sellers are directed to search Amazon's product "catalog" for existing listings. If the third-party seller's product exists within Amazon's product catalog, the Add a Product tool directs the sellers to enter certain information and select "Sell this Product."
- 40. If the third-party seller's product does not exist within Amazon's product catalog, Amazon's "Add a Product" tool directs the third-party seller to associate the product with Amazon's product categories and enter certain information regarding the product.
- 41. In accordance with the "Product Detail Page Rules" each product listing on Amazon.com must comply with Amazon's listing standards and restrictions, including:
  - (a) All products must be categorized in accordance with categories provided by Amazon;
  - (b) Product images must meet Amazon's image standards;
  - (c) Product detail page titles, descriptions, bullet points, or images cannot contain adverts, promotional material, or watermarks on images, photos, or videos; and
  - (d) Product detail page titles, descriptions, bullet points, or images cannot contain links to other websites for placing orders, or alternative shipping offers, such as free shipping.
- 42. Amazon provides category-specific templates for third-party sellers to use to develop product detail page(s).
- 43. In accordance with Selling on Amazon Service Terms, Section 2.1 "Sale and Fulfillment" of the Agreement, third-party sellers must conform to certain shipping, logistics, and customer service requirements and restrictions, including:
  - (a) Package and label the products in a commercially reasonable manner;
  - (b) Ship each product on or before its expected ship date;
  - (c) Retrieve order information provided by Amazon at least once per business day;
  - (d) Provide to Amazon information regarding fulfillment and order status and tracking, using the process designated by Amazon;

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- (e) Include an order specific packing slip and, if applicable, a tax invoice, within each shipment; and
- (f) Not send customers emails confirming orders or fulfillment of orders.
- 44. Amazon provides third-party sellers with advertising services called "Amazon Advertising." According to the "Amazon Advertising Service Terms" section of the Agreement, the Amazon Advertising services is governed by the Amazon Advertising Agreement.
- 45. In accordance with the Amazon Advertising Agreement, Amazon will make available to third-party sellers a variety of tools and services to place ads on certain websites.
- 46. In accordance with the Amazon Advertising Agreement, third parties participating in the Amazon Advertising service grant Amazon a worldwide, non-exclusive, royalty-free, fully-paid, and sublicensable right and license to use all information provided to Amazon, including the third party's ads, campaign details, fee data, technology, and trademarks, information, photographs, images, and videos.
- 47. The Amazon Advertising services includes the following:
  - (a) Sponsored Products: Ads for individual product listings on Amazon
  - (b) Sponsored Brands: Search result ads that feature product logos, a custom headline, and up to three products;
  - (c) Amazon Stores: Custom multipage webpages on Amazon.com for individual brands;
  - (d) Sponsored Display: Provides ad placements on and off Amazon.com
- 48. The Sponsored Products, Sponsored Brands, and Sponsored Display services are available to "Professional Sellers" for a monthly subscription fee. EPA has reason to believe that all of the third-party sellers associated with the products subject to this Order are or have been "Professional Sellers."
- 49. Amazon advertises sponsored products within the detail pages of products of similar categories. Amazon places these advertisements under the banner entitled "Sponsored products related to this item." These advertisements contain links to other Amazon detail pages, which include offers for sale.
- 50. The purpose of Amazon's advertising services as described in Paragraphs 44 through 49 are to induce the sale of products listed on Amazon.com.
- 51. All persons wishing to register as a third-party seller with Amazon must provide Amazon with the person's credit card information and bank account number and routing number.
- 52. The Selling on Amazon Service Terms, Section S-1.2 "Product Listing; Merchandising; Order Processing" of the Agreement provides that Amazon will, and has the exclusive right to, receive all proceeds from the sale of products on Amazon.com on behalf of third-party sellers for each transaction and will remit sales proceeds to the third-party seller in accordance with the Selling on Amazon Service Terms portion of the Agreement.

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- 53. In accordance with Selling on Amazon Service Terms, Section S-2.2 "Cancellations, Returns, and Refunds" of the Agreement, Amazon may in its sole discretion accept, calculate, and process cancellations, returns, refunds, and adjustments. Amazon may also make payments to customers in the manner Amazon determines. The Agreement requires the third-party seller to reimburse Amazon for all refund payments made to customers.
- 54. In accordance with Selling on Amazon Service Terms, Section S-4 "Compensation" of the Agreement, third-party sellers must pay Amazon several fees, including:
  - (a) Referral Fees, which apply to each product sale and are determined based on the sales proceeds, the product categorization, and Amazon's fee schedule;
  - (b) Variable Closing Fees, which apply to each product sale and are determined based on Amazon's variable closing fee schedule; and
  - (c) Selling on Amazon Subscription Fee.
- 55. In accordance with Selling on Amazon Service Terms, Section S-5 "Remittance of Sales Proceeds & Refunds" of the Agreement, Amazon will remit a seller's available balance on a bi-weekly (14 day) (or more frequent) basis. A seller's available balance is equal to any sales proceeds not previously remitted as of the applicable remittance calculation date (which seller must accept as payment in full for transactions), less the compensation fees described in paragraph 54 and any taxes that Amazon automatically calculates.
- 56. In accordance with the Transaction Process Service Terms within the Agreement:
  - (a) The third-party seller must authorize Amazon or Amazon's affiliates to act as the third-party seller's agent for purposes of processing payments, refunds, and adjustments to each transaction;
  - (b) The third-party seller agrees that buyers satisfy their obligations to the third-party seller when Amazon receives the sales proceeds and that third-party sellers do not have a right or entitlement to collect sales proceeds directly from any customer; and
  - (c) Amazon holds sales proceeds in its own, or its affiliates' own, accounts and may invest these proceeds.

#### Fulfillment by Amazon

- 57. Section F-4 of the Agreement contains Amazon's covenants to provide storage services for participants desiring to sell products using the FBA service. Participants in the FBA service are subject to the conditions and requirements laid out in Paragraphs 32 through 56, above.
- 58. According to Section F-4 of the Agreement, Amazon is not required to segregate product units based on the third-party seller and may commingle product units.
- 59. Section F-5 of the Agreement contains Amazon's covenants as part of the FBA service to ship products from Amazon's warehouses to customers.

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#### III. BASIS FOR THE ORDER

- 60. Since December 1, 2019, EPA has been collecting and reviewing a substantial amount of publicly available information concerning products being distributed or sold on Amazon.com in violation of FIFRA and has discovered multiple offers for sale of pesticides and devices on Amazon.com. EPA's review of the information gathered formed the basis of the factual allegations set forth herein and EPA's reason to believe Amazon has distributed or sold and intends to continue distributing or selling unregistered and misbranded pesticides in violation of FIFRA.
- 61. On multiple occasions between at least December 1, 2019, and the present, pesticides and devices identified in Attachment A to this Order were advertised and offered for sale on Amazon.com. Amazon's actions discussed in section II, above, constitute distributions or sales of the pesticides and devices listed on Amazon.com as the phrase "to distribute or sell" is defined in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg) and 40 C.F.R. § 152.3, and interpreted in 40 C.F.R. § 168.22.
- 62. Therefore, on multiple occasions between at least December 1, 2019, and the present Amazon distributed or sold the pesticides and devices listed in Attachment A.
- 63. The products listed in Attachment A are either pesticides as that term is defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), which must be registered under Section 3 of FIFRA or devices as that term is defined in Section 2(h) of FIFRA, 7 U.S.C. § 136(h), which are subject to the requirements laid out in 40 C.F.R. § 152.500. Attachment A lists the labeling statements for each pesticide or device that indicate the pesticides or devices are intended for preventing, destroying, repelling, or mitigating any pest. The column titled "Violative Product" of Attachment A includes pesticides or devices subject to this order as the terms "pesticide" and "device" are defined by Section 2 of FIFRA, 7 U.S.C. § 136. The columns titled Example Product Name(s) on Amazon.com, Example Third-Party Seller(s), and Example Amazon.com ASIN's of Attachment A provide a non-exhaustive list of identical or materially similar pesticides or devices, irrespective of variations in the product name, ASIN, or third-party seller as this information appears on Amazon.com.
- 64. At no time relevant to this Order were the pesticides or devices listed in Attachment A registered with EPA under Section 3 of FIFRA, 7 U.S.C. § 136a.
- 65. Many of the pesticides or devices listed in Attachment A are misbranded under Section 2(q) of FIFRA. Each misbranded product contains one or more false or misleading statements, which are listed in Attachment A. See Section 2(q)(1)(A) and 2(q)(1)(D) of FIFRA, 7 U.S.C. §§ 136(q)(1)(A) and (D).
- 66. Therefore, EPA has reason to believe that on multiple occasions between at least December 1, 2019 and the present, Amazon distributed and sold the unregistered and misbranded pesticides and devices listed in Attachment A in violation of Sections 12(a)(1)(A), 12(a)(1)(E) and 12(a)(1)(F) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A), (E) and (F).

In the Matter of: AMAZON.COM SERVICES LLC Docket Number: FIFRA-10-2020-0102 Stop Sale, Use, or Removal Order Page of 199. 78 of 280 67. EPA also has reason to believe that Amazon intends to further distribute or sell, the unregistered and misbranded pesticides and devices listed in Attachment A.

#### IV. ORDER

- 68. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Amazon to **immediately cease** the sale, use, or removal of the unregistered and misbranded pesticides and devices listed in Attachment A (collectively "Violative Products") under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 69. This Order extends to all quantities of the Violative Products intended for sale, distribution and/or any stocks returned to Amazon from its sellers, customers, or other end-users. This Order also extends to all versions of the Violative Products irrespective of a change in product name as it appears on Amazon.com, the identity of the third-party seller, or ASIN.
- 70. The Violative Products shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, or offered for delivery.
- 71. Amazon may move or remove any Violative Products from any facility or establishment ONLY after obtaining prior written approval from EPA, in accordance with the following:
  - (a) Movement or removal requests must be made in writing addressed to Chad Schulze, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, 1200 Sixth Avenue, Suite 155, Mail Stop 20-C04, Seattle, Washington 98101, or at Schulze.chad@epa.gov;
  - (b) Any request for movement or removal must include a written accounting of the products to be moved, the address of the facility from which the products will be moved from, the address of the destination facility, and a description of the reasons for the movement or removal;
  - (c) If the movement or removal is for the purposes of disposal, Amazon must provide written proof of disposal to EPA and the disposal must comply with all applicable federal, state, and local laws; and
  - (d) Any movement or removal of any Violative Products made without prior written authorization from EPA in accordance with this Paragraph constitutes a violation of this Order and distribution and sale of illegal pesticides in violation of FIFRA.
- 72. Within 30 days of receipt of this Order, Amazon must submit to EPA a written accounting of the Violative Products subject to this Order. The accounting must be submitted to Chad Schulze, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, 1200 Sixth Avenue, Suite 155, Mail Stop 20-C04, Seattle, Washington 98101, or at Schulze.chad@epa.gov, and must include an accounting of all existing product inventory, including the locations(s) where the products are held, quantities, and container sizes. Amazon must provide EPA with an updated accounting at least every 30 days until 150 days following receipt of this order or when Amazon no longer has any Violative Products in its ownership, custody or control, whichever occurs earlier.

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- 73. The information requested in Paragraphs 71 and 72 must be provided whether or not Amazon regards part or all of it as a trade secret or confidential business information. Amazon is entitled to assert a claim of business confidentiality covering all or any required information, in the manner described at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. Part 2, Subpart B. Unless Amazon makes a claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Amazon.
- 74. Amazon may seek federal judicial review of this Order pursuant to Section 16 of FIFRA, 7 U.S.C. § 136n. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 75. This Order shall be effective immediately upon receipt by Amazon or any agents of Amazon.
- 76. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 77. If any provision or provisions of this Order is/are subsequently held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.
- 78. EPA may amend this Order and Attachment A at any time to include additional pesticides or devices that EPA has a reason to believe Amazon is distributing or selling, or intends to distribute or sell, in violation of FIFRA.

#### V. OTHER MATTERS

Lauris C. Davies, Acting Director

Enforcement and Compliance Assurance Division

79.	For any additional information about this Order, please contact Chad Schulze, Pesticide
	Enforcement Coordinator, at 206-553-0505. For any legal matters concerning this Order,
	including questions from legal counsel, please contact Brett Dugan, Assistant Regional
	Counsel, at 206-553-8562.

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Date

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Violative Product	Example Product Name on Amazon.com	Example Seller Name/ Shipping Service	Example Amazon.com ASIN	Pesticidal Claims on Product Labeling*  Misbranding and/or False and Misleading Claims on Product Labeling*
Repellents - Any unregistered or misbranded defense spray used to deter vertebrate pests.	Advanced Tech – Police Magnum OC-17	Studio SOLO (FBS)	B07PSC9PKV	a) Pepper Spray is great for defending yourself against not just human attackers, but wild animals as well Especially effective againstvicious animals and more.
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer spray used to kill or inactivate microorganisms (bacteria or viruses) on inanimate objects.	PlaneAire Travel Mist  Fails to meet Minimum Risk Pesticide Exemption as follows: makes public health claim, does not list ingredients.  Otherwise unregistered.	EverywhereAire (FBS)	B07QMHMV87	<ul> <li>a) Kills 99.99% of harmful bacteria</li> <li>b) PlaneAire is laboratory tested to kill 99.99% of harmful bacteria including MRSA</li> <li>c) Eliminates Surface Bacteria &amp; Purifies the Air Naturally</li> <li>d) The six oils were carefully selected for their powerful antibacterial, antiviral, antimicrobial and antifungal properties</li> <li>a) Kills 99.99% of harmful bacteria</li> <li>b) Ingredients are biodegradable and have no harmful impact on the environment</li> <li>c) Although PlaneAire® is not intended to be used as a hand sanitizer, its all- natural, organic ingredients make it safe to do so</li> <li>d) SAFE AND NON-TOXIC</li> </ul>
	Antibacterial Yoga Mat Spray, Energizing Scent, by Diva Stuff (Energizing)	Diva Stuff (FBS)	B00YKP2W5M	<ul> <li>a) Antibacterial Yoga Mat Spray</li> <li>b) Great For Beach Chairs, Gym Equipment and More</li> <li>c) Diva Stuff is introducing a new line of antibacterial yoga mat sprays</li> <li>d) Antibacterial Formula</li> </ul>
	Portable Mini Disinfectant Spray	Messgod (Coron avirus Protection Clear ance Sale) (FBS)	B086DRVXKG	<ul> <li>a) Alcohol free disinfectant - 99.99% clean with 24-hour protection.</li> <li>b) Antibacterial disinfection</li> <li>c) Disinfectant spray</li> <li>d) Effectively inactive bacterial viruses</li> <li>e) The sterilization rate can reach 99.99%</li> <li>a) 2020 Coronavirus Protection Clearance Sale</li> <li>Coronavirus Protection Clearance Sale</li> </ul>
	Edens Garden Cleaning Essential Oil Synergy Blend	Edens Garden (FBS)	B071XPKF2D	<ul> <li>a) Sanitizes and disinfects</li> <li>b)this synergy blend functions as an antiviral, antibacterial, antifungal and antiseptic remedy. This all-natural concoction can be applied to counters,</li> </ul>

In the Matter of: AMAZON.COM SERVICES, LLC

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## Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 Attachment A

	Fails to meet Minimum Risk Pesticide Exemption as follows: ingredients ineligible for exemption, does not list active ingredient by weight percentage, lack of company contact information.  Otherwise unregistered. TOTAMALA 20ML Alcohol-Free Bacteriostatic Portable Mini All in One Disinfectant Spray	TOTAMALA (FBS)	B085H77TP5	a) alcohol free disinfectant - kills 99.99% bacteria with 24-hour protection b) Suitable for a variety of appliances c) Inhibit harmful substances d) 1x Disinfectant Spray  a) 24-hour protection with just one application b) Surface throughout useing (sic) to protecting your from harmful bacteria
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer wipe used to kill or inactivate microorganisms (bacteria and viruses) on inanimate objects.	Ainany Cleaning Water Wipes for Hand Suitable for Household Travel Protection - 10 Pads/Pack	Ainany (FBS)	B086HF5CT8	a) Disinfectant wet wipes b) Sterilizing Rate 99.9% Use for wiping door handles, doors, elevator buttons and other public place items, and disinfect children's toys  a) Sterilizing Rate 99.9% b) Help keep your family and those you care for healthy
	2 PACK Disinfecting Wipes for Hands, Cleaning Wipes, Antibacterial Wipes, Sanitizing Wipe	OWLHWEH (FBS)	B086173KRW	a) 100 percent bacteria freedisinfecting wipes for a bleach-free, all-in-one cleaning alternative b) Bacteriostasis Wet Towel c) New easy to pull flip top pack allows for the easiest way to clean and disinfect  a) Safe for use on hard, non-porous surfaces, everyday including food preparation areas, baby equipment, furniture, fridges, taps, sinks, door knobs, kitchen and bathroom surfaces floor cleaning, children's surfaces and electronics

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## Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 Attachment A

	20piter 6 Pack Disinfectant Wipes, 75% Alcohol Cleaning Wet Wipes(1 Pack,10 Wipes), Daily Disinfecting Use for Hand Home House Travel Office Electronics School All Purpose	20piter (FBS)	B086DRXYF4	a) b) c)	75% alcohol efficient sterilization (includes images of red lines through four types of bacteria: Candida albicans, E.coli, Staphylococcus aureus, Pseudomonas aeruginosa) 99.99% sterilization Daily Disinfecting Use for Hand Home House Travel Office Electronics School All Purpose	a) b)	You can received (sic) 60/100 pieces cleaning wipes, meeting your daily use to keep safe and clean Safe for all people using
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer tablets used to kill or inactivate microorganisms (bacteria and viruses) on inanimate objects or in water.	Epidemic prevention Chlorinating Tablets Disinfectant Chlorine Tablets Swimming Pool Instant Disinfection Tablets Chlorine Dioxide Effervescent Tablet Chlorine Disinfectant 100g Cozy apposite Fun	mingzuo (FBS)	B084RMYPTG	a) b) c)	Function: Deep cleaning, sterilization, epidemic prevention, deodorization, bleaching Product name: Sanitizer and disinfectant Disinfectant Chlorine Tablets	a) b)	Family disinfection in addition to the mold Chlorine Disinfectant 100g Cozy apposite (sic) Fun
water.	KOVIPGU 100Pcs Chlorine Dioxide Disinfectant Cleaning 84 Instant Effervescent Tablets	KOVIPGU (FBS)	B08625RDR8	a) d)	Function: Deep cleaning, sterilization, deodorization, mildew, bleaching Can be used for regular disinfection of the living room, kitchen, bathroom, bed linen and other clothes and furniture surface disinfection	<ul><li>a)</li><li>b)</li><li>c)</li></ul>	Efficient disinfection to prevent the spread of disease Use chlorine dioxide as the main active ingredient, safe and nonirritating 100% brand new and high quality
	Explopur 84 Disinfection Tablets- Chlorine 84 Instant Disinfectant Effervescent Tablets	PPOshop (FBS)	B085DKC13G	a) b) c)	Mop disinfection and cleaning Dissolve in water and spray air to sterilize Home antivirus is important: hand- foot-mouth virus, mycobacterium tuberculosis, flu virus, norovirus, chickenpox virus Kill invisible bacteria	a)	With this bottle of effervescent tab-let, you can easily purify the living environment, providing a clean and safe home for yourself.

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## Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 Attachment A

			e) Air disinfection, washing machine disinfection	
Zhance Epidemic Prevention Chlorinating Tablets Disinfectant Chlorine Tablets Swimming Pool Instant Disinfection Dioxide 100g Cozy apposite Fun Suitable	Zhanceus (FBS)	B085HFTM2D	<ul> <li>a) Function: Deep cleaning, sterilization, epidemic prevention, deodorization, bleaching</li> <li>b) Instant Disinfection Dioxide</li> <li>c) Sanitizer and disinfectant</li> </ul>	a) Deep cleaning, sterilization, epidemic prevention, deodorization, bleaching
Aike Home 200 Pieces Swimming Pool Instant Disinfectant Tablets Chlorine Dioxide Effervescent Tablets Chloride Disinfectant	Aike Home (FBS)	B0855MSLXF	<ul> <li>a) Material: disinfectant, Function:         Disinfection     </li> <li>b) Sterilization: Continuous         Bacteriostasis     </li> <li>c) Furniture disinfection, floor         disinfection, toilet disinfection,         bathtub disinfection     </li> </ul>	a) Features: There is no damage to the environment and birds, and it is also a safety guarantee.
Coldcedar Chlorine 84 Disinfectant Effervescent Tablet Bleaching Pet Sterilization	Coldcedar (FBS)	B08663XRD9	<ul> <li>a) Coldcedar Chlorine 84 Disinfectant         Effervescent Tablet Bleaching Pet         Sterilization</li> <li>b) Package included: 100pcs * Chlorine         84 disinfectant effervescent tablets</li> </ul>	A perfect hepler (sic) to easy understand your purify the living environment.
Explopur 100g Disinfection Effervescent Tablets Chlorine-containing 84 Disinfection Tablets Each Dissolves 500ml Water Sterilization for Home Pets Hospitals Public Places (Bottle Packaged)	PPOshop (FBS)	B085MH5FG7	<ul> <li>a) Package includes 1 bottle of disinfection tablet (100g)</li> <li>b) Water Sterilization for Home Pets Hospitals Public Places</li> <li>c) For external disinfection only</li> <li>d) Sterilization</li> </ul>	a) Water Sterilization for Home Pets Hospitals Public Places

In the Matter of: AMAZON.COM SERVICES, LLC

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## Case 3:24-EVIETMONTTERCOFTICAMAZONICOMS SUBSECTION OF 281

## Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 Attachment A

Explopur 300 Pcs Disinfection Effervescent Tablets Chlorine-containing 84 Disinfection Tablets 2g Each Dissolves 1.6kg Water Sterilization for Home Pets Hospitals Public Places (Bottle Packaged)	PPOshop (FBS)	B085MHD77D	a) b) c) e)	Package includes 1 bottle of disinfection tablet (300 pieces) For external disinfection only Sterilization Disinfection Tablets		
84 Dioxidochlorine Effervescent Tablets Indoor and Outdoor	South Ranch (FBS)	B0861YHW4C	a) b)	High efficient disinfection and sterilization, keep clean for a long time.  Tableware disinfection, washing machine disinfection, furniture sterilization, Air sterilization	a)	High efficient disinfection and sterilization, keep clean for a long time.
Decdeal 1000PCS 84 Effervescent Tablets Cloth Bleach Sterilization Deodorization Cleaner Tablets for Household Floor Pool	Decdeal (FBS)	B0868P9YJ4	a) b)	84 disinfectant effervescent tablets Daily Sterilization	a) b)	Safety and convenience 84 cleaning effervescent tablets can bring you a cleaner and safer environment
500PCS/Bottle Convenient 84 Disinfectant Effervescent Tablets Clothing Bleaching Pool Floor Household Deodorant Disinfection Handmade Spray Containing Chlorine Liquid,Daily Cleaning	fanLI (FBS)	B086GS7M4T	a) b)	It can be used for the regular disinfection of the four corners of the living room, kitchen and toilet, as well as the surface disinfection of fabrics and furniture such as bed sheets and quilt covers It can also be used for children's toys, pet products, instruments and equipment, air disinfection, and effectively Disinfection Tablet	a) b)	The disinfectant tablet with trichloroisocyanuric acid as the main effective component has an effective chlorine content of 450m-550mg/tablet, which is safe and non irritant Efficient, One disinfectant tablet after dissoving (sic) is equal to one bottle of disinfectant, safe and environmental protection, convenient for preservation

In the Matter of: AMAZON.COM SERVICES, LLC

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## Case 3:14-THE1MATTER-OFFICAMAZONICOMSTR2/4CESage 67 of 281

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100PCS/Bottle Convenient Household Disinfectant Pills Effervescent Tablets,Clothing Furniture Floor Surface Disinfection Handmade Spray Cleaner Containing Chlorine Liquid,Cleaning Supplies (D)	fanLI (FBS)	B086MT1WSF	a) b) c)	It can be used for the regular disinfection of the four corners of the living room, kitchen and toilet, as well as the surface disinfection of fabrics and furniture such as bed sheets and quilt covers It can also be used for children's toys, pet products, instruments and equipment, air disinfection, and effectively Chlorine-containing, Disinfection Tablets	c)	The disinfectant tablet with trichloroisocyanuric acid as the main effective component has an effective chlorine content of 450m-550mg/tablet, which is safe and non irritant Efficient, One disinfectant tablet after dissoving (sic) is equal to one bottle of disinfectant, safe and environmental protection, convenient for preservation Gentle to Child & Pets Less Harmful to surfaces and skin
1Bottle Convenient Household Disinfectant Pills Effervescent Tablets, Clothing Furniture Floor Surface Cleaner Disinfection Handmade Spray Containing Chlorine Liquid, Daily Cleaning	fanLI (FBS)	B086MC9Q4Q	a) b)	It can be used for the regular disinfection of the four corners of the living room, kitchen and toilet, as well as the surface disinfection of fabrics and furniture such as bed sheets and quilt covers  Surface disinfection of daily necessities, tableware, containers, pipes, etc., toilets, ceramic tiles, schools, hospitals, pet shops, etc Disinfection Tablet	a) b)	Medical quality, safe and non-toxic, easy to store The disinfectant tablet with trichloroisocyanuric acid as the main effective component has an effective chlorine content of 450m-550mg/tablet, which is safe and non irritant Efficient, One disinfectant tablet after dissoving (sic) is equal to one bottle of disinfectant, safe and environmental protection, convenient for preservation
100 Pcs 84 Instant Effervescent Cleaning Tablets Multifunctional Office School Spray	Chenyue US (FBS)	B086PLR1MR	a) b) c) d)	Disinfecting effervescent tablets Sterilization rate>99.999% One bottle equals one hundred bottles of disinfection water Affordable, one tablet is equal to one liter of disinfectant	a) b)	Home Cleaning to protect the health of the family There are patients at home, pets at home, daily life at home, hotels and hotels, and healthy and clean environments need this product Home cleaning is preferred, medical quality, fast effervescence, effective cleaning, health and environmental protection.

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### Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 Attachment A

Antimicrobials, Disinfectants and Sanitizers - Any unregistered or	Nano Liquid Screen Protector	Blobabe (FBA)	B07XGK96RF		no liquid protects it and bacteria too.
misbranded Antimicrobial, Disinfectant or Sanitizer coating used to kill or inactivate microorganisms (bacteria and viruses) on inanimate objects.	Amazon's Choice				
	Original Nano Liquid Screen Protector	7TECH (FBA)	B07JF9ZFQ2	Anti-bacterial	
	HomeLifairy Upgraded 0.352 oz Liquid Screen Protector	Office- Selection (FBA)	B07SGXW1TB	Antibacterial	
	DOTSOG Nano Liquid Screen Protector	DOTSOG (FBA)	B07S2HX6ST	Anti-bacteria	
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer sterilization card used to kill or inactivate microorganisms (bacteria and viruses) in the surrounding air or on inanimate objects.	TOAMIT Card with Neck Strap	Healcier Store Official (FBS)	B086YLWRSZ B086Y8LV5Q	Aluminum foil bag lanyard terilization card Virus Shut Out Effective Antibacterial	oacterial

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## Case 3:24-THE MOST TER COFFICAMAZONIC ON SUBSECUTION OF 281

Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 Attachment A

Pesticide Devices - Any misbranded pesticide device intended for trapping, destroying, repelling or mitigating any pest.	hOmeLabs 3,000 Sq. Ft Energy Star Dehumidifier for Large Rooms and Basements - Efficiently Removes Moisture to Reduce Likelihood of Mold and Mildew	hOmeLabs (FBS)	B06X9MFTZZ	b) c)	Efficiently Removes Moisture to Reduce Likelihood of Mold and Mildew Keep the humidity out of indoor rooms to help protect clothes, home goods, and furniture from mildew, mold, and moisture rot When less moisture is in the air, the living environment is less susceptible to mold, mildew, and allergens that may cause irritation	a) b)	Additionally, this dehumidifier targets humidity that can lead to mold, which can damage your health and valuable items in your living space.  Not only does our dehumidifier benefit the surrounding environment, but it can benefit human health, as well  Product lacks an EPA registered establishment number
	TOLOCO Indoor Insect Trap - Zap T3 Pro Mosquito Trap,USB Powered UV Lamps - for Bug,Fruit Fly,Moths,Mosquito Killer - No Zapper Non- Toxic (Black/Blue)	TOLOCO Inc (FBA)	B085ZZ6S11	b)	Bug,Fruit Fly,Moths,Mosquito Killer Mosquitoes, fruit flies, and moths are attracted by the lights, and the fans suck them in,and the sticky glue boards trap it Enjoy an insect free home	a) b) c) d) e)	TOLOCO Insect traps use simple physical principles to safely capture and kill insects. Does not contain chemicals or toxic substances Safe for kids and pets Non-toxic, no electric zapping and odorless The TOLOCO insects trap is currently the most safest and simplest mosquito killer. Product lacks an EPA registered establishment number
	Eras Edge Ultrasonic Pest Repeller,Upgraded Electronic Pest Repellent Plug in Indoor Pest Control for Insects, Mosquito, Mouse, Cockroaches, Rats, Bug, Spider, Ant, Human & Pet Safe (Set of 4-Packs)	James a Driver (FBA)	B083DRFC22 B083DRG3RS	b) c) d)	Produce good injuring effects on mouse, cockroach, spider, mosquitoes, insect, rat, rodent, flies, ant, fleas and more pests.  Indoor Pest Control for Insects, Mosquito, Mouse, Cockroaches, Rats, Bug, Spider, Ant This time the machine began to work, and watch the pests go away!  Just plug it in - effectively chases away pests in home or office	a) b) c) d)	More Safe for Child & Pets:Our pest repeller is safer than traditional mosquito repellents. Ultrasonic sound is inaudible to humans and household pets, environmental friendly alternative to dangerous poisons and Sprayers, chemicals and traps, no bad smell and Corpses.  Human & Pet Safe The ultrasonic Pest Repellent is effective for an area up to 8001200 Square feet simple to use and safe around family and most reject household pets

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					e)	Product lacks an EPA registered establishment number
Frigidaire High 70 Pints-Per-Day Portable Dehumidifier with SpaceWise Design for Effective and Efficient Moisture Control, FAD704DWD, Fit for Use in any Damp Spaces in the Home, White	Amazon (Amazon)	B00AU7GZXE	a) b) c) d) e)	This dehumidifier quietly removes excess moisture from the air, preventing mold and mildew The benefits of this dehumidifier go beyond moisture removal thanks to the washable mesh filter that cleans the air of dust and allergens, reduces bacteria, and freshens the air Design for Effective and Efficient Moisture Control Protects your home from mold and mildew caused by excess moisture Protects your home from mold and mildew caused by excess moisture	a)	This dehumidifier quietly removes excess moisture from the air, preventing mold and mildew, keeping your family safe and healthy
Indoor: Bug, Fruit Fly, Gnat, Mosquito Killer - Child and Kids Safe - No Zapper - Non-Toxic (Grey)	INLASK-US (FBA)	B083LSZDWT B083LTHK92 B083LTJ393 B083LSVS6Q	a) b) c)	Bug, Fruit Fly, Gnat, Mosquito Killer Muliple powe traps - the UV light attest the fruit fly, gnat, or mouito, the fa sucks it in, espe pvention funnel stops bugs from geing out (sic) INLASK inect trap (sic)	a) b) c) d) e) f)	Child and Kids (sic) Safe Safe for Pets and Kids Non-Toxic Family Safe Chemical Free Product lacks an EPA registered establishment number

Date

Lauris C. Davies, Acting Director
Enforcement and Compliance Assurance Division

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NOTE: Shaded products are from the June 10, 2020, version of Attachment A.

Violative Product	Example Product Name on Amazon.com	Example Seller Name/ Shipping Service	Example Amazon.com ASIN	Pesticidal Claims on Product Labeling*	Misbranding and/or False and Misleading Claims on Product Labeling*
Repellents - Any unregistered or misbranded defense spray used to deter vertebrate pests.	Advanced Tech – Police Magnum OC-17	Studio SOLO (FBS)	B07PSC9PKV	a) Pepper Spray is great for defending yourself against not just human attackers, but wild animals as well Especially effective againstvicious animals and more.	a) Nontoxic causes no permanent injuries
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer used to kill or inactivate microorganisms (bacteria or viruses) on inanimate objects.	PlaneAire Travel Mist  Fails to meet Minimum Risk Pesticide Exemption as follows: makes public health claim, does not list ingredients.  Otherwise unregistered.  Antibacterial Yoga Mat Spray, Energizing Scent, by Diva Stuff	EverywhereAire  (FBS)  Diva Stuff (FBS)	B07QMHMV87  B00YKP2W5M	<ul> <li>a) Kills 99.99% of harmful bacteria</li> <li>b) PlaneAire is laboratory tested to kill 99.99% of harmful bacteria including MRSA</li> <li>c) Eliminates Surface Bacteria &amp; Purifies the Air Naturally</li> <li>d) The six oils were carefully selected for their powerful antibacterial, antiviral, antimicrobial and antifungal properties</li> <li>a) Antibacterial Yoga Mat Spray</li> <li>b) Great For Beach Chairs, Gym Equipment and More</li> </ul>	<ul> <li>a) Kills 99.99% of harmful bacteria</li> <li>b) Ingredients are biodegradable and have no harmful impact on the environment</li> <li>c) Although PlaneAire® is not intended to be used as a hand sanitizer, its all-natural, organic ingredients make it safe to do so</li> <li>d) SAFE AND NON-TOXIC</li> </ul>
	(Energizing)  Portable Mini Disinfectant Spray	Messgod (Coron avirus Protection Clear ance Sale) (FBS)	B086DRVXKG	c) Diva Stuff is introducing a new line of antibacterial yoga mat sprays d) Antibacterial Formula  a) Alcohol free disinfectant - 99.99% clean with 24-hour protection. b) Antibacterial disinfection c) Disinfectant spray d) Effectively inactive bacterial viruses	a) 2020 Coronavirus Protection Coronavirus Protection Clearance Sale
	Edens Garden Cleaning Essential Oil Synergy Blend	Edens Garden (FBS)	B071XPKF2D	<ul> <li>e) The sterilization rate can reach 99.99%</li> <li>a) Sanitizes and disinfects</li> <li>b)this synergy blend functions as an antiviral, antibacterial, antifungal and antiseptic remedy. This all-natural</li> </ul>	a) Only pure, safe and effective products

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Fails to meet Minimum Risk Pesticide Exemption as follows: ingredients ineligible for exemption, does not list active ingredient by weight percentage, lack of company contact information. Otherwise unregistered.			concoction can be applied to counters, floors, tiles, toilets, sinks, ovens, windows and wood for a safer, cleaner home.	
TOTAMALA 20ML Alcohol-Free Bacteriostatic Portable Mini All in One Disinfectant Spray	TOTAMALA (FBS)	B085H77TP5	<ul> <li>a) alcohol free disinfectant - kills 99.99% bacteria with 24-hour protection</li> <li>b) Suitable for a variety of appliances</li> <li>c) Inhibit harmful substances</li> <li>c) 1x Disinfectant Spray</li> </ul>	<ul> <li>a) 24-hour protection with just one application</li> <li>b) Surface throughout useing (sic) to protecting your from harmful bacteria</li> </ul>
Spot Gone Stain Remover and All Purpose Cleaner, Natural Eco Friendly Nontoxic Multi-Surface Formula. Saturate, Dab & Let it Dry! 32 Fl Oz	Spot Gone (FBA)	B08713FYZC	<ul> <li>a) All Natural Cleaner with Hydrogen Peroxide – Kills Bacteria &amp; Viruses</li> <li>b) Disinfectant Cleaner</li> <li>c) One-Step Disinfectant Cleaner</li> <li>d) Soft Surface Sanitizer</li> <li>e) Destroys germs, including most bacteria and viruses</li> </ul>	<ul> <li>a) Natural Eco Friendly Nontoxic Multi-Surface Formula</li> <li>b) All Natural Cleaner with Hydrogen Peroxide – Kills Bacteria &amp; Viruses</li> <li>c) ECO Friendly</li> <li>d) 100% Toxin-Free</li> <li>e) Developed at home, friendly to the environment and never tested on animals</li> </ul>
Xtreme Bio Antimicrobial Multi Surface Cleaner 4-1 Gallons	All- GreenJanitorial Products (FBS)	B088K5T55P	<ul> <li>a) Xtreme Bio Antimicrobial Multi         Surface Cleaner</li> <li>b) Kills bacterial and fungus that cause         spoilage or deterioration on a variety         of surfaces, textiles, and paper         products</li> <li>c) Antimicrobial</li> <li>d) Broad Spectrum Disnfectant for First         Responders or Anyone in Infectious         Environments</li> </ul>	<ul> <li>a) Non-toxic, non-mutagenic, and is biodegradable in less then 10 days</li> <li>b) Odorless, Non-Hazardous, Non-Corrosive, Non-Toxic, Non-Mutagenic Formula</li> <li>c) Safe and easy to use</li> <li>d) Xtreme Bio is a non-toxic, non-mutagenic and provides a proven shield to bio security for you and your home</li> </ul>

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Is P 4	Artnatural Rubbing sopropyl Alcohol - 99% Pure - 1 Gallon (Pack of Quart) - Made in USA Industrial Grade IPA Concentrated	ArtNaturals US (FBS) Organic Nature Bin (FBS)	B08DLC9JK6 B08P286KVB B08MT4MSJ2 B08P2CPJJZ	e) a) b) c) d) e) f)	Inactivates viruses and KILLS bacteria and germs  Great for cleaning, sterilizing equipment, chemistry, and creating hand sanitizer Our 99% purity Isopropyl Alcohol is a truly high-grade & pure sanitizer. It makes a terrific addition to any emergency kit as it can sterilize tools and help prevent infections. You can also use it to create your very own homemade hand sanitizer, sanitizing spray, and wipes Isopropyl alcohol (2-propanol) is the most common and widely used disinfectant within pharmaceutics, hospitals, cleanrooms, and electronics or medical devise manufacturing Different solutions, purity grades, concentrations, and alchol types yield beneficial cleaning and disinfectant properties when applied correctly You can also use our Isopropyl alcohol to sterilize tools Whether you're using it as a topical	a) b)	A terrific addition for any first aid kit with zero harmful organics or heavy metals. It is completely safe to use
				f)			
S P C P L V	Sin1 Screen Cleaning Spray Bottle and Cloth - Pack of 2 - Instantly Clean the Screen of your Phone, Tablet, TV, Laptop - Just Spray and Wipe - Compact - Ideal or Travel - Works Great on Flat Surfaces	ECO-FUSED (FBA)	B07C7MZLPQ	a)	The antibacterial cleaning spray and microfiber cloth will make dust and fingerprints disappear instantly		

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Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer wipe used to kill or inactivate microorganisms (bacteria and viruses) on inanimate objects.	Ainany Cleaning Water Wipes for Hand Suitable for Household Travel Protection - 10 Pads/Pack	Ainany (FBS)	В086НF5СТ8	Disinfectant wet wipes Sterilizing Rate 99.9% Use for wiping door handles, doors, elevator buttons and other public place items, and disinfect children's toys  a) Sterilizing Rate 99.9% Help keep your family care for healthy	
	2 PACK Disinfecting Wipes for Hands, Cleaning Wipes, Antibacterial Wipes, Sanitizing Wipe	OWLHWEH (FBS)	B086173KRW	100 percent bacteria freedisinfecting wipes for a bleach-free, all-in-one cleaning alternative Bacteriostasis Wet Towel New easy to pull flip top pack allows for the easiest way to clean and disinfect  a) Safe for use on hard, n surfaces, everyday inc preparation areas, baby furniture, fridges, taps knobs, kitchen and bat floor cleaning, children electronics	luding food  requipment, sinks, door hroom surfaces,
	20piter 6 Pack Disinfectant Wipes, 75% Alcohol Cleaning Wet Wipes(1 Pack,10 Wipes), Daily Disinfecting Use for Hand Home House Travel Office Electronics School All Purpose	20piter (FBS)	B086DRXYF4	75% alcohol efficient sterilization (includes images of red lines through four types of bacteria: Candida albicans, E.coli, Staphylococcus aureus, Pseudomonas aeruginosa) 99.99% sterilization Daily Disinfecting Use for Hand Home House Travel Office Electronics School All Purpose	g your daily ean
	Wet Wipes (80 Wipes per Pack) Deep Cleaning of Hands/Toys/Tables/ Electronic Equipment, Etc.	Shenzhen LAGPOUSI Technology Co., Ltd (FBS)	B08BJ333JF	Cleaning and Sanitizing Application scope: suitable for skin surface, home surfaceSterilization (sic), toy disinfection cleaning of public goods, surfaces, etc Kill Bacteria Effective Sterilization of Wipes 99.9%	

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			e) Multiple occasions Children Play Games – Outdoor Travel – Public Equipment – Hand-Held Elevator – Mobile Phone Computer
120 Wipes Hand Wet Wipes for Audlts, Hand Refreshing Cleaning Wipes for Travel Size, Disposable Wipes Suitable for Daily Cleaning	Rise-sun (FBS) KEW LLC (FBS)	B0893V593N	a) Effectively Inhibit Bacteria 99.9% b) Cleaning and Sanitizing c) 75% Alcohol, 99.9% Sterilization Rate d) Provides All-round Protection e) Cleaning wipes for all-protections [above a graphic of glass ware, a toilet and a hand]  a) Provides All-round Protection b) Gentle and Skin-friendly c) Mild and Safe Formula d) CE FDA MSDS Approved e) Safer
Antibacterial Sanitizing Disinfecting Alcohol Wipes (250 Wipes) - Disinfectant Hand Sanitizer Wipes - Wet Disinfect Cleaning Wipes for House - 5 Pack of 50	Kerrie's Counter (FBS)	B08CRRYJPB	a) Antibacterial Sanitizing Disinfecting Alcohol Wipes b) Ag+ Alcohol Antibacterial Wipes c) Effective sterilization 99.99% - Household Outdoor Travel d) Disinfecting – Triple Sterilization – Sanitizing – Antibacterial e) Alcohol Kills germs by breaking down it's cell walls, destroying the plasma membranes, and interfering with the metabolism of the cell f) Benzalkonium Bromide is an active active antimicrobial agent that fights bacteria on all surfaces g) Silver Ions (Ag+) block and destroy bacteria energy production, inhibiting cell replication and killing off the bacteria h) Where to use – Hands – Car – House - Office i) They fit comfortably in any travel bag or car and are a great alternative to

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			public transit, gyms, public toilets, parks, and more.
5 Pack Wipes, Replaceable Wipes Made of Sterile Non- Woven Fabric, Disposable Wipes for Adults. (50 Pieces in Total)	JDHF Manufacturing (FBA)  L Will (FBS)	B08CZYB2W6 B08BK7VCW1 B08BK7T863 B08D11376P	a) Disinfection Wet Wipes b) 99.9% Sterilization Rate c) Sanitary Care Sterilized Wet Wipes d) Scope of Use: Applicable to the hand skin, object surface e) Usage: From one side of the surface of the object, from the top down by the s-type wipe to the entire surface, action for 3 minutes f) Category of Killing Microorganisms: Can kill the intestinal pathogenic bacterium, staphylococcus aureus pseudomonas aeruginosa candida albicans g) Widely used: wipes can be used indoors and outdoors, such as wiping door handles, elevator buttons and other easily accessible objects h) Effective sterilization and sterilization without residue i) Great for disinfecting on the go [with photographs of interior car door, desk draw with items, bus handrail and an airplane tray table]  a) Safety: The cleaning wipes are made of high-quality non-woven fabric, which is soft and skin-friendly b) It can effectively provide a safe living environment c) Professional purification and care for your health d) Universal wipes can be widely used for outdoor travel, parks, parties and family use, adding a sense of security to your life
Cleaning Wipes, Hand Wet Refreshing Wipes(5 Pack=50 Piece), Clean Wipe for Adults Family, Travel, Bathroom & Kitchen PraLA507	Pradonna (FBS)	B08D8X69CF B08C4MPJ4G	a) Effective sterilization and Health Care b) 75% alcohol disinfectant towel c) 99.9% Sterilization Rate d) Computer keyboard – Childrens Toys – Mobile phone – elevator – Refrigerator [Listed next to a graphic of the product label which states,

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Alcohol Formula Wipes (20 Packs x 10 Sheets Total 200 PCS), Bulk 75% Alcohol Cotton Sanitizing Sheet Sterile Gauze Pads, Suitable for Outdoor Skin Cleansing Care, Individually Packaged Wet Tissues	God's Dream (FBS)	B08D7SLV3J	"Effective sterilization and Health Care"] e) 75% Disinfection Wipes f) Open a new sterile life 99.9% sterilization rate g) Sterilization, cleaning, sanitation h) 75% Sterile with Alcohol i) Clean antibacterial  a) Bulk 75% Alcohol Cotton Sanitizing Sheet b) Sterilization Rate 99.9% c) Disinfect&Clean d) Disinfection for office items such as keyboards, LCD monitors, glasses and mobile phones etc e) Travel environment and use of sanitation of carry-on items f) Inhibits Bacteria Cleanses Efficiently g) Antibacterial h) Effective sterilization and sterilization
Antibacterial Alcohol Wipes, 6 Pack of 50 (300 Wipes), Kills 99.9% of Germs, Portable Cleaning Wipes for Home Outdoor Skin Toys	Sipa Masks (FBS)	B08BN4K52T	a) Antibacterial Alcohol Wipes b) Kills 99.9% of Germs c) 99.9% Kill Germs Naturally d) Alcohol Wipes (50PCS, PACK OF 6) kills 99.9% of germs, help prevent the spread of bacterial. Portable design, suitable for daily use and travel use.
Wet Wipes, All Purpose 75% Portable 3Pack 80 Sheet Hand Wipes Family, Travel,Outdoor, Kitchen,Hand Skin Cleaning	Yinyin shares (FBS)	B08DQN9DZV	a) Disinfectant Wipes b) Kills 99.9% of Viruses & Bacteria  a) Take good care of your family's health

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60PCS Wet Wipes for Large Size, Hand Wipes for Adults Daily Cleansing	Shenzhen LAGPOUSI Technology Co., Ltd (FBS)	B08B4GQCWG B0892ZHYGT B08D8XVGJ3 B08D8YD6HY B08D8WRFY6	a) b)	Disinfection Wipes For Use in Health Dental offices, Ophthalmic offices, Areas such as kitchens And Bathrooms Wide Used- Suitable for keyboard, phone, office supplies, portable supplies, tableware, children's toys, etc. Perfect for use in offices, schools and home.	b)	Safe and Clean
Wipes Out Anitbacterial Wipes Lemon Scent 80 Wipes	Multiple (FBA and FBS)	B08HPFP6CM	c)	Wipe Out Anitbacterial Wipes KILLS 99.9% OF GERMS KILLS GERMS FAST Kills 99.9% of germs - Use it anytime, anywhere Cleans and sanitizes	a)	Safe and gentle on hands
Household Cleaning Wipes, Cleaning Supplies, Heavy Duty Cleaning Wipes for House, Kitchen, Home, Bathroom, Microwave, Hands, Office, Pets, Floor   35 ct, 3 bottles, total 105 units	Doneesha-Smith (FBA) Enthusiasmr (FBA)	B08BL5VPKY B08CVN3NRD B08B38RWD5 B08B16SQF6		NARRAH – The Easy Way To Clean And Disinfect. Use On The Hard, Nonporous, Non- food-contact Surface, Kill Germs Around Tour (sic) Home, Kitchen Room, Bathroom, Safe For Use On Finished Wood, Sealed Granite, Glass, And Stainless Steel Disinfect: Pre-clean surface. Use enough fresh wipes to a (sic) throughly wet surface To prevent the growthof mold and mildew and their odors: Pre-clean hard, nonporous surfaces	a) b) c)	Maintains a clean and healthy living environment.  Natural soft formula, does not harm the skin  Naturally Mild & Not Irritating
Waxman Kleen Freak Wipes 70 Count Canister (3 Canisters)	Waxman Consumer Products Inc. (FBA)	B08FRN1QXT B08FCWTRJK	a) b) c) d)	Sanitizing Wipes To help reduce viruses and bacteria Disinfecting wipes Wipe surface with product and allow to dry		

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	AlertCare Alcohol Prep Pads - Medical-Grade Sterile - 75% Alcohol Cotton Slices - 50 Pcs Large Size Gauze Pads Individually Wrapped - 11 x 15cm/4.3in x 5.9in	OnHand HealthCare	B08956RD91	e) Waxman Kleen Freak disinfecting wipes kill 99.9% of harmful viruses and bacteria  f) Our wipes are designed to hold moisture longer, and disinfect while that clean away dirt, dust and germs – making clean-ups easier and faster at home, work, school or anywhere messes occur  g) Fast, one-step cleaning and disinfecting  a) Large Alcohol Wipes - Big enough for your targeted use perfect for biabetics Skin Cleaning Care, Jewelry Computer, Cell Phone, Digital Camera, Notebook Clean  b) KILLS 99.99% OF GERMS THAT MAY CAUSE ILLNESS  C) Kills Bacteria & Germs & Viruses  d) The product may seem small since it's folded, just unfold it to see the 6x6cm size alcohol pad and its good to go and use it to sterile (sic) and clean your phone, doorknob, remote control, car wheels, grocery carts, bags and all things you wanted  e) [photographs of people using the pads on a phone, eye-glasses and a keyboard
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer tablets used to kill or	Epidemic prevention Chlorinating Tablets Disinfectant Chlorine Tablets Swimming Pool Instant Disinfection Tablets Chlorine Dioxide Effervescent Tablet Chlorine	mingzuo (FBS)	B084RMYPTG	a) Function: Deep cleaning, sterilization, epidemic prevention, deodorization, bleaching b) Product name: Sanitizer and disinfectant c) Disinfectant Chlorine Tablets  a) Family disinfection in addition to the mold b) Chlorine Disinfectant 100g Cozy apposite (sic) Fun

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inactivate microorganisms (bacteria and viruses) on inanimate objects or in water.	Disinfectant 100g Cozy apposite Fun				
	KOVIPGU 100Pcs Chlorine Dioxide Disinfectant Cleaning 84 Instant Effervescent Tablets	KOVIPGU (FBS)	B08625RDR8	<ul> <li>a) Function: Deep cleaning, sterilization, deodorization, mildew, bleaching</li> <li>d) Can be used for regular disinfection of the living room, kitchen, bathroom, bed linen and other clothes and furniture surface disinfection</li> </ul>	<ul> <li>a) Efficient disinfection to prevent the spread of disease</li> <li>b) Use chlorine dioxide as the main active ingredient, safe and nonirritating</li> <li>c) 100% brand new and high quality</li> </ul>
	Explopur 84 Disinfection Tablets- Chlorine 84 Instant Disinfectant Effervescent Tablets	PPOshop (FBS)	B085DKC13G	<ul> <li>a) Mop disinfection and cleaning</li> <li>b) Dissolve in water and spray air to sterilize</li> <li>c) Home antivirus is important: handfoot-mouth virus, mycobacterium tuberculosis, flu virus, norovirus, chickenpox virus</li> <li>d) Kill invisible bacteria</li> <li>e) Air disinfection, washing machine disinfection</li> </ul>	a) With this bottle of effervescent tab-let, you can easily purify the living environment, providing a clean and safe home for yourself.
	Zhance Epidemic Prevention Chlorinating Tablets Disinfectant Chlorine Tablets Swimming Pool Instant Disinfection Dioxide 100g Cozy apposite Fun Suitable	Zhanceus (FBS)	B085HFTM2D	<ul> <li>a) Function: Deep cleaning, sterilization, epidemic prevention, deodorization, bleaching</li> <li>b) Instant Disinfection Dioxide</li> <li>c) Sanitizer and disinfectant</li> </ul>	a) Deep cleaning, sterilization, epidemic prevention, deodorization, bleaching
	Aike Home 200 Pieces Swimming Pool Instant Disinfectant Tablets	Aike Home (FBS)	B0855MSLXF	<ul> <li>a) Material: disinfectant, Function:     Disinfection</li> <li>b) Sterilization: Continuous     Bacteriostasis</li> </ul>	a) Features: There is no damage to the environment and birds, and it is also a safety guarantee.

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Chlorine Dioxide Effervescent Tablets Chloride Disinfectant			c) Furniture disinfection, floor disinfection, toilet disinfection, bathtub disinfection
Coldcedar Chlorine 84 Disinfectant Effervescent Tablet Bleaching Pet Sterilization	Coldcedar (FBS)	B08663XRD9	a) Coldcedar Chlorine 84 Disinfectant Effervescent Tablet Bleaching Pet Sterilization  b) Package included: 100pcs * Chlorine 84 disinfectant effervescent tablets  a) A perfect hepler (sic) to easy understand your purify the living environment.
Explopur 100g Disinfection Effervescent Tablets Chlorine-containing 84 Disinfection Tablets Each Dissolves 500ml Water Sterilization for Home Pets Hospitals Public Places (Bottle Packaged)	PPOshop (FBS)	B085MH5FG7	a) Package includes 1 bottle of disinfection tablet (100g) b) Water Sterilization for Home Pets Hospitals Public Places c) For external disinfection only d) Sterilization
Explopur 300 Pcs Disinfection Effervescent Tablets Chlorine-containing 84 Disinfection Tablets 2g Each Dissolves 1.6kg Water Sterilization for Home Pets Hospitals Public Places (Bottle Packaged)	PPOshop (FBS)	B085MHD77D	a) Package includes 1 bottle of disinfection tablet (300 pieces) b) For external disinfection only c) Sterilization e) Disinfection Tablets
84 Dioxidochlorine Effervescent Tablets Indoor and Outdoor	South Ranch (FBS)	B0861YHW4C	<ul> <li>a) High efficient disinfection and sterilization, keep clean for a long time.</li> <li>b) Tableware disinfection, washing machine disinfection, furniture sterilization, Air sterilization</li> <li>a) High efficient disinfection and sterilization, keep clean for a long time.</li> </ul>

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Decdeal 1000PCS 84 Effervescent Tablets Cloth Bleach Sterilization Deodorization Cleaner Tablets for Household Floor Pool	Decdeal (FBS)	B0868P9YJ4	a) b)	84 disinfectant effervescent tablets Daily Sterilization	a) b)	Safety and convenience 84 cleaning effervescent tablets can bring you a cleaner and safer environment
500PCS/Bottle Convenient 84 Disinfectant Effervescent Tablets Clothing Bleaching Pool Floor Household Deodorant Disinfection Handmade Spray Containing Chlorine Liquid,Daily Cleaning	fanLI (FBS)	B086GS7M4T		It can be used for the regular disinfection of the four corners of the living room, kitchen and toilet, as well as the surface disinfection of fabrics and furniture such as bed sheets and quilt covers  It can also be used for children's toys, pet products, instruments and equipment, air disinfection, and effectively  Disinfection Tablet	a) b)	The disinfectant tablet with trichloroisocyanuric acid as the main effective component has an effective chlorine content of 450m-550mg/tablet, which is safe and non irritant Efficient, One disinfectant tablet after dissoving (sic) is equal to one bottle of disinfectant, safe and environmental protection, convenient for preservation
100PCS/Bottle Convenient Household Disinfectant Pills Effervescent Tablets,Clothing Furniture Floor Surface Disinfection Handmade Spray Cleaner Containing Chlorine Liquid,Cleaning Supplies (D)	fanLI (FBS)	B086MT1WSF	a) b)	It can be used for the regular disinfection of the four corners of the living room, kitchen and toilet, as well as the surface disinfection of fabrics and furniture such as bed sheets and quilt covers It can also be used for children's toys, pet products, instruments and equipment, air disinfection, and effectively Chlorine-containing, Disinfection Tablets	a) b) c) d)	The disinfectant tablet with trichloroisocyanuric acid as the main effective component has an effective chlorine content of 450m-550mg/tablet, which is safe and non irritant Efficient, One disinfectant tablet after dissoving (sic) is equal to one bottle of disinfectant, safe and environmental protection, convenient for preservation Gentle to Child & Pets Less Harmful to surfaces and skin
1Bottle Convenient Household Disinfectant Pills Effervescent Tablets, Clothing	fanLI (FBS)	B086MC9Q4Q	a)	It can be used for the regular disinfection of the four corners of the living room, kitchen and toilet, as well as the surface disinfection of fabrics	a) b)	Medical quality, safe and non-toxic, easy to store The disinfectant tablet with trichloroisocyanuric acid as the main

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Furniture Floor Surface Cleaner Disinfection Handmade Spray Containing Chlorine Liquid, Daily Cleaning			b)	and furniture such as bed sheets and quilt covers Surface disinfection of daily necessities, tableware, containers, pipes, etc., toilets, ceramic tiles, schools, hospitals, pet shops, etc Disinfection Tablet	c)	effective component has an effective chlorine content of 450m-550mg/tablet, which is safe and non irritant Efficient, One disinfectant tablet after dissoving (sic) is equal to one bottle of disinfectant, safe and environmental protection, convenient for preservation
100 Pcs 84 Instant Effervescent Cleaning Tablets Multifunctional Office School Spray	Chenyue US (FBS)	B086PLR1MR	a) b) c) d)	Disinfecting effervescent tablets Sterilization rate>99.999% One bottle equals one hundred bottles of disinfection water Affordable, one tablet is equal to one liter of disinfectant	a) b)	Home Cleaning to protect the health of the family There are patients at home, pets at home, daily life at home, hotels and hotels, and healthy and clean environments need this product Home cleaning is preferred, medical quality, fast effervescence, effective cleaning, health and environmental protection.
FEINASU Magic Pool Cleaning Tablet & Floating Dispenser (100 Tablets 1 Bottle+ Dispenser 1pc)	lonko5DING (FBA)	B07WLDP7JS		Automatic Disinfection Drug Dispenser for Swimming Pool Obvious Effect - Purification of Fouling in Swimming Pools [Before and after graphic of an algae filled pool becoming clean]	a) b)	Made of safe and quality materials Ensures the swimming poll is safe and will not hurt the skin
COLORCASA Magic Pool Cleaning Tablet (100 Tablets 1 Bottle) Magic Swimming Pool Tup Cleaner	AFGQIANG LLC. (FBS)	B07VVNNCKC	a) b)	Swimming Pool Disinfection Effervesent Tablets [Before and after graphic of an algae filled pool becoming clean]	a) b)	Made of safe and quality materials It ensures that the swimming pool is safe and will not hurt the skin
MAMaiuh Magic Swimming Pool Cleaning Tablet with Floating Chemical Dispenser, 1 Bottle /100 Pieces Chlorine Tablet Chlorinating Tablets,	MAMaiuh (FBS)	B07XRX5PYJ	a) b) c)	Effectively Guard Against Bacteria, Algae and Other Organism These swimming pool water sanitizers create a safer, cleaner, and more enjoyable swimming experience [Before and after graphic of an algae filled pool becoming clean]	a) b)	These swimming pool water sanitizers create a safer, cleaner, and more enjoyable swimming experience Made of safe and high-quality materials. It ensures that the swimming pool is safe and will not hurt the skin

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Effectively Guard Against Bacteria, Algae and Other Organism LOVFASHION 4 Bottles Pool Cleaning Tablet Effectively Purify Water-Enjoy Crystal Clear Pool	Molly & Lily (FBS)	B07VT4SJFZ B07W7Y18N7	<ul> <li>a) Effectively Purify Water</li> <li>b) Effective cleaning, effective sterilization, make your children safe and more reassuring</li> <li>c) Bacteria are everywhere – It can be used in wards, pets, kitchens, toilets and other places</li> <li>d) Effective sterilization</li> <li>e) These swimming pool water sanitizers create a safer, cleaner, and more enjoyable swimming experience</li> <li>f) Swimming Pool Disinfectant Effervescent Tablets</li> <li>g) Purify water</li> <li>h) [Before and after graphic of an algae filled pool becoming clean]</li> </ul>	c) Safe and non-toxic – Will not hurt the skin  a) Effective cleaning, effective sterilization, make your children safe and more reassuring b) These swimming pool water sanitizers create a safer, cleaner, and more enjoyable swimming experience.
Zooyooarts Magic Swimming Pool Cleaning Tablet with Floating Chemical Dispenser, Pool Maintenance Tablets, Effectively Eliminate Harmful Organisms [1] Bottle(100Tablets)]	cftaro (FBS)	B0895YCHWK	<ul> <li>a) Effectively Eliminate Harmful Organisms</li> <li>b) [Before and after graphic of an algae filled pool becoming clean]</li> <li>c) [Before and after graphic of an algae filled pool, with magnifying glass showing algae cells, becoming clean]</li> <li>d) Swimming Pool Disinfectant Effervescent Tablets</li> </ul>	<ul> <li>a) Made of safe and high-quality materials. It ensures that the swimming pool is safe and will not hurt the skin</li> <li>b) Safe and non-toxic – Will not hurt the skin</li> </ul>
Aquatabs Water Purification Tablets	Preparation Apparel (FBA) and (FBS) Cascade Supply (FBS)	B06XPCCD4Y B01IIRD2MO B077737MBN B071464NPG B07SNS3B9G B07DTSRB6S B07Q25KJ75 B0825SC66G	<ul> <li>a) World's #1 Water Purification Tablets</li> <li>b) Aquatabs are effervescent tablets which kill microorganisms in water to prevent cholera, typhoid, dysentery and other water borne diseases.</li> <li>c) Drinking Water Tablets/Purify</li> <li>d) Aquatabs Water Purification Tablets</li> </ul>	<ul> <li>a) [Products appear to be repackaged from the original packaging]</li> <li>b) Aquatabs are effervescent tablets which kill microorganisms in water to prevent cholera, typhoid, dysentery and other water borne diseases</li> </ul>

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Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer coating used to kill or inactivate microorganisms (bacteria and viruses) on inanimate objects.	Nano Liquid Screen Protector  Amazon's Choice	Blobabe (FBA)	B07XGK96RF	a) b)	Anti-bacteria The coat of nano liquid protects it from microbes and bacteria too.	a)	The coat of nano liquid protects it from microbes and bacteria too.
	Original Nano Liquid Screen Protector	7TECH (FBA)	B07JF9ZFQ2	a)	Anti-bacterial		
	HomeLifairy Upgraded 0.352 oz Liquid Screen Protector	Office- Selection (FBA)	B07SGXW1TB	a)	Antibacterial		
	DOTSOG Nano Liquid Screen Protector	DOTSOG (FBA)	B07S2HX6ST	a)	Anti-bacteria		
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer treated article making claims beyond the article itself.	Secure-A-Pen Antimicrobial Counter Pen with 3 Refills, Black (514455)	BestSource OfficeSupplies. (FBS)	B00Q8TEL2K	a)	Antimicrobial Protected		
	gb Home Collection Premium Antibacterial Door Mat   24 x 36 inches   Indoor Outdoor Doormat w Anti-Skid Rubber Back   Water	GrayBunny (FBA)	B07B67SQDL B07WGHX535	a) b)	Premium Antibacterial Door Mat The polypropylene surface is stain resistant, naturally anti-bacterial and quick to dry Polypropylene Surface is Naturally Anti-Bacterial and Dries Quickly		

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	Absorbent Entryway Mat   Easy to Clean Bootscaper   Low Profile Entry Mat  Jamm Hands Free Touchless Arm Pull Door Handle Opener Treated with Antimicrobial Technology, 1 Pack	Hilwate Holdings (FBA)	B089LQHYRL B089LYWV1N	a) Treated with Antimicrobial Technology b) This innovative technology, a highly active silver ion additive that assists in keeping surfaces sanitary, is dispersed throughout the handle c) It remains active for the LIFETIME of the product making for the best germaphobe door opener d) Never requires recoating of antimicrobial treatment. e) Innovative antimicrobial technology f) Bacteria lands on the biomaster surface the bacteria can't survive g) Biomaster interups the cell's DNA preventing replication  a) Welcome to a stress, virus and germ free way to open a door b) This innovative technology, a highly active silver ion additive that assists in keeping surfaces sanitary, is dispersed throughout the handle c) It remains active for the LIFETIME of the product making for the best germaphobe door opener
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer made of or containing elemental metal intended to kill, control or destroy bacteria, viruses or germs.	Aviano Copper Protector Door Opener Tool & Button Pusher – (2 PACK) 99.9% Copper Hands Free Germ Keychain Utility Hook Tool Key– No Touch Tool for Infected Surfaces, Touchscreens, Handles, Buttons	BELLA AMAZING (FBA)	B087YZZ4XD	<ul> <li>a) Our anti-touch door opener and stylus is ideally made with 99.9% copper that naturally kills pathogens, unlike brass keychain</li> <li>b) Copper is a proven and tested material that naturally kills – Viruses – Bacteria – Germs</li> <li>c) Copper releases ions which destroy the whole cells of pathogens including the DNA and RNA, making bacteria impossible to mutate</li> <li>d) Prevent Germs</li> <li>d) Prevent Germs</li> <li>e) Made of 99.9% Antimicrobial Copper</li> </ul>
	StayWell Copper GermStopper Large Patch Cell Phone, Laptop, iPads or to Any	Stay Well Copper (FBS)	B07VFB3KHY B07VF9M2R5	<ul> <li>a) StayWell Copper kills bacteria and germs on contact</li> <li>b) LAST FOREVER - StayWell Copper never stops killing germs when you</li> <li>a) The Copper GermStopper Phone Patch reduces the spread of germs</li> <li>b) Simply attach a Staywell GermStopper Cellphone Patch to your phone and</li> </ul>

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Product to Eliminate Germs Without Chemicals   Pure Copper Made in The USA (Large) (2.125" x 3.375")			c) d)	rub, roll, and touch it. The benefit from copper's 'halo effect' is that it kills 70% of all germs in a 50 cm radius (19")  Researchers worldwide agree copper is a natural "antimicrobial", killing germs and bacteria, just by touch.  Microbe cells have an internal electric charge which copper's high conductance short—circuits, destroying the cell in seconds.  The Copper GermStopper Phone Patch reduces the spread of germs and kills germs on your phone	c)	voila! Now you're carrying protection against germs - an extra layer of protection from unwanted sickness StayWell Copper Phone Patches are 1.2 mm thick, packed full of all natural, chemical free germ killing power. Lasts forever.
Original StayWell Copper GermStopper Portable Roller   Kills Germs On Contact Without Chemicals   Pure Copper Made in the USA (Single Unit)	Stay Well Copper (FBS)	B086H3SVJG B087X9HFSW	a) b) c) d) e)	Kills Germs On Contact Without Chemicals StayWell Copper HAS A HALO EFFECT: StayWell Copper is completely safe with no side effects. Unlike any other metal, copper has halos which can kills 70% of all germs within 16" of contact. Our copper products kill 99.97% of germs on contact. HOW IT WORKS: When a germ comes in contact with StayWell Copper, the copper causes the outer membrane of the germ to rupture. Once ruptured, the germ's cell contents interact with the copper and their function is destroyed! Due to its antimicrobial properties copper sterilizes itself! Put your old staywell copper phone patch on any surface you want to protect from germs	a) b) c)	Kills Germs On Contact Without Chemicals StayWell Copper is completely safe with no side effects SAFE, DURABLE & LASTS FOREVER StayWell Copper products require no warning labels. They are 100% safe for mothers, teachers, doctors, salespersons, children, teenagers, young adults, sanitation workers, food service employees, public officials and receptionistseveryone benefits from the germ-killing power of StayWell Copper!

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Keyclean Copper Hands Free Door Opener Tool   Button Pusher & Stylus Key   No Touch - Avoid Germs   Made in The USA	Mom + Pop (FBA)	B08882WV8X	a) b) a)	The key to germ free living has finally arrived. Made from 99.9 percent antimicrobial copper This germ protector germ key or germ hook can be used as a sanitary door opener Keyclean is self-sanitizing comfortable to use, compact, durable and designed to keep you safe at all times from the millions of germs on public surfaces that we interact with on a daily basis.	a) b) c) d)	This germ protector germ key or germ hook can be used as a sanitary door opener Keyclean is self-sanitizing comfortable to use, compact, durable and designed to keep you safe at all times from the millions of germs on public surfaces that we interact with on a daily basis Help keep you, your family, your friends, your coworkers, and your community safer by minimizing the spread with this elegant no touch tool Thank you for making your community safer, one less touch at a time!
N3XISM_STUDIO Copper Protector Door Opener Tool & Button Pusher - 99.9% Copper Hands Free Germ Keychain Utility Hook Tool Key - No Touch Tool for Touchscreens, Handles, Buttons and More	ONEWKTS (FBA)	B088WKQQM4	a) b)	Why Copper? – Copper is a proven and tested material that naturally kills:  - Viruses – Bacteria – Germs  How? – Copper releases ions which destroy the whole cells of pathogens including the DNA or RNA, making bacteria impossible to mutate	a)	Our Hands-Free Door Opener Tool is designed to keep you safe and stop the spread by limiting exposure to surfaces in day-to-day activities
Antimicrobial Pure Copper Therapy Ring Band for Men & Women, Uncoated Solid Copper, Effective Against Viruses, Germs, Bacteria; Trace Mineral, Natural Relief of Arthritis, Joint Pain; Size 5-12	Samie Collection (FBA)	B07NDCP5BF B07NDD4TR4	a) b) c)	Effective Against Viruses, Germs, Bacteria Our natural copper has antimicrobial properties, meaning it kills bacteria and viruses Copper is an essential trace metal which has healing and antimicrobial properties		
Hy-Genie 3 inch Brass No Touch Door Opener Hand Multi Tool	Addison & Sheffield (FBA)	B087NHGC9P	a)	Hy-Genie uses copper's natural ANTIMICROBIAL ability to kill germs	a)	Hy-Genie Hand Tool will keep you and your hands safe from coming into direct contact with harmful germs;

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				b) Manufactured from C280 Brass - a copper/zinc alloy that uses its natural ability to kill germs on its surface in up to 4 hours  b) Great gift idea for friends and family who need to stay clean and protected while out and about
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer film used to kill or inactivate microorganisms (bacteria and viruses).	CLOBO Anti Virus Film ZnO Film Elevator Kiosk Desk (1.6FT X 16.6FT)	Clobo (FBA)	B087MY4Z74	a) Anti Virus Film b) This is ZnO antivirus film c) ZnO has a powerful antimicrobial effect for removing 99.9% of germs in daily life, such as staphylococ-us aures (sic), colon bacillus and bacillus pyocyaneus, when used for sanitary products d) Antimicrobial mechanism of Zinc Oxide e) Ion contact generates monovalence due to destruction of cell wall and cell membrance (sic) f) Electrostatic attraction induces virus death by electrostatic attraction between ZnO and bacteria
	Sneeze Guard Antimicrobial Film, ETROBOT Anti-viral Film Adhesive Counter Shield for Desk, Elevator Button, Handle Sticker Car Film Transparent Protective Cover, Surface Protection 32ft x 1.3ft	YK Trading Inc. (FBS)	B08C9QB6NZ B08C2MBTVJ B08D3G72ZQ	a) 99.9% Anti-virus & All purpose Sterilization b) Proven certified antimicrobial copper technology rapidly penetrates into bacterial cells, our antimicrobial copper film destroys the body and genome of the virus and rapidly deactivated the bacteria and virus within couple minutes, kills 99.9% of germs according to our professional lab test without producing any harmful substances, no odor, no chemical, safe to use c) Easy to Use & 7/24 Away from Bacteria d) Anti-microbial Copper Laminate Film

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				e) Principle behind the Antiviral effect of Copper - Antimicrobial Copper acts as an inhibitor of the virus replication f) However, virus is deactivated in the Copper surface within 30 minutes and Copper destroys the body structure and genome of the virus g) 99.99% Anti-virus Copper Film – Protects 24h a day, 7 days a week h) Rapidly Block and Destroy 99.99% of Surface Bacteria i) Sterilization Rate up to 99.99%
Antimicrobials, Disinfectants and Sanitizers - Any unregistered or misbranded Antimicrobial, Disinfectant or Sanitizer sterilization card used to kill or inactivate microorganisms (bacteria and viruses) in the surrounding air or on inanimate objects.	TOAMIT Card with Neck Strap	Healcier Store Official (FBS)	B086YLWRSZ B086Y8LV5Q	a) Aluminum foil bag lanyard sterilization card b) Virus Shut Out c) Effective Antibacterial
Antimicrobials/Herbici des - Any unregistered or misbranded Antimicrobial/Herbicide used to remove mold and mildew and kill weeds.	Green Gobbler ULTIMATE VINEGAR Home & Garden - 30% Vinegar Concentrate, Hundreds of Uses! 5 Gallon Pail	EcoClean Solutions (FBS)	B01EXSPF5O B07939DYBP	a) Remove mold and mildew b) Horticultural Applications: Use at full strength with any type of pressure sprayer c) Restore Brickwork [on a picture of a brick patio with excessive weeds] d) Use as a Handy Garden Helper [under a photograph of someone hoeing weeds] e) It easily dissolves grease, soap scum, mildew, mold, rust and other organic matter  a) THE ALL-NATURAL ALTERNATIVE FOR CLEANING b) Our OMRI-listed 30% vinegar is a safer alternative to bleach and ammonia c) Use all-natural vinegar for cleaning, deodorizing, gardening, laundry, chrome polishing, grease removal, etc d) Environmentally Friendly e) Safe, natural and certified for organic use f) ALL-NATURAL ALTERNATIVE

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				f) Question: So if I wanted to use this kill grass & weeds and I wanted to use a 30 gallon tank sprayer, what would the dilution rate be & how many gallons needed? Answer: Use in full sunshine. Completely saturate grass & weeds. There's no need to dilute the vinegar; just add to a sprayer and start using the product. This kills all the plants in the area. Avoid spraying on any grass and plants you wish to protect. It doesn't leave residue in the soil that could prevent new plants from growing. A 30-gallon tank sprayer should cover approximately a half acre & you would need 30 gallons of vinegar. That's a little less than half a football field. see less - By EcoClean Solutions SELLER on February 6, 2019  g) This powerful vinegar solution is typically reserved for agricultural and industrial tasks  h) Whether you want a handy garden helper or a powerful household cleaner, you can trust 30% Pure Vinegar to get the job done—naturally
Pesticide Devices - Any misbranded pesticide device intended for trapping, destroying, repelling or mitigating any pest.	hOmeLabs 3,000 Sq. Ft Energy Star Dehumidifier for Large Rooms and Basements - Efficiently Removes Moisture to Reduce Likelihood of Mold and Mildew	hOmeLabs (FBS)	B06X9MFTZZ	<ul> <li>a) Efficiently Removes Moisture to Reduce Likelihood of Mold and Mildew</li> <li>b) Keep the humidity out of indoor rooms to help protect clothes, home goods, and furniture from mildew, mold, and moisture rot</li> <li>c) When less moisture is in the air, the living environment is less susceptible to mold, mildew, and allergens that may cause irritation</li> <li>a) Additionally, this dehumidifier targets humidity that can lead to mold, which can damage your health and valuable items in your living space.</li> <li>b) Not only does our dehumidifier benefit the surrounding environment, but it can benefit human health, as well</li> <li>c) Product lacks an EPA registered establishment number</li> </ul>

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TOLOCO Indoor Insect Trap - Zap T3 Pro Mosquito Trap,USB Powered UV Lamps - for Bug,Fruit Fly,Moths,Mosquito Killer - No Zapper Non- Toxic (Black/Blue)	TOLOCO Inc (FBA)	B085ZZ6S11	a) b)	Bug,Fruit Fly,Moths,Mosquito Killer Mosquitoes, fruit flies, and moths are attracted by the lights, and the fans suck them in,and the sticky glue boards trap it Enjoy an insect free home	a) b) c) d) e)	TOLOCO Insect traps use simple physical principles to safely capture and kill insects. Does not contain chemicals or toxic substances Safe for kids and pets Non-toxic, no electric zapping and odorless The TOLOCO insects trap is currently the most safest and simplest mosquito killer. Product lacks an EPA registered establishment number
Eras Edge Ultrasonic Pest Repeller, Upgraded Electronic Pest Repellent Plug in Indoor Pest Control for Insects, Mosquito, Mouse, Cockroaches, Rats, Bug, Spider, Ant, Human & Pet Safe (Set of 4-Packs)	James a Driver (FBA)	B083DRFC22 B083DRG3RS	a) b) c) d)	Produce good injuring effects on mouse, cockroach, spider, mosquitoes, insect, rat, rodent, flies, ant, fleas and more pests.  Indoor Pest Control for Insects, Mosquito, Mouse, Cockroaches, Rats, Bug, Spider, Ant This time the machine began to work, and watch the pests go away!  Just plug it in - effectively chases away pests in home or office	a) b) c) d) e)	More Safe for Child & Pets:Our pest repeller is safer than traditional mosquito repellents. Ultrasonic sound is inaudible to humans and household pets, environmental friendly alternative to dangerous poisons and Sprayers, chemicals and traps, no bad smell and Corpses.  Human & Pet Safe The ultrasonic Pest Repellent is effective for an area up to 8001200 Square feet simple to use and safe around family and most reject household pets Product lacks an EPA registered establishment number
Frigidaire High 70 Pints-Per-Day Portable Dehumidifier with SpaceWise Design for Effective and Efficient Moisture Control, FAD704DWD, Fit for Use in any Damp Spaces in the Home, White	Amazon (Amazon)	B00AU7GZXE	a) b)	This dehumidifier quietly removes excess moisture from the air, preventing mold and mildew The benefits of this dehumidifier go beyond moisture removal thanks to the washable mesh filter that cleans the air of dust and allergens, reduces bacteria, and freshens the air Design for Effective and Efficient Moisture Control	a)	This dehumidifier quietly removes excess moisture from the air, preventing mold and mildew, keeping your family safe and healthy

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			d)	Protects your home from mold and		
			- \	mildew caused by excess moisture		
			e)	Protects your home from mold and mildew caused by excess moisture		
				illidew caused by excess moisture		
Indoor: Bug, Fruit Fly,	INLASK-US	B083LSZDWT	a)	Bug, Fruit Fly, Gnat, Mosquito Killer	a)	Child and Kids (sic) Safe
Gnat, Mosquito Killer -	(FBA)	B083LTHK92	b)	Muliple powe traps - the UV light	b)	Safe for Pets and Kids
Child and Kids Safe -	, , ,	B083LTJ393		attcts the fruit fly, gnat, or mouito, the	c)	Non-Toxic
No Zapper - Non-Toxic		B083LSVS6Q		fa sucks it in, espe pvention funnel	d)	Family Safe
(Grey)				stops bugs from geing out (sic)	e)	Chemical Free
			c)	INLASK inect trap (sic)	f)	Product lacks an EPA registered
						establishment number
UV Light Sanitizer Box-	8 Joy My Home	B086WRYSG5	a)	Sanitizer Box	a)	No liquid, heat or chemical is used in
Cell Phone UV Light	(FBA)		b)	Multi-Function Sterilizer		cell phone cleaners, so it's safe to
Sanitizer Box-Cell			c)	The phone cleaner can provide 360 °		sanitize anything that will fit inside!
Phone Cleaner UV Light				protection, it can sterilize anything	b)	Multi-Function Sterilizer
Sanitizer Box for				even hidden microorganisms in	c)	UV sterilization box is great electronic
Cellphone, Jewelry,				crevices that even cleaning wipes can't		cleaner for cell phones up to 7 inches
Credit Card, Watch,			10	reach	d)	Safe Protection: cell phone box
Keys-USB Charge-			d)	UV light sanitizer box can sanitize any		effectively sterilize any home personal
Aromatherapy				devices in 5 minutes		items, while is safe to the human body
			e)	Phone Cleaner: iphone disinfector fits	-)	when using precautions
			f)	all phones below 7 inches Sterilization	e)	It is now more needed than ever to stay safe and be protected
			1)	Stermzation	f)	Keep the entire family safe from
					1)	illnesses and deadly infections
					g)	This iphone cleaner will be a great gift
					g)	for your parents, kids or friend to keep
						them safe.
					h)	Harmless
					11/	
UV Light Sanitizer	59S Official	B0861BK9LQ	a)	20pcs UVC & 100% OZONE FREE-	a)	Enjoy a healthier life with less germs
Wand, Portable UVC	Store			Powered by 20 x UVC LED, disinfects		around
Light Disinfector Lamp	(FBA)			and eliminates up to 99.9% of germs,	b)	Side Effect – none
Chargable Foldable for				viruses and bacteria	c)	UVC LED Handheld Sterilizer
Home Hotel Travel Car			b)	Disinfection Wand made your life	d)	Sterilization rate: up to 99.9%
Kills 99% of Germs				easier with a simple press and scan	e)	Convenience, Safe, Effective
Viruses & Bacteria 59S			c)	UVC LED Handheld Sterilizer	f)	Sterilization for Travel & Hotel

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UV Light Sanitizer Ultraviolet Light Wand UVC Disinfector Timing Lamp Portable Sterilizer Rechargeable for Hotel Household Wardrobe Toilet Car Pet Area	GAKUS (FBA)	B08CRGVLHQ B08CRKQRJK	d) e) a) b) c) d)	Sterilization for Travel & Hotel Sterilization rate: up to 99.9%  EFFICIENT STERILIZATION Anti-germ Rate 99.9% This uv wand has 3 Disinfection Timing sets: 5 minutes, 10 minutes, 15 minutes This sanitizer wand uses latest UV-C LED technology ,which reproduces the UV-C light using LED beads to	a) b)	EFFICIENT STERILIZATION This sanitizer wand uses latest UV-C LED technology ,which reproduces the UV-C light using LED beads to provide a 100% clean environment and energy efficient disinfection Timing and Smart Display Function for Sterilization
LIVINO Portable UV Wand Sanitizer Machine, Handheld UV Light Sanitizer for Household and Travel. UV Light Sterilizer Wand Disinfects Phones, Toys, Wardrobe and Baby Items [Trade Mark Registered]	AutumnFall (FBS)	B089WCGB4Z	e) a) b) c) d)	provide a 100% clean environment and energy efficient disinfection UV-C UV Disinfector Wand – Powerful sterilization  UV Light Sanitizer UV light disinfection kills the germ from 95% to 99% in just 20 seconds UVC Wand: lightweight handheld UV light Sterilizer wand and portable design, you can take it with you anywhere and keep you and your family healthy and protected from germs UV Lights Disinfect germs and allows you to avoid the usage of chemical base traditional fluids on body and objects Remove bacteria, yeasts with-in a seconds (sic)	a) a) b)	Safe without Chemical UV-C UV Disinfector Wand – Powerful sterilization  UVC Wand: lightweight handheld UV light Sterilizer wand and portable design, you can take it with you anywhere and keep you and your family healthy and protected from germs UV Light Sterilizer is made up of premium plastic having a manageable size of 10.5 x 1.49 inches It is a super strong LED ultraviolet light that is non-toxic and harmless
HISAN Effective UV Light Sanitizer & Sterilizer   Portable USB Rechargeable Led UV Light, Automatic Timer UV Sanitizer Wand for Grocery Bags,	HISAN Co. (FBA)	B08743PWNV	a) b) c)	Proven certified technology kills 99.99% of germs It can sterilize cell phones, iPads, toothbrushes, toilets, toys, pillows and much more Professionally designed for household disinfection	a) b)	Certified Anti-germ [EPA EST: NO.95138-CHN-1] It can sterilize cell phones, iPads, toothbrushes, toilets, toys, pillows and much more Whether at home or on a trip, it will make sure that you stay in a clean and

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Cellphones, Baby Toys, Boxes, Door knobs, Toilet			<ul> <li>d) Proven Effective UV Light Sanitizer</li> <li>e) Sterilization rate up to 99.9%</li> <li>f) Not only disinfecting and sterilizing, but safety (sic) to use</li> <li>g) UV sanitizer light is a powerful and comprehensive disinfection device.</li> </ul>	safe place to avoid getting sick d) The uv sterilizer light are FCC, CE, RoHs certified, not only proven works for disinfecting and sanitizing, but safety in use e) This UV light will protect you from harmful bacteria and viruses that are surfacing the casino f) Sterilization rate up to 99.9% g) Not only disinfecting and sterilizing, but safety (sic) to use
LED UV Sterilizer Box Ultraviolet Light Bacteria Sanitizer Cosmetic Cleaning Tool Kid Pacifiers Toy Cleaner Toothbrush Nail Beauty Salon Art Makeup Equipment Phone Disinfectant	UV-POD (FBA)	B07DYFPGTV	<ul> <li>a) LED UV Sterilizer Box Ultraviolet Light Bacteria Sanitizer Cosmetic Cleaning Tool</li> <li>b) ALL-PURPOSE STERILIZER BOX</li> <li>c) This salon quality sterilizing box can be used for nails as well as baby pacifiers, small toys, keys, glasses, mobile devices, hearing aids and personal items</li> <li>d) Using the UV POD UV-C light storage box to help sterilize tools &amp; accessories can help reduce the spread of germs, bacteria and impurities.</li> <li>e) 99.99% Sterilization Rate</li> <li>f) One-Tough Sterilization in a Portable Box</li> <li>g) UV-C Light Sterilizer</li> </ul>	<ul> <li>a) LED UV Sterilizer Box</li> <li>b) ALL-PURPOSE STERILIZER BOX</li> <li>c) This salon quality sterilizing box can be used for nails as well as baby pacifiers, small toys, keys, glasses, mobile devices, hearing aids and personal items</li> <li>d) Using the UV POD UV-C light storage box to help sterilize tools &amp; accessories can help reduce the spread of germs, bacteria and impurities.</li> <li>e) That's why we created the UV POD LED Sterilization Box that helps you quickly and easily protect against antisepsis with powerful and safe UV-C light</li> <li>f) Safe and Eco-Friendly</li> <li>g) 99.99% Sterilization Rate</li> <li>h) One-Tough Sterilization in a Portable Box</li> <li>i) UV-C Light Sterilizer</li> </ul>
Cell Phone Wireless Charger, Marnana Portable Cell Phone Case with USB Charger, Multi-Use Smartphone Box for iPhone Android	MOBNAS (FBS)	B07X54YM93	a) UV Phone Sterilizer	<ul> <li>a) Protect your phone within 15 minutes, helps you stay healthy</li> <li>b) Stay Healthy - Have you thought how dirty your phone is? Marnana phone wireless charger is designed to thoroughly protect your phone and</li> </ul>

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## Case 3:24NcVHI MOST TEREOFFICAM AZONICOM/SERVICES GEL 116 of 281 Stop Sale, Use, or Removal Order Docket No. FIFRA-10-2020-0102 First Amended Attachment A

Mobile Phone Jewelry Keys  UV Phone Sanitizer Wireless Charger Cell Phone Cleaner UV Light Sterilizer Smartphone Charging Station Disinfection Box Aromatherapy Function for iOS Android Device, Watches, Masks, Keys	Yillc (FBA)	B08BR2V2YV	<ul> <li>a) UV Phone Sanitizer</li> <li>b) UV Light Sterilizer</li> <li>c) Disinfection Box</li> <li>d) Germicidal UV light eliminating germs and bacteria up to 99.99% without harmful heat, liquids or chemicals</li> <li>e) The UV-C light can get to the microorganisms that hide in crevices where even cleaning wipes can't reach,</li> </ul>	helps you stay healthy c) UV Phone Sterilizer a) UV Light Sterilizer b) Protect yourself and those closest to you by sanitizing your phone regularly c) Safe and Effective d) Safely kill up to 99.99% of germs and bacteria with UV light in less than 8 minutes e) Just plug it into the USB cable, put the items into the internal chamber, close the lid, then press and hold the button
			neutralizes harmful bacteria and viruses that other phone cleaners can't kill  f) Just plug it into the USB cable, put the items into the internal chamber, close the lid, then press and hold the button for one second to start sterilizing  g) Your things can be grem-free and fragrantly refreshed from the essential oil of your choice	for one second to start sterilizing f) Safely disinfect your cell phone, watch, keys, jewelry, wallets, eyeglasses, credit cards and more
UV Light Sanitizer   UV Sterilizer Box   Sterilizes in Minutes with No Cleaning Required   Touch Screen Control   for Babies & The Whole Family	EVLA'S (FBA)	B07W7HSDPZ	<ul> <li>a) LARGE UV STERILIZER BOX – Keep Your FAMILY SECURE and HEALTHY with Our Large UV Sterilizer in Your Own Home</li> <li>b) STERILIZES IN JUST 11 MINUTES – Keys, Phones, Credit Cards, Work Passes are Sterilized in Just 11 Minutes</li> <li>c) Sterilize your essentials in minutes</li> </ul>	<ul> <li>a) Sterilizes in Minutes with No         Cleaning Required</li> <li>b) for Babies &amp; The Whole Family</li> <li>c) LARGE UV STERILIZER BOX –         Keep Your FAMILY SECURE and         HEALTHY with Our Large UV         Sterilizer in Your Own Home</li> <li>d) Independently tested for safety and         effectiveness</li> </ul>
UV Light sanitizer Box with Aromatherapy Function for iOS Android Mobile Phone Jewelry Toothbrush Watch - Black	MONIGE (FBA)	B086JYX47G	<ul> <li>a) UV Light sanitizer Box</li> <li>b) Mobile phone sanitizer box with double upgrade 253.7nm UV wavelength light can kill up to 99.99% of unhealthy things for your devices</li> </ul>	<ul> <li>a) It does work when you close it down. It can keep you safe</li> <li>b) And in this particular period of time, just let this cell phone cleaning box keep your safe everyday</li> <li>c) Multi-function Sterilization Box</li> </ul>

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			c) There are some protruding points for holding up your stuff so that the bad thing on the back can be killed. d) This cell phone sanitizer has a 6.6*3.5*0.87 inches inner space e) This ultraviolet sanitizer machine is designed with USB charging port to be compatible with 5V/2A chargers. f) Many researches show that the upgrade DOUBLE 253.7nm UV WAVELENGTH LIGHT is most effective to kill the bad things in daily life g) Multi-function Sterilization Box
Eccomum Baby Bottle Sterilizer and Dryer, LED Touch Screen, 360° Steam Disinf tion & Drying, Super Large Capacity, HEPA Filter, Homemade Dried Fruit	fashioni (FBA)	B07T2R43MB	a) Eccomum Baby Bottle Sterilizer and Dryer  b) 360° Steam Disinf tion & Drying c) This machine is highly steam steri lized by high temperature circulating steam, which can kill 99.9% of harmful substances; drying simultaneously d) This machine combines multiple functions into one: Steri-lizer&Drying/Drying/ Steri-lizer/ e) 360° Disinfection Without Dead Ends f) Sterilize & Dry More Throughly g) HEPA Filtration: PM2.5, Dust, Germ
59S UV Light Sanitizer Box, Large Size UV- Clean Sterilizing Bag, 24 LEDs UVC Light Box for Cell P hone/ Wallet/Toys/Beauty Tools/Tableware/Bottle/ Clothes	59S Official Store (FBS)	B08CXKYCG7	a) 59S UV Light Sanitizer Box b) Clean Sterilizing Bag c) Efficient Sterilization: Built-in 24 high energy UV LEDs, cover wavelength 260-280nm, can be thoroughly disinfected in 3 minutes with a sterilization rate of 99.9%  a) Professional Disinfect: 59S UV light sanitizer bag has obtained EPA filing (EPA Est: No.95175-CHN-1), SGS sterilization test and FDA certificate b) Safe Sanitizing: Highly reflective inner surface with UVC lamps up and down, real sterilization without dead ends c) 59S, The Pioneer of LED Sterilization

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			n)	Safe Sanitizing: Highly reflective inner surface with UVC lamps up and down, real sterilization without dead ends 59S, The Pioneer of LED Sterilization Sterilization rate: up to 99.9% Quick Disinfection to kill 99.99% of Bacteria Disinfect with 59S Just UVC LED Sterilization! Eliminates 99.99% Germs & Bacteria in 3 Minutes Disinfect Underwear Regularly Killing rate (%) 99.999 P55 UV LED Sterilizer Bag Kills 99.99% Germs Viruses & Bacteria	d) e) f) g) h) i) j) k)	59S, design and develop uv based disinfection solutions for families and healthcare environment Join the 59S family and experience the difference of healthier life Sterilization rate: up to 99.9% 3 Sets for epidemic prevention Just UVC LED Sterilization! Disinfect Underwear Regularly – Give women one more protection to prevent female diseases Create a Healthy Life and Eliminate Harmful Bacteria Disinfect your phone regularly to prevent virus protection Killing rate (%) 99.999
Ultra Violet Wand Sanitizing Light Wand UV Sterilizer Wand UV Light Germicidal Germ Wand UV Light Wand UV Germ Killer	GSNOW Direct (FBA)	B0892ZCY44	a) b) c) d) e)	Ultra Violet Wand Sanitizing Light Wand UV Sterilizer Wand UV Light Germicidal Germ Wand According to the approved laboratory research, the ultraviolet disinfection stick can kill 99.99% of harmful substance Ultraviolet Germicidal Irradiation (UVGI) is a shortwave light that removes 99.9% of microorganisms and bacteria - all without the health hazards of harsh chemicals.	a) b) c) d)	UV Sterilizer Wand 10s FAST STERILIZATION Turn on the UV light, simply sweep the UV light wand across the surface or stuff you desire to clean, it makes the environment safe and clean in 9 seconds without damaging any surface, makes non-toxic, no residue, no odor, no secondary pollution Ultraviolet Germicidal Irradiation (UVGI) is a shortwave light that removes 99.9% of microorganisms and bacteria - all without the health hazards of harsh chemicals. Our UV-C light wand adopted the selected ABS material and advanced led light beads to ensure obvious clean effect and durable LED UV Lamp lifespan more than 10,000+ hours, proven works for effective cleaning, and safety in use

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Ultrawand - UV Light Sanitizer Wand for Rooms, Homes, Travel, Face Covers, Phones   254 nm Ultraviolet Wavelength UVC Lamp Bulb Germicidal Sterilizer (1-Year Warranty)	Hygea Direct (FBA)	B085KSPXGF	b) c) d) e) f) g)	Ultrawand - UV Light Sanitizer Wand for Rooms, Homes, Travel, Face Covers, Phones Germicidal Sterilizer CLEANS THOROUGHLY: 254nm UV wavelength is lab-tested to fight against harmful organisms The Ultrawand is a UV Light Sanitizer and Sterilizer that utilizes UVC light to fight against harmful organisms UV Sanitizer For Packages UV Sterilizer for Masks UV Germicidal Wand For Doors UV Sanitizer For Phones	a) b) c) d) e) f)	Germicidal Sterilizer Lamp The Ultrawand is a UV Light Sanitizer and Sterilizer that utilizes UVC light to fight against harmful organism UV Sterilizer for Masks You can safely use the wand over all sides of the package and be confident it is safe to pick up and open within a few minutes! You can feel confident about reusing the masks you've purchased when sterilizing with the Ultrawand, just hover the wand over each side of the mask for a minute to remove harmful organisms! Create a global healing center of cleanliness around you, wherever you are.
JJ CARE Premium UV Wand Sanitizer, UV Sterilizer Wand, UVC Wand for 99.9% Sterilization, Sanitizing Wand for Travel or Home Use, Handheld UV Light Wand Powered by Adapter or Batteries	JJ CARE (FBA)	B085FWV6BM	b) c) d) e) f) g)	JJ CARE Premium UV Wand Sanitizer UV Sterilizer Wand UVC Wand for 99.9% Sterilization Sanitizing Wand for Travel or Home Use UVC DISINFECTION IN MINUTES - The Handheld UV Wand does a good job cleaning in such little time. Always bring the light wand for disinfection on-the-go. STERILIZING MUST-HAVE MULTI-SURFACE STERILIZING - Inside the home, the JJ CARE portable sterilizer wand can be used in the kitchen, living room, bedroom and virtually anywhere inside the house PROTABLE STERILIZER – Sterolize anytime, anywhere	a) b) c) d) e)	UV Sterilizer Wand UVC Wand for 99.9% Sterilization SAFE AND EFFECTIVE - Using this UV Cleaner Wand is absolutely safe, no chemicals (and chemical smells) involved! STERILIZING MUST-HAVE MULTI-SURFACE STERILIZING - Inside the home, the JJ CARE portable sterilizer wand can be used in the kitchen, living room, bedroom and virtually anywhere inside the house PROTABLE STERILIZER – Sterolize anytime, anywhere DISINFECT IN SECONDS
AA Aquarium Green	VerSure	B0051C62IQ	a)	AA Aquarium Green Killing Machine	a)	Green Killing Machine

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Killing Machine 3 Watt   Internal UV Sterilizer System with Power	(FBA) One Way Pet (FBA)	B001KP9B2W B002ZVODP0	b) Internal UV Sterilizer System with Power Head c) Kills Algae, Bacteria, and Waterborne b) Internal UV Sterilizer System with Power Head c) Safety Tested internal UV kit – Be
Head   Kills Algae, Bacteria, and Waterborne Pathogens   Easy, Submersible Installation  [9 and 24-Watt versions are available]	Sweetner (FBA)		Pathogens d) GKM makes fighting green water easier. UV light rays are effective in controlling free flowing bacteria, yeast, molds and other pathogens, in turn clearing up green water or cloudiness without any chemicals  When you need to control the bacteria in your fish tank and want to safely eliminate algae, improve clarity, and keep fish healthy, you need the AA Aquarium Green Killing Machine f) Adds life to your environment
Aquatop PF40-UV Hang-On Filter with UV Sterilization	Cellar_Doors_B ooks (Zentra LLC) (FBA)	B005G03ZQU	<ul> <li>a) Aquatop PF40-UV Hang-On Filter with UV Sterilization</li> <li>b) The industry's first hang-on filter with integrated U.V. Sterilization</li> <li>c) The UV Sterilizer of the PFUV-40 helps eliminate unwanted algae blooms, keeping aquarium water crystal clear and aids in the health of your aquatic creatures by eradicating free-floating parasites</li> <li>a) Aquatop PF40-UV Hang-On Filter with UV Sterilization</li> <li>b) The UV Sterilizer of the PFUV-40 helps eliminate unwanted algae blooms, keeping aquarium water crystal clear and aids in the health of your aquatic creatures by eradicating free-floating parasites</li> </ul>
AquaTop In-Line UV Sterilizer 10W - IL10UV	TAG Supplies (FBS)	B005HJYXNO	<ul> <li>a) AquaTop In-Line UV Sterilizer</li> <li>b) AQUATOP'S IL-UV Series clarifies and sterilizes aquarium water, providing clear and healthy water so your aquatic creatures to thrive</li> <li>c) The UV sterilizer will keep your aquarium fish tank water clean and reduce cleaning time</li> <li>d) Water traveling through the IL-UV Series is exposed to UV-C light, known as germicidal- grade UV light</li> <li>a) AquaTop In-Line UV Sterilizer and sterilizes aquarium water, providing clear and healthy water so your aquatic creatures to thrive</li> <li>c) The UV sterilizer will keep your aquarium fish tank water clean and reduce cleaning time</li> </ul>
Jebao UV Clarifier Sterilizer for Aquarium	Amazon.com	B00JDTXHI6	a) Jebao UV Clarifier Sterilizer for Aquarium Fish Pond Fountain a) Jebao UV Clarifier Sterilizer for Aquarium Fish Pond Fountain

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Fish Pond Fountain			b) c) d)	Tackle heavy pond algae blooms with safe, cleansing ultraviolet light Powerful UV clarifier keeps pond or aquarium water clean and "green free" UV light effectively destroys unsightly green pond water algae	b)	Tackle heavy pond algae blooms with safe, cleansing ultraviolet light
Killer's Instinct Outdoors JUP-01 9W UV Sterilizer Submersible Filter UV Sterilizer for Aquarium and Tank Aquarium UV Sterilizer Green Killing Machine Water Fliter Green Killing Machine That Work	Killer's Instinct Outdoors (FBA)	B0865TBM1N	a) b) c) d) e)	Killer's Instinct Outdoors JUP-01 9W UV Sterilizer Submersible Filter UV Sterilizer for Aquarium and Tank Aquarium UV Sterilizer Green Killing Machine Water Fliter SIMPLE AND EFFECTIVE - UV control of harmful microorganisms & free-floating algae Built-in pump directs waterborne organisms past the UV-C lamp for clean, clear aquarium water This amazing JUP-01 submersible UV sterilizer allows simple and effective UV control of harmful microorganisms & free-floating alga	a) b) c)	Killer's Instinct Outdoors JUP-01 9W UV Sterilizer Submersible Filter UV Sterilizer for Aquarium and Tank Aquarium UV Sterilizer This amazing JUP-01 submersible UV sterilizer allows simple and effective UV control of harmful microorganisms & free-floating alga
Aquarium Lights 13W, Anntuk Submersible Fish Tank Light Aquarium Clean Light with Timer,Aquarium Water Clean Green Clear Waterproof Clean Lamp for Pond,Swimming Pool,Indoor	Jingshang (FBA)	B087Y6WLMN	a) b) c) d) e) f) g) h) i)	Water Purification For the disinfection work of others, it is recommended to AIR PURIFICATION Instructions: within 200 square feet, this product can be used for 30 minutes to achieve sterilization effect (the light area is the disinfection area) After bacteria absorb ultraviolet ray, cause DNA strand to break Kill the biological activity of nucleic acid and kill bacteria Mold spores algae bacteria virus [crossed out] UV Sterilizer for aquarium Purified Green Algae Bloom	a) b)	Instructions: within 200 square feet, this product can be used for 30 minutes to achieve sterilization effect (the light area is the disinfection area) UV Sterilizer for aquarium

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Daily necessities Ultrasonic Watch, IP67 Waterproof Smart	High Section (FBS) KSTEE	B08961N2W6 B086YM8FT7	a) b) c)	Physical mosquito repellent USB mosquito repellent bracelet Mosquito repellent implanted with 6	a)	The bracelet has an automatic frequency conversion function, making it unable to adapt to the
Electronic Bracelet with USB Rechargeable, Reusable Electronic Wristbands for Adults and Children	(FBS)		d)	kinds of biological sound waves, mosquito repellent is more effective Intelligent chip superimposed circulation drive, efficient mosquito repellent		constantly changing sound wave frequency, so as to achieve the driving effect, without worrying about the impact on the human body, no odor, silent and no radiation, available for
					b)	the whole family Significant effect, more suitable for infants and young children, even
					c)	pregnant women and pets can be used Safe and non-toxic: This smart bracelet can work on 6 kinds of biological wave conversion frequency, which is harmless to the safety of human life
					d)	The high-quality, skin-friendly silicone bracelet is very comfortable, non-toxic and safe.
					e)	Pure physical, not chemical drugs, safer, more environmentally friendly, safer and healthier.
					f)	The elderly, children, pregnant women and pets can wear it
					g) h)	It can protect loved ones from harm Save sound waves, can not affect normal life
					i) j)	Physical mosquito repellent is better Using silicone, health and environmental protection, comfortable
Panow Ultrasonic	pannow	B0882NVCW1	a)	Panow Ultrasonic Mosquito Repellent	a)	Made of safe materials,
Mosquito Repellent Bracelet Rechargeable Smart Electronic	(FBA)	B0882QWBC9 B088327MPQ	b)	Bracelet	b)	environmentally friendly, non-toxic, safe, safe for children and adults Made of environmental protection
Mosquito Repellent Watch Wristband Band for Adult Children with			c)	The wristband uses high-frequency, incredible sound waves to protect you	c)	material, deet-free & non- toxic, environmentally friendly [Image of a sleeping infant wearing

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Clock Function				from mosquito bites no matter where you are The mosquito repellent bracelet can be worn on the wrist, you can connect it to the backpack, the stroller for more convenience Effective for driving mosquitoes, both children and adults can use it, whether you are indoors, camping, fishing, sports, barbecue, barbecue, barbecue is very suitable for your comfortable summer experience		the mosquito repellent bracelet]
FADZECO Ultrasonic Mosquito Repellent Bracelet - Electronic Mosquito Repeller Wristband Suitable for Adults, Children Indoors and Outdoors	FADZWECO CLOTHING (FBA) CecilisSz (FBS)	B07V1LYRTF B0896V9KH8	b) c) d) e)	FADZECO Ultrasonic Mosquito Repellent Bracelet Electronic Mosquito Repeller Wristband Wristband uses high frequency, unobtrusive soundwaves to create a SONIC BARRIER that protects you from mosquito bites wherever you are pure physical repellent Efficiently drive 90% of mosquitoes Simulate specific sound frequencies to drive mosquitoes	a) b) c) d) e) f)	and no radiation

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						enjoy while preventing more insects
Ewer 2 Pack Ultrasonic Mosquito Repellent Bracelet for Kids Adults, Electronic Anti Mosquito Bracelet Wristband with USB Charging Cable, Non- Toxic & Waterproof, Perfect for Indoor Outdoor Protection	Zacchaeu (FBS) Gallop (FBS) Steady inc (FBS) HUGEPA1 (FBS)	B07T6J6G8F B086MGR4MZ B07X6D743N B0881L5GH8	a) b) c) d) e) f)	Ewer 2 Pack Ultrasonic Mosquito Repellent Bracelet Electronic Anti Mosquito Bracelet Wristband with USB Charging Cable Our ultrasonic mosquito repellent bracelets are reusable, providing convenience and saving money for you Perfect for Indoor Outdoor Protection Effective against mosquitoes and other annoying insects Whether you are camping, fishing, hiking, running or shopping, our smart wristband is the best mosquito repellent 70% DECREASE in mosquito bites	a) b) c) d)	Safe Enough: Use ultrasonic and physical methods to achieve mosquito repellent purposes, no chemical additives, no noise and no odor, completely safe to the old, pregnant women, kids and pets.  HARMLESSNESS by sound and frequency [Image of a sleeping infant wearing the mosquito repellent bracelet] Free radiation-free and no chemicals completely eco-friendly and healthy
Ultrasonic Mosquito Repellent Bracelets, Reusable Portable Electronic Mosquito Repellent Wristband Band,Rechargeable,eco Friendly,Available for Infant and Pregnant Women	JUAN220 (FBS) greencountrysid e (FBS) Pannow (FBS)	B085NZ1C7L B087TVDZLV B0882TBZGT	a) b) c) d)	Ultrasonic Mosquito Repellent Bracelets Reusable Portable Electronic Mosquito Repellent Wristband Band Ultrasonic Mosquito Repellent Bracelets: 2020 latest technology smart electronic mosquito repellent wristband band, unobtrusive ultrasonic to create a sonic barrier that protects you from mosquito bites wherever you are! The Principle Of Mosquito Repellent: the bracelet rings to imitate the sounds that female mosquitoes hate, such as the sound of male mosquitoes and cockroaches, to achieve mosquito repellent effect Product Features: pure physical mosquito repellent	a) b) c) d)	eco Friendly, Available for Infant and Pregnant Women Product Features: pure physical mosquito repellent, not chemical drugs to repel mosquitoes, safer, more environmentally friendly, more assured, healthier Old people, children, even pregnant women and pets can be worn for seaside, park, camping, hiking, fishing and more intelligent electronic mosquito repellent bracelet, unobtrusive ultrasound, creating a sound barrier, physical principle repellent, not chemical repellent, safer, more environmentally friendly, more assured, healthier, elderly, children, and Pets can be worn Safety Mosquito Bracelet - Made of safe materials, environmentally

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ZFRANC Ultrasonic Mosquito Repellent Bracelet with Clock Function Rechargeable Smart Electronic Watch Wristband Band for Adult Children	zhenFran (FBS)	B08833JHQ8	<ul> <li>a) ZFRANC Ultrasonic Mosquito Repellent Bracelet</li> <li>b) POWERFUL WRISTBAND: Wristband uses high frequency, unobtrusive sound-waves to create a sonic barrier that protects you from mosquito bites wherever you are</li> <li>c) The bracelet can effectively drive away 70% of mosquitoes by imitating the sounds of insect</li> <li>d) Efficiently drive 70%-80% of mosquitoes</li> <li>e) Effective driving mosquitoes, children and adults can use, whether you are indoors, camping, fishing, hiking, doing sports, barbecue are very suitable, give you a comfortable summer</li> </ul>	friendly, non-toxic, safe, safe for children and adults. Whether you are indoors or outdoors, our mosquito repellent bracelet protects you from mosquitoes  a) Physical mosquito repellent environmental health b) Naturally Non-Toxic And Pollution-Free c) Pure physical mosquito repellent, not chemical drugs to repel mosquitoes, safer, more environmentally friendly, more assured, healthier d) [Image of a sleeping infant wearing the mosquito repellent bracelet]
Mosquito Repellent Bracelets for Kids, Electronic Ultrasonic Anti Mosquito Repeller Watch for Babies, Adults, Indoor or Outdoor Protection	Youliwj( Goo d Quality and Cheap) (FBS)	B07RPZHLCW	<ul> <li>a) Mosquito Repellent Bracelets for Kids</li> <li>b) Electronic Ultrasonic Anti Mosquito Repeller Watch for Babies, Adults, Indoor or Outdoor Protection</li> <li>c) anti mosquito travel anti mosquito home anti mosquito bracelet waterproof anti mosquito button</li> <li>d) Efficacy: Mosquito repellent, insect repellent, salamander repellent, rat repellent</li> <li>e) can eliminate mosquitoes</li> <li>f) Watch mosquito repellent repellent devices repellent bracelet</li> </ul>	a) Electronic Ultrasonic Anti Mosquito Repeller Watch for Babies b) anti mosquito candle c) anti mosquito net for door anti mosquito curtau (sic) anti mosquito detergent anti mosquito pants toddler anti mosquito garden anti mosquito pants mosquito repellent candle for lantern mosquito repellent wipes for kids mosquito repellent coils mosquito outdoor killer mosquito bulb mosquito net hammock mosquito killer lamp indoor anti mosquito soap anti mosquito spray d) anti mosquito spray for kids anti

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				mosquito wipes anti mosquito light bulb anti mosquito buckle anti mosquito for baby anti mosquito device for babies anti mosquito plant seeds anti mosquito granules anti mosquito keychain mosquito repellent for kids organic mosquito repellent wipes bulk mosquito outdoor candle mosquito outdoor cordless mosquito net for car seat anti mosquito stick anti mosquito window screen an  e) can eliminate mosquitoes, at the same time non-toxic, no need to disinfect, safe for children and babies, can relax and enjoy, while preventing more insects! can eliminate mosquitoes, at the same time non-toxic, no need to disinfect, safe for children and babies, can relax and enjoy, while preventing more insects! safe for children and babies, can relax and enjoy, while preventing more insects!  f) repellent stickers repellent travel size spray electric bug repellent plug indoor insect repellent spray repellent granules mosquito repellent for kids mosquito repellent stickers off repellent deep woods repellent baby ultrasonic repellent electronic repellent lotion repellent repellent electronic repellent torches repellent wipes individually wrapped repellent devices insect repellent baby repellent air freshener repellent
lRICE-sport Portable Outdoor Non-Toxic Ultrasonic Electronic	IWEING (FBS) Industry9688	B07TMB1DSN B07TB5ZBVW B0869DC8SB	a) lRICE-sport Portable Outdoor Non- Toxic Ultrasonic Electronic Mosquito Repellent	a) IRICE-sport Portable Outdoor Non- Toxic Ultrasonic Electronic Mosquito Repellent

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Mosquito Repellent Mosquito Repellent Bracelet Wristband	(FBS) TRAINWER SECRET (FBS)		b) Mosquito Repellent Bracelet Wristband c) The bracelet works by mimicking the unwanted sounds of female mosquitoes, such as those of males and dragonflies d) Pure physical mosquito repellent e) Effectively driving mosquitoes, can be used by the whole family f) Mosquito Repellent Bracelet  b) Pure physical mosquito repellent, no chemical additives, no radiation, nontoxic safer and more environmental (sic) friendly c) Smaller than a watch, it guarantees your safety without disappointing you d) Features: Portable, Non-toxic, Anti-Mosquito e) Simultaneous non-toxic, no need for disinfection, safe for children and babies, can relax and enjoy while preventing more insects
CONRAL IP67 Waterproof Intelligent Mosquito Repellent Bracelet, Ultrasonic and Biological Waves Technology Insects Repeller Wristband, USB Rechargeable Battery, Non Toxic, for Kids and Adults,Black	Car && Outdoor (FBA)	B07RC8FGVD	a) CONRAL IP67 Waterproof Intelligent Mosquito Repellent Bracelet b) Ultrasonic and Biological Waves Technology Insects Repeller Wristband c) BATTERY OPERATED MOSQUITO INSECT REPELLENT BRACELET: Experience innovation; get enhanced protection against mosquitoes, insect and bugs d) First of its kind in the world, this bracelet uses the advanced technology of ultrasonic and simulated biological waves to keep away mosquitoes, insect and flies from you and your loved ones  a) Non Toxic b) SAFE AND NON-TOXIC: This smart and intelligent mosquito repellent bracelet works on 6 biological waves conversion frequencies safe and harmless to human life c) High quality and skin-friendly silicone body of the mosquito and insect repellent bracelet is very comfortable, non-toxic and safe
A&Dan Electronic Ultrasonic Mosquito Repellent Wristband, Electronic Mosquito Repellent Ultrasonic Mosquito Repellent Wristband	baofu123	B07D33JN4G	a) A&Dan Electronic Ultrasonic Mosquito Repellent Wristband b) Electronic Mosquito Repellent c) Ultrasonic Mosquito Repellent Wristband d) 70% DECREASE in mosquito bites  a) Non-toxic - This sonic wristband prevents mosquitoes from biting without producing harmful chemicals, odors or smoke b) HARMLESSNESS by sound and frequency c) [Image of a sleeping infant wearing the mosquito repellent bracelet]

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Trapbedbugs Bed Interceptors - Bed Traps and Detecto Bed 8 Pack - Bug Detector Trap Sys for Beds - Climb I Prevention Interce Cups - No Pesticic Chemicals Or Pow White	bug warehouse rs for s tem Up pptor des,	B073Z6R44W B074QVXKJP B07FP5WPZB B07FCW5VX2	a) b) c) d)	Trapbedbugs Bed Bug Interceptors - Bedbug Traps Climb Up Prevention Interceptor Cups - No Pesticides, Chemicals Or Powder PROTECT YOURSELF, YOUR KIDS & YOUR LOVED ONES: Now you can finally prevent insect infestations and say goodbye to those itchy bites with the Trapbedbugs ultimate bed bug traps and detectors 8- pack! TURN YOUR BED INTO A BUG- FREE FORTRESS: Our convenient, universal and durable climb up bed bug interceptors are ideal for your bed, sofa, crib, dresser, upholstered chair, armchair or office desk! PREVENT MAJOR INFESTATION & SAVE MONEY: You can easily monitor if you have bed bugs with our interceptor cups for bed bugs, which will help prevent bed bug infestations and costly bug treatment	a) b) c) d) e) f) g) h)	UNLIKE ALL THOSE CHEAPLY-MADE BED BUG TRAPS Eco-Friendly Bed Bug Interceptor What you need is a set of rugged interception cups for bed bugs that will not only trap bed bugs, but also keep you and your family safe! Better Safe Than Sorry Bedbug monitors are eco-friendly Kid And Pet Safe No Chemicals [No EPA Establishment Number]
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<sup>\*</sup> The claims presented in these columns are not necessarily exhaustive. The product labeling may contain additional pesticidal claims and/or false and misleading claims.

EDWARD
KOWALSKI
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Edward J. Kowalski, Director

Enforcement and Compliance Assurance Division

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Date

The gold standard in gravity-fed water filtration. Berkey® systems equipped with Black Berkey® Elements made from our proprietary blend of media are backed by independent third-party testing, and are capable of greater contaminant reduction and a longer lifespan than virtually any of the other filtration elements on the market.

tion Systems





Enjoy Kerresning, rotable Water in the Great Outdoors

Filter raw freshwater sources like lakes, streams and ponds.

Berkey+ systems equipped with Black Berkey® Elements remove or dramatically reduce typical contaminants found in freshwater sources such as viruses, pathogenic bacteria, protozoa, heavy metals, VOCs, perfluorinated chemicals, pesticides,

Economical and long lasting, authentic Black Berkey® Elements will help you enjoy delicious, refreshing water every day for just pennies a gallon!

Berkey\* gravity-fed water systems are portable, powerful and easy to use.

- 1. Simply pour untreated water from freshwater source into system's top
- 2. Berkey\* systems equipped with powerful Black Berkey\* Elements address 200+ potential
- 3. Dispense refreshing potable water from spigot. Berkey\* systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.



Ready for adventure! Take your Berkey' system along in your RV, or set it up at the campsite



# Travel Berkey® 1.5 GALLON (5.6L)



# Berkey Water Filtration Systems









Travel Berkey® 1.5 GALLON (5.6L)

**Travel Berkey**\* **System** 

1.5 GALLON (5.6L)

Exhibit B-13, pg.1 of 81













FILTERS

Berkey

Berkey® systems equipped with Black Berkey® Elements made from our proprietary blend of media are backed by independent third-party testing, and are capable of greater contaminant reduction and a longer lifespan than virtually any of the other filtration elements on the market.

# ion Systems





ne Gold Standard in Gravity-Fed Water iltration Systems.

Berkey\* systems equipped with Black Berkey\* Elements remove or dramatically reduce typical contaminants found in tap water and reshwater sources such as viruses, pathogenic bacteria, protozoa, heavy metals, VOCs, perfluorinated chemicals, pesticides, rust, silt, pharmaceuticals and more

Economical and long lasting authentic Black Berkey® Elements will help you enjoy delicious, refreshing water every day for just pennies a gallon!

#### Easily Enjoy Refreshing, Potable Water at Home or in the Great Outdoors

- Simply pour untreated water from freshwater source into system's top
- 2. Berkey\* systems equipped with powerful Black Berkey\* Elements address 200+ potential
- . Dispense refreshing potable water from spigot. Berkey\* systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

Exhibit B, pg. 129 of 280



Big Berkey<sup>®</sup> 2.25 GALLON (8.5L)



### **Berkey\* Water Filtration Systems**









Big Berkey<sup>®</sup> 2.25 GALLON (8.5L)

**Big Berkey**\* System

2.25 GALLON (8.5L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.

Berkey











MULTI-USE SYSTEMS

FIITERED



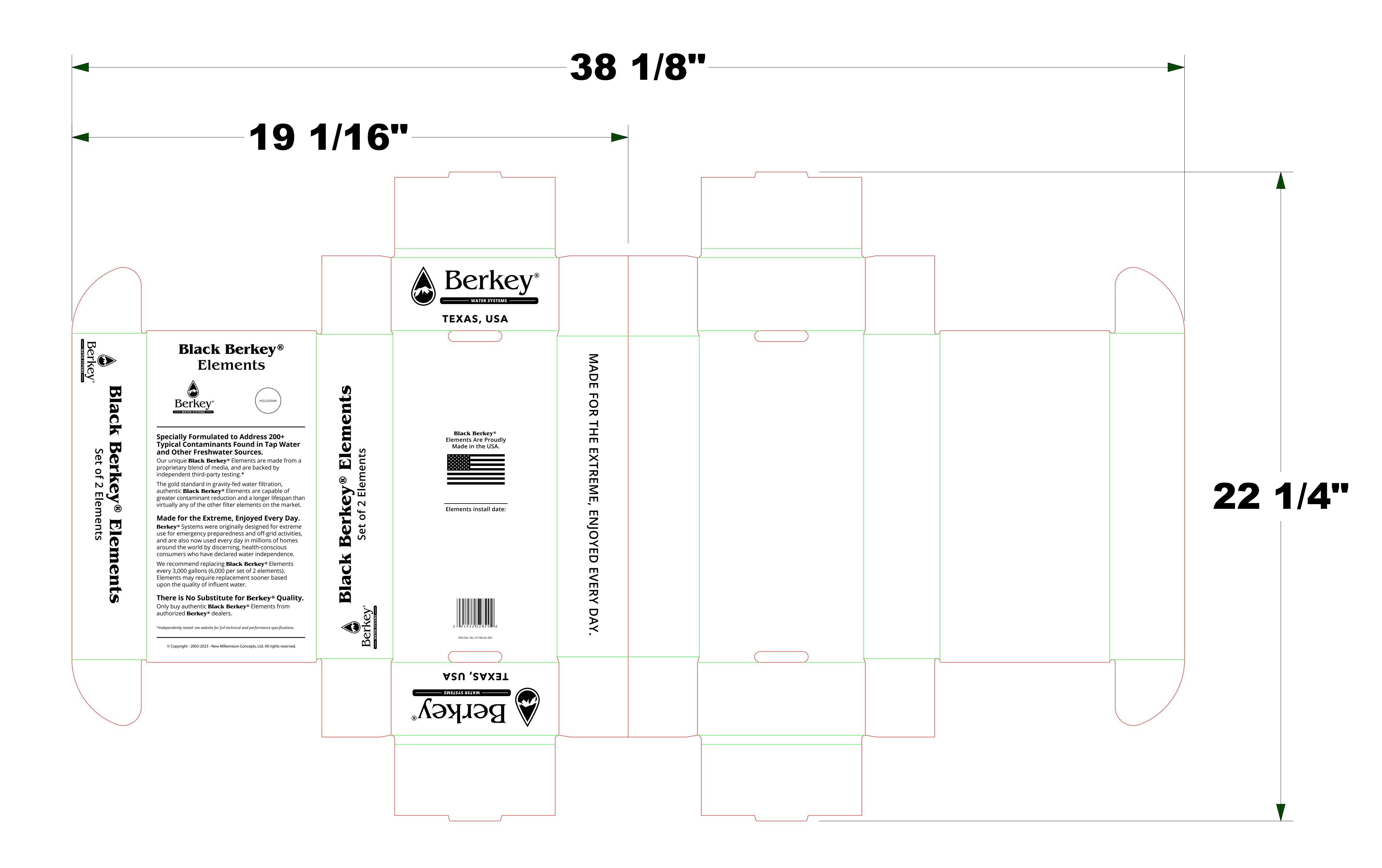
PURIFIED THE NATURAL WAY













# Travel Berkey® System 1.5 GALLON (5.6L)

### Berkey® Water Filtration Systems













## Berkey® Water Filtration Systems









Travel Berkey®
1.5 GALLON (5.6L)

THE POWERFUL POTABLE WATER SOLUTION FOR

# **Enjoy Refreshing, Potable Water** in the Great Outdoors

Filter raw freshwater sources like lakes, streams and ponds.

The gold standard in gravity-fed water filtration systems, **Berkey**® systems provide economical, long-lasting water filtration for just pennies a gallon! **Berkey**® systems are portable, powerful and easy to use.

#### No electricity, tools or plumbing required.

- 1. Simply pour untreated water from freshwater source into system's top chamber.
- 2. **Berkey**® systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water and freshwater sources.
- 3. Dispense refreshing potable water from spigot. **Berkey**® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

\*Independently tested: see website for full technical and performance specifications.

### MADE FOR THE EXTREME. ENJOYED EVERY DAY.





**Ready for adventure!** Take your **Berkey**\* system along in your RV, or set it up at the campsite.

Believ

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS

Berkey<sup>®</sup>

Kit 1 Qt

Berkey<sup>®</sup>

1.5 Gal

Berkey® Bottle

MULTI-USE SYSTEMS

Berkey<sup>®</sup>

4.5 Gal

Berkey™

CAMPING, RVING AND OTHER OFF-GRID ADVENTURES.

R

K

Berkey<sup>®</sup>

3.25 Gal

Berkey<sup>®</sup>

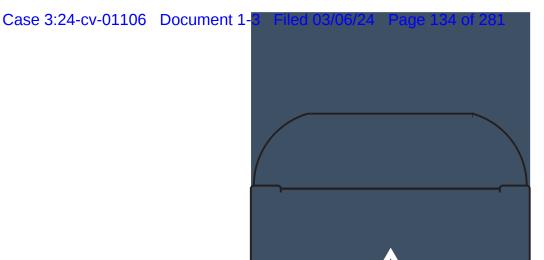
2.25 Gal

R

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### **Sport Berkey**®

**Berkey**® Water Systems, the leader in gravity-fed filtration systems and trusted choice of adventurers, preppers, off-grid homesteaders and families for over 20 years, brings you the **Sport Berkey**® water filter bottle.

#### Versatile, Easy to Use



Daily at home, work or school



Off-grid: remote lakes, ponds, streams



Traveling abroad



Emergencies

### **More Outdoor Water Solutions Available**

Contact an authorized **Berkey**° dealer today.





BPA FREE



#### **Superior Reduction**

The **Sport Berkey**® water filter bottle has been tested by multiple independent third-party labs\* for its ability to remove or reduce 200+ typical contaminants found in tap water and other freshwater sources such as lakes, ponds and streams.



Mechanically extracts waterborne pathogens

Test results showed up to a 99.9% reduction for other typical contaminants found in water, such as:

- Heavy metals Herbicides
- Pesticides Pharmaceuticals
- Organic chemicalsPetroleum-based products
- Unpleasant tastes, odors
- Silt and sediment

#### **Replaceable Filter**

Filter replacement is recommended after 160 refills for untreated water, or 640 refills for tap water.

\*Independently tested: see website for full technical and performance specifications.



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### **Sport Berkey**®



0

m

FILTER

22 OZ.

.6 L

### GREAT OUTDOORS

Berkey® Water On-the-Go







# Big Berkey® System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems









The Gold Standard in





0









Big Berkey® 2.25 GALLON (8.5L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.



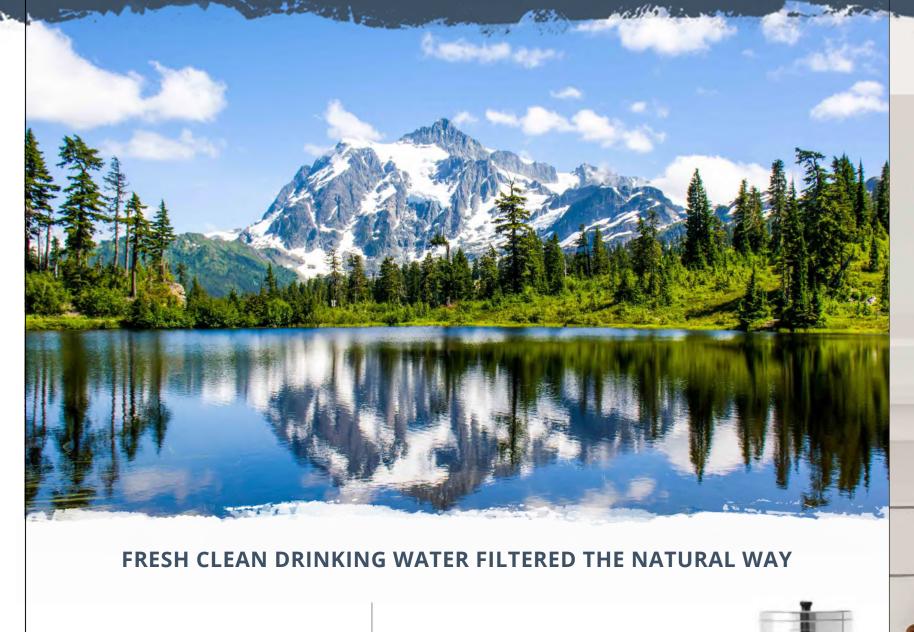
FILTER FRESHWATER SOURCES LIKE LAKES, STREAMS, PONDS

NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

- freshwater source into system's top chamber.
- 2. **Berkey**<sup>®</sup> systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water and
- . Dispense refreshing potable water from spigot. **Berkey**® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

\*Independently tested: see website for full technical and performance specifications.













Crown Berkey™ 6 Gaľ 4.5 Gal

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

OUTDOOR SYSTEMS MULTI-USE SYSTEMS

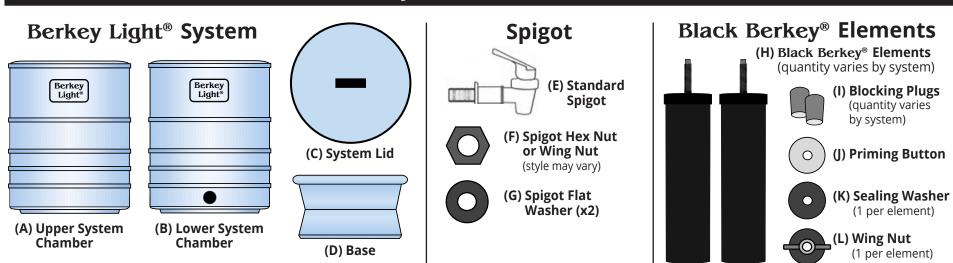
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# Instructions for the **Berkey Light®** gravity-fed water filtration system

#### **System Parts List**



Parts shown for illustration only and are not to scale.

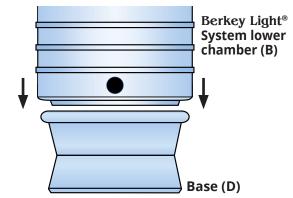
Failure to read, thoroughly understand, and follow all instructions may result in injury, water damage, or voiding of the warranty! It is the assembler's responsibility to make sure all components are properly assembled and installed using the instructions provided. While your **Berkey®** System should not have any leaking problems, there is always the chance that a leak might occur due to being improperly assembled or perhaps a faulty part. In an overabundance of caution, we recommend that for the first 24 hours the filled system be placed in an area wherein if such a leak were to occur, the resulting spillage would not damage anything.

#### **System Assembly**

We recommend setting up your system on a countertop or other waterproof surface.

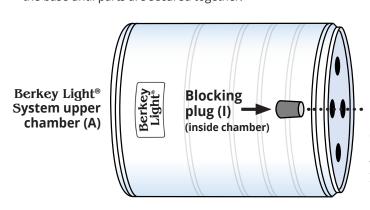
- Wash your hands, upper and lower chambers, and spigot before assembly to reduce the chances of contaminating the system's components.
- Be sure to keep all parts and original packaging in the unlikely event that your system needs to be returned to the manufacturer.

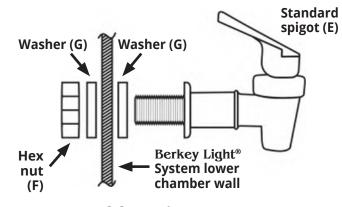




#### 1. Place Lower Chamber on Base

Place base on a flat, stable surface. Carefully place empty lower system chamber onto base. Press lower chamber down onto the base until parts are secured together.





#### 2. Assemble Spigot

To assure a proper seal, place one washer on stem of spigot. Insert spigot into system and turn spigot counterclockwise to the 9 o'clock position. Then, place the other washer on stem inside of the system, then the nut, and hand-turn nut until it is tight while holding spigot at the 9 o'clock position. Then, hold nut in place and rotate spigot clockwise until spigot is upright. This action should apply the right amount of pressure to complete the seal.

#### 3. Insert Blocking Plugs

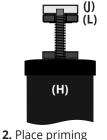
Use blocking plugs to fill the remaining open holes in the upper chamber where you will <u>not</u> be installing **Black Berkey®** Elements. Press plugs into holes from inside the upper chamber, smaller end first.

#### 4. Prime the Black Berkey® Elements

Priming uses water to displace air out of the elements' pores, ensuring that water can flow freely. **Elements will not operate properly if they are not primed.**We recommend setting up your system on a countertop or other waterproof surface. If process dust is present, wipe it off with a Scotch-Brite® pad under cold running water.



1. Loosen wing nut (L) on Black Berkey® Element (H) stem until the top of wing nut (L) reaches the top of stem's threads (about 1/8" from top end of stem).



2. Place priming button (J) on top of wing nut. Top of priming button should be slightly higher than the top of the stem.



3. Place the threaded stem of element between fingers, and press priming button up against faucet.



4. Slowly turn on cold water (gradually increasing water pressure) while holding element and priming button firmly against faucet to create a seal, allowing water to saturate element.



5. As water pushes air out of element, allow element to sweat beads of water for 10-20 seconds. Water may be discolored at first, as excess media exits element. Continue running water until it runs clear, and the entire element appears to be saturated.

The element is now primed and ready for installation. Repeat steps 1-5 at left for your remaining elements.

**Tip:** Your **Black Berkey**® Elements will be wet after priming them—we recommend placing your elements in a clean bowl or sink while assembling the rest of your system.

#### Questions About Using or Assembling Your Berkey Light® System?

Instructional Videos • Product FAQs • Support Via Email or Live Chat **support.berkeywater.com** 

Phone: (888) 803-4438 Monday - Friday 9AM - 5PM CST Holiday hours may vary.

# 5. Install Primed Elements and Place Upper Chamber on Lower Chamber

- 1. Remove wing nut from threaded stem while leaving sealing washer on **Black Berkey**® Element.
- 2. Place threaded stem, with sealing washer attached, into the hole in the interior base of upper chamber.
- 3. Secure element in the base of the chamber by screwing wing nut onto threaded mount until hand-tight. Caution: hand tighten only. Over-tightening wing nut can strip the nut's threads, which could cause the system to leak. Repeat these 3 steps for remaining elements.
- 4. Please remember to plug unused holes in the upper chamber with included blocking plugs.
- 5. Carefully place upper chamber with primed elements on lower chamber, and press into place.
- 6. System is now assembled and ready to use.

# Black Berkey® Sealing washer (K) Pight Sealing washer (K) Wing nut (L)

#### Alternate/Off-Grid Priming Methods

When using the system off-grid or traveling where treated water is not available, we strongly recommend using the **Black Berkey Primer™** (sold separately), a handheld priming pump that makes the elements easy to prime without the need for faucets or hose connections. **Black Berkey Primers™** are available from Authorized **Berkey®** Dealers worldwide.

Black Berkey® Elements may also be primed using a bottle of filtered water. Have one person hold the element, with the priming button attached and facing upward. Have a second person press the mouth of the bottled water against the priming button and squeeze until water is forced through entire exterior wall of element and it begins to sweat beads of water.

#### Using Your Berkey Light® System

upper chamber (A)

Always use only the cleanest freshwater source available. **Use of softened water or salt water can clog** the filter's pores and will void your warranty.

Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc.

- 1. Fill upper chamber with cold or room temperature water. **DO NOT use hot or boiling water.** Only fill upper chamber with as much water as the lower chamber can hold. **Overfilling system could cause lower chamber to overflow.**
- 2. Place lid on system. Allow water to filter into lower chamber.
- 3. Open the spigot to completely empty the lower chamber, and discard water. If water is slightly discolored due to any remaining particulate, do not be concerned—simply repeat steps 1-3 in this section as many times as needed until dispensed water is clear.
- 4. Your system is now ready to use. Refill upper chamber with water.

#### Notes:

- Water may begin to drip immediately when upper chamber is filled, but could take as long as 15 minutes based on how well elements are primed and the quality of influent water used.
- Maximum flow rate will be achieved after the initial 12-24 hours of use as micro air pockets within the elements are replaced with water.
- It is normal to have a few inches of water left in the upper chamber when using the system, as it is gravity fed and the water cannot process through the bottom of the element.
- Air hole on rim of lower chamber prevents vapor lock.

#### **Assembly Verification\* (Red Food Coloring Test)**

This simple test verifies that your system has been assembled correctly, and that there are no internal leaks in your system. We recommend this test be done after the first assembly of this system, after removal or replacement of **Black Berkey®** Elements, or the first use after drying and storing the elements for an extended period of time. **Ensure that you do not have Berkey PF-2™ Fluoride and Arsenic Reduction Elements installed in the system when performing this test.** 

- 1. Add up to 1 teaspoon of artificial <u>red</u> food coloring (must be red) for every gallon that your **Berkey®** System can hold into the upper chamber. We recommend McCormick's red food coloring or any <u>artificial</u> food coloring. Acceptable food color ingredients include water, propylene glycol, FD&C Red 40 and FD&C Red 3, and propylparaben. **Avoid using food** coloring that is not red, or contains citric acid, sodium benzoate or natural ingredients such beet juice, turmeric, etc. Using organic food colorings will result in a false failed test (stating that your system is not sealed correctly).
- 2. Place a cup under spigot and drain water. If dispensed water does not have a red or pink hue, this indicates that the elements are sealed and system has been assembled correctly.

  \*Note: This test does not demonstrate the complete reduction of all possible water contaminants; it is meant to confirm that the system was assembled as intended.

# If water drained from system has a red or pink hue during the assembly verification test, repeat the procedure again in this manner to determine the source of the leak:

- 1. Place the <u>upper system chamber only</u> (with **Black Berkey®** Elements installed) on top of same-sized cups or jars, each positioned so that an element can drip water into it. This will help you identify which blocking plug or element may be leaking.
- 2. Fill upper chamber with water and red food coloring as directed above.
- 3. Allow system to filter water. Check the color of water expelled from the elements. If water color is clear, your system is ready to use. If red dye is still present, reinstall the element(s) or blocking plug(s) where leaking occurs and re-run test.

  Clear water
- 4. If system continues to fail the test, contact our Customer Service department for assistance.

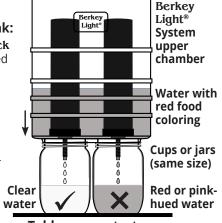


Table or countertop

#### **Precautions**

- Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc. Excessive heat can create conditions that could facilitate microbiological growth (mold, biofilm, bacteria, etc.) inside the upper chamber, where untreated (and possibly contaminated) water is poured into the system.
- When lower chamber is partially filled, be cautious not to overfill upper chamber, as this could cause lower chamber to overflow.

  For example: if the lower chamber is 1/3 full, the upper chamber can be refilled by 2/3.
- If the lower chamber is 1/2 full, the upper chamber can be refilled by 1/2, etc.
   Never allow wet Black Berkey® Elements to freeze—exposure to freezing temperatures can expand the water into ice, which may damage the elements and

# cause them to crack or break. Allowing elements to freeze will void your warranty. Black Berkey® Element Storage

If you are going to be leaving the system unattended for 4-15 days and want to reduce the necessity of re-priming the elements, remove the elements from your system and place them in a sealable plastic bag (gallon-size or larger) while elements are still damp (this allows the elements to stay wet, making priming unnecessary). Then, place the elements in your refrigerator where they will not freeze. When ready, thoroughly rinse elements under cold water, then reinstall them in your system.

For longer-term storage, we recommend completely drying the elements first. Ensuring they are bone-dry (zero moisture) before storing them long-term helps prevent any potential microbiological growth (mold, biofilm, bacteria, etc.). Shake excess water from elements, then air-dry by leaving them on a windowsill or other sunny location for 1-3 days until completely dry.

Once elements are bone-dry (zero moisture), store them in a sealable plastic bag (gallon-size or larger)—this prevents elements from absorbing odors. When you are ready to re-use your elements, clean them by scrubbing the outside with a stiff brush or a Scotch-Brite® pad under cold running water. Then re-prime the elements before putting them back in your system.

Alternatively, you can use a **Black Berkey Primer™** (sold separately) which assists in both priming and purging. Purging speeds up the drying process by pushing water out of the element before you place them in the sun or air dry to complete the process. Note: when purging, valves on the **Black Berkey Primer™** must be reversed.

#### **Maintaining Your System**

#### We recommend performing maintenance every 30 days as needed: Clean the lower chamber and spigot

- 1. Remove upper chamber (be sure to drain any water and remove optional **Berkey PF-2™** Fluoride and Arsenic Reduction Elements, if attached).
- With the Black Berkey® Elements remaining installed in the upper chamber, place upper chamber upside down or securely on its side to ensure it will not roll off of your counter or other work surface. Caution: breaking an element's stem will void its warranty.
- 3. Clean lower chamber with mild dish soap or a 1:1 mixture of water and vinegar, and rinse thoroughly.
- 4. Remove spigot and soak it in a 1:1 mixture of clean water and vinegar for 5-10 minutes to help remove any mineral deposits. Rinse spigot thoroughly.
- 5. Reattach spigot. Reinstall any optional Berkey PF-2™ Fluoride and Arsenic Reduction Elements to the stems of the system's Black Berkey® Elements. With elements in place, carefully place upper chamber onto lower chamber.

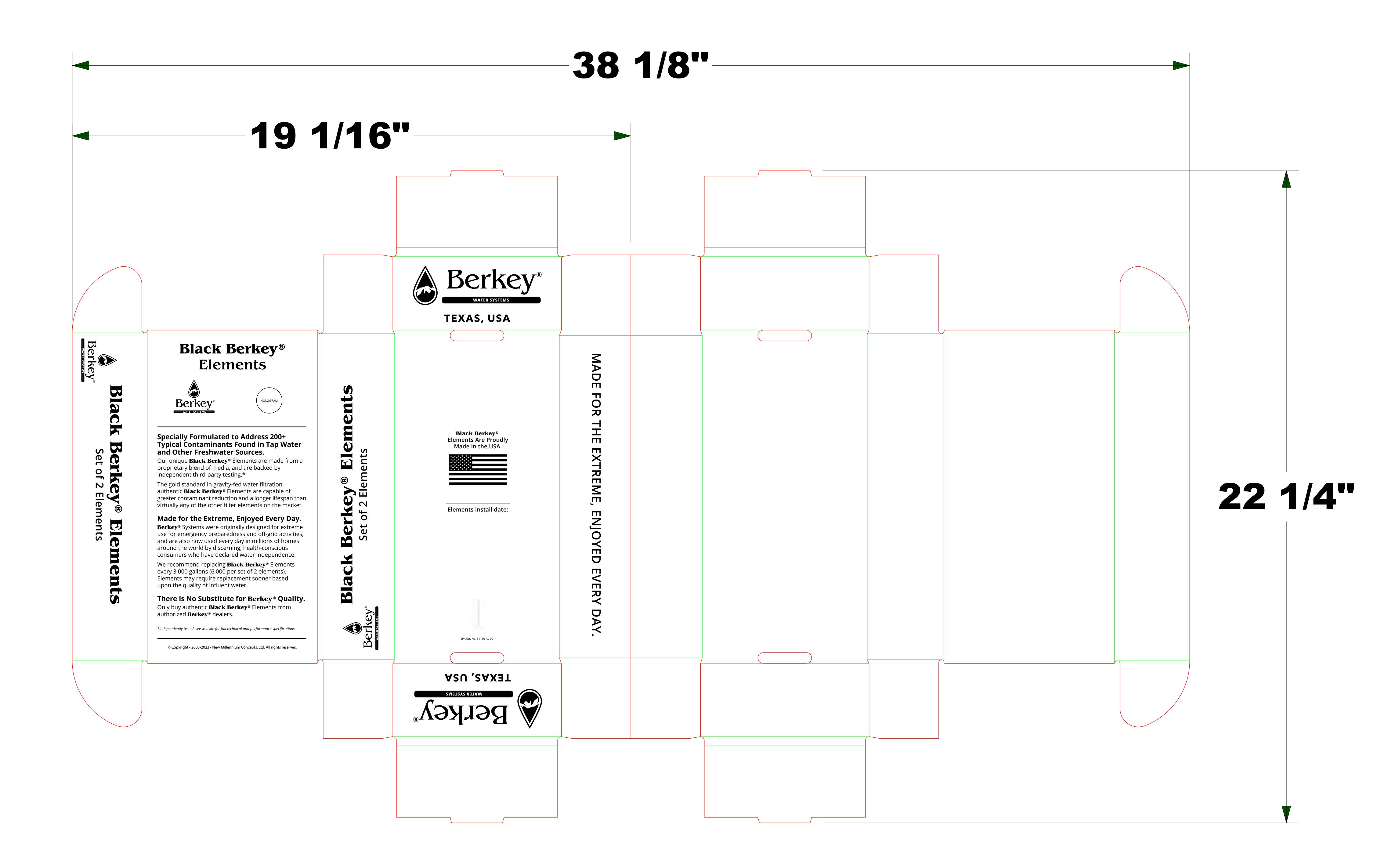
#### **System Troubleshooting**

After prolonged use, flow rate may decrease significantly. To improve flow rate:

- 1. Carefully remove the elements from the upper chamber and gently scrub them with a stiff brush or Scotch-Brite® pad under cold running water (never apply soap or other cleaning agents to your **Black Berkey**® Elements). Re-prime elements, and reinstall them inside the upper chamber.
- 2. Place upper chamber back onto lower chamber, then perform the Assembly Verification process (Red Food Coloring Test). Your system is ready to use.

New Millennium Concepts, Ltd. Limited Warranty

New Millennium Concepts, Ltd. warrants their product against defects in materials or workmanship during ordinary consumer use. This Limited Warranty does not cover product issues caused by any other reason, for the time periods and conditions set forth below when purchased directly from an Authorized Berkey® Dealer. New Millennium Concepts, Ltd. shall not be held liable for incidental or consequential damage to personal property from, but not limited to, a defective unit, improper use, abuse, accident, or neglect, etc. It is the customer's responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must be responsible to pay for any shipping charges incurred to return the product to New Millennium Concepts, Ltd. when required. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty is for the original retail purchaser only, and cannot be transferred. For a period not to exceed the specified warranty coverage from the date of receipt of the product by the original purchaser on the original invoice, New Millennium Concepts, Ltd. will, solely at its discretion, replace said product or component that New Millennium Concepts, Ltd. deems is not functioning properly during the stated warranty period. The laws of the state of Texas, USA will govern any disputes regarding this warranty or claim made. This warranty, which is given expressly in lieu of all warranties, expressed or implied, or merchantability and fitness for a particular purpose, constitutes the only warranty made by New Millennium Concepts, Ltd. This warranty applies only to products manufactured or exclusively distributed by New Millennium Concepts, Ltd. and its Authorized Berkey® Dealers. Berkey® System Housing: Berkey® System upper and lower chambers including lids, excluding orders for factory-blem





# Royal Berkey® System

3.25 GALLON (12.3L)

# Berkey® Water Filtration Systems









SURVIVAL



**Berkey**<sup>®</sup> systems provide economical, long-lasting water filtration for just pennies a gallon—no electricity, tools or plumbing required.







NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

Exhibit B, pg. 138 of 280

#### **Easily Enjoy** Refreshing, Potable Water at Home or in the Great Outdoors

- . Simply pour untreated water from freshwater source into system's top chamber.
- 2. **Berkey**<sup>®</sup> systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water and freshwater sources.
- B. Dispense refreshing potable water from spigot. **Berkey**® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

\*Independently tested: see website for full technical and performance specifications.

# Royal Berkey®

3.25 GALLON (12.3L)



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey® Water Filtration Systems









Royal Berkey®

# MADE FOR THE EXTREME. ENJOYED EVERY DAY.

3.25 GALLON (12.3L)



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS



**MULTI-USE SYSTEMS** 



Berkey<sup>®</sup>

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# Imperial Berkey® System

4.5 GALLON (17L)

# Berkey® Water Filtration Systems











# Berkey® Water Filtration Systems









# Imperial Berkey® 4.5 GALLON (17L)



FILTER FRESHWATER SOURCES LIKE LAKES, STREAMS, PONDS

NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

The Gold Standard in Gravity-Fed Water Filtration Systems

**Berkey**<sup>®</sup> systems provide economical, long-lasting water filtration for just pennies a gallon—no electricity, tools or plumbing required.



- 1. Simply pour untreated water from freshwater source into system's top chamber.
- 2. **Berkey**® systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water and freshwater sources.
- 3. Dispense refreshing potable water from spigot. **Berkey**® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

\*Independently tested: see website for full technical and performance specifications.









OUTDOOR SYSTEMS

MULTI-USE SYSTEMS



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Exhibit B, pg. 139 of 280



### Travel Berkey® System 1.5 GALLON (5.6L)

### Berkey® Water Filtration Systems



















Travel Berkey® 1.5 GALLON (5.6L)

THE POWERFUL POTABLE WATER SOLUTION FOR

# **Enjoy Refreshing, Potable Water** in the Great Outdoors

Filter raw freshwater sources like lakes, streams and ponds.

The gold standard in gravity-fed water filtration systems, **Berkey**® systems provide economical, long-lasting water filtration for just pennies a gallon! **Berkey**® systems are portable, powerful and easy to use.

#### No electricity, tools or plumbing required.

- 1. Simply pour untreated water from freshwater source into system's top chamber.
- 2. **Berkey**<sup>®</sup> systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water
- 3. Dispense refreshing potable water from spigot. **Berkey**® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use

\*Independently tested: see website for full technical and performance specifications.

#### MADE FOR THE EXTREME. ENJOYED EVERY DAY.





Ready for adventure! Take your Berkey\* system along in your RV, or set it up at the campsite.

R



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS

Berkey<sup>®</sup>

Kit 1 Qt

Berkey<sup>®</sup>

1.5 Gal

Berkey<sup>®</sup>

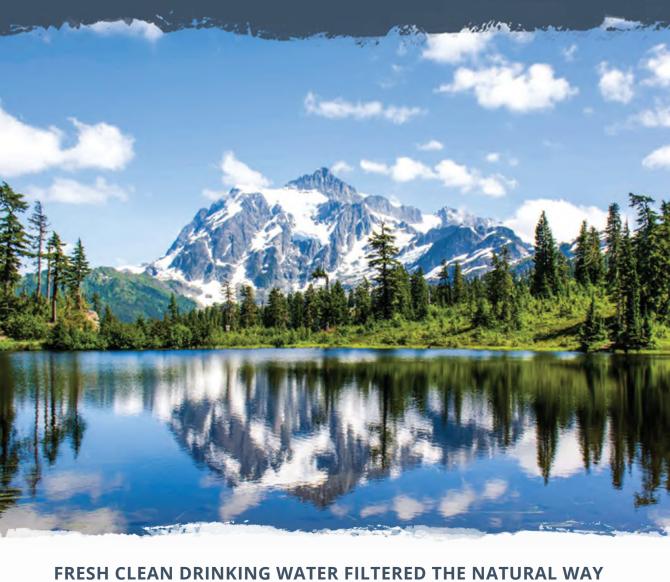
2.25 Gal

Berkey® Bottle

MULTI-USE SYSTEMS

Berkey<sup>®</sup>

4.5 Gal



**Berkey® Water Filtration Systems** 

Berkey<sup>®</sup>

3.25 Gal



R

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Berkey™

Exhibit B, pg. 140 of 280









### **Sport Berkey**®

Berkey® Water Systems, the leader in gravity-fed filtration systems and trusted choice of adventurers, preppers, off-grid homesteaders and families for over 20 years, brings you the Sport Berkey® water filter bottle.

#### Versatile, Easy to Use



Daily at home, work or school



Off-grid: remote lakes, ponds, streams



Traveling abroad



Emergencies

#### **More Outdoor Water Solutions Available**

Contact an authorized Berkey<sup>®</sup> dealer today.





**FREE** 



#### **Superior Reduction**

The **Sport Berkey**® water filter bottle has been tested by multiple independent third-party labs\* for its ability to remove or reduce 200+ typical contaminants found in tap water and other freshwater sources such as lakes, ponds and streams.



Mechanically extracts waterborne pathogens

#### **Test results showed** up to a 99.9% reduction for other typical contaminants found in water, such as:

- Heavy metals Herbicides
- Pesticides
   Pharmaceuticals
- Organic chemicals
- Petroleum-based products • Unpleasant tastes, odors
- Silt and sediment

#### **Replaceable Filter**

Filter replacement is recommended after 160 refills for untreated water, or 640 refills for tap water.

\*Independently tested: see website for full technical and performance specifications.



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### **Sport Berkey**®



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# Crown Berkey<sup>™</sup> System 6 GALLON (22.7L)

# Berkey® Water Filtration Systems













# Berkey® Water Filtration Systems

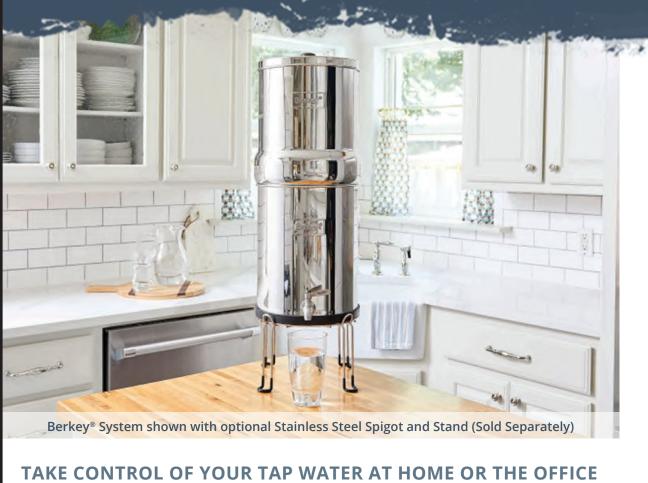








Crown Berkey<sup>TM</sup> 6 GALLON (22.7L)





ILTER FRESHWATER SOURCES LIKE LAKES, STREAMS, PONDS



NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

### The Gold Standard in **Gravity-Fed Water Filtration Systems**

**Berkey**<sup>®</sup> systems provide economical, long-lasting water filtration for just pennies a gallon—no electricity, tools or plumbing required.

### **Easily Enjoy** Refreshing, Potable Water at Home or in the Great Outdoors

- 1.Simply pour untreated water from freshwater source into system's top chamber.
- 2.**Berkey**® systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water and freshwater sources.
- 3. Dispense refreshing potable water from spigot. Berkey® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.
- \*Independently tested: see website for full technical and performance specifications.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY





OUTDOOR SYSTEMS



**MULTI-USE SYSTEMS** 



EPA EST. NO. 102008-PR-1

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Exhibit B, pg. 144 of 280



#### Instructions for Black Berkey® Elements

#### Parts List

Parts shown for illustration only and are not to scale.





(B) Sealing Washers (Set of 2)



(C) Wing Nuts (Set of 2) (D) Tan **Priming** Button

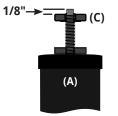
#### Priming and Installing Your Black Berkey® Elements

#### **Before You Get Started:**

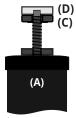
- Wash your hands before installing and priming elements to reduce the chances of contaminating the system's components.
- Keep all parts, instructions and original packaging in the event that your elements need to be returned to the manufacturer. Write the installation date in the space provided on the elements' box to serve as a reminder as to when elements need replacement.

#### 1. Prime the Black Berkey® Elements

Priming uses water to displace air out of the elements' pores, ensuring that water can flow freely. **Elements will not operate properly** if they are not primed. We recommend setting up your system on a countertop or other waterproof surface. If process dust is present, wipe it off with a Scotch-Brite® pad under cold running water.



**1.** Loosen wing nut **2.** Place tan (C) on Black Berkey® Element (A) stem until the top of wing nut (C) reaches the top of stem's threads (about 1/8" from top end of stem).

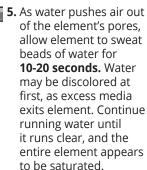


priming button (D) on top of wing nut. Top of tan priming button should be slightly higher than the top of the stem.





Tip: Your Black Berkey® Elements will be wet after priming them. We recommend placing your primed elements in a clean bowl or sink while priming and installing your other remaining Black Berkey® Elements.

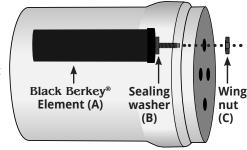


The element is now primed and ready for installation. Repeat steps 1-5 for remaining elements.

#### 2. Install Primed Elements In Your System

- 1. Remove wing nut from threaded stem while leaving sealing washer on element.
- 2. Place threaded stem, with sealing washer attached, into the hole in the interior base of upper chamber.
- 3. Secure element in the base of the chamber by screwing wing nut onto threaded mount until hand-tight. Caution: hand tighten only. Over-tightening wing nut can strip the nut's threads, which could cause the system to leak. Repeat these 3 steps for remaining elements.
- 4. With elements (and blocking plugs, if needed) in place, carefully place upper chamber onto lower chamber. Your system is ready to use.

For more information about operating your system, visit: support.berkeywater.com



Berkey® System upper chamber (A)

#### Alternate/Off-Grid Priming Methods

When using the system off-grid or traveling where treated water is not available, we strongly recommend using the Black Berkey Primer™ (sold separately), a handheld priming pump that makes the elements easy to prime without the need for faucets or hose connections. Black Berkey Primers™ are available from Authorized Berkey® Dealers worldwide.

Black Berkey® Elements may also be primed using a bottle of filtered water. Have one person hold the element, with the priming button attached and facing upward. Have a second person press the mouth of the bottled water against the priming button and squeeze until water is forced through entire exterior wall of element and it begins to sweat beads of water.

#### Questions About Installing or Using Your Black Berkey® Elements?

Instructional Videos • Product FAOs • Support Via Email or Live Chat support.berkeywater.com

Phone: (888) 803-4438 Monday - Friday 9AM - 5PM CST Holiday hours may vary.

#### Case 3:24-cv-01106 Document 1-3 Exhibit B-13, pg-147 of 281 of 81

#### 3. Assembly Verification\* (Red Food Coloring Test)

This simple test verifies that your system has been assembled correctly, and that there are no internal leaks in your system. We recommend this test be done after the first assembly of this system, after removal or replacement of Black Berkey® Elements, or the first use after drying and storing the elements for an extended period of time. Ensure that you do not have Berkey PF-2™ Fluoride and Arsenic Reduction Elements installed in the system when performing this test.

- 1. Add up to 1 teaspoon of artificial red food coloring (must be red) for every gallon that your Berkey® System can hold into the upper chamber. We recommend McCormick's red food coloring or any artificial food coloring. Acceptable food color ingredients include water, propylene glycol, FD&C Red 40 and FD&C Red 3, and propylparaben. Avoid using food coloring that is not red, or contains citric acid, sodium benzoate or natural ingredients such beet juice, turmeric, etc. Using organic food colorings will result in a false failed test (stating that your system is not sealed correctly).
- 2. Place a cup under spigot and drain water. If dispensed water does not have a red or pink hue, this indicates that the elements are sealed and system has been assembled correctly.

\*Note: This test does not demonstrate the complete reduction of all possible water contaminants; it is meant to confirm that the system was assembled as intended.

If water drained from system has a red or pink hue during the assembly verification test, repeat the procedure again in this manner to determine the source of the leak:

- 1. Place the upper system chamber only (with Black Berkey® Elements installed) on top of same-sized cups or jars, each positioned so that an element can drip water into it. This will help you identify which blocking plug or element may be leaking.
- 2. Fill upper chamber with water and red food coloring as directed above.
- 3. Allow system to filter water. Check the color of water expelled from the elements. If water color is clear, your system is ready to use. If red dye is still present, reinstall the element(s) or blocking plug(s) where leaking occurs and re-run test.
- 4. If system continues to fail the test, contact our Customer Service department for assistance.

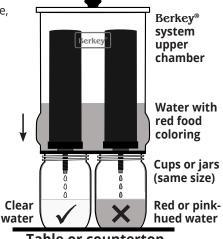


Table or countertop

#### Black Berkey® Elements Precautions and Storage

Always use only the cleanest freshwater source available. Use of softened water or salt water can clog the filter's pores and will void your warranty.

Never allow wet Black Berkey® Elements to freeze. Exposure to freezing temperatures can expand the water into ice, which may damage the elements and cause them to crack or break. Allowing elements to freeze will void your warranty.

If you are going to be leaving the system unattended for 4-15 days and want to reduce the necessity of re-priming the elements, remove the elements from your system and place them in a sealable plastic bag (gallon-size or larger) while elements are still damp (this allows the elements to stay wet, making priming unnecessary). Then, place the elements in your refrigerator where they will not freeze. When ready, thoroughly rinse elements under cold water, then reinstall them in your system.

For longer-term storage, we recommend completely drying the elements first. Ensuring they are bone-dry (zero moisture) before storing them long-term helps prevent any potential microbiological growth (mold, biofilm, bacteria, etc.). Shake excess water from elements, then air-dry by leaving them on a windowsill or other sunny location for 1-3 days until completely dry.

Once elements are bone-dry (zero moisture), store them in a sealable plastic bag (gallon-size or larger)—this prevents elements from absorbing odors. When you are ready to re-use your elements, clean them by scrubbing the outside with a stiff brush or a Scotch-Brite® pad under cold running water. Then re-prime the elements before putting them back in your system.

Alternatively, you can use a **Black Berkey Primer™** (sold separately) which assists in both priming and purging. Purging speeds up the drying process by pushing water out of the element before you place them in the sun or air dry to complete the process. Note: when purging, valves on the **Black Berkey Primer™** must be reversed.

New Millennium Concepts, Ltd. Limited Warranty
New Millennium Concepts, Ltd. warrants their product against defects in materials or workmanship during ordinary consumer use. This Limited Warranty does not cover product issues caused by any other reason, for the time periods and conditions set forth below when purchased directly from an Authorized Berkey® Dealer. New Millennium Concepts, Ltd. shall not be held liable for incidental or consequential damage to personal property from, but not limited to, a defective unit, improper use, abuse, accident, or neglect, etc. It is the customer's responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must provide a dated receipt for the product and may be responsible to pay for any shipping charges incurred to return the product to New Millennium Concepts, Ltd. when required. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty is for the original retail purchaser only, and cannot be transferred. For a period not to exceed the specified warranty coverage from the date of receipt of the product by the original purchaser on the original invoice, New Millennium Concepts, Ltd. will, solely at its discretion, replace said product or component that New Millennium Concepts, Ltd. deems is not functioning properly during the stated warranty period. The laws of the state of Texas, USA will govern any disputes regarding this warranty or claim made. This warranty, which is given expressly in lieu of all warranties, expressed or implied, or merchantability and fitness for a particular purpose, constitutes the only warranty made by New Millennium Concepts, Ltd. This warranty applies only to products manufactured or exclusively distributed by New Millennium Concepts, Ltd. and its Authorized Berkey® Dealers, and does not apply to extended warranties offered by some Authorized Berkey® Dealers. Black Berkey® Elements are covered under a two year limited prorated warranty, calculated in six-month intervals. Warranty period begins from the date of receipt of the product by the original purchaser on the original invoice.

Black Berkey® Elements have been tested by accredited third-party labs that have reported that the elements exceed EPA and ANSI/NSF (Std. 53) protocol, and remove or reduce over 200+ typical contaminants found in tap water and other freshwater sources. We recommend replacing Black Berkey® Elements every 3,000 gallons (6,000 per set of 2 elements). Elements may require replacement sooner based upon the quality of influent water.

Exhibit B, pg. 146 of 280



# Big Berkey® System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems











Big Berkey®





# Berkey® Water Filtration Systems









Big Berkey® 2.25 GALLON (8.5L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.



FILTER FRESHWATER SOURCES LIKE LAKES, STREAMS, PONDS



NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

# **Gravity-Fed Water Filtration Systems**

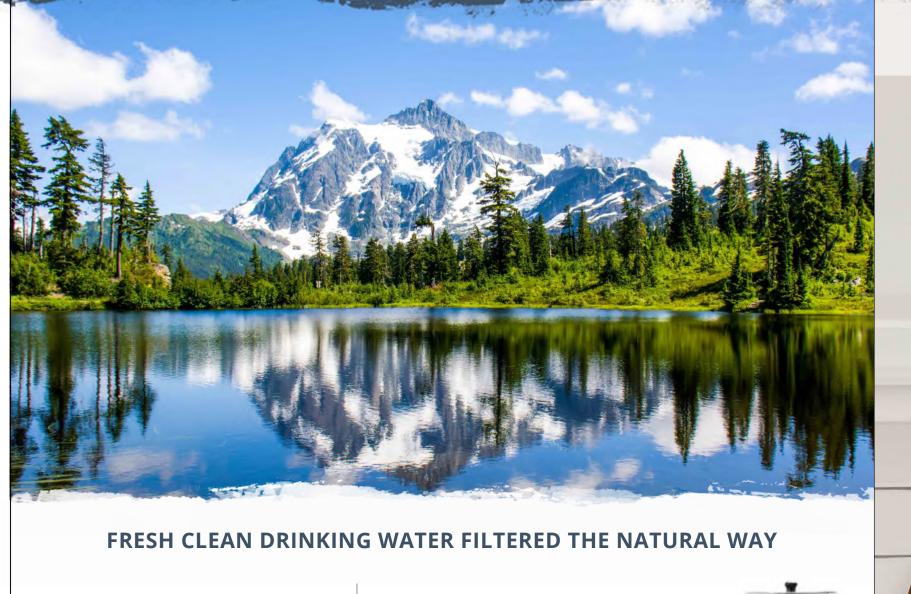
The Gold Standard in

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon—no electricity, tools or plumbing required.

#### **Easily Enjoy** Refreshing, Potable Water at Home or in the Great Outdoors

- . Simply pour untreated water from freshwater source into system's top chamber.
- 2. **Berkey**<sup>®</sup> systems have been tested by independent third-party labs\* for their ability to address 200+ potential contaminants commonly found in tap water and freshwater sources.
- . Dispense refreshing potable water from spigot. **Berkey**® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

\*Independently tested: see website for full technical and performance specifications.





OUTDOOR SYSTEMS

MULTI-USE SYSTEMS

Crown

Berkey™

6 Gal

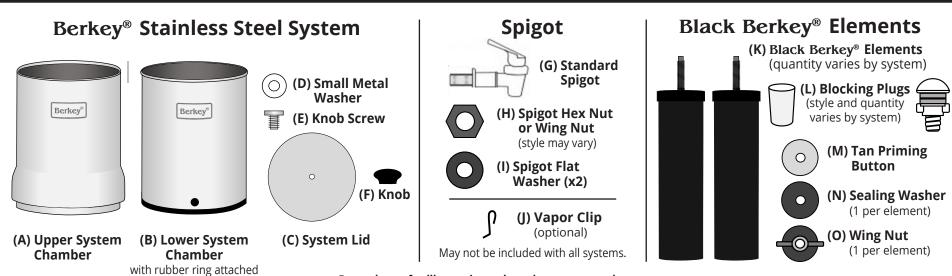


FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



Instructions for Big Berkey<sup>®</sup>, Crown Berkey<sup>™</sup>, Imperial Berkey<sup>®</sup>, Royal Berkey<sup>®</sup> and Travel Berkey<sup>®</sup> water filtration systems

#### **System Parts List**



Failure to read, thoroughly understand, and follow all instructions may result in injury, water damage, or voiding of the warranty! It is the assembler's responsibility to make sure all components are properly assembled and installed using the instructions provided. While your **Berkey**® System should not have any leaking problems, there is always the chance that a leak might occur due to being improperly assembled or perhaps a faulty part. In an overabundance of caution, we recommend that for the first 24 hours the filled system be placed in an area wherein if such a leak were to occur, the resulting spillage would not damage anything.

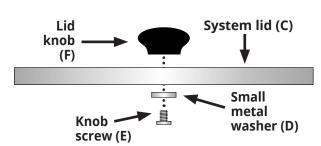
Parts shown for illustration only and are not to scale.

#### **System Assembly**

**Tools you'll need:** standard screwdriver (not included). We recommend setting up your system on a countertop or other waterproof surface.

- Wash your hands, stainless steel chambers and spigot before assembly to reduce the chances of contaminating the system's components.
- Be sure to keep all parts and original packaging in the unlikely event that your system needs to be returned to the manufacturer.

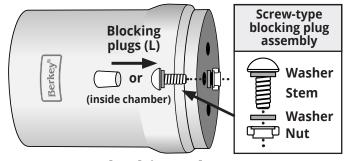




#### 1. Attach Knob to Lid

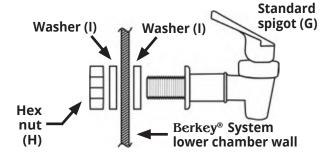
Fit knob onto lid by inserting the knob screw up through the washer into hole in the underside of lid, then screw on the knob.

#### Berkey® System upper chamber (A)



#### 3. Insert Blocking Plugs

Use blocking plugs to fill remaining open holes in the upper chamber where you will <u>not</u> be installing **Black Berkey**® Elements. **For push-in blocking plugs**, simply press plugs into holes from inside the upper chamber (smaller end first). **For screw-type blocking plugs**, place one washer on threaded stem, and insert plug (stem) through one of the holes inside the system's upper chamber. Place other washer on the threaded stem outside of system, then the nut. Hold plug securely with one hand inside system, and hand-turn nut on outside of system until snug. Do not over-tighten. Repeat for remaining plugs.



#### 2. Assemble Spigot

To assure a proper seal, place one washer on stem of spigot. Insert spigot into system and turn spigot counterclockwise to the 9 o'clock position. Then, place the other washer on stem inside of the system, then the nut, and hand-turn nut until it is tight while holding spigot at the 9 o'clock position. Then, hold nut in place and rotate spigot clockwise until spigot is upright.



lower chamber (B)

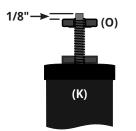
## 4. Install the Vapor Lock Clip

Climate, elevation and other factors can create a tighter fit, preventing air flow between chambers, which slows down or prevents water flow (a natural phenomenon known as vapor lock). To prevent vapor lock, create air flow by placing clip on edge of lower chamber, making sure that the long portion of the airlock clip is hanging inside of the lower chamber.

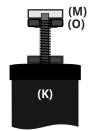
**Note:** All systems may not include a vapor lock clip. If you experience vapor lock, please contact our Customer Service department to obtain a clip. For customers outside the United States, please contact a local Authorized **Berkey®** Dealer.

#### 5. Prime the Black Berkey® Elements

Priming uses water to displace air out of the elements' pores, ensuring that water can flow freely. **Elements will not operate properly if they are not primed.**We recommend setting up your system on a countertop or other waterproof surface. If process dust is present, wipe it off with a Scotch-Brite® pad under cold running water.



1. Loosen wing nut (O) on Black Berkey® Element (K) stem until the top of wing nut (O) reaches the top of stem's threads (about 1/8" from top end of stem).



2. Place tan priming button (M) on top of wing nut. Top of tan priming button should be slightly higher than the top of the stem.



3. Place the threaded stem of element between fingers, and press tan priming button up against faucet.



4. Slowly turn on cold water (gradually increasing water pressure) while holding element and tan priming button firmly against faucet to create a seal, allowing water to saturate element.



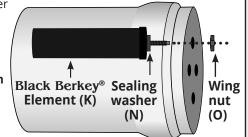
**5.** As water pushes air out of element, allow element to sweat beads of water for **10-20 seconds.** Water may be discolored at first, as excess media exits element. Continue running water until it runs clear, and the entire element appears to be saturated.

The element is now primed and ready for installation. Repeat steps 1-5 at left for your remaining elements.

**Tip:** Your **Black Berkey**® Elements will be wet after priming them—we recommend placing your elements in a clean bowl or sink while assembling the rest of your system.

#### 6. Install Primed Elements In The System

- 1. Remove wing nut from threaded stem while leaving sealing washer on Black Berkey® Element.
- 2. Place threaded stem, with sealing washer attached, into the hole in the interior base of upper chamber.
- 3. Secure element in the base of the chamber by screwing wing nut onto threaded mount until hand-tight. Caution: hand tighten only. Over-tightening wing nut can strip the nut's threads, which could cause the system to leak. Repeat these 3 steps for remaining elements.
- 4. With elements in place, carefully place upper chamber onto lower chamber. Your system is now assembled and ready to use.



Berkey® System upper chamber (A)

#### **Alternate/Off-Grid Priming Methods**

When using the system off-grid or traveling where treated water is not available, we strongly recommend using the **Black** Berkey Primer™ (sold separately), a handheld priming pump that makes the elements easy to prime without the need for faucets or hose connections. Black Berkey Primers™ are available from Authorized Berkey® Dealers worldwide.

Black Berkey® Elements may also be primed using a bottle of filtered water. Have one person hold the element, with the priming button attached and facing upward. Have a second person press the mouth of the bottled water against the priming button and squeeze until water is forced through entire exterior wall of element and it begins to sweat beads of water.

#### Using Your System

Always use only the cleanest freshwater source available. Use of softened water or salt water can clog the filter's pores and will void your warranty.

1. Fill upper chamber with cold or room temperature water. **DO NOT use hot or boiling water.** 

Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc.

- 2. Place lid on system. Allow water to filter into lower chamber.
- 3. Open the spigot to completely empty the lower chamber, and discard water. If water is slightly discolored due to any remaining particulate, do not be concerned—simply repeat steps 1-3 in this section as many times as needed until dispensed water is clear.
- 4. Your system is now ready to use. Refill upper chamber with water.

#### Notes:

- It may take up to 15 minutes for elements to begin dripping
- water from the upper chamber into the lower chamber. • Maximum flow rate will be achieved after the initial 12-24
- hours of use as micro air pockets within the elements are replaced with water.
- It is normal to have a few inches of water left in the upper chamber when using the system, as it is gravity fed and the water cannot process through the bottom of the element.

#### Assembly Verification\* (Red Food Coloring Test)

This simple test verifies that your system has been assembled correctly, and that there are no internal leaks in your system. We recommend this test be done after the first assembly of this system, after removal or replacement of Black Berkey® Elements, or the first use after drying and storing the elements for an extended period of time. Ensure that you do not have Berkey PF-2™ Fluoride and Arsenic Reduction Elements installed in the system when performing this test.

- 1. Add up to 1 teaspoon of artificial red food coloring (must be red) for every gallon that your Berkey® System can hold into the upper chamber. We recommend McCormick's red food coloring or any artificial food coloring. Acceptable food color ingredients include water, propylene glycol, FD&C Red 40 and FD&C Red 3, and propylparaben. Avoid using food coloring that is not red, or contains citric acid, sodium benzoate or natural ingredients such beet juice, turmeric, etc. Using organic food colorings will result in a false failed test (stating that your system is not sealed correctly).
- 2. Place a cup under spigot and drain water. If dispensed water does not have a red or pink hue, this indicates that the elements are sealed and system has been assembled correctly. \*Note: This test does not demonstrate the complete reduction of all possible water contaminants; it is meant to confirm that the system was assembled as intended.

#### If water drained from system has a red or pink hue during the assembly verification test, repeat the procedure again in this manner to determine the source of the leak:

- 1. Place the upper system chamber only (with Black Berkey® Elements installed) on top of same-sized cups or jars, each positioned so that an element can drip water into it. This will help you identify which blocking plug or element may be leaking.
- 2. Fill upper chamber with water and red food coloring as directed above.
- 3. Allow system to filter water. Check the color of water expelled from the elements. If water color is clear, your system is ready to use. If red dye is still present, reinstall the element(s) or blocking plug(s) where leaking occurs and re-run test.
- 4. If system continues to fail the test, contact our Customer Service department for assistance.

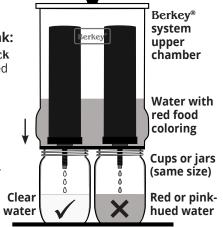


Table or countertop

#### **Precautions**

- Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc. Excessive heat can create conditions that could facilitate microbiological growth (mold, biofilm, bacteria, etc.) inside the upper chamber, where untreated (and possibly contaminated) water is poured into the system.
- When lower chamber is partially filled, be cautious not to overfill upper chamber, as this could cause lower chamber to overflow. For example: if the lower chamber is 1/3 full, the upper chamber can be refilled by 2/3. If the lower chamber is 1/2 full, the upper chamber can be refilled by 1/2, etc.
- Never allow wet Black Berkey® Elements to freeze—exposure to freezing temperatures can expand the water into ice, which may damage the elements and cause them to crack or break. Allowing elements to freeze will void your warranty.

#### **Maintaining Your System**

#### We recommend performing maintenance every 30 days as needed: Clean the lower chamber and spigot

- 1. Remove upper chamber (be sure to drain any water and remove optional Berkey PF-2™ Fluoride and Arsenic Reduction Elements, if attached).
- 2. With the Black Berkey® Elements remaining installed in the upper chamber, place upper chamber upside down or securely on its side to ensure it will not roll off of your counter or other work surface. Caution: breaking an element's stem will void its warranty.
- 3. Clean lower chamber with mild dish soap or a 1:1 mixture of water and vinegar, and rinse thoroughly.
- 4. Remove spigot and soak it in a 1:1 mixture of clean water and vinegar for 5-10 minutes to help remove any mineral deposits. Rinse spigot thoroughly.
- 5. Reattach spigot. Reinstall any optional **Berkey PF-2™** Fluoride and Arsenic Reduction Elements to the stems of the system's **Black Berkey**® Elements. With elements in place, carefully place upper chamber onto lower chamber.

#### Black Berkey® Element Storage

If you are going to be leaving the system unattended for 4-15 days and want to reduce the necessity of re-priming the elements, remove the elements from your system and place them in a sealable plastic bag (gallon-size or larger) while elements are still damp (this allows the elements to stay wet, making priming unnecessary). Then, place the elements in your refrigerator where they will not freeze. When ready, thoroughly rinse elements under cold water, then reinstall them in your system.

For longer-term storage, we recommend completely drying the elements first. Ensuring they are bone-dry (zero moisture) before storing them long-term helps prevent any potential microbiological growth (mold, biofilm, bacteria, etc.). Shake excess water from elements, then air-dry by leaving them on a windowsill or other sunny location for 1-3 days until completely dry.

Once elements are bone-dry (zero moisture), store them in a sealable plastic bag (gallon-size or larger)—this prevents elements from absorbing odors. When you are ready to re-use your elements, clean them by scrubbing the outside with a stiff brush or a Scotch-Brite® pad under cold running water. Then re-prime the elements before putting them back in your system.

Alternatively, you can use a **Black Berkey Primer™** (sold separately) which assists in both priming and purging. Purging speeds up the drying process by pushing water out of the element before you place them in the sun or air dry to complete the process. Note: when purging, valves on the **Black Berkey Primer™** must be reversed.

#### **System Troubleshooting**

#### After prolonged use, flow rate may decrease significantly. To improve flow rate:

- 1. Slow flow rate could be caused by vapor lock. Insert vapor lock clip, if supplied. See page 1, assembly step #4.
- 2. Carefully remove the elements from the upper chamber and gently scrub them with a stiff brush or Scotch-Brite® pad under cold running water (never apply soap or other cleaning agents to your Black Berkey® Elements). Re-prime elements, and reinstall them inside the upper chamber.
- 3. Place upper chamber back onto lower chamber, then perform the Assembly Verification process (Red Food Coloring Test). Your system is ready to use.

New Millennium Concepts, Ltd. Limited Warranty

New Millennium Concepts, Ltd. warrants their product against defects in materials or workmanship during ordinary consumer use. This Limited Warranty does not cover product issues caused by any other reason, for the time periods and conditions set forth below when purchased directly from an Authorized Berkey® Dealer. New Millennium Concepts, Ltd. shall not be held liable for incidental or consequential damage to personal property from, but not limited to, a defective unit, improper use, abuse, accident, or neglect, etc. It is the customer's responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty and may be responsible to pay for any chiraling charges incurred to return the product to New Millennium Concepts. Ltd. when required This warranty. responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must provide a dated receipt for the product and may be responsible to pay for any shipping charges incurred to return the product to New Millennium Concepts, Ltd. when required. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty is for the original retail purchaser only, and cannot be transferred. For a period not to exceed the specified warranty coverage from the date of receipt of the product by the original purchaser on the original invoice, New Millennium Concepts, Ltd. will, solely at its discretion, replace said product or component that New Millennium Concepts, Ltd. deems is not functioning properly during the stated warranty period. The laws of the state of Texas, USA will govern any disputes regarding this warranty or claim made. This warranty, which is given expressly in lieu of all warranties, expressed or implied, or merchantability and fitness for a particular purpose, constitutes the only warranty made by New Millennium Concepts, Ltd. This warranty applies only to products manufactured or exclusively distributed by New Millennium Concepts, Ltd. and its Authorized Berkey® Dealers, and does not apply to extended warranties offered by some Authorized Berkey® Dealers. Berkey® System Housing: Berkey® System upper and lower chambers including lids, excluding orders for factory-blemished systems, are covered under a one-year warranty. The warranty period begins from the date of receipt of the product by the original invoice. Included spigot and accessories that are sold separately are covered under a six-month warranty. The warranty period begins from the date of receipt of the product by the original purchaser on the original invoice. Included spigot and accessories that are sold separ date of receipt of the product by the original purchaser on the original invoice.

#### Questions About Using or Assembling Your Berkey® System?

Instructional Videos • Product FAQs • Support Via Email or Live Chat support.berkeywater.com

Phone: (888) 803-4438 Monday - Friday 9AM - 5PM CST Holiday hours may vary.

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# Sport Berkey® Water Filter Bottle



The **Sport Berkey**® water filter bottle has been tested by multiple independent third-party labs for its ability to remove or reduce 200+ typical contaminants found in tap water and other freshwater sources such as lakes, ponds and streams.

Test results showed up to a 99.9% reduction for typical contaminants found in water, such as: heavy metals, herbicides, pesticides, pharmaceuticals, organic chemicals, petroleum-based products, unpleasant tastes and odors, silt and sediment.

#### **Precautions**

- To prevent leaks, do not store filled bottle on its side or upside down.
- Do not allow filter to freeze.
- Do not place bottle or filter in dishwasher or microwave oven.
- Do not run hot water through filter.
- Make sure straw is clean before using. If straw is dirty, or you suspect that the outside of straw has come into contact with contaminated water, reclean straw (see cleaning instructions on next page).

#### **Specifications**

- Capacity: 22 oz. (0.6 L)
- 50 year shelf life
- Filter replacement is recommended after 160 refills of untreated water, or 640 refills of tap water.

#### **Warranty Information**

The **Sport Berkey**® water filter bottle is covered by the NMCL Limited Warranty: 6 Months. Warranty coverage begins the date product is received.

For the most up to date list of warranty exclusions, please visit: support.berkeywater.com

For support and service, visit:

support.berkeywater.com

# Usage & Storage

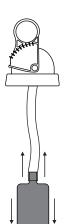
#### **IMPORTANT!** Flush Filter Before Use

Flushing clears excess carbon from the manufacturing process.

- 1. Pull lid closure down so that straw is exposed.
- 2. With bottle full of water, squeeze the bottle for 3-4 seconds to flush water through filter and straw.
- 3. Repeat until water runs clear.
- 4. Bottle is ready to use.

#### **Using Your Bottle**

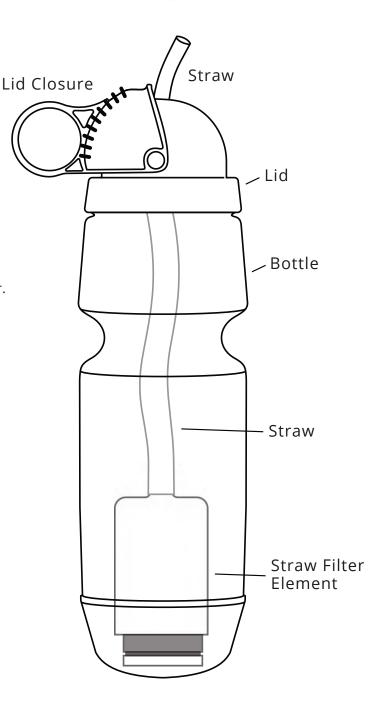
- 1. Fill the **Sport Berkey**® water filter bottle with water.
- 2. Screw on lid and tighten securely to prevent leaks.
- 3. To drink: pull lid closure down to expose straw. Squeeze bottle to squirt water out of straw into mouth, or suck water through straw, or use both actions together.
- 4. To close: simply pull lid closure up to conceal straw (this helps prevent drips or leaks while carrying).



#### Replacing the Filter

Filter replacement is recommended after 160 refills of untreated water, or 640 refills of tap water.

- 1. Unscrew lid from bottle.
- 2. Pull existing filter from straw.
- 3. Push new filter onto straw.
- 4. Flush new filter before using (see above for instructions).



#### **Cleaning and Storage**

Periodically remove straw filter element and clean the bottle and straw with warm water and mild, unscented dish soap.

#### If straw filter element will not be used for an extended period of time:

- 1. Remove filter from straw and allow to air dry.
- 2. Once filter is dry, place it back on straw inside bottle.



# Big Berkey® System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems









Big Berkey® 2.25 GALLON (8.5L)











Big Berkey® 2.25 GALLON (8.5L)





FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

#### The Gold Standard in **Gravity-Fed Water Filtration Systems**

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon—no electricity, tools or plumbing required.

#### **Easily Enjoy Refreshing Water at** Home or in the Great **Outdoors**

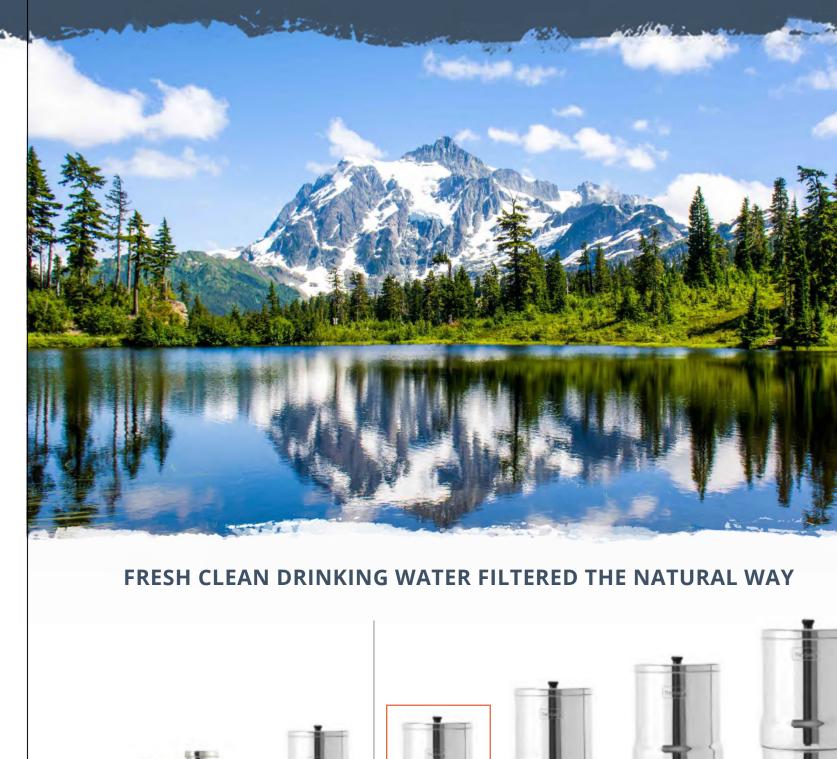
**Berkey**<sup>®</sup> systems provide economical, long-lasting water filtration for just pennies a gallon! Berkey® systems are portable, powerful and easy to use.

**Made for the Extreme, Enjoyed Every Day.** 

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS

Berkey<sup>®</sup>

Kit 1 Qt

Berkey<sup>®</sup>

1.5 Gal

Berkey<sup>®</sup>

**MULTI-USE SYSTEMS** 

Royal

Berkey<sup>®</sup>

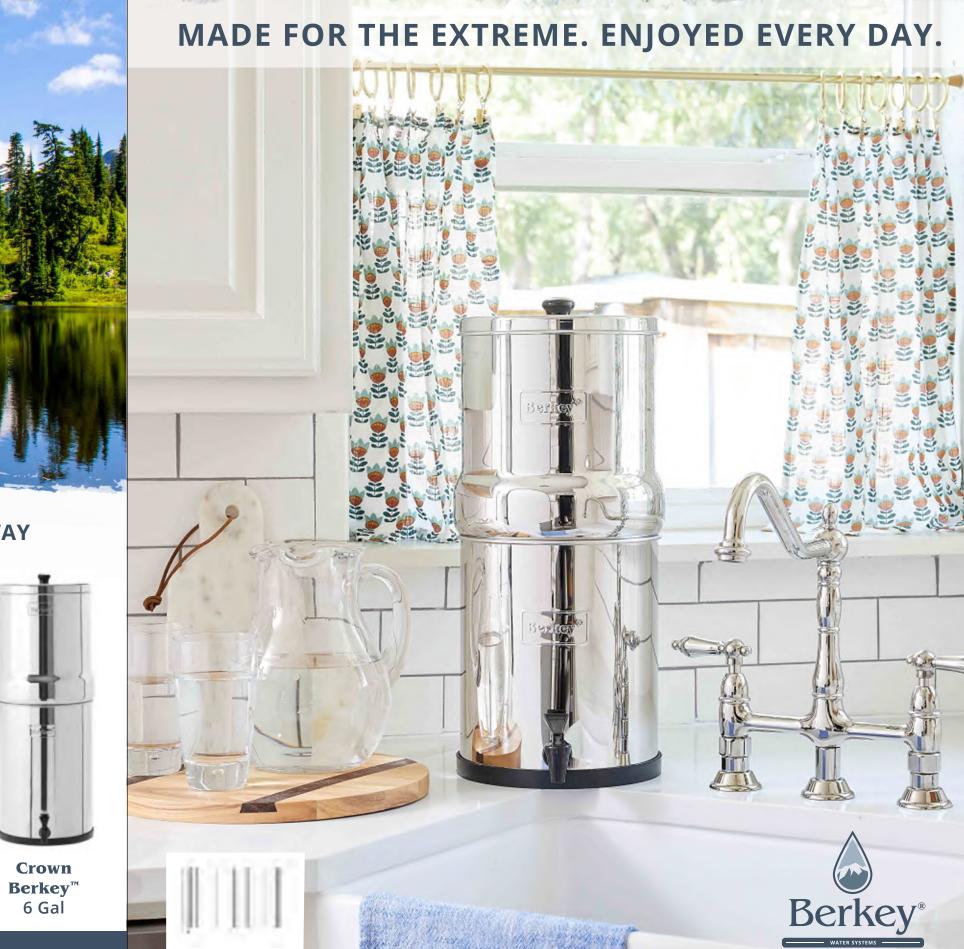
3.25 Gal

**Imperial** 

Berkey<sup>®</sup>

4.5 Gal

6 Gal



**Berkey**®

2.25 Gal

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Exhibit B, pg. 152 of 280



### **Sport Berkey**®

**Berkey**<sup>®</sup> Water Systems, the leader in gravity-fed filtration systems and trusted choice of adventurers, preppers, off-grid homesteaders and families for over 20 years, brings you the Sport Berkey® water filter bottle.

#### Versatile, Easy to Use



Daily at home, work or school



Traveling abroad



Emergencies

#### **More Outdoor Water Solutions Available**

Contact an authorized Berkey® dealer today.





**FREE** 



#### **Superior Filtration**

The **Sport Berkey**® water filter bottle has been tested by multiple independent third-party labs for its ability to remove or reduce 200+ typical contaminants found in tap water and other freshwater sources.

#### **Test results showed** up to a 99.9% reduction for typical contaminants found in water, such as:

- Heavy metals
- Herbicides
- Pesticides
- Pharmaceuticals
- Organic chemicals
- Petroleum-based products
- Silt and sediment

#### **Replaceable Filter**

Filter is operable for up to 640 refills for tap water based upon the quality of influent water.



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### **Sport Berkey**®



TER

WATER

22 OZ.

.6 L

BOT

Berkey® Water On-the-Go





## Travel Berkey® System 1.5 GALLON (5.6L)

### Berkey® Water Filtration Systems









# Travel Berkey® 1.5 GALLON (5.6L)

### **Berkey® Water Filtration Systems**









# Travel Berkey® 1.5 GALLON (5.6L)

### **Enjoy Refreshing Water in** the Great Outdoors

#### The Gold Standard in Gravity-Fed Water Filtration Systems

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon! Berkey® systems are portable, powerful and easy to use.

#### Made for the Extreme, Enjoyed Every Day.

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.

### MADE FOR THE EXTREME. ENJOYED EVERY DAY.

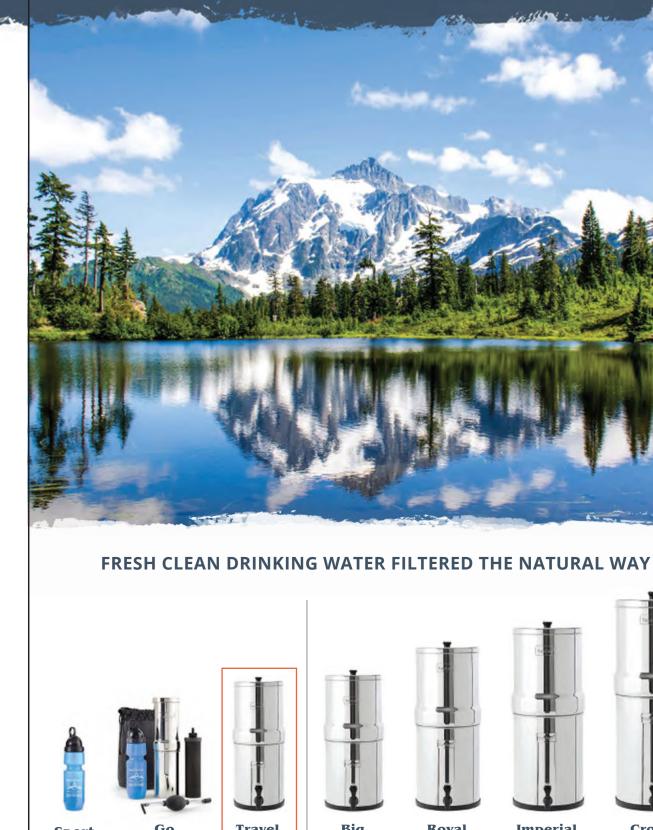




Ready for adventure!

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

R



OUTDOOR SYSTEMS

**MULTI-USE SYSTEMS** 

THE POWERFUL WATER FILTER SOLUTION FOR CAMPING, RVING AND OTHER OFF-GRID ADVENTURES.



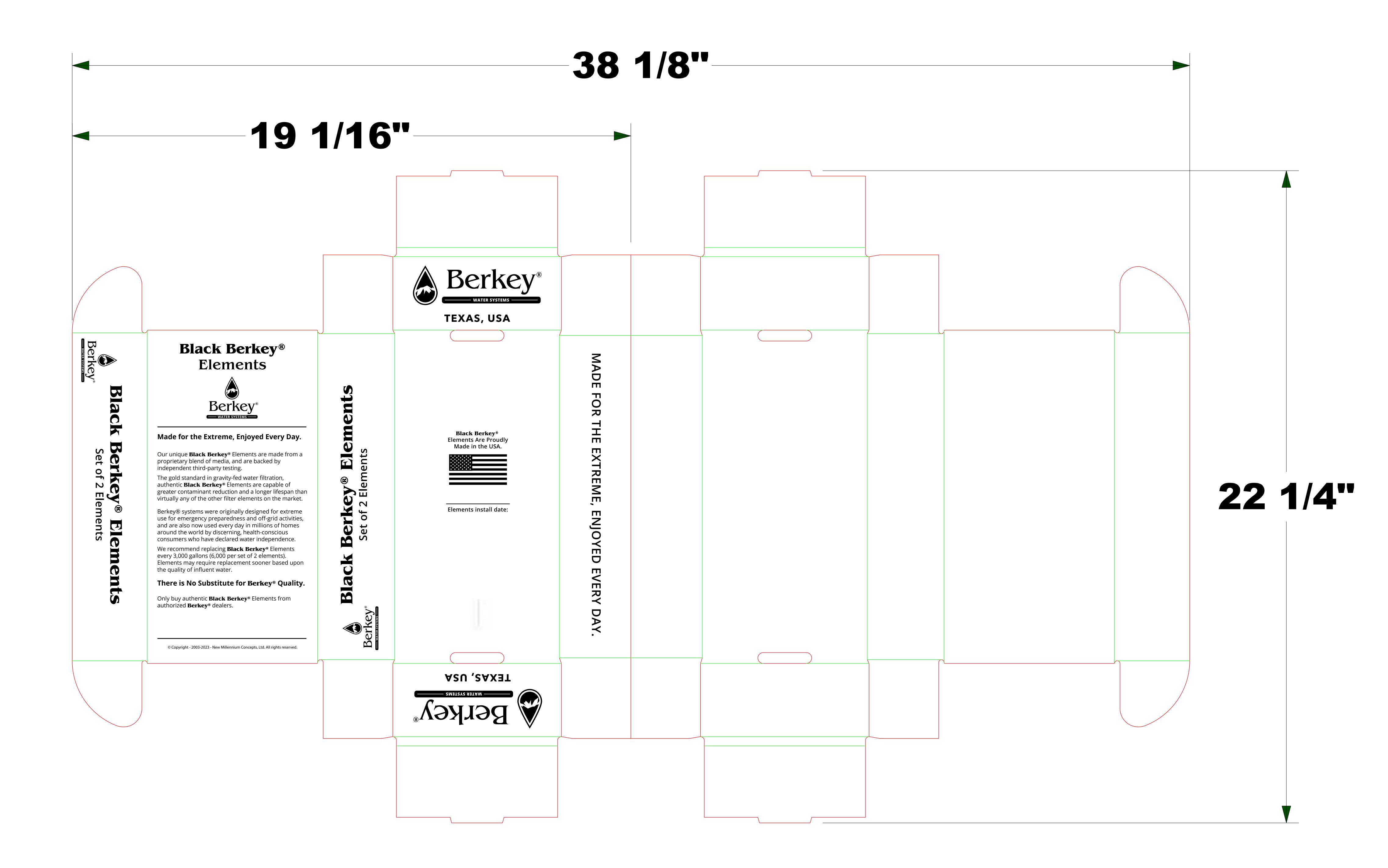


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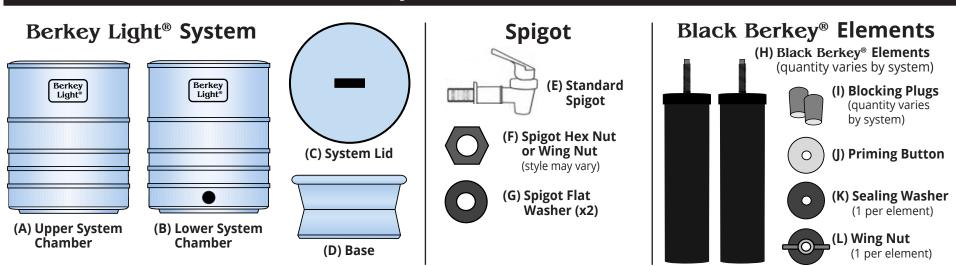
Exhibit B, pg. 154 of 280





# Instructions for the **Berkey Light®** gravity-fed water filtration system

#### **System Parts List**



Parts shown for illustration only and are not to scale.

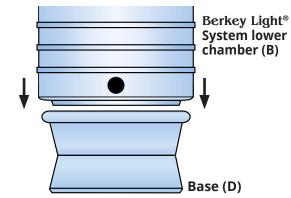
Failure to read, thoroughly understand, and follow all instructions may result in injury, water damage, or voiding of the warranty! It is the assembler's responsibility to make sure all components are properly assembled and installed using the instructions provided. While your **Berkey®** System should not have any leaking problems, there is always the chance that a leak might occur due to being improperly assembled or perhaps a faulty part. In an overabundance of caution, we recommend that for the first 24 hours the filled system be placed in an area wherein if such a leak were to occur, the resulting spillage would not damage anything.

#### **System Assembly**

We recommend setting up your system on a countertop or other waterproof surface.

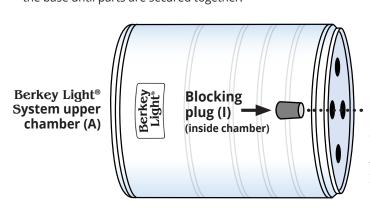
- Wash your hands, upper and lower chambers, and spigot before assembly to reduce the chances of contaminating the system's components.
- Be sure to keep all parts and original packaging in the unlikely event that your system needs to be returned to the manufacturer.

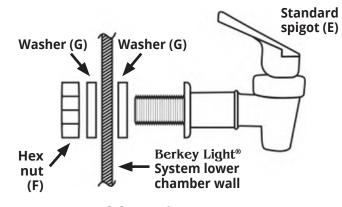




#### 1. Place Lower Chamber on Base

Place base on a flat, stable surface. Carefully place empty lower system chamber onto base. Press lower chamber down onto the base until parts are secured together.





#### 2. Assemble Spigot

To assure a proper seal, place one washer on stem of spigot. Insert spigot into system and turn spigot counterclockwise to the 9 o'clock position. Then, place the other washer on stem inside of the system, then the nut, and hand-turn nut until it is tight while holding spigot at the 9 o'clock position. Then, hold nut in place and rotate spigot clockwise until spigot is upright. This action should apply the right amount of pressure to complete the seal.

#### 3. Insert Blocking Plugs

Use blocking plugs to fill the remaining open holes in the upper chamber where you will <u>not</u> be installing **Black Berkey®** Elements. Press plugs into holes from inside the upper chamber, smaller end first.

#### 4. Prime the Black Berkey® Elements

Priming uses water to displace air out of the elements' pores, ensuring that water can flow freely. **Elements will not operate properly if they are not primed.**We recommend setting up your system on a countertop or other waterproof surface. If process dust is present, wipe it off with a Scotch-Brite® pad under cold running water.



1. Loosen wing nut (L) on Black Berkey® Element (H) stem until the top of wing nut (L) reaches the top of stem's threads (about 1/8" from top end of stem).



2. Place priming button (J) on top of wing nut. Top of priming button should be slightly higher than the top of the stem.



3. Place the threaded stem of element between fingers, and press priming button up against faucet.



4. Slowly turn on cold water (gradually increasing water pressure) while holding element and priming button firmly against faucet to create a seal, allowing water to saturate element.



5. As water pushes air out of element, allow element to sweat beads of water for 10-20 seconds. Water may be discolored at first, as excess media exits element. Continue running water until it runs clear, and the entire element appears to be saturated.

The element is now primed and ready for installation. Repeat steps 1-5 at left for your remaining elements.

**Tip:** Your **Black Berkey**® Elements will be wet after priming them—we recommend placing your elements in a clean bowl or sink while assembling the rest of your system.

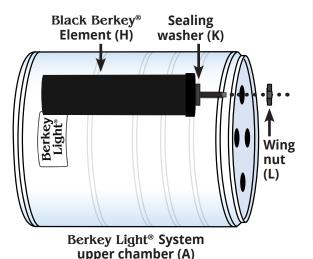
#### Questions About Using or Assembling Your Berkey Light® System?

Phone: (888) 803-4438 Monday - Friday 9AM - 5PM CST Holiday hours may vary.

Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 158 of B-13, pg.30 of 81

# 5. Install Primed Elements and Place Upper Chamber on Lower Chamber

- 1. Remove wing nut from threaded stem while leaving sealing washer on **Black Berkey**® Element.
- 2. Place threaded stem, with sealing washer attached, into the hole in the interior base of upper chamber.
- 3. Secure element in the base of the chamber by screwing wing nut onto threaded mount until hand-tight. Caution: hand tighten only. Over-tightening wing nut can strip the nut's threads, which could cause the system to leak. Repeat these 3 steps for remaining elements.
- 4. Please remember to plug unused holes in the upper chamber with included blocking plugs.
- 5. Carefully place upper chamber with primed elements on lower chamber, and press into place.
- 6. System is now assembled and ready to use.



#### Alternate Priming Methods

We strongly recommend using the **Black Berkey Primer™** (sold separately), a handheld priming pump
that makes the elements easy to prime without the need
for faucets or hose connections. **Black Berkey Primers™** are available from Authorized **Berkey®**Dealers worldwide.

Black Berkey® Elements may also be primed using a bottle of filtered water. Have one person hold the element, with the priming button attached and facing upward. Have a second person press the mouth of the bottled water against the priming button and squeeze until water is forced through entire exterior wall of element and it begins to sweat beads of water.

#### Using Your Berkey Light® System

Use of softened water or salt water can clog the filter's pores and will void your warranty. Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc.

- 1. Fill upper chamber with cold or room temperature water. **DO NOT use hot or boiling water.** Only fill upper chamber with as much water as the lower chamber can hold. **Overfilling system could cause lower chamber to overflow.**
- 2. Place lid on system. Allow water to filter into lower chamber.
- 3. Open the spigot to completely empty the lower chamber, and discard water. If water is slightly discolored due to any remaining particulate, do not be concerned—simply repeat steps 1-3 in this section as many times as needed until dispensed water is clear.
- 4. Your system is now ready to use. Refill upper chamber with water.

#### Water may begin to drip immediately when upper chamber is filled, but could take as long as 15 minutes based on how well elements are primed and the quality.

Notes:

- based on how well elements are primed and the quality of influent water used.Maximum flow rate will be achieved after the initial
- 12-24 hours of use as micro air pockets within the elements are replaced with water.
- It is normal to have a few inches of water left in the upper chamber when using the system, as it is gravity fed and the water cannot process through the bottom of the element.
- Air hole on rim of lower chamber prevents vapor lock.

#### **Assembly Verification\* (Red Food Coloring Test)**

This simple test verifies that your system has been assembled correctly, and that there are no internal leaks in your system. We recommend this test be done after the first assembly of this system, after removal or replacement of **Black Berkey®** Elements, or the first use after drying and storing the elements for an extended period of time. **Ensure that you do not have Berkey PF-2™ Fluoride and Arsenic Reduction Elements installed in the system when performing this test.** 

- 1. Add up to 1 teaspoon of artificial <u>red</u> food coloring (must be red) for every gallon that your **Berkey**® System can hold into the upper chamber. We recommend McCormick's red food coloring or any <u>artificial</u> food coloring. Acceptable food color ingredients include water, propylene glycol, FD&C Red 40 and FD&C Red 3, and propylparaben. **Avoid using food** coloring that is not red, or contains citric acid, sodium benzoate or natural ingredients such beet juice, turmeric, etc. Using organic food colorings will result in a false failed test (stating that your system is not sealed correctly).
- 2. Place a cup under spigot and drain water. If dispensed water does not have a red or pink hue, this indicates that the elements are sealed and system has been assembled correctly. **\*Note: This test is meant to confirm that the system was assembled as intended.**

#### If water drained from system has a red or pink hue during the assembly verification test, repeat the procedure again in this manner to determine the source of the leak:

- 1. Place the <u>upper system chamber only</u> (with **Black Berkey**® Elements installed) on top of same-sized cups or jars, each positioned so that an element can drip water into it. This will help you identify which blocking plug or element may be leaking.
- 2. Fill upper chamber with water and red food coloring as directed above.
- 3. Allow system to filter water. Check the color of water expelled from the elements. If water color is clear, your system is ready to use. If red dye is still present, reinstall the element(s) or blocking plug(s) where leaking occurs and re-run test.

  Clear water
- 4. If system continues to fail the test, contact our Customer Service department for assistance.

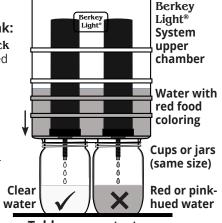


Table or countertop

#### **Precautions**

**Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc.** Excessive heat createsconditions that facilitate microbiological growth inside the upper chamber.

When lower chamber is partially filled, be cautious not to overfill upper chamber, as this could cause lower chamber to overflow.

For example: if the lower chamber is 1/3 full, the upper chamber can be refilled by 2/3. If the lower chamber is 1/2 full, the upper chamber can be refilled by 1/2, etc.

**Never allow wet Black Berkey® Elements to freeze**—exposure to freezing temperatures can expand the water into ice, which may damage the elements and cause them to crack or break. Allowing elements to freeze will void your warranty.

#### **Maintaining Your System**

We recommend performing maintenance every 30 days as needed: Clean the lower chamber and spigot

- 1. Remove upper chamber (be sure to drain any water and remove optional **Berkey PF-2™** Fluoride and Arsenic Reduction Elements, if attached).
- 2. With the **Black Berkey®** Elements remaining installed in the upper chamber, place upper chamber upside down or securely on its side to ensure it will not roll off of your counter or other work surface. **Caution: breaking an element's stem will void its warranty.**
- 3. Clean lower chamber with mild dish soap or a 1:1 mixture of water and vinegar, and rinse thoroughly.
- 4. Remove spigot and soak it in a 1:1 mixture of clean water and vinegar for 5-10 minutes to help remove any mineral deposits. Rinse spigot thoroughly.
- 5. Reattach spigot. Reinstall any optional **Berkey PF-2™** Fluoride and Arsenic Reduction Elements to the stems of the system's **Black Berkey®** Elements. With elements in place, carefully place upper chamber onto lower chamber.

#### Black Berkey® Element Storage

If you are going to be leaving the system unattended for 4-15 days and want to reduce the necessity of re-priming the elements, remove the elements from your system and place them in a sealable plastic bag (gallon-size or larger) while elements are still damp (this allows the elements to stay wet, making priming unnecessary). Then, place the elements in your refrigerator where they will not freeze. When ready, thoroughly rinse elements under cold water, then reinstall them in your system.

**For longer-term storage, we recommend completely drying the elements first.** Ensuring they are bone-dry (zero moisture) before storing them long-term. Shake excess water from elements, then air-dry by leaving them on a windowsill or other sunny location for 1-3 days until completely dry.

Once elements are bone-dry (zero moisture), store them in a sealable plastic bag (gallon-size or larger)—this prevents elements from absorbing odors. When you are ready to re-use your elements, clean them by scrubbing the outside with a stiff brush or a Scotch-Brite® pad under cold running water. Then re-prime the elements before putting them back in your system.

Alternatively, you can use a **Black Berkey Primer™** (sold separately) which assists in both priming and purging. Purging speeds up the drying process by pushing water out of the element before you place them in the sun or air dry to complete the process. Note: when purging, valves on the **Black Berkey Primer™** must be reversed.

#### **System Troubleshooting**

After prolonged use, flow rate may decrease significantly. To improve flow rate:

- 1. Carefully remove the elements from the upper chamber and gently scrub them with a stiff brush or Scotch-Brite® pad under cold running water (never apply soap or other cleaning agents to your **Black Berkey**® Elements). Re-prime elements, and reinstall them inside the upper chamber.
- 2. Place upper chamber back onto lower chamber, then perform the Assembly Verification process (Red Food Coloring Test). Your system is ready to use.

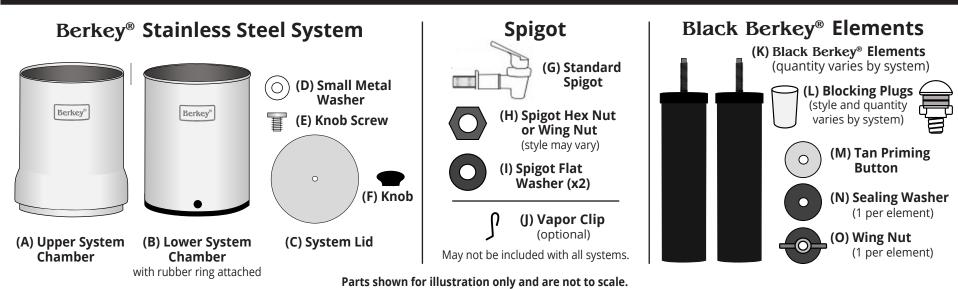
New Millennium Concepts, Ltd. Limited Warranty

New Millennium Concepts, Ltd. warrants their product against defects in materials or workmanship during ordinary consumer use. This Limited Warranty does not cover product issues caused by any other reason, for the time periods and conditions set forth below when purchased directly from an Authorized Berkey® Dealer. New Millennium Concepts, Ltd. shall not be held liable for incidental or consequential damage to personal property from, but not limited to, a defective unit, improper use, abuse, accident, or neglect, etc. It is the customer's responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must provide a dated receipt for the product and may be responsible to pay for any shipping charges incurred to return the product to New Millennium Concepts, Ltd. when required. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty coverage from the date of receipt of the specified warranty overage from the date of receipt of the product by the original invoice. Berkey® Dealers. Ltd. will, solely at its discretion, replace said pro



Instructions for Big Berkey<sup>®</sup>, Crown Berkey<sup>™</sup>, Imperial Berkey<sup>®</sup>, Royal Berkey<sup>®</sup> and Travel Berkey<sup>®</sup> water filtration systems

#### **System Parts List**



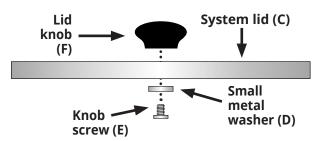
Failure to read, thoroughly understand, and follow all instructions may result in injury, water damage, or voiding of the warranty! It is the assembler's responsibility to make sure all components are properly assembled and installed using the instructions provided. While your **Berkey®** System should not have any leaking problems, there is always the chance that a leak might occur due to being improperly assembled or perhaps a faulty part. In an overabundance of caution, we recommend that for the first 24 hours the filled system be placed in an area wherein if such a leak were to occur, the resulting spillage would not damage anything.

#### **System Assembly**

**Tools you'll need:** standard screwdriver (not included). We recommend setting up your system on a countertop or other waterproof surface.

- Wash your hands, stainless steel chambers and spigot before assembly to reduce the chances of contaminating the system's components.
- Be sure to keep all parts and original packaging in the unlikely event that your system needs to be returned to the manufacturer.

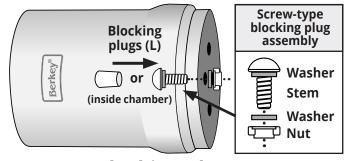




#### 1. Attach Knob to Lid

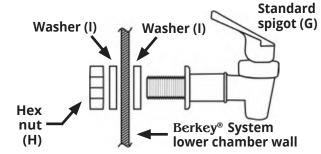
Fit knob onto lid by inserting the knob screw up through the washer into hole in the underside of lid, then screw on the knob.

Berkey® System upper chamber (A)



#### 3. Insert Blocking Plugs

Use blocking plugs to fill remaining open holes in the upper chamber where you will <u>not</u> be installing **Black Berkey**® Elements. **For push-in blocking plugs**, simply press plugs into holes from inside the upper chamber (smaller end first). **For screw-type blocking plugs**, place one washer on threaded stem, and insert plug (stem) through one of the holes inside the system's upper chamber. Place other washer on the threaded stem outside of system, then the nut. Hold plug securely with one hand inside system, and hand-turn nut on outside of system until snug. Do not over-tighten. Repeat for remaining plugs.



#### 2. Assemble Spigot

To assure a proper seal, place one washer on stem of spigot. Insert spigot into system and turn spigot counterclockwise to the 9 o'clock position. Then, place the other washer on stem inside of the system, then the nut, and hand-turn nut until it is tight while holding spigot at the 9 o'clock position. Then, hold nut in place and rotate spigot clockwise until spigot is upright.



# 4. Install the Vapor Lock Clip Climate, elevation and other

factors can create a tighter fit, preventing air flow between chambers, which slows down or prevents water flow (a natural phenomenon known as vapor lock). To prevent vapor lock, create air flow by placing clip on edge of lower chamber, making sure that the long portion of the airlock clip is hanging inside of the lower chamber.

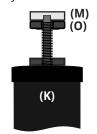
**Note:** All systems may not include a vapor lock clip. If you experience vapor lock, please contact our Customer Service department to obtain a clip. For customers outside the United States, please contact a local Authorized **Berkey®** Dealer.

#### 5. Prime the Black Berkey® Elements

Priming uses water to displace air out of the elements' pores, ensuring that water can flow freely. **Elements will not operate properly if they are not primed.**We recommend setting up your system on a countertop or other waterproof surface. If process dust is present, wipe it off with a Scotch-Brite® pad under cold running water.



 Loosen wing nut (O) on Black Berkey® Element (K) stem until the top of wing nut (O) reaches the top of stem's threads (about 1/8" from top end of stem).



2. Place tan priming button (M) on top of wing nut. Top of tan priming button should be slightly higher than the top of the stem.



3. Place the threaded stem of element between fingers, and press tan priming button up against faucet.



4. Slowly turn on cold water (gradually increasing water pressure) while holding element and tan priming button firmly against faucet to create a seal, allowing water to saturate element.



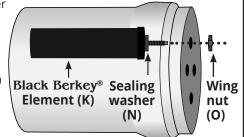
**5.** As water pushes air out of element, allow element to sweat beads of water for **10-20 seconds.** Water may be discolored at first, as excess media exits element. Continue running water until it runs clear, and the entire element appears to be saturated.

The element is now primed and ready for installation. Repeat steps 1-5 at left for your remaining elements.

**Tip:** Your **Black Berkey**® Elements will be wet after priming them—we recommend placing your elements in a clean bowl or sink while assembling the rest of your system.

#### 6. Install Primed Elements In The System

- 1. Remove wing nut from threaded stem while leaving sealing washer on Black Berkey® Element.
- 2. Place threaded stem, with sealing washer attached, into the hole in the interior base of upper chamber.
- 3. Secure element in the base of the chamber by screwing wing nut onto threaded mount until hand-tight. Caution: hand tighten only. Over-tightening wing nut can strip the nut's threads, which could cause the system to leak. Repeat these 3 steps for remaining elements.
- 4. With elements in place, carefully place upper chamber onto lower chamber. Your system is now assembled and ready to use.



Berkey® System upper chamber (A)

#### **Alternate Priming Methods**

We strongly recommend using the Black Berkey Primer™ (sold separately), a handheld priming pump that makes the elements easy to prime without the need for faucets or hose connections. Black Berkey Primers™ are available from Authorized Berkey® Dealers worldwide.

Black Berkey® Elements may also be primed using a bottle of filtered water. Have one person hold the element, with the priming button attached and facing upward. Have a second person press the mouth of the bottled water against the priming button and squeeze until water is forced through entire exterior wall of element and it begins to sweat beads of water.

#### Using Your System

Use of softened water or salt water can clog the filter's pores and will void your warranty. Avoid placing your system in direct sunlight or near a heat source such as a stove, indoor heater, etc.

- 1. Fill upper chamber with cold or room temperature water. **DO NOT use hot or boiling water.**
- 2. Place lid on system. Allow water to filter into lower chamber.
- 3. Open the spigot to completely empty the lower chamber, and discard water. If water is slightly discolored due to any remaining particulate, do not be concerned—simply repeat steps 1-3 in this section as many times as needed until dispensed water is clear.
- 4. Your system is now ready to use. Refill upper chamber with water.

#### Notes:

- It may take up to 15 minutes for elements to begin dripping water from the upper chamber into the lower chamber.
- Maximum flow rate will be achieved after the initial 12-24 hours of use as micro air pockets within the elements are replaced with water.
- It is normal to have a few inches of water left in the upper chamber when using the system, as it is gravity fed and the water cannot process through the bottom of the element.

#### **Assembly Verification\*** (Red Food Coloring Test)

This simple test verifies that your system has been assembled correctly, and that there are no internal leaks in your system. We recommend this test be done after the first assembly of this system, after removal or replacement of Black Berkey® Elements, or the first use after drying and storing the elements for an extended period of time. Ensure that you do not have Berkey PF-2™ Fluoride and Arsenic Reduction Elements installed in the system when performing this test.

- 1. Add up to 1 teaspoon of artificial red food coloring (must be red) for every gallon that your Berkey® System can hold into the upper chamber. We recommend McCormick's red food coloring or any artificial food coloring. Acceptable food color ingredients include water, propylene glycol, FD&C Red 40 and FD&C Red 3, and propylparaben. Avoid using food coloring that is not red, or contains citric acid, sodium benzoate or natural ingredients such beet juice, turmeric, etc. Using organic food colorings will result in a false failed test (stating that your system is not sealed correctly).
- 2. Place a cup under spigot and drain water. If dispensed water does not have a red or pink hue, this indicates that the elements are sealed and system has been assembled correctly. \*Note: This test is meant to confirm that the system was assembled as intended.

#### If water drained from system has a red or pink hue during the assembly verification test, repeat the procedure again in this manner to determine the source of the leak:

- 1. Place the upper system chamber only (with Black Berkey® Elements installed) on top of same-sized cups or jars, each positioned so that an element can drip water into it. This will help you identify which blocking plug or element may be leaking.
- 2. Fill upper chamber with water and red food coloring as directed above.
- 3. Allow system to filter water. Check the color of water expelled from the elements. If water color is clear, your system is ready to use. If red dye is still present, reinstall the element(s) or blocking plug(s) where leaking occurs and re-run test.
- 4. If system continues to fail the test, contact our Customer Service department for assistance.

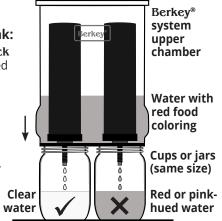


Table or countertop

#### **Precautions**

Avoid placing your system in direct sunlight or near a heat source such as a **stove**, **indoor heater**, **etc**. Excessive heat can create conditions that facilitate microbiological growth inside the upper chamber.

When lower chamber is partially filled, be cautious not to overfill upper **chamber**, as this could cause lower chamber to overflow.

For example: if the lower chamber is 1/3 full, the upper chamber can be refilled by 2/3. If the lower chamber is 1/2 full, the upper chamber can be refilled by 1/2, etc.

Never allow wet Black Berkey® Elements to freeze—exposure to freezing temperatures can expand the water into ice, which may damage the elements and cause them to crack or break. Allowing elements to freeze will void your warranty.

#### **Maintaining Your System**

#### We recommend performing maintenance every 30 days as needed: Clean the lower chamber and spigot

- 1. Remove upper chamber (be sure to drain any water and remove optional Berkey PF-2™ Fluoride and Arsenic Reduction Elements, if attached).
- 2. With the Black Berkey® Elements remaining installed in the upper chamber, place upper chamber upside down or securely on its side to ensure it will not roll off of your counter or other work surface. Caution: breaking an element's stem will void its warranty.
- 3. Clean lower chamber with mild dish soap or a 1:1 mixture of water and vinegar, and rinse thoroughly.
- 4. Remove spigot and soak it in a 1:1 mixture of clean water and vinegar for 5-10 minutes to help remove any mineral deposits. Rinse spigot thoroughly.
- 5. Reattach spigot. Reinstall any optional **Berkey PF-2™** Fluoride and Arsenic Reduction Elements to the stems of the system's **Black Berkey**® Elements. With elements in place, carefully place upper chamber onto lower chamber.

#### Black Berkey® Element Storage

If you are going to be leaving the system unattended for 4-15 days and want to reduce the necessity of re-priming the elements, remove the elements from your system and place them in a sealable plastic bag (gallon-size or larger) while elements are still damp (this allows the elements to stay wet, making priming unnecessary). Then, place the elements in your refrigerator where they will not freeze. When ready, thoroughly rinse elements under cold water, then reinstall them in your system.

For longer-term storage, we recommend completely drying the elements first. Ensuring they are bone-dry (zero moisture) before storing them long-term helps prevent any potential microbiological growth (mold, biofilm, bacteria, etc.). Shake excess water from elements, then air-dry by leaving them on a windowsill or other sunny location for 1-3 days until completely dry.

Once elements are bone-dry (zero moisture), store them in a sealable plastic bag (gallon-size or larger)—this prevents elements from absorbing odors. When you are ready to re-use your elements, clean them by scrubbing the outside with a stiff brush or a Scotch-Brite® pad under cold running water. Then re-prime the elements before putting them back in your system.

Alternatively, you can use a **Black Berkey Primer™** (sold separately) which assists in both priming and purging. Purging speeds up the drying process by pushing water out of the element before you place them in the sun or air dry to complete the process. Note: when purging, valves on the **Black Berkey Primer™** must be reversed.

#### **System Troubleshooting**

#### After prolonged use, flow rate may decrease significantly. To improve flow rate:

- 1. Slow flow rate could be caused by vapor lock. Insert vapor lock clip, if supplied. See page 1, assembly step #4.
- 2. Carefully remove the elements from the upper chamber and gently scrub them with a stiff brush or Scotch-Brite® pad under cold running water (never apply soap or other cleaning agents to your **Black Berkey**® Elements). Re-prime elements, and reinstall them inside the upper chamber.
- 3. Place upper chamber back onto lower chamber, then perform the Assembly Verification process (Red Food Coloring Test). Your system is ready to use.

New Millennium Concepts, Ltd. Limited Warranty

New Millennium Concepts, Ltd. warrants their product against defects in materials or workmanship during ordinary consumer use. This Limited Warranty does not cover product issues caused by any other reason, for the time periods and conditions set forth below when purchased directly from an Authorized Berkey® Dealer. New Millennium Concepts, Ltd. shall not be held liable for incidental or consequential damage to personal property from, but not limited to, a defective unit, improper use, abuse, accident, or neglect, etc. It is the customer's responsibility to prevent missues of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must provide the product to New Millengian Consents Ltd. responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must provide a dated receipt for the product and may be responsible to pay for any shipping charges incurred to return the product to New Millennium Concepts, Ltd. when required. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty is for the original retail purchaser only, and cannot be transferred. For a period not to exceed the specified warranty coverage from the date of receipt of the product by the original purchaser on the original invoice, New Millennium Concepts, Ltd. will, solely at its discretion, replace said product or component that New Millennium Concepts, Ltd. deems is not functioning properly during the stated warranty period. The laws of the state of Texas, USA will govern any disputes regarding this warranty or claim made. This warranty, which is given expressly in lieu of all warranties, expressed or implied, or merchantability and fitness for a particular purpose, constitutes the only warranty made by New Millennium Concepts, Ltd. This warranty applies only to products manufactured or exclusively distributed by New Millennium Concepts, Ltd. and its Authorized Berkey® Dealers, and does not apply to extended warranties offered by some Authorized Berkey® Dealers. Berkey® System Housing: Berkey® System upper and lower chambers including lids, excluding orders for factory-blemished systems, are covered under a one-year warranty. The warranty period begins from the date of receipt of the product by the original invoice. Included spigot and accessories that are sold separately are covered under a six-month warranty. The warranty period begins from the date of receipt of the product by the original purchaser on the original invoice. date of receipt of the product by the original purchaser on the original invoice.

#### Questions About Using or Assembling Your Berkey® System?

Phone: (888) 803-4438 Monday - Friday 9AM - 5PM CST Holiday hours may vary.



#### Instructions for Black Berkey® Elements

#### Parts List

Parts shown for illustration only and are not to scale.





(B) Sealing Washers (Set of 2)



**4.** Slowly turn on cold

(C) Wing Nuts (Set of 2)

(D) Tan **Priming** Button

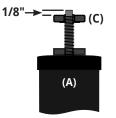
#### Priming and Installing Your Black Berkey® Elements

#### **Before You Get Started:**

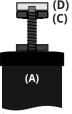
- Wash your hands before installing and priming elements to reduce the chances of contaminating the system's components.
- Keep all parts, instructions and original packaging in the event that your elements need to be returned to the manufacturer. Write the installation date in the space provided on the elements' box to serve as a reminder as to when elements need replacement.

#### 1. Prime the Black Berkey® Elements

Priming uses water to displace air out of the elements' pores, ensuring that water can flow freely. **Elements will not operate properly** if they are not primed. We recommend setting up your system on a countertop or other waterproof surface. If process dust is present, wipe it off with a Scotch-Brite® pad under cold running water.



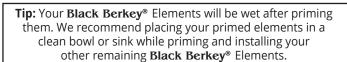
**1.** Loosen wing nut **2.** Place tan (C) on Black Berkey® Element (A) stem until the top of wing nut (C) reaches the top of stem's threads (about 1/8" from top end of stem).



priming button (D) on top of wing nut. Top of tan priming button should be slightly higher than the top of the stem.



water (gradually increasing water pressure) while holding element and tan priming button firmly against faucet to create a seal, allowing water to saturate element.



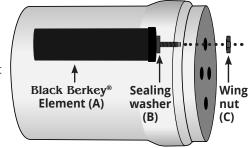
**5.** As water pushes air out of the element's pores, allow element to sweat beads of water for 10-20 seconds. Water may be discolored at first, as excess media exits element. Continue running water until it runs clear, and the entire element appears to be saturated.

The element is now primed and ready for installation. Repeat steps 1-5 for remaining elements.

#### 2. Install Primed Elements In Your System

- 1. Remove wing nut from threaded stem while leaving sealing washer on element.
- 2. Place threaded stem, with sealing washer attached, into the hole in the interior base of upper chamber.
- 3. Secure element in the base of the chamber by screwing wing nut onto threaded mount until hand-tight. Caution: hand tighten only. Over-tightening wing nut can strip the nut's threads, which could cause the system to leak. Repeat these 3 steps for remaining elements.
- 4. With elements (and blocking plugs, if needed) in place, carefully place upper chamber onto lower chamber. Your system is ready to use.

For more information about operating your system, visit: support.berkeywater.com



Berkey® System upper chamber (A)

#### **Alternate Priming Methods**

We strongly recommend using the **Black Berkey Primer™** (sold separately), a handheld priming pump that makes the elements easy to prime without the need for faucets or hose connections. Black Berkey Primers™ are available from Authorized Berkey® Dealers worldwide.

Black Berkey® Elements may also be primed using a bottle of filtered water. Have one person hold the element, with the priming button attached and facing upward. Have a second person press the mouth of the bottled water against the priming button and squeeze until water is forced through entire exterior wall of element and it begins to sweat beads of water.

#### Questions About Installing or Using Your Black Berkey® Elements?

Phone: (888) 803-4438 Monday - Friday 9AM - 5PM CST Holiday hours may vary.

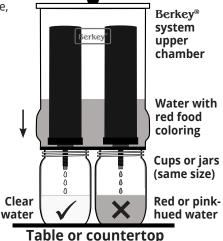
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This simple test verifies that your system has been assembled correctly, and that there are no internal leaks in your system. We recommend this test be done after the first assembly of this system, after removal or replacement of **Black Berkey®** Elements, or the first use after drying and storing the elements for an extended period of time. **Ensure that you do not have Berkey PF-2™ Fluoride and Arsenic Reduction Elements installed in the system when performing this test.** 

- 1. Add up to 1 teaspoon of artificial <u>red</u> food coloring (must be red) for every gallon that your **Berkey®** System can hold into the upper chamber. We recommend McCormick's red food coloring or any <u>artificial</u> food coloring. Acceptable food color ingredients include water, propylene glycol, FD&C Red 40 and FD&C Red 3, and propylparaben. **Avoid using food coloring that is not red, or contains citric acid, sodium benzoate or natural ingredients such beet juice, turmeric, etc. Using organic food colorings will result in a false failed test (stating that your system is not sealed correctly).**
- 2. Place a cup under spigot and drain water. If dispensed water does not have a red or pink hue, this indicates that the elements are sealed and system has been assembled correctly.

\*Note: This test is meant to confirm that the system was assembled as intended. If water drained from system has a red or pink hue during the assembly verification test, repeat the procedure again in this manner to determine the source of the leak:

- 1. Place the <u>upper system chamber only</u> (with **Black Berkey®** Elements installed) on top of same-sized cups or jars, each positioned so that an element can drip water into it. This will help you identify which blocking plug or element may be leaking.
- 2. Fill upper chamber with water and red food coloring as directed above.
- 3. Allow system to filter water. Check the color of water expelled from the elements. If water color is clear, your system is ready to use. If red dye is still present, reinstall the element(s) or blocking plug(s) where leaking occurs and re-run test.
- 4. If system continues to fail the test, contact our Customer Service department for assistance.



#### Black Berkey® Elements Precautions and Storage

Use of softened water or salt water can clog the filter's pores and will void your warranty.

**Never allow wet Black Berkey® Elements to freeze.** Exposure to freezing temperatures can expand the water into ice, which may damage the elements and cause them to crack or break. Allowing elements to freeze will void your warranty.

If you are going to be leaving the system unattended for 4-15 days and want to reduce the necessity of re-priming the elements, remove the elements from your system and place them in a sealable plastic bag (gallon-size or larger) while elements are still damp (this allows the elements to stay wet, making priming unnecessary). Then, place the elements in your refrigerator where they will not freeze. When ready, thoroughly rinse elements under cold water, then reinstall them in your system.

**For longer-term storage, we recommend completely drying the elements first.** Ensuring they are bone-dry (zero moisture) before storing them long-term. Shake excess water from elements, then air-dry by leaving them on a windowsill or other sunny location for 1-3 days until completely dry.

Once elements are bone-dry (zero moisture), store them in a sealable plastic bag (gallon-size or larger)—this prevents elements from absorbing odors. When you are ready to re-use your elements, clean them by scrubbing the outside with a stiff brush or a Scotch-Brite® pad under cold running water. Then re-prime the elements before putting them back in your system.

Alternatively, you can use a **Black Berkey Primer™** (sold separately) which assists in both priming and purging. Purging speeds up the drying process by pushing water out of the element before you place them in the sun or air dry to complete the process. Note: when purging, valves on the **Black Berkey Primer™** must be reversed.

#### New Millennium Concepts, Ltd. Limited Warranty

New Millennium Concepts, Ltd. warrants their product against defects in materials or workmanship during ordinary consumer use. This Limited Warranty does not cover product issues caused by any other reason, for the time periods and conditions set forth below when purchased directly from an Authorized Berkey® Dealer. New Millennium Concepts, Ltd. shall not be held liable for incidental or consequential damage to personal property from, but not limited to, a defective unit, improper use, abuse, accident, or neglect, etc. It is the customer's responsibility to prevent misuse of the system and to replace parts, when, due to the natural course of wear and tear, they must be replaced. To obtain warranty service, you must provide a dated receipt for the product and may be responsible to pay for any shipping charges incurred to return the product to New Millennium Concepts, Ltd. when required. This warranty will not apply to units which have been used for purposes not intended, which have been altered so as, in the manufacturer's judgment, to adversely affect its performance. This warranty is for the original retail purchaser only, and cannot be transferred. For a period not to exceed the specified warranty coverage from the date of receipt of the product by the original purchaser on the original invoice, New Millennium Concepts, Ltd. will, solely at its discretion, replace said product or component that New Millennium Concepts, Ltd. deems is not functioning properly during the stated warranty period. The laws of the state of Texas, USA will govern any disputes regarding this warranty or claim made. This warranty, which is given expressly in lieu of all warranties, expressed or implied, or merchantability and fitness for a particular purpose, constitutes the only warranty made by New Millennium Concepts, Ltd. This warranty applies only to products manufactured or exclusively distributed by New Millennium Concepts, Ltd. and its Authorized Berkey® Dealers, and does not apply to extended warranties offered by some Authori

We recommend replacing **Black Berkey**® Elements every 3,000 gallons (6,000 per set of 2 elements). Elements may require replacement sooner based upon the quality of influent water.

Case 3:24-cv-01106 Document 1-3 Exhibit B- 13, pg 163 05281 of 81/2923-SP

# Sport Berkey® Water Filter Bottle



The **Sport Berkey**® water filter bottle uses the same filtration formulation as our **Black Berkey**® Elements, which are used in our popular gravity-fed systems.

The **Sport Berkey**® water filter bottle has been tested by multiple independent third-party labs for its ability to remove or reduce typical contaminants found in water.

Test results showed up to a 99.9% reduction for typical contaminants found in water, such as: heavy metals, herbicides, pesticides, pharmaceuticals, organic chemicals, petroleum-based products, silt and sediment.

#### **Precautions**

- To prevent leaks, do not store filled bottle on its side or upside down.
- Do not allow filter to freeze.
- Do not place bottle or filter in dishwasher or microwave oven.
- Do not run hot water through filter.
- Make sure straw is clean before using. If straw is dirty, reclean straw (see cleaning instructions on next page).

#### **Specifications**

- Capacity: 22 oz. (0.6 L)
- 50 year shelf life
- Filter is operable for up to 640 refills for tap water based upon the quality of influent water.

#### **Warranty Information**

The **Sport Berkey**® water filter bottle is covered by the NMCL Limited Warranty: 6 Months. Warranty coverage begins the date product is received.

# Usage & Storage

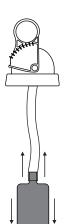
#### **IMPORTANT!** Flush Filter Before Use

Flushing clears excess carbon from the manufacturing process.

- 1. Pull lid closure down so that straw is exposed.
- 2. With bottle full of water, squeeze the bottle for 3-4 seconds to flush water through filter and straw.
- 3. Repeat until water runs clear.
- 4. Bottle is ready to use.

#### **Using Your Bottle**

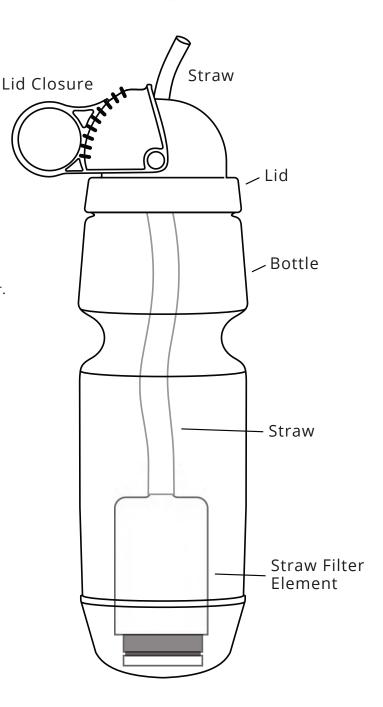
- 1. Fill the **Sport Berkey**® water filter bottle with water.
- 2. Screw on lid and tighten securely to prevent leaks.
- 3. To drink: pull lid closure down to expose straw. Squeeze bottle to squirt water out of straw into mouth, or suck water through straw, or use both actions together.
- 4. To close: simply pull lid closure up to conceal straw (this helps prevent drips or leaks while carrying).



#### Replacing the Filter

Filter is operable for up to 640 refills for tap water based upon the quality of influent water.

- 1. Unscrew lid from bottle.
- 2. Pull existing filter from straw.
- 3. Push new filter onto straw.
- 4. Flush new filter before using (see above for instructions).



#### **Cleaning and Storage**

Periodically remove straw filter element and clean the bottle and straw with warm water and mild, unscented dish soap.

#### If straw filter element will not be used for an extended period of time:

- 1. Remove filter from straw and allow to air dry.
- 2. Once filter is dry, place it back on straw inside bottle.



# Big Berkey<sup>®</sup> System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems









# Big Berkey® 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems









Big Berkey®
2.25 GALLON (8.5L)

# **Specially Formulated to Address 200+ Typical Contaminants found in Tap Water**



AVE CONTROL OF VOLID TAR WATER AT HOME OF THE OFFICE



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Our unique **Black Berkey**<sup>®</sup> Elements are made from a proprietary blend of media, and are back by independent thrid-party testing.

# The Gold Standard in Gravity-Fed Water Filtration Systems

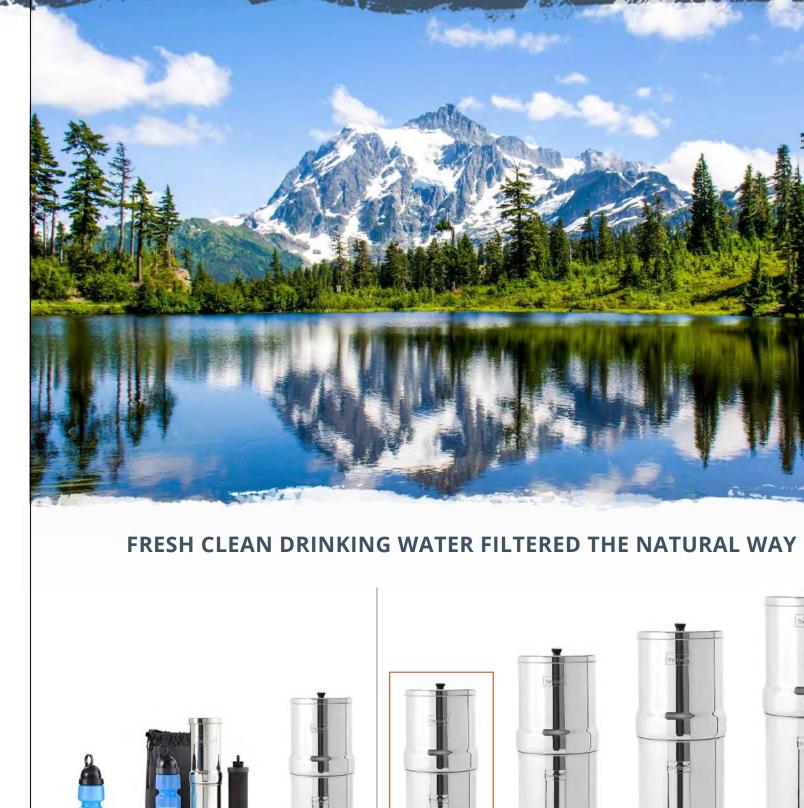
Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon! Berkey® systems are portable, powerful and easy to use.

Made for the Extreme, Enjoyed Every Day.

**Berkey**® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS

Berkey<sup>®</sup>

Kit 1 Qt

Berkey<sup>®</sup>

1.5 Gal

Berkey<sup>®</sup>

MULTI-USE SYSTEMS

**Imperial** 

Berkey<sup>®</sup>

4.5 Gal

Royal

Berkey<sup>®</sup>

3.25 Gal







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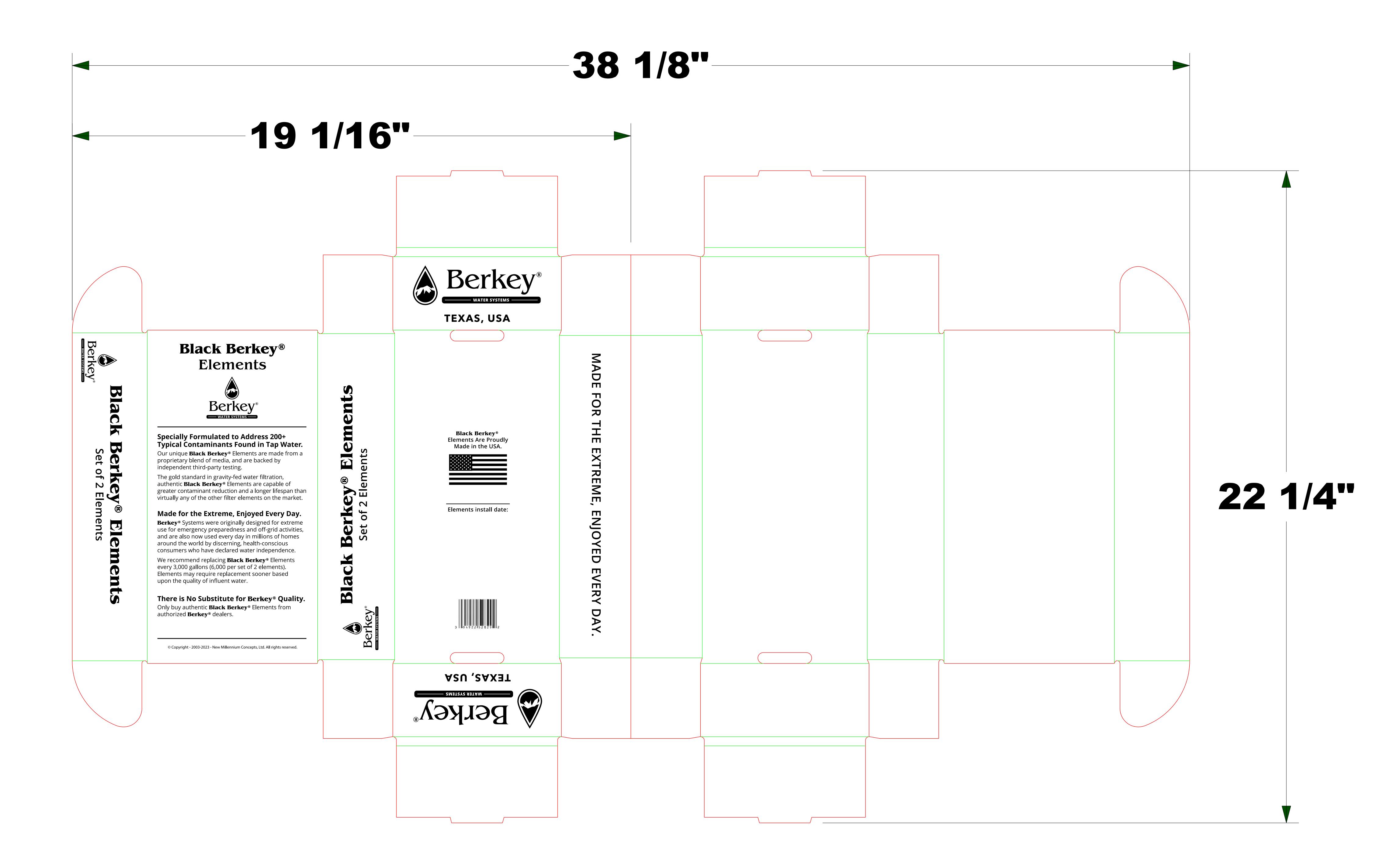
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Berkey<sup>®</sup>

2.25 Gal

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# Imperial Berkey® System

4.5 GALLONS (17L)

# Berkey® Water Filtration Systems









# Imperial Berkey®

4.5 GALLONS (17L)

# Berkey® Water Filtration Systems







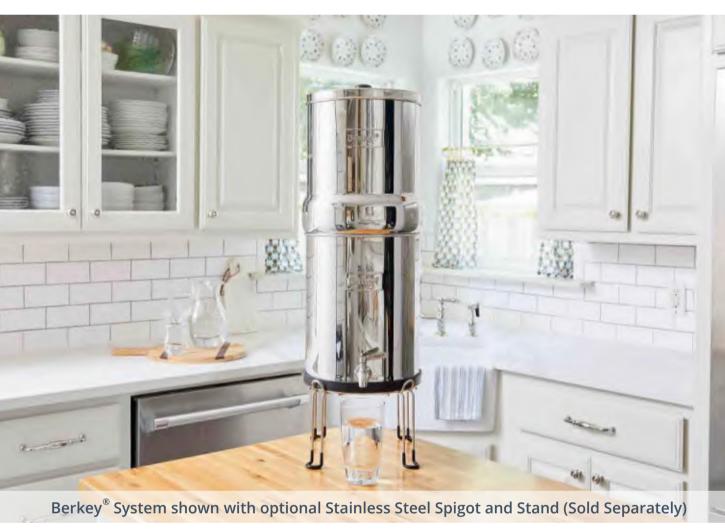


# Imperial Berkey®

4.5 GALLONS (17L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.

### Specially Formulated to Address 200+ Typical Contaminants found in Tap Water





FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Our unique **Black Berkey**<sup>®</sup> Elements are made from a proprietary blend of media, and are back by independent thrid-party testing.

#### The Gold Standard in Gravity-Fed Water **Filtration Systems**

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon! Berkey® systems are portable, powerful and easy to use.

Made for the Extreme, Enjoyed Every Day.

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.



# FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



**Travel** 

**Berkey**®





3.25 Gal

**Imperial Berkey**® **Berkey**<sup>TI</sup> 4.5 Gal 6 Gal





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FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

OUTDOOR SYSTEMS

**MULTI-USE SYSTEMS** 

Exhibit B, pg. 166 of 280



# Berkey® Water Filtration Systems









# Crown Berkey<sup>TM</sup>

# Berkey® Water Filtration Systems









Crown Berkey TM 6 GALLONS (22.7L)

Exhibit B-13, pg.40 of 81

### Specially Formulated to Address 200+ Typical Contaminants found in Tap Water



TAKE CONTROL OF YOUR TAP WATER AT HOME OR THE OFFICE



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Exhibit B, pg. 167 of 280

Our unique **Black Berkey**® Elements are made from a proprietary blend of media, and are back by independent thrid-party testing.

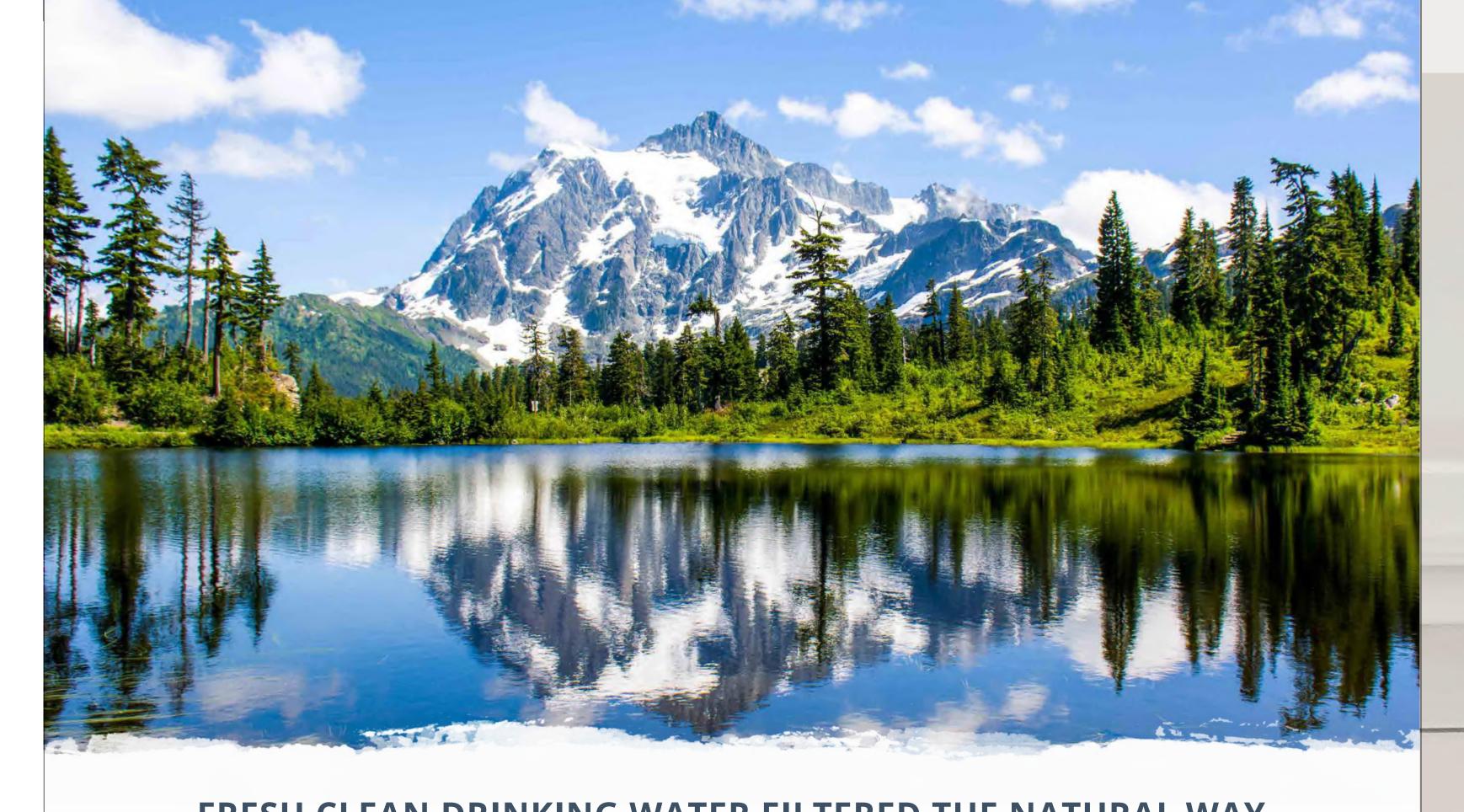
# The Gold Standard in Gravity-Fed Water Filtration Systems

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon!
Berkey® systems are portable, powerful and easy to use.

Made for the Extreme, Enjoyed Every Day.

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.





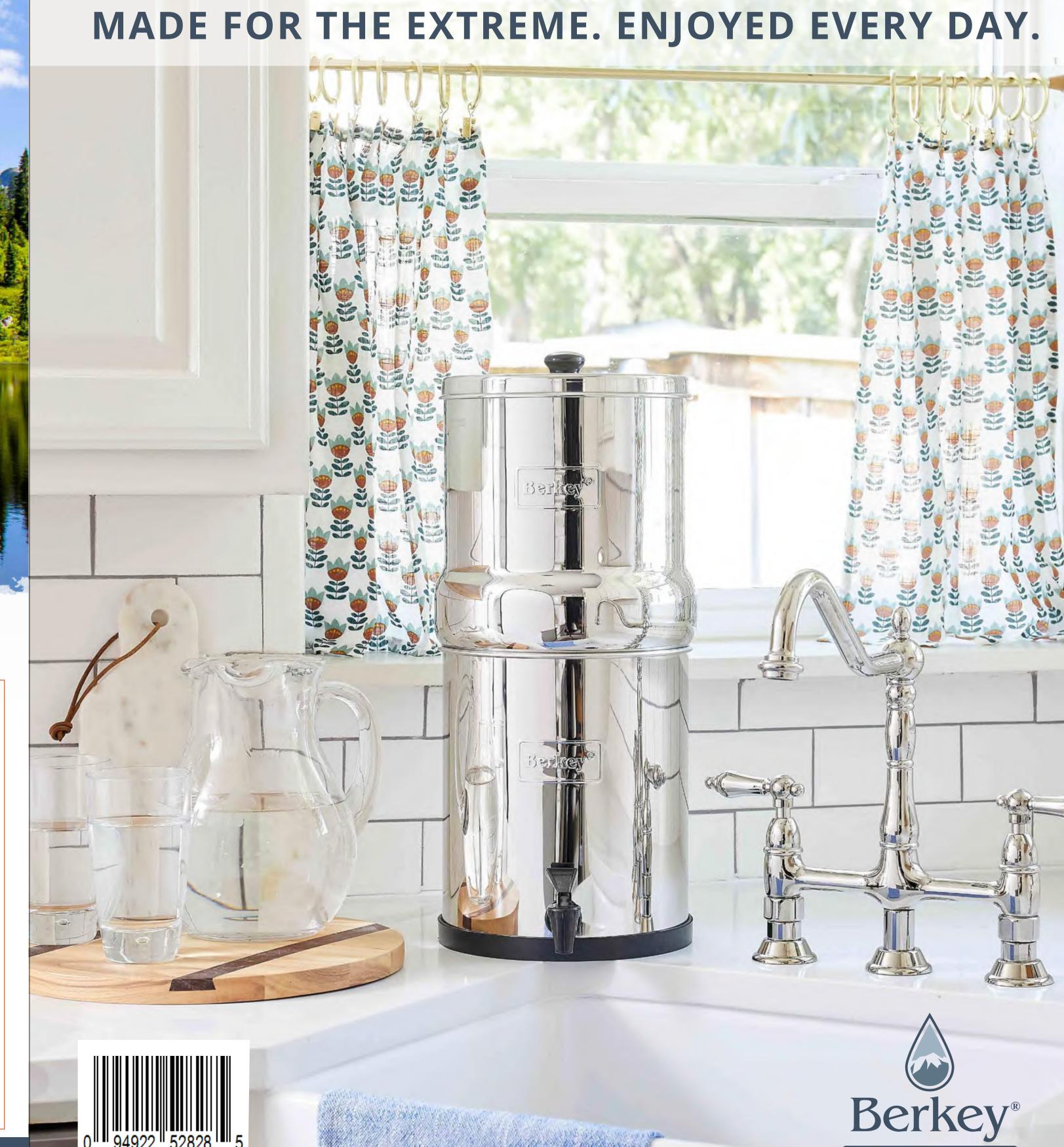
FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

OUTDOOR SYSTEMS

MULTI-USE SYSTEMS



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# Royal Berkey® System

3 GALLONS (11.36L)

### Berkey® Water Filtration Systems











### Berkey® Water Filtration Systems









# Royal Berkey®

MADE FOR THE EXTREME. ENJOYED EVERY DAY.

3 GALLONS (11.36L)

# **Specially Formulated to Address 200+ Typical Contaminants found in Tap Water**



AKE CONTROL OF YOUR TAP WATER AT HOME OR THE OFFICE



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Our unique **Black Berkey**<sup>®</sup> Elements are made from a proprietary blend of media, and are back by independent thrid-party testing.

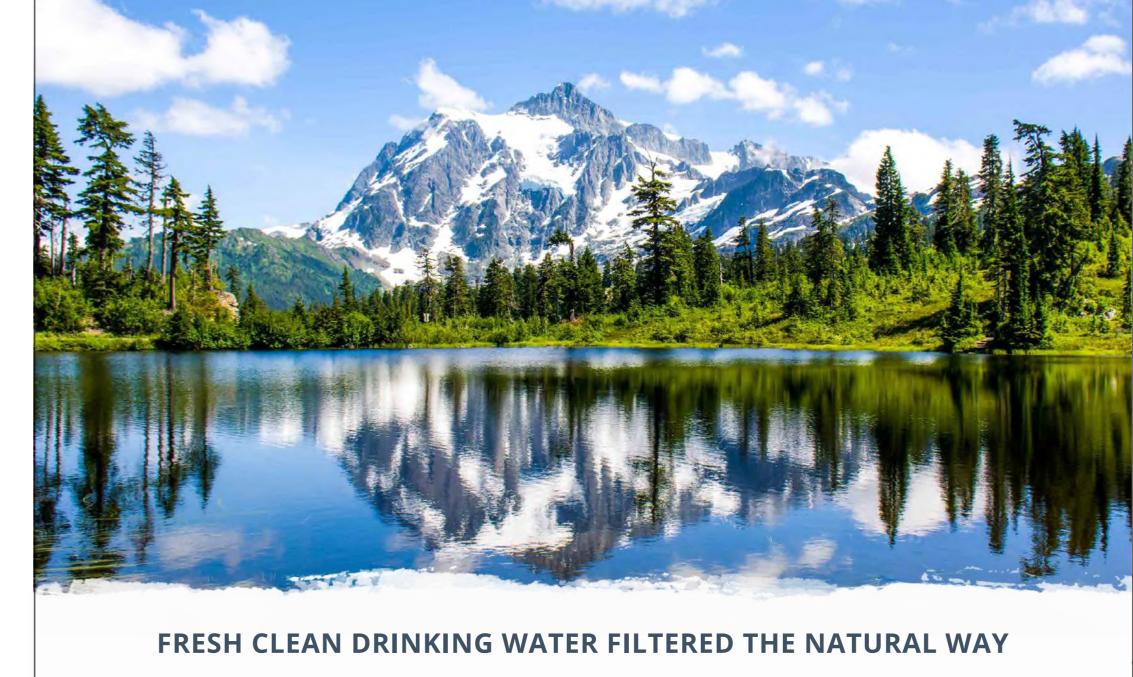
# The Gold Standard in Gravity-Fed Water Filtration Systems

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon! Berkey® systems are portable, powerful and easy to use.

Made for the Extreme, Enjoyed Every Day.

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.









1.5 Gal



2.25 Gal



3.25 Gal







FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

OUTDOOR SYSTEMS

MULTI-USE SYSTEMS

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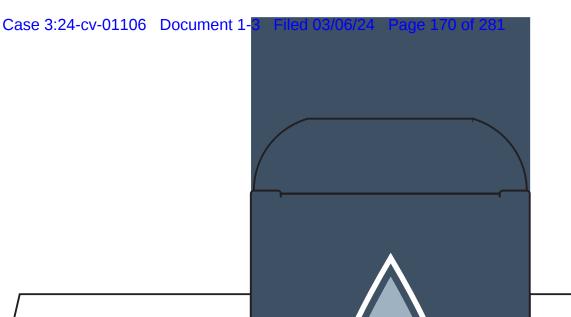
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Berkey<sup>®</sup>

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Exhibit B, pg. 168 of 280



# **Sport Berkey**®

**Berkey**<sup>®</sup> Water Systems, the leader in gravity-fed filtration systems and trusted choice of adventurers, preppers, off-grid homesteaders and families for over 20 years, brings you the Sport Berkey® water filter bottle.

#### Versatile, Easy to Use



Daily at home, work or school



Traveling abroad



Emergencies

#### **More Outdoor Water Solutions Available**

Contact an authorized Berkey® dealer today.







#### **Superior Filtration**

The **Sport Berkey**® water filter bottle has been tested by multiple independent third-party labs for its ability to remove or reduce 200+ typical contaminants found in tap water and other freshwater sources.

**Test results showed** up to a 99.9% reduction for typical contaminants found in water, such as:

- Heavy metals
- Herbicides
- Pesticides
- Pharmaceuticals
- Organic chemicals
- Petroleum-based products
- Silt and sediment

#### **Replaceable Filter**

Filter is operable for up to 640 refills for tap water based upon the quality of influent water.



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#### **Sport Berkey**®



TER

WATER

22 OZ.

.6 L

# BOT

Berkey® Water On-the-Go









#### Berkey® Water Filtration Systems











#### Berkey® Water Filtration Systems









Travel Berkey® 1.5 GALLON (5.6L)

#### **Enjoy Refreshing Water in** the Great Outdoors

Specially Formulated to Address 200+ Typical Contaminants found in Tap Water.

Our unique Black Berkey Elements are made from a proprietary blend of media, and are back by independent thrid-party testing.

#### The Gold Standard in Gravity-Fed Water Filtration Systems

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon! **Berkey**® systems are portable, powerful and easy to use.

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence.

#### MADE FOR THE EXTREME. ENJOYED EVERY DAY.





Ready for adventure!

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



**OUTDOOR SYSTEMS** 

Berkey<sup>®</sup>

Kit 1 Qt

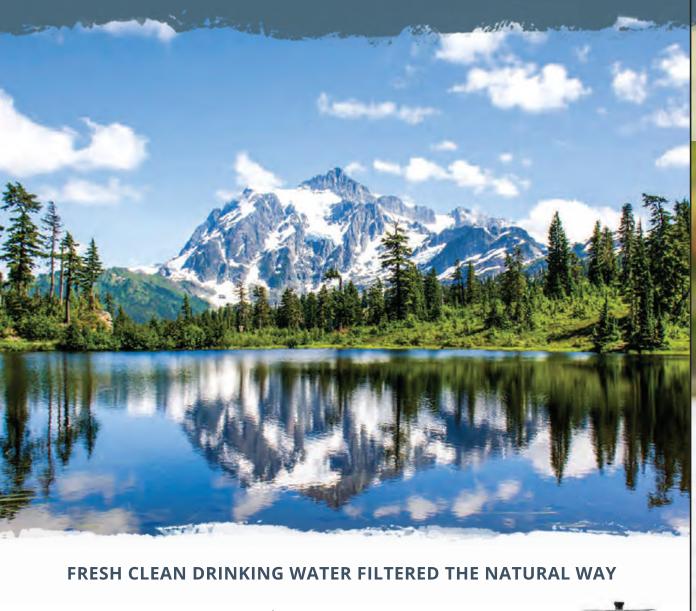
Berkey<sup>®</sup>

1.5 Gal

Sport Berkey® Bottle



**MULTI-USE SYSTEMS** 





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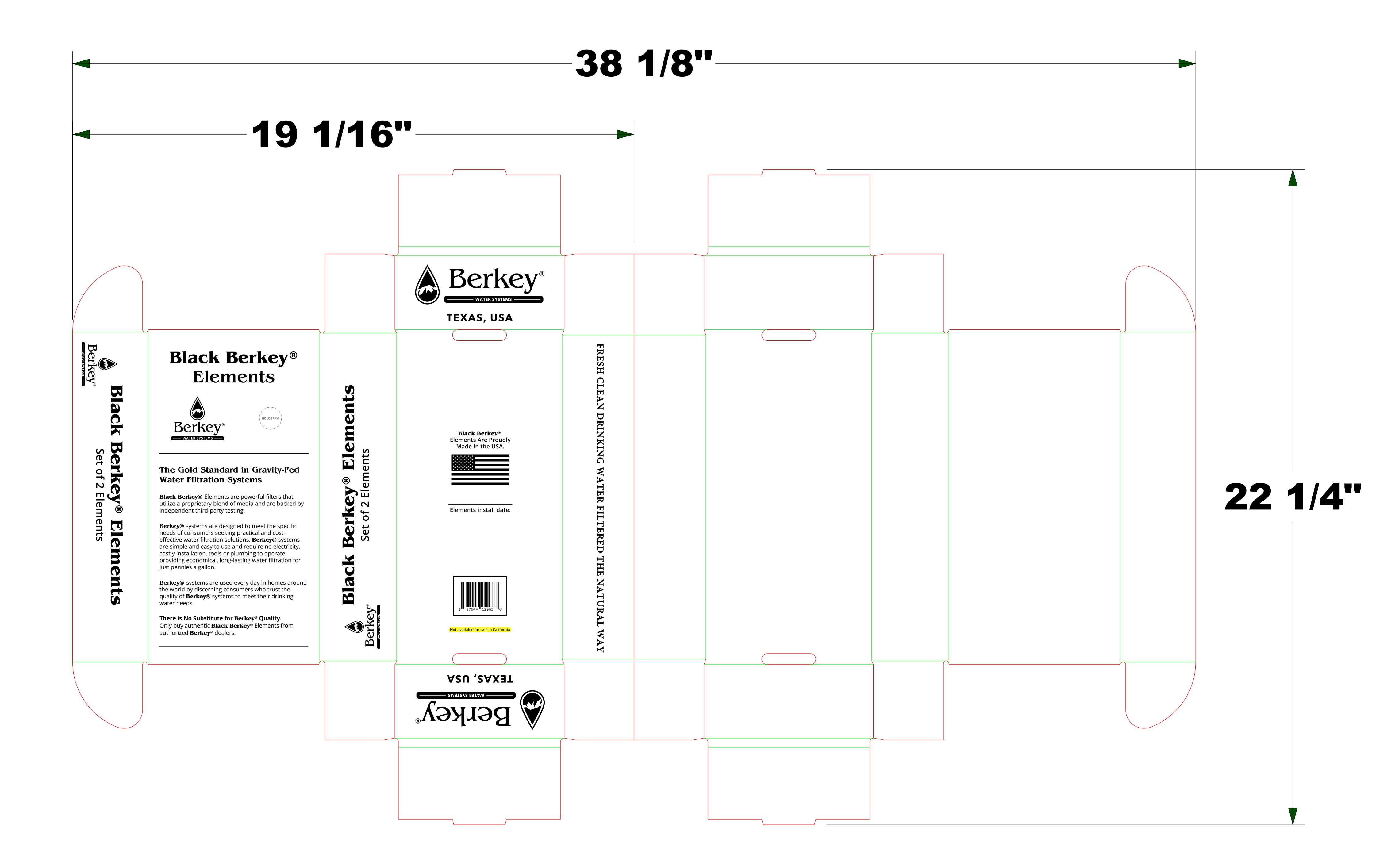
Exhibit B, pg. 172 of 280

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Exhibit B-13, pg.46 of 81



Exhibit B, pg. 1







Berkey<sup>®</sup> Water Filtration Systems



# Super Simple and Easy to Use

No Electricity, Tools or Plumbing Required

- Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**<sup>®</sup> systems are ideal for everyday use wherever you are.

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey Light® 2.75 GALLON (10.4L)



# Our Most Economical Water Filtration Solution

Equipped with powerful Filtration Elements, the Berkey Light® gravity-fed water filtration system offers the same contaminant reduction perfomance as our stainless steel systems, but in a more rugged design that's super-durable and very lightweight.

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey<sup>®</sup> Water Filtration Systems

# The Gold Standard in Gravity-Fed Water Filtration Systems

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey®** systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.



8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs

# Berkey Light® System

2.75 GALLON (10.4L)

# Berkey Light® 2.75 GALLON (10.4L)



# Our Most Economical Water Filtration Solution

- Lightweight, durable construction
- Made from BPA-free copolyester
- Easy to use anywhere—no tools, plumbing or electricity required
- Backed by independent third-party testing



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



# Big Berkey<sup>®</sup> System 2.25 GALLON (8.5L)

### Berkey<sup>®</sup> Water Filtration Systems

# The Gold Standard in Gravity-Fed Water Filtration Systems



**Berkey®** systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey®** systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

#### Super Simple and Easy to Use! No Electricity, Tools or Plumbing Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.

# Big Berkey<sup>®</sup> 2.25 GALLON (8.5L)



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

### Berkey<sup>®</sup> Water Filtration Systems

# 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs







Kit 1 Qt



Travel Berkey® 1.5 Gal



Light®

2.75 Gal



**Berkey**®

3.25 Gal



4.5 Gal

Crow Berk

Crown Berkey™ 6 Gal

Big Berkey®
2.25 GALLON (8.5L)

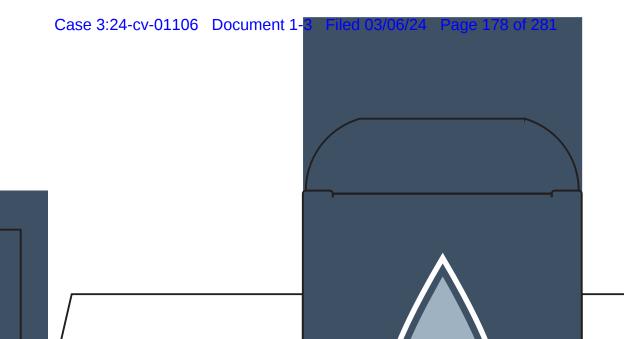


AY FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

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#### **Berkey® Systems**

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey®** systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of Berkey® systems to meet their drinking water needs.

#### **Available in 6 Larger Sizes**



Contact an authorized **Berkey**® dealer today to learn more.



BPA FREE



#### **Superior Reduction**

The **Sport Berkey**® water filter bottle uses the same filtration formulation as our **Black Berkey**® Elements, which are used in our popular gravity-fed systems.

The unique **Sport Berkey**® filter is made from a proprietary blend of media, and is backed by independent third-party testing.

#### **Versatile, Easy to Use**

- 1. Fill the **Sport Berkey**® water filter bottle with water.
- 2. Screw on lid and tighten securely to prevent leaks.
- 3. To drink: pull lid closure down to expose straw. Squeeze bottle to squirt water out of straw into mouth, or suck water through straw, or use both actions together.
- 4. To close: simply pull lid closure up to conceal straw (this helps prevent drips or leaks while carrying).

Sport Berkey® water filter bottle includes lid, straw and replaceable filter



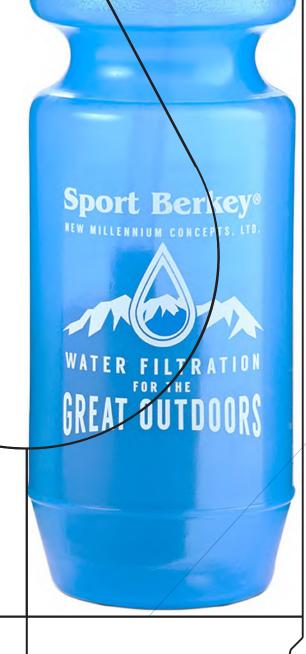
#### **Sport Berkey**®



22 OZ. .6 L

Berkey<sup>®</sup> Water On-the-Go









#### Berkey<sup>®</sup> Water Filtration Systems

# Travel Berkey® 1.5 GALLON (5.6L)

#### Berkey<sup>®</sup> Water Filtration Systems

# Travel Berkey® 1.5 GALLON (5.6L)

### The Gold Standard in Gravity-Fed Water Filtration Systems



**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey®** systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.



- No Electricity, Tools of Pl
- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

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FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

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# Crown Berkey™ System 6 GALLON (22.7L)

### Berkey® Water Filtration Systems









SURVIVAL













Crown Berkey<sup>TM</sup> 6 GALLON (22.7L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.







NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

#### The Gold Standard in Gravity-Fed Water **Filtration Systems**

Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence. Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon. No electricity, tools, or plumbing required.

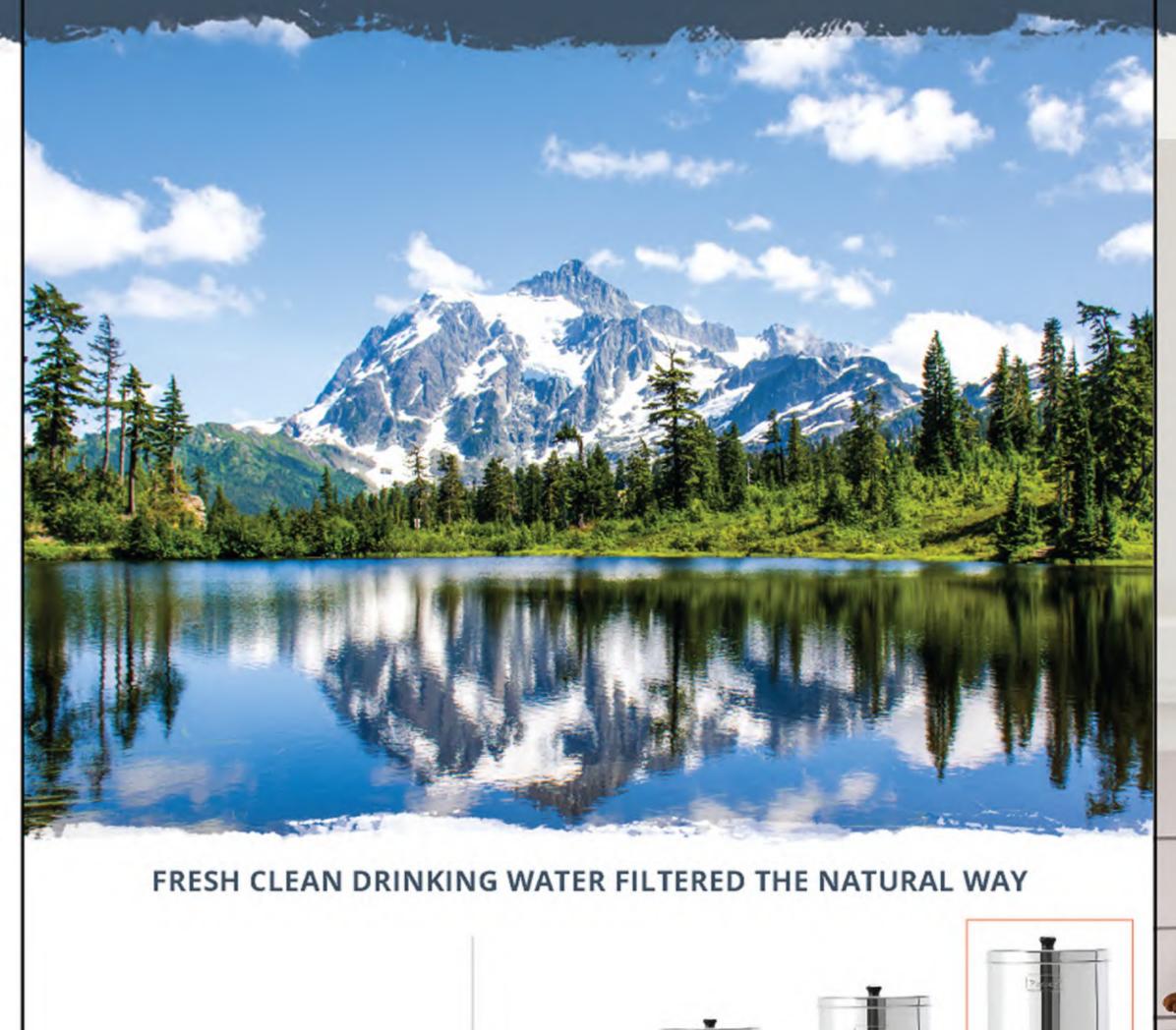
#### **Easily Enjoy** Refreshing, Potable Water at Home or in the Great Outdoors

- .Simply pour water into system's top chamber.
- 2.Water is then filtered by our unique Black Berkey® Elements, which are made from a proprietary blend of media and are backed by independent third-party testing.
- 3.Dispense refreshing water from spigot. Berkey® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

R





OUTDOOR SYSTEMS







Crown Berkey™







Exhibit B, pg. 179 of 280



### Big Berkey® System 2.25 GALLON (8.5L)

#### Berkey<sup>®</sup> Water Filtration Systems









SURVIVAL

Big Berkey® 2.25 GALLON (8.5L)











Big Berkey® 2.25 GALLON (8.5L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.







NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

#### The Gold Standard in **Gravity-Fed Water Filtration Systems**

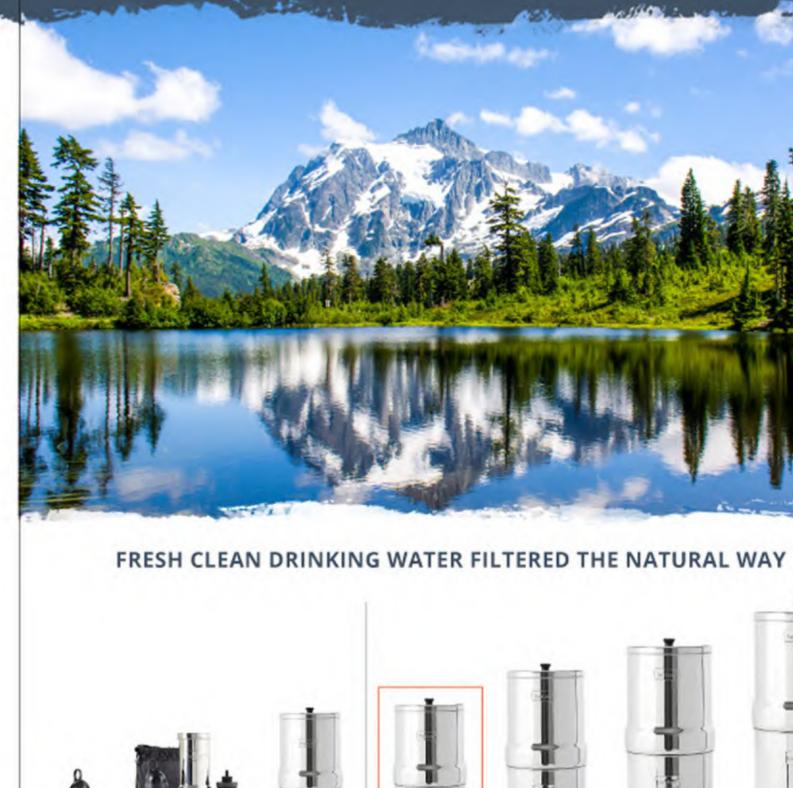
Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence. Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon. No electricity, tools, or plumbing required.

#### **Easily Enjoy Refreshing** Water at Home or in the **Great Outdoors**

- . Simply pour water into system's top chamber.
- . Water is then filtered by our unique Black Berkey® Elements, which are made from a proprietary blend of media and are backed by independent third-party testing.
- Dispense refreshing water from spigot. Berkey® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS







MULTI-USE SYSTEMS





# Royal Berkey® System

3.25 GALLON (12.3L)

### Berkey® Water Filtration Systems













Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious insumers who have declared water independence. Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon. No electricity, tools, or plumbing required.



- Simply pour water into system's top chamber.
- 2. Water is then filtered by our unique Black Berkey® Elements, which are made from a proprietary blend of media and are backed by independent third-party testing.
- . Dispense refreshing water from spigot. Berkey® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

# Royal Berkey®

3.25 GALLON (12.3L)





### Berkey® Water Filtration Systems









Royal Berkey® 3.25 GALLON (12.3L)

MADE FOR THE EXTREME. ENJOYED EVERY DAY.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS





MULTI-USE SYSTEMS





NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

Berkey\*

Exhibit B, pg. 181 of 280



#### **Berkey**\* Water Filtration Systems











#### Berkey<sup>®</sup> Water Filtration Systems









Travel Berkey® 1.5 GALLON (5.6L)

### Enjoy Refreshing, Filtered Water in the Great Outdoors

The gold standard in gravity-fed water filtration systems, **Berkey**<sup>®</sup> systems provide economical, long-lasting water filtration for just pennies a gallon! **Berkey**<sup>®</sup> systems are portable, powerful and easy to use.

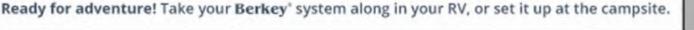
#### No electricity, tools or plumbing required.

- 1. Simply pour water into system's top chamber.
- Water is then filtered by our unique Black Berkey® Elements, which are made from a proprietary blend of media and are backed by independent third-party testing.
- Dispense refreshing water from spigot. Berkey\* systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.

#### MADE FOR THE EXTREME. ENJOYED EVERY DAY.









FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS

Berkey\*

Berkey®

1.5 Gal

Berkey\* Bottle

MULTI-USE SYSTEMS

Berkey®

3.25 Gal

Berkey® 4.5 Gal Berkey" 6 Gal



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Berkey\*

2.25 Gal

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Exhibit B, pg. 182 of 280



### Imperial Berkey® System 4.5 GALLON (17L)

### Berkey® Water Filtration Systems













4.5 GALLON (17L)





Berkey® Water Filtration Systems





Imperial Berkey® 4.5 GALLON (17L)







NO ELECTRICITY, TOOLS OR PLUMBING REQUIRED

#### The Gold Standard in Gravity-Fed Water **Filtration Systems**

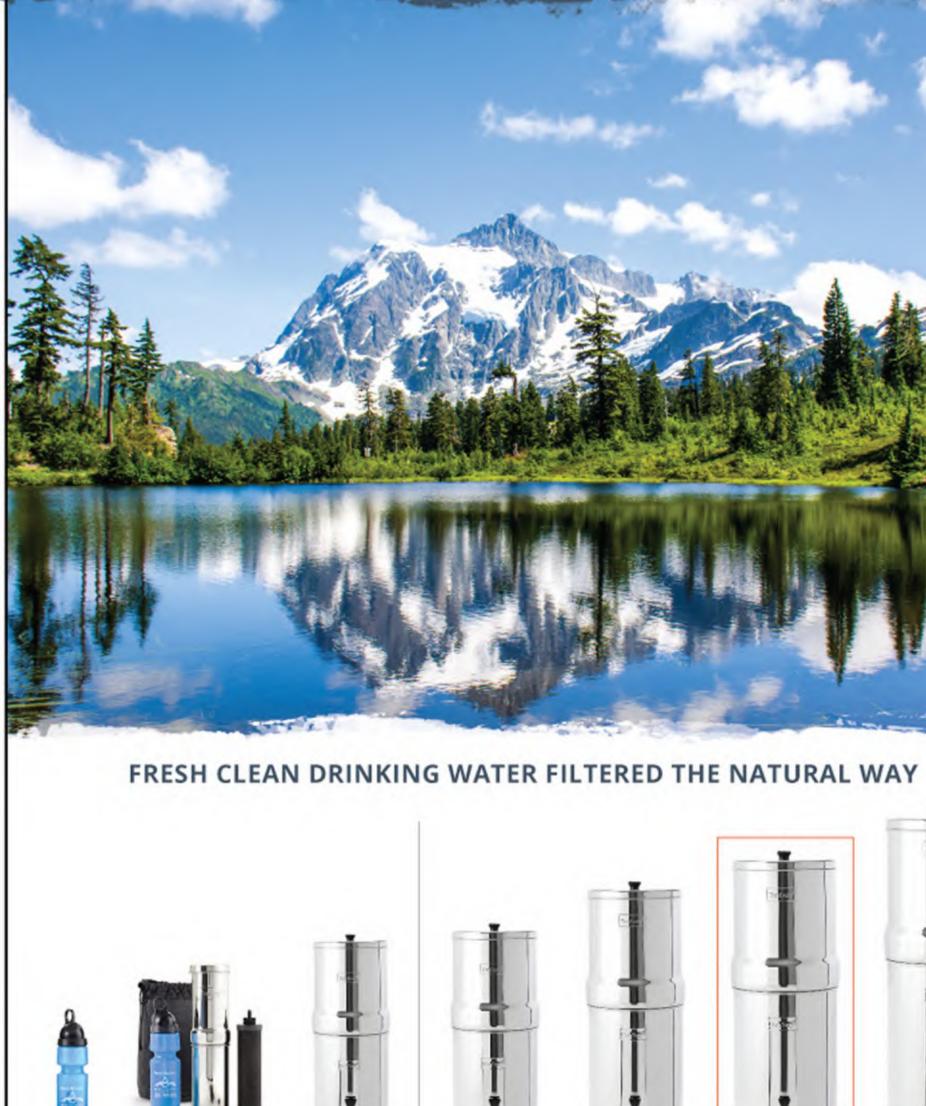
Berkey® Systems were originally designed for extreme use for emergency preparedness and off-grid activities, and are also now used every day in millions of homes around the world by discerning, health conscious consumers who have declared water independence. Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon. No electricity, tools, or plumbing required.

#### **Easily Enjoy** Refreshing, Potable Water at Home or in the Great Outdoors

- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered by our unique Black Berkey® Elements, which are made from a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. Berkey® systems are ideal for camping, RVing, off-grid living, emergency scenarios and everyday use wherever you are.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



OUTDOOR SYSTEMS

Kit 1 Qt

Berkey®

MULTI-USE SYSTEMS

Royal

Berkey®

3.25 Gal

Imperial

Berkey® 4.5 Gal

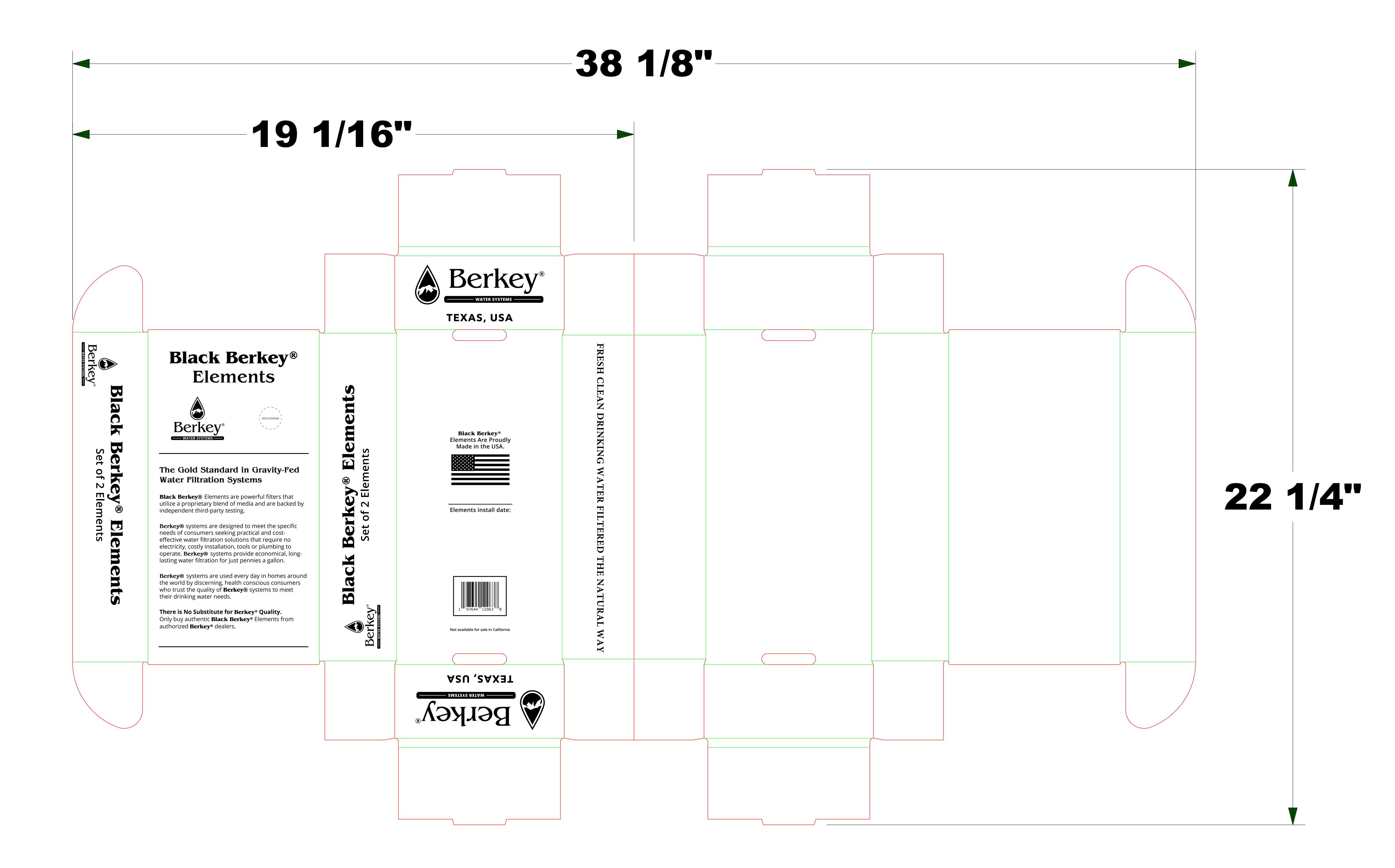


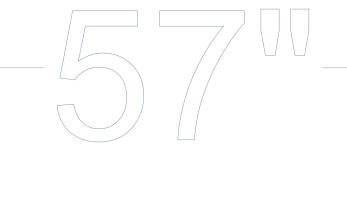
Berkey®

2.25 Gal

Berkey®

1.5 Gal







# Berkey<sup>®</sup> Water Filtration Systems



### Super Simple and Easy to Use

No Electricity, Tools or Plumbing Required

- 1. Simply pour water into system's top
- 2. Water is then filtered through our backed by independent third-party
- 3. Dispense refreshing water from spigot. Berkey® systems are ideal for everyday use wherever you are.

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

- unique and powerful filters that utilize a proprietary blend of media and are

# Berkey Light® 2.75 GALLON (10.4L)



### Our Most Economical Water Filtration Solution

Equipped with powerful Filtration Elements, the Berkey Light® gravity-fed water filtration system offers the same contaminant reduction perfomance as our stainless steel systems, but in a more rugged design that's super-durable and very lightweight.



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey<sup>®</sup> Water Filtration Systems

#### The Gold Standard in Gravity-Fed **Water Filtration Systems**

**Berkey®** systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions that require no electricity, costly installation, tools or plumbing to operate.

Berkey® systems are used every day in homes around the world by discerning, health conscious consumers who trust the quality of **Berkey®** systems to meet their drinking water needs.

Berkey® systems provide economical, long-lasting water filtration for just pennies a gallon.



#### 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs

# Berkey Light® System

2.75 GALLON (10.4L)

# Berkey Light® 2.75 GALLON (10.4L)



### Our Most Economical Water Filtration Solution

- Lightweight, durable construction
- Made from BPA-free copolyester
- Easy to use anywhere—no tools, plumbing or electricity required
- Backed by independent third-party



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY



### Big Berkey® System 2.25 GALLON (8.5L)

### Berkey® Water Filtration Systems

#### The Gold Standard in Gravity-Fed **Water Filtration Systems**



Berkey® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions that require no electricity, costly installation, tools or plumbing

Berkey® systems are used every day in homes around the world by discerning, health conscious consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

**Berkey**® systems provide economical, long-lasting water filtration for just pennies a gallon.

#### Super Simple and Easy to Use! No Electricity, Tools or Plumbing Required.



- Simply pour water into system's top chamber.
- Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever

# Big Berkey® 2.25 GALLON (8.5L)



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

## Berkey<sup>®</sup> Water Filtration Systems

#### 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs



Light®

2.75 Gal





Kit 1 Qt



1.5 Gal





3.25 Gal



4.5 Gal



Crown **Berkey**<sup>™</sup> 6 Gal

# Big Berkey® 2.25 GALLON (8.5L)





FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Berkey®
water systems



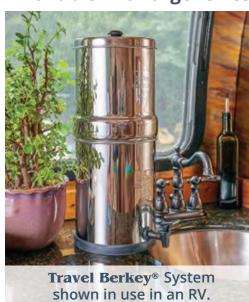
#### Berkey® Systems

**Berkey®** systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions that require no electricity, costly installation, tools or plumbing to operate.

**Berkey**® systems are used every day in homes around the world by discerning, health conscious consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

**Berkey®** systems provide economical, long-lasting water filtration for just pennies a gallon.

#### **Available in 6 Larger Sizes**



Contact an authorized **Berkey**® dealer today to learn more.



BPA FREE



#### **Superior Reduction**

The **Sport Berkey**® water filter bottle uses the same filtration formulation as our **Black Berkey**® Elements, which are used in our popular gravity-fed systems.

The unique **Sport Berkey**® filter is made from a proprietary blend of media, and is backed by independent third-party testing.

#### **Versatile, Easy to Use**

- 1. Fill the **Sport Berkey**® water filter bottle with water.
- 2. Screw on lid and tighten securely to prevent leaks.
- 3. To drink: pull lid closure down to expose straw. Squeeze bottle to squirt water out of straw into mouth, or suck water through straw, or use both actions together.
- 4. To close: simply pull lid closure up to conceal straw (this helps prevent drips or leaks while carrying).

Sport Berkey® water filter bottle includes lid, straw and replaceable filter



#### **Sport Berkey**®



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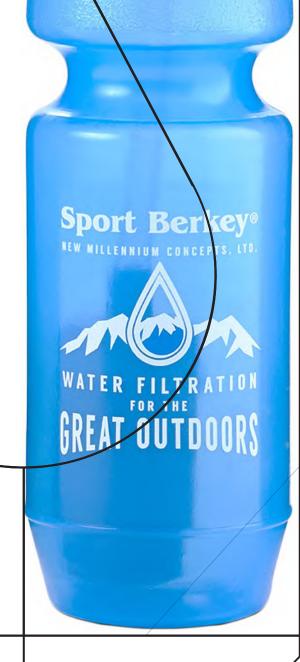
FILTER

WATER

22 OZ.

.6 L

Berkey® Water
On-the-Go







### Berkey<sup>®</sup> Water Filtration Systems

# The Gold Standard in Gravity-Fed Water Filtration Systems

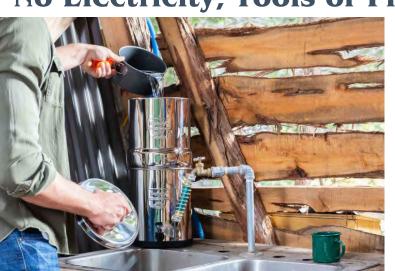


**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions that require no electricity, costly installation, tools or plumbing to operate.

**Berkey**® systems are used every day in homes around the world by discerning, health conscious consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

**Berkey**® systems provide economical, long-lasting water filtration for just pennies a gallon.

#### Super Simple and Easy to Use! No Electricity, Tools or Plumbing Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- Dispense refreshing water from spigot. **Berkey**<sup>®</sup> systems are ideal for everyday use wherever you are.

# Travel Berkey® 1.5 GALLON (5.6L)



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

R

### Berkey<sup>®</sup> Water Filtration Systems

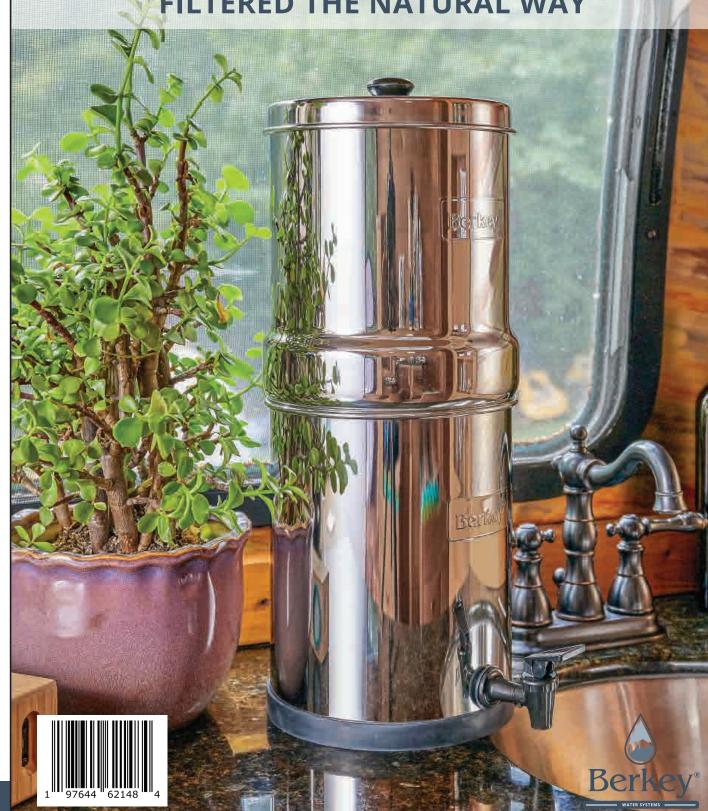
### 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Travel Berkey®
1.5 GALLON (5.6L)

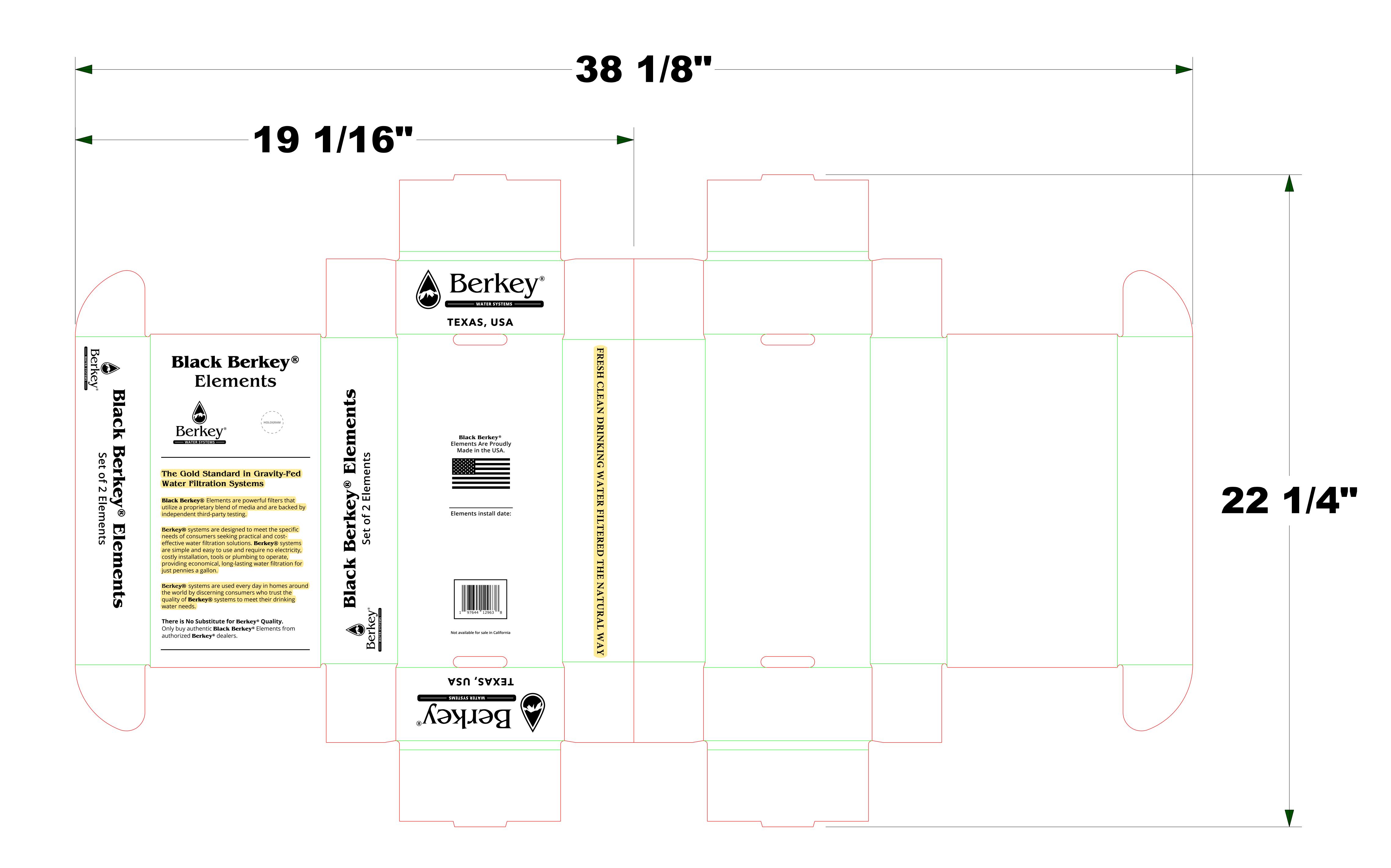




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R

R



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#### **Sport Berkey**®



**Water Filter Bottle** 

The unique **Sport Berkey**® water filter is made from a proprietary blend of media, and is backed by independent third-party testing. Test results showed up to a 99.9% reduction of typical contaminants found in tap water.





BPA FREE MADE IN THE USA



### Berkey® Water Filtration Systems

### The Gold Standard in Gravity-Fed Water Filtration Systems



**Berkey®** System shown with optional **Berkey Stainless Steel™** Spigot and **Berkey Base™** (sold separately)

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

#### Super Simple and Easy to Use! No Electricity, Tools or Plumbing Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- s. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.

# Travel Berkey® 1.5 GALLON (5.6L)



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

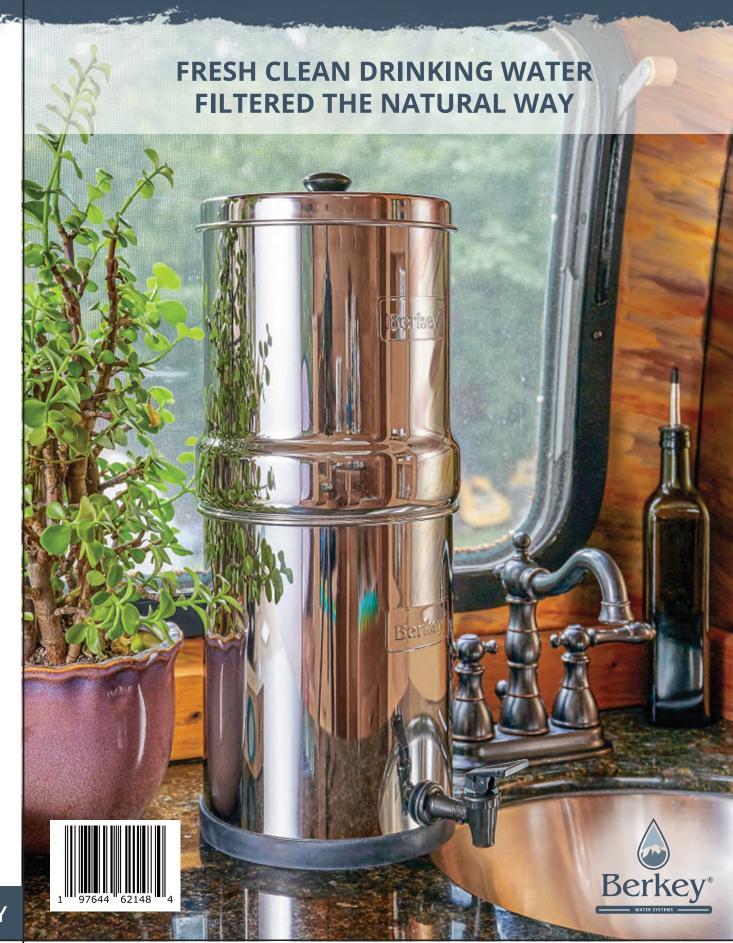
### Berkey<sup>®</sup> Water Filtration Systems

8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Travel Berkey®
1.5 GALLON (5.6L)



R

R

R

R

Exhibit B, pg. 191 of 280



#### **Berkey® Systems**

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

#### **Berkey® Systems are Available in 6 Larger Sizes**



Travel Berkey® Outdoor System shown in use in an RV.

Contact an authorized **Berkey**® dealer today to learn more.



BPA FREE



#### **Superior Reduction**

The **Sport Berkey**® water filter bottle uses the same filtration formulation as the **Berkey**® filter elements used in our larger gravity-fed systems.

Case 3:24-cv-01106 Document 1-

The unique **Sport Berkey**® filter is made from a proprietary blend of media, and is backed by independent third-party testing.

#### Versatile, Easy to Use

- 1. Fill the **Sport Berkey**® water filter bottle with water.
- 2. Screw on lid and tighten securely to prevent leaks.
- 3. To drink: pull lid closure down to expose straw. Squeeze bottle to squirt water out of straw into mouth, or suck water through straw, or use both actions together.
- 4. To close: simply pull lid closure up to conceal straw (this helps prevent drips or leaks while carrying).

Sport Berkey® water filter bottle includes lid, straw and replaceable filter



#### **Sport Berkey**®



22 OZ.

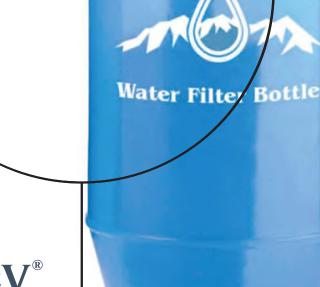
.6 L

Berkey® Water On-the-Go





Sport Berkey







Go Berkey® Kit

#### Berkey® Water Filtration Systems

#### Enjoy Refreshing, Filtered Water, On-the-Go

#### 1 Qt. Go Berkey® System

Our lightest and most compact gravity-fed water filtration system provides the same contaminant reduction performance as our larger gravity-powered systems.

#### No electricity, tools, or plumbing required.

- Simply pour water into the Go Berkey\* system's top chamber.
- Water is then filtered through a single Berkey\* element, a powerful filter that utilizes a proprietary blend of media and is backed by independent third-party testing.
- Lift top chamber and pour out refreshing water from the system's bottom chamber.



The **Go Berkey**® Kit is the ideal personal water filtration system for on-the-go, travel, and everyday use wherever you are.

#### 22 Oz. Sport Berkey® Water Filter Bottle

Fast, easy water filtration on the go. The Sport Berkey® water filter bottle uses the same filtration formulation as the Berkey® filter elements used in our larger gravity-fed systems.

The **Sport Berkey**\* water bottle's filter is made from a proprietary blend of media, and is backed by independent third-party testing.



#### Berkey Filter Primer™

Prime **Berkey\*** Elements off-grid, without the need for a pressurized faucet.



Also included: compartmentalized carrying case for convenient storage and transport of system, element, bottle and primer.

# Go Berkey<sup>®</sup> Kit 1 Quart (.9L)



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

#### Berkey® Water Filtration Systems



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

Go Berkey® Kit
1 Quart (.9L)

### YOUR PERSONAL WATER FILTRATION SOLUTION FOR ON-THE-GO



R

R

R



### Big Berkey® System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems

#### The Gold Standard in Gravity-Fed **Water Filtration Systems**



**Berkey**<sup>®</sup> System shown with optional **Berkey Stainless** Steel™ Spigot and Berkey Base™ (sold separately)

**Berkey**<sup>®</sup> systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**<sup>®</sup> systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**<sup>®</sup> systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

#### **Super Simple and Easy to Use!** No Electricity, Tools or Plumbing Required.



- . Simply pour water into system's top chamber.
- Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- B. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.

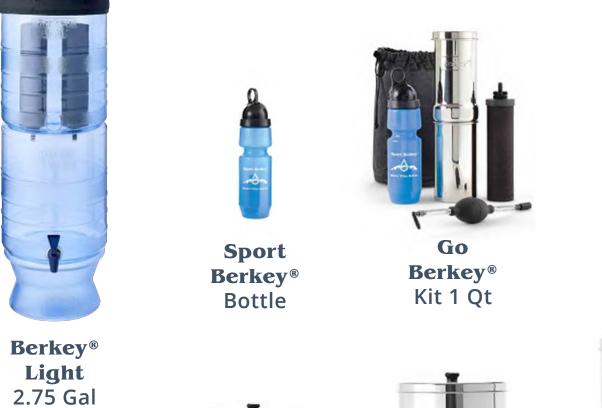
### Big Berkey® 2.25 GALLON (8.5L)



#### FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey® Water Filtration Systems

8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs







3.25 Gal



4.5 Gal



**Travel** 

**Berkey**®

1.5 Gal

Berkey™ 6 Gal

# Big Berkey®

2.25 GALLON (8.5L)



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

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Exhibit B-13, pg.68 of 81



# Berkey<sup>®</sup> Water Filtration Systems



# Super Simple and Easy to Use

No Electricity, Tools or Plumbing Required

Simply pour water into system's top chamber.
 Water is then filtered through our

unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.

3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.

FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey Light® 2.75 GALLON (10.4L)



**MADE IN THE USA** 

# Our Most Economical Water Filtration Solution

Equipped with powerful filtration elements, the **Berkey Light®** gravity-fed water filtration system offers the same contaminant reduction performance as our stainless steel systems, but in a more rugged design that's super-durable and very lightweight.



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY

# Berkey<sup>®</sup> Water Filtration Systems

# The Gold Standard in Gravity-Fed Water Filtration Systems

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, tools or plumbing to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**<sup>®</sup> systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**<sup>®</sup> systems to meet their drinking water needs.



8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs

# Berkey Light® System

2.75 GALLON (10.4L)

# Berkey Light<sup>®</sup> 2.75 GALLON (10.4L)

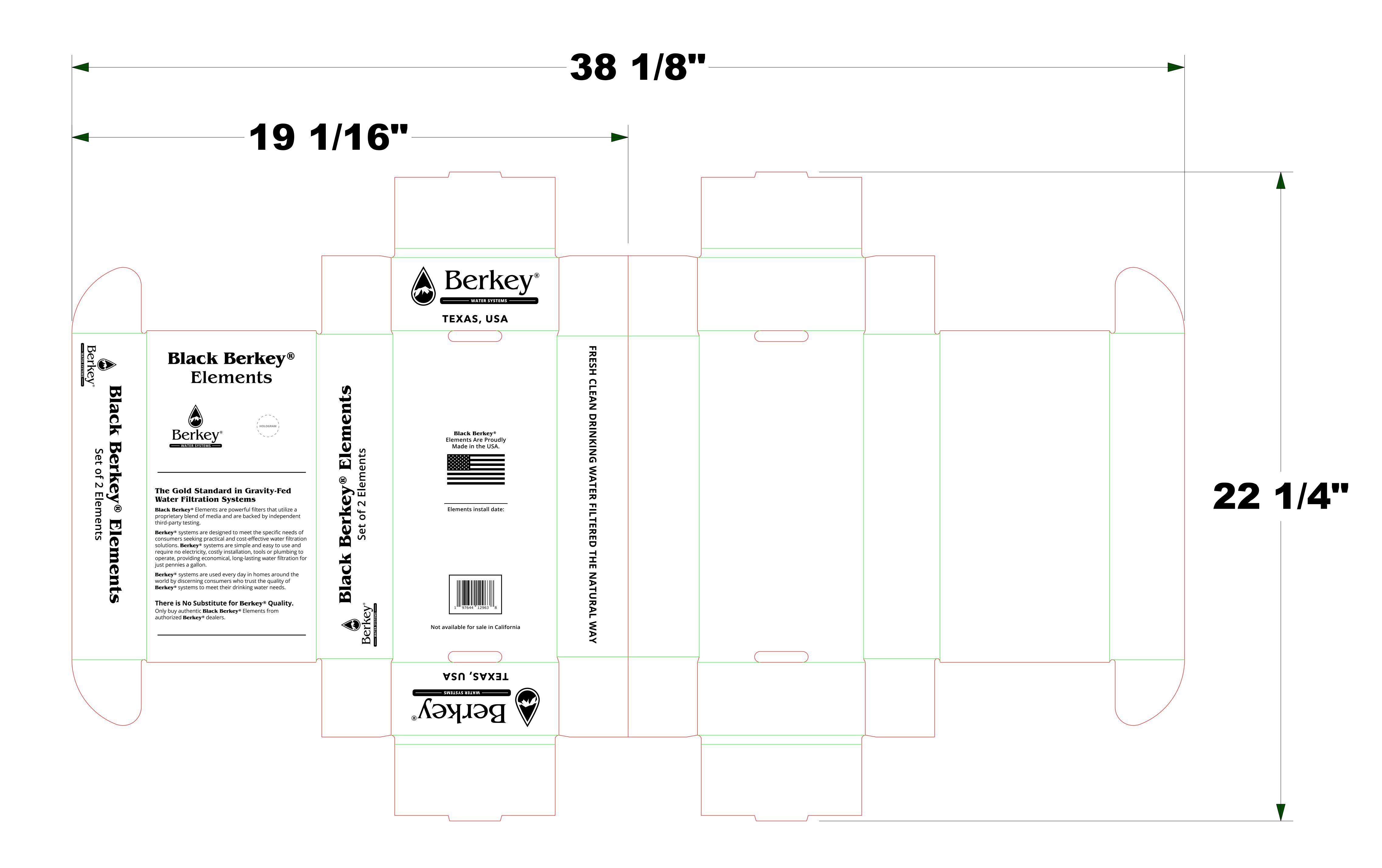


# Our Most Economical Water Filtration Solution

- Lightweight, durable construction
- Made from BPA-free copolyester
- Easy to use anywhere—no tools, plumbing or electricity required
- Backed by independent third-party testing



FRESH CLEAN DRINKING WATER FILTERED THE NATURAL WAY





### Big Berkey® System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems

#### The Gold Standard in Gravity-Fed **Water Filtration Systems**



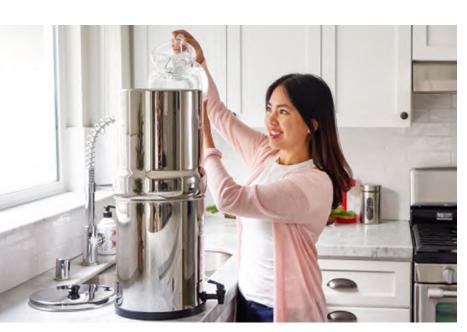
**Berkey**<sup>®</sup> System shown with optional **Berkey Stainless Steel™** Spigot and **Berkey Base™** (sold separately)

**Berkey**<sup>®</sup> systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**<sup>®</sup> systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

Berkey® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

#### **Super Simple and Easy to Use!** No Electricity, Costly Installation, or Tools Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.

# Big Berkey® 2.25 GALLON (8.5L)



# Berkey® Water Filtration Systems

8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs















Berkey<sup>®</sup> Kit 1 Qt

**Travel** 

Berkey<sup>®</sup>

1.5 Gal

Crown

Berkey™

6 Gal

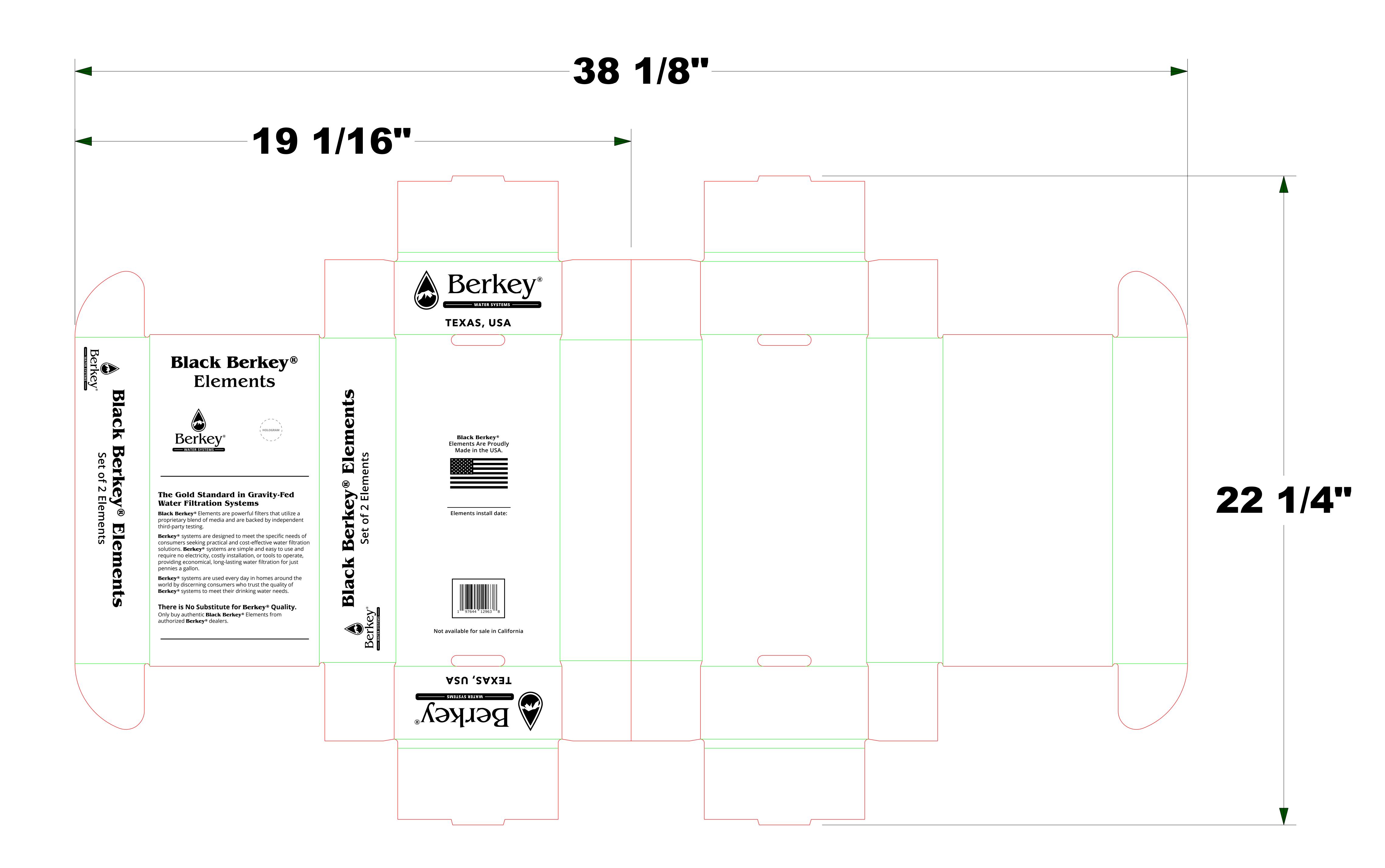


**Imperial Berkey**® 4.5 Gal

### Big Berkey® 2.25 GALLON (8.5L)



Exhibit B, pg. 197 of 280





# Big Berkey<sup>®</sup> System 2.25 GALLON (8.5L)

# Berkey® Water Filtration Systems

## The Gold Standard in Gravity-Fed Water Filtration Systems



**Berkey**® System shown with optional **Berkey Stainless Steel™** Spigot and **Berkey Base™** (sold separately)

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, or tools to operate, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

### **Super Simple and Easy to Use!**No Electricity, Costly Installation, or Tools to Operate.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use wherever you are.

# Big Berkey® 2.25 GALLON (8.5L)



# Berkey® Water Filtration Systems

# 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs









**Berkey**®

**Bottle** 





Go Berkey® Kit 1 Qt

**Imperial** 

**Berkey**®

4.5 Gal



Crown Berkey™ 6 Gal

**Travel** 

Berkey<sup>®</sup>

1.5 Gal

# Big Berkey® 2.25 GALLON (8.5L)





A



### Berkey® Water Filtration Systems

### The Gold Standard in Gravity-Fed Water Filtration Systems



Berkey® System shown with optional Berkey Stainless Steel™ Spigot and Berkey Base™ (sold separately)

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

### No Electricity, Costly Installation, or Tools Required.

R



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- Dispense refreshing water from spigot. **Berkey**<sup>®</sup> systems are ideal for everyday use.

# Travel Berkey® 1.5 GALLON (5.6L)



### Berkey® Water Filtration Systems



# Travel Berkey® 1.5 GALLON (5.6L)



R

R



Imperial Berkey®

# Imperial Berkey® System

4.5 GALLON (17L)

# Berkey® Water Filtration Systems

# 4.5 GALLON (17L)

# Berkey® Water Filtration Systems

# Imperial Berkey® 4.5 GALLON (17L)

### The Gold Standard in Gravity-Fed **Water Filtration Systems**



meet the specific needs of consumers water filtration solutions.

**Berkey**<sup>®</sup> systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

Berkey® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

Berkey® System shown with optional Berkey Stainless Steel™ Spigot and Berkey Base™ (sold separately)









3.25 Gal





Go

**Berkey**®



**Travel** 



#### No Electricity, Costly Installation, or Tools Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- . Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use.

Berkey

**Light**®

2.75 Gal

Big

**Berkey**®

2.25 Gal

Exhibit B, pg. 201 of 280



## Royal Berkey® System

3.25 GALLON (12.3L)

## Berkey® Water Filtration Systems

## The Gold Standard in Gravity-Fed Water Filtration Systems



**Berkey**<sup>®</sup> System shown with optional **Berkey Stainless Steel™** Spigot and **Berkey Base™** (sold separately)

**Berkey**<sup>®</sup> systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

## No Electricity, Costly Installation, or Tools Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use.

## Royal Berkey® 3.25 GALLON (12.3L)



## Berkey® Water Filtration Systems



## Royal Berkey® 3.25 GALLON (12.3L)



R

D



### Crown Berkey<sup>™</sup> System 6 GALLON (22.7L)

## Berkey® Water Filtration Systems

#### The Gold Standard in Gravity-Fed **Water Filtration Systems**



Berkey<sup>®</sup> System shown with optional Berkey Stainless Steel<sup>™</sup> Spigot and Berkey Base<sup>™</sup> (sold separately)

Berkey® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

Berkey® systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

Berkey® systems are used every day in homes around the world by discerning consumers who trust the quality of Berkey® systems to meet their drinking

#### No Electricity, Costly Installation, or Tools Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use.

## Crown Berkey<sup>TM</sup> 6 GALLON (22.7L)



## Berkey® Water Filtration Systems

### 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs







**Light**®

2.75 Gal

Big **Berkey**® 2.25 Gal



**Berkey**® Bottle



Royal Berkey<sup>®</sup>



**Berkey**® Kit 1 Qt

**Travel** 

**Berkey**®

1.5 Gal

Crown

**Berkey**<sup>™</sup>

6 Gal



**Imperial Berkey**® 4.5 Gal

## Crown Berkey<sup>TM</sup> 6 GALLON (22.7L)



Exhibit B, pg. 203 of 280



## Big Berkey<sup>®</sup> System 2.25 GALLON (8.5L)

## Berkey® Water Filtration Systems

### The Gold Standard in Gravity-Fed Water Filtration Systems



Berkey® System shown with optional Berkey Stainless
Steel™ Spigot and Berkey Base™ (sold separately)

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**<sup>®</sup> systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

### No Electricity, Costly Installation, or Tools Required.



- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use.

## Big Berkey<sup>®</sup> 2.25 GALLON (8.5L)



## Berkey® Water Filtration Systems

## 8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs









**Berkey**®

Bottle





Go Berkey® Kit 1 Qt



Imperial Berkey® 4.5 Gal

## Big Berkey® 2.25 GALLON (8.5L)





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R

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Exhibit B-13, pg.78 of 81



## Berkey® Water Filtration Systems



## Super Simple and Easy to Use

No Electricity, Costly Installation, or Tools Required.

- 1. Simply pour water into system's top chamber.
- 2. Water is then filtered through our unique and powerful filters that utilize a proprietary blend of media and are backed by independent third-party testing.
- 3. Dispense refreshing water from spigot. **Berkey**® systems are ideal for everyday use.





**MADE IN THE USA** 

## Our Most Economical Water Filtration Solution

Equipped with powerful filtration elements, the **Berkey Light®** gravity-fed water filtration system offers the same contaminant reduction performance as our stainless steel systems, but in a more rugged design that's super-durable and very lightweight.



## Berkey<sup>®</sup> Water Filtration Systems

## The Gold Standard in Gravity-Fed Water Filtration Systems

**Berkey**<sup>®</sup> systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**<sup>®</sup> systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**<sup>®</sup> systems to meet their drinking water needs.



8 Berkey® Systems to Choose From to Meet Your Water Filtration Needs

## Berkey Light® System

2.75 GALLON (10.4L)

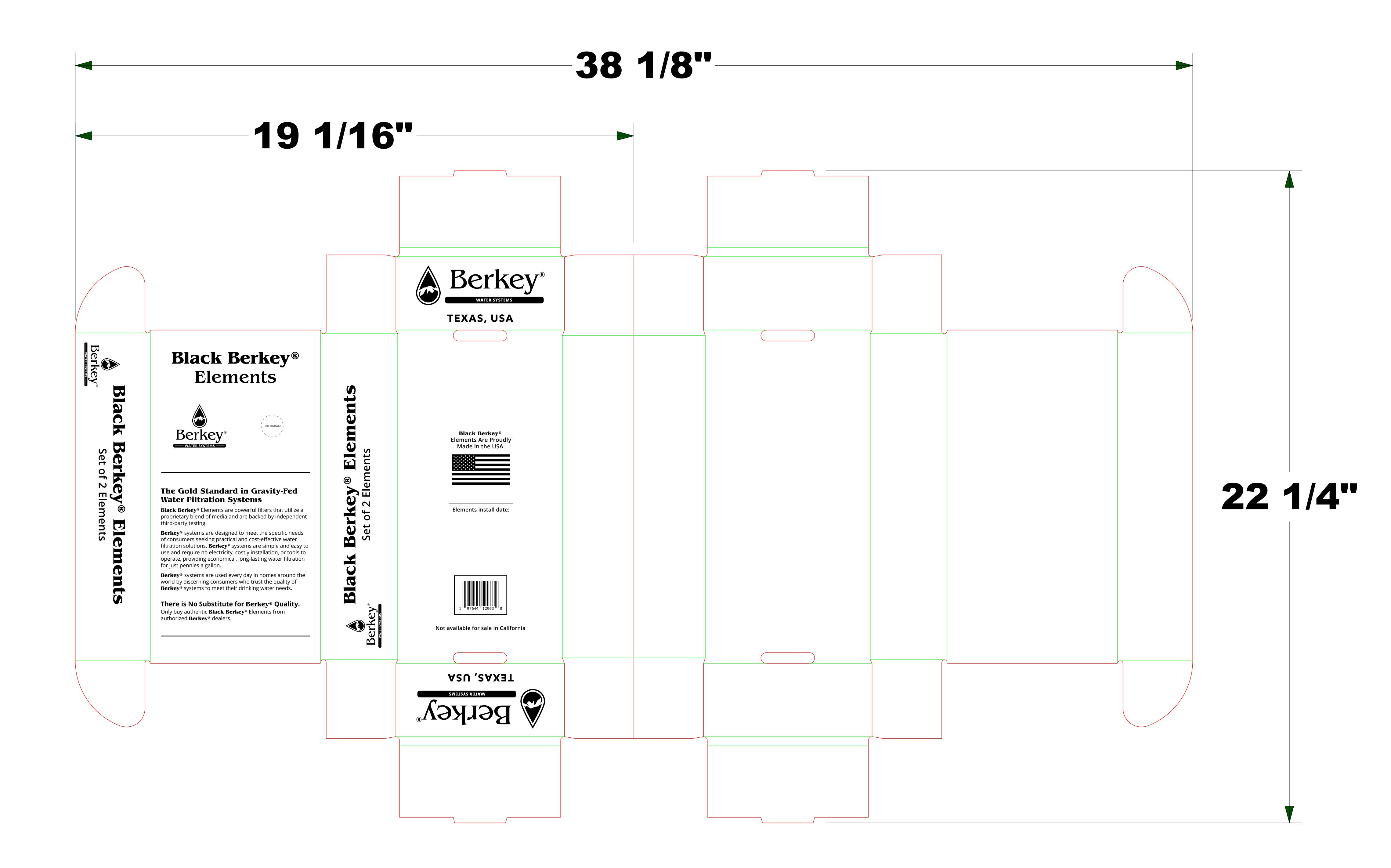
# Berkey Light® 2.75 GALLON (10.4L)



## Our Most Economical Water Filtration Solution

- Lightweight, durable construction
- Made from BPA-free copolyester
- Easy to use —no electricity, costly installation or tools required
- Backed by independent third-party testing







#### **Berkey® Systems**

**Berkey**® systems are designed to meet the specific needs of consumers seeking practical and cost-effective water filtration solutions.

**Berkey**® systems are simple and easy to use and require no electricity, costly installation, or tools, providing economical, long-lasting water filtration for just pennies a gallon.

**Berkey**® systems are used every day in homes around the world by discerning consumers who trust the quality of **Berkey**® systems to meet their drinking water needs.

#### **Berkey® Systems are Available in 6 Larger Sizes**



Travel Berkey® shown here.

Contact an authorized **Berkey**® dealer today to learn more.



BPA FREE



#### **Superior Reduction**

The **Sport Berkey**® water filter bottle uses the same filtration formulation as the **Berkey**® filter elements used in our larger gravity-fed systems.

Case 3:24-cv-01106 Document 1-

The unique **Sport Berkey**® filter is made from a proprietary blend of media, and is backed by independent third-party testing.

#### Versatile, Easy to Use

- 1. Fill the **Sport Berkey**® water filter bottle with water.
- 2. Screw on lid and tighten securely to prevent leaks.
- 3. To drink: pull lid closure down to expose straw. Squeeze bottle to squirt water out of straw into mouth, or suck water through straw, or use both actions together.
- 4. To close: simply pull lid closure up to conceal straw (this helps prevent drips or leaks while carrying).

Sport Berkey® water filter bottle includes lid, straw and replaceable filter



#### **Sport Berkey**®



22 OZ. | .6 L

Berkey<sup>®</sup> Water On-the-Go





Sport Berkey







#### 

Exhibit B-14, pg. 1 of 5

From: James.M
To: "Shawn Elliott"

**Subject:** FW: Big problem of Berkey diffamation in France

**Date:** Wednesday, June 7, 2023 4:24:56 PM

Attachments: <u>bfm2022.png</u>

dealer2022.png

FIFRA-08-2023-0038-SSURO-BerkeyInternational-2023.pdf

**From:** Céline SEBAN - Berkey®France Millenium <<u>admin@berkey-france-millenium.fr</u>>

Sent: Wednesday, June 7, 2023 4:57 AM

To: James Mathis < <u>james.m@berkeywater.com</u>>; Shawn < <u>shawn.e@berkeybynmcl.com</u>>

**Subject:** Big problem of Berkey diffamation in France

Dear James and Shawn,

Today we learn of a document that has been published on the website of Berkefeld's official reseller in France, the company Aquatechniques <a href="https://eaudoulton.com/berkey-condamnation/?">https://eaudoulton.com/berkey-condamnation/?</a> <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/?</a> <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/?</a> <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/?</a> <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/?</a> <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a>? <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a>? <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a>? <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a>? <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a>? <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a>? <a href="https://eaudoulton.com/berkey-condamnation/">https://eaudoulton.com/berkey-condamnation/</a> <a href="https://eaudoulton.com/berkey-condamna

A document has been published which purports to be a court decision against Berkey International LLC.

The introduction to this document is entitled: "Berkey cartridges ineffective, banned from export sales" and "Berkey finally guilty in the USA".

In addition, the document mentions a URL for our European store berkey-store.com (page 4).

Please give us your reaction to this document and the official way to react.

--

Best regards,



Céline SEBAN | Présidente
Distributeur agréé Berkey® France | Europe
Boutique en ligne berkey-france-millenium.fr
+33 (0)5 31 61 61 06 / +33 (0)6 01 18 04 81



#### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 211 of 281

Exhibit B-14, pg. 2 of 5

From: Shawn shawn@berkeywater.com @

Subject: URGENT Part#1 of 2 FW: Defamation of our Berkey products in Europe by Aqua-Techniques

Date: June 19, 2023 at 12:49 PM

To: Jim js-tw@startmail.com, Warren Norred wnorred@norredlaw.com



Hi Jim,

Here is a request from our main dealer in France/Brussels area for support in pushing back attacks by Aqua-Techniques (Doulton/British Berkefeld distributor in France) who has been slandering Berkey, and tagging all the dealers in the EU on Social media, so their slander shows up in our Berkey dealers social media feeds. They are looking to take legal action, and want our help to either join in the legal action or contact Doulton/British Berkefeld HQ.

Please advise on how I should respond.

I also received a request from another dealer in France (with whom Pure Berkey has been in contact) asking for an official response or "denial" see the email that will follow this one (Part #2 of 2).

They see this as an URGENT request as does the other dealer in France (other email - part 2). I'm not saying drop everything to address this, but **your advice on how I can respond to them would be much appreciated ASAP**.

Thanks,

Shawn Elliott
Senior Executive Manager
Berkey® Water Systems

From: Sébastien Kaiser < Sebastien@pure-berkey.eu>

Sent: Monday, June 19, 2023 9:36 AM

To: shawn@berkeywater.com; James Mathis <james.m@berkeywater.com>

Cc: Gaetan Marechal <gaetan@pure-berkey.eu>

Subject: FW: Defamation of our Berkey products in Europe by Aqua-Techniques

Importance: High

Dear Shawn, James,

As you can read below (scroll down), we have already been in touch (written a letter) with the Doulton team to discuss the situation and seek an amicable resolution.

However, given the extent of the impact, we believe that support from the parent company, Berkey, could be beneficial in managing this situation.

Several Berkey resellers in Europe are currently considering initiating a class action lawsuit for defamation (we are in contact with Celine Seban). Your support, be it through a public statement, legal resources, or simply moral backing, would be greatly appreciated during this difficult time.

We have complete faith in the quality of Berkey products. However, the seriousness of these

detamatory accusations requires a coordinated and strong response from all parties involved.

If necessary, I have good contacts with the American law firm Wilson Sonsini (WSGR.com) which is based in Brussels and also in Austin, which could allow us to take joint action.

We sincerely hope that we can overcome this hurdle together, defending the values of quality and transparency that have always characterized the brand.

We look forward to your prompt response.

Best regards,

Sébastien



Sébastien Kaiser
M&L Distribution
[mob lu] +352 671 250 458
[mob be] +32 496 250 458
[mob fr] +33 6 12 90 43 76
sebastien@pure-berkey.eu

From: Sébastien Kaiser

Sent: Monday, June 19, 2023 3:39 PM

To: rjackson@doulton.com; OHarrison@doulton.com

Cc: gaetan@pure-berkey.eu

Subject: Defamation of our Berkey products in Europe by Aqua-Techniques

Importance: High

Dear Doulton Team,

I am writing to you as a representative of Pure Berkey, in response to a series of concerning incidents that have recently taken place in Europe. We have received reports that Aqua-Techniques, one of your resellers, has made defamatory statements about our Berkey products. These remarks have not only damaged our reputation but also negatively impacted several of our dealers across Europe (<a href="https://www.instagram.com/aquatechniques/">https://www.instagram.com/aquatechniques/</a>).

We firmly believe in fair competition and market transparency, and we are deeply perplexed by these actions that seem to contradict these principles. Every brand has the right to promote its products, but this should not be done at the expense of other companies' reputation.

In light of this situation, several of our affected dealers in Europe are currently considering initiating a joint legal action for defamation. However, before undertaking such a step, we would like to discuss this matter with you to seek an amicable resolution.

We trust in the quality of our Berkey products. Consequently, we expect an appropriate response from you to this situation. This could involve a public retraction from Aqua-Techniques, a clarification of your communication standards to prevent such incidents in the future, or other suitable measures.

We sincerely hope that this matter can be resolved in a constructive and fair manner, respecting the values that we all share as industry players.

Looking forward to your prompt response.

Best regards,

Sébastien



**Sébastien Kaiser M&L Distribution**[mob lu] +352 671 250 458
[mob be] +32 496 250 458
[mob fr] +33 6 12 90 43 76
sebastien@pure-berkey.eu

From: Shawn shawn@berkeywater.com @

Subject: URGENT Part#2 of 2 FW: REQUEST FOR OFFICIAL DENIAL

Date: June 19, 2023 at 12:51 PM

To: Jim js-tw@startmail.com, Warren Norred wnorred@norredlaw.com



Here is Part #2, referenced in my part#1 email.

Shawn

From: Céline SEBAN - Berkey®France Millenium <a dmin@berkey-france-millenium.fr>

Sent: Monday, June 19, 2023 7:58 AM

To: James Mathis < <u>james.m@berkeywater.com</u>>; shawn < <u>shawn.e@berkeywater.com</u>>

Subject: REQUEST FOR OFFICIAL DENIAL

Dear James, Dear Shawn,

For 2 weeks now, Aqua-Technique, a Doulton and Berkefeld dealer, has been publishing articles accusing Berkey® of selling ineffective filters, of being condemned by the courts and even of being banned from importing into Europe. These articles are appearing on their website, on Facebook and on Instagram, damaging not only the Berkey® brand, but also the French and European retailers that we are, since we are systematically tagged in these publications - and that's unacceptable!

We've asked for your help in getting an official reaction, or even taking legal action for defamation to stop these attacks. To date, nothing has been done and, once again, we're left to fend for ourselves, since this isn't the first time we've asked for your help with similar attacks and nothing has happened...

Are we just another entity generating sales for Berkey®, or are we part of a real network, and if so, can we count on your help at least once to hope for some action on your part?

I confess to being somewhat irritated by your systematic lack of reaction when it comes to coming to our aid when the brand and retailers are under attack. We spend an enormous amount of energy to ensure that Berkey® continues to be seen as a brand of impeccable quality and high standards, and I don't think you can imagine how much this kind of event damages Berkey®'s reputation and ultimately everyone's business.

Do you have anything concrete to suggest to us to ensure that this individual stops these illegal and defamatory attacks?

Best regards,



Céline SEBAN | Présidente
Distributeur agréé Berkey® France | Europe
Boutique en ligne berkey-france-millenium.fr
+33 (0)5 31 61 61 06 / +33 (0)6 01 18 04 81

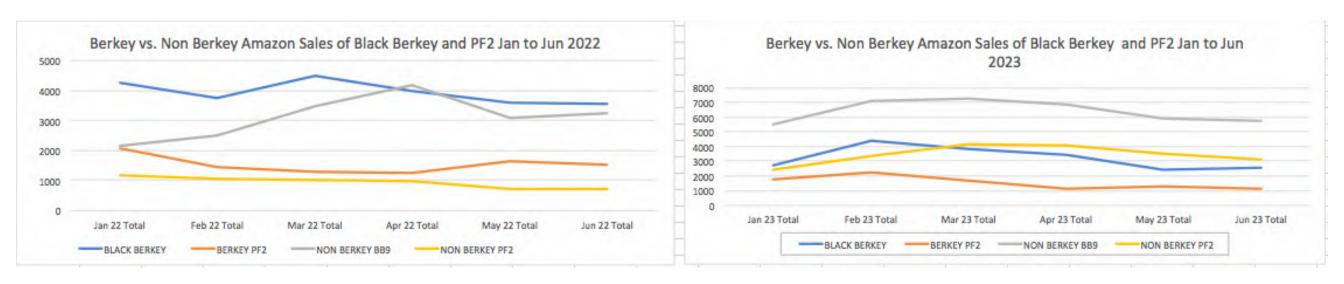


Cordialement,



Frédéric | Berkey® Customer Support Berkey® Authorized Dealer for Europe Boutique en ligne berkey-store.com





#### One Sample of a Counterfeit Black Berkey® Box (Front)

Badly faked artwork, wrong fonts



Missing "LTD." from the end of the manufacturer's name, "New Millennium Concepts, Ltd."



Numerous typographical errors, including misspelled words such as "Inorganic", and a lack of spaces between many words



99%(Log 5) - Exceeds Purification Standard (Log 4): Ms2 Coliphage; Fr Coliphage

#### PATHOGENIC BACTERIA(AND SURROGATES)

>99.9999%-Exceeds Purification Standard(Log 6): Bacillus atrophaeus (Anthrax Surrogate);Raoultella temigena (Pathogenic Bacteria Surrogate). Salmonella Enterica.

PHARMACEUTICAL DRUGS-Romoved to>99.5%[Below Lab Detectable Limits]: 4-tert-Octylphenol Acetaminophen Bisphenol AIBPA) Caffeine Ciprofloxacin Erythromycin: buprofeel Namoxen Sodium Primidone Progesterone Triclosan Trimethoprim and many more TRIHALOME HANES-Removed to>99.8%(Below Lab Detectable Limits): Bromodichloromethane:Bromoform:Chloroform:Dibromochioromethane: INRGANIC MINERALS-Removed to Below Lab Detectable Limits: Chloramine hloride: Chlorine Residual (Total Residual): Free Chlorine. PESTICIDES & (SEMI) VOLATILE ORGANIC COMPOUNDS (VOCs)

Removed to Below Laboratory Detectable Limits: ethane 111-Trichloroethane(TCA) 1122-Tetrachloroeth oroethane 1 1.2-Trichlorotrifluoroethane 1 1-Dichloroethane(11-DCA) 1 1-Dichloroethyler (1 IDCE) 11-Dichloropropene 1 2 3-Trichlorobenzene 1 2 3-Trichloropropane 1 2 4-Trichlorobenzene 1 2 4-Trimethylbenzene 1 2-Dibromo-3-chloropropane(DBCP) 1 2-Dibromoethane 1.2-Dichloro-1.1.2-trifluoroethane(CFC 123a), 1.2-Dichlorobenzene 1.2-Dichlorobenzene-d4.1.2-Dichloroethane 1.2-Dichloropropane 1.3.5-Trimethylbenzene 1.3 chlorobenzene 1.3-Dichloropropene 1.4-Dichlorobenzene 2.2-Dichloropropane 2.4.5-T.2.4.5-TP(Silvex) 2 4-D 2 4-DB 2-Butanone(MEK) 2-Chlorotoluene 2-Hexanone 2-Methyl-2-propan 3.5-Dichlorobenzoic Acid 3-Hydroxycarbofuran 4-Bromofluorobenzane 4-Chiorotoluene 4
 Isopropyltoluene,4-Methyl-2-pentanone 4-Nitrophenol 4 4-DDD 4 4-DDE 4 4-DDT 5-Hydroxydicamba, Acelone Acenaphthylene Acifluorfen Alachior Aldicarb Aldicarb Sulfone, licaarb Sulfoxide, Aldrin, alpha-Chlordane, Ametryn, Anthracene, Aroclor (1016, 1221, 1232, 1242). 1248 1254, 1260) Atraion, Atrazine, Baygon, Bentazon, Benzene, Bromacii, Bromoacetic, Acid Bromobenzene, Bromochloromethane, Bromomethane, Butachlor Butylate, Butylbenzylphthallate Carbanyl, Carbon Tertachloride, Carboxin, Chloramben, Chlorodane, Chlorocacetic, Acid Chlorobenzene, Chlorobenzilate, Chloroethane, Chloromethane, Chloropophane, Chloropo cis-1.2-Dichloroethylene.cis-1.3-Dichloropropene.cis-Nonachlor Cycloate.Dacthal Acid.Dalapon Diazinona.Dibromoacetic Acid Dibromochloropropane(DBCP).Dibromomethane.Dicamba. Dichloroacetic Acid Dichlorodifluoromethane(CFC 12).Dichloromethane.Dichlorvos.Dictorprop Dieldrin, Diethylphthalate, Dinoseb, Piphenzmid, Disulfoton, Disulfoton, Sulfonorvos, Dietorprop Dieldrin, Diethylphthalate, Dinoseb, Piphenzmid, Disulfoton, Disulfoton, Sulfone, Dirulfoton Sulfoxidea, Endrin, EPTC Ethoprop, Ethylbenzene, Ethylene Dibromide (EDB), Fenamiphos Fenamimol, Fluorobenzene, Fluoridone, gamma—Chlordane, Glyphosate, Halo acidic Acids(HAA5) Heptachlor Heptachlor Epoxide, Hexachlorobenzenc, Hexachlorobuladiene (CCC) Heptachlor Heptachlor Epoxide, Flexachlorobenzenc, Hexachlorobutadiene (CCC)

Hexachlorocyclopentadiene Hexazinone Isophorone, Isopropylbenzene (Cumene), Lindane
(Gamma-BHC) Merphos, Methocarb, Methomyl, Methoxychior Methylcyclothexane-methane,
Methyl Paraoxon, Methyl thri-Butyl Ether(MTBE) Metolachlor Methibuzin, Mevinphos, MGK 264
Molinate, Monochlorobenzene, m-Xylenes, Naphthalene, Napropamide, n-Butylbenzene,
Norflurazon, n-Propylbenzene, Oxamyl, o-Xylene, Pebulate, Pentachlorophenol Pictoram
Prometryn, Pronamidea, Propazine, p-Xylenes, sec-Butylbenzene, Simazine, Simetryn,
Stirofos, Styrene, Tebulhurich, Terback, Terbutyn, tert-Butylbenzene, Tetrachloroethylene
(PCE), Tetrahydrofuran(THF), Thiobencarb, Toluene, Toxaphene, trans-1, 2-Dichloroethylene, trans1, 3-Dichloropropene trans-Nonachlor Triademeton, Tribromocacebc Acid, Trichloroethylene, Trichloroethylene, Trichloroethylene

Trichloroethene(TCE) Trichloroethylene, Trichlorofluoromethane(CFC 11), Tricyclazole, Trifuralin

#### Authentic Black Berkey® Box (Front)

Original Berkey® artwork and fonts



Full name of manufacturer, New Millennium Concepts, Ltd. (notice the "LTD.", which was missing on counterfeit sample)



Text on authentic box has correct spellings (i.e. "inorganic") and proper typography



#### Black Berkey **Purification Elements**

VIRUSES; >99 999% (Log 5) - Exceeds Purification Standard (Log 4); MS2 Coliphage; Fr Coliphage.

PATHOGENIC BACTERIA (AND SURROGATES) >99.9999% - Exceeds Purification Standard (Log 6):

Bacillus atrophaeus (Anthrax Surrogate); Raoultella terrigene (Pathogenic Bacteria Surrogate); Salmonella Enterica.

PHARMACEUTICAL DRUGS - Removed to >99.5% (Below Lab Detectable Limits):

4-tert-Octylphenol; Acetaminophen, Bisphenol A (BPA); Caffeine; Ciprofloxacin, Erythromycin;
Ibuprofes, Maeroxan Sodium; Primidone; Progesterone; Triclosan; Trimethoprim and many more.\* TRIHALOMETHANES - Removed to >99.8% (Below Lab Detectable Limits): Fromodichio methane; Bromoform; Chloroform; Dibromochloromethane.

INORGANIC MINERALS - Removed to Below Lab Detectable Limits;

Chloramine; Chloride; Chlorine Residual (Total Residual); Free Chlorine.

PESTICIDES & (SEMI) VOLATILE ORGANIC COMPOUNDS (VOCs)

PESTICIDES & (SEMI) VOLATILE ORGANIC COMPOUNDS (VOCs)
Removed to Below Laboratory Detectable Limits;

1,1,1-2-fetrachloroethane; 1,1,1-Trichloroethane (TCA); 1,1-2,2-Tetrachloroethane; 1,1,2-Trichlorothane; 1,1,2-Trichloroethane; 1,1-Dichloroethane; 1,2-Dichloroethane; 1,3-Dichloroethane; 1,2-Dichloroethane; 1,3-Dichloroethane; 1,3-Dichloroetha Heptachlor, Heptachlor Epoxide; Hexachlorobenzene; Hexachlorobutadiene (CCC); Hexachlorocyclopentadiene; Hexacinone; Isophorone; Isopropylbenzene (Cumene); Lindane (Gamma-BHC); Merphos; Methiocarb; Methomyl; Methoxychlor; Methylcyclohexane-methane; Aethyl Paraoxon; Methyl tert-Butyl Ether (MTBE); Metolachlor; Metribuzin; Mevinphos; MGK 264; Mollinate; Monochlorobenzene; m-Xylenes; Naphthalene; Napropamide; n-Butylbenzene; Norflurazon; n-Propylbenzene; Oxamyl; o-Xylene; Pebulate; Pentachloropheno; Picloram; rometon; Prometryn; Pronamidea; Propazine; p-Xylenes; seo-Butylbenzene; Simazine; Simetryn; irofos; Styrene; Tebuthluron; Terbacil; Terbufos; Terbutyn; tert-Butylbenzene; Tetrachloroethylene

> Printed text and logo have a thicker appearance than, on counterfeit box



#### One Sample of a <u>Counterfeit</u> Black Berkey® Box (Side of Box)

Counterfeit box has faked NMCL logo (note jagged lines and lack of "Ltd." after "New Millennium Concepts")

Fake hologram has no unique verifiable serial number, and is of much lower quality than official NMCL holograms used on authentic Black Berkey\* Elements boxes

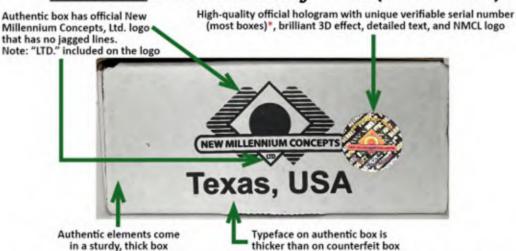
Texas, USA

Typeface on counterfeit box is thinner than on the authentic box

#### Goodman, Benjamin 12/7/2022 12:14 PM

**Comment [1]:** In the asterisk at the bottom of the page, the first two sentences seem to conflict. The first says that all packing has holograms with serial numbers, and the second says that some packages do not.

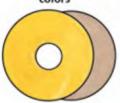
#### Authentic Black Berkey® Box (Side of Box)



\*Authenticity verification holograms with unique verifiable serial numbers are found on all packaging for Berkey\* filters including Black Berkey\* Elements and Berkey PF-2\*\* Fluoride and Arsenic Reduction Elements. Due to mixed inventory in our distribution channels, some Black Berkey\* Elements boxes may not have a verifiable serial number on them. Absence of the verifiable serial number on the hologram on Black Berkey\* Elements box does not necessarily indicate that the elements inside are not authentic. Consumers that identify they have received Black Berkey\* Elements in a counterfeit box can be 100% sure they have counterfeit Black Berkey\* Elements. At some point, all holograms on Black Berkey\* Elements boxes will have an identifiable serial number. However, consumers that receive Berkey PF-2\*\* Fluoride and Arsenic Reduction Elements without a hologram displaying a serial number is an indication that the elements are counterfeit. Consumers may contact NMCL Customer Service to verify if they have authentic Berkey\* elements.

#### One Sample of a <u>Counterfeit</u> Black Berkey® Box (Element Packaging Inside Box)





Priming button may be yellow (an obvious counterfeit) or tan but also be <u>harder and less flexible</u>, which could prevent a good seal when priming



Counterfeit Black Berkey® Elements almost always come individually shrink-wrapped in plastic, but may also be packaged in bubble wrap

If you receive filters that are shrink-wrapped, you can be 100% sure that you have received counterfeit filters.

#### Authentic Black Berkey® Box (Element Packaging Inside Box)





Authentic priming button has a tan color, and is both pliable and durable to help create a good seal when priming



Authentic Black Berkey® Elements are enclosed in bubble wrap, not shrink-wrapped

#### **Using Holograms to Combat Counterfeits**

With the appearance of knock-off and counterfeit filters in the market, NMCL took strategic measures to develop authenticity verification holograms that were affixed on all **Berkey**®-branded filters. After a period of time, we discovered that not only had criminals copied our filters and packaging, but they were also copying our authentication holograms. We therefore began to add features to our holograms to help consumers distinguish between authentic and counterfeit filters, including verifiable serial numbers for which consumers could call our customer service department to verify if the **Berkey**® filters they purchased were genuine or fake.

In an effort to stay ahead of the illegal counterfeit activities impacting the **Berkey**® brand, we have had to make several iterations of holograms. Second-generation holograms are currently being used on all **Berkey**®-brand filters, and we will soon release a more advanced third-generation hologram with more advanced features.

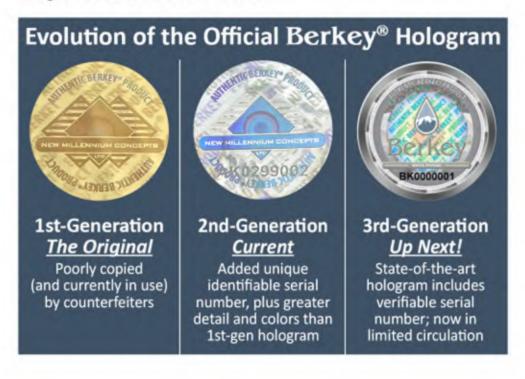
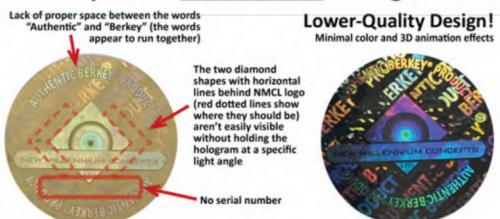


Exhibit B-16, pg. 6 of 7

Goodman, Benjamin 12/7/2022 12:14 PM

Comment [2]: Same as previous comment.

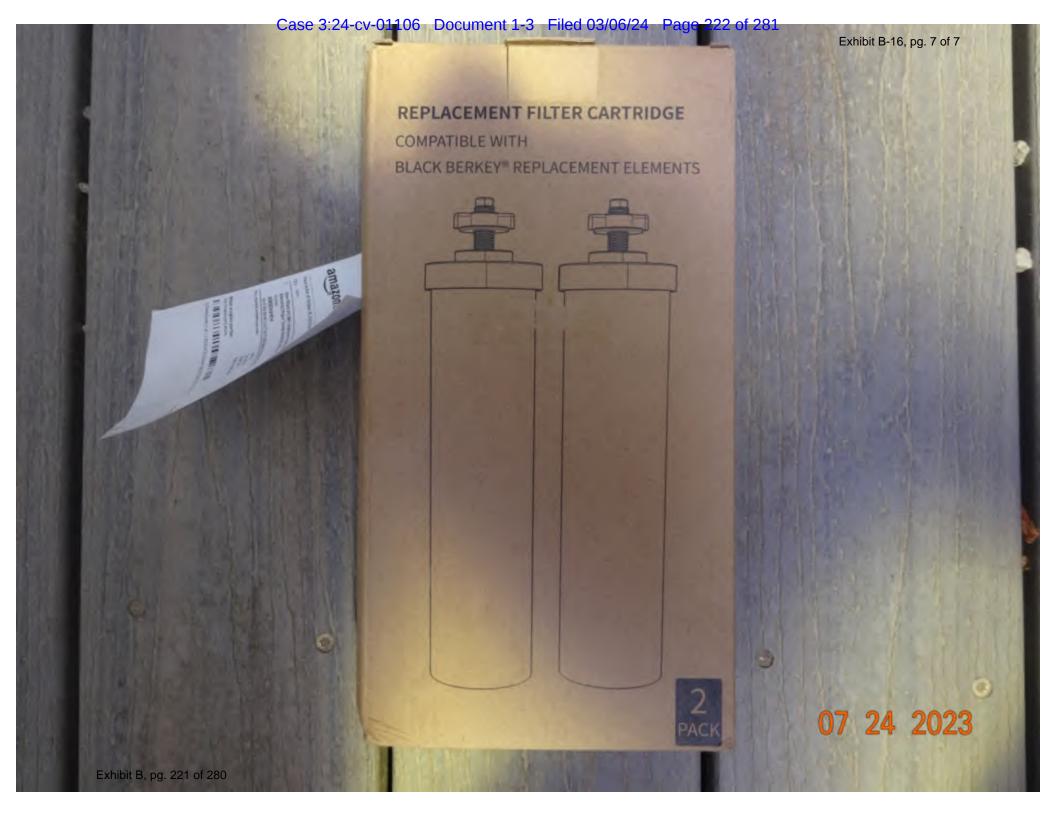
#### Samples of Counterfeit Holograms



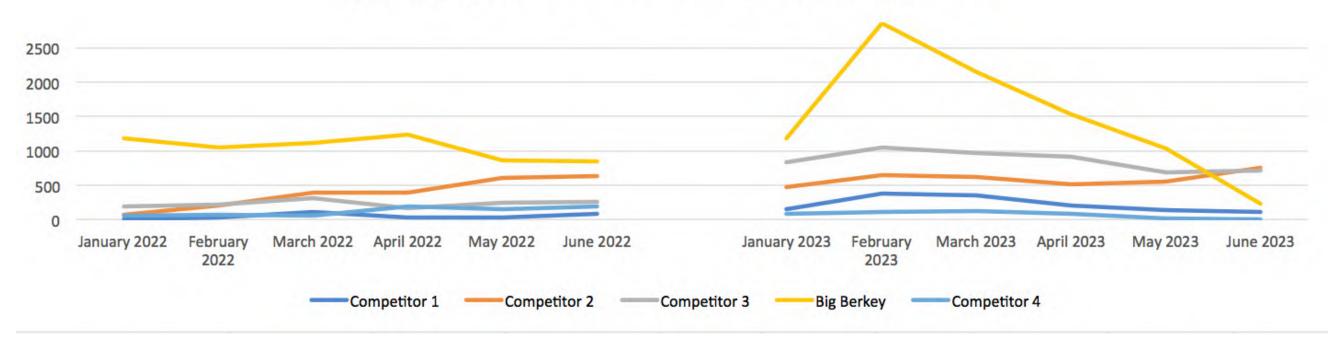


Authentic hologram displays impressive 3D/animation effects as viewing and lighting angle changes

\*Authenticity verification holograms with unique verifiable serial numbers are found on all packaging for Berkey® filters including Black Berkey® Elements and Berkey PF-2™ Fluoride and Arsenic Reduction Elements. Due to mixed inventory in our distribution channels, some Black Berkey® Elements boxes may not have a verifiable serial number on them. Absence of the verifiable serial number on the hologram on Black Berkey® Elements box does not necessarily indicate that the elements inside are not authentic. Consumers that identify they have received Black Berkey® Elements in a counterfeit box can be 100% sure they have counterfeit Black Berkey® Elements. At some point, all holograms on Black Berkey® Elements boxes will have an identifiable serial number. However, consumers that receive Berkey PF-2™ Fluoride and Arsenic Reduction Elements without a hologram displaying a serial number is an indication that the elements are counterfeit. Consumers may contact NMCL Customer Service to verify if they have authentic Berkey® elements.



Big Berkey Equivilant Unit Sales on Amazon Jan to June 22' vs 23'



Accueil > News & Blog > Blogs > Les cartouches Berkey inefficaces!







dimanche, mai 28th, 2023 / Publié dans Blogs

#### Les cartouches Berkey inefficaces!

AVIS DE NOS CLIENTS

AVIS DE NOS CLIENTS

4.6/5

de la condamnation par l'agence d'environnement des Etats Unis, la FIFRA. Les cartouches Becontrairement aux cartouches British Berkefeld sont très loin de fournir la filtration promise ce ce de la simple tromperie sur la marchandise qu'ils vous vendent. La société Berkey a dénigré pe des années la société British Berkefeld en expliquant le contraire. La justice a tranché!!

Ci-dessous le détail du jugement.

Machine	Trans	lated	by	Googl	e

ÉTATS-UNIS AGENCE DE PROTECTION DE L'ENVIRONNEMENT RÉGION 8

Date:	Par:

David Cobb, superviseur de section

Section de l'application des lois sur les substances toxiques et les pesticides

Division de l'application de la loi et de l'assurance de la conformité

Interdiction de vente -BerkeyInternational 2023 -04-05-2023-français Télécharger





#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION

Date:	·	By:	
			David Cobb, Section Supervisor
			Toxics and Pesticides Enforcement Section
			Enforcement and Compliance Assurance Division

FIFRA-08-2023-0038 SSURO BerkeyInternational 2023 Télécharger

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CGV Contact







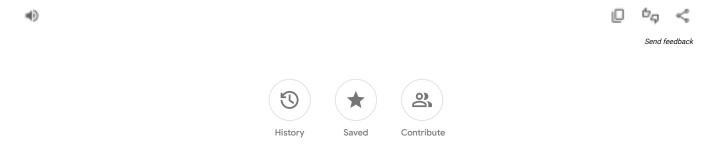
Les cartouches de filtration BERKEY sont interdites de vente à l'export. Cette interdiction est issue de la condamnation par l'agence d'environnement des Etats Unis, la FIFRA. Les cartouches Berkey, contrairement aux cartouches British Berkefeld sont très loin de fournir la filtration promise ce qui est de la simple tromperie sur la marchandise qu'ils vous vendent. La société Berkey a dénigré pendant des années la société British Berkefeld en expliquant le contraire. La justice a tranché!!

Ci-dessous le détail du jugement.

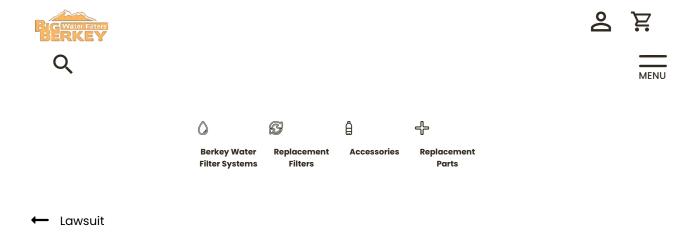


Berkey filtration cartridges are prohibited from export sales. This prohibition is the result of the conviction by the environmental agency of the United States, the FIFRA. The Berkey cartridges, unlike the British Berkefeld cartridges are far from providing the promised filtration which is simple deception on the goods they sell to you. The Berkey company has denied British Berkefeld for years, explaining the opposite. Justice has decided!!

Below is the detail of the judgment.



#### QUESTIONS? CALL 877-992-3753 OR VISIT HELPFUL RESOURCES >>>



### Berkey Statement Regarding Berkey Water Filter Lawsuit



By Dan DeBaun

December 19, 2022

Over the past couple months we have been receiving inquiries from customers regarding Berkey's involvement in litigation for the Black Berkey filters. We asked the manufacturer of Berkey products (New Millennium Concepts, LTD) to release a statement to our customers so that they would feel at more ease in understanding the merits of this lawsuit. Counterfeit products are a real problem for Berkey and the following official statement speaks to that. At the bottom of this statement is a link to NMCL's page that shows examples of Berkey counterfeit products that are unfortunately saturating the market.

#### **Berkey Official Statement Regarding Lawsuit**

Attorneys typically advise clients not to discuss ongoing litigation, and New Millennium Concepts, Ltd. (NMCL), provider of Berkey® water filters, has remained silent until now.

'ever, NMCL believes that our loyal customers deserve a public response to the false oneous misinformation appearing online regarding a lawsuit filed against NMCL.

Tany problematic issues in the lawsuit that we cannot address here, but

below are some brief highlights:

- One of the named plaintiffs previously filed a lawsuit, but later withdrew after NMCL responded to the suit and showed that the plaintiff's claims were so weak that she would obviously lose. Now the plaintiffs have filed a second lawsuit, apparently attempting to engineer around the arguments that NMCL made during the first lawsuit. This current lawsuit seems to be just another attempt to "do-over" the first suit in order to force NMCL to settle.
- We also believe that much of the information that the plaintiff collected for the lawsuit came from Berkey knock-off filter websites because of their carbon block descriptions (Black Berkey® Elements are not carbon block filters), and the plaintiff repeatedly uses the term "Berkey Black" in their lawsuit, which is a term utilized by knock-off filter websites in order to engineer around our trademark "Black Berkey®".
- While the plaintiffs claim Black Berkey® Elements do not perform as advertised, the plaintiffs do not claim that they have suffered any physical or health-related harm in anyway by their Berkey® systems. Instead, plaintiffs claim that they are representing everyone that has ever purchased a Berkey® system, claiming that Berkey® systems are "nothing more than an empty can or plastic bottle".
- We strongly believe the plaintiffs' allegations are not based on valid testing of authentic Black Berkey® Elements, but are based on counterfeits which are deceptively similar in appearance, but are mere carbon block filters which look like Berkey® filter elements. The plaintiffs' testing results in no way comport with the factual results of other independent accredited third-party labs that have tested genuine Black Berkey® Elements.

NMCL vigorously denies the plaintiff's allegations and we believe that the plaintiff is utilizing counterfeit product to exact a settlement. History of Black Berkey® Elements and Counterfeit Products

**History of Black Berkey® Elements and Counterfeit Products** Unlock Perks

o decades ago, NMCL developed the proprietary formulation for our Black ments, and during their history they have undergone what we believe to be the most rigorous testing of any other gravity-fed filter elements. Berkey® water systems have been utilized in off-grid applications by relief groups for disaster recovery, charities, and people worldwide without access to clean water for over two decades without a complaint of which we are aware as to their ability to remove contaminants from unpotable water sources. More importantly, to our knowledge there has never been a successful suit filed against the Black Berkey® Elements because they have historically provided customers with exceptional performance and value—a perception that has been challenged only because Chinese and other foreign counterfeit filtersentered the market failing to meet consumers' performance expectations and appear so similar to genuine Black Berkey® Elements that consumers are being misled by not being able to determine the difference between the authentic Black Berkey® Elements and the counterfeit carbon block filters.

 Worse, NMCL discovered that major online retail marketplaces were commingling at their warehouses counterfeit elements supplied by unauthorized sellers with authentic Black Berkey® Elements supplied by our authorized Berkey® dealers. The marketplaces then shipped product from the commingled inventory to consumers who purchased authentic Black Berkey® Elements. Since that discovery, NMCL has required its authorized dealers to opt out of all commingling programs, and keep separate inventories at Amazon and other platforms to prevent comingling from occurring in the future. However, it is important to note that the majority of plaintiffs claim to have purchased their products on Amazon prior to NMCL discovering the commingling issue. NMCL believes that the plaintiffs likely tested counterfeit Berkey® elements, and that NMCL is being required to defend itself against the performance of Chinese and other foreign counterfeit carbon block filters rather than the proven performance of authentic Black Berkey® Elements. Moreover, NMCL is also being required to defend itself against various websites, social media and video-sharing platforms that presume the likely imitation carbon block filters tested in the lawsuit are authentic Black Berkey® Elements, when they are not. If the plaintiff tested counterfeit or knockoff filters, then obviously any testing they conducted is irrelevant to the performance of authentic Black Berkey® Elements.

#### Regarding Black Berkey® Elements Test Results

'ultiple accredited third-party laboratories have tested Black Berkey® Elements and independent results validate that they meet exceptional standards of quality.

available on our website at: Black Berkey Water Filter Test Results

• NMCL has had an extremely difficult time in getting cooperation from major online retail platforms in removing the counterfeit filters. This only allows the counterfeit problem to continue metastasizing. In fact, of 57 test buys of Black Berkey® Elements purchased from unauthorized sellers on two major platforms, 51 test buys (89%) were confirmed as being counterfeit—meaning that 89% of sales from unauthorized sellers were just generic, untested Chinese or foreign carbon block filters packaged to imitate the appearance of authentic Black Berkey® Elements. The problem has become so pervasive that the estimated sales of verified counterfeit filters have exceeded more than two and a quarter million dollars during the first nine months of 2022 on just one major U.S. online retail marketplace alone.

We also ask that Berkey® customers assist NMCL in purging the market of counterfeit filters by always buying Berkey® systems and Black Berkey® Elements from authorized Berkey® dealers. Customers can verify authorized dealers by calling our customer service department at 888-803-4438.

If you suspect your online marketplace purchase (from Amazon, eBay, etc.) may contain counterfeit elements, please check this page (https://support.berkeywater.com/buyerbeware/) for a guide to identifying counterfeit elements. Then, after reviewing those examples, if you believe you have received counterfeit filters, we suggest the following course of action:

Unlock Perks

- Demand a full refund from the dealer or marketplace.
- Return the product stating the specific seller from whom you purchased, shipped you counterfeit filters.
- Leave a review on the specific seller's storefront stating that the seller sold and shipped you counterfeit filters, rather than authentic Black Berkey® Elements.
- Contact NMCL to report the marketplace and seller that sold you the counterfeit product (this helps us identify and take action against unauthorized sellers). We also urge customers who have been fooled into purchasing untested knock-off carbon block filters advertised as replacements to follow the same procedure.
- Replace the counterfeit filters by purchasing genuine Black Berkey® Elements from an authorized Berkey® dealer.

We appreciate the countless Berkey® Water System users around the world and want to assure you that we fully stand by the quality of Berkey® products and intend to defend and defeat this baseless lawsuit.

Following this link will show you the extent counterfeiters are willing to go to decieve our Berkey customer base.

CLICK HERE TO SEE SAMPLES OF COUNTFEIT PRODUCTS

Previous post Next post

#### 7 thoughts on "Berkey Statement Regarding Unlock perks rkey Water Filter Lawsuit"

#### **LEAVE A COMMENT**



Dawn July 6, 2023 at 8:50 AM

Feeling better about it. Stopped drinking water! Now will begin again.

Wanted to purchase set for my daughter. She saw lawsuits. Said no

Feel like I can approach her again to buy for her. Our tap water even smells like poison! Reply



Conchscooter April 26, 2023 at 10:24 AM

We use our Berkey in our van traveling Central America and it works perfectly. I think Berkey is brave to sell filters in this stupidly litigious society. I hope they stay in business. Reply



Dan DeBaun April 26, 2023 at 12:21 PM

Hi Conchscooter -

The owner of the company is a longterm prepper and believes it's essential folks have access to high quality gravity filtration in case of emergencies. As a result, they are fighting this lawsuit and will continue to prove the quality of the Berkey products.

**Thanks** 

Dan

concern is the ur

concern is the unaddressed (correct if wrong), multiple test results showing

Exhibit B, pg. 234 of 280

an increase in aluminum-presence after the water goes through the filters.

Reply



Dan DeBaun April 5, 2023 at 11:12 AM

Hi Haris -

There is alot of misinformation being circulated about this subject. We have addressed this in prior posts and comments, and here it is again to provide clarity.

- 1) This claim is not based/associated with the black berkey filters themselves.
- 2) This claim is associated with the PF-2 fluoride filters when they are used in conjunction with the black berkeys.
- 3) As for the higher aluminum test results from the use of the PF-2 filters: This is aluminum oxide (alumina) and not aluminum. Typical lab tests do not distinguish between the 2 forms and it is commonly accepted that alumina (used in the Berkey PF-2) is inert and not absorbed by the body like aluminum would be. So, this is a critically important distinguishing chemical trait that should be made clear. What is being read by the test as aluminum is actually alumina which is a non bioavailable form which is not absorbed by the body.
- 4) Here's an article with more details on what alumina is: https://www.bigberkeywaterfilters.com/blog/fluoride-water-filters/what-is-aluminum-oxide

**Thanks** 

Dan

Rob M March 8, 2023 at 1:18 PM

rere a way customers can independently test the filters they receive? Preferably ing cheap we can do ourselves that only real Black Berkey filters can do.



Dan DeBaun March 10, 2023 at 10:34 AM

Hi Rob -

Sometimes your local water authority will perform the tests inexpensively.

**Thanks** 

Dan



Tobe January 7, 2023 at 7:42 AM

In this day of so many corrupt companies getting away with evil deceitful practices one would tend to believe they are being duped easily after hearing about this lawsuit, But all of my fears went away quickly after this statement was made by berkey. I received this gift about a year ago and have only one complaint! one of my four black filters thread's are slightly stripped and came so, so it won't tighten correctly, and is not going to last the lifetime since I follow the cleaning protocol. I haven't taken The time to deal with this since it was a gift and didn't want to burden my Dad with it. So I don't hold berkey responsible! I'd also like to add after about a month of research of my own I decided on berkey. my father not only bought me the biggest berkey they offer for me, but one for himself as well. I'm a trusting customer of berkey I just hope I can get the filter situated at some point. Thanks Berkey for the statement

Reply



Dan DeBaun January 9, 2023 at 12:55 PM

Hi Tobe -

We appreciate your comments. The manufacturer is and has always been a family owned business and earnestly believes in providing a high quality product and standing behind it's performance. Outside investors and large corporations have fered to purchase Berkey many times over the past 10 years, and each time these are rejected. As a dealer, we are also a 20 year customer and a constructive

critic as well, and so we make sure all our customer feedback (as well as ours) gets to the decision makers and is taken seriously. While NMCL is not perfect, their intentions are good and have never been in the business of deception.

As far as your black berkey not tightening fully, contact our customerservice@bigberkeywaterfilters.com and rep can send you an additional wingnut to help solve that problem for you.

Thanks Dan



Jim December 27, 2022 at

I'm glad this response was bashing Berkey based on ; They were then promoting made in China. It was com tested it myself, so I sleep | Reply



oard commandos

f an outstanding lawsuit.

nat are actually probably

ny Berkey and have



#### Kathy P December 23, 2022 at 12:18 PM

This is alarming. I just checked my filter box, and they are genuine, but I could have easily been duped. I'll be sure to order my filters from you going forward. Thank you for posting. Reply

Unlock Perks

#### **Recent articles:**



Filtered Water for Pets

By Dan DeBaun

June 22, 2023



Do Berkey Water Filter Systems Leach Aluminum Into Your Drinking Water?

Activated alumina shown in the form of a fine, adsorptive powder as found in our Berkey PF-2<sup>n</sup> Fluoride and Arsenic Reduction Element media

By Dan DeBaun

June 2, 2023



Ultimate Guide to Choosing a Berkey Water Filter: Find Your Perfect Match Today

By Dan DeBaun

May 26, 2023



Why you Should be Using Filtered Water on your Plants and Garden

Tryusit DeBaun

May 9, 2023



Choosing a Berkey Water Filter System for Your Home

+

Exhibit B, pg. 238 of 280

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Unlock Perks

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#### March 6, 2000

#### PESTICIDE REGISTRATION (PR) NOTICE 2000 - 1\*

### NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Applicability of the Treated Articles Exemption to Antimicrobial Pesticides

This notice clarifies current EPA policy with respect to the scope of the "treated articles exemption" in 40 CFR 152.25(a). This exemption covers qualifying treated articles and substances bearing claims to protect the article or substance itself. EPA does not regard this exemption as including articles or substances bearing implied or explicit public health claims against human pathogens. This notice addresses the types of claims which are not permitted for antimicrobial pesticide products exempt from registration under this provision and gathers together in one place guidance the Agency has offered in recent years on labeling statements which it believes would or would not be covered under this provision. This notice also explains the requirement that the pesticide in a treated article be "registered for such use."

This notice provides guidance to producers and distributors of pesticide treated articles and substances, and to producers and distributors of pesticides used as preservatives to protect treated articles from microbial deterioration.

#### I. BACKGROUND

EPA regulations in 40 CFR 152.25(a) exempt certain treated articles and substances from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if specific conditions are met. The specific regulatory language is:

#### Section 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation

"(a) *Treated articles or substances*. An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect

<sup>\*</sup> This version makes corrections to the February 3, 2000 PR Notice 2000-1. Corrections in bold/italics or editorial deletions were made on pages 3, 4, 7, and 9.

the paint coating, or wood products treated to protect the wood against insect or fungus infestation),

if the pesticide is registered for such use."

Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:

- (1) the incorporated pesticide is registered for use in or on the article or substance, and;
- (2) the sole purpose of the treatment is to protect the article or substance itself.

The exemption gives two examples of treatments that are intended to protect only the treated article or substance itself. In the first case, paint is being protected from deterioration of the paint film or coating. In the second case, wood is being protected from fungus or insect infestations which may originate on the surface of the wood. Pesticides used in this manner are generally classified as preservatives. Other pesticides are incorporated into treated articles because of their ability to inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew. Because of this treatment, it is claimed that a fresher and more pleasing surface can be maintained.

To qualify for the treated articles exemption, both conditions stated above must be met. If both are not met, the article or substance does not qualify for the exemption and is subject to regulation under FIFRA.

In recent years, the marketplace has experienced a proliferation of products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms which may cause food poisoning, infectious diseases or respiratory disorders. Examples of such articles include toothbrushes, denture cleansers, children's toys, kitchen accessories such as cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, mattresses and various types of finished consumer textiles. In many cases, these products have made public health claims that extend beyond the protection of the article itself, and thus, they do not qualify for the treated articles exemption.

#### II. TYPES OF ANTIMICROBIAL CLAIMS

#### A. Public Health Claims

Because consumers have long associated the following widely used claims and references to microorganisms harmful to humans with products providing public health protection, EPA considers an article or substance to make a public health claim if any of the following claims are made either explicitly or implicitly:

1. A claim for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *E. coli*, *HIV*,

Streptococcus and Staphylococcus aureus.

- 2. A claim for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site of use of the product, and regardless of whether specific microorganisms are identified.
- 3. A claim of "antibacterial," "bactericidal," or "germicidal" activity or references in any context to activity against germs or human pathogenic organisms implying public health related protection is made.
- 4. A claim for the product as a fungicide against fungi infections or fungi pathogenic to man, or the product does not clearly indicate it is intended for use against non-public health fungi.
- 5. A claim to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew.
- 6. A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.
  - 7. An unqualified claim of "antimicrobial" activity. Refer to Unit IV.C.

#### **B.** Non-Public Health Claims

EPA considers a product to make a non-public health claim if any of the following applies:

- 1. A claim to inhibit the growth of mildew on the surface of a dried paint film or paint coating.
- 2. A claim to inhibit microorganisms which may cause spoilage or fouling of the treated article or substance.
  - 3. A claim to inhibit offensive odors in the treated article or substance.
- 4. EPA considers terms such as "antimicrobial," "fungistatic," "mildew-resistant," and " preservative," as being acceptable for exempted treated articles or substances provided that they are properly, and very clearly, qualified as to their intended non-public health use. Refer to Unit IV.C. Use of these terms in product names or elsewhere in the labeling in bolder text than accompanying information may render such qualifications inadequate.

#### III. PAST EPA LABELING CLAIMS INTERPRETATIONS

#### A. Odor and Mildew-Resistant Properties May Be Claimed

Over the past twenty-five years the Agency has issued several interpretations concerning the

exemption from FIFRA regulations *of* certain types of antimicrobial treated article claims associated with mildew-resistant paint, films and coatings. In the same period, EPA has also issued other interpretations concerning certain types of odor-resistant antimicrobial treated article claims.

During this period there has been widespread dissemination and adoption by the antimicrobial pesticide product community of these EPA interpretations regarding mildew-resistant and odor-resistant claims under the "treated articles exemption." Furthermore, the Agency continues to treat these general types of claims as covered by the term "to protect the treated article or substance itself" because mitigation of these non-public health related organisms can contribute to the protection of the appearance and maintenance of the intended useful life of the treated article or substance. Because during this period, there has also been widespread misinterpretation of EPA's guidance, the Agency has developed a representative set of statements designed to clarify its position in this area. Consequently, if they otherwise qualify for the exemption, properly labeled treated articles and substances bearing claims such as those described under Unit IV.B. continue to be eligible for the treated articles exemption.

#### **B. Product Names May Not Contain Public Health Claims**

The Agency regards trademarked product names of treated articles or substances [or references to trademarked names of registered pesticides] as potential sources of public health claims that could render a product ineligible for the "treated articles exemption" just as could other direct or indirect public health claims on or in a product's packaging or in its labeling or advertising literature. The Agency has maintained this position in enforcement actions against pesticide-treated articles, such as pesticide-treated cutting boards and other items, which bore names suggesting health or other benefits beyond mere preservation of the treated article itself. In determining the eligibility of a treated article or substance for the exemption, the Agency will examine the product name, its context, labeling claims and other related elements on a case-by-case basis

#### IV. TREATED ARTICLE LABELING CLAIMS

Products treated with antimicrobial pesticides with claims such as those described in Section A below are likely to not be acceptable under the "treated articles exemption" because they imply or express protection that extends beyond the treated article or substance itself. Products treated with antimicrobial pesticides registered for such use and which only bear claims for protection of the article or substance itself such as those described in Section B below are likely to be acceptable and eligible for the "treated articles exemption", assuming all other conditions have been met. Section C below contains examples of appropriate qualifying and prominence statements which have been extracted from multiple enforcement proceedings dealing with claims that can be made for treated articles without obtaining registration.

### A. Examples of Labeling Claims That the Agency is Likely to Consider Unacceptable Under the Exemption

The following examples are not intended to be an all-inclusive listing of unacceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the Antimicrobials Division at one of the addresses listed under Unit VII.

These examples represent claims or types of claims for a treated article that would lead to a requirement to register the article as a pesticide product.

- o Antibacterial
- o Bactericidal
- o Germicidal
- o Kills pathogenic bacteria.
- o Effective against E. coli and Staphylococcus.
- o Reduces the risk of food-borne illness from bacteria.
- o Provides a germ-resistant surface.
- o Provides a bacteria-resistant surface.
- o Surface kills common gram positive and negative bacteria.
- o Surface controls both gram positive and negative bacteria.
- o Surface minimizes the growth of both gram positive and negative bacteria.
- o Reduces risk of cross-contamination from bacteria.
- o Controls allergy causing microorganisms.
- o Improves indoor air quality through the reduction of microorganisms.

### B. Examples of Labeling Claims the Agency is Likely to Consider Acceptable Under the Exemption

The following examples are not intended to be an all-inclusive listing of acceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the

#### Case 3:24-cv-01106 Document 1-3 Filed 03/06/24 Page 247 of 281 **Exhibit B-20, p.6**

Antimicrobials Division at one of the addresses listed under Unit VII.

#### 1. Mold and Mildew Resistant Claims

- o This article has been treated with a fungistatic agent to protect the product from fungal growth.
- o Mildew Resistant treated with a fungistatic agent to protect the paint itself from the growth of mildew.
- o Mildew Resistant This paint contains a preservative which inhibits the growth of mildew on surface of this paint film.
- o Mildew Resistant Extends useful life of article by controlling deterioration caused by mildew.
- o Algae Resistant This article contains a preservative to prevent discoloration by algae.
- o A fungistatic agent has been incorporated into the article to make it resistant to stain caused by mildew.
- o Article treated to resist deterioration by mold fungus.
- o Article treated to resist deterioration from mildew.
- o The fungistatic agent in this article makes it especially useful for resisting deterioration caused by mildew.
- o Dry coating of this paint mildew resistant.
- o Dried paint film resists mold fungus.
- o Dry enamel coating resists discoloration from mildew.
- o Cured sealant is mildew resistant.
- o Dried film resists stains by mold.
- o A mold or mildew resisting component has been incorporated in this article to make its dry film mildew resistant.
- o Specially formulated to resist mildew growth on the paint film.
- o Gives mildew-resistant coating.

- o The mildew resistance of this outside house paint film makes it especially useful in high humidity areas.
- o Retards paint film spoilage.
- o Resists film attack by mildew.

#### 2. Odor Resistant Claims

- o This product contains an antimicrobial agent to control odors.
- o This product contains an antimicrobial agent to prevent microorganisms from degrading the product.
- o Resists Odors This product has been treated to resist bacterial odors.
- o Inhibits the growth of bacterial odors.
- o Resists microbial odor development.
- o Retards the growth and action of bacterial odors.
- o Guards against the growth of odors from microbial causes.
- o Guards against degradation from microorganisms.
- o Reduces odors from microorganisms.
- o Odor-resistant.
- o Acts to mitigate the development of odors.

#### C. Antimicrobial Qualifying and Prominence Considerations

EPA does not believe that claims such as "antimicrobial," "fungistatic," "mildew-resistant," and "preservative" or related terms are consistent with the intent of 40 CFR 152.25(a) if they are: (1) part of the name of the product; or (2) not properly qualified as to their intended non-public health use. Examples of *permissible* statements would include, but not be limited to: "Antimicrobial properties built in to protect the product" and "Provides mildew-resistant dried paint coating." All references to the pesticidal properties and the required qualifying statements should be located together, should be printed in type of the same size, style, and color, and should be given equal prominence. Moreover, such references should not be given any greater prominence than any other described product feature.

In addition, treated articles or substances intended for microbial odor control or article preservation in areas where food-borne or disease-causing organisms may be present have the potential to create the impression that the article provides protection against food-borne and disease-causing bacteria. This potential should be addressed through very careful narrowing and qualification of the non-public health claims. A complete assurance that there is no misleading impression could be achieved through use of language like: "This product does not protect users or others against food-borne (or disease-causing) bacteria. Always clean this product thoroughly after each use." or "This product does not protect users or others against bacteria, viruses, germs or other disease organisms. Always clean this product thoroughly after each use."

#### V. ADDITIONAL INFORMATION

#### A. Registration of Treated Articles Making Public Health Claims

Treated articles or substances with implied or explicit public health claims or which otherwise fail to qualify for exemption are pesticide products subject to all requirements of FIFRA. They may not be legally sold or distributed unless they are registered with EPA or unless such claims have been removed and the article otherwise qualifies for exemption. To obtain a registration, an applicant must submit acceptable data supporting all the proposed claims under which the product will be marketed and meet all other applicable registration requirements. Refer to 40 CFR Parts 152, 156, and 158.

The Agency currently has no established protocols for the development of data to support public health claims on treated articles for which registration is sought. Acceptable protocols for product testing reflecting actual use conditions need to be submitted and approved by EPA prior to the development of these data. As part of this review process, the Agency will require that these protocols be independently validated for accuracy and reproducibility. Antimicrobial treated articles requiring registration must meet the same efficacy performance standards that are required for corresponding antimicrobial public health products. For any questions regarding the need for registration or the registration requirements for specific treated articles or substances, contact the Antimicrobials Division at the address listed under Unit VII.

#### B. The Term "Registered for Such Use"

In order to qualify for the treated articles exemption, 40 CFR 152.25(a) specifies that an article or substance must be treated with, or contain, a pesticide to protect the treated article or substance itself. The terms "treated with, or containing, a pesticide" and "if the pesticide is registered for such use" in 40 CFR 152.25(a) refer to actual incorporation or adding of an antimicrobial pesticide specifically registered for that use. To qualify under the "treated articles exemption" (assuming the article or substance otherwise qualifies), it is not sufficient that the antimicrobial pesticidal substance in the treated article merely resemble or have activity like a registered pesticide. The antimicrobial pesticide in the treated article or substance must be present in the article or substance solely as the result of

incorporating an antimicrobial pesticide which is registered for treating the specific article or substance.

Because of the wide range of exposure scenarios associated with the use of treated articles such as cutting boards and conveyor belts used in the food processing industry, and the wide range of household consumer uses, the Agency has interpreted 40 CFR 152.25(a) to mean that the registration and the labeling of the antimicrobial pesticide intended for incorporation into the treated article or substance needs to include specific listings of the articles or substances that may be treated. Accordingly, in registration actions over the past several years, EPA has not permitted broad general use patterns, such as the preservation of hard surfaces, plastics, adhesives or coatings for the registered pesticide. Instead, it has required that specific listings such as toys, kitchen accessories and clothing articles be reflected in the product registration and labeling as a prerequisite for incorporation of the pesticide into an article or substance under 40 CFR 152.25(a).

#### VI. EFFECTIVE DATE AND PROCEDURES

In order to remain in compliance with FIFRA and avoid regulatory or enforcement consequences as described here and below, it is the Agency's position that producers, distributors, and any other person selling or distributing pesticide treated articles and substances not in compliance with the Agency's interpretation of 40 CFR 152.25(a), as clarified by this notice, need to bring their products, labeling and packaging, any collateral literature, advertisements or statements made or distributed in association with the marketing (*sale or distribution*) of the treated article or substance into full compliance with the regulation as clarified by this notice as soon as possible.

Because some of the elements of this interpretation may not have been well understood by the regulated community, the Agency expects that some companies may need up to a year in order to comply with those elements that have been clarified by this notice. Therefore, for the present, the Agency is following the approach set forth in the April 17, 1998 **Federal Register** (63 FR 19256). Although non-public health claims for microbial odor control and mold and mildew claims associated with deterioration, discoloration, and staining were not specifically mentioned in the April 17, 1998 **Federal Register**, such claims are also consistent with the enforcement approach set forth in that notice, as well as with this guidance, provided that they are properly, and very clearly, qualified as to their non-public health use. The Agency will begin to rely on the guidance provided in this Notice on February 11, 2001. Products in commerce after that date *which make statements*, *etc. that do not reflect the clarification offered in this notice* would risk being considered out of compliance with 40 CFR 152.25(a).

#### VII. ADDRESSES

By mail:

Antimicrobials Division (7510C) U. S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, D. C. 20460-0001

#### 

### **Exhibit B-20, p.10**

By courier:

Antimicrobials Division (7510C) U. S. Environmental Protection Agency Room 300, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202-4501

#### VIII. FOR FURTHER INFORMATION CONTACT

If you have questions about the content of this notice, you should contact Debra Edwards at (703) 308-7891.

/signed/

Marcia E. Mulkey, Director Office of Pesticide Programs

#### February 23, 2023

#### Pesticide Registration Notice (PR Notice) 2023-01

### NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, REGISTRANTS AND APPLICATORS OF PESTICIDE PRODUCTS

**ATTENTION:** Persons Responsible for Public Health Programs and Those Responsible for

Registration of Pesticide Products

**SUBJECT:** Lists of Pests of Significant Public Health Importance – Revised 2023

This notice updates and replaces PR Notice 2002-1, which identifies pests of significant public health importance. Section 28(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the United States Environmental Protection Agency (EPA), in coordination with the United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA), to identify pests of significant public health importance and to develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to combat and control such pests of public health importance.

The lists were first published in 2002, fulfilling the requirement of FIFRA section to identify pests of significant public health importance. EPA, HHS and USDA believe that pests, diseases, and control techniques have changed since 2002. The lists provide an interagency baseline for the federal government and the public to begin any discussions on government regulation and control of disease or vectors of disease agents. EPA makes this information available, in part, to establish a platform for stakeholders, such as public health departments or pesticide registrants to prioritize their workloads and resource allocations. The Office of Pesticide Programs, EPA, coordinated the review by experts in public health and/or pesticide use patterns to compile these lists. No person is required to take any action in response to this notice.

The publication of these lists do not affect the regulatory status of any pesticide registration, pesticide registration exemption under FIFRA section 25(b), pesticide device, or application for registration of any pesticide product or device. These lists do not, by itself, determine whether a pesticide product might be considered a "public health pesticide" as that term is used in FIFRA. That term is defined in FIFRA section 2(nn); determining whether any specific pesticide is a public health pesticide is beyond the scope of this PR Notice.

The Agency has determined that the lists of pests of significant public health importance required under FIFRA section 28(d) can be established independently of the definition of "public health pesticide" in section 2(nn). EPA is interpreting the term "significant public health importance" broadly, to include pests that pose a widely recognized risk to considerable numbers of people.

#### I. BACKGROUND

FIFRA section 28(d) charges EPA with identifying "pests of significant public health importance." FIFRA section 2(t) defines the term "pest" as meaning:

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(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organism on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1).

Pursuant to the authorization in the second part of this definition, EPA has broadly declared that the term pest includes all members of each of the categories of organisms identified in FIFRA section 2(t) in circumstances where they are deleterious to man or the environment, except for the organisms specifically excluded by the definition (See 40 CFR 152.5).

#### II. THE LISTS

EPA has determined that the pests identified in the Appendix are pests of significant public health importance as that term is used in FIFRA section 28(d). Although these lists are derived in large part from review of the pesticide/pest combinations for which efficacy (product performance) data are generally required to be submitted and reviewed prior to registration; in no way should this be interpreted to mean that EPA has or would base any regulatory action solely on these lists. EPA is publishing these lists separate from any statutory or regulatory conclusions which may be associated with public health pesticides. Additionally, these lists do not account for unanticipated nomenclature changes and/or novel pests. A brief description of the pests and their potential impact on the public's health each is provided below:

<u>Arthropods</u>. The listed arthropods may cause asthma or trigger allergies, contaminate food, irritate skin, cause direct injury, or carry agents causing diseases such as Lyme disease, epidemic typhus, trench fever, epidemic relapsing fever, malaria, encephalitis (St. Louis, Eastern, Western, West Nile and LaCrosse), yellow fever, dengue fever and many others.

<u>Vertebrates</u>. The listed organisms have the potential for direct human injury and can act as disease reservoirs for rabies and other diseases. The rats and mice include those that spread rodent-borne diseases and contaminate food for human consumption.

Microorganisms and acellular particles. This category includes listed bacteria, fungi, protozoans, viruses, virusoids, and prions. The microorganisms and acellular particles listed in this category cause diseases such as COVID-19, cholera, meningitis, Legionnaire's Disease and many others.

As with the original 2002 lists (PR Notice 2002-1)<sup>1</sup>, these lists identify the pests that EPA, HHS and USDA currently consider to be of significant public health importance. As deemed necessary, the Agency will update the lists of pests of significant public health importance. Also, EPA notes that the listings in the "Public Health Importance/Possible Clinical Significance" column are not exhaustive and can vary in their presence and severity (up to and including death) based on a variety of situation specific factors.

<sup>&</sup>lt;sup>1</sup> https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf

Interested parties are invited to petition the Agency regarding the amendment of these lists. This petition should include the common use name and scientific name of the pest, and a rationale regarding the public health threat posed by this pest. These petitions can be sent to the contact under **Part V. For Additional Information**.

### III. USE OF THE LISTS OF PESTS OF SIGNIFICANT PUBLIC HEALTH IMPORTANCE BY THE AGENCY

The Agency will use the lists of pests of significant public health importance to:

- 1. Fulfill the requirements set forth in FIFRA section 28(d)
- 2. Together with other federal agencies, develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to control pests of public health importance
- 3. To identify pests that might warrant additional scrutiny and analyses of benefits before changing, restricting or eliminating a use to control a pest of public health significance

#### IV. WHAT REGISTRANTS SHOULD DO

Registrants do not need to do anything in response to this notice.

#### V. FOR ADDITIONAL INFORMATION

If you have questions regarding this PR Notice, please contact one of the following individuals:

Name: Susan Jennings phone: (706) 355-8574

e-mail: jennings.susan@epa.gov

You may also mail a written inquiry to EPA using the following address:

U.S. Environmental Protection Agency Office of Pesticide Programs (Mailcode 7505M) 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

#### VI. Signature

This PR Notice is digitally signed today, February 23, 2023.

MICHAEL
GOODIS

Digitally signed by MICHAEL
GOODIS
Date: 2023.02.23 14:25:50 -05'00'

Michael Goodis,

Acting Director, Office of Pesticide Programs.

#### **Appendix**

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### Appendix to PR Notice 2023-01 (02/23/2023)

Arthropod Pests	2
Vertebrate Pests	7
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Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
ARACHNIDS		
Ixodida		
Soft Ticks	Argasidae	
	Ornithodoros turicata	
Relapsing fever ticks (and allied species)	Ornithodoros hermsi	Tick-borne relapsing fever
amed species)	Ornithodoros parkeri	
Hard Ticks	Ixodidae	
American dog tick	Dermacentor variabilis	Rocky Mountain spotted fever, Tularemia, tick paralysis,
Rocky Mountain wood tick	Dermacentor andersoni	Colorado tick fever, Rocky Mountain spotted fever, Tularemia, tick paralysis,
Pacific Coast tick	Dermacentor occidentalis	Pacific Coast tick fever
Western blacklegged tick	Ixodes pacificus	Anaplasmosis, <i>Borrelia miyamotoi</i> disease, Lyme disease
Blacklegged tick (deer tick)	Ixodes scapularis	Anaplasmosis, <i>Borrelia miyamotoi</i> disease, Lyme disease, Babesiosis, Powassan encephalitis
Brown dog tick	Rhipicephalus sanguineus	Rocky Mountain spotted fever
Lone star tick	Amblyomma americanum	Ehrlichiosis, Bourbon virus disease, Heartland virus disease, Alpha-gal syndrome (red meat allergy)
Gulf Coast tick	Amblyomma maculatum	Rickettsia parkeri rickettsiosis
Trombidiformes		
Chigger mites	Trombiculidae	
Common chiggers	Eutrombicula spp.	Dermatitis with risk of secondary infection
Follicle mites	Demodicidae	
Dog follicle mite	Demodex canis	Scabies
Human follicle mites	Demodex brevis	Roseacea, Demodicosis,
	Demodex folliculorum	Demodicidosis, eye infections
Sarcoptiformes		
Dust Mites	Pyroglyphidae	
American house dust mite	Dermatophagoides farina	Allergic reaction, Asthma
European house dust mite	Chorioptes pteronyssinus	inorgio reaction, richinia
Itch Mites	Sarcopidae	
Scabies mite	Sarcoptes scabiei	Scabies

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Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Araneae		
Spiders		
Widow spiders, including: Southern black widow Northern black widow Western black widow Brown widow	Latrodectus mactans Latrodectus variolus Latrodectus hesperus Latrodectus geometricus	Venomous bite
Recluse spiders, including: Brown recluse	Loxosceles reclusa	
Scorpiones		
Scorpions		
	Centruroides sculpturatus	
Bark scorpions	Centruroides exilicauda	Venomous sting
	Centruroides vittatus	
Chilopoda		
Centipedes		
House centipede	Scutigera coleoptrata	
Florida blue centipede	Hemiscolopendra marginata	Venomous bite
Scolopendra centipedes	Scolopendra spp.	
INSECTS		
Blattodea		
Cockroaches		
American cockroach	Periplaneta americana	
Australian cockroach	Periplaneta australasiae	
Brown cockroach	Periplaneta brunnea	Allergic reaction, asthma,
Smokybrown cockroach	Periplaneta fuliginosa	Salmonellosis, <i>E. coli</i> infection,
Brownbanded cockroach	Supella longipalpa	hepatitis
German cockroach	Blattella germanica	
Oriental cockroach	Blatta orientalis	
Anoplura		
Sucking lice		
Body louse (cootie)	Pediculus humanus humanus	Epidemic typhus, epidemic
Head louse	Pediculus humanus capitis	relapsing fever, Trench fever,
Crab louse (crabs)	Phthirus pubis	dermatitis with risk of secondary infection

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Arthropod Pests			
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance	
Heteroptera			
True bugs			
Bed bug	Cimex lectularis	Bites, allergic reactions	
Tropical bed bug	Cimex hemipterus	Bites, affergic feactions	
Masked hunter	Reduvius personatus	Chagas disease, allergic reactions	
Large kissing bug	Triatoma rubrofasciata		
Bloodsucking conenose	Triatoma sanguisuga	Chagas disease, allergic reactions	
Western bloodsucking conenose	Triatoma protracta	Chagas disease, anergic reactions	
Diptera			
Horse & Deer Flies			
Horse flies	Tabanus spp.	Painful Bite, allergic reactions, mechanical transmission of anthrax	
Deer flies	Chrysops spp.	Painful Bite, allergic reactions, Tularemia	
Calyptrate Flies			
House fly	Musca domestica	Salmonellosis, Shigella,	
Stable fly	Stomoxys calcitrans	dysentery, myiasis, allergic	
Little house fly	Fannia canicularis	reactions	
Horse bot fly	Gasterophilus intestinalis		
Nose bot fly	Gasterophilus haemorrhoidalis	Ocular myiasis, cutaneous	
Torsalo (human bot fly)	Dermatobia hominus	-myiasis	
Sheep ked	Melophagus ovinus	Myiasis	
Flesh flies	Sarcophagidae, including Sarcophaga and Wohlfahrtia spp.	Myiasis, mechanical vector of pathogens	
Blow flies	Calliphoridae, including <i>Phaenicia</i> and <i>Calliphora</i> spp.	Myiasis, mechanical vector of pathogens	
Screwworm	Cochliomyia hominivorax	-Myiasis	
Secondary screwworm	Cochliomyia macellaria		

Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Biting Midges and Sand Flies		
"No-See-Ums"		
Punkies	Culicoides spp., Leptoconops	Dermatitis with risk of secondary
Biting midges	-spp.	infection, allergic reactions
Sand flies	Lutzomyia spp., Phlebotomus spp.	Dermatitis with risk of secondary infection, American dermal leishmaniasis
Black flies	Simuliidae; includes Simulium	River blindness, dermatitis with
Black gnats	and <i>Prosimulium</i> spp.	risk of secondary infection, painful bite, allergic reactions
Mosquitoes	Culicidae	
Mosquito species that vector disease  Siphonaptera	Aedes spp. Culex spp. Culiseta spp. Ochlerotatus spp. Anopheles spp. Psorophora spp. Coquillettidia spp. Mansonia spp.	Viral diseases, such as:  West Nile, St. Louis encephalitis Eastern equine encephalitis, Western equine encephalitis, Venezuelan equine encephalitis, LaCrosse, Jamestown Canyon, Cache Valley virus disease, Dengue fever, Yellow fever, Malaria, Zika, Chikungunya, Japanese encephalitis  (note: not all diseases are vectored by every genera)
Fleas		
Cat flea	Ctenocephalides felis	Bartonella, Murine typhus, tapeworm infection, dermatitis
Dog flea	Ctenocephalides canis	with a risk of secondary infection allergic reactions, painful bite
Human flea	Pulex irritans	Dermatitis with risk of secondar infection, allergic reactions, painful bite
Sticktight flea	Echidnophaga gallinacea	
Oriental rat flea	Xenopsylla cheopis	Bubonic plague, Murine plague
Chigoe	Tunga penetrans	(endemic typhus), Dermatitis with
Other fleas	Oropsylla spp. Thrassis spp. Ceratophyllus gallinae	risk of secondary infection, allergic reactions, painful bite

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Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Hymenoptera		
Stinging Wasps, Bees, & A	nts	
Yellowjackets	Vespula spp.	
European hornet	Vespa crabro	
Bald-faced hornet	Dolichovespula maculata	Painful stings, allergic reactions
Paper wasps	Polistes spp.	Fainful stiligs, allergic reactions
Thread-waisted wasps (including mud daubers)	Sphecidae: Various species	
Ants	Formicidae	•
Pharaoh ant	Monomorium pharaonis	Feed on wounds
Fire ants, including: Southern fire ant Tropical fire ant Red imported fire ant Black imported fire ant European fire ant	Solenopsis spp. Solenopsis xyloni Solenopsis geminata Solenopsis invicta, Solenopsis richteri Myrmica rubra	Painful stings, allergic reactions
Harvester ants	Pogonomyrmex spp.	Painful stings, allergic reactions
Bees	Apidae	
Africanized honey bee	Apis mellifera scutellata	Painful stings, allergic reactions

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Vertebrate Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Reptiles		
Rattlesnakes	Crotalus spp.	
Copperhead and cottonmouth snakes	Agkistrodon spp.	Direct injury, venomous bites
Coral snakes	Micrurus spp.	
Brown tree snake	Boiga irregularis	
Fish		
Great white shark	Carcharodon carcharias	
Tiger shark	Galeocerdo cuvier	
Bull shark	Carcharhinus leucas	Direct Injury
Asian carps	Cyprinus spp. Ctenopharyngodon spp. Hypophthalmichthys spp.	Direct injury
Birds		
Geese	Subfamily Anserinae	
Mute swan	Cygus olor	
Gulls	Subfamily Larinae	
Coot	Fulica americana	
Rock dove (domestic pigeon)	Columba livia	
Cliff swallow	Petrochelidon pyrrhonota	
Barn swallow	Hirundo rustica	
House (English) sparrow	Passer domesticus	Histoplasmosis, cryptococcosis, psittacosis, avian influenza, direct
American crow	Corvus brachyrhynchos	injury, bird strike at airports
Fish crow	Corvus ossifragus	1
European starling	Sturnus vulgaris	
House finch	Cardodacus purpureus	
Blackbirds	Family Icteridae	
Common raven	Corvus corax	
Chihuahuan raven	Corvus cryptoleucus	
Black vulture	Cathartes aura	
Turkey vulture	Coragyps atratus	

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Vertebrate Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Mammals		
Bats		
Big brown bat	Eptesicus fuscus	
Little brown bat	Myotis lucifugus	Rabies, histoplasmosis,
Brazilian (Mexican) free-tailed bat	Tadarida brasiliensis	salmonellosis, yersiniosis, Nipah virus, Ebola virus, SARS
Big eared bat	Corynorhinus townsendii	coronavirus
Common vampire bat	Desmodus rotundus	
Mice		
House mouse	Mus musculus	
Deer mouse	Peromyscus maniculatus	Hantavirus, salmonellosis,
Cotton mouse	Peromyscus gossypinus	tularemia, leptospirosis,
White-footed mouse (White-footed deer mouse)	Peromyscus leucopus	lymphocytic chorio-meningitis, rat bite fever, other diseases, allergy and asthma triggers from
Eastern harvest mouse	Reithrodontomys humuli	urine/hair/dander
Golden mouse	Ochrotomys nuttalli	
Rats		
Norway rat	Rattus norvegicus	
Roof rat	Rattus rattus	
Polynesian rat	Rattus exulans	Leptospirosis, plague, rat bite
Cotton rats	Sigmodon spp.	fever, salmonellosis, tularemia,
Mexican woodrat	Neotoma mexicana	lymphocytic chorio-meningitis,
Southern plains woodrat	Neotoma micropus	direct injury, allergy and asthmatriggers from urine/hair/dander
White-throated woodrat	Neotoma albigula	

Vertebrate Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Squirrels		
Flying squirrels	Glaucomys spp.	Sylvatic typhus, leptospirosis
Ground squirrels and prairie dogs	Urocitellus spp., Spermophilus spp., Ictidomys spp., Poliocitellus spp., Cynomys spp., Xerospermophilus spp., Callospermophilus spp., Otospermopjilus spp., Ammospermophilus spp.	Plague, tularemia
Tree squirrels and	Sciurus spp., Tamias spp.,	
chipmunks	Eutamias spp., Tamiasciurus spp.	Leptospirosis, salmonellosis,
Woodchuck	Marmota monax	tularemia, rabies, direct injury
Yellow-bellied marmot	Marmota flaviventris	tulatenna, rables, direct injury
Other Mammals		
Bears	Family Ursidae	Toxoplasmosis, brucellosis, trichinellosis, direct injury
Coyote	Canis latrans	
Arctic fox	Alopex lagopus	
Gray fox	Urocyon cinereoargenteus	Rabies, canine distemper virus,
Red fox	Vulpes vulpes	leptospirosis, direct injury
Gray wolf	Canis lupus	
Wild (feral) dog	Canis lupus familiaris	
Wild (feral) cat	Felis catus	Toxoplasmosis, rabies, direct injury
Wild (feral) horse	Equus caballus	Rabies, leptospirosis, salmonellosis, campylobacterosis, cryptosporidiosis, direct injury
Wild (feral) swine Javelina (collared peccary)	Sus scrofa Dicotyles tajacu	Leptospirosis, brucellosis, <i>E. coli</i> infection, salmonellosis, toxoplasmosis, rabies, swine influenza viruses, trichinosis, giardiasis, cryptosporidiosis, direct injury
Deer and elk	Family Cervidae	Leptospirosis, salmonellosis, chlamydiosis, campylobacterosis, cryptosporidiosis, giardiasis, direct injury
American bison	Bison bison	Brucellosis, direct injury
Mongooses	Family Herpestidae	Leptospirosis, direct injury

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Vertebrate Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Other Mammals (co	ontinued)	
Mountain lion (cougar)	Puma concolor	Toxoplasmosis, plague, rabies, direct injury
Nutria	Myocastor coypus	Tuberculosis, septicemia, rabies, leptospirosis
Porcupine	Erethizon dorsatum	Rabies, tularemia, direct injury
North American beaver	Castor canadensis	Giardiasis, leptospirosis, hantavirus, direct injury, waterway impoundment that can lead to life-threatening flooding
Badger	Taxidea taxus	Rabies, direct injury
Muskrat	Ondatra zibethicus	Leptospirosis, tularemia
Striped skunk Spotted skunk Raccoon	Mephitis mephitis Spilogale putorius Procyon lotor	Leptospirosis, tularemia, direct injury
Rabbits	Family Leporidae	Cryptosporidoisis, tularemia, rabbit hemorrhagic fever
Virginia opossum	Didelphis virginiana	Leptospirosis, tularemia, direct injury
Nine-banded armadil	llo Dasypus novemcinctus	Leprosy, Chagas disease

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Microorganisms	
Taxonomic Name	Public Health Importance
(Organism or Particle Type)	(Possible Clinical Significance)
Bacteria	
Spirochetes	
•	Lyme disease, Borrelia miyamotoi disease,
Borrelia spp.	tick-borne relapsing fever
Leptospira spp.	Leptospirosis
Treponema spp.	Syphilis, yaws, pinta
Gram-Negative Bacteria – aerobic rods and c	
Campylobacter spp.	Enteritis, abscesses,
	Septicemia, abscesses, respiratory and urinary
Pseudomonas spp.	infections, bacteremia
Stenotrophomonas spp.	Respiratory infections, urinary tract infections
Burkholderia spp.	Endocarditis, septicemia, wound infections
Legionella spp.	Legionnaires' Disease, pneumonia
Neisseria spp.	Meningitis, gonorrhea, urinary tract infections
Elizabethkingia spp. (Chryseobacterium -	Nassacomial infection, maningitic continuous
Flavobacteria spp.)	Nosocomial infection, meningitis, septicemia
Bordetella spp.	Whooping cough
Brucella spp.	Brucellosis, undulant fever
Moraxella spp.	Conjunctivitis
Acinetobacter spp.	Nosocomial infections
Aeromonas spp.	Gastroenteritis, wound, septicemia
Haemophilus spp.	Bronchitis, sinusitis, otitis, septicemia, venereal disease
Chromobacterium spp.	Pyogenic infections, septicemia
Gram-Negative Bacteria –facultatively anaero	
Vibrio spp.	Cholera, gastroenteritis, septicemia, ear infections
Plesiomonas spp.	Gastroenteritis
	Meningitis, arthritis, otitis, septicemia,
Pasteurella spp.	sinusitis, encephalitis
Actinobacillus spp.	Pneumonia, bronchitis, septicemia, sinusitis
11	Diarrhea, intra-abdominal abscesses,
Bacteroide spp.	peritoneal infections, inflammatory bowel
* *	disease, anaerobic bacteremia, colon cancer
Cardiobacterium spp.	Endocarditis
Gardnerella spp.	Vaginitis
Eikenella spp.	Sinusitis, pulmonary infections, arthritis, endocarditis, pancreatic abscesses

Microorganisms	
Taxonomic Name	Public Health Importance
(Organism or Particle Type)	(Possible Clinical Significance)
Enteric Bacteria	
Escherichia spp.	Urinary tract infections, septicemia, diarrhea,
	hemorrhagic colitis
Shigella spp.	Dysentery, diarrhea
Salmonella spp.	Gastroenteritis, septicemia, bacteremia, arthritis, typhoid fever, enterocolitis, gallbladder infection
Citrobacter spp.	Opportunistic infections, neonatal meningitis
Klebsiella spp.	Pneumoniae, infant diarrhea and urinary tract infection
Enterobacter spp./Other related species	Wound infection, nosocomial infections, urinary tract infections, gastroenteritis
Hafnia spp.	Opportunistic infections
Proteus spp.	Urinary tract infections, infant diarrhea, respiratory infections
Serratia spp.	Cystitis, bloodstream and central nervous system infections
Providencia spp.	Nosocomial infections, urinary tract infections, burn wound infections
Morganella spp.	Bacteremia, respiratory/urinary tract infections, wound infections
Yersinia spp.	Gastroenteritis, wound infections, septicemia
Gram-Negative, Anaerobic, Straight, Curved	
Bacterioides spp.	Periodontal disease, bacteremia
Fusobacterium spp.	Abscesses
Rickettsia and Chlamydia – obligate, intra	acellular parasites
Rickettsia—Rod-shaped bacteria or Coccobatransmitted by arthropods	
	Rickettsialpox, Rocky Mountain spotted
Rickettsia spp.	fever, <i>Rickettsia parkeri</i> rickettsiosis, Pacific
Richelista Spp.	Coast tick fever
Anaplasma spp.	Anaplasmosis
Ehrlichia spp.	Ehrlichiosis  Englishiosis
Coxiella spp.	Q fever
Chlamydia –coccoid bacteria, Gram-negativ	
Chlamydia spp.	Trachoma (blindness), nongonococcal
• • • • • • • • • • • • • • • • • • • •	urethritis, lymphoma venereum, pneumonia
Mycoplasma spp.	Pneumonia, urogenital tract infections
Ureaplasma spp.	Urogenital tract infections

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Microorganisms	
Taxonomic Name	Public Health Importance
(Organism or Particle Type)	(Possible Clinical Significance)
Gram-Positive Cocci	
Staphylococcus spp.	Cellulitis, boils, carbuncles, impetigo, toxic shock syndrome, bacteremia, endocarditis, meningitis, pneumonia, osteomyelitis
Coagulase-negative Staphylococcus spp.	Bacteremia, endocarditis, peritonitis, genitourinary tract infections
Group A Streptococci spp.	Pharyngitis, tonsillitis, sinusitis, arthritis, rheumatic fever, scarlet fever, impetigo
Group B Streptococci spp.	Neonatal disease, pneumonia, septicemia, meningitis, endocarditis
Group C Streptococci spp.	Pneumonia, pharyngitis, endocarditis, meningitis
Enterococcus spp.	Wound infections, bacteremia, endocarditis, meningitis
Additional Streptococci spp.	Pneumonia, otitis media, bacteremia, meningitis
Endospore-forming Gram-positive rods and	l cocci
Bacillus spp.	Anthrax, gastroenteritis
Clostridioides spp.	Pseudomembranous colitis
Clostridium spp.	Tetanus, botulism, gangrene
Non-Endospore forming Gram-Positive Ro	
Listeria spp.	Food poisoning, abscess, abortion, meningitis
Erysipelothrix spp.	Erysipeloid, arthritis, endocarditis
Irregular, non-endospore forming, Gram-po	ositive rods
Corynebacterium spp.	Diphtheria
Actinomyces spp.	Actinomyces-granulomatous, ocular infections, caries, periodontal disease, intrauterine infection
Propionibacterium spp.	Acne
Mycobacterium spp.	Tuberculosis, pulmonary disease, cutaneous abscesses, post-operative wound infections
Actinomycetes—Irregular, non-endospore f	forming, Gram-positive
Nocardia spp.	Cutaneous/subcutaneous infections, nocardiosis, mycetoma
Rhodococcus spp.	Opportunist pathogens
Streptomyces spp. Actinomadura spp.	Actinomycetoma

Microorganisms		
Taxonomic Name	Public Health Importance	
(Organism or Particle Type)	(Possible Clinical Significance)	
Fungi		
Rhizopus spp.		
Rhizomucor spp.		
Absidia spp.		
Mucor spp.		
Cunninghamella spp.	Opportunistic infectionsMucormycosis	
Mortierella spp.		
Saksenaea spp.		
Apophysomyces spp.		
Penicillium spp.	Pneumonia, endocarditis, urinary tract infections	
Candida spp.	Candidiasis, thrush, iatrogenic infections, Genitourinary tract infections	
Fusarium spp.	Disseminated skin lesions in patients with leukemia	
Pseudalleschericia spp.	Local lesions in paranasal sinuses, disseminated in kidney, thyroid, brain, heart	
Cryptococcus spp.	Meningitis	
Trichosporon spp.	Trichosporonosis	
Epidermophyton spp.	Tinea cruris, tinea pedis	
Malassezia spp.	Tinea versicolor	
Exophiala spp.	Tinea nigra palmaris	
Trichophyton spp.	Athlete's foot, tinea pedis, tinea corporis, tinea pedis, tinea barbae, tinea cruris, tinea capitis, tinea favosa	
Microsporum spp.	Tinea capitis	
Pneumocystis spp.	Pneumonia	
Histoplasma spp.	Histoplasmosis	
Coccidioides spp.	Coccidioidomycosis	
Paracoccidioides spp.	Paracoccidioidomycosis	
Blastomyces spp.	Blastomycosis	
Sporothrix spp.	Sporotrichosis	
Aspergillus spp.	Aspergillosis, pneumonia, ear infections, food-borne intoxication (aflatoxin)	
Stachybotrys spp. / Memnoniella spp.	Allergic reactions	
Protozoans		
Amoebas		
Entamoeba spp.	Amoebic dysentery	
Naegleria spp.	Meningoencephalitis	
Acanthamoeba spp.	Keratitis, chronic granulomatous amoebic encephalitis	

Microorganisms		
Taxonomic Name	Public Health Importance	
(Organism or Particle Type)	(Possible Clinical Significance)	
Flagellates	g /	
Giardia spp.	Dysentery	
Trichomonas spp.	Urethritis, vaginitis	
Ciliates	, ,	
Balantidium spp.	Dysentery	
Sporozoans		
Babesia spp.	Babesiosis	
Cryptosporidium spp.	Diarrhea	
Cyclospora spp.	Food poisoning	
Toxoplasma spp.	Toxoplasmosis	
Isospora spp.	Watery diarrhea, abdominal pain/cramping,	
	vomiting, fever	
Viruses  Adapoviruses (Infectious coning honotitis	Deposition manages dismits	
Adenoviruses (Infectious canine hepatitis	Bronchitis, pneumonia, diarrhea,	
virus)	conjunctivitis, fever, bladder inflammation	
Alphaviruses (Eastern equine encephalitis virus, chikungunya virus)	Fever, headache, joint swelling, pain,	
	seizures, neurocognitive symptoms	
Papillomaviruses (HPV),	Cancers, papilloma, warts	
Polyomaviruses (simian vacuolating virus, Simian Virus 40, BK virus)	Usually asymptomatic, hemorrhagic cystitis,	
Herpesviruses (herpes simplex viruses, varicella-zoster virus, cytomegalovirus,	Shingles, chicken pox, fever, sore throat,	
Epstein-Barr virus)	swollen glands, hepatitis	
Parvoviruses (parvovirus B19, canine parvovirus)	Fifth disease, rash, rhinitis, headache, painful joints	
Poxviruses (smallpox virus, cow pox virus, sheep pox virus, monkey pox, vaccinia virus, molluscum contagiosum)	Lesions, skin nodules, disseminated rash	
Picornaviruses (poliovirus, rhinovirus, coxsackie virus, enterovirus, hepatovirus, cardiovirus)	Hand, foot, and mouth disease, viral meningitis, myocarditis, acute flaccid paralysis, inflammatory muscle disease, stomach pain, nausea	
Reoviruses (rotavirus)	Acute necrotizing encephalopathy, vomiting, diarrhea, abdominal pain	
Caliciviruses (norovirus)	Diarrhea, vomiting, stomach pain	
Togoviruses (rubella virus, alphavirus)	German measles, rash, sore throat	
Flaviviruses (dengue virus, hepatitis C virus, yellow fever virus, Zika virus, West Nile virus, Powassan virus, tick-borne encephalitis virus)	Fever, headache, neurological symptoms, nausea, vomiting, rash, aches, pains, bleeding from nose or gums	
Orthomyxoviruses (influenza viruses, Thogotovirus)	Fever, child, cough, sore throat, rhinitis	

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Microorganisms		
Taxonomic Name	Public Health Importance	
(Organism or Particle Type)	(Possible Clinical Significance)	
Viruses (continued)		
Paramyxoviruses (measles virus, measles virus, respiratory syncytial virus (RSV), canine distemper virus)	High fever, coryza, conjunctivitis, coughing, wheezing,	
Bunyaviruses (California encephalitis virus, hantavirus, Crimean-Congo hemorrhagic fever)	Fever, fatigue, muscle aches, vomiting, diarrhea, lethargy, shortness of breath	
Rhabdoviruses (rabies virus)	Flu-like symptoms, weakness, fever, headache	
Filoviruses (Ebola virus, Marburg virus)	Muscle pains, fatigue, diarrhea, unexplained bleeding or bruising	
Coronaviruses (coronavirus, SARS-CoV, MERS-CoV)	Rhinitis, cough, sore throat, fever, fatigue, difficulty breathing	
Astroviruses (astrovirus)	Vomiting, diarrhea	
Retroviruses (HIV)	Night sweats, continual fevers, extreme fatigue, prolonged swelling of lymph glands, immune deficiency (i.e., AIDS)	
Hepeviruses (Hepatitis E virus)	Nausea, jaundice, liver failure	
Hepadnaviruses (Hepatitis B virus)	Fever, vomiting, nausea, dark urine, jaundice	
Arenaviruses (Lymphocytic choriomeningitis virus (LCMV), Lujo Hemorrhagic Fever (LHF) virus, Sabia Virus, Lassa virus)	Meningitis, encephalitis, hydrocephalus, rash on face and trunk, respiratory distress, circulatory issues	
Prions		
TSEs (transmissible spongiform encephalopathies)	Gerstmann-Straussler-Scheinker Syndrome, fatal familial insomnia, kuru, Creutzfeldt-Jakob Disease, bovine spongiform encephalopathy, scrapie, transmissible mink encephalopathy, feline spongiform encephalopathy, ungulate spongiform encephalopathy, chronic wasting disease	

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HEALTH

# Environmental group tests to find the best water filters for removing PFAS



BY STEPHANIE STAHL
JULY 11, 2023 / 5:51 PM / CBS PHILADELPHIA



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PHILADELPHIA (CBS) -- Water filters have become more popular following studies that show nearly half of the country's <u>tap water</u> could be contaminated with potentially toxic compounds. But which are the best water filters?

There are different ways to filter your water at home, according to a recent study focused on specialized pitchers that are designed to block <u>PFAS</u>, also known as <u>forever chemicals</u>.

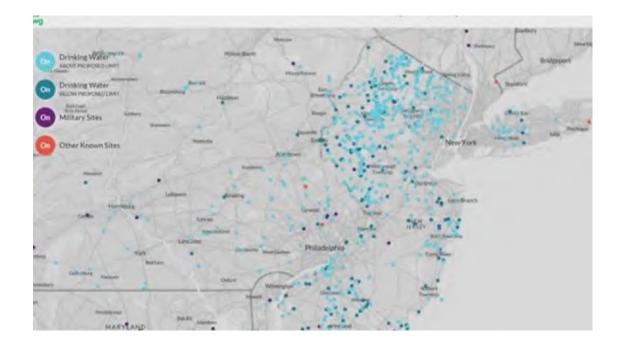
The Environmental Working Group tested 10 water pitchers and found some of the most well-known are "not" effective at fully filtering out PFAS.

# ALSO SEE: West Deptford chemical manufacturing company agrees to \$392.7M settlement for PFAS pollution

The so-called forever chemicals -- used in products like nonstick cookware, stain-resistant carpets and cosmetics -- have been linked to an increased risk for a number of health problems, including certain cancers, high cholesterol and pregnancy complications.



"We've since discovered that all these PFAS are immune suppressants, so they suppress your immune system and that means any opportunistic disease, including some types of cancer, could take over," said Graham Peaslee, who is a biochemist. PFAS have also been found in drinking water. A map from the Environmental Working Group shows contamination in the Phila region, as well as north into New York.



Now, there's growing interest in water filtration systems.

# ALSO SEE: Pennsylvania sets limit on "forever chemicals" in drinking water

The <u>Environmental Working Group testing</u> showed three of the filters tested stood above the rest.

"They actually reduced PFAS down to non-detectable levels, which is really great," said Sydney Evans, with the Environmental Working Group.

In the study, pitchers from "Clearly Filtered" and "Zero Water" blocked 100% of PFAS tested. So did the standing travel Berkey filter system.



6 of 9



The Epic Pure pitcher was close, blocking 98% of PFAS.

However, for them to work properly, filters need to be changed, which can be costly.

The travel Berkey sells for \$327, but the filter lasts eight years.

The other recommended pitchers have a lower up-front price but changing the filters can cost hundreds of dollars a year.

For a full year's use, Epic has the lowest price.

# ALSO SEE: Toxic "forever chemicals" found in U.S. farmland soil

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Exhibit B, pg. 278 of 280

# **Regional Hearing Clerk Filing** Coversheet

Date	5/8/23
Suggested close date	Immediately after docketing
Specific date (if applicable)	
Response urgency level	Within 1 week
Program contact (extension required)	Christine Tokarz, 303-312-6147
Attorney contact (extension required)	Shaula Eakins, 303-312-6317
Statute	FIFRA
Type of Filing	Stop Sale, Use or Removal Order
RJO review requested	Yes No
Final Order requested	Yes No
If Complaint:	
Proposed penalty (if proposed under 40 C.F.R. § 22.14(a)(4)(i))	\$ 0
If Consent Agreement:	
Penalty amount	\$ 0
Penalty installment payments	☐ Yes ✓ No
If yes, terms of installment payments (number of payments, when due)	not applicable
Respondent contact name & address (including email)	Berkey International LLC Royal Industrial Park, B-2 869 Km 1.5, Barrio Palmas
Represented by legal counsel	Yes No
Legal counsel name & address (including email)	
Public notice required	Yes No
Public notice period (in days)	
Comments received	Yes No

Last updated: 10/14/2021 Exhibit B, pg. 279 of 280

# Exhibit B-24



ttps://yosemite.epa.gov/OA/RHC/EPAAdmin.nsf/All+Dockets+by+Case+Number/FIFRA-08-2023-0038 Last updated on 6/14/2023

# **EPA Administrative Enforcement Dockets**

# Berkey International LLC

Docket Number: FIFRA-08-2023-0038

Status: Closed

Statute: FIFRA Federal Insecticide, Fungicide and Rodenticide Act (Administrative Order -

Notice of Refusal of Admission)

Complaint Date:

Closed Date: 05/09/2023 12:00:00 AM Disposition: No Further Action Needed

Location Filed: Region 08

Filings:

(05/08/2023) #1 Stop Sale, Use or Removal Order

# 7 USC CHAPTER 6, SUBCHAPTER II: ENVIRONMENTAL PESTICIDE CONTROL

#### From Title 7—AGRICULTURE

CHAPTER 6—INSECTICIDES AND ENVIRONMENTAL PESTICIDE CONTROL

#### SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

# §§135 to 135k. Omitted

#### **EDITORIAL NOTES**

# **CODIFICATION**

Sections 135 to 135k, acts June 25, 1947, ch. 125, §§2–13, 61 Stat. 163–172; Aug. 7, 1959, Pub. L. 86–139, §2, 73 Stat. 286; May 12, 1964, Pub. L. 88–305, §§1–6, 78 Stat. 190–193; Oct. 15, 1970, Pub. L. 91–452, title II, §204, 84 Stat. 928; Dec. 30, 1970, Pub. L. 91–601, §6(b), formerly §7(b), 84 Stat. 1673, renumbered, Aug. 13, 1981, Pub. L. 97–35, title XII, §1205(c), 95 Stat. 716, which related to economic poison control, were superseded by the amendments made to act June 25, 1947, by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 975. See section 4 of Pub. L. 92–516, set out as a note under section 136 of this title. The provisions of act June 25, 1947, as amended by Pub. L. 92–516, are set out in section 136 et seq. of this title.

Section 135 provided definitions for the purposes of this subchapter.

Section 135a related to prohibited acts.

Section 135b related to registration of economic poisons.

Section 135c related to access, inspection, and use in criminal prosecutions of books and records.

Section 135d related to rules and regulations, examination of economic poisons or devices, notification to violators, certification to United States attorney, duty of attorney, and publication of judgments.

Section 135e related to exemptions from penalties.

Section 135f provided for penalties.

Section 135g related to seizure, disposal, and award of costs against claimant.

Section 135h related to refusal of admission of imports.

Section 135i related to delegation of duties.

Section 135j related to authorization of appropriations and expenditure of funds.

Section 135k related to cooperation between departments and agencies.

# §136. Definitions

For purposes of this subchapter—

# (a) Active ingredient

The term "active ingredient" means—

- (1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;
- (2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;
  - (3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;
  - (4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and
- (5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

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(b) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

#### (c) Adulterated

The term "adulterated" applies to any pesticide if—

- (1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;
  - (2) any substance has been substituted wholly or in part for the pesticide; or
  - (3) any valuable constituent of the pesticide has been wholly or in part abstracted.

# (d) Animal

The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

# (e) Certified applicator, etc.

# (1) Certified applicator

The term "certified applicator" means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

# (2) Private applicator

The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

#### (3) Commercial applicator

The term "commercial applicator" means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

#### (4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

#### (f) Defoliant

The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

# (q) Desiccant

The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

# (h) Device

The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

#### (i) District court

The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

# (j) Environment

The term "environment" includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

#### (k) Fungus

The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria,

except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

#### (I) Imminent hazard

The term "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973 [16 U.S.C. 1531 et seq.].

#### (m) Inert ingredient

The term "inert ingredient" means an ingredient which is not active.

# (n) Ingredient statement

The term "ingredient statement" means a statement which contains—

- (1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and
- (2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

#### (o) Insect

The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

# (p) Label and labeling

# (1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

#### (2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

- (A) accompanying the pesticide or device at any time; or
- (B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

#### (q) Misbranded

- (1) A pesticide is misbranded if—
- (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
- (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
  - (C) it is an imitation of, or is offered for sale under the name of, another pesticide;
- (D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;
- (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;
- (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or
- (H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to

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be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

# (2) A pesticide is misbranded if—

- (A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if-
  - (i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and
  - (ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;
- (B) the labeling does not contain a statement of the use classification under which the product is registered;
- (C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—
  - (i) the name and address of the producer, registrant, or person for whom produced;
  - (ii) the name, brand, or trademark under which the pesticide is sold;
  - (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
  - (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and
- (D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—
  - (i) the skull and crossbones;
  - (ii) the word "poison" prominently in red on a background of distinctly contrasting color; and
  - (iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

#### (r) Nematode

The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

#### (s) Person

The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

#### (t) Pest

The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

# (u) Pesticide

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w)  $\frac{1}{2}$  of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section  $321(x)^{\frac{1}{2}}$  of title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

# (v) Plant regulator

The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

#### (w) Producer and produce

The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this subchapter.

# (x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

# (y) Registrant

The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this subchapter.

# (z) Registration

The term "registration" includes reregistration.

#### (aa) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

#### (bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

#### (cc) Weed

The term "weed" means any plant which grows where not wanted.

#### (dd) Establishment

The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

# (ee) To use any registered pesticide in a manner inconsistent with its labeling

The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not

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include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

## (ff) Outstanding data requirement

# (1) In general

The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data

- (A) has not been submitted to the Administrator: or
- (B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

#### (2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

# (gg) To distribute or sell

The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

#### (hh) Nitrogen stabilizer

The term "nitrogen stabilizer" means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

- (1) dicyandiamide;
- (2) ammonium thiosulfate; or
- (3) any substance or mixture of substances.— $\frac{2}{}$ 
  - (A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and
  - (B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January
- 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization  $\frac{3}{2}$  urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

# (jj) <sup>4</sup> Maintenance applicator

The term "maintenance applicator" means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term "maintenance applicator" does not include private applicators as defined in subsection (e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

#### (kk) Service technician

The term "service technician" means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term "service technician" does not include individuals who use

antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

#### (II) Minor use

The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

- (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
- (2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and
  - (A) there are insufficient efficacious alternative registered pesticides available for the use;
  - (B) the alternatives to the pesticide use pose greater risks to the environment or human health;
  - (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
  - (D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

# (mm) Antimicrobial pesticide

#### (1) In general

The term "antimicrobial pesticide" means a pesticide that—

- (A) is intended to—
  - (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or
- (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and
- (B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of title 21 or a food additive regulation under section 348 of title 21.

#### (2) Excluded products

The term "antimicrobial pesticide" does not include—

- (A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;
  - (B) an agricultural fungicide product; or
  - (C) an aquatic herbicide product.

#### (3) Included products

The term "antimicrobial pesticide" does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

# (nn) Public health pesticide

The term "public health pesticide" means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

# (oo) Vector

The term "vector" means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

(June 25, 1947, ch. 125, §2, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 975; amended Pub. L. 93-205, §13(f), Dec. 28, 1973, 87 Stat. 903; Pub. L. 94–140, §9, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, §1, Sept. 30, 1978, 92 Stat. 819; Pub. L. 100-532, title I, §101, title VI, §601(a), title VIII, §801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub. L. 102–237, title X, §1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub. L. 104–170, title I, §§105(a), 120, title II, §§210(a), 221, 230, title III, §304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

#### **EDITORIAL NOTES**

# REFERENCES IN TEXT

The Endangered Species Act of 1973, referred to in subsec. (I), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified generally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Section 321 of title 21, referred to in subsec. (u), was subsequently amended, and subsecs. (w) and (x) of section 321 no longer define the terms "new animal drug" and "animal feed", respectively. However, such terms are defined elsewhere in that section.

Section 27(b) of Federal Pesticide Act of 1978, referred to in subsec. (ee), is section 27(b) of Pub. L. 95–396, Sept. 30, 1978, 92 Stat. 841, which was formerly set out as a note under section 136w–4 of this title.

#### **PRIOR PROVISIONS**

A prior section 2 of act June 25, 1947, was classified to section 135 of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

### **AMENDMENTS**

**1996**—Subsec. (a)(1). Pub. L. 104–170, §105(a)(1)(A), substituted "defoliant, desiccant, or nitrogen stabilizer" for "defoliant, or desiccant".

Subsec. (a)(5). Pub. L. 104-170, §105(a)(1)(B)-(D), added par. (5).

Subsec. (u). Pub. L. 104–170, §§105(a)(2), 221(1), struck out "and" before "(2)", inserted "and (3) any nitrogen stabilizer," after "desiccant,", and inserted at end "The term 'pesticide' does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term 'critical device' includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term 'semi-critical device' includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

Subsec. (bb). Pub. L. 104–170, §304, which directed amendment of section 2(bb) by inserting "(1)" after "means" and adding cl. (2), without specifying the Act being amended, was executed to this subsection, which is section 2(bb) of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Pub. L. 104–170, §230(a), inserted at end "The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide."

Subsec. (hh). Pub. L. 104–170, §105(a)(3), added subsec. (hh).

Subsecs. (jj), (kk). Pub. L. 104-170, §120, added subsecs. (jj) and (kk).

Subsec. (II). Pub. L. 104-170, §210(a), added subsec. (II).

Subsec. (mm). Pub. L. 104-170, §221(2), added subsec. (mm).

Subsecs. (nn), (oo). Pub. L. 104–170, §230(b), added subsecs. (nn) and (oo).

**1991**—Subsec. (e)(1). Pub. L. 102–237, §1006(a)(1), substituted "section 136i" for "section 136b" and "uses dilutions" for "use dilutions" and made technical amendment to reference to subsection (ee) of this section involving corresponding provision of original act.

Subsec. (e)(2). Pub. L. 102–237, §1006(b)(3)(A), substituted "the applicator or the applicator's" for "him or his".

Subsec. (e)(3). Pub. L. 102–237, §1006(b)(3)(B), substituted "the applicator" for "he".

Subsec. (q)(2)(A)(i). Pub. L. 102–237,  $\S1006(a)(2)$ , substituted "size or form" for "size of form".

1988—Subsec. (c). Pub. L. 100-532, §801(a)(1), substituted "if—" for "if:".

Subsec. (p)(2)(B). Pub. L. 100–532, §801(a)(2), substituted "Health and Human Services" for "Health, Education, and Welfare".

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Subsec. (q)(2)(A). Pub. L. 100-532, §801(a)(3), substituted "if—" for "if:".

Subsec. (q)(2)(C)(iii). Pub. L. 100–532, §801(a)(4), substituted ", except that" for ": *Provided*, That".

Subsec. (u). Pub. L. 100–532, §801(a)(5), substituted ", except that" for ": *Provided*, That", struck out "(1)(a)" after "include any article" and "or (b)" after "section 321(w) of title 21,", and substituted "Health and Human Services" for "Health, Education, and Welfare", "or that is" for "or (2) that is", and "a new animal drug" for "an article covered by clause (1) of this proviso".

Subsec. (ee). Pub. L. 100–532, §§601(a)(1), 801(a)(6), substituted ", except that" for ": *Provided*, That", inserted "unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency" and "unless the labeling specifically states that the product may be applied only by the methods specified on the labeling", substituted "labeling, (4) mixing" for "labeling, or (4) mixing", ", (5)" for ": *Provided further*, That the term also shall not include", "or (6) any use" for "or any use", and ". After" for ": *And provided further*, That after".

Subsec. (ff). Pub. L. 100-532, §101, added subsec. (ff).

Subsec. (gg). Pub. L. 100–532, §601(a)(2), added subsec. (gg).

**1978**—Subsec. (e)(1). Pub. L. 95–396, §1(1), inserted provision deeming an applicator not a seller or distributor of pesticides when providing a service of controlling pests.

Subsec. (e)(3). Pub. L. 95-396, §1(2), substituted "an applicator" for "a certified applicator".

Subsec. (q)(1)(H). Pub. L. 95–396, §1(3), added subpar. (H).

Subsec. (w). Pub. L. 95–396, §1(4), (5), amended definition of "producer" and "produce" to include reference to active ingredient used in producing a pesticide and inserted provision that an individual did not become a producer when there was dilution of a pesticide for personal use according to directions on registered labels.

Subsec. (dd). Pub. L. 95–396, §1(6), inserted "or active ingredient used in producing a pesticide". Subsec. (ee). Pub. L. 95–396, §1(7), added subsec. (ee).

**1975**—Subsec. (u). Pub. L. 94–140 inserted proviso which excluded from term "pesticide" any article designated as "new animal drug" and any article denominated as animal feed.

1973—Subsec. (I). Pub. L. 93–205 substituted "or threatened by the Secretary pursuant to the Endangered Species Act of 1973" for "by the Secretary of the Interior under Public Law 91–135".

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

# **EFFECTIVE DATE OF 1988 AMENDMENT**

Pub. L. 100–532, title IX, §901, Oct. 25, 1988, 102 Stat. 2688, provided that: "Except as otherwise provided in this Act, the amendments made by this Act [see Short Title of 1988 Amendment note below] shall take effect on the expiration of 60 days after the date of enactment of this Act [Oct. 25, 1988]."

# **EFFECTIVE DATE OF 1973 AMENDMENT**

Amendment by Pub. L. 93–205 effective Dec. 28, 1973, see section 16 of Pub. L. 93–205, set out as an Effective Date note under section 1531 of Title 16, Conservation.

#### **EFFECTIVE DATE**

Pub. L. 92–516, §4, Oct. 21, 1972, 86 Stat. 998, as amended by Pub. L. 94–140, §4, Nov. 28, 1975, 89 Stat. 752; Pub. L. 95–396, §28, Sept. 30, 1978, 92 Stat. 842, provided that:

- "(a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter], as amended by this Act and as otherwise provided by this section, the amendments made by this Act [see Short Title note set out below] shall take effect at the close of the date of the enactment of this Act [Oct. 21, 1972], provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.
- "(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter] and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder.
- "(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

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- "(2) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until five years from the date of enactment of this Act.
- "(3) A period of five years from date of enactment shall be provided for certification of applicators.
  - "(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.
  - "(B) Each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).
  - "(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.
- "(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.
- (d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.
- (e) For purposes of determining any criminal or civil penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted."

# SHORT TITLE OF 2022 AMENDMENT

Pub. L. 117–328, div. HH, title VI, §701, Dec. 29, 2022, 136 Stat. 5996, provided that: "This title [amending sections 136a, 136a–1, and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under sections 136a, 136a-1, and 136w of this title] may be cited as the 'Pesticide Registration Improvement Act of 2022'."

# SHORT TITLE OF 2019 AMENDMENT

Pub. L. 116-8, §1(a), Mar. 8, 2019, 133 Stat. 484, provided that: "This Act [amending sections 136a-1, 136c, and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136w of this title may be cited as the 'Pesticide Registration' Improvement Extension Act of 2018'."

# **SHORT TITLE OF 2012 AMENDMENT**

Pub. L. 112–177, §1, Sept. 28, 2012, 126 Stat. 1327, provided that: "This Act [amending sections 136a-1 and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136a-1 of this title] may be cited as the 'Pesticide Registration Improvement Extension Act of 2012'."

#### SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110-94, §1, Oct. 9, 2007, 121 Stat. 1000, provided that: "This Act [amending sections 136a, 136a-1, and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136a of this title] may be cited as the 'Pesticide Registration Improvement Renewal Act'."

# SHORT TITLE OF 2004 AMENDMENT

Pub. L. 108–199, div. G, title V, \$501(a), Jan. 23, 2004, 118 Stat. 419, provided that: "This section [enacting section 136w–8 of this title, amending sections 136a, 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under section 136a of this title and section 346a of Title 21, Food and Drugs] may be cited as the 'Pesticide Registration Improvement Act of 2003'."

# SHORT TITLE OF 1996 AMENDMENT

Pub. L. 104–170, §1, Aug. 3, 1996, 110 Stat. 1489, provided that: "This Act [enacting sections 136i–2, 136r-1, and 136w-5 to 136w-7 of this title, amending this section, sections 136a, 136a-1, 136d, 136g,

136s, 136w, 136w-3, 136x, and 136y of this title, and sections 321, 331, 333, 342, and 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136i–2 of this title and sections 301 and 346a of Title 21] may be cited as the 'Food Quality Protection Act of 1996'."

[Another Food Quality Protection Act of 1996 was enacted by Pub. L. 104-170, title IV, 110 Stat. 1513, see section 401(a) of Pub. L. 104–170, set out as a note under section 301 of Title 21, Food and Drugs.]

# SHORT TITLE OF 1988 AMENDMENT

Pub. L. 100-532, §1(a), Oct. 25, 1988, 102 Stat. 2654, provided that: "This Act [enacting section 136a-1 of this title, amending this section and sections 136a to 136d, 136f to 136g, 136s, 136v to 136w-2, and 136y of this title, and enacting provisions set out as notes under this section and sections 136m and 136v of this title may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988'."

# **SHORT TITLE OF 1978 AMENDMENT**

Pub. L. 95–396, §29, Sept. 30, 1978, 92 Stat. 842, provided that: "This Act [enacting sections 136w-1 to 136w-4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136l, 136o, 136g, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136o, and 136w–4 of this title, and amending provisions set out as a note under this section] may be cited as the 'Federal Pesticide Act of 1978'."

# SHORT TITLE

Pub. L. 92-516, §1, Oct. 21, 1972, 86 Stat. 973, provided: "That this Act [amending this subchapter generally, enacting notes set out under this section, and amending sections 1261 and 1471 of Title 15, Commerce and Trade, and sections 321 and 346a of Title 21, Foods and Drugs] may be cited as the 'Federal Environmental Pesticide Control Act of 1972'."

Act June 25, 1947, ch. 125, §1(a), as added by Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 973, provided that: "This Act [enacting this subchapter] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act'."

#### **EXECUTIVE DOCUMENTS**

# TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

# FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42. The Public Health and Welfare.

- <sup>1</sup> See References in Text note below.
- <sup>2</sup> So in original. Period probably should not appear.
- <sup>3</sup> So in original. Probably should be followed by ", or".
- <sup>4</sup> So in original. No subsec. (ii) was enacted.

# §136a. Registration of pesticides

# (a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of

any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

#### (b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

- (1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or
  - (2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

# (c) Procedure for registration

# (1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

- (A) the name and address of the applicant and of any other person whose name will appear on the labeling;
  - (B) the name of the pesticide;
- (C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use:
  - (D) the complete formula of the pesticide;
  - (E) a request that the pesticide be classified for general use or for restricted use, or for both; and
- (F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:
  - (i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.
  - (ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—
    - (I) there are insufficient efficacious alternative registered pesticides available for the use;
    - (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health:
      - (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or
    - (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed

on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

- (iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.
- (v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.
- (vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.
- (G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

# (2) Data in support of registration

#### (A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in

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relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

#### (B) Additional data

- (i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.
- (ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.
- (iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.
- (iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.
- (v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

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- (vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to
  - support that minor use until the final deadline for submission of data under section 136a–1 of this title for the other uses of the pesticide established as of August 3, 1996, if—
    - (I) the data to support other uses of the pesticide on a food are being provided;
    - (II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;
    - (III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a–1 of this title; and
    - (IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.
- (vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.
- (viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.
  - (II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).
- (III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

# (C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

# (D) Exemption

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No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

- (i) submit or cite data pertaining to such purchased product; or
- (ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

# (E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

- (i) the incremental risk presented by the minor use of the pesticide; and
- (ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

# (3) Application

# (A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

#### (B) Identical or substantially similar

- (i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—
  - (I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currentlyregistered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or
  - (II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.
  - (ii) In expediting the review of an application for an action described in clause (i), the Administrator shall
  - (I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;
  - (II) not later than the applicable decision review time established pursuant to section 136w–8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and
  - (III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

#### (C) Minor use registration

- (i) The Administrator shall, as expeditiously as possible, review and act on any complete application—
- (I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or
  - (II) for a registration or a registration amendment that proposes significant minor uses.

# (ii) For the purposes of clause (i)—

- (I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and
- (II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

# (D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

#### (4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

#### (5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)-

- (A) its composition is such as to warrant the proposed claims for it:
- (B) its labeling and other material required to be submitted comply with the requirements of this
  - (C) it will perform its intended function without unreasonable adverse effects on the environment; and
- (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

#### (6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

#### (7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)—

- (A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.
- (B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice

stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

# (8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

#### (9) Labeling

#### (A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

#### (B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

# (C) Notification and disapproval

# (i) Notification

A registration may be modified under subparagraph (A) if—

- (I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and
  - (II) the Administrator does not disapprove of the modification under clause (ii).

#### (ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

#### (iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

#### (iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

#### (v) Final action

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A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

#### (D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that—

- (i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and
- (ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

#### (10) Expedited registration of pesticides

- (A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.
- (B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:
  - (i) Reduce the risks of pesticides to human health.
  - (ii) Reduce the risks of pesticides to nontarget organisms.
  - (iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.
  - (iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.
- (C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

# (11) Interagency working group

#### (A) Definition of covered agency

In this paragraph, the term "covered agency" means any of the following:

- (i) The Department of Agriculture.
- (ii) The Department of Commerce.
- (iii) The Department of the Interior.
- (iv) The Council on Environmental Quality.
- (v) The Environmental Protection Agency.

#### (B) Establishment

The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

# (C) Duties

The interagency working group established under subparagraph (B) shall—

- (i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including-
  - (I) requirements under this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et
  - (II) Federal case law regarding the intersection of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and
    - (III) Federal regulations relating to the pesticide consultation process;
  - (ii) provide advice regarding methods of—
  - (I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

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- (II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;
- (iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);
- (iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;
- (v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including—
  - (I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;
  - (II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation:
  - (III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and
  - (IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and
- (vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

#### (D) Reports

## (i) Progress reports

#### (I) In general

Not later than 18 months after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group in developing the recommendations under subparagraph (B).

#### (II) Requirements

The report under this clause shall—

- (aa) reflect the perspectives of each covered agency; and
- (bb) identify areas of new consensus and continuing topics of disagreement and debate.

#### (ii) Results

#### (I) In general

Not later than 1 year after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

- (aa) the recommendations developed under subparagraph (B); and
- (bb) plans for implementation of those recommendations.

#### (II) Requirements

The report under this clause shall—

- (aa) reflect the perspectives of each covered agency; and
- (bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

#### (iii) Implementation

Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

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- (I) the implementation of the recommendations referred to in that clause;
- (II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and
- (III) any additional recommendations for improvements to the process described in subparagraph (B).

# (iv) Other reports

Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

- (I) the implementation of the recommendations referred to in that clause;
- (II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and
- (III) any additional recommendations for improvements to the process described in subparagraph (B).

# (E) Consultation with private sector

In carrying out the duties under this paragraph, the working group shall, as appropriate—

- (i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and
- (ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

# (F) Chapter 10 of title 5

Chapter 10 of title 5 shall not apply to the working group established under this paragraph.

# (G) Savings clause

Nothing in this paragraph supersedes any provision of—

- (i) this subchapter; or
- (ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

# (d) Classification of pesticides

# (1) Classification for general use, restricted use, or both

- (A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.
- (B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.
- (C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:
  - (i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.
  - (ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable

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adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

# (2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

# (3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

#### (e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

# (f) Miscellaneous

# (1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

#### (2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

#### (3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

#### (4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of—

- (A) 1 or more nitrogen stabilizers registered under this subchapter; and
- (B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136o(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

#### (5) Bilingual labeling

#### (A) Requirement

#### (i) In general

Subject to clause (ii), not later than the applicable deadline described in subparagraph (B), each registered pesticide product released for shipment shall include—

(I) the translation of the parts of the labeling contained in the Spanish Translation Guide described in subparagraph (G) on the product container; or

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(II) a link to such translation via scannable technology or other electronic methods readily accessible on the product label.

#### (ii) Exceptions

Notwithstanding clause (i)—

- (I) an antimicrobial pesticide product may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label; or
- (II) a non-agricultural pesticide product that is not classified by the Administrator as restricted use under subsection (d)(1)(A) may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label.

#### (B) Deadlines for bilingual labeling

#### (i) Pesticide products classified as restricted use

In the case of pesticide products classified by the Administrator as restricted use under subsection (d) (1)(A), the deadline specified in this subparagraph is the date that is 3 years following December 29, 2022.

#### (ii) Pesticide products not classified as restricted use

In the case of pesticide products not classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph shall be as follows:

# (I) Agricultural

# (aa) Acute Toxicity Category I

For agricultural pesticides classified as Acute Toxicity Category I, the date that is 3 years after December 29, 2022.

# (bb) Acute Toxicity Category II

For agricultural pesticides classified as Acute Toxicity Category II, the date that is 5 years after December 29, 2022.

# (II) Antimicrobial and non-agricultural

#### (aa) Acute Toxicity Category I

For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category I, the date that is 4 years after December 29, 2022.

#### (bb) Acute Toxicity Category II

For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category II, the date that is 6 years after December 29, 2022.

#### (III) Other pesticide products

With respect to pesticide products not described in subclause (I) or (II), the date that is 8 years after December 29, 2022.

#### (C) Implementation

#### (i) Non-notification

#### (I) In general

In carrying out this paragraph, the Administrator shall allow translations of the parts of the label of a pesticide contained in the Spanish Translation Guide described in subparagraph (G) and scannable technology or other electronic methods to be added using non-notification procedures.

#### (II) Non-notification procedure defined

In this clause, the term "non-notification procedure" refers to a procedure under which a change may be made to a pesticide label without notifying the Administrator.

#### (ii) Cooperation and consultation

In carrying out this paragraph, the Administrator shall cooperate and consult with State lead agencies for pesticide regulation for the purpose of implementing bilingual labeling as provided in this paragraph as expeditiously as possible.

#### (iii) End use labeling

The labeling requirements of this paragraph shall apply to end use product labels.

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#### (iv) Incorporation timeframe

After initial translation deadlines provided in subparagraph (B), updates to the Spanish Translation Guide described in subparagraph (G) shall be incorporated into labeling on the earlier of—

- (I) in the case of agricultural use pesticide labels, as determined by the Administrator—
- (aa) 1 year after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or
- (bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); and
- (II) in the case of antimicrobial and non-agricultural use pesticide labels, as determined by the Administrator—
  - (aa) 2 years after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or
  - (bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G).

#### (v) Notification of updates to the Spanish Translation Guide for Pesticide Labeling

Not later than 10 days after updating the Spanish Translation Guide described in subparagraph (G), the Administrator shall notify registrants of the update to such guide.

# (D) Accessibility of bilingual labeling for farm workers

Not later than 180 days after December 29, 2022, to the maximum extent practicable, the Administrator shall seek stakeholder input on ways to make bilingual labeling required under this paragraph accessible to farm workers.

#### (E) Plan

Not later than 3 years after December 29, 2022, the Administrator shall implement a plan to ensure that farm workers have access to the bilingual labeling required under this paragraph.

# (F) Reporting

Not later than 2 years after December 29, 2022, the Administrator shall develop and implement, and make publicly available, a plan for tracking the adoption of the bilingual labeling required under this paragraph.

#### (G) Spanish Translation Guide described

The Spanish Translation Guide described in this subparagraph is the Spanish Translation Guide for Pesticide Labeling issued in October 2019, as in effect on December 29, 2022, and any successor guides or amendments to such guide.

#### (g) Registration review

# (1) General rule

#### (A) Periodic review

#### (i) In general

The registrations of pesticides are to be periodically reviewed.

#### (ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

#### (iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of-

- (I) October 1, 2022; or
- (II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

#### (iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

#### (v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

#### (B) Docketing

#### (i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

- (I) the date that is 45 days after the meeting; or
- (II) the date of issuance of the registration review decision.

#### (ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 136h of this title.

# (C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

# (2) Data

# (A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

# (B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

# (h) Registration requirements for antimicrobial pesticides

# (1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including-

- (A) new antimicrobial active ingredients:
- (B) new antimicrobial end-use products;
- (C) substantially similar or identical antimicrobial pesticides; and
- (D) amendments to antimicrobial pesticide registrations.

#### (2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than-

- (A) 540 days for a new antimicrobial active ingredient pesticide registration;
- (B) 270 days for a new antimicrobial use of a registered active ingredient;
- (C) 120 days for any other new antimicrobial product;
- (D) 90 days for a substantially similar or identical antimicrobial product;
- (E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and
- (F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

#### (3) Implementation

#### (A) Proposed rulemaking

# (i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

# (ii) Requirements

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Proposed regulations issued under clause (i) shall—

- (I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;
  - (II) differentiate the types of review undertaken for antimicrobial pesticides;
- (III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;
- (IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and
  - (V) implement effective and reliable deadlines for process management.

# (iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

# (B) Final regulations

#### (i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

#### (ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

# (iii) Requirements

In issuing final regulations, the Administrator shall—

- (I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;
- (II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;
  - (III) use all appropriate and cost-effective review mechanisms, including—
    - (aa) expanded use of notification and non-notification procedures;
    - (bb) revised procedures for application review; and
  - (cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and
  - (IV) clarify criteria for determination of the completeness of an application.

#### (C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

# (D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

- (i) 2 years for a new antimicrobial active ingredient pesticide registration;
- (ii) 1 year for a new antimicrobial use of a registered active ingredient;
- (iii) 180 days for any other new antimicrobial product;
- (iv) 90 days for a substantially similar or identical antimicrobial product;
- (v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and
- (vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

#### (E) Wood preservatives

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An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

#### (F) Notification

# (i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

# (ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5.

#### (iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after August 3, 1996.

# (iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within—

- (I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or
- (II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

#### (4) Annual report

#### (A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

#### (B) Requirements

A report submitted under subparagraph (A) shall include a description of—

- (i) measures taken to reduce the backlog of pending registration applications;
- (ii) progress toward achieving reforms under this subsection; and
- (iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

(June 25, 1947, ch. 125, §3, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 979; amended Pub. L. 94– 140, §12, Nov. 28, 1975, 89 Stat. 755; Pub. L. 95–396, §§2(a), 3–8, Sept. 30, 1978, 92 Stat. 820, 824-827; Pub. L. 100-532, title I, §§102(b), 103, title VI, §601(b)(1), title VIII, §801(b), Oct. 25, 1988, 102 Stat. 2667, 2677, 2680; Pub. L. 101–624, title XIV, §1492, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(3), (b)(1), (2), (c), Dec. 13, 1991, 105 Stat. 1894–1896; Pub. L. 104–170, title I, §§105(b), 106(b), title II, §§210(b), (c)(1), (d), (e), (f)(2), 222–224, 231, 250, Aug. 3, 1996, 110 Stat. 1491, 1494-1497, 1499, 1503, 1504, 1508, 1510; Pub. L. 108-199, div. G, title V, §501(b), Jan. 23, 2004, 118 Stat. 419; Pub. L. 110-94, §§2, 3, Oct. 9, 2007, 121 Stat. 1000; Pub. L. 115-334, title X, §10115, Dec. 20, 2018, 132 Stat. 4914; Pub. L. 117-286, §4(a)(21), Dec. 27, 2022, 136 Stat. 4307; Pub. L. 117–328, div. HH, title VI, §702, Dec. 29, 2022, 136 Stat. 5996.)

#### **EDITORIAL NOTES**

# REFERENCES IN TEXT

The Endangered Species Act of 1973, referred to in subsec. (c)(11)(C)(i)(I), (II), (v), (vi), (G)(ii), is Pub. L. 93-205, Dec. 28, 1973, 87 Stat. 884, which is classified generally to chapter 35 (§1531 et seq.) of

Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

# **PRIOR PROVISIONS**

A prior section 3 of act June 25, 1947, was classified to section 135a of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

# **AMENDMENTS**

2022—Subsec. (c)(11)(F). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "Federal Advisory Committee Act" in heading and "Chapter 10 of title 5" for "The Federal Advisory Committee Act (5 U.S.C. App.)" in text.

Subsec. (f)(5). Pub. L. 117-328 added par. (5).

**2018**—Subsec. (c)(11). Pub. L. 115–334 added par. (11).

2007—Subsec. (c)(3)(B)(ii)(I). Pub. L. 110–94, §2(1), substituted "review the application in accordance with section 136w-8(f)(4)(B) of this title and," for "within 45 days after receiving the application, notify the registrant whether or not the application is complete and,".

Subsec. (c)(3)(B)(ii)(II). Pub. L. 110–94, §2(2), substituted "not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than" for "within".

Subsec. (g)(1)(A). Pub. L. 110–94, §3(1), designated first sentence as cl. (i) and inserted heading, designated second sentence as cl. (ii), inserted heading, and substituted "In accordance with this subparagraph, the Administrator" for "The Administrator", added cls. (iii) and (iv), designated fourth sentence as cl. (v) and inserted heading, and struck out third sentence which read as follows: "The goal of these regulations shall be a review of a pesticide's registration every 15 years."

Subsec. (g)(1)(B), (C). Pub. L. 110–94, §3(2), (3), added subpar. (B) and redesignated former subpar. (B) as (C).

2004—Subsec. (h)(2)(F). Pub. L. 108–199, §501(b)(1), substituted "120 days" for "90 to 180 days".

Subsec. (h)(3)(D)(vi). Pub. L. 108–199, §501(b)(2)(A), substituted "120 days" for "240 days".

Subsec. (h)(3)(F)(iv). Pub. L. 108–199, §501(b)(2)(B), added cl. (iv).

1996—Subsec. (c)(1)(F)(ii) to (vi). Pub. L. 104–170, §210(b), added cls. (ii), (v), and (vi), redesignated former cls. (ii) and (iii) as (iii) and (iv), respectively, and in cl. (iv) substituted "(i), (ii), and (iii)" for "(i) and (ii)".

Subsec. (c)(1)(G). Pub. L. 104–170, §250(1), added subpar. (G).

Subsec. (c)(2)(A). Pub. L. 104–170, §§210(d)(1), 231, inserted heading, inserted "the public health and agricultural need for such minor use," after "pattern of use,", and substituted "potential beneficial or adverse effects on man and the environment" for "potential exposure of man and the environment to the pesticide".

Subsec. (c)(2)(B). Pub. L. 104–170, §210(d)(2), inserted heading.

Subsec. (c)(2)(B)(vi). Pub. L. 104–170, §210(c)(1), added cl. (vi).

Subsec. (c)(2)(B)(vii). Pub. L. 104-170, §210(f)(2), added cl. (vii).

Subsec. (c)(2)(B)(viii). Pub. L. 104–170, §222, added cl. (viii).

Subsec. (c)(2)(C). Pub. L. 104–170, §210(d)(3), inserted heading.

Subsec. (c)(2)(E). Pub. L. 104-170, §210(d)(4), added subpar. (E).

Subsec. (c)(3)(A), (B). Pub. L. 104–170, §210(e)(1), (2), inserted headings.

Subsec. (c)(3)(C), (D). Pub. L. 104–170, §210(e)(3), added subpars. (C) and (D).

Subsec. (c)(9). Pub. L. 104-170, §223, added par. (9).

Subsec. (c)(10). Pub. L. 104-170, §250(2), added par. (10).

Subsec. (f)(4). Pub. L. 104–170, §105(b), added par. (4).

Subsec. (g). Pub. L. 104–170, §106(b), added subsec. (g).

Subsec. (h). Pub. L. 104-170, §224, added subsec. (h).

1991—Subsec. (c)(1)(D). Pub. L. 102–237, §1006(a)(3)(B), (C), added subpar. (D) and redesignated former subpar. (D) as (F).

Subsec. (c)(1)(E). Pub. L. 102-237, §1006(a)(3)(A), (C), added subpar. (E) and struck out former subpar. (E) which read as follows: "the complete formula of the pesticide; and".

Subsec. (c)(1)(F). Pub. L. 102–237, §1006(a)(3)(A), (B), (D), redesignated former subpar. (D) as (F), in cl. (i) substituted "With" for "with" and a period for semicolon at end, in cl. (ii) substituted "Except" for "except" and a period for semicolon at end, in cl. (iii) substituted "After" for "after" and

a period for semicolon at end, and struck out former subpar. (F) which read as follows: "a request that the pesticide be classified for general use, for restricted use, or for both."

Subsec. (c)(2)(A). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "requires", "shall permit", "shall make", and "deems", and substituted "the Administrator's" for "his".

Subsec. (c)(2)(D). Pub. L. 102–237, §1006(c), clarified amendment made by Pub. L. 100–532, §102(b)(2)(A). See 1988 Amendment note below.

Subsec. (c)(3)(A). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c)(5). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (c)(6). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "shall notify" in two places and "the Administrator's" for "his" in four places.

Subsec. (d)(1). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall classify it for both" in subpar. (A), before "will classify" in subpar. (B), and before "shall classify" in subpar. (C).

Subsec. (d)(2). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall notify".

**1990**—Subsec. (c)(2)(A). Pub. L. 101–624 inserted after third sentence "The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use."

1988—Subsec. (a). Pub. L. 100–532, §601(b)(1), substituted "Requirement of registration" for "Requirement" in heading and amended text generally. Prior to amendment, text read as follows: "Except as otherwise provided by this subchapter, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator."

Subsec. (c)(1)(D). Pub. L. 100–532, §801(b)(1)–(4), in introductory provisions, substituted "paragraph (2)(D)" for "subsection (c)(2)(D) of this section", in cl. (i), substituted "(i) with" for "(i) With" and ", except that" for ": *Provided*, That", in cl. (ii), substituted "clause (i)" for "subparagraph (D)(i) of this paragraph", and in cl. (iii), substituted "clauses (i) and (ii)" for "subparagraphs (D)(i) and (D)(ii) of this paragraph".

Subsec. (c)(2)(A). Pub. L. 100–532, §801(b)(5)(A), (B), substituted "(2) Data in support of registration.—

"(A) The"

for "(2)(A) Data in support of registration.—The", and directed that subpar. (A) be aligned with left margin of subsec. (d)(1)(A) of this section.

Subsec. (c)(2)(B). Pub. L. 100–532, §§102(b)(1), 801(b)(5)(C)–(F), substituted "(B)(i) If" for "(B) Additional data to support existing registration.—(i) If", directed that cls. (ii) to (v) be aligned with left margin of subpar. (A), in cls. (ii) and (iii), inserted "The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.", in cl. (iv), substituted "title. The only" for "title: *Provided*, that the only", and in cl. (v), substituted "paragraph (1)(D)" for "subsection (c)(1)(D) of this section".

Subsec. (c)(2)(C). Pub. L. 100–532, §801(b)(5)(G), (H), struck out "Simplified procedures" after " (C)" and directed that text be aligned with left margin of subpar. (A).

Subsec. (c)(2)(D). Pub. L. 100–532, §102(b)(2)(A), and Pub. L. 102–237, §1006(c), substituted "the pesticide that is the subject of the application" for "an end-use product".

Subsec. (c)(2)(D)(i). Pub. L. 100–532, §102(b)(2)(B), struck out "the safety of" after "data pertaining to".

Subsec. (c)(3). Pub. L. 100–532, §103, substituted "(A) The Administrator" for "The Administrator" and added subpar. (B).

Subsec. (c)(7). Pub. L. 100–532, §801(b)(6), in introductory provisions, substituted "paragraph (5)" for "subsection (c)(5) of this section", in subpars. (A) and (B), substituted "paragraph (5). If" for "subsection (c)(5) of this section: *Provided*, That, if", and in subpar. (C), substituted "prescribe. A" for "prescribe: *Provided*, that a".

Subsec. (d)(1)(A). Pub. L. 100–532, §801(b)(7), substituted "restricted use. If" for "restricted use, provided that if" and "restricted uses. The Administrator" for "restricted uses: *Provided, however*, That the Administrator".

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Subsec. (f)(2). Pub. L. 100–532, §801(b)(8), substituted "this subchapter. As" for "this subchapter: *Provided*, That as".

Subsec. (g). Pub. L. 100–532, §801(b)(9), struck out subsec. (g) which read as follows: "The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided*, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process."

**1978**—Subsec. (c)(1)(D). Pub. L. 95–396, §2(a)(1), added subpar. (D), and struck out provisions which required the applicant for registration of a pesticide to file with the Administrator a statement containing "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted on or after January 1, 1970. in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 136h(b) of this title. This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972. If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If either party does not agree with said determination, he may, within thirty days, take an appeal to the Federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. Registration shall not be delayed pending the determination of reasonable compensation between the applicants, by the Administrator or by the court.".

Subsec. (c)(2). Pub. L. 95–396, §§2(a)(2)(A)–(D), 3, 4, designated existing provisions as subpar. (A), inserted in second sentence "under subparagraph (B) of this paragraph" after "kind of information", struck out from introductory text of third sentence "subsection (c)(1)(D) of this section and" after "Except as provided by", and inserted provisions relating to establishment of standards for data requirements for registration of pesticides with respect to minor uses and consideration of economic factors in development of standards and cost of development, and added subpars. (B) to (D).

Subsec. (c)(5). Pub. L. 95–396, §5, provided for waiver of data requirements pertaining to efficacy. Subsec. (c)(7), (8). Pub. L. 95–396, §6, added pars. (7) and (8).

Subsec. (d)(1)(A). Pub. L. 95–396, §7(1), authorized classification of pesticide uses by regulation on the initial classification and registered pesticides prior to reregistration.

Subsec. (d)(2). Pub. L. 95-396, §7(2), substituted "forty-five days" for "30 days".

Subsec. (d)(3). Pub. L. 95-396, §7(3), added par. (3).

Subsec. (g). Pub. L. 95-396, §8, added subsec. (g).

1975—Subsec. (c)(1)(D). Pub. L. 94–140 inserted exception relating to test data submitted on or after January 1, 1970, in support of application, inserted provision that compensation for producing test data shall apply to all applications submitted on or after October 21, 1972, and provision relating to delay of registration pending determination of reasonable compensation, struck out requirement that payment determined by court not be less than amount determined by Administrator, and substituted "If either party" for "If the owner of the test data".

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 2007 AMENDMENT**

Pub. L. 110–94, §6, Oct. 9, 2007, 121 Stat. 1007, provided that: "This Act [see Short Title of 2007 Amendment note set out under section 136 of this title] and the amendments made by this Act take effect on October 1, 2007."

#### **EFFECTIVE DATE OF 2004 AMENDMENT**

Pub. L. 108–199, div. G, title V, §501(h), Jan. 23, 2004, 118 Stat. 434, provided that: "Except as otherwise provided in this section [enacting section 136w–8 of this title, amending this section and sections 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under sections 136

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of this title and section 346a of Title 21, Food and Drugs] and the amendments made by this section. this section and the amendments made by this section take effect on the date that is 60 days after the date of enactment of this Act [Jan. 23, 2004]."

#### **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

#### **EFFECTIVE DATE OF 1978 AMENDMENT**

Pub. L. 95–396, §2(b), Sept. 30, 1978, 92 Stat. 824, provided that: "The amendment to section 3(c) (1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act [subsec. (c)(1)(D) of this section] made by [subsec. (a)(1) of] this section shall apply with respect to all applications for registration approved after the date of enactment of this Act [Sept. 30, 1978]."

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

#### REGISTRATION REVIEW DEADLINE EXTENSION

Pub. L. 117-328, div. HH, title VI, §711, Dec. 29, 2022, 136 Stat. 6083, provided that:

- "(a) IN GENERAL.—Notwithstanding section 3(g)(1)(A)(iii)(I) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(g)(1)(A)(iii)(I)), the Administrator of the Environmental Protection Agency (referred to in this section as the 'Administrator') shall complete the initial registration review of each pesticide or pesticide case covered by that section not later than October 1, 2026.
  - '(b) Interim Registration Review Decision Requirements.—
  - "(1) DEFINITION OF COVERED INTERIM REGISTRATION REVIEW DECISION.—In this subsection, the term 'covered interim registration review decision' means an interim registration review decision—
    - "(A) that is associated with an initial registration review described in subsection (a);
    - "(B) that is noticed in the Federal Register during the period beginning on the date of enactment of this Act [Dec. 29, 2022] and ending on October 1, 2026; and
    - "(C) for which the Administrator has not, as of the date on which the decision is noticed in the Federal Register, made effects determinations or completed any necessary consultation under section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)).
  - "(2) Requirements.—Any covered interim registration review decision shall include, where applicable, measures to reduce the effects of the applicable pesticide on—
    - "(A) species listed under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seg.); or
    - "(B) any designated critical habitat.
  - "(3) Consultation.—In developing measures described in paragraph (2), the Administrator shall take into account the input received from the Secretary of Agriculture and other members of the interagency working group established under section 3(c)(11) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(11))."

#### **BIOLOGICAL PESTICIDE HANDLING STUDY**

Pub. L. 101-624, title XIV, §1498, Nov. 28, 1990, 104 Stat. 3631, provided that the National Academy of Sciences would conduct a study of the biological control programs and registration procedures utilized by the Food and Drug Administration, the Animal and Plant Health Inspection Service, and the Environmental Protection Agency, and within 1 year after completion of the study, develop and implement a common process for reviewing and approving biological control applications submitted to such agencies and offices based on the study conducted, the recommendation of the National Academy of Sciences, and other public comment.

## **EDUCATION, STUDY, AND REPORT**

Pub. L. 100-478, title I, §1010, Oct. 7, 1988, 102 Stat. 2313, provided that:

"(a) Education.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior, promptly upon enactment of this Act IOct. 7, 1988], shall conduct a program to inform and educate fully persons engaged in agricultural food and fiber commodity production of any proposed pesticide labeling program or requirements

that may be imposed by the Administrator in compliance with the Endangered Species Act [of 1973] (16 U.S.C. 1531 et seq.). The Administrator also shall provide the public with notice of, and opportunity for comment on, the elements of any such program and requirements based on compliance with the Endangered Species Act [of 1973], including (but not limited to) an identification of any pesticides affected by the program; an explanation of the restriction or prohibition on the user or applicator of any such pesticide; an identification of those geographic areas affected by any pesticide restriction or prohibition; an identification of the effects of any restricted or prohibited pesticide on endangered or threatened species; and an identification of the endangered or threatened species along with a general description of the geographic areas in which such species are located wherein the application of a pesticide will be restricted, prohibited, or its use otherwise limited, unless the Secretary of the Interior determines that the disclosure of such information may create a substantial risk of harm to such species or its habitat.

- "(b) Stuby.—The Administrator of the Environmental Protection Agency, jointly with the Secretary of Agriculture and the Secretary of the Interior, shall conduct a study to identify reasonable and prudent means available to the Administrator to implement the endangered species pesticides labeling program which would comply with the Endangered Species Act of 1973, as amended, and which would allow persons to continue production of agricultural food and fiber commodities. Such study shall include investigation by the Administrator of the best available methods to develop maps and the best available alternatives to mapping as means of identifying those circumstances in which use of pesticides may be restricted; identification of alternatives to prohibitions on pesticide use, including, but not limited to, alternative pesticides and application methods and other agricultural practices which can be used in lieu of any pesticides whose use may be restricted by the labeling program; examination of methods to improve coordination among the Environmental Protection Agency, Department of Agriculture, and Department of the Interior in administration of the labeling program; and analysis of the means of implementing the endangered species pesticides labeling program or alternatives to such a program, if any, to promote the conservation of endangered or threatened species and to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.
- "(c) Report.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior shall submit a report within one year of the date of enactment of this Act [Oct. 7, 1988], presenting the results of the study conducted pursuant to subsection (b) of this section to the Committee on Merchant Marine and Fisheries and the Committee on Agriculture of the United States House of Representatives, and the Committee on Environment and Public Works and the Committee on Agriculture, Nutrition, and Forestry of the United States Senate."

## §136a-1. Reregistration of registered pesticides

#### (a) General rule

The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

- (1) there are no outstanding data requirements; and
- (2) the requirements of section 136a(c)(5) of this title have been satisfied.

#### (b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

- (1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.
- (2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.
- (3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

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- (4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.
- (5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

#### (c) Phase one

#### (1) Priority for reregistration

For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of this section) that-

- (A) are in use on or in food or feed and may result in postharvest residues;
- (B) may result in residues of potential toxicological concern in potable ground water, edible fish, or
- (C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or
- (D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

#### (2) Reregistration lists

For purposes of reregistration under this section, the Administrator shall by order—

- (A) not later than 70 days after the effective date of this section, list pesticide active ingredients for which registration standards have been issued before such effective date;
- (B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);
- (C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and
- (D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

#### (3) Judicial review

The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

#### (4) Notice to registrants

On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (d) whether the registrants intend to seek or not to seek reregistration of such pesticides.

#### (d) Phase two

#### (1) In general

The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

#### (2) Notice of intent to seek or not to seek reregistration

- (A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.
- (B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

#### (3) Missing or inadequate data

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 136a of this title, an identification of-

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- (i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;
- (ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and
  - (iii) data identified under clause (i) that have not been submitted to the Administrator; and

#### (B) either—

- (i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or
- (ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause
- (i) to replace or submit the data and an offer to submit to arbitration as described by section 136a(c)(2)
- (B) of this title with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (e)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

#### (4) Time periods

- (A) A submission under paragraph (2) or (3) shall be made—
- (i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;
- (ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and
- (iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

- (B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—
  - (i) the data to support other uses of the pesticide on a food are being provided;
  - (ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;
  - (iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and
  - (iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall

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instead be due in accordance with the date then established by the Administrator for submission of the data.

#### (5) Cancellation and removal

- (A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

  (B)(i) If—
  - (I) no registrant of a pesticide containing an active ingredient listed under subsection (c)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;
    - (II) no such registrant complies with paragraph (3)(A); or
  - (III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (c)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

- (ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—
  - (I) during the comment period a person acquires the rights of the registrant in that registration;
  - (II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and
  - (III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by this section has been paid.

#### (6) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

#### (e) Phase three

#### (1) Information about studies

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Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

- (A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;
- (B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 136a of this title and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;
- (C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;
- (D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 136a of this title, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;
- (E) an identification of data that are required to be submitted to the Administrator under section 136d(a) (2) of this title, indicating an adverse effect of the pesticide;
- (F) an identification of any other information available that in the view of the registrant supports the registration;
- (G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);
  - (H) either-
    - (i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or
  - (ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing; and
- (I) evidence of compliance with section 136a(c)(1)(D)(ii) of this title and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this subchapter and shall be subject to the penalties prescribed by section 136l of this title.

#### (2) Time periods

- (A) The information required by paragraph (1) shall be submitted to the Administrator—
- (i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;
- (ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient; and
- (iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.
- (B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—
  - (i) the data to support other uses of the pesticide on a food are being provided;
  - (ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

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- (iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and
- (iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

#### (3) Cancellation

- (A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination. the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.
- (B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.
- (ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.
- (iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.
- (II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.
- (III) If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title, except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

#### (4) Guidelines

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  - (A) Not later than 1 year after the effective date of this section, the Administrator, by order, shall issue guidelines to be followed by registrants in—
    - (i) summarizing studies;
    - (ii) reformatting studies;
    - (iii) identifying adverse information; and
    - (iv) identifying studies that have been submitted previously that may not meet the requirements of section 136a of this title or regulations issued under such section,

under paragraph (1).

(B) Guidelines issued under subparagraph (A) shall not be subject to judicial review.

#### (5) Monitoring

The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under paragraph (1).

#### (f) Phase four

#### (1) Independent review and identification of outstanding data requirements

- (A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (e)(1).
- (B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 136a(c)(2)(B) of this title for the submission of the additional data that are required to meet such requirements.

#### (2) Time periods

- (A) The Administrator shall take the action required by paragraph (1)—
- (i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 18 months after the date of the listing of such active ingredient;
- (ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and
- (iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 33 months after the date of the listing of such active ingredient.
- (B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—
  - (i) the data to support other uses of the pesticide on a food are being provided;
  - (ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;
  - (iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and
  - (iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this

subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

#### (3) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

#### (g) Phase five

#### (1) Data review

The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) and of all other available data found by the Administrator to be relevant.

#### (2) Reregistration and other actions

- (A) IN GENERAL.—The Administrator shall make a determination as to eligibility for reregistration—
- (i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(g)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C)); and
- (ii) for all other active ingredients subject to reregistration under this section, not later than October 3, 2008.

#### (B) PRODUCT-SPECIFIC DATA.—

(i) IN GENERAL.—Before reregistering a pesticide, the Administrator shall obtain any needed productspecific data regarding the pesticide by use of section 136a(c)(2)(B) of this title and shall review such data within 90 days after its submission.

#### (ii) TIMING.—

(I) IN GENERAL.—Subject to subclause (II), the Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

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- (II) EXTRAORDINARY CIRCUMSTANCES.—In the case of extraordinary circumstances, the Administrator may provide such a longer period, of not more than 2 additional years, for submission of data to the Administrator under this subparagraph.
- (C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 136a(c)(5) of this title. If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).
  - (D) DETERMINATION TO NOT REREGISTER.—
  - (i) IN GENERAL.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.
  - (ii) TIMING FOR REGULATORY ACTION.—Regulatory action under clause (i) shall be completed as expeditiously as possible.
- (E) As soon as the Administrator has sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall-
  - (i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a);
  - (ii) determine whether such tolerance or exemption meets the requirements of that Act [21 U.S.C. 301 et seq.];
    - (iii) determine whether additional tolerances or exemptions should be issued:
  - (iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph; and
  - (v) commence promptly such proceedings under this subchapter and section 408 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 346a] as are warranted by such determinations.

#### (h) Compensation of data submitter

If data that are submitted by a registrant under subsection (d), (e), (f), or (g) are used to support the application of another person under section 136a of this title, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section  $136a(c)(1)(D)^{\frac{1}{2}}$  of this title. In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

#### (i) Fees

#### (1) Maintenance fee

- (A) In GENERAL.—Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by January 15 of each year for each registration, except that no fee shall be charged for more than 200 registrations held by any registrant.
- (B) In the case of a pesticide that is registered for a minor agricultural use, the Administrator may reduce or waive the payment of the fee imposed under this paragraph if the Administrator determines that the fee would significantly reduce the availability of the pesticide for the use.
- (C) TOTAL AMOUNT OF FEES.—The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an average amount of \$31,000,000 for each of fiscal years 2019 through 2022, and \$42,000,000 for each of fiscal years 2023 through 2027.
- (D) MAXIMUM AMOUNT OF FEES FOR REGISTRANTS.—The maximum annual fee payable under this paragraph by-
  - (i) a registrant holding not more than 50 pesticide registrations shall be \$129,400 for each of fiscal years 2019 through 2022, and \$172,000 for each of fiscal years 2023 through 2027; and
  - (ii) a registrant holding over 50 registrations shall be \$207,000 for each of fiscal years 2019 through 2022, and \$277,200 for each of fiscal years 2023 through 2027.

#### (E) MAXIMUM AMOUNT OF FEES FOR SMALL BUSINESSES.—

(i) IN GENERAL.—For a small business, the maximum annual fee payable under this paragraph by—

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- (I) a registrant holding not more than 50 pesticide registrations shall be \$79,100 for each of fiscal years 2019 through 2022, and \$105,000 for each of fiscal years 2023 through 2027; and
- (II) a registrant holding over 50 pesticide registrations shall be \$136,800 for each of fiscal years 2019 through 2022, and \$184,800 for each of fiscal years 2023 through 2027.

#### (ii) DEFINITION OF SMALL BUSINESS.—

- (I) IN GENERAL.—In clause (i), the term "small business" means a corporation, partnership, or unincorporated business that—
  - (aa) has 500 or fewer employees; and
  - (bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed \$60,000,000.

#### (II) AFFILIATES.—

- (aa) IN GENERAL.—In the case of a business entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including parents and subsidiaries, if applicable.
- (bb) AFFILIATED PERSONS.—For the purpose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third person controls or has the power to control both persons.
- (cc) INDICIA OF CONTROL.—For the purpose of item (aa), indicia of control include interlocking management or ownership, identity of interests among family members, shared facilities and equipment, and common use of employees.

#### (F) FEE REDUCTION FOR CERTAIN SMALL BUSINESSES.—

- (i) Definition.—In this subparagraph, the term "qualified small business entity" means a corporation, partnership, or unincorporated business that—
  - (I) has 500 or fewer employees;
  - (II) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from all sources that did not exceed \$10,000,000; and
    - (III) holds not more than 5 pesticide registrations under this paragraph.
- (ii) WAIVER.—Except as provided in clause (iii), the Administrator shall waive 25 percent of the fee under this paragraph applicable to the first registration of any qualified small business entity under this paragraph.
- (iii) LIMITATION.—The Administrator shall not grant a waiver under clause (ii) to a qualified small business entity if the Administrator determines that the entity has been formed or manipulated primarily for the purpose of qualifying for the waiver.

#### (G) FARM WORKER TRAINING AND EDUCATION GRANTS.—

- (i) SET-ASIDE.—In addition to amounts otherwise available, for fiscal years 2023 through 2027, the Administrator shall use not more than \$7,500,000 of the amounts collected under this paragraph to provide grants to organizations described in clause (ii) for purposes of facilitating—
  - (I) training of farm workers;
  - (II) education of farm workers with respect to—
    - (aa) rights of farm workers relating to pesticide safety; and
  - (bb) the worker protection standard under part 170 of title 40, Code of Federal Regulations (or successor regulations);
  - (III) the development of new informational materials;
  - (IV) the development of training modules; and
  - (V) the development of innovative methods of delivery of such informational materials and training modules.
- (ii) ELIGIBILITY.—To be eligible to receive a grant under this subparagraph, an organization shall have demonstrated experience in—
  - (I) providing training and education services for farm workers or handlers of pesticides; or
  - (II) developing informational materials for farm workers or handlers of pesticides.

#### (iii) COMMUNITY-BASED ORGANIZATIONS.—

(I) COMMUNITY-BASED NON-PROFIT FARM WORKER ORGANIZATION GRANTS.—The Administrator shall use funds available under clause (i) to provide grants to community-based non-profit farm worker

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- (II) APPLICATION OF FUNDS.—The Administrator shall apply the unspent balance of funds available (up to \$1,800,000) under clause (i) in fiscal years 2025 through 2027 to carry out subclause (I).
- (iv) INTERIM FUNDING.—In addition to amounts otherwise available, the Administrator may use not more than \$1,200,000 in fiscal years 2023 and 2024 to fund existing cooperative agreements that were authorized under section 136w–8(c)(3)(B) of this title, as such section was in effect as of March 8, 2019.
- (v) Partnerships.—Organizations described in clause (ii) may apply for a grant under this subparagraph as a partnership with another organization, provided such organizations, at the time of application, have entered into an agreement designating—
  - (I) a member of the partnership that will enter into the assistance agreement with the Environmental Protection Agency for the purposes of accountability for the proper expenditure of Federal funds;
    - (II) performance of the assistance agreement;
    - (III) liability for claims for recovery of unallowable costs incurred under the agreement; and
    - (IV) specifying roles in performing the proposed scope of work for the assistance agreement.

#### (H) HEALTH CARE PROVIDER TRAINING.—

- (i) SET-ASIDE.—In addition to other amounts available, for the period of fiscal years 2023 through 2027, the Administrator shall use not more than \$2,500,000 of the amounts collected under this paragraph to provide grants to nonprofit organizations described in clause (ii) for purposes of facilitating—
  - (I) technical assistance and training of health care providers relating to the recognition, treatment, and management of pesticide-related injuries and illnesses;
  - (II) the development of informational materials for technical assistance and training described in subclause (I); and
  - (III) the development of outreach and delivery methods relating to the recognition, treatment, and management of pesticide-related illnesses.
- (ii) ELIGIBILITY.—To be eligible to receive a grant under this subparagraph, a nonprofit organization shall have demonstrated experience in providing technical assistance and training to health care providers who serve farm worker populations.
- (iii) PARTNERSHIPS.—Organizations described in clause (ii) may apply for a grant under this subparagraph as a partnership with another organization, provided such organizations, at the time of application, have entered into an agreement designating—
  - (I) a member of the partnership that will enter into the assistance agreement with the Environmental Protection Agency for the purposes of accountability for the proper expenditure of Federal funds;
    - (II) performance of the assistance agreement;
    - (III) liability for claims for recovery of unallowable costs incurred under the agreement; and
    - (IV) roles in performing the proposed scope of work for the assistance agreement.
- (I) Partnership grants.—In addition to funds otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts collected under this paragraph for partnership grants.
- (J) PESTICIDE SAFETY EDUCATION PROGRAM.—In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts collected under this paragraph to carry out the pesticide safety education program.
  - (K) TECHNICAL ASSISTANCE TO GRANTEES.—
  - (i) SET-ASIDE.—In addition to other amounts available, for fiscal years 2023 through 2027, the Administrator shall use not more than \$1,750,000 of the amounts collected under this paragraph to provide grants to nonprofit organizations, subject to such conditions as the Administrator establishes to prevent conflicts of interest, to provide easily accessible technical assistance to grantees receiving, and potential grantees applying for, grants under subparagraphs (G) and (H).
  - (ii) Considerations.—In evaluating requests for grants under this subparagraph, the Administrator shall consider, at a minimum, the extent to which—
    - (I) the organization applying for the grant has experience providing technical assistance to farm worker or clinician-training organizations; and
    - (II) the proposed project would make specific technical assistance available to organizations seeking information and assistance concerning—
      - (aa) the grant application process;
      - (bb) the drafting of grant applications; and
      - (cc) compliance with grant management and reporting requirements.

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- (iii) No suitable organization.—If no suitable organization requests a grant under this subparagraph, the Administrator shall provide technical assistance described in clause (i) using the amounts made available by that clause.
- (iv) STAKEHOLDER INPUT.—In formulating requests for proposals for grants under subparagraphs (G) and (H) for a fiscal year, the Administrator shall solicit and consider, in an open and transparent manner that does not provide a competitive advantage to any person or persons, input from persons who conduct farm worker education and training, or technical assistance and training of clinicians, regarding the request for proposals.
- (L) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under this paragraph if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.
- (M) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.
  - (N) The authority provided under this paragraph shall terminate on September 30, 2027.

#### (2) Other fees

Except as provided in section 136w-8 of this title, during the period beginning on December 29, 2022, and ending on September 30, 2029, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter or any other action covered under a table specified in section 136w-8(b)(3) (B) of this title, except as provided in paragraph (1).

#### (j) Exemption of certain registrants

The requirements of subsections (d), (e), (f), and (i) (other than subsection (i)(1)) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 136a(c)(2)(D) of this title, the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

#### (k) Reregistration and expedited processing fund

#### (1) Establishment

There shall be established in the Treasury of the United States a reregistration and expedited processing fund which shall be known as the Reregistration and Expedited Processing Fund.

#### (2) Source and use

- (A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the Reregistration and Expedited Processing Fund and shall be available to the Administrator, without fiscal year limitation, including, to the maximum extent practicable, during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to offset the costs of registration review under section 136a(g) of this title, including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the information systems capabilities to improve the tracking of pesticide registration decisions. The Administrator shall, prior to expending any such moneys derived from fees-
  - (i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the Government Accountability Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely for the purposes specified in the first sentence of this subparagraph;
  - (ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve the purposes specified in the first sentence of this subparagraph; and
  - (iii) ensure that personnel and facility costs associated with the functions to be carried out under this paragraph do not exceed agency averages for comparable personnel and facility costs.

#### (B) The Administrator shall also—

- (i) complete the review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion in accordance with subsection (I)(2); and
- (ii) contract for such outside assistance as may be necessary for review of required studies, using a generally accepted competitive process for the selection of vendors of such assistance.

#### (3) Review of registrant submissions not covered by section 136w-8(b)(3)(B) of this title

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### (A) Definition of submission not covered by section 136w-8(b)(3)(B) of this title

In this paragraph, the term "submission not covered by section 136w-8(b)(3)(B) of this title" means any submission filed by a registrant with the Administrator relating to a registration that is not covered by a fee table under section 136w-8(b)(3)(B) of this title.

#### (B) Set-aside

#### (i) In general

In addition to amounts otherwise available for each of fiscal years 2023 through 2027, the Administrator shall use approximately 1/8 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in clause (ii).

#### (ii) Activities

In addition to amounts otherwise available, the Administrator shall use amounts made available under clause (i) to obtain sufficient personnel and resources to process submissions not covered by section 136w-8(b)(3)(B) of this title to meet the applicable deadlines described in—

- (I) the notice of the Administrator entitled "Pesticide Registration Notice (PR) 98–10: Notifications, Non-Notifications and Minor Formulation Amendments" and dated October 22, 1998 (and any successor amendments to such notice); and
  - (II) subsections (c)(3)(B) and (h) of section 136a of this title.

#### (4) Development of public health performance standards for antimicrobial pesticide devices

#### (A) Set-aside

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

#### (B) Antimicrobial pesticide devices

The Administrator shall use amounts made available under subparagraph (A) to develop efficacy test methods for antimicrobial pesticide devices making public health claims.

#### (5) Good laboratory practices inspections

#### (A) Set-aside

For each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

#### (B) Activities

The Administrator shall use amounts made available under subparagraph (A) for enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or successor regulations), with respect to laboratory inspections and data audits conducted in support of pesticide product registrations under this subchapter. As part of such monitoring program, the Administrator shall make available to each laboratory inspected under such program in support of such registrations a preliminary summary of inspection observations not later than 60 days after the date on which such an inspection is completed.

#### (6) Agency training and staff

#### (A) Set-aside

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

#### (B) Activities

The Administrator shall use amounts made available under subparagraph (A) to carry out the following activities:

#### (i) Training for agency employees

The Administrator shall administer training and education programs for employees of the Environmental Protection Agency, relating to the regulatory responsibilities and policies established by this Act, including programs—

- (I) for improving the scientific, technical, and administrative skills of officers and employees authorized to administer programs under this subchapter;
  - (II) to align competencies identified by the Administrator for mission accomplishment;

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- (III) for addressing best practices for operational performance and improvement;
- (IV) for improving administrative processes and procedures and addressing efficiency issues;
- (V) to promote consistent regulatory decision-making; and
- (VI) for educating registrants and regulated stakeholders on regulatory procedures.

#### (ii) Agreements with institutions of higher education

Not later than 1 year, to the maximum extent practicable, after December 29, 2022, the Administrator shall establish a competitive grant program to develop training curricula and programs in accordance with clause (i) through financial assistance agreements with 1 or more of the following institutions of higher education:

- (I) Non-land-grant colleges of agriculture (as defined in section 3103 of this title).
- (II) Land-grant colleges and universities (as defined in section 3103 of this title).
- (III) 1994 Institutions (as defined in section 532 of the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note; Public Law 103–382)).

#### (7) Vector expedited review vouchers

#### (A) Set-aside

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to establish and carry out the Vector Expedited Review Voucher program in accordance with subparagraph (B).

#### (B) Vector Expedited Review Voucher program

#### (i) Definitions

In this subparagraph:

#### (I) Program

The term "program" means the Vector Expedited Review Voucher program established under clause (ii).

#### (II) Voucher

The term "voucher" means a voucher—

- (aa) issued under the program by the Administrator to a pesticide registration applicant that entitles the holder to an expedited review described under clause (vi) of a single different pesticide registration action; and
- (bb) the entitlement to which may be transferred (including by sale) by the holder of the voucher, without limitation on the number of times the voucher may be transferred, before the voucher is redeemed.

#### (ii) Establishment

Not later than one year after December 29, 2022, the Administrator, acting though the Office of Pesticide Programs, shall establish a program to be known as the Vector Expedited Review Voucher program.

#### (iii) Purpose

The purpose of the program is to incentivize the development of new insecticides to control and prevent the spread of vector borne disease by expediting reviews by decreasing decision review times provided in section 136w–8(b)(3)(B) of this title.

#### (iv) Issuance of vouchers

#### (I) In general

For each of fiscal years 2023 through 2027, the Administrator shall issue a voucher to a pesticide registration applicant for a new active ingredient if the applicant submits and has successfully registered a mosquito-control product that—

- (aa) demonstrates a proven efficacy against pyrethroid or other insecticide-resistant mosquitoes;
- (bb) prevents, mitigates, destroys, or repels pyrethroid or other insecticide-resistant mosquitoes, with a novel or unique mechanism or mode of action, different from other insecticides already registered by the Administrator for mosquito control;
- (cc) targets mosquitoes capable of spreading such diseases as Malaria, Dengue, Zika, Chikungunya, St. Louis encephalitis, Eastern encephalitis, Western encephalitis, West Nile encephalitis, Cache Valley encephalitis, LaCrosse encephalitis, and Yellow Fever;

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- (dd) the registrant has submitted a global access plan that will be made publicly available for the active ingredient and that includes—
- (AA) manufacturing locations, including any licensed third-party manufacturers;
- (BB) distribution and procurement processes for malaria vector control programs in selected countries; and
- (CC) the prices for common quantities of the product;
  - (ee) meets the appropriate guidelines as being effective in the primary vector control intervention areas, including insecticide-treated nets and indoor residual spray;
    - (ff) is made accessible for use in-
- (AA) the United States, including territories or possessions of the United States; and
- (BB) countries where mosquito-borne diseases, such as malaria, are prevalent;
  - (gg) meets registration requirements for human health and environmental effects, labeling, and presents no unreasonable adverse effects to the environment;
  - (hh) broadens the adoption of integrated pest management strategies, such as insecticide resistance management, or makes those strategies more effective;
  - (ii) is not contained in any pesticide product registered by the Administrator as of December 29, 2022; or
  - (jj) does not contain as attested to by the registrant, an active ingredient approved in the 2-year period preceding the date of registration by any global stringent regulatory authority for the same uses, vectors, and applications.

#### (II) Mosquito vector priority

For each of fiscal years 2023 through 2027, the focus of the program shall be to incentivize the development of insecticides to control and prevent the spread of mosquitoes bearing diseases described in subclause (I)(cc).

#### (III) Exception

If the Administrator determines that there is a significant public health benefit, an active ingredient that is registered for agricultural use that is repurposed and submitted for control of mosquitoes and that otherwise meets the requirements of subclause (I) (excluding items (bb) and (jj)) as determined necessary by the Administrator, shall be considered a mosquito control product meeting the criteria specified in such subclause.

#### (IV) Eligibility criteria modifications

#### (aa) In general

Beginning in fiscal year 2028, the Administrator shall review the program and recommend—(AA) modifications to the requirements described in subclause (I); and

(BB) additional vectors to be included in the program, prioritizing vectors that pose the most significant population health risks.

#### (bb) Public involvement

In carrying out item (aa), the Administrator shall solicit the involvement of registrants, nongovernmental organizations, and governmental agencies engaged in vector-borne disease mitigation and treatment.

#### (v) Redemption of vouchers

To redeem a voucher, the holder shall—

- (I) notify the Administrator of the intent of the holder to submit a pesticide application with a voucher for expedited review not less than 90 days before the submission of the application; and
  - (II) pay the applicable registration service fee under section 136w-8(b) of this title.

#### (vi) Expedited review

On redemption of a voucher, in furtherance of the purpose described in clause (iii), the Administrator shall expedite decision review times as follows:

- (I) 6 months less than the decision review time for Category R010, New Active Ingredient, Food use.
- (II) 6 months less than the decision review time for Category R020, New Active Ingredient, Food use: reduced risk.
- (III) 6 months less than the decision review time for Category R060, New Active Ingredient, Nonfood use; outdoor.
- (IV) 6 months less than the decision review time for Category R110, New Active Ingredient, Nonfood use; indoor.

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- (V) 4 months less than the decision review time for Category R070, New Active Ingredient, Non-food use; outdoor; reduced risk.
- (VI) 2 months less than the decision review time for Category R120, New Active Ingredient, Non-food use; indoor; reduced risk.

#### (vii) Reports

Not later than September 30, 2025, and not later than September 30 of each year thereafter, the Administrator shall issue a report on the program, including—

- (I) the number of submissions seeking a voucher;
- (II) the total time in review for each such submission;
- (III) the number of such vouchers awarded;
- (IV) the number of such vouchers redeemed; and
- (V) with respect to each such redeemed voucher—
- (aa) the decision review time for the pesticide application for which the voucher was redeemed; and
  - (bb) the average standard decision review time for the applicable pesticide category.

#### (C) Unused amounts

Any unused amounts made available under this paragraph at the end of each fiscal year shall be made available to the Administrator to carry out other activities for which amounts in the Reregistration and Expedited Processing Fund are authorized to be used.

#### (8) Pesticide surveillance program

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than \$500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to support the interagency agreement with the National Institute for Occupational Safety and Health to support the Sentinel Event Notification System for Occupational Risk pesticides program—

- (A) with a goal of increasing the number of participating States, prioritizing expansion in States with the highest numbers of agricultural workers; and
  - (B) to improve reporting by participating States.

#### (9) Unused funds

Money in the fund not currently needed to carry out this section shall be-

- (A) maintained on hand or on deposit;
- (B) invested in obligations of the United States or guaranteed thereby; or
- (C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

#### (10) Accounting and performance

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii) <sup>1</sup>/<sub>2</sub> are used only for the purposes described in paragraphs (2) through (8) and to carry out the goals established under subsection (I). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31. The annual audit required under section 3521 of such title of the financial statements of activities under this subchapter under section 3515(b) of such title shall include an audit of the fees collected under subsection (i) (1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (I). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

#### (I) Performance measures and goals

The Administrator shall establish and publish annually in the Federal Register performance measures and goals. Such measures and goals shall include—

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 136a(c)(2)(B) of this title issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) that were approved or disapproved;

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(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) in the current fiscal year and the succeeding fiscal year; and

(3) the projected year of completion of the reregistrations under this section.

#### (m) Judicial review

Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 136n(b) of this title.

#### (n) Authorization of funds to develop public health data

#### (1) "Secretary" defined

For the purposes of this section, "Secretary" means the Secretary of Health and Human Services, acting through the Public Health Service.

#### (2) Consultation

In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 136a(c)(2)(B)(iv) of this title, or cancel a registration under section 136a-1, 136d(e), or 136d(f) of this title. In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

#### (3) Benefits to support family

The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 136a of this title or reregistration under this section.

#### (4) Additional time

If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 136a(c)(2)(B) of this title to specify additional reasonable time periods for submission of the data.

#### (5) Arrangements

The Secretary shall make such arrangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Administrator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic, public health, or other organizations qualified by experience and training to conduct such studies.

#### (6) Support

The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act [42 U.S.C. 201 et seq.], or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

#### (7) Authorization of appropriations

There is authorized to be appropriated to carry out the purposes of this section \$12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.

(June 25, 1947, ch. 125, §4, formerly §3A, as added and renumbered §4, Pub. L. 100–532, title I, §102(a), title VIII, §801(q)(2)(A), Oct. 25, 1988, 102 Stat. 2655, 2683; amended Pub. L. 101–624, title XIV, §1493, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(4), (e), (f), Dec. 13, 1991, 105 Stat. 1895–1897; Pub. L. 104-170, title I, §103, title II, §§210(c)(2), (f)(1), 232, 237, title V, §501, Aug. 3, 1996, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Pub. L. 107–73, title III, [(1)–(4)], Nov. 26, 2001, 115 Stat. 686; Pub. L. 108–7, div. K, title III, [(1)–(4)], Feb. 20, 2003, 117 Stat. 513; Pub. L. 108–199, div. G, title V, §501(c), (d)(1), (e), Jan. 23, 2004, 118 Stat. 419, 422; Pub. L. 108–271, §8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110–94, §4(a)–(d)(1), (e), Oct. 9, 2007, 121 Stat. 1001, 1002; Pub. L. 112–177, §2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329; Pub. L. 116–8, §§2(a), (b), 3, Mar. 8, 2019, 133 Stat. 484, 485; Pub. L. 117–328, div. HH, title VI, §§703(a), 704, Dec. 29, 2022, 136 Stat. 5999, 6002.)

EDITORIAL NOTES

#### REFERENCES IN TEXT

The effective date of this section, referred to in subsecs. (a), (c)(1), (2), and (e)(4)(A), is 60 days after Oct. 25, 1988. See Effective Date note below.

Section 136a(c)(1)(D) of this title, referred to in subsecs. (e)(1)(I) and (h), was redesignated section 136a(c)(1)(F) of this title by Pub. L. 102-237, title X,  $\S1006(a)(3)(B)$ , Dec. 13, 1991, 105 Stat. 1894.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(A)(1), (E)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 136w–8(c)(3)(B) of this title, as such section was in effect as of March 8, 2019, referred to in subsec. (i)(1)(G)(iv), means section 136w–8(c)(3)(B) of this title as amended by Pub. L. 116–8,  $\S5(b)$ , and prior to its repeal and reenactment by Pub. L. 117–328,  $\S705(b)(1)$ . See 2022 Amendment note under section 136w–8 of this title.

The Endangered Species Act of 1973, referred to in subsec. (k)(2)(A), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified principally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Subsection (i)(1)(C)(ii) of this section, referred to in subsec. (k)(10), was previously a reference to subsec. (i)(5)(C)(ii), which was repealed and a new subsec. (i)(5)(C)(ii) was added by Pub. L. 108-199, §501(c)(2). Subsec. (i)(5)(C) was amended by Pub. L. 110-94, §4(a), and, as so amended, related to fees but no longer contained a cl. (ii). Subsec. (i)(5) was redesignated (i)(1) by Pub. L. 112-177, §2(a)(1)(C).

The Public Health Service Act, referred to in subsec. (n)(6), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

### **PRIOR PROVISIONS**

A prior section 4 of act June 25, 1947, which was classified to section 136b of this title was transferred to section 11(a)–(c) of act June 25, 1947, which is classified to section 136i(a)–(c) of this title.

Another prior section 4 of act June 25, 1947, was classified to section 135b of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

#### **AMENDMENTS**

**2022**—Subsec. (i)(1)(C). Pub. L. 117–328,  $\S703(a)(1)(A)$ , substituted "2022, and \$42,000,000 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(D)(i). Pub. L. 117–328, §703(a)(1)(B)(i), substituted "2022, and \$172,000 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(D)(ii). Pub. L. 117–328, §703(a)(1)(B)(ii), substituted "2022, and \$277,200 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(E)(i)(I). Pub. L. 117–328, §703(a)(1)(C)(i), substituted "2022, and \$105,000 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(E)(i)(II). Pub. L. 117–328, §703(a)(1)(C)(ii), substituted "2022, and \$184,800 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(G) to (M). Pub. L. 117–328, §703(a)(1)(D), (E), added subpars. (G) to (K) and redesignated former subpars. (G) and (H) as (L) and (M), respectively. Former subpar. (I) redesignated (N).

Subsec. (i)(1)(N). Pub. L. 117–328, §703(a)(1)(D), (F), redesignated subpar. (I) as (N) and substituted "2027" for "2023".

Subsec. (i)(2). Pub. L. 117–328, §703(a)(2), substituted "December 29, 2022, and ending on September 30, 2029" for "March 8, 2019, and ending on September 30, 2025" and "section 136w–8(b)(3)(B)" for "section 136w–8(b)(3)".

Subsec. (k)(2)(A). Pub. L. 117–328, §704(1), inserted "including, to the maximum extent practicable, during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations," after "limitation,".

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Subsec. (k)(3), (4). Pub. L. 117–328, §704(2), added pars. (3) and (4) and struck out former pars. (3) and (4) which related, respectively, to use of maintenance fees for review of inert ingredients and expedited processing of similar applications and to expedited rulemaking and guidance development for certain product performance data requirements.

Subsec. (k)(5)(A). Pub. L. 117–328, §704(3), substituted "2023 through 2027" for "2018 through 2023".

Subsec. (k)(6) to (9). Pub. L. 117–328, §704(4), (5), added pars. (6) to (8) and redesignated former par. (6) as (9). Former par. (7) redesignated (10).

Subsec. (k)(10). Pub. L. 117–328, §704(4), (6), redesignated par. (7) as (10) and substituted "paragraphs (2) through (8)" for "paragraphs (2), (3), (4), and (5)".

**2019**—Subsec. (i)(1)(C). Pub. L. 116–8, §2(a)(1), substituted "an average amount of \$31,000,000 for each of fiscal years 2019 through 2023" for "an aggregate amount of \$27,800,000 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(D)(i). Pub. L. 116–8, §2(a)(2)(A), substituted "\$129,400 for each of fiscal years 2019 through 2023" for "\$115,500 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(D)(ii). Pub. L. 116–8, §2(a)(2)(B), substituted "\$207,000 for each of fiscal years 2019 through 2023" for "\$184,800 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(E)(i)(I). Pub. L. 116–8, §2(a)(3)(A), substituted "\$79,100 for each of fiscal years 2019 through 2023" for "\$70,600 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(E)(i)(II). Pub. L. 116–8,  $\S 2(a)(3)(B)$ , substituted "\$136,800 for each of fiscal years 2019 through 2023" for "\$122,100 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(I). Pub. L. 116-8, §2(a)(4), substituted "2023." for "2017.."

Subsec. (i)(2). Pub. L. 116–8, §2(b), substituted "March 8, 2019, and ending on September 30, 2025" for "October 25, 1988, and ending on September 30, 2019" and inserted "or any other action covered under a table specified in section 136w–8(b)(3) of this title," after "registration of a pesticide under this subchapter".

Subsec. (k)(2)(A). Pub. L. 116–8, §3(a)(1), (2), in introductory provisions, substituted "the Reregistration and Expedited Processing Fund" for "the fund" and "paragraph (3), to offset the costs of registration review under section 136a(g) of this title, including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the information systems capabilities to improve the tracking of pesticide registration decisions." for "paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title. Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications."

Subsec. (k)(2)(A)(i). Pub. L. 116–8, §3(a)(3), substituted "are allocated solely for the purposes specified in the first sentence of this subparagraph;" for "are allocated solely to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title;".

Subsec. (k)(2)(A)(ii). Pub. L. 116–8, §3(a)(4), substituted "necessary to achieve the purposes specified in the first sentence of this subparagraph;" for "necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title;".

Subsec. (k)(3)(A). Pub. L. 116–8, §3(b), in introductory provisions, substituted "For each of fiscal years 2018 through 2023, the Administrator shall use between 1/9 and 1/8 of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—" for "The Administrator shall use for each of the fiscal years 2004 through 2006, approximately \$3,300,000, and for each of fiscal years 2013 through 2017, between 1/9 and 1/8, of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—".

Subsec. (k)(4). Pub. L. 116–8, §3(c), amended par. (4) generally. Prior to amendment, par. (4) related to enhancements of information technology systems for improvement in review of pesticide

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applications.

Subsec. (k)(5) to (7). Pub. L. 116–8, §3(d), added par. (5), redesignated former pars. (5) and (6) as (6) and (7), respectively, and substituted "paragraphs (2), (3), (4), and (5)" for "paragraphs (2), (3), and (4)" in par. (7).

**2012**—Subsec. (d)(5)(B)(ii)(III). Pub. L. 112–177, §2(a)(2)(A)(i), substituted "this section" for "subsection (i)(1)".

Subsec. (i)(1) to (4). Pub. L. 112–177, §2(a)(1)(C), (D), redesignated pars. (5) and (6) as (1) and (2), respectively, and struck out former pars. (1) to (4) which related to initial fee for food or feed use pesticide active ingredients, final fee for food or feed use pesticide active ingredients, fees for other pesticide active ingredients, and reduction or waiver of fees for minor use and other pesticides, respectively.

Subsec. (i)(5). Pub. L. 112–177, §2(a)(1)(D), redesignated par. (5) as (1).

Subsec. (i)(5)(C). Pub. L. 112–177, §2(a)(1)(A)(i), substituted "aggregate amount of \$27,800,000 for each of fiscal years 2013 through 2017." for "aggregate amount of \$22,000,000 for each of fiscal years 2008 through 2012".

Subsec. (i)(5)(D)(i). Pub. L. 112–177, §2(a)(1)(A)(ii)(I), substituted "shall be \$115,500 for each of fiscal years 2013 through 2017;" for "shall be \$71,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(D)(ii). Pub. L. 112–177, §2(a)(1)(A)(ii)(II), substituted "shall be \$184,800 for each of fiscal years 2013 through 2017." for "shall be \$123,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(E)(i)(I). Pub. L. 112–177,  $\S 2(a)(1)(A)(iii)(I)$ , substituted "shall be \$70,600 for each of fiscal years 2013 through 2017;" for "shall be \$50,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(E)(i)(II). Pub. L. 112–177, §2(a)(1)(A)(iii)(II), substituted "shall be \$122,100 for each of fiscal years 2013 through 2017." for "shall be \$86,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(F). Pub. L. 112–177, §2(a)(1)(A)(vi), added subpar. (F). Former subpar. (F) redesignated (G).

Pub. L. 112–177, §2(a)(1)(A)(iv), substituted "this paragraph" for "paragraph (3)" and "Human" for "Humans".

Subsec. (i)(5)(G), (H). Pub. L. 112–177,  $\S 2(a)(1)(A)(v)$ , redesignated subpars. (F) and (G) as (G) and (H), respectively.

Subsec. (i)(5)(I). Pub. L. 112–177, §2(a)(1)(A)(v), (vii), redesignated subpar. (H) as (I) and substituted "2017" for "2012".

Subsec. (i)(6). Pub. L. 112–177, §2(a)(1)(D), redesignated par. (6) as (2).

Pub. L. 112–177, §2(a)(1)(B), substituted "2019" for "2014" and "paragraph (1)" for "paragraphs (1) through (5)".

Subsec. (i)(7). Pub. L. 112–177, §2(a)(1)(C), struck out par. (7) which related to apportionment of certain fees among registrants of pesticides.

Subsec. (j). Pub. L. 112–177, §2(a)(2)(A)(ii), substituted "subsection (i)(1)" for "subsection (i)(5)".

Subsec. (k)(2)(A). Pub. L. 112–177, §2(a)(4)(A)(i), inserted ", to enhance the information systems capabilities to improve the tracking of pesticide registration decisions," after "paragraph (3)" wherever appearing.

Subsec. (k)(2)(A)(i). Pub. L. 112–177,  $\S 2(a)(4)(A)(ii)$ , inserted "offset" before "the costs of reregistration" and struck out "in the same portion as appropriated funds" before semicolon at end.

Subsec. (k)(3)(A). Pub. L. 112–177, §2(a)(4)(B), in introductory provisions, substituted "2013 through 2017, between 1/9 and 1/8" for "2008 through 2012, between 1/8 and 1/7"; in cl. (i), struck out "new" before "inert"; and, in cl. (ii), substituted "any application that—" for "any application that—"

Subsec. (k)(4). Pub. L. 112–177, §2(a)(4)(C)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 112–177, §2(a)(4)(C)(i), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 112–177,  $\S2(a)(2)(A)(iii)$ , substituted "subsection (i)(1)(C)(ii)" for "subsection (i)(5)(C)(ii)" and "subsection (i)(1)(C)" for "subsection (i)(5)(C)" in two places.

Subsec. (k)(6). Pub. L. 112–177, §2(a)(4)(C)(i), (iii), redesignated par. (5) as (6) and substituted "for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (I)" for "to carry out the goals established under subsection (I)".

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2007—Subsec. (i)(5)(C). Pub. L. 110-94, §4(a), which directed substitution of "amount of \$22,000,000 for each of fiscal years 2008 through 2012" for "amount of" and all that follows through the end of clause (v), was executed by making the substitution for "amount of—

- '(i) for fiscal year 2004, \$26,000,000;
- "(ii) for fiscal year 2005, \$27,000,000;
- "(iii) for fiscal year 2006, \$27,000,000;
- "(iv) for fiscal year 2007, \$21,000,000; and
- "(v) for fiscal year 2008, \$15,000,000."

to reflect the probable intent of Congress. The words "amount of" appeared in the heading and twice in the text.

Subsec. (i)(5)(D)(i). Pub. L. 110–94, §4(b)(1)(A), substituted "shall be \$71,000 for each of fiscal years 2008 through 2012; and for "shall be-

- "(I) for fiscal year 2004, \$84,000;
- "(II) for each of fiscal years 2005 and 2006, \$87,000;
- "(III) for fiscal year 2007, \$68,000; and
- "(IV) for fiscal year 2008, \$55,000; and".

Subsec. (i)(5)(D)(ii). Pub. L. 110–94, §4(b)(1)(B), substituted "shall be \$123,000 for each of fiscal years 2008 through 2012." for "shall be-

- "(I) for fiscal year 2004, \$145,000;
- "(II) for each of fiscal years 2005 and 2006, \$151,000;
- "(III) for fiscal year 2007, \$117,000; and
- "(IV) for fiscal year 2008, \$95,000."

Subsec. (i)(5)(E)(i)(I). Pub. L. 110–94, §4(b)(2)(A), substituted "shall be \$50,000 for each of fiscal years 2008 through 2012; and" for "shall be-

- "(aa) for fiscal year 2004, \$59,000;
- "(bb) for each of fiscal years 2005 and 2006, \$61,000:
- "(cc) for fiscal year 2007, \$48,000; and
- "(dd) for fiscal year 2008, \$38,500; and".

Subsec. (i)(5)(E)(i)(II). Pub. L. 110–94, §4(b)(2)(B), substituted "shall be \$86,000 for each of fiscal years 2008 through 2012." for "shall be-

- "(aa) for fiscal year 2004, \$102,000;
- "(bb) for each of fiscal years 2005 and 2006, \$106,000;
- "(cc) for fiscal year 2007, \$82,000; and
- "(dd) for fiscal year 2008, \$66,500."

Subsec. (i)(5)(H). Pub. L. 110-94, §4(c), substituted "2012." for "2008".

Subsec. (i)(6). Pub. L. 110-94, §4(d)(1), substituted "2014" for "2010".

Subsec. (k)(2)(A). Pub. L. 110-94, §4(e)(1), inserted "and to offset the costs of registration review under section 136a(g) of this title" after "paragraph (3)" wherever appearing.

Subsec. (k)(3)(A). Pub. L. 110–94, §4(e)(2), substituted "2008 through 2012" for "2007 and 2008". **2004**—Subsec. (g)(2)(A). Pub. L. 108–199, §501(c)(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (f) of this section, the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1

Subsec. (g)(2)(B). Pub. L. 108–199, §501(c)(5)(B), inserted subpar. (B) and cl. (i) headings, designated first sentence of existing provisions as cl. (i), inserted cl. (ii) and subcl. (I) headings, designated second sentence of existing provisions as cl. (ii)(I), substituted "Subject to subclause (II), the Administrator" for "The Administrator" in subcl. (I), and added subcl. (II).

Subsec. (g)(2)(D). Pub. L. 108–199, §501(c)(5)(C), inserted subpar. (D) and cl. (i) headings, designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (i)(5)(A). Pub. L. 108-199, §501(c)(1)(A), inserted subpar. (A) heading and substituted "for each registration" for "of—

"(i) \$650 for the first registration; and

additional year."

"(ii) \$1,300 for each additional registration".

Subsec. (i)(5)(C). Pub. L. 108–199, §501(c)(2), struck out cl. (i) designation before "The amount of each", inserted subpar. (C) heading, substituted "aggregate amount of—" for "aggregate amount of

\$21,500,000 for fiscal year 2003.", added cls. (i) to (v), and struck out former cl. (ii), which related to collection of additional fees in fiscal years 1998, 1999, and 2000.

Subsec. (i)(5)(D). Pub. L. 108–199, §501(c)(1)(B), inserted subpar. (D) heading, substituted "shall be—" for "shall be \$55,000; and" and added subcls. (I) to (IV) in cl. (i), and substituted "shall be—" for "shall be \$95,000." and added subcls. (I) to (IV) in cl. (ii).

Subsec. (i)(5)(E)(i). Pub. L. 108-199,  $\S501(c)(1)(C)$ , inserted subpar. (E) and cl. (i) headings, realigned margins of subcls. (I) and (II), substituted "shall be—" for "shall be \$38,500; and" and inserted items (aa) to (dd) in subcl. (I), and substituted "shall be—" for "shall be \$66,500." and inserted items (aa) to (dd) in subcl. (II).

Subsec. (i)(5)(E)(ii). Pub. L. 108–199, §501(c)(3), inserted cl. (ii) heading, redesignated existing provisions as subcl. (I), inserted subcl. (I) heading, substituted "In" for "For purposes of" in subcl. (I), redesignated former subcls. (I) and (II) as items (aa) and (bb) respectively, and realigned margins, substituted "500" for "150" in item (aa), substituted "global gross revenue from pesticides that did not exceed \$60,000,000." for "gross revenue from chemicals that did not exceed \$40,000,000." in item (bb), and added subcl. (II).

Subsec. (i)(5)(H). Pub. L. 108–199, §501(c)(4), substituted "2008" for "2003".

Subsec. (i)(6). Pub. L. 108–199, §501(d)(1), substituted "Except as provided in section 136w–8 of this title, during" for "During", and substituted "2010" for "2003".

Subsec. (k)(2)(A)(i). Pub. L. 108–271 substituted "Government Accountability Office" for "General Accounting Office".

Subsec. (k)(3). Pub. L. 108–199, §501(e)(1), substituted "Review of inert ingredients; expedited" for "Expedited" in par. heading.

Subsec. (k)(3)(A). Pub. L. 108–199, §501(e)(2), substituted "2004 through 2006, approximately \$3,300,000, and for each of fiscal years 2007 and 2008, between 1/8 and 1/7, of the maintenance fees" for "1997 through 2003, not more than 1/10 of the maintenance fees", substituted "resources" for "resources to assure the expedited processing and review of any application that", added cl. (i), inserted cl. (ii) designation and introductory provisions, and redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii).

**2003**—Pub. L. 108–7, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 108–7, [(1)], substituted "\$21,500,000 for fiscal year 2003" for "\$17,000,000 fiscal year 2002".

Subsec. (i)(5)(H). Pub. L. 108–7, [(2)], substituted "2003" for "2002".

Subsec. (i)(6). Pub. L. 108-7, [(3)], substituted "2003" for "2002".

Subsec. (k)(3)(A). Pub. L. 108-7, [(4)], substituted "2003" for "2002".

**2001**—Pub. L. 107–73, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 107–73, [(1)], substituted "\$17,000,000" for "\$14,000,000" and "fiscal year 2002" for "each fiscal year".

Subsec. (i)(5)(H). Pub. L. 107–73, [(2)], substituted "2002" for "2001".

Subsec. (i)(6). Pub. L. 107-73, [(3)], substituted "2002" for "2001".

Subsec. (k)(3)(A). Pub. L. 107–73, [(4)], substituted "2002" for "2001" and "1/10" for "1/7" in introductory provisions.

1996—Pub. L. 104–170, §501, which directed amendment of section 4 without specifying the name of the Act being amended, was executed to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Subsec. (d)(4)(B). Pub. L. 104–170, §210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (d)(6). Pub. L. 104–170, §210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of

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temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (e)(2)(B). Pub. L. 104–170, §210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (e)(3)(A). Pub. L. 104–170, §210(f)(1)(B), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (f)(2)(B). Pub. L. 104–170, §210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (f)(3). Pub. L. 104–170, §210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (g)(2)(E). Pub. L. 104–170, §103, added subpar. (E).

Subsec. (i)(4)(B) to (D). Pub. L. 104-170, §232(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (i)(5)(C). Pub. L. 104–170, §501(a)(2), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (i)(5)(F), (G). Pub. L. 104–170, §232(2), added subpar. (F) and redesignated former subpar. (F) as (G).

Subsec. (i)(5)(H). Pub. L. 104–170, §501(a)(1), substituted "2001" for "1997".

Pub. L. 104–170, §232(2), redesignated subpar. (G) as (H).

Subsec. (i)(6). Pub. L. 104–170, §501(a)(1), substituted "2001" for "1997".

Subsec. (i)(7)(B). Pub. L. 104–170, §232(3), substituted ", to determine the registrant's eligibility" for "or to determine the registrant's eligibility" and inserted before period at end ", or to determine the volume usage for public health pesticides".

Subsec. (k)(1). Pub. L. 104–170, §501(b), inserted "which shall be known as the Reregistration and Expedited Processing Fund" before period at end.

Subsec. (k)(2). Pub. L. 104–170, §501(c), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: "All fees collected by the Administrator under subsection (i) of this section shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications."

Subsec. (k)(3)(A). Pub. L. 104–170, §501(d)(1), which directed the amendment of introductory provisions by substituting "for each of the fiscal years 1997 through 2001, not more than 1/7 of the maintenance fees collected in such fiscal year" for "for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to 2 million each year", was executed by making the substitution for text which contained the phrase "\$2 million", to reflect the probable intent of Congress.

Subsec. (k)(3)(A)(iii). Pub. L. 104–170, §232(4), added cl. (iii).

Subsec. (k)(3)(C). Pub. L. 104–170, §501(d)(2), added subpar. (C).

Subsec. (k)(5). Pub. L. 104–170, §501(e), amended heading and text of par. (5) generally. Prior to amendment, text read as follows: "The Administrator shall-

"(A) provide an annual accounting of the fees collected and disbursed from the fund; and

"(B) take all steps necessary to ensure that expenditures from such fund are used only to carry out this section."

Subsec. (I). Pub. L. 104–170, §501(f), added subsec. (I). Former subsec. (I) redesignated (m).

Subsec. (m). Pub. L. 104–170, §501(f), redesignated subsec. (l) as (m). Former subsec. (m) redesignated (n).

Pub. L. 104-170, §237, added subsec. (m).

Subsec. (n). Pub. L. 104–170, §501(f), redesignated subsec. (m) as (n).

**1991**—Subsec. (f)(3). Pub. L. 102–237, §1006(a)(4), realigned margin.

Subsec. (i)(5). Pub. L. 102-237, §1006(e), amended par. (5) generally, substituting, in subpar. (A), provisions relating to January 15 for provisions relating to March 1, in subpar. (A)(i), provisions relating to fee of \$650 for first registration for provisions relating to fee of \$425 for each registration for registrants holding not more than 50 registrations, and in subpar. (A)(ii), provisions relating to fee of \$1,300 for each additional registration up to 200 registrations, with no fee thereafter, for provisions relating to fee of \$425 for each registration up to 50, \$100 for each registration over 50, with no fee after 200 registrations, redesignating provisions formerly set out in subpar. (A), following cl. (ii), as subpar. (B), and substituting provisions relating to fee under this par. for provisions relating to fee under this subpar., redesignating former subpar. (B) as (C), striking former subpar. (C), which set maximum annual fee for registrants under subpar. (A)(i) at \$20,000, and for registrants under subpar. (A)(ii) at \$35,000, adding subpars. (D) and (E), and redesignating former subpars. (D) and (E) as (F) and (G), respectively.

Subsec. (k)(3)(A). Pub. L. 102–237, §1006(f), substituted "for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to \$2 million each year" for "each fiscal year not more than \$2,000,000 of the amounts in the fund".

1990—Subsec. (i)(5)(A). Pub. L. 101-624 inserted sentence at end relating to reduction or waiver of fee where pesticide is registered for minor agricultural use.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE OF 2012 AMENDMENT**

Pub. L. 112–177, §2(c), Sept. 28, 2012, 126 Stat. 1407, provided that: "This section [amending this section, section 136w-8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] and the amendments made by this section take effect on October 1, 2012."

#### **EFFECTIVE DATE OF 2007 AMENDMENT**

Amendment by Pub. L. 110-94 effective Oct. 1, 2007, see section 6 of Pub. L. 110-94, set out as a note under section 136a of this title.

#### **EFFECTIVE DATE OF 2004 AMENDMENT**

Amendment by Pub. L. 108-199 effective on the date that is 60 days after Jan. 23, 2004, except as otherwise provided, see section 501(h) of Pub. L. 108-199, set out as a note under section 136a of this title.

#### **EFFECTIVE DATE**

Section effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as an Effective Date of 1988 Amendment note under section 136 of this title.

#### IMPLEMENTATION DATES WITH RESPECT TO FEES

Pub. L. 117–328, div. HH, title VI, §708, Dec. 29, 2022, 136 Stat. 6082, provided that: "(a) Fee Increases.—

- "(1) Registration service fees.—With respect to amendments made by this title [see Short Title of 2022 Amendment note set out under section 136 of this title to increase registration service fees specified in section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-8), such increases shall not be effective until the date that is 60 days after the date of the enactment of this title [Dec. 29, 2022], regardless of whether such section 33 specifies (as so amended) that such increases are effective for fiscal year 2023.
- "(2) MAINTENANCE FEES.—With respect to amendments made by this title to increase the amount of maintenance fees to be collected under section 4(i) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a-1(i)), such increases shall be effective beginning on October 1, 2022.

"(b) Set-Asides.—With respect to any set-asides specified in subsection (i) or (k) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1), such set-asides shall be effective beginning on October 1, 2022."

### EXTENSION OF LIMITATIONS ON FEE AMOUNTS AND USAGE OF FEES

Pub. L. 115–141, div. M, title IV, §401(a), Mar. 23, 2018, 132 Stat. 1049, provided that subsecs. (i)(1) (C)–(E) and (k)(3), (4) of this section and section 136w–8(c)(3)(B) of this title would continue in effect through Sept. 30, 2018.

Pub. L. 115–141, div. M, title IV, §401(b)(1), Mar. 23, 2018, 132 Stat. 1050, extended the authority under subsec. (i)(1) of this section through Sept. 30, 2018.

#### RELATIONSHIP OF PUB. L. 112-177 TO OTHER LAW

Pub. L. 112–177, §2(d), Sept. 28, 2012, 126 Stat. 1407, provided that: "In the case of any conflict between this section [amending this section, section 136w–8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] (including the amendments made by this section) and a joint resolution making continuing appropriations for fiscal year 2013 (including any amendments made by such a joint resolution), this section and the amendments made by this section shall control."

### ADJUSTMENT OF MAXIMUM ANNUAL FEE PAYABLE BY PESTICIDE REGISTRANTS

Pub. L. 108–11, title II, Apr. 16, 2003, 117 Stat. 603, provided that: "Within 30 days of enactment of this Act [Apr. 16, 2003], the Administrator of the Environmental Protection Agency shall adjust each 'maximum annual fee payable' pursuant to 7 U.S.C. 136a–1(i)(5)(D) and (E) in a manner such that maintenance fee collections made to reach the level authorized in division K of Public Law 108–7 [see Tables for classification] shall be established in the same proportion as those maintenance fee collections authorized in Public Law 107–73 [see Tables for classification]."

<sup>1</sup> See <u>References in Text note below.</u>

## §136b. Transferred

#### **EDITORIAL NOTES**

#### CODIFICATION

Section, act June 25, 1947, ch. 125, §4, as added Oct. 21, 1972, Pub. L. 92–516, §2, 86 Stat. 983; amended Nov. 28, 1975, Pub. L. 94–140, §§5, 11, 89 Stat. 753, 754; Sept. 30, 1978, Pub. L. 95–396, §9, 92 Stat. 827; Oct. 25, 1988, Pub. L. 100-532, title VIII, §801(c), (q)(1)(A), (B), 102 Stat. 2681, 2683, which related to use of restricted use pesticides and certification of applicators, was transferred to subsecs. (a) to (c) of section 11 of act June 25, 1947, by section 801(q)(1)(A) of Pub. L. 100-532 and is classified to section 136i(a) to (c) of this title.

## §136c. Experimental use permits

#### (a) Issuance

Any person may apply to the Administrator for an experimental use permit for a pesticide. An application for an experimental use permit for a covered application under section 136w–8(b) of this title shall conform with the requirements of that section. The Administrator shall review the application. After completion of the review, but not later than one hundred and twenty days after receipt of the application and all required supporting data (or in the case of an application for an experimental use permit for a covered application under section 136w–8(b) of this title, not later than the last day of the applicable timeframe for such application specified in such section), the Administrator shall either issue the permit or notify the applicant of the Administrator's determination not to issue the permit and the reasons therefor. The applicant may correct the application or request a waiver of the conditions for such permit within thirty days of receipt by the applicant of such notification. The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit

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in order to accumulate information necessary to register a pesticide under section 136a of this title. An application for an experimental use permit may be filed at any time.

#### (b) Temporary tolerance level

If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, the Administrator may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit.

#### (c) Use under permit

Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

#### (d) Studies

When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies shall be reported to the Administrator before such pesticide may be registered under section 136a of this title.

#### (e) Revocation

The Administrator may revoke any experimental use permit, at any time, if the Administrator finds that its terms or conditions are being violated, or that its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment.

#### (f) State issuance of permits

Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as the Administrator may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section 136i of this title relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

#### (g) Exemption for agricultural research agencies

Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require. Such pesticide may be used only by such research agency or educational institution for purposes of experimentation.

(June 25, 1947, ch. 125, §5, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 983; amended Pub. L. 94–140, §10, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, §10, Sept. 30, 1978, 92 Stat. 828; Pub. L. 100–532, title VIII, §801(d), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102–237, title X, §1006(b)(1), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 116–8, §4, Mar. 8, 2019, 133 Stat. 487.)

#### **EDITORIAL NOTES**

#### **PRIOR PROVISIONS**

A prior section 5 of act June 25, 1947, was classified to section 135c of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

#### **AMENDMENTS**

**2019**—Subsec. (a). Pub. L. 116–8 substituted "permit for a pesticide. An application for an experimental use permit for a covered application under section 136w–8(b) of this title shall conform with the requirements of that section." for "permit for a pesticide." and inserted "(or in the case of an application for an experimental use permit for a covered application under section 136w–8(b) of this title, not later than the last day of the applicable timeframe for such application specified in such section)" after "all required supporting data".

1991—Subsecs. (b), (e), (f). Pub. L. 102–237 substituted "the Administrator" for "he" before "may" in subsec. (b), before "finds" in subsec. (e), and before "may" in subsec. (f).

1988—Subsec. (f). Pub. L. 100-532, §801(q)(1)(D), substituted "136i" for "136b".

Subsec. (g). Pub. L. 100–532, §801(d), substituted "require. Such pesticide" for "require: *Provided*, That such pesticide".

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1978—Subsec. (a). Pub. L. 95–396, §10(1), provided for review of application, issuance or nonissuance of experimental use permit within prescribed period including reasons for denial, correction of application, and waiver of conditions and substituted provision for filing an application for experimental use permit at any time for prior provision for filing at the time of or before or after an application for registration is filed.

Subsec. (f). Pub. L. 95-396, §10(2), substituted in first sentence "shall" for "may" where first appearing.

1975—Subsec. (g). Pub. L. 94-140 added subsec. (g).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

## §136d. Administrative review; suspension

#### (a) Existing stocks and information

#### (1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a-1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

#### (2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

#### (b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either-

- (1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or
- (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon

such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c). When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

#### (c) Suspension

#### (1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b). Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

#### (2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of title 5. except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

#### (3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

#### (4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension

order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

#### (d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

#### (e) Conditional registration

- (1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.
- (2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

#### (f) General provisions

#### (1) Voluntary cancellation

- (A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.
- (B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt of the request and provide for a 30-day period in which the public may comment.

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- (C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator—
  - (i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and
  - (ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.
- (D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

#### (2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a-1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

#### (3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

- (A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.
- (B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the transfer and shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.
- (C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.
- (D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

#### (4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

#### (g) Notice for stored pesticides with canceled or suspended registrations

#### (1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

- (A) such possession,
- (B) the quantity of such pesticide such person possesses, and
- (C) the place at which such pesticide is stored.

## (2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

#### (h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

(June 25, 1947, ch. 125, §6, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 984; amended Pub. L. 94–140, §1, Nov. 28, 1975, 89 Stat. 751; Pub. L. 95–251, §2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub. L. 95–396, §§11, 12, Sept. 30, 1978, 92 Stat. 828; Pub. L. 98–620, title IV, §402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title II, §201, title IV, §404, title VIII, §801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub. L. 101–624, title XIV, §1494, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(5), (b)(1), (2), (3)(C)–(E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub. L. 104–170, title I, §§102, 106(a), title II, §§210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

#### **EDITORIAL NOTES**

#### CODIFICATION

"Subchapter II of chapter 5 of title 5", referred to in subsec. (c)(2), was in the original "subchapter II of Title 5", and was editorially changed to reflect the probable intent of Congress.

#### **PRIOR PROVISIONS**

A prior section 6 of act June 25, 1947, was classified to section 135d of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

#### **AMENDMENTS**

**1996**—Subsec. (a). Pub. L. 104–170, §106(a)(1), substituted "Existing stocks and information" for "Cancellation after five years" in heading.

Subsec. (a)(1). Pub. L. 104–170, §106(a)(2), amended heading and text generally. Prior to amendment, text read as follows: "The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect."

Subsec. (b). Pub. L. 104–170, §233, inserted "When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides." before "The proposed action shall become final".

Subsec. (c)(1). Pub. L. 104–170, §102(a), amended second sentence generally. Prior to amendment, second sentence read as follows: "No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator's intention to cancel the registration or change the classification of the pesticide."

Subsec. (c)(3). Pub. L. 104–170, §102(b), inserted after first sentence "The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of

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this section within 90 days of issuing an emergency order, the emergency order shall expire." and substituted "In the case of an emergency order" for "In that case".

Subsec. (f)(1)(C)(ii). Pub. L. 104–170, §210(g)(1), substituted "180-day" for "90-day" in two places.

Subsec. (f)(3)(A). Pub. L. 104–170, §210(g)(2), substituted "180-day" for "90-day".

Subsec. (f)(4). Pub. L. 104–170, §210(h), added par. (4).

1991—Subsec. (a)(1). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "may specify" and before "determines".

Subsec. (a)(2). Pub. L. 102–237, §1006(b)(3)(C), substituted "the registrant" for "he" before "shall".

Subsec. (b). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator's" for "his" in introductory provisions and par. (1), and "the Administrator" for "he" before "shall publish" in last sentence.

Subsec. (c)(1). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "may" and "the Administrator's" for "his" before "intention".

Subsec. (c)(3). Pub. L. 102–237, §1006(b)(1), (3)(D), substituted "the Administrator" for "he" before "may" and "the Administrator" for "him" after "permit".

Subsec. (d). Pub. L. 102–237, §1006(b)(2), (3)(E), in penultimate sentence substituted "the Administrator's" for "his" and "the Administrator" for "him" before "and issue".

Subsec. (f)(3)(B). Pub. L. 102–237, §1006(a)(5), substituted "adverse effect" for "adverse affect".

1990—Subsec. (f)(1). Pub. L. 101–624, §1494(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request."

Subsec. (f)(3). Pub. L. 101–624, §1494(2), added par. (3).

1988—Subsec. (a)(1). Pub. L. 100–532, §801(e)(1), substituted "effect. The Administrator" for "effect: Provided. That the Administrator".

Subsec. (c). Pub. L. 100-532, §801(e)(2)-(4), in par. (1) directed that undesignated paragraph beginning "Except as provided" be run into sentence ending "of the pesticide." and substituted "before the Administrator" for "before the Agency", in par. (2) substituted "submitted to the Administrator" for "submitted to the Agency" and "and the Administrator" for "and the Agency", and in par. (3) substituted "(A)" for "(i)", "and the Administrator" for "and the Agency", and "(B)" for "(ii)".

Subsec. (e). Pub. L. 100-532, §801(e)(5), (6), in par. (1), substituted "met. The Administrator" for "met: Provided, That the Administrator", and in par. (2), substituted "section. The only" for "section: Provided, That the only".

Subsec. (f). Pub. L. 100-532, §201, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (f)(2). Pub. L. 100–532, §801(q)(2)(B), made a technical amendment to the reference to section 136a-1 of this title to reflect the renumbering of the corresponding section of the original act.

Subsec. (g). Pub. L. 100-532, §404, added subsec. (g).

Subsec. (h). Pub. L. 100-532, §201, redesignated former subsec. (f) as (h).

1984—Subsec. (c)(4). Pub. L. 98–620 struck out provisions requiring petitions to review orders on the issue of suspension to be advanced on the docket of the court of appeals.

1978—Subsec. (b). Pub. L. 95–396, §11, required the Administrator, in taking any final action under subsec. (b), to consider restricting a pesticide's use or uses as an alternative to cancellation and to fully explain the reasons for the restrictions.

Subsec. (c)(2). Pub. L. 95–251 substituted "administrative law judge" for "hearing examiner". Subsecs. (e), (f). Pub. L. 95–396, §12, added subsec. (e) and redesignated former subsec. (e) as (f).

1975—Subsec. (b). Pub. L. 94–140 established criteria which Administrator must use in determining the issuance of a suspension of registration notice and the time periods relating to such notice, set forth required procedures to be followed by Administrator prior to publication of such notice, required procedures when the Secretary elects to comment or fails to comment on suspension notice, waiver or modification of time periods in specified required procedures, required procedures for waiver of notice and consent by Secretary for suspension of registration. and established criteria for Secretary taking any final action.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

#### **EFFECTIVE DATE OF 1984 AMENDMENT**

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

## §136e. Registration of establishments

#### (a) Requirement

No person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

#### (b) Registration

Whenever the Administrator receives an application under subsection (a), the Administrator shall register the establishment and assign it an establishment number.

#### (c) Information required

- (1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—
  - (A) which the producer is currently producing:
  - (B) which the producer has produced during the past year; and
  - (C) which the producer has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 136k of this title, inform the Administrator of the name and address of any recipient of any pesticide produced in any registered establishment which the producer operates.

#### (d) Confidential records and information

Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 136h of this title.

(June 25, 1947, ch. 125, §7, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 987; amended Pub. L. 95– 396, §13, Sept. 30, 1978, 92 Stat. 829; Pub. L. 102–237, title X, §1006(b)(1), (3)(F), (G), Dec. 13, 1991, 105 Stat. 1895, 1896.)

#### **EDITORIAL NOTES**

#### **PRIOR PROVISIONS**

A prior section 7 of act June 25, 1947, was classified to section 135e of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

#### **AMENDMENTS**

1991—Subsec. (b). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall".

Subsec. (c)(1)(A) to (C). Pub. L. 102-237, §1006(b)(3)(F), substituted "the producer" for "he".

Subsec. (c)(2). Pub. L. 102–237, §1006(b)(3)(G), substituted "the Administrator" for "him" after "inform" and "the producer" for "he".

1978—Subsec. (a). Pub. L. 95–396, §13(1), made requirement of registration applicable to production of active ingredient used in producing a pesticide subject to this subchapter.

Subsec. (c)(1). Pub. L. 95–396, §13(2), required information pertaining to types and amounts of active ingredients used in producing pesticides where applicable.

Subsec. (d). Pub. L. 95–396, §13(3), considered names of pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment as not being confidential information.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

### §136f. Books and records

#### (a) Requirements

The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this subchapter and to make the records available for inspection and copying in the same manner as provided in subsection (b). No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

#### (b) Inspection

For the purposes of enforcing the provisions of this subchapter, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this subchapter, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data; and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.

(June 25, 1947, ch. 125, §8, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 987; amended Pub. L. 95-396, §14, Sept. 30, 1978, 92 Stat. 829; Pub. L. 100–532, title III, §301, Oct. 25, 1988, 102 Stat. 2668; Pub. L. 102–237, title X, §1006(b)(1), Dec. 13, 1991, 105 Stat. 1895.)

#### **EDITORIAL NOTES**

#### **PRIOR PROVISIONS**

A prior section 8 of act June 25, 1947, was classified to section 135f of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

#### **AMENDMENTS**

1991—Subsec. (a). Pub. L. 102–237 substituted "the Administrator" for "he" before "determines". 1988—Subsec. (a). Pub. L. 100–532 inserted ", registrants, and applicants for registration" after "requiring producers" and "and to make the records available for inspection and copying in the same manner as provided in subsection (b) of this section" before period at end of first sentence.

1978—Subsec. (b). Pub. L. 95–396 required, in connection with inspection of records and information, the presentation of credentials, written statement as to the reason for inspection, including statement of suspected violation, or an alternative but sufficient reason, and commencement and completion of inspection with reasonable promptness.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

# §136g. Inspection of establishments, etc.

## (a) In general

- (1) For purposes of enforcing the provisions of this subchapter, officers or employees of the Environmental Protection Agency or of any State duly designated by the Administrator are authorized to enter at reasonable times (A) any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices, or (B) any place where there is being held any pesticide the registration of which has been suspended or canceled for the purpose of determining compliance with section 136q of this title.
- (2) Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, the officer or employee shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

#### (b) Warrants

For purposes of enforcing the provisions of this subchapter and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this subchapter have been violated. officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

- (1) entry, inspection, and copying of records for purposes of this section or section 136f of this title;
- (2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this subchapter and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and
  - (3) the seizure of any pesticide or device which is in violation of this subchapter.

## (c) Enforcement

#### (1) Certification of facts to Attorney General

The examination of pesticides or devices shall be made in the Environmental Protection Agency or elsewhere as the Administrator may designate for the purpose of determining from such examinations whether they comply with the requirements of this subchapter. If it shall appear from any such examination that they fail to comply with the requirements of this subchapter, the Administrator shall cause notice to be

given to the person against whom criminal or civil proceedings are contemplated. Any person so notified shall be given an opportunity to present the person's views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Administrator it appears that the provisions of this subchapter have been violated by such person, then the Administrator shall certify the facts to the Attorney General, with a copy of the results of the analysis or the examination of such pesticide for the institution of a criminal proceeding pursuant to section 136l(b) of this title or a civil proceeding under section 136l(a) of this title, when the Administrator determines that such action will be sufficient to effectuate the purposes of this subchapter.

## (2) Notice not required

The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceeding by the Attorney General.

## (3) Warning notices

Nothing in this subchapter shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this subchapter whenever the Administrator believes that the public interest will be adequately served by a suitable written notice of warning.

(June 25, 1947, ch. 125, §9, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 988; amended Pub. L. 100–532, title III, §302, Oct. 25, 1988, 102 Stat. 2669; Pub. L. 102–237, title X, §1006(b)(1), (3)(H), (I), Dec. 13, 1991, 105 Stat. 1895, 1896.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 9 of act June 25, 1947, was classified to section 135g of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

## **AMENDMENTS**

**1991**—Subsec. (a)(2). Pub. L. 102–237, §1006(b)(3)(H), substituted "the officer or employee" for "he" before "shall" in fourth sentence.

Subsec. (c)(1). Pub. L. 102–237, §1006(b)(3)(I), substituted "the person's" for "his" in third sentence.

Subsec. (c)(3). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "believes".

**1988**—Subsec. (a). Pub. L. 100–532, §302(a), substituted "(1) For purposes of" for "For purposes of", inserted "of the Environmental Protection Agency or of any State", substituted "at reasonable times (A)" for "at reasonable times,", added cl. (B), and substituted "(2) Before" for "Before".

Subsec. (b)(1). Pub. L. 100–532, §302(b), amended par. (1) generally, substituting "entry, inspection, and copying of records for purposes of this section or section 136f of this title" for "entry for the purpose of this section".

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136h. Protection of trade secrets and other information

## (a) In general

In submitting data required by this subchapter, the applicant may (1) clearly mark any portions thereof which in the applicant's opinion are trade secrets or commercial or financial information and (2) submit such market

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material separately from other material required to be submitted under this subchapter.

#### (b) Disclosure

Notwithstanding any other provision of this subchapter and subject to the limitations in subsections (d) and (e) of this section, the Administrator shall not make public information which in the Administrator's judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this subchapter, information relating to formulas of products acquired by authorization of this subchapter may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

## (c) Disputes

If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), the Administrator shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).

## (d) Limitations

- (1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. The use of such data for any registration purpose shall be governed by section 136a of this title. This paragraph does not authorize the disclosure of any information that—
  - (A) discloses manufacturing or quality control processes,
  - (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or
    - (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

- (2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.
- (3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice. Where the Administrator finds that disclosure of information described in clause (A), (B), or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—
  - (A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or
  - (B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

#### (e) Disclosure to contractors

Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this subchapter and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information

under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

## (f) Penalty for disclosure by Federal employees

- (1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than \$10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this subchapter. Nothing in this subchapter shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.
- (2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.

## (g) Disclosure to foreign and multinational pesticide producers

- (1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this subchapter to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this subchapter, which information is relevant to a determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.
- (2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliations of such persons.
- (3) Section 1001 of title 18 shall apply to any affirmation made under paragraph (1) of this subsection. (June 25, 1947, ch. 125, §10, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 989; amended Pub. L. 95– 396, §15, Sept. 30, 1978, 92 Stat. 829; Pub. L. 98–620, title IV, §402(4)(B), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100-532, title VIII, §801(f), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102-237, title X, §1006(b)(1), (2), (3)(J), Dec. 13, 1991, 105 Stat. 1895, 1896.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 10 of act June 25, 1947, was classified to section 135h of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

## **AMENDMENTS**

1991—Subsec. (a). Pub. L. 102–237, §1006(b)(3)(J), substituted "the applicant's" for "his". Subsec. (b). Pub. L. 102-237, §1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c). Pub. L. 102-237, §1006(b)(1), substituted "the Administrator" for "he" before "shall notify".

1988—Subsec. (d). Pub. L. 100–532 in par. (1), substituted "public. The use" for "public: Provided, That the use" and "title. This paragraph" for "title: Provided further, That this paragraph", and in par. (3), "notice. Where" for "notice: Provided, That where".

1984—Subsec. (d)(3). Pub. L. 98–620 struck out provisions requiring the court to give expedited consideration to actions involving injunctions or limitations of proposed disclosure.

1978—Subsec. (b). Pub. L. 95–396, §15(1), made disclosure of information by the Administrator subject to the limitations of subsecs. (d) and (e) of this section.

Subsecs. (d) to (g). Pub. L. 95–396, §15(2), added subsecs. (d) to (g).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE OF 1984 AMENDMENT**

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136i. Use of restricted use pesticides; applicators

#### (a) Certification procedure

#### (1) Federal certification

In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of the pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification. The certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by the applicator completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this subchapter, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to a requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by the Administrator.

#### (2) State certification

If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Administrator shall approve the plan submitted by any State, or any modification thereof, if such plan in the Administrator's judgment—

- (A) designates a State agency as the agency responsible for administering the plan throughout the State;
- (B) contains satisfactory assurances that such agency has or will have the legal authority and qualified personnel necessary to carry out the plan;
- (C) gives satisfactory assurances that the State will devote adequate funds to the administration of the plan;
- (D) provides that the State agency will make such reports to the Administrator in such form and containing such information as the Administrator may from time to time require; and

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(E) contains satisfactory assurances that State standards for the certification of applicators of pesticides conform with those standards prescribed by the Administrator under paragraph (1).

Any State certification program under this section shall be maintained in accordance with the State plan approved under this section.

#### (b) State plans

If the Administrator rejects a plan submitted under subsection (a)(2), the Administrator shall afford the State submitting the plan due notice and opportunity for hearing before so doing. If the Administrator approves a plan submitted under subsection (a)(2), then such State shall certify applicators of pesticides with respect to such State. Whenever the Administrator determines that a State is not administering the certification program in accordance with the plan approved under this section, the Administrator shall so notify the State and provide for a hearing at the request of the State, and, if appropriate corrective action is not taken within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of such plan.

## (c) Instruction in integrated pest management techniques

Standards prescribed by the Administrator for the certification of applicators of pesticides under subsection (a), and State plans submitted to the Administrator under subsection (a), shall include provisions for making instructional materials concerning integrated pest management techniques available to individuals at their request in accordance with the provisions of section 136u(c) of this title, but such plans may not require that any individual receive instruction concerning such techniques or to be shown to be competent with respect to the use of such techniques. The Administrator and States implementing such plans shall provide that all interested individuals are notified on the availability of such instructional materials.

## (d) In general

No regulations prescribed by the Administrator for carrying out the provisions of this subchapter shall require any private applicator to maintain any records or file any reports or other documents.

## (e) Separate standards

When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.

(June 25, 1947, ch. 125, §11, formerly §§4, 11, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 983, 989; amended Pub. L. 94-140, §§5, 11, Nov. 28, 1975, 89 Stat. 753, 754; Pub. L. 95-396, §9, Sept. 30, 1978, 92 Stat. 827; Pub. L. 100-532, title VIII, §801(c), (q)(1)(A)-(C), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102-237, title X, §1006(a)(6), (b)(1), (2), (3)(K), Dec. 13, 1991, 105 Stat. 1895, 1896.)

#### **EDITORIAL NOTES**

#### CODIFICATION

Pub. L. 100–532, §801(q)(1)(A), transferred subsecs. (a) to (c) of section 4 of act June 25, 1947, which was classified to section 136b of this title, to subsecs. (a) to (c) of this section.

## **PRIOR PROVISIONS**

A prior section 11 of act June 25, 1947, was classified to section 135i of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

#### **AMENDMENTS**

1991—Pub. L. 102–237, §1006(a)(6)(A), substituted "applicators" for "appplicators" in section catchline.

Subsec. (a)(1). Pub. L. 102–237, §1006(b)(3)(K), substituted "the applicator" for "his" in ninth sentence and "the Administrator" for "him" before period at end.

Subsec. (a)(2). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his" in introductory provisions.

Subsec. (b). Pub. L. 102–237, §1006(a)(6)(B), (b)(1), substituted "subsection (a)(2) of this section" for "this paragraph" in two places and "the Administrator" for "he" before "shall afford" and before

Subsec. (c). Pub. L. 102-237, §1006(a)(6)(C), substituted "subsection (a)" for "subsections (a) and (b)" after "Administrator under".

1988—Pub. L. 100–532, §801(q)(1)(A), (C), substituted section catchline for one which read: "Standards applicable to pesticide applicators", redesignated subsecs. (a) and (b) as (d) and (e), respectively, and transferred subsecs. (a) to (c) of section 136b of this title to subsecs. (a) to (c), respectively, of this section.

Subsec. (a)(1). Pub. L. 100–532, §801(c), substituted "pesticides. Such program" for "pesticides: *Provided*, That such program" and "certification. The certification" for "certification: *Provided, however*, That the certification".

1978—Subsec. (a)(1). Pub. L. 95–396 required that, in any State without a State plan for applicator certification approved by the Administrator, the Administrator, in consultation with the Governor of the State, shall conduct a program for the certification of applicators of pesticides under a Federal plan for applicator certification, and also that in such a State records be maintained and reports submitted by persons engaged in commercial application, sale or distribution of pesticides classified for restricted use.

**1975**—Subsec. (a)(1). Pub. L. 94–140, §5, inserted proviso relating to Administrator's powers and duties with respect to the certification forms and requirement for pesticide dealers participating in certification program.

Subsec. (c). Pub. L. 94-140, §11, added subsec. (c).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136i–1. Pesticide recordkeeping

## (a) Requirements

- (1) The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, shall require certified applicators of restricted use pesticides (of the type described under section 136a(d)(1)(C) of this title) to maintain records comparable to records maintained by commercial applicators of pesticides in each State. If there is no State requirement for the maintenance of records, such applicator shall maintain records that contain the product name, amount, approximate date of application, and location of application of each such pesticide used for a 2-year period after such use.
- (2) Within 30 days of a pesticide application, a commercial certified applicator shall provide a copy of records maintained under paragraph (1) to the person for whom such application was provided.

## (b) Access

Records maintained under subsection (a) shall be made available to any Federal or State agency that deals with pesticide use or any health or environmental issue related to the use of pesticides, on the request of such agency. Each such Federal agency shall conduct surveys and record the data from individual applicators to facilitate statistical analysis for environmental and agronomic purposes, but in no case may a government agency release data, including the location from which the data was derived, that would directly or indirectly reveal the identity of individual producers. In the case of Federal agencies, such access to records maintained under subsection (a) shall be through the Secretary of Agriculture, or the Secretary's designee. State agency requests for access to records maintained under subsection (a) shall be through the lead State agency so designated by the State.

#### (c) Health care personnel

When a health professional determines that pesticide information maintained under this section is necessary to provide medical treatment or first aid to an individual who may have been exposed to pesticides for which the information is maintained, upon request persons required to maintain records under subsection (a) shall promptly provide record and available label information to that health professional. In the case of an emergency, such record information shall be provided immediately.

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#### (d) Penalty

The Secretary of Agriculture shall be responsible for the enforcement of subsections (a), (b), and (c). A violation of such subsection shall—

- (1) in the case of the first offense, be subject to a fine of not more than \$500; and
- (2) in the case of subsequent offenses, be subject to a fine of not less than \$1,000 for each violation, except that the penalty shall be less than \$1,000 if the Secretary determines that the person made a good faith effort to comply with such subsection.

#### (e) Federal or State provisions

The requirements of this section shall not affect provisions of other Federal or State laws.

## (f) Surveys and reports

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall survey the records maintained under subsection (a) to develop and maintain a data base that is sufficient to enable the Secretary and the Administrator to publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use. The Secretary and Administrator shall enter into a memorandum of understanding to define their respective responsibilities under this subsection in order to avoid duplication of effort. Such reports shall be transmitted to Congress not later than April 1 of each year.

## (g) Regulations

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency shall promulgate regulations on their respective areas of responsibility implementing this section within 180 days after November 28, 1990.

(Pub. L. 101–624, title XIV, §1491, Nov. 28, 1990, 104 Stat. 3627; Pub. L. 102–237, title X, §1006(d), Dec. 13, 1991, 105 Stat. 1896.)

#### **EDITORIAL NOTES**

#### CODIFICATION

Section was enacted as part of the Conservation Program Improvements Act, and also as part of the Food, Agriculture, Conservation, and Trade Act of 1990, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

#### **AMENDMENTS**

**1991**—Subsec. (a)(1). Pub. L. 102–237, §1006(d)(1), inserted closing parenthesis after "section 136a(d)(1)(C) of this title".

Subsec. (d)(1). Pub. L. 102-237, §1006(d)(2), inserted "of" after "fine".

# §136i–2. Collection of pesticide use information

## (a) In general

The Secretary of Agriculture shall collect data of statewide or regional significance on the use of pesticides to control pests and diseases of major crops and crops of dietary significance, including fruits and vegetables.

#### (b) Collection

The data shall be collected by surveys of farmers or from other sources offering statistically reliable data.

#### (c) Coordination

The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

(Pub. L. 104-170, title III, §302, Aug. 3, 1996, 110 Stat. 1512.)

#### **EDITORIAL NOTES**

#### CODIFICATION

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Section was enacted as part of the Food Quality Protection Act of 1996, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## PESTICIDE USE INFORMATION STUDY

Pub. L. 104-170, title III, §305, Aug. 3, 1996, 110 Stat. 1512, required the Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, to prepare a report to Congress evaluating the current status and potential improvements in Federal pesticide use information gathering activities and to submit the report not later than 1 year following Aug. 3, 1996.

# §136j. Unlawful acts

## (a) In general

- (1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person—
  - (A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;
  - (B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;
  - (C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title:
  - (D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title:
    - (E) any pesticide which is adulterated or misbranded; or
    - (F) any device which is misbranded.
  - (2) It shall be unlawful for any person—
    - (A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;
    - (B) to refuse to—
    - (i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title:
      - (ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or
      - (iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;
  - (C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which quaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking:
  - (D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;
  - (E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title:
  - (F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;
    - (G) to use any registered pesticide in a manner inconsistent with its labeling:

- (H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;
  - (I) to violate any order issued under section 136k of this title;
  - (J) to violate any suspension order issued under section 136a(c)(2)(B), 136a-1, or 136d of this title;
- (K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(a) of this title:
  - (L) who is a producer to violate any of the provisions of section 136e of this title;
- (M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;
- (N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter:
- (O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;
- (P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test;
- (Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;
  - (R) to submit to the Administrator data known to be false in support of a registration; or
  - (S) to violate any regulation issued under section 136a(a) or 136q of this title.

## (b) Exemptions

The penalties provided for a violation of paragraph (1) of subsection (a) shall not apply to—

- (1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this subchapter, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this subchapter;
- (2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;
  - (3) any public official while engaged in the performance of the official duties of the public official;
- (4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or
- (5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

(June 25, 1947, ch. 125, §12, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 989; amended Pub. L. 95– 396, §16, Sept. 30, 1978, 92 Stat. 832; Pub. L. 100-532, title VI, §§601(b)(2), 603, title VIII, §801(g), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2677, 2678, 2682, 2683; Pub. L. 102–237, title X, §1006(a)(7), (b)(3)(L)–(O), Dec. 13, 1991, 105 Stat. 1895, 1896.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 12 of act June 25, 1947, was classified to section 135j of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

#### **AMENDMENTS**

1991—Subsec. (a)(2)(C). Pub. L. 102–237, §1006(b)(3)(L), substituted "the person's" for "his" and "the person" for "he" before "received".

Subsec. (a)(2)(D). Pub. L. 102–237, §1006(b)(3)(M), substituted "the person's" for "his".

Subsec. (a)(2)(F). Pub. L. 102-237, §1006(a)(7)(A), substituted "thereunder, except that it" for "thereunder. It".

Subsec. (a)(2)(O). Pub. L. 102–237, §1006(a)(7)(B), struck out "or" after semicolon at end.

Subsec. (a)(2)(P). Pub. L. 102–237, §1006(a)(7)(C), substituted a semicolon for period at end.

Subsec. (b)(1). Pub. L. 102–237, §1006(b)(3)(N), substituted "the person" for "he" after "from whom" and for "him" after "delivery to".

Subsec. (b)(3). Pub. L. 102–237, §1006(b)(3)(O), substituted "the official duties of the public official" for "his official duties".

1988—Subsec. (a)(1). Pub. L. 100–532, §601(b)(2)(A), in introductory provisions, substituted "distribute or sell to any person" for "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person".

Subsec. (a)(1)(A). Pub. L. 100–532, §603(1), added subpar. (A) and struck out former subpar. (A) which read as follows: "any pesticide which is not registered under section 136a of this title, except as provided by section 136d(a)(1) of this title;".

Subsec. (a)(2)(B). Pub. L. 100–532, §603(2)(A), added subpar. (B) and struck out former subpar. (B) which read as follows: "to refuse to keep any records required pursuant to section 136f of this title, or to refuse to allow inspection of any records or establishment pursuant to section 136f or 136g of this title, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 136g of this title;".

Subsec. (a)(2)(F). Pub. L. 100-532, §§601(b)(2)(B), 801(g), substituted "to distribute or sell, or to make" for "to make" and "thereunder, It" for "thereunder: Provided, That it".

Subsec. (a)(2)(J). Pub. L. 100–532, §801(q)(2)(B), made a technical amendment to the reference to section 136a-1 of this title to reflect the renumbering of the corresponding section of the original

Pub. L. 100-532, §603(2)(B), added subpar. (J) and struck out former subpar. (J) which read as follows: "to violate any suspension order issued under section 136d of this title:".

Subsec. (a)(2)(K). Pub. L. 100-532, §603(2)(B), added subpar. (K) and struck out former subpar. (K) which read as follows: "to violate any cancellation of registration of a pesticide under section 136d of this title, except as provided by section 136d(a)(1) of this title;".

Subsec. (a)(2)(M). Pub. L. 100-532, §603(2)(C), substituted "this subchapter" for "section 136f of this title".

Subsec. (a)(2)(Q), (R), (S). Pub. L. 100-532, §603(2)(D), added subpars. (Q), (R), and (S).

1978—Subsec. (a)(2)(F). Pub. L. 95–396 inserted proviso exempting from prohibition the sale, under regulations issued by the Administrator, of a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

# §136k. Stop sale, use, removal, and seizure

## (a) Stop sale, etc., orders

Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this subchapter, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall

sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

## (b) Seizure

Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

- (1) in the case of a pesticide—
  - (A) it is adulterated or misbranded;
  - (B) it is not registered pursuant to the provisions of section 136a of this title:
  - (C) its labeling fails to bear the information required by this subchapter;
  - (D) it is not colored or discolored and such coloring or discoloring is required under this subchapter; or
- (E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;
- (2) in the case of a device, it is misbranded; or
- (3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this subchapter and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

## (c) Disposition after condemnation

If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this subchapter or the laws of the jurisdiction in which it is sold. On payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the subchapter or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

#### (d) Court costs, etc.

When a decree of condemnation is entered against the pesticide or device, court costs and fees, storage, and other proper expenses shall be awarded against the person, if any, intervening as claimant of the pesticide or device.

(June 25, 1947, ch. 125, §13, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 991; amended Pub. L. 100– 532, title VIII, §801(h), Oct. 25, 1988, 102 Stat. 2682.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 13 of act June 25, 1947, was classified to section 135k of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

## **AMENDMENTS**

1988—Subsec. (b). Pub. L. 100–532, §801(h)(1), directed that sentence beginning "In the case of" be moved from par. (3) and become a full measure sentence after par. (3).

Subsec. (c). Pub. L. 100-532, §801(h)(2), substituted "sold. On" for "sold. Provided, That upon".

STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

## EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

# §1361. Penalties

## (a) Civil penalties

## (1) In general

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than \$5,000 for each offense.

## (2) Private applicator

Any private applicator or other person not included in paragraph (1) who violates any provision of this subchapter subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than \$1,000 for each offense, except that any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than \$500 for the first offense nor more than \$1,000 for each subsequent offense.

## (3) Hearing

No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

## (4) Determination of penalty

In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

#### (5) References to Attorney General

In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

#### (b) Criminal penalties

## (1) In general

- (A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this subchapter shall be fined not more than \$50,000 or imprisoned for not more than 1 year, or both.
- (B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this subchapter shall be fined not more than \$25,000 or imprisoned for not more than 1 year, or both.

#### (2) Private applicator

Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this subchapter shall be guilty of a misdemeanor and shall on conviction be fined not more than \$1,000, or imprisoned for not more than 30 days, or both.

## (3) Disclosure of information

Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 136a of this title, shall be fined not more than \$10,000, or imprisoned for not more than three years, or both.

## (4) Acts of officers, agents, etc.

When construing and enforcing the provisions of this subchapter, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

(June 25, 1947, ch. 125, §14, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 992; amended Pub. L. 95– 396, §17, Sept. 30, 1978, 92 Stat. 832; Pub. L. 100–532, title VI, §604, Oct. 25, 1988, 102 Stat. 2678; Pub. L. 102-237, title X, §1006(a)(8), Dec. 13, 1991, 105 Stat. 1895.)

#### **EDITORIAL NOTES**

#### **AMENDMENTS**

1991—Subsec. (a)(2). Pub. L. 102–237 substituted ", except that" for ": Provided, That" and "uses" for "use".

1988—Subsec. (b)(1). Pub. L. 100–532 amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this subchapter shall be guilty of a misdemeanor and shall on conviction be fined not more than \$25,000, or imprisoned for not more than one year, or both."

1978—Subsec. (a)(2). Pub. L. 95–396, §17(1), authorized assessment of a civil penalty of not more than \$500 for a first offense and not more than \$1,000 for each subsequent offense against any applicator providing a service of controlling pests for violations of this subchapter.

Subsec. (a)(3). Pub. L. 95–396, §17(2), struck out provision respecting certain considerations when determining amount of penalty, now covered in par. (4).

Subsec. (a)(4). Pub. L. 95–396, §17(4), reenacted second sentence of par. (3) as par. (4) and authorized Administrator to issue a warning in lieu of assessing a penalty. Former par. (4) redesignated (5).

Subsec. (a)(5). Pub. L. 95–396, §17(3), redesignated former par. (4) as (5).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

## EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

# §136m. Indemnities

## (a) General indemnification

#### (1) In general

Except as otherwise provided in this section, if—

- (A) the Administrator notifies a registrant under section 136d(c)(1) of this title that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 136d(c)(3) of this title has been issued;
- (B) the registration in question is suspended under section 136d(c) of this title, and thereafter is canceled under section 136d(b), 136d(d), or 136d(f) of this title; and
- (C) any person who owned any quantity of the pesticide immediately before the notice to the registrant under subparagraph (A) suffered losses by reason of suspension or cancellation of the registration;

the Administrator shall make an indemnity payment to the person.

#### (2) Exception

Paragraph (1) shall not apply if the Administrator finds that the person—

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- (A) had knowledge of facts that, in themselves, would have shown that the pesticide did not meet the requirements of section 136a(c)(5) of this title for registration; and
- (B) continued thereafter to produce the pesticide without giving timely notice of such facts to the Administrator.

## (3) Report

If the Administrator takes an action under paragraph (1) that requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate on-

- (A) the action taken that requires the payment of indemnification:
- (B) the reasons for taking the action;
- (C) the estimated cost of the payment; and
- (D) a request for the appropriation of funds for the payment.

## (4) Appropriation

The Administrator may not make a payment of indemnification under paragraph (1) unless a specific line item appropriation of funds has been made in advance for the payment.

## (b) Indemnification of end users, dealers, and distributors

## (1) End users

If—

- (A) the Administrator notifies a registrant under section 136d(c)(1) of this title that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 136d(c)(3) of this title has been issued;
- (B) the registration in question is suspended under section 136d(c) of this title, and thereafter is canceled under section 136d(b), 136d(d), or 136d(f) of this title; and
- (C) any person who, immediately before the notice to the registrant under subparagraph (A), owned any quantity of the pesticide for purposes of applying or using the pesticide as an end user, rather than for purposes of distributing or selling it or further processing it for distribution or sale, suffered a loss by reason of the suspension or cancellation of the pesticide;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

#### (2) Dealers and distributors

(A) Any registrant, wholesaler, dealer, or other distributor (hereinafter in this paragraph referred to as a "seller") of a registered pesticide who distributes or sells the pesticide directly to any person not described as an end user in paragraph (1)(C) shall, with respect to any quantity of the pesticide that such person cannot use or resell as a result of the suspension or cancellation of the pesticide, reimburse such person for the cost of first acquiring the pesticide from the seller (other than the cost of transportation, if any), unless the seller provided to the person at the time of distribution or sale a notice, in writing, that the pesticide is not subject to reimbursement by the seller.

#### (B) If—

- (i) the Administrator notifies a registrant under section 136d(c)(1) of this title that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 136d(c)(3) of this title has been issued:
- (ii) the registration in question is suspended under section 136d(c) of this title, and thereafter is canceled under section 136d(b), 136d(d), or 136d(f) of this title;
  - (iii) any person who, immediately before the notice to the registrant under clause (i)—
  - (I) had not been notified in writing by the seller, as provided under subparagraph (A), that any quantity of the pesticide owned by such person is not subject to reimbursement by the seller in the event of suspension or cancellation of the pesticide; and
    - (II) owned any quantity of the pesticide for purposes of—
      - (aa) distributing or selling it; or
      - (bb) further processing it for distribution or sale directly to an end user;

suffered a loss by reason of the suspension or cancellation of the pesticide; and

- (iv) the Administrator determines on the basis of a claim of loss submitted to the Administrator by the person, that the seller—
  - (I) did not provide the notice specified in subparagraph (A) to such person; and
  - (II) is and will continue to be unable to provide reimbursement to such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of the insolvency or bankruptcy of the

seller and the seller's resulting inability to provide such reimbursement;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(C) If an indemnity payment is made by the United States under this paragraph, the United States shall be subrogated to any right that would otherwise be held under this paragraph by a seller who is unable to make a reimbursement in accordance with this paragraph with regard to reimbursements that otherwise would have been made by the seller.

#### (3) Source

Any payment required to be made under paragraph (1) or (2) shall be made from the appropriation provided under section 1304 of title 31.

## (4) Administrative settlement

An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28 and shall be regarded as if it were made under that section for purposes of section 1304 of title 31.

## (c) Amount of payment

#### (1) In general

The amount of an indemnity payment under subsection (a) or (b) to any person shall be determined on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

## (2) Special rule

Notwithstanding any other provision of this subchapter, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adjustment shall be made for any pesticide used or otherwise disposed of by the owner.

(June 25, 1947, ch. 125, §15, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 993; amended Pub. L. 100– 532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674.)

#### **EDITORIAL NOTES**

#### **AMENDMENTS**

1988—Pub. L. 100–532 amended section generally, in subsec. (a), substituting provisions relating to general indemnification for provisions relating to requirements for payment, adding subsec. (b), and redesignating provisions of former subsec. (b), with further amendment, as subsec. (c).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Pub. L. 100-532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674, provided that amendment made by Pub. L. 100-532 is effective 180 days after Oct. 25, 1988.

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

## **INTERIM PAYMENTS**

Pub. L. 100-532, title V, §501(b), Oct. 25, 1988, 102 Stat. 2676, provided that:

- "(1) Source.—Any obligation of the Administrator to pay an indemnity arising under section 15 [this section], as it existed prior to the effective date of the amendment made by this section [see Effective Date of 1988 Amendment note above], shall be made from the appropriation provided under section 1304 of title 31, United States Code.
- "(2) ADMINISTRATIVE SETTLEMENT.—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and

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shall be regarded as if it were made under that section for purposes of section 1304 of title 31. United States Code."

# §136n. Administrative procedure; judicial review

## (a) District court review

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

#### (b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of title 28. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

#### (c) Jurisdiction of district courts

The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

#### (d) Notice of judgments

The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this subchapter.

(June 25, 1947, ch. 125, §16, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 994; amended Pub. L. 98-620, title IV, §402(4)(C), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100-532, title VIII, §801(i), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), (3)(P), Dec. 13, 1991, 105 Stat. 1895, 1896.)

#### **EDITORIAL NOTES**

#### **AMENDMENTS**

1991—Subsec. (b). Pub. L. 102–237, §1006(b)(1), (2), (3)(P), substituted "the Administrator" for "he" before "based", "the Administrator's" for "his", and "the Administrator" for "him" after "designated by".

Subsec. (d). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "may". 1988—Subsec. (a). Pub. L. 100–532 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "Except as is otherwise provided in this subchapter, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts."

1984—Subsec. (b), Pub. L. 98-620 struck out provisions requiring the court to advance on the docket and expedite the disposition of all cases filed pursuant to this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE OF 1984 AMENDMENT**

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

#### EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

# §136<sub>0</sub>. Imports and exports

## (a) Pesticides and devices intended for export

Notwithstanding any other provision of this subchapter, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this subchapter—

- (1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 136(p), 136(q)(1)(A), (C), (D), (E), (G), and (H), 136(q)(2)(A), (B), (C)(i) and (iii), and (D), 136e, and 136f of this title; and
- (2) in the case of any pesticide other than a pesticide registered under section 136a or sold under section 136d(a)(1) of this title, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

## (b) Cancellation notices furnished to foreign governments

Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 136a of this title and that could be used in lieu of such pesticide.

## (c) Importation of pesticides and devices

## (1) In general

The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon the Administrator's request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this subchapter, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe. The Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

#### (2) Importation of seed

Notwithstanding any other provision of law, no person is required to notify the Administrator of the arrival of a plant-incorporated protectant (as defined in section 174.3 of title 40, Code of Federal Regulations (or any successor regulation)) that is contained in a seed, if-

- (A) that plant-incorporated protectant is registered under section 136a of this title;
- (B) the Administrator has issued an experimental use permit for that plant-incorporated protectant under section 136c of this title: or
- (C) the seed is covered by a permit (as defined in part 340 of title 7, Code of Federal Regulations (or any successor regulation)) or a notification.

## (3) Cooperation

## (A) In general

In response to a request from the Administrator, the Secretary of Agriculture shall provide to the Administrator a list of seed containing plant-incorporated protectants (as defined in section 174.3 of title 40, Code of Federal Regulations (or any successor regulation)) if the importation of that seed into the United States has been approved under a permit or notification referred to in paragraph (2).

#### (B) Contents

The list under subparagraph (A) shall be provided in a form and at such intervals as may be agreed to by the Secretary and the Administrator.

## (4) Applicability

Nothing in this subsection precludes or limits the authority of the Secretary of Agriculture with respect to the importation or movement of plants, plant products, or seeds under-

- (A) the Plant Protection Act (7 U.S.C. 7701 et seq.); and
- (B) the Federal Seed Act (7 U.S.C. 1551 et seq.).

## (d) Cooperation in international efforts

#### (1) In general

The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

#### (2) Department of State expenses

Any expenses incurred by an employee of the Environmental Protection Agency who participates in any international technical, economic, or policy review board, committee, or other official body that is meeting in relation to an international treaty shall be paid by the Department of State.

#### (e) Regulations

The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) of this section.

(June 25, 1947, ch. 125, §17, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 995; amended Pub. L. 95– 396, §18(a), Sept. 30, 1978, 92 Stat. 833; Pub. L. 100–532, title VIII, §801(j), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(a)(9), (b)(2), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 110–234, title XIV, §14209(a), May 22, 2008, 122 Stat. 1463; Pub. L. 110–246, §4(a), title XIV, §14209(a), June 18, 2008, 122 Stat. 1664, 2225; Pub. L. 113–79, title X, §10008, Feb. 7, 2014, 128 Stat. 948.)

#### **EDITORIAL NOTES**

## REFERENCES IN TEXT

The Plant Protection Act, referred to in subsec. (c)(4)(A), is title IV of Pub. L. 106–224, June 20, 2000, 114 Stat. 438, which is classified principally to chapter 104 (§7701 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 7701 of this title and Tables.

The Federal Seed Act, referred to in subsec. (c)(4)(B), is act Aug. 9, 1939, ch. 615, 53 Stat. 1275, which is classified generally to chapter 37 (§1551 et seq.) of this title. For complete classification of this Act to the Code, see section 1551 of this title and Tables.

## CODIFICATION

Pub. L. 110–234 and Pub. L. 110–246 made identical amendments to this section. The amendments by Pub. L. 110-234 were repealed by section 4(a) of Pub. L. 110-246.

## **AMENDMENTS**

**2014**—Subsec. (c). Pub. L. 113–79 designated existing provisions as par. (1), inserted heading, and added pars. (2) to (4).

**2008**—Subsec. (d). Pub. L. 110–246, §14209(a), designated existing provisions as par. (1), inserted heading, and added par. (2).

1991—Subsec. (a). Pub. L. 102–237, §1006(a)(9), removed last sentence from par. (2) and placed it as a full measure sentence under par. (2).

Subsec. (c). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

**1988**—Subsec. (c). Pub. L. 100–532 substituted "prescribe. The Secretary" for "prescribe: *Provided*, That the Secretary" and "bond. All" for "bond: *And provided further*, That all".

1978—Subsec. (a). Pub. L. 95–396, §18(a)(1), amended subsec. (a) generally.

Subsec. (b). Pub. L. 95–396, §18(a)(2), inserted sentence at end relating to information to be included in notification.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 2008 AMENDMENT**

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of this title.

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE OF 1978 AMENDMENT**

Pub. L. 95–396, §18(b), Sept. 30, 1978, 92 Stat. 833, provided that: "The amendment made by subsection (a)(1) of this section [amending this section] shall become effective one hundred and eighty days after the date of enactment of this Act [Sept. 30, 1978]."

#### EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136p. Exemption of Federal and State agencies

The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this subchapter if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

(June 25, 1947, ch. 125, §18, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 995; amended Pub. L. 94–140, §8, Nov. 28, 1975, 89 Stat. 754; Pub. L. 100–532, title VIII, §801(k), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895.)

## **EDITORIAL NOTES**

## **AMENDMENTS**

**1991**—Pub. L. 102–237 substituted "the Administrator" for "he" before "determines" and "the Administrator's" for "his".

**1988**—Pub. L. 100–532 substituted "and" for "or" in section catchline, and directed that sentence beginning "The Administrator, in" be run in after first sentence beginning "The Administrator may".

**1975**—Pub. L. 94–140 inserted provision requiring Administrator to consult with Secretary of Agriculture and Governor of State concerned in determining whether an emergency situation exists.

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## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

# §136q. Storage, disposal, transportation, and recall

## (a) Storage, disposal, and transportation

#### (1) Data requirements and registration of pesticides

The Administrator may require under section 136a or 136d of this title that—

- (A) the registrant or applicant for registration of a pesticide submit or cite data or information regarding methods for the safe storage and disposal of excess quantities of the pesticide to support the registration or continued registration of a pesticide;
- (B) the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide, any container of the pesticide, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and
- (C) the registrant of a pesticide provide evidence of sufficient financial and other resources to carry out a recall plan under subsection (b), and provide for the disposition of the pesticide, in the event of suspension and cancellation of the pesticide.

## (2) Pesticides

The Administrator may by regulation, or as part of an order issued under section 136d of this title or an amendment to such an order-

- (A) issue requirements and procedures to be followed by any person who stores or transports a pesticide the registration of which has been suspended or canceled;
- (B) issue requirements and procedures to be followed by any person who disposes of stocks of a pesticide the registration of which has been suspended; and
- (C) issue requirements and procedures for the disposal of any pesticide the registration of which has been canceled.

#### (3) Containers, rinsates, and other materials

The Administrator may by regulation, or as part of an order issued under section 136d of this title or an amendment to such an order-

- (A) issue requirements and procedures to be followed by any person who stores or transports any container of a pesticide the registration of which has been suspended or canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide;
- (B) issue requirements and procedures to be followed by any person who disposes of stocks of any container of a pesticide the registration of which has been suspended, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and
- (C) issue requirements and procedures for the disposal of any container of a pesticide the registration of which has been canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide.

## (4) Container recycling

The Secretary may promulgate a regulation for the return and recycling of disposable pesticide containers used for the distribution or sale of registered pesticide products in interstate commerce. Any such regulation requiring recycling of disposable pesticide containers shall not apply to antimicrobial pesticides (as defined in section 136 of this title) or other pesticide products intended for non-agricultural uses.

## (b) Recalls

#### (1) In general

If the registration of a pesticide has been suspended and canceled under section 136d of this title, and if the Administrator finds that recall of the pesticide is necessary to protect health or the environment, the

Administrator shall order a recall of the pesticide in accordance with this subsection.

#### (2) Voluntary recall

If, after determining under paragraph (1) that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

## (3) Mandatory recall

If, after determining under paragraph (1) that a recall is necessary, the Administrator does not request the submission of a plan under paragraph (2) or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor, or seller of the pesticide, or any successor in interest to such a person.

#### (4) Recall procedure

A regulation issued under this subsection may require any person that is subject to the regulation to—

- (A) arrange to make available one or more storage facilities to receive and store the pesticide to which the recall program applies, and inform the Administrator of the location of each such facility;
- (B) accept and store at such a facility those existing stocks of such pesticide that are tendered by any other person who obtained the pesticide directly or indirectly from the person that is subject to such
- (C) on the request of a person making such a tender, provide for proper transportation of the pesticide to a storage facility; and
- (D) take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

## (5) Contents of recall plan

A recall plan established under this subsection shall include—

- (A) the level in the distribution chain to which the recall is to extend, and a schedule for recall; and
- (B) the means to be used to verify the effectiveness of the recall.

#### (6) Requirements or procedures

No requirement or procedure imposed in accordance with paragraph (2) of subsection (a) may require the recall of existing stocks of the pesticide except as provided by this subsection.

#### (c) Storage costs

## (1) Submission of plan

A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall prescribed under subsection (b) for a pesticide whose registration has been suspended and canceled shall, as soon as practicable after the suspension of the registration of the pesticide, submit to the Administrator a plan for the storage and disposal of the pesticide that meets criteria established by the Administrator by regulation.

#### (2) Reimbursement

Within a reasonable period of time after such storage costs are incurred and paid by the registrant, the Administrator shall reimburse the registrant, on request, for—

- (A) none of the costs incurred by the registrant before the date of submission of the plan referred to in paragraph (1) to the Administrator;
- (B) 100 percent of the costs incurred by the registrant after the date of submission of the plan to the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, but before the approval of the plan by the Administrator;
- (C) 50 percent of the costs incurred by the registrant during the 1-year period beginning on the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later;
- (D) none of the costs incurred by the registrant during the 3-year period beginning on the 366th day following approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later; and

(E) 25 percent of the costs incurred by the registrant during the period beginning on the first day of the 5th year following the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, and ending on the date that a disposal permit for the pesticide is issued by a State or an alternative plan for disposal of the pesticide in accordance with applicable law has been developed.

## (d) Administration of storage, disposal, transportation, and recall programs

## (1) Voluntary agreements

Nothing in this section shall be construed as preventing or making unlawful any agreement between a seller and a buyer of any pesticide or other substance regarding the ultimate allocation of the costs of storage, transportation, or disposal of a pesticide.

#### (2) Rule and regulation review

Section 136w(a)(4) of this title shall not apply to any regulation issued under subsection (a)(2) or (b).

## (3) Limitations

No registrant shall be responsible under this section for a pesticide the registration of which is held by another person. No distributor or seller shall be responsible under this section for a pesticide that the distributor or seller did not hold or sell.

#### (4) Seizure and penalties

If the Administrator finds that a person who is subject to a regulation or order under subsection (a)(2) or (b) has failed substantially to comply with that regulation or order, the Administrator may take action under section 136k or 136l of this title or obtain injunctive relief under section 136n(c) of this title against such person or any successor in interest of any such person.

#### (e) Container design

#### (1) Procedures

- (A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.
  - (B) The regulations shall ensure, to the fullest extent practicable, that the containers—
  - (i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers:
  - (ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from the containers:
    - (iii) facilitate the safe disposal of the containers; and
    - (iv) facilitate the safe refill and reuse of the containers.

#### (2) Compliance

The Administrator shall require compliance with the regulations referred to in paragraph (1) not later than 5 years after the effective date of this subsection.

## (f) Pesticide residue removal

#### (1) Procedures

- (A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.
  - (B) The regulations may—
  - (i) specify, for each major type of pesticide container, procedures and standards providing for, at a minimum, triple rinsing or the equivalent degree of pesticide removal;
  - (ii) specify procedures that can be implemented promptly and easily in various circumstances and conditions;
    - (iii) provide for reuse, whenever practicable, or disposal of rinse water and residue; and
  - (iv) be coordinated with requirements for the rinsing of containers imposed under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).
- (C) The Administrator may, at the discretion of the Administrator, exempt products intended solely for household use from the requirements of this subsection.

## (2) Compliance

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Effective beginning 5 years after the effective date of this subsection, a State may not exercise primary enforcement responsibility under section 136w-1 of this title, or certify an applicator under section 136i of this title, unless the Administrator determines that the State is carrying out an adequate program to ensure compliance with this subsection.

## (3) Solid Waste Disposal Act

Nothing in this subsection shall affect the authorities or requirements concerning pesticide containers under the Solid Waste Disposal Act (42 U.S.C. 6901).

## (g) Pesticide container study

#### (1) Study

- (A) The Administrator shall conduct a study of options to encourage or require—
  - (i) the return, refill, and reuse of pesticide containers;
- (ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and
  - (iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

## (B) In conducting the study, the Administrator shall—

- (i) consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations: and
- (ii) assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures or actions.

## (2) Report

Not later than 2 years after the effective date of this subsection, the Administrator shall submit to Congress a report describing the results of the study required under paragraph (1).

## (h) Relationship to Solid Waste Disposal Act

#### (1) In general

Nothing in this section shall diminish the authorities or requirements of the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

## (2) Antimicrobial products

A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.) shall not be subject to the provisions of subsections (a), (e), and (f), unless the Administrator determines that such product must be subject to such provisions to prevent an unreasonable adverse effect on the environment.

(June 25, 1947, ch. 125, §19, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 995; amended Pub. L. 95-396, §19, Sept. 30, 1978, 92 Stat. 833; Pub. L. 100-532, title IV, §§401-403, title VIII, §801(q)(1)(D), Oct. 25, 1988, 102 Stat. 2669, 2672, 2683; Pub. L. 104–170, title II, §225, Aug. 3, 1996, 110 Stat. 1507; Pub. L. 110– 234, title XIV, §14209(b), May 22, 2008, 122 Stat. 1463; Pub. L. 110–246, §4(a), title XIV, §14209(b), June 18, 2008, 122 Stat. 1664, 2225.)

#### **EDITORIAL NOTES**

## REFERENCES IN TEXT

The effective date of this subsection, referred to in subsecs. (e), (f)(1)(A), (2), and (g)(2), is 60 days after Oct. 25, 1988, the effective date of Pub. L. 100-532. See Effective Date of 1988 Amendment note below.

The Solid Waste Disposal Act, referred to in subsecs. (f)(1)(B)(iv), (3) and (h), is title II of Pub. L. 89–272, Oct. 20, 1965, 79 Stat. 997, as amended generally by Pub. L. 94–580, §2, Oct. 21, 1976, 90 Stat. 2795, which is classified generally to chapter 82 (§6901 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 6901 of Title 42 and Tables.

#### CODIFICATION

Pub. L. 110-234 and Pub. L. 110-246 made identical amendments to this section. The amendments by Pub. L. 110-234 were repealed by section 4(a) of Pub. L. 110-246.

## **AMENDMENTS**

2008—Subsec. (a)(4). Pub. L. 110-246, §14209(b), added par. (4).

**1996**—Subsec. (h). Pub. L. 104–170 designated existing provisions as par. (1), inserted heading, and added par. (2).

1988—Pub. L. 100–532, §401, amended section generally, in subsec. (a) substituting provisions which related to storage, disposal, and transportation, for provisions which directed Secretary to establish procedures for disposal or storage, in subsec. (b) substituting provisions which related to recalls, for provisions which directed Administrator to provide advice to Secretary of Transportation, in subsec. (c) substituting provisions which related to storage costs, for provisions which related to disposal of unused quantities, and adding subsec. (d).

Subsec. (a)(3). Pub. L. 100–532, §402, added par. (3).

Subsecs. (e), (f). Pub. L. 100-532, §403, added subsecs. (e) and (f).

Subsec. (f)(2). Pub. L. 100–532, §801(q)(1)(D), substituted "136i" for "136b".

Subsecs. (g), (h). Pub. L. 100-532, §403, added subsecs. (g) and (h).

1978—Subsec. (c). Pub. L. 95–396 added subsec. (c).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 2008 AMENDMENT**

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of this title.

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136r. Research and monitoring

#### (a) Research

The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.

## (b) National monitoring plan

The Administrator shall formulate and periodically revise, in cooperation with other Federal, State, or local agencies, a national plan for monitoring pesticides.

## (c) Monitoring

The Administrator shall undertake such monitoring activities, including, but not limited to monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this subchapter and of the national pesticide monitoring plan. The Administrator shall establish procedures for the monitoring of man and animals and their environment for incidential <sup>1</sup> pesticide exposure, including, but not limited to, the quantification of incidental human and environmental pesticide pollution and the secular trends thereof, and identification of the sources of contamination and their relationship to human and environmental effects. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.

(June 25, 1947, ch. 125, §20, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996; amended Pub. L. 95–396, §20, Sept. 30, 1978, 92 Stat. 834; Pub. L. 102–237, title X, §1006(a)(10), (b)(1), Dec. 13, 1991, 105 Stat. 1895.)

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#### **EDITORIAL NOTES**

#### **AMENDMENTS**

**1991**—Subsec. (a). Pub. L. 102–237 substituted "ensure" for "insure" and "the Administrator" for "he" before "shall conduct".

**1978**—Subsec. (a). Pub. L. 95–396, §20(1), substituted in first sentence "shall conduct research into integrated pest management in coordination with the Secretary of Agriculture" for "shall give priority to research to develop biologically integrated alternatives for pest control".

Subsec. (c). Pub. L. 95–396, §20(2), inserted provision requiring establishment of monitoring procedures and the carrying out of the activities in cooperation with other Federal, State, and local agencies.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

## **AVAILABILITY OF GRANTS**

Pub. L. 106–74, title III, Oct. 20, 1999, 113 Stat. 1081, provided in part: "That notwithstanding 7 U.S.C. 136r and 15 U.S.C. 2609, beginning in fiscal year 2000 and thereafter, grants awarded under section 20 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136r], as amended, and section 10 of the Toxic Substances Control Act [15 U.S.C. 2609], as amended, shall be available for research, development, monitoring, public education, training, demonstrations, and studies".

<sup>1</sup> So in original. Probably should be "incidental".

# §136r-1. Integrated Pest Management

The Secretary of Agriculture, in cooperation with the Administrator, shall implement research, demonstration, and education programs to support adoption of Integrated Pest Management. Integrated Pest Management is a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks. The Secretary of Agriculture and the Administrator shall make information on Integrated Pest Management widely available to pesticide users, including Federal agencies. Federal agencies shall use Integrated Pest Management techniques in carrying out pest management activities and shall promote Integrated Pest Management through procurement and regulatory policies, and other activities.

(Pub. L. 104-170, title III, §303, Aug. 3, 1996, 110 Stat. 1512.)

#### **EDITORIAL NOTES**

## CODIFICATION

Section was enacted as part of the Food Quality Protection Act of 1996, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

# §136s. Solicitation of comments; notice of public hearings

#### (a) Secretary of Agriculture

The Administrator, before publishing regulations under this subchapter, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 136w(a) of this title.

## (b) Secretary of Health and Human Services

The Administrator, before publishing regulations under this subchapter for any public health pesticide, shall solicit the views of the Secretary of Health and Human Services in the same manner as the views of the

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Secretary of Agriculture are solicited under section 136w(a)(2) of this title.

## (c) Views

In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this subchapter, the Administrator may, at the Administrator's discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as the Administrator deems proper.

## (d) Notice

In connection with all public hearings under this subchapter the Administrator shall publish timely notice of such hearings in the Federal Register.

(June 25, 1947, ch. 125, §21, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996; amended Pub. L. 94–140, §2(b), Nov. 28, 1975, 89 Stat. 752; Pub. L. 100–532, title VIII, §801(I), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 104–170, title II, §234, Aug. 3, 1996, 110 Stat. 1509.)

#### **EDITORIAL NOTES**

## **AMENDMENTS**

**1996**—Subsecs. (b) to (d). Pub. L. 104–170 added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

1991—Subsec. (b). Pub. L. 102–237 substituted "the Administrator" for "he" before "deems" and "the Administrator's" for "his".

**1988**—Pub. L. 100–532, §801(I), inserted headings for subsecs. (a) to (c).

**1975**—Subsec. (a). Pub. L. 94–140 inserted "in accordance with the procedure described in section 136w(a) of this title" after "Secretary of Agriculture".

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136t. Delegation and cooperation

## (a) Delegation

All authority vested in the Administrator by virtue of the provisions of this subchapter may with like force and effect be executed by such employees of the Environmental Protection Agency as the Administrator may designate for the purpose.

## (b) Cooperation

The Administrator shall cooperate with Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this subchapter, and in securing uniformity of regulations.

(June 25, 1947, ch. 125, §22, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 996.)

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

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# §136u. State cooperation, aid, and training

## (a) Cooperative agreements

The Administrator may enter into cooperative agreements with States and Indian tribes—

- (1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this subchapter through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this subchapter, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants-in-aid; and
- (2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agreements, to train and certify applicators consistent with the standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.

## (b) Contracts for training

In addition, the Administrator may enter into contracts with Federal, State, or Indian tribal agencies for the purpose of encouraging the training of certified applicators.

## (c) Information and education

The Administrator shall, in cooperation with the Secretary of Agriculture, use the services of the cooperative State extension services to inform and educate pesticide users about accepted uses and other regulations made under this subchapter.

(June 25, 1947, ch. 125, §23, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996; amended Pub. L. 95–396, §21, Sept. 30, 1978, 92 Stat. 834.)

#### **EDITORIAL NOTES**

## **AMENDMENTS**

**1978**—Subsec. (a). Pub. L. 95–396 extended provisions to Indian tribes, authorized annual appropriation of funds for training and certification programs, and required proportionate reduction of shares in the allocation of available funds when appropriations do not cover 50 percent of the annual costs.

Subsec. (b). Pub. L. 95–396 authorized contracts with Indian tribal agencies.

Subsec. (c). Pub. L. 95–396 substituted "shall" for "may", substituted "use" for "utilize", and "to inform and educate pesticide users about accepted uses and other regulations" for "for informing farmers of accepted uses and other regulations".

## STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# AVAILABILITY OF GRANTS FOR PESTICIDE PROGRAM DEVELOPMENT AND IMPLEMENTATION

Pub. L. 105–276, title III, Oct. 21, 1998, 112 Stat. 2499, provided in part: "That beginning in fiscal year 1999 and thereafter, pesticide program implementation grants under section 23(a)(1) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended [7 U.S.C. 136u(a)(1)], shall be available for pesticide program development and implementation, including enforcement and compliance activities".

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# §136v. Authority of States

## (a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

## (b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

#### (c) Additional uses

- (1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.
- (2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.
- (3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.
- (4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

(June 25, 1947, ch. 125, §24, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 997; amended Pub. L. 95–396, §22, Sept. 30, 1978, 92 Stat. 835; Pub. L. 100–532, title VIII, §801(m), Oct. 25, 1988, 102 Stat. 2682.)

## **EDITORIAL NOTES**

## REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(3), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

#### **AMENDMENTS**

**1988**—Pub. L. 100–532, §801(m), inserted headings for subsecs. (a) to (c) and realigned margins of pars. (1) to (4) of subsec. (c).

**1978**—Subsec. (a). Pub. L. 95–396 inserted "federally registered" before "pesticide or device". Subsec. (b). Pub. L. 95–396 substituted "labeling or packaging" and "required under" for "labeling and packaging" and "required pursuant to", respectively.

Subsec. (c)(1). Pub. L. 95–396 incorporated existing text in provisions designated par. (1) and substituted "registration for additional uses of federally registered pesticides" for "registration for pesticides".

Subsec. (c)(2). Pub. L. 95–396 incorporated existing text in provisions designated par. (2), conditioned disapproval of registration on communication of intention to disapprove and reasons

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for disapproval and provision for time to respond, and restricted authority of Administrator to prohibit or disapprove a State registration.

Subsec. (c)(3). Pub. L. 95–396 added par. (3).

Subsec. (c)(4). Pub. L. 95–396 incorporated existing text in provisions designated par. (4) and authorized suspension of registration authority of the State based on findings of inability or failure to exercise adequate controls following an indication of intention to suspend and reasons for the suspension and provision for time to respond.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

# §136w. Authority of Administrator

## (a) In general

#### (1) Regulations

The Administrator is authorized, in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, and public health pesticides.

## (2) Procedure

## (A) Proposed regulations

At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

## (B) Final regulations

At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

#### (C) Time requirements

The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

#### (D) Publication in the Federal Register

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The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

#### (3) Congressional committees

At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

## (4) Congressional review of regulations

Simultaneously with the promulgation of any rule or regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

## (b) Exemption of pesticides

The Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter.

#### (c) Other authority

The Administrator, after notice and opportunity for hearing, is authorized—

- (1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;
- (2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;
- (3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91–601) [15 U.S.C. 1471 et seq.]) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this subchapter as well as to accomplish the other purposes of this subchapter;
- (4) to specify those classes of devices which shall be subject to any provision of section 136(q)(1) or section 136e of this title upon the Administrator's determination that application of such provision is necessary to effectuate the purposes of this subchapter;
- (5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator determines that such requirement is feasible and is necessary for the protection of health and the environment; and
  - (6) to determine and establish suitable names to be used in the ingredient statement.

#### (d) Scientific advisory panel

## (1) In general

The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 136d(b) of this title and of the proposed and final form of regulations issued under subsection (a) within the same time periods as provided for the comments of the Secretary of Agriculture under such section 136d(b) and subsection (a) of this section. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 136d(b) of this title or subsection (a) of this section, as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this subchapter. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel. after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed

about:blank 96/152 action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as the Administrator deems necessary, and the Administrator shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this section shall be permanent. In performing the functions assigned by this subchapter, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978 [42 U.S.C. 4365]. Whenever the Administrator exercises authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

## (2) Science Review Board

There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. Members of the Board shall be selected in the same manner as members of temporary subpanels created under paragraph (1). Members of the Board shall be compensated in the same manner as members of the Panel.

## (e) Peer review

The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this subchapter by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification. suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts. either within or outside the Environmental Protection Agency, in the appropriate disciplines.

(June 25, 1947, ch. 125, §25, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 997; amended Pub. L. 94–140, §§2(a), 6, 7, Nov. 28, 1975, 89 Stat. 751, 753; Pub. L. 95–396, §23, Sept. 30, 1978, 92 Stat. 836; Pub. L. 96–539, §§1, 2(a), 4, Dec. 17, 1980, 94 Stat. 3194, 3195; Pub. L. 98–201, §1, Dec. 2, 1983, 97 Stat. 1379; Pub. L. 98–620, title IV, §402(4)(D), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–352, §6(i), June 27, 1988, 102 Stat. 664; Pub. L. 100–532, title VI, §§602, 605, title VIII, §801(n), Oct. 25, 1988, 102 Stat. 2678, 2679, 2683; Pub. L. 102–237, title X, §1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 104–170, title I, §104, title II, §235, Aug. 3, 1996, 110 Stat. 1490, 1509.)

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#### **EDITORIAL NOTES**

## REFERENCES IN TEXT

The Poison Prevention Packaging Act, referred to in subsec. (c)(3), probably means the Poison Prevention Packaging Act of 1970, Pub. L. 91–601, Dec. 30, 1970, 84 Stat. 1670, which is classified principally to chapter 39A (§1471 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1471 of Title 15, and Tables.

References in subsec. (c)(4) to "section 136(q)(1)" was, in the original, a reference to "paragraph 2(q)(1)" and has been editorially translated as "section 136(q)(1)" as the probable intent of Congress.

The Environmental Research, Development, and Demonstration Authorization Act of 1978, referred to in subsec. (d), is Pub. L. 95–155, Nov. 8, 1977, 91 Stat. 1257. Provisions of the Act establishing the Science Advisory Board are classified to section 4365 of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Tables.

#### **AMENDMENTS**

**1996**—Subsec. (a)(1). Pub. L. 104–170, §235, inserted ", including public health pesticides," after "various classes of pesticides" and substituted ", nonagricultural, and public health pesticides" for "and nonagricultural pesticides".

Subsec. (d). Pub. L. 104–170, §104, designated existing text as par. (1), inserted heading, and added par. (2).

**1991**—Subsec. (a)(3). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall".

Subsec. (b). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (c)(4). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c)(5). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (d). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "deems necessary" and before "shall publish".

**1988**—Subsec. (a). Pub. L. 100–532, §801(n)(1), amended heading and directed that pars. (1) to (3) be aligned at left margin with subsec. (c)(1), and that subpars. (A) to (D) of par. (2) be indented, and in par. (3) substituted "Committee on Agriculture, Nutrition, and Forestry" for "Committee on Agriculture and Forestry".

Subsec. (a)(4). Pub. L. 100–532, §605, amended par. (4) generally, substituting single unlettered par. (4) for former subpars. (A) to (E).

Pub. L. 100–352, in subpar. (É), struck out "(i)" before "Any interested" and struck out cl. (ii) which provided that notwithstanding any other provision of law, any decision on a matter certified under cl. (i) of this subparagraph be reviewable by appeal directly to the Supreme Court of the United States, with such appeal to be brought not later than 20 days after the decision of the court of appeals.

Subsec. (d). Pub. L. 100–532, §602, substituted "section shall be permanent" for "subsection shall terminate September 30, 1987".

Subsec. (e). Pub. L. 100–532, §801(n)(2), substituted "pesticide. Whenever" for "pesticide: *Provided*, That whenever".

**1984**—Subsec. (a)(4)(E)(iii). Pub. L. 98–620 struck out cl. (iii) requiring the court of appeals and the Supreme Court to advance on the docket and expedite the disposition of any matter certified under cl. (i) of this subparagraph.

1983—Subsec. (d). Pub. L. 98–201 in fourth sentence, inserted "under this subsection" after "submitted"; in eighth sentence, provided for utilization of a system of staggered terms of appointment and substituted "7" and "6" for "seven" and "six", respectively, and inserted ninth through fourteenth sentences respecting basis for selection of members, multidisciplinary representation, appointments to fill vacancies, extension of term pending filling of vacancies, appointment for unexpired term, and request for additional set of nominees from nominating

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entities; and in present eighteenth, formerly twelfth sentence, extended termination date to Sept. 30, 1987, from Sept. 30, 1981.

1980—Subsec. (a)(4). Pub. L. 96-539, §4, added par. (4).

Subsec. (d). Pub. L. 96-539, §1, inserted provisions relating to composition of subpanels and submissions to advisory panels respecting registration suspensions.

Subsec. (e). Pub. L. 96-539, §2(a), added subsec. (e).

1978—Subsec. (a)(1). Pub. L. 95–396, §23(1), required regulations to take into account differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

Subsec. (a)(2)(B), Pub. L. 95–396, §23(2), required the Administrator, before taking any final action, to consider certain factors bearing on the agricultural economy and to publish an analysis of the effect in the Federal Register.

Subsec. (d). Pub. L. 95–396, §23(3), (4), required the Administrator to solicit operating guidelines from the scientific advisory panel to improve scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out this subchapter; extended requirement of publication in the Federal Register to evaluations and recommendations of the advisory panel; authorized creation of temporary subpanels on specific projects to assist in accelerating the work of the advisory panel; set forth Sept. 30, 1981, as the termination date of the advisory panel; and required the panel to consult and coordinate its activities with the Science Advisory Board established under section 4365 of title 42.

1975—Subsec. (a)(1). Pub. L. 94–140, §2(a)(1), (2), redesignated existing provision as subsec. (a) (1) and inserted ", in accordance with the procedure described in paragraph (2)," after "is authorized".

Subsec. (a)(2). Pub. L. 94-140, §2(a)(3), added par. (2).

Subsec. (a)(3). Pub. L. 94-140, §6, added par. (3).

Subsec. (d). Pub. L. 94-140, §7, added subsec. (d).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

Amendment by Pub. L. 100-352 effective ninety days after June 27, 1988, except that such amendment not to apply to cases pending in Supreme Court on such effective date or affect right to review or manner of reviewing judgment or decree of court which was entered before such effective date, see section 7 of Pub. L. 100-352, set out as a note under section 1254 of Title 28, Judiciary and Judicial Procedure.

## **EFFECTIVE DATE OF 1984 AMENDMENT**

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

## **EFFECTIVE DATE OF 1980 AMENDMENT**

Pub. L. 96–539, §2(b), Dec. 17, 1980, 94 Stat. 3195, provided that: "The provisions of this section [amending this section] shall become effective upon publication in the Federal Register of final procedures for peer review as provided in this section, but in no event shall such provisions become effective later than one year after the date of enactment of this Act [Dec. 17, 1980]."

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

## REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of

Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

#### INFORMATION

- Pub. L. 117–328, div. HH, title VI, §707, Dec. 29, 2022, 136 Stat. 6082, provided that: "Not later than 180 days after the date of enactment of this title [Dec. 29, 2022], the Administrator of the Environmental Protection Agency shall post on a single webpage of the website of the Environmental Protection Agency aggregated information on pesticide regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seg.), including—
  - "(1) all guidance relating to risk assessment, risk mitigation, benefits assessments, and cost-benefit balancing;
  - "(2) hyperlinks to resources, including the Department of Agriculture's 'national list of allowed and prohibited substances' for organic crop and livestock production:
  - "(3) biopesticides and pesticides exempt pursuant to section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w(b)); and
  - "(4) integrated pest management principles developed under section 28(c) of such Act (7 U.S.C. 136w-3(c)), including technical assistance for implementation of those principles."

# AGRICULTURAL WORKER PROTECTION STANDARD; CERTIFICATION OF PESTICIDE **APPLICATORS**

Pub. L. 116–8, §7(a), (b), Mar. 8, 2019, 133 Stat. 578, provided that:

- "(a) In General.—Except as provided in subsection (b), during the period beginning on the date of enactment of this Act [Mar. 8, 2019] and ending not earlier than October 1, 2021, the Administrator of the Environmental Protection Agency (referred to in this section as the 'Administrator')—
  - "(1) shall carry out—
  - "(A) the final rule of the Administrator entitled 'Pesticides; Agricultural Worker Protection Standard Revisions' (80 Fed. Reg. 67496 (November 2, 2015)); and
  - "(B) the final rule of the Administrator entitled 'Pesticides; Certification of Pesticide Applicators' (82 Fed. Reg. 952 (January 4, 2017)); and
  - (2) shall not revise or develop revisions to the rules described in subparagraphs (A) and (B) of paragraph (1).
- "(b) Exceptions.—Prior to October 1, 2021, the Administrator may propose, and after a notice and public comment period of not less than 90 days, promulgate revisions to the final rule described in subsection (a)(1)(A) addressing application exclusion zones under part 170 of title 40, Code of Federal Regulations, consistent with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.)."

## **USER FEES**

Pub. L. 101-508, title I, §1204(e), Nov. 5, 1990, 104 Stat. 1388-11, provided that: "Notwithstanding any provision of the Omnibus Budget Reconciliation Act of 1990 [Pub. L. 101–508, see Tables for classification], nothing in this title or the other provisions of this Act shall be construed to require or authorize the Administrator of the Environmental Protection Agency to assess or collect any fees or charges for services and activities authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.)."

# §136w-1. State primary enforcement responsibility

#### (a) In general

For the purposes of this subchapter, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

- (1) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State to have pesticide use laws that are more stringent than this subchapter;
- (2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

## (b) Special rules

Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 136u of this title for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 136i of this title that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 136i of this title in effect on September 30, 1978, not later than six months after that date.

#### (c) Administrator

The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this subchapter. Notwithstanding the provisions of section 136(e)(1) of this title, during any period when the Administrator has such enforcement responsibility, section 136f(b) of this title shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or uses dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 136g(a) of this title shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

(June 25, 1947, ch. 125, §26, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 836; amended Pub. L. 100–532, title VIII, §801(o), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2683; Pub. L. 102–237, title X, §1006(a)(11), Dec. 13, 1991, 105 Stat. 1895.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 26 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

#### **AMENDMENTS**

1991—Subsec. (c). Pub. L. 102-237 substituted "uses" for "use".

**1988**—Subsec. (a). Pub. L. 100–532, §801(o)(1), (2), inserted heading and substituted "regulations. The Administrator" for "regulations; *Provided*, That the Administrator" in par. (1). Subsec. (b). Pub. L. 100–532, §801(o)(3), (q)(1)(D), inserted heading and substituted "136i" for "136b" in two places.

Subsec. (c). Pub. L. 100-532, §801(o)(4), inserted heading.

## STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

# §136w–2. Failure by the State to assure enforcement of State pesticide use regulations

## (a) Referral

Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this subchapter, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this subchapter. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this subchapter.

#### (b) Notice

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Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

## (c) Construction

Neither section 136w-1 of this title nor this section shall limit the authority of the Administrator to enforce this subchapter, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

(June 25, 1947, ch. 125, §27, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 837; amended Pub. L. 100–532, title VIII, §801(p), Oct. 25, 1988, 102 Stat. 2683.)

#### **EDITORIAL NOTES**

#### **PRIOR PROVISIONS**

A prior section 27 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136v of this title.

#### **AMENDMENTS**

1988—Pub. L. 100–532 inserted headings for subsecs. (a) to (c).

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

# §136w–3. Identification of pests; cooperation with Department of Agriculture's program

## (a) In general

The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.

## (b) Pest control availability

#### (1) In general

The Administrator, in cooperation with the Secretary of Agriculture, shall identify—

- (A) available methods of pest control by crop or animal;
- (B) minor pest control problems, both in minor crops and minor or localized problems in major crops; and
- (C) factors limiting the availability of specific pest control methods, such as resistance to control methods and regulatory actions limiting the availability of control methods.

## (2) Report

The Secretary of Agriculture shall, not later than 180 days after November 28, 1990, and annually thereafter, prepare a report and send the report to the Administrator. The report shall—

- (A) contain the information described in paragraph (1);
- (B) identify the crucial pest control needs where a shortage of control methods is indicated by the information described in paragraph (1); and
- (C) describe in detail research and extension efforts designed to address the needs identified in subparagraph (B).

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## (c) Integrated pest management

The Administrator, in cooperation with the Secretary of Agriculture, shall develop approaches to the control of pests based on integrated pest management that respond to the needs of producers, with a special emphasis on minor pests.

## (d) Public health pests

The Administrator, in coordination with the Secretary of Agriculture and the Secretary of Health and Human Services, shall identify pests of significant public health importance and, in coordination with the Public Health Service, develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance.

(June 25, 1947, ch. 125, §28, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 838; amended Pub. L. 101–624, title XIV, §1495, Nov. 28, 1990, 104 Stat. 3629; Pub. L. 104–127, title VIII, §862(b)(1), Apr. 4, 1996, 110 Stat. 1174; Pub. L. 104–170, title II, §236, Aug. 3, 1996, 110 Stat. 1509.)

#### **EDITORIAL NOTES**

## **AMENDMENTS**

**1996**—Subsec. (b)(2)(A). Pub. L. 104–127 struck out "and the information required by section 5882 of this title" after "paragraph (1)".

Subsec. (d). Pub. L. 104-170 added subsec. (d).

**1990**—Pub. L. 101–624 designated existing provisions as subsec. (a) and added subsecs. (b) and (c).

# §136w-4. Omitted

#### **EDITORIAL NOTES**

#### CODIFICATION

Section, act June 25, 1947, ch. 125, §29, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 838, which required the Administrator of the Environmental Protection Agency to submit an annual report to Congress relating to applications filed for conditional registration under section 136a(c)(7)(B), (C) of this title, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 164 of House Document No. 103–7.

# §136w–5. Minimum requirements for training of maintenance applicators and service technicians

Each State may establish minimum requirements for training of maintenance applicators and service technicians. Such training may include instruction in the safe and effective handling and use of pesticides in accordance with the Environmental Protection Agency approved labeling, and instruction in integrated pest management techniques. The authority of the Administrator with respect to minimum requirements for training of maintenance applicators and service technicians shall be limited to ensuring that each State understands the provisions of this section.

(June 25, 1947, ch. 125, §30, as added Pub. L. 104–170, title I, §121(2), Aug. 3, 1996, 110 Stat. 1492.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 30 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

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# §136w–6. Environmental Protection Agency minor use program

- (a) The Administrator shall assure coordination of minor use issues through the establishment of a minor use program within the Office of Pesticide Programs. Such office shall be responsible for coordinating the development of minor use programs and policies and consulting with growers regarding minor use issues and registrations and amendments which are submitted to the Environmental Protection Agency.
- (b) The Office of Pesticide Programs shall prepare a public report concerning the progress made on the registration of minor uses, including implementation of the exclusive use as an incentive for registering new minor uses, within 3 years of the passage of the Food Quality Protection Act of 1996.

(June 25, 1947, ch. 125, §31, as added Pub. L. 104–170, title II, §210(i), Aug. 3, 1996, 110 Stat. 1500.)

#### **EDITORIAL NOTES**

## REFERENCES IN TEXT

The passage of the Food Quality Protection Act of 1996, referred to in subsec. (b), probably means the date of enactment of Pub. L. 104–170, which was approved Aug. 3, 1996.

## **PRIOR PROVISIONS**

A prior section 31 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

# §136w–7. Department of Agriculture minor use program

#### (a) In general

The Secretary of Agriculture (hereinafter in this section referred to as the "Secretary") shall assure the coordination of the responsibilities of the Department of Agriculture related to minor uses of pesticides, including—

- (1) carrying out the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e))  $\frac{1}{2}$  and the national pesticide resistance monitoring program established under section 1651  $\frac{1}{2}$  of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5882);
  - (2) supporting integrated pest management research;
  - (3) consulting with growers to develop data for minor uses; and
- (4) providing assistance for minor use registrations, tolerances, and reregistrations with the Environmental Protection Agency.

## (b) Minor use pesticide data and revolving fund

## (1) Minor use pesticide data

#### (A) Grant authority

The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed  $\frac{1}{2}$  of the cost of the project for which the grant is made.

## (B) Applicants

Any person who wants to develop data to support minor use pesticide registrations and reregistrations may apply for a grant under subparagraph (A). Priority shall be given to an applicant for such a grant who does not directly receive funds from the sale of pesticides registered for minor uses.

## (C) Data ownership

Any data that is developed under a grant under subparagraph (A) shall be jointly owned by the Department of Agriculture and the person who received the grant. Such a person shall enter into an agreement with the Secretary under which such person shall share any fee paid to such person under section 136a(c)(1)(F) of this title.

## (2) Minor Use Pesticide Data Revolving Fund

## (A) Establishment

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There is established in the Treasury of the United States a revolving fund to be known as the Minor Use Pesticide Data Revolving Fund. The Fund shall be available without fiscal year limitation to carry out the authorized purposes of this subsection.

## (B) Contents of the Fund

There shall be deposited in the Fund—

- (i) such amounts as may be appropriated to support the purposes of this subsection; and
- (ii) fees collected by the Secretary for any data developed under a grant under paragraph (1)(A).

## (C) Authorizations of appropriations

There are authorized to be appropriated for each fiscal year to carry out the purposes of this subsection \$10,000,000 to remain available until expended.

(June 25, 1947, ch. 125, §32, as added Pub. L. 104–170, title II, §210(j), Aug. 3, 1996, 110 Stat. 1501.)

## **EDITORIAL NOTES**

## REFERENCES IN TEXT

Section 2 of Public Law 89–106, referred to in subsec. (a)(1), was formerly classified to secton 450i of this title prior to editorial reclassification and renumbering as section 3157 of this title. Section 1651 of the Food, Agriculture, Conservation, and Trade Act of 1990, referred to in subsec. (a)(1), was classified to section 5882 of this title prior to repeal by Pub. L. 104-127, title VIII, §862(a), Apr. 4, 1996, 110 Stat. 1174.

<sup>1</sup> See References in Text note below.

# §136w–8. Pesticide registration service fees

## (a) Definition of costs

In this section, the term "costs", when used with respect to review and decisionmaking pertaining to an application for which registration service fees are paid under this section, means—

- (1) costs to the extent that—
- (A) officers and employees provide direct support for the review and decisionmaking for covered pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses;
- (B) persons and organizations under contract with the Administrator engage in the review of the applications, and corresponding risk and benefits information and assessments; and
- (C) advisory committees and other accredited persons or organizations, on the request of the Administrator, engage in the peer review of risk or benefits information associated with covered pesticide applications;
- (2) costs of management of information, and the acquisition, maintenance, and repair of computer and telecommunication resources (including software), used to support review of pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses; and
- (3) costs of collecting registration service fees under subsections (b) and (c) and reporting, auditing, and accounting under this section.

#### (b) Fees

## (1) In general

Effective beginning on the effective date of the Pesticide Registration Improvement Act of 2003, the Administrator shall assess and collect covered pesticide registration service fees in accordance with this section.

## (2) Covered applications

#### (A) In general

An application for the registration of a pesticide covered by this subchapter that is received by the Administrator on or after the effective date of the Pesticide Registration Improvement Act of 2003 or for any other action covered by a table specified in paragraph (3)(B) shall be subject to a registration service fee under this section.

## (B) Existing applications

#### (i) In general

Subject to clause (ii), an application for the registration of a pesticide that was submitted to the Administrator before the effective date of the Pesticide Registration Improvement Act of 2003 and is pending on that effective date shall be subject to a service fee under this section if the application is for the registration of a new active ingredient that is not listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency.

#### (ii) Tolerance or exemption fees

The amount of any fee otherwise payable for an application described in clause (i) under this section shall be reduced by the amount of any fees paid to support the related petition for a pesticide tolerance or exemption under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

#### (C) Documentation

An application subject to a registration service fee under this section shall be submitted with documentation certifying—

- (i) payment of the registration service fee; or
- (ii) payment of at least 25 percent of the registration service fee and a request for a waiver from or reduction of the remaining amount of the registration service fee.

## (D) Payment

The registration service fee required under this subsection shall be due upon submission of the application.

## (E) Applications subject to additional fees

An application may be subject to additional fees if—

- (i) the applicant identified the incorrect registration service fee and decision review period:
- (ii) after review of a waiver request, the Administrator denies the waiver request; or
- (iii) on completion of, where appropriate, the initial screening of the contents of the application or the preliminary technical screening of the application, the Administrator determines that a different registration service fee and decision review period apply to the application.

#### (F) Effect of failure to pay fees

The Administrator shall reject any application submitted without the required registration service fee.

## (G) Non-refundable portion of fees

#### (i) In general

The Administrator shall retain 25 percent of the applicable registration service fee.

#### (ii) Limitation

Any waiver, refund, credit or other reduction in the registration service fee shall not exceed 75 percent of the registration service fee.

#### (H) Collection of unpaid fees

In any case in which the Administrator does not receive payment of a registration service fee (or applicable portion of the registration service fee) by the date that is 30 days after the fee is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

#### (3) Schedule of covered applications and other actions and their registration service fees

## (A) Data evaluation records

At the decision review time under a fee table specified in subparagraph (B) or as agreed upon under subsection (f)(5), for each covered application under a fee table specified in such subparagraph (B), the Administrator shall—

- (i) complete data evaluation records for studies submitted by the applicant in support of the application: and
- (ii) release those data evaluation records to the applicant, using appropriate protections for confidential business information.

#### (B) Schedule, actions, and fees

Subject to paragraph (6), the schedule of registration applications and other covered actions and their corresponding registration service fees shall be as follows:

# TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS

EPA No	New CR No	Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
R010	1	New Active Ingredient, Food use. (2)(3)	36	1,079,356
R020	2	New Active Ingredient, Food use; reduced risk. (2)(3)	27	899,464
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	18	662,883
R060	4	New Active Ingredient, Non-food use; outdoor. (2)(3)	30	749,886
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk. (2)(3)	24	624,905
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	16	463,930
R110	7	New Active Ingredient, Non-food use; indoor. (2)(3)(4)	20	417,069
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)(4)	14	347,556
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	18	261,322
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3)	27	454,526
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; non-food use, not requiring a tolerance. (2)(3)	27	676,296
R126 (r	12 new)	New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (2)(3)	31	743,925
R125	13	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	16	463,930

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the

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Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES

EPA No	New CF No	R Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
R130	14	First food use; indoor; food/food handling. (2)(3)(5)	23	274,388
R140	15	Additional food use; Indoor; food/food handling. (3)(4)(5)	17	64,028
R150	16	First food use. (2)(3)(5)	23	454,490
R155	17	First food use, Experimental Use Permit application; active ingredient registered for non-food use. (3)(4)(5)	21	378,742
R160	18	First food use; reduced risk. (2)(3)(5)	18	378,742
R170	19	Additional food use. (3)(4)(5)	17	113,728
R175	20	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3)(4)(5)	14	94,774
R180	21	Additional food use; reduced risk. (3)(4)(5)	12	94,774
R190	22	Additional food uses; 6 or more submitted in one application. (3)(4)(5)	17	682,357
R200	23	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4)(5)	12	568,632
R210	24	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4)(5)	12	70,210
R220	25	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4)(5)	6	28,434
R230	26	Additional use; non-food; outdoor. (3)(4)(5)	16	45,453
R240	27	Additional use; non-food; outdoor; reduced risk. (3)(4)(5)	10	37,878
R250	28	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)(5)	6	28,434
R251	29	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3)(5)	8	28,434
R260	30	New use; non-food; indoor. (3)(4)(5)	12	21,954
R270	31	New use; non-food; indoor; reduced risk. (3)(4)(5)	9	18,296
R271	32	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)(5)	6	13,940
R273	33	Additional use; seed treatment only; use not requiring a new tolerance; includes crops with established tolerances (e.g., for soil or foliar application). (3)(4)(5)	12	72,302
R274	34	Additional use; seed treatment only; 6 or more submitted in one application; uses not requiring new tolerances; includes crops with established tolerances (e.g., for soil or foliar application). (3)(4)(5)	12	433,793
R276 (r	35 new)	Additional use, seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (3)(4)(5)	14	79,560

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R277 36 Additional use, seed treatment only; 6 or more submitted in one (new) application; limited uptake into raw agricultural commodities; use requiring a tolerance. (3)(4)(5)

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(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

- (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (4) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.
- (5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

EPA No	New CR No	Action	Decision Review Time (Months)	Registration Service Fee (\$)
R280	37	Establish tolerances for residues in imported commodities; new active ingredient or first food use. (2)	22	457,311
R290	38	Establish tolerances for residues in imported commodities; Additional new food use.	16	91,465
R291	39	Establish tolerances for residues in imported commodities; additional food uses; 6 or more crops submitted in one petition.	16	548,773
R292	40	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex Maximum Residue Limits; domestic or import; applicant-initiated.	12	64,987
R293	41	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	13	76,656
R294	42	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	13	459,922
R295	43	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3)(4)	16	94,774
R296	44	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3)(4)	16	568,632
R297	45	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	12	389,897
R298	46	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3)(4)	14	83,940
R299	47	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3)(4)	14	408,853
R281 (r	48 new)	Establish tolerances for residues in imported commodities; additional new food use; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	68,599
R282 (r	49 new)	Establish tolerances for residues in imported commodities; additional new food uses; 6 or more crops submitted in one petition; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	411,580

<sup>(1)</sup> A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

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<sup>(2)</sup> All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and

decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (4) Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.

TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS

EPA No	New CR No.		Decision Review Time (Months) (1)	Registration Service Fee (\$)
R300	50	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or child-resistant packaging — only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)	4	2,270
R301	51	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	2,720
R310	52	New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:	7	10,466
	2	l. product chemistry and/or 2. acute toxicity and/or I.[sic] Child-resistant packaging and/or I. pest(s) requiring efficacy – for up to 3 target pests. (2)(3)(4)		
R314	53	New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product;	8	12,364

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active ingredient(s) including products containing two or more

10

21.932

4. pest(s) requiring efficacy - for 4 to 7 target pests. (2)(3)(4)

59 New end-use or manufacturing-use product with registered source(s) of

R317

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	registered active ingredients previously combined in other registered	
products; excludes products requiring or citing an animal safety study;		
and requires review of data and/or waivers for only:		

1. product chemistry and/or

- 2. acute toxicity and/or
- 3. child resistant packaging and/or

	4. Pest(s) requiring efficacy - for greater than 7 target pests, (2)(3)(4)		
R320 60	New product; new physical form; requires data review in science divisions. (2)(3)(5)	12	18,958
R331 61	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2)(3)	3	3,627
R332 62	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2)(3)	24	405,919
R333 63	New product; manufacturing-use product or end-use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2)(3)	11	28,434
R334 64	New product; manufacturing-use product or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2)(3)	12	33,108
R361 65 (new)	new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:  1. product chemistry and/or 2. acute toxicity and/or	12	23,400
	<ol> <li>Child resistant packaging and/or</li> <li>pest(s) requiring efficacy – for more than 7 target pests. (2)(3)(4)</li> </ol>		
R362 66 (new)	New end-use product containing four or more registered active	13	25,350
	<ol> <li>acute toxicity and/or</li> <li>Child resistant packaging and/or</li> <li>pest(s) requiring efficacy – for more than 7 target pests. (2)(3)(4)</li> </ol>		
R363 67 (new)	New product; repack of identical registered manufacturing-use product	6	7,800

<sup>(1)</sup> A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

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<sup>(2)</sup> An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

<sup>(3)</sup> Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-

stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

- (4) For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.
- (5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 5. — REGISTRATION DIVISION (RD) — AMENDMENTS

EPA No	New CF No	R Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
R340	68	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests; excludes products requiring or citing an animal safety study. (2)(3)	4	7,150
R341	69	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests; excludes products requiring or citing an animal safety study. (2)(3)	6	8,584
R345		Amending on-animal products previously registered, with the submission of data and/or waivers for only:  1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging. (2)(3)(4)	7	12,643
R350	71	Amendment requiring data review in science divisions (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or Preharvest Interval, or use rate, or number of applications; or add aerial application; or modify Ground Water/Surface Water advisory statement). (2)(3)(5)	9	18,958
R351	72	Amendment adding a new unregistered source of active ingredient. (2) (3)	8	18,958
R352	73	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2)(3)	8	18,958
R371	74	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	14,463

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- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (4) For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.
- (5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS

EPA No	New CF No	Action Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
R124	75	Conditional Ruling on Pre-application Study Waivers; applicant-initiated.	6	3,627
R272	76	Review of Study Protocol applicant-initiated; excludes Data Analysis Reporting Tool, pre-registration conference, Rapid Response review, developmental neurotoxicity protocol review, protocol needing Human Studies Review Board review, companion animal safety protocol.	3	3,627
R275	77	Rebuttal of Agency reviewed protocol, applicant initiated.	3	3,627
R278 (r	78 new)	Review of Protocol for companion animal safety study.	5	4,927
R279 (r	79 new)	Comparative product determination for reduced risk submission, applicant initiated; submitted before application for reduced risk new active ingredient or reduced risk new use.	3	5,200

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(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

EPA No		Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
A380	80	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2)(3)(4)	26	227,957
A390	81	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2)(3)(4)	26	329,265
A410	82	New Active Ingredient Non-food use. (2)(3)(4)	23	278,659
A431	83	New Active Ingredient, Non-food use; low-risk. (2)(3)(4)	14	114,984

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agencystamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the
- (4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES

EPA	New	Action Decision	Registration
No	CR	Review	Service
	No.	Time	Fee

			(Months) (1)	(\$)
A440	84	New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2)(3)(4)(6)	23	45,737
A441	85	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4) (5)(6)	23	164,639
A450	86	New use, Direct food use, establish tolerance or tolerance exemption. (2)(3)(4)(6)	23	137,198
A451	87	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4) (5)(6)	22	261,333
A500	88	New use, non-food. (4)(5)(6)	15	45,737
A501	89	New use, non-food; 6 or more submitted in one application. (4)(5)(6)	17	109,764

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.
- (3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.
- (4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to

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submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS

EPA No	New CR No	Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
A530	90	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)	4	1,833
A531	91	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	2,616
A532	92	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2)(3)	5	7,322
A550	93	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5)	9	18,958
A560	94	New manufacturing-use product; registered active ingredient; selective data citation. (2)(3)	6	18,054
A565	95	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2)(3)	18	26,135
A572	96 I	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or use rate). (2)(3)(4)(7)	9	18,958
A460 (r	97 new)	New end-use product; FIFRA §2(mm) uses only; 0 to 10 public health organisms. (2)(3)(5)(6)	5	7,322
A461 (r	98 new)	New end-use product; FIFRA §2(mm) uses only; 11 to 20 public health organisms. (2)(3)(5)(6)	6	10,158
A462 (r	99 new)	New end-use product; FIFRA §2(mm) uses only; 21 to 30 public health organisms. (2)(3)(5)(6)	7	12,995
A463 (r	100 new)	New end-use product; FIFRA §2(mm) uses only; 31 to 40 public health organisms. (2)(3)(5)(6)	9	15,831
A464 (r	101 new)	New end-use product; FIFRA §2(mm) uses only; 41 to 50 public health organisms. (2)(3)(5)(6)	10	18,668
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- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.
- (5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.
- (6) Once an application for an amendment or a new product with public health organisms has been submitted and classified into any of categories A460 through A465 or A470 through A475, additional organisms submitted for the same product before the first application is granted will result in combination and reclassification of both the original and subsequent submissions into the appropriate new category based on the sum of the number of organisms in both submissions. Submission of additional organisms would result in a new PRIA start date and may require additional fees to meet the fee of a new category.
- (7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

EPA	New	Action Decision	Registration
No	CR	Review	Service
	No.	Time	Fee

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		Exhibit	(Months) (1)	(\$)
A520	109	Experimental Use Permit application, non-food use. (2)(3)	9	9,151
A521	110	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 1.	6	6,776
A522	111	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 2.	12	17,424
A537	112	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	219,512
A538	113	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	137,198
A539	114	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	15	132,094
A529	115	Amendment to Experimental Use Permit; requires data review or risk assessment. (2)(3)	9	16,383
A523	116	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	17,424
A571	117	Science reassessment: refined ecological risk, and/or endangered species; applicant-initiated. (3)	18	137,198
A533	118	Exemption from the requirement of an Experimental Use Permit. (2)	4	3,559
A534	119	Rebuttal of Agency reviewed protocol, applicant initiated.	4	6,776
A535	120	Conditional ruling on pre-application study waiver or data bridging argument; applicant-initiated.	6	3,454
A536	121	Conditional ruling on pre-application direct food, indirect food, nonfood use determination; applicant-initiated.	4	3,559
A575 (r	122 new)	Efficacy similarity determination; if two products can be bridged or if confirmatory efficacy data are needed.	4	3,389

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- 3) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

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## TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE **INGREDIENTS**

EPA No	New CR No.	· · · · · · · · · · · · · · · · · · ·	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B580	123	New active ingredient; petition to establish a tolerance. (2)(3)(4)	22	73,173
B590	124	New active ingredient; petition to establish a tolerance exemption. (2) (3)(4)	20	45,737
B600	125 N	New active ingredient; no change to a permanent tolerance or tolerance exemption (includes non-food uses). (2)(3)(4)	15	27,443
B610	126	New active ingredient; Experimental Use Permit application; petition to establish a permanent or temporary tolerance or temporary tolerance exemption. (3)(4)	12	18,296
B620	127	New active ingredient; Experimental Use Permit application; non-food use (includes crop destruct). (3)(4)	9	9,151

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agencystamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 12. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW USES

EPA No	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B630	128	First food use; petition to establish/amend a tolerance exemption. (2) (4)(5)	13	18,296
B640	129	First food use; petition to establish/amend a tolerance. (2)(4)(5)	19	27,443
B644	130	New use, no change to an established tolerance or tolerance exemption (includes non-food uses). (3)(4)(5)	8	18,296
B645	131	New use; Experimental Use Permit; petition to establish a permanent or temporary tolerance or tolerance exemption. (4)(5)	12	18,296
B646	132	New use; Experimental Use Permit; non-food use (includes crop destruct). (4)(5)	7	9,151

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.
- (3) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.
- (4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described

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- in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS

EPA No		R Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B660	133	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or submission of product chemistry data only). (2)(3)	6	1,833
B670	134	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific Data Requirements. (2)(3)	9	7,322
B672	135	New product; unregistered source of at least one active ingredient (or registered source with new generic data package); no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (2)(3)	15	13,069
B673	136	New product; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency; requires an Agency determination that the cited data support the new product. (2)(3)	12	7,322
B674	137	New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses only. (2)(3)	4	1,833
B677	138	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only:	12	12,643
		product chemistry and/or		
		2. acute toxicity and/or		
		3. public health pest efficacy and/or		
		4. animal safety studies and/or 5. child resistant packaging (2)(3)		
		5. child resistant packaging. (2)(3)		

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agencystamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and reguests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described

in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS

EPA No	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B621	139	Amendment; Experimental Use Permit; no change to an established temporary or permanent tolerance or tolerance exemption. (3) (4)	7	7,322
B622	140	Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance exemption. (3)(4)	11	18,296
B641	141	Amendment; changes to an established tolerance or tolerance exemption. (4)	13	18,296
B680	142	Amendment; registered sources of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption; requires data submission. (2)(3)	5	7,322
B681	143	Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data submission. (2)(3)	7	8,714
B683	144	Amendment; no change to an established tolerance or tolerance exemption; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to Restricted Entry Interval, Personal Protective Equipment, Preharvest Interval). (2)(3)	6	7,322
B684	145	Amending non-food animal product that includes submission of target animal safety data; previously registered. (2)(3)	8	12,643
B685	146	Amendment; add a new biochemical unregistered source of active ingredient or a new microbial production site; requires submission of analysis of samples data and source/production site-specific manufacturing process description. (3)	5	7,322

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fasttrack amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.
- (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agencystamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using quidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)

EPA No		R Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B690	147	SCLP; new active ingredient; food or non-food use. (2)(6)(7)	7	3,662
B700	148	SCLP; Experimental Use Permit application; new active ingredient or new use. (6)(7)	7	1,833
B701	149	SCLP; Extend or amend Experimental Use Permit. (6)(7)	4	1,833
B710	150	SCLP; new product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or only product chemistry data); (Includes 100% re-pack; repack of registered end-use product as a manufacturing-use product). (3)(6)	4	1,833
B720	151	SCLP; new product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption (including nonfood); Must address Product-Specific Data Requirements. (3)(6)	5	1,833
B721	152	SCLP: new product; unregistered source of active ingredient; no change in an established tolerance or tolerance exemption (including nonfood); must address Product-Specific and Generic Data Requirements.  (3)(6)	7	3,836
B722	153	SCLP; new use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6)(7)	7	3,552
B730	154	SCLP; amendment requiring data submission. (4)(6)	5	1,833

<sup>(1)</sup> A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

<sup>(2)</sup> All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

<sup>(3)</sup> An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

<sup>(4) (</sup>a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fasttrack amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to

registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

- (5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.
- (6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — OTHER ACTIONS

EPA No	New CR No.	2 1011011	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B614	155	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time.	3	3,627
B682	156	Protocol review; applicant initiated; excludes time for Human Studies Review Board review (Includes rebuttal of protocol review).	3	3,487
B616 (n	157 new)	Pre-application; Conditional Ruling on a non-food use determination.	5	4,715
B617 (n	158 new)	Pre-application; biochemical classification determination.	5	4,715

<sup>(1)</sup> A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

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# TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)

EPA No	New CR No	Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
B740		Experimental Use Permit application; no petition for tolerance/tolerance exemption; includes:  1. non-food/feed use(s) for a new (2) or registered (3) PIP (12);  2. food/feed use(s) for a new or registered PIP with crop destruct;  3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4)(5)(12)	9	137,198
B750	160	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4)(12)	12	182,927
B771	161	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (5)(12)	13	182,927
B772	162	Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B773	163	Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B780	164	Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption. (5)(12)(14)	16	228,657
B800	165	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5)(12) (14)	17	246,949
B820	166	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (5) (12)(14)	19	292,682
B851	167	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	182,927
B870	168	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4)(12)(14)	9	54,881
B880	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5)(6)(7)(12)(14)	9	45,737
B883	170	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5)(8) (12)(14)	13	182,927
B884	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (5) (8)(12)(14)	19	228,657
B885	172	Registration application; registered (2) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a	6	45,737

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	permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9)(12)	o 1, pg. 120 o.	102
B890 173	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5)(12)(14)	9	91,465
B900 174	an IRM plan, or adding an insect to be controlled. (5)(10)(11)(12)	6	18,296
B902 175	PIP Protocol review.	3	9,151
B903 176	Inert ingredient permanent tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	12	91,465
B904 177	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	12	182,927
B905 178	FIFRA Scientific Advisory Panel Review.	6	91,465
B906 179	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	9	45,733
B907 180	Petition to establish a permanent tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	9	18,296
B909 181 (new)	PIP tolerance exemption determination; applicant-initiated; request to determine if an existing tolerance exemption applies to a PIP.	6	18,296
B910 182 (new)	Biotechnology Notification for small-scale field testing of genetically engineered microbes.	3	9,151
B921 183 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B921 fee toward registration application for the new active ingredient that follows (B922). (5)(12)(13)	12	182,927
B922 184 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5)(12)(13)(14)	16	228,657
B923 185 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B923 fee toward registration application for the new active ingredient that follows (B924). (5)(12) (13)(14)	15	228,658
B924 186 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5)(12)(13)(14)	19	292,682
B925 187 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed; credit 75% of B925 fee toward registration application for the new active ingredient that follows (B926). (5)(12)	11	27,452

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B926 188 (new)	Registration application; new active ingredient; exogenous applications	17	82,329
B927 189 (new)	· · · · · · · · · · · · · · · · · · ·	14	54,889
B928 190 (new)		22	137,210
B929 191 (new)		10	7,322
B930 192 (new)	11	3	18,296
B931 193 (new)	11	9	45,737
B932 194 (new)		6	18,296

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
  - (2) "New PIP" means a PIP with an active ingredient that has not been registered.
  - (3) "Registered PIP" means a PIP with an active ingredient that is currently registered.
- (4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn.
- (5) If, during review of the application, it is determined that review by the FIFRA Scientific Advisory Panel (SAP) is needed, the applicant will submit an application for category B905, which will be processed concurrently, and the decision review time for both applications will be the longer of the two associated applications. The scientific data involved in this category are complex. EPA often seeks technical advice from the SAP on risks that pesticides pose to wildlife, farm workers, pesticide applicators, non-target species, insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed.
  - (6) Registered PIPs stacked through conventional breeding.
- (7) Deployment of a registered PIP with a different Insecticide Resistance Management (IRM) plan (e.g., seed blend).
- (8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.
  - (9) Application can be submitted prior to or concurrently with an application for commercial registration.
  - (10) For example, IRM plan modifications that are applicant-initiated.
- (11) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such

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as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

- (12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agencystamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
- (13) This category does not include genetic modifications in animals not intended for use as a pesticide, e.g., genetic modifications in animals intended for food use or animals intended for use as companion animals.
- (14) If the Administrator determines that endangered species analysis is required for this action, using quidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 18. — INERT INGREDIENTS

EPA No		R Action	Decision Review Time (Months) (1)	Registration Service Fee (\$)
1001	195	Approval of new food use inert ingredient. (2)(3)	15	38,698
1002	196	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	13	10,750
1003	197	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	11	4,742
1004	198	Approval of new non-food use inert ingredient. (2)	6	15,803
1005	199	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	7,903
1006	200	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	4	4,742
1007	201	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	5	2,371
1008	202	Approval of new or amended polymer inert ingredient, food use. (2)	7	5,374
1009	203	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	4,427
1010	204	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	7	2,371
I011	205	Approval of new food use safener with tolerance or exemption from tolerance. (2)	26	856,631
1012	206	Approval of new non-food use safener. (2)	21	595,147
1013	207	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	17	90,260
I014	208	Approval of additional non-food use for previously approved safener. (2)	15	36,074
I015	209	Approval of new generic data for previously approved food use safener. (2)	26	386,589
1016	210	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	15	79,942

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1017 211	Add new source of previously approved safener.	8	18,958
(new)			
1018 212	Petition to add one approved inert ingredient (CASRN) to the	3	2,371
(new)	Commodity Inert Ingredient List: no data. (4)		

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.
- (3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.
  - (4) Due to low fee and short time frame this category is not eligible for small business waivers.

TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No	New CR No.		Decision Review Time (Months) (1)	Registration Service Fee (\$)
M001	213	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of a currently registered active ingredient.	14	11,378
M002	214	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (2)	14	11,378
M003	215	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months.  Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA §25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active .ingredients. (3)	12	91,651
M004	216	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months.  Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA §25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	18	91,651
M005	217 N	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (4)(5)(6)	9	31,604
M006	218	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (7)	1	398
M007	219	Request to extend Exclusive Use of data as provided by FIFRA Section $3(c)(1)(F)(ii)$ .	12	7,903
M008	220	Request to grant Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(II)(2) determination is required.	15	2,371
M009	221	Non-FIFRA Regulated Determination; applicant-initiated, per product.	6	3,389

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M010 222	Conditional ruling on pre-application, product substantial similarity.	4	3,389
M011 223	Label amendment to add the DfE logo; requires data review; no other label changes. (8)	4	5,230
M012 224 (new)	, , , , , , , , , , , , , , , , , , ,	1	398
M013 225 (new)	, 11	18	284,144
M014 227 (new)	''	8	17,424

- (1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.
- (2) Any other covered application that is associated with and dependent on the review by the Human Studies Review Board will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.
- (3) Any other covered application that is associated with and dependent on the FIFRA Scientific Advisory Panel review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.
- (4) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.
- (5) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.
- (6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
  - (7) Due to low fee and short time frame this category is not eligible for small business waivers.
- (8) This category includes amendments the sole purpose of which is to add "Design for the Environment" (DfE) (or equivalent terms that do not use "safe" or derivatives of "safe") logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA.

## (4) Pending pesticide registration applications

#### (A) In general

An applicant that submitted a registration application to the Administrator before the effective date of the Pesticide Registration Improvement Act of 2003, but that is not required to pay a registration service fee under paragraph (2)(B), may, on a voluntary basis, pay a registration service fee in accordance with paragraph (2)(B).

#### (B) Voluntary fee

The Administrator may not compel payment of a registration service fee for an application described in subparagraph (A).

## (C) Documentation

An application for which a voluntary registration service fee is paid under this paragraph shall be submitted with documentation certifying—

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- (i) payment of the registration service fee; or
- (ii) a request for a waiver from or reduction of the registration service fee.

## (5) Resubmission of covered applications

If a covered application is submitted by a person that paid the fee for the application under paragraph (2), is determined by the Administrator to be complete, and is not approved or is withdrawn (without a waiver or refund), the submission of the same covered application by the same person (or a licensee, assignee, or successor of the person) shall not be subject to a fee under paragraph (2).

## (6) Fee adjustment

#### (A) In general

Subject to the following sentence, effective for a covered application received during the period beginning on October 1, 2024, and ending on September 30, 2026, the Administrator may increase by 5 percent the registration service fee payable for the application under paragraph (3). No adjustment may be made under the preceding sentence until the date on which the Administrator begins to implement clauses (i) and (ii) of subsection (k)(2)(A).

#### (B) Additional adjustment

Subject to the following sentence, effective for a covered application received on or after October 1, 2026, the Administrator may increase by an additional 5 percent the registration service fee in effect as of September 30, 2026. No adjustment may be made under the preceding sentence until the date on which the Administrator begins to implement any recommendations for process improvements contained in the report under subsection (c)(4), as appropriate.

## (C) Publication

The Administrator shall publish in the Federal Register the service fee schedules revised pursuant to this paragraph.

#### (7) Waivers and reductions

## (A) In general

An applicant for a covered application may request the Administrator to waive or reduce the amount of a registration service fee payable under this section under the circumstances described in subparagraphs (D) through (G), except that no waiver or fee reduction shall be provided in connection with a request for a letter of certification (including a Gold Seal letter and a Certificate of Establishment).

#### (B) Documentation

#### (i) In general

A request for a waiver from or reduction of the registration service fee shall be accompanied by appropriate documentation demonstrating the basis for the waiver or reduction.

#### (ii) Certification

The applicant shall provide to the Administrator a written certification, signed by a responsible officer, that the documentation submitted to support the waiver or reduction request is accurate.

#### (iii) Inaccurate documentation

An application shall be subject to the applicable registration service fee payable under paragraph (3) (B) if, at any time, the Administrator determines that—

- (I) the documentation supporting the waiver or reduction request is not accurate; or
- (II) based on the documentation or any other information, the waiver or reduction should not have been granted or should not be granted.

#### (C) Determination to grant or deny request

As soon as practicable, but not later than 60 days, after the date on which the Administrator receives a request for a waiver or reduction of a registration service fee under this paragraph, the Administrator shall

(i) determine whether to grant or deny the request; and

(ii) notify the applicant of the determination.

## (D) Minor uses

## (i) In general

The Administrator may exempt from, or waive a portion of, the registration service fee for an application for minor uses for a pesticide.

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## (ii) Supporting documentation

An applicant requesting a waiver or exemption under this subparagraph shall provide supporting documentation that demonstrates, to the satisfaction of the Administrator, that anticipated revenues from the uses that are the subject of the application would be insufficient to justify imposition of the full application fee.

#### (E) IR-4 exemption

The Administrator shall exempt an application from the registration service fee if the Administrator determines that—

- (i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR-4) as described in section 2 of Public Law 89-106 (7 U.S.C. 450i(e)); <sup>1</sup>/<sub>2</sub>
  - (ii) the exemption is in the public interest.

#### (F) Small businesses

#### (i) In general

The Administrator shall waive 50 percent of the registration service fees payable by an entity for a covered application under this section if the entity is a small business (as defined in section 136a-1(i)(1) (E)(ii) of this title) at the time of application.

#### (ii) Waiver of fees

The Administrator shall waive 75 percent of the registration service fees payable by an entity under this section if the entity—

- (I) is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application; and
- (II) has average annual global gross revenues described in section 136a-1(i)(1)(E)(ii)(I)(bb) of this title that does not exceed \$10,000,000, at the time of application.

#### (iii) Formation for waiver

The Administrator shall not grant a waiver under this subparagraph if the Administrator determines that the entity submitting the application has been formed or manipulated primarily for the purpose of qualifying for the waiver.

#### (iv) Documentation

An entity requesting a waiver under this subparagraph shall provide to the Administrator—

- (I) documentation demonstrating that the entity is a small business (as defined in section 136a–1(i) (1)(E)(ii) of this title) at the time of application; and
- (II) if the entity is requesting a waiver of 75 percent of the applicable registration service fees payable under this section, documentation demonstrating that the entity has an average annual global gross revenue described in section 136a-1(i)(1)(E)(ii)(I)(bb) of this title that does not exceed \$10,000,000, at the time of application.

#### (G) Federal and State agency exemptions

An agency of the Federal Government or a State government shall be exempt from covered registration service fees under this section.

## (8) Refunds

#### (A) Early withdrawals

If, during the first 60 days after the beginning of the applicable decision time review period under subsection (f)(3), a covered application is withdrawn by the applicant, the Administrator shall refund all but 25 percent.  $\frac{2}{3}$  of the total registration service fee payable under paragraph (3)(B) for the application.

## (B) Withdrawals after the first 60 days of decision review time period

## (i) In general

If a covered application is withdrawn after the first 60 days of the applicable decision time review period, the Administrator shall determine what portion, if any, of the total registration service fee payable under paragraph (3)(B) for the application may be refunded based on the proportion of the work completed at the time of withdrawal.

#### (ii) Timina

The Administrator shall—

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- (I) make the determination described in clause (i) not later than 90 days after the date the application is withdrawn; and
  - (II) provide any refund as soon as practicable after the determination.

## (C) Discretionary refunds

## (i) In general

In the case of a covered application that has been filed with the Administrator and has not been withdrawn by the applicant, but for which the Administrator has not yet made a final determination, the Administrator may refund a portion of a covered registration service fee if the Administrator determines that the refund is justified.

#### (ii) Basis

The Administrator may provide a refund for an application under this subparagraph—

- (I) on the basis that, in reviewing the application, the Administrator has considered data submitted in support of another covered application;
- (II) on the basis that the Administrator completed portions of the review of the application before the effective date of this section; or
  - (III) on the basis that the Administrator rejected the application under subsection (f)(4)(B).

## (D) Credited fees

In determining whether to grant a refund under this paragraph, the Administrator shall take into account any portion of the registration service fees credited under paragraph (2) or (4).

## (c) Pesticide Registration Fund

## (1) Establishment

There is established in the Treasury of the United States a Pesticide Registration Fund to be used in carrying out this section (referred to in this section as the "Fund"), consisting of—

- (A) such amounts as are deposited in the Fund under paragraph (2);
- (B) any interest earned on investment of amounts in the Fund under paragraph (5); and
- (C) any proceeds from the sale or redemption of investments held in the Fund.

#### (2) Deposits in Fund

Subject to paragraph (4), the Administrator shall deposit fees collected under this section in the Fund.

## (3) Expenditures from Fund

#### (A) In general

Subject to subparagraphs (B) and (C) and paragraph (4), the Administrator may make expenditures from the Fund—

- (i) to cover the costs associated with the review and decisionmaking pertaining to all applications for which registration service fees have been paid under this section; and
  - (ii) to otherwise carry out this section.

## (B) Endangered species review of outdoor use of pesticide products

## (i) In general

The Administrator shall use the amounts made available in the Fund to develop, receive comments with respect to, and finalize, guidance to registrants regarding analysis necessary to support the review of outdoor uses of pesticide products under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.).

# (ii) Deadlines for guidance

The Administrator shall issue final guidance required by clause (i) in accordance with the following:

- (I) With respect to new active ingredients or any registration review decision proposed for 1 or more outdoor uses, not later than 9 months after December 29, 2022.
- (II) With respect to new outdoor uses of a registered pesticide, not later than 1 year after December 29, 2022.
  - (III) With respect to antimicrobial pesticide products, not later than 3 years after December 29, 2022.

## (C) Independent third party assessments

## (i) In general

The Administrator shall use the amounts made available in the Fund to carry out the activities described in clauses (ii) and (iii).

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#### (ii) Workforce assessment

## (I) In general

The Administrator shall procure a competitive contract with a qualified, independent contractor with expertise in assessing public sector workforce data analysis and reporting to conduct an assessment of current methodologies and data or metrics available to represent the workforce implementing the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act, including an assessment of filled and vacant positions and full-time equivalent employees relating to that implementation.

## (II) Report

Not later than 2 years after December 29, 2022—

- (aa) the contractor selected under subclause (I) shall submit to the Administrator a report
- (AA) the findings from the assessment under that subclause; and
- (BB) recommendations for improved methodologies to represent full-time equivalent resources described in that subclause: and
  - (bb) the Administrator shall publish the report submitted under item (aa) on the website of the **Environmental Protection Agency.**

#### (iii) Process assessment

# (I) In general

#### (aa) Contracts

Within 1 year of December 29, 2022, to the extent practicable, the Administrator shall issue a competitive contract to a private, independent consulting firm—

- (AA) to conduct the assessment described in subclause (II); and
- (BB) to submit to the Administrator a report describing the findings of the assessment and the processes and performance of the Environmental Protection Agency relating to the implementation of the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act.

#### (bb) Eligibility

The firm described in item (aa) shall be capable of performing the technical analysis. management assessment, and program evaluation tasks required to address the scope of the assessment under subclause (II).

#### (II) Assessment

#### (aa) In general

The Administrator, applicants, and registrants shall participate in a targeted assessment of the process for the review of applications submitted under this subchapter.

#### (bb) Consultation

The firm selected under subclause (I) shall consult with the Administrator and applicants at the start of the assessment under item (aa) and prior to submission of the report under subclause (I)(aa) (BB).

#### (cc) Requirements

The assessment under item (aa) shall evaluate and make recommendations regarding—

- (AA) the initial content screen;
- (BB) the preliminary technical screen;
- (CC) performance, processes, and progress toward reducing renegotiation rates and the average length of renegotiations:
- (DD) performance, processes, and progress toward eliminating the backlog of registrant submissions not covered by subsection (b)(3);
- (EE) performance, processes, and progress toward ensuring that all registrant submissions not covered by subsection (b)(3) are completed by the applicable deadlines described in the notice of the Administrator entitled "Pesticide Registration Notice (PR) 98–10: Notifications, Non-Notifications and Minor Formulation Amendments" and dated October 22, 1998 (and any successor amendments to that notice) and described in subsections (c)(3)(B) and (h) of section 136a of this title;
- (FF) compliance with the provisions of this subchapter relating to renegotiations and registrant submissions not covered by subsection (b)(3);

(GG) information technology systems;

(HH) recommended improvements to employee training;

- (II) performance, progress, and processes in completing registration review; and
- (JJ) other appropriate issues, such as submissions by inert suppliers and fast-track amendments under subsections (c)(3)(B) and (h) of section 136a of this title.

## (III) Report to Congress

Not later than 1 year after the receipt of an assessment required under this section, the Administrator shall submit to the Committee on Agriculture, Nutrition, and Forestry of the Senate and the Committee on Agriculture of the House of Representatives—

- (aa) a copy of each such assessment; and
- (bb) the Administrator's evaluation of the findings and recommendations contained in each such assessment.

#### (IV) Recommendations

The Administrator shall include with the report submitted under subclause (III) a classification of each recommendation described in the report as—

- (aa) can be implemented through administrative action of the Administrator; or
- (bb) requires a statutory change.

## (4) Collections and appropriations Acts

The fees authorized by this section and amounts deposited in the Fund—

- (A) shall be collected and made available for obligation only to the extent provided in advance in appropriations Acts;
- (B) shall be available during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations; and
  - (C) shall be available without fiscal year limitation.

## (5) Unused funds

## (A) In general

Amounts in the Fund not currently needed to carry out this section shall be—

- (i) maintained readily available or on deposit;
- (ii) invested in obligations of the United States or guaranteed by the United States; or
- (iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

## (B) Use of investment income

After consultation with the Secretary of the Treasury, the Administrator may use income from investments described in clauses (ii) and (iii) of subparagraph (A) to carry out this section.

## (d) Assessment of fees

#### (1) Definition of covered functions

In this subsection, the term "covered functions" means functions of the Office of Pesticide Programs of the Environmental Protection Agency, as identified in key programs and projects of the final operating plan for the Environmental Protection Agency submitted as part of the budget process for fiscal year 2002, regardless of any subsequent transfer of 1 or more of the functions to another office or agency or the subsequent transfer of a new function to the Office of Pesticide Programs.

#### (2) Minimum amount of appropriations

Registration service fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions of the Office of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than \$166,000,000.

#### (3) Use of fees

Registration service fees authorized by this section shall be available, in the aggregate, only to defray increases in the costs associated with the review and decisionmaking for the review of pesticide registration applications and associated tolerances (including increases in the number of full-time equivalent positions in the Environmental Protection Agency engaged in those activities) over the costs for fiscal year 2002, excluding costs paid from fees appropriated for the fiscal year.

## (4) Subsequent authority

If the Administrator does not assess registration service fees under subsection (b) during any portion of a fiscal year as the result of paragraph (2) and is subsequently permitted to assess the fees under subsection

(b) during the fiscal year, the Administrator shall assess and collect the fees, without any modification in rate, at any time during the fiscal year, notwithstanding any provisions of subsection (b) relating to the date fees are to be paid.

## (e) Reforms to reduce decision time review periods and prevent double payment of registration fees

## (1) Reduction of decision time review periods

To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this subchapter with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Extension Act of 2018 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications). Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process.

## (2) Prevention of double payment of registration service fees

The Administrator shall develop and implement a process to determine the appropriate fee category or categories for an application that qualifies for more than one fee category in order to assist applicants and prevent unnecessary payment of fees for multiple categories for a single application.

## (f) Decision time review periods

## (1) In general

Not later than 30 days after the effective date of the Pesticide Registration Improvement Act of 2022, the Administrator shall make publicly available a schedule of decision review periods for covered pesticide registration actions or for any other action covered by a table specified in subsection (b)(3)(B) and corresponding registration service fees under this subchapter.

## (2) Report

The schedule shall be the same as the applicable schedule provided under subsection (b)(3)(B).

## (3) Applications subject to decision time review periods

The decision time review periods specified in paragraph (1) shall apply to—

- (A) covered pesticide registration applications subject to registration service fees under subsection (b) (2);
- (B) covered pesticide registration applications for which an applicant has voluntarily paid registration service fees under subsection (b)(4); and
  - (C) applications for any other action covered by a table specified in subsection (b)(3)(B).

### (4) Start of decision time review period

## (A) In general

Except as provided in subparagraphs (C), (D), and (E), in the case of a covered application accompanied by the registration service fee required under this section, the decision time review period begins 21 days after the date on which the Administrator receives the covered application and fee.

## (B) Initial content and preliminary technical screenings

#### (i) Screenings

#### (I) Initial content

Not later than 21 days after receiving an application and the required registration service fee, the Administrator shall conduct an initial screening of the contents of the application in accordance with clause (iii).

#### (II) Preliminary technical screening

After conducting the initial content screening described in subclause (I) and in accordance with clause (iv), the Administrator shall conduct a preliminary technical screening—

- (aa) not later than 45 days after the date on which the decision time review period begins (for applications with decision time review periods of not more than 180 days); and
- (bb) not later than 90 days after the date on which the decision time review period begins (for applications with decision time review periods greater than 180 days).

## (III) Final fee category

The fee category of a covered application or other actions may not be changed, without providing the information to the applicant, after completion of the preliminary technical screening described in clause (iv).

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## (ii) Rejection

## (I) In general

If the Administrator determines at any time before the Administrator completes the preliminary technical screening under clause (i)(II) that the application failed the initial content or preliminary technical screening and the applicant does not correct the failure before the date that is 10 business days after the applicant receives a notification of the failure, the Administrator shall reject the application.

## (II) Written notification

The Administrator shall make every effort to provide a written notification of a rejection under subclause (I) during the 10-day period that begins on the date the Administrator completes the preliminary technical screening.

## (iii) Requirements of initial content screening

In conducting an initial content screening of an application, the Administrator shall automate the process, to the maximum extent practicable, and determine whether—

- (I)(aa) the applicable registration service fee has been paid; or
- (bb) at least 25 percent of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request: and
- (II) the application appears to contain all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Administrator.

## (iv) Requirements of preliminary technical screening

In conducting a preliminary technical screening of an application, the Administrator shall—

- (I) determine if the application and the data and information submitted with the application are accurate and complete;
- (II) determine if the application, data, and information are consistent with the proposed labeling and any proposal for a tolerance or exemption from the requirement for a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), and are such that, subject to full review under the standards of this subchapter, could result in the granting of the application;
- (III) determine, if applicable, whether an application qualifies for a reduced risk determination under subsection (c)(10) or (h) of section 136a of this title;
  - (IV) grant or deny any data waiver requests submitted by the applicant with the application;
  - (V) verify and validate the accuracy of the fee category selected by the applicant; and
- (VI) notify the applicant, in writing, if a new or different fee category is required and calculate the new decision review time based on the original submission date.

## (C) Applications with waiver or reduction requests

#### (i) In general

In the case of an application submitted with a request for a waiver or reduction of registration service fees under subsection (b)(7), the decision time review period shall be determined in accordance with this subparagraph.

## (ii) Request granted with no additional fees required

If the Administrator grants the waiver or reduction request and no additional fee is required, the decision time review period begins on the earlier of-

- (I) the date on which the Administrator grants the request; or
- (II) the date that is 60 days after the date of receipt of the application.

## (iii) Request granted with additional fees required

If the Administrator grants the waiver or reduction request, in whole or in part, but an additional registration service fee is required, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

#### (iv) Request denied

If the Administrator denies the waiver or reduction request, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

## (D) Pending applications

## (i) In general

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The start of the decision time review period for applications described in clause (ii) shall be the date on which the Administrator receives certification of payment of the applicable registration service fee.

## (ii) Applications

Clause (i) applies to—

- (I) covered pesticide registration applications for which voluntary fees have been paid under subsection (b)(4); and
- (II) covered pesticide registration applications received on or after the effective date of the Pesticide Registration Improvement Act of 2003 but submitted without the applicable registration service fee required under this section due to the inability of the Administrator to assess fees under subsection (d) (1).

## (E) Applications for reduced risk

## (i) Fee

If an application for a reduced risk new active ingredient or a reduced risk new use is determined not to qualify as reduced risk, the applicant shall pay the difference in fee for the corresponding non-reduced risk application.

## (ii) Decision review time period

After receipt by the Administrator of the original covered reduced risk application and fee, the decision time review period for the corresponding non-reduced risk application shall begin within the time periods described in subparagraph (A), based on the submission date of the original covered reduced risk application.

## (5) Extension of decision time review period

## (A) Notification

If the Administrator cannot meet a decision time review period under this subsection, the Administrator shall notify the applicant, in writing, of—

- (i) the reasons why additional time is needed; and
- (ii) the number of days needed that would allow the Administrator to make a regulatory decision.

## (B) Extension by negotiation or mutual agreement

The Administrator, acting solely through the Director of the Office of Pesticide Programs, and the applicant may mutually agree, in writing, to extend a decision time review period under this subsection if—

- (i) there is new or additional data or information from the applicant that is necessary for the Administrator to make a decision on the application that cannot be made available within the original decision time review period; or
- (ii) a public comment period associated with the application generates significant comments that cannot be addressed within the original decision time review period.

## (C) Priority

Once a decision time review period for a covered action described in subsection (b)(3)(B) is missed or extended, the Administrator shall make any action on the application a priority.

## (g) Judicial review

#### (1) In general

Any applicant adversely affected by the failure of the Administrator to make a determination on the application of the applicant for registration of a new active ingredient or new use for which a registration service fee is paid under this section may obtain judicial review of the failure solely under this section.

#### (2) Scope

#### (A) In general

In an action brought under this subsection, the only issue on review is whether the Administrator failed to make a determination on the application specified in paragraph (1) by the end of the applicable decision time review period required under subsection (f) for the application.

## (B) Other actions

No other action authorized or required under this section shall be judicially reviewable by a Federal or State court.

#### (3) Timing

## (A) In general

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A person may not obtain judicial review of the failure of the Administrator to make a determination on the application specified in paragraph (1) before the expiration of the 2-year period that begins on the date on which the decision time review period for the application ends.

## (B) Meeting with Administrator

To be eligible to seek judicial review under this subsection, a person seeking the review shall first request in writing, at least 120 days before filing the complaint for judicial review, a decision review meeting with the Administrator.

## (4) Remedies

The Administrator may not be required or permitted to refund any portion of a registration service fee paid in response to a complaint that the Administrator has failed to make a determination on the covered pesticide registration application specified in paragraph (1) by the end of the applicable decision review period.

## (h) Accounting

The Administrator shall—

- (1) provide an annual accounting of the registration service fees paid to the Administrator and disbursed from the Fund, by providing financial statements in accordance with-
  - (A) the Chief Financial Officers Act of 1990 (Public Law 101-576; 104 Stat. 2838) and amendments made by that Act; and
  - (B) the Government Management Reform Act of 1994 (Public Law 103-356; 108 Stat. 3410) and amendments made by that Act;
  - (2) provide an accounting describing expenditures from the Fund authorized under subsection (c); and
  - (3) provide an annual accounting describing collections and expenditures authorized under subsection (d).

## (i) Auditing

## (1) Financial statements of agencies

For the purpose of section 3515(c) of title 31, the Fund shall be considered a component of an executive agency.

## (2) Components

The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this section shall include an analysis of-

- (A) the fees collected under subsection (b) and disbursed;
- (B) compliance with subsection (f);
- (C) the amount appropriated to meet the requirements of subsection (d)(1); and
- (D) the reasonableness of the allocation of the overhead allocation of costs associated with the review and decisionmaking pertaining to applications under this section.

#### (3) Inspector General

The Inspector General of the Environmental Protection Agency shall—

- (A) conduct the annual audit required under this subsection; and
- (B) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

#### (j) Personnel levels

All full-time equivalent positions supported by fees authorized and collected under this section shall not be counted against the agency-wide personnel level goals of the Environmental Protection Agency.

### (k) Reports and information technology

#### (1) Reports

## (A) In general

Not later than 120 days after the last day of each of fiscal years 2023 through 2027, the Administrator shall publish an annual report describing-

- (i) actions taken under this section;
- (ii) registrant submissions not covered by subsection (b)(3)(B);
- (iii) the initial content and preliminary technical screenings required in subsection (f)(4)(B); and
- (iv) staffing relating to implementing the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act.

## (B) Contents

Each report published under subparagraph (A) shall include a summary of the following information:

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## (i) Actions under this section

To the extent practicable, data for each action taken under this section that is completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

- (I) the Action Code;
- (II) the application receipt date;
- (III) the electronic portal tracking number assigned to the application at the time of submission to the electronic submission portal or the Environmental Protection Agency tracking number;
  - (IV) the original decision due date based on the Action Code;
  - (V) the dates of any renegotiations and the renegotiated due dates, if applicable;
  - (VI) the reasons for each renegotiation, if applicable;
  - (VII) if the submission had to be recoded, reassigned codes, if applicable:
  - (VIII) the date that the submission was recoded, if applicable;
  - (IX) the decision completion date, if the action has been completed;
  - (X) the status of the action, which may be—
    - (aa) failed initial content screen;
    - (bb) failed preliminary technical screen;
    - (cc) approved;
    - (dd) withdrawn;
    - (ee) denied;
    - (ff) do not grant; or
    - (gg) pending;
  - (XI) the reason for any denial or do not grant decision, if applicable;
- (XII) a review of the progress made in carrying out each requirement of subsections (e) and (f), including, to the extent determined appropriate by the Administrator and consistent with the authorities of the Administrator and limitations on delegation of functions by the Administrator, recommendations for the allowance and use of summaries of acute toxicity studies;
  - (XIII) a review of the progress in carrying out section 136a(g) of this title, including—
  - (aa)  $\frac{3}{2}$  the number of pesticides or pesticide cases reviewed and the number of registration review decisions completed, including—
- (AA) the number of cases cancelled;
- (BB) the number of cases requiring risk mitigation measures;
- (CC) the number of cases removing risk mitigation measures;
- (DD) the number of cases with no risk mitigation needed; and
- (EE) the number of cases in which risk mitigation has been fully implemented;
  - (XIV) a review of the progress made toward implementing enhancements to—
    - (aa) the electronic tracking of conditional registrations; and
    - (bb) the endangered species database;
  - (XV) a review of the progress made in updating the Pesticide Incident Data System, including progress toward making the information contained in the System available to the public (as the Administrator determines is appropriate);
    - (XVI) an assessment of the public availability of summary pesticide usage data;
  - (XVII) the number of the active ingredients approved, new uses, and pesticide end use products granted in connection with the Design for the Environment program (or any successor program) of the Environmental Protection Agency;
  - (XVIII) with respect to funds in the Reregistration and Expedited Processing Fund described under section 136a–1(k) of this title, a review that includes—
    - (aa) a description of the amount and use of such funds—
- (AA) to carry out activities relating to worker protection under subparagraphs (G) and (H) of section 136a–1(i) (1) of this title;
  - (BB) to award partnership grants under subparagraph (I) of such section; and
  - (CC) to carry out the pesticide safety education program under subparagraph (J) of such section;
    - (bb) an evaluation of the appropriateness and effectiveness of the activities, grants, and program under subparagraphs (G), (H), (I), and (J) of such section;
    - (cc) a description of how stakeholders are engaged in the decision to fund such activities, grants, and program in accordance with the stakeholder input provided under such subparagraphs; and

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(dd) with respect to activities relating to worker protection carried out under subparagraphs (G) and (H) of section 136a–1(i)(1) of this title, a summary of the analyses from stakeholders, including from worker community-based organizations, on the appropriateness and effectiveness of such activities.

(XIX) beginning two years after enactment, report on the progress of meeting the deadlines listed in paragraph (5) of section 136a(f) of this title; and

(XX) a review of progress made in implementing the pesticide surveillance program referred to in paragraph (8) of section 136a–1(k) of this title.

## (ii) Registrant submissions not covered by subsection (b)(3)(B)

Each registrant submission not covered by subsection (b)(3)(B), that is completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

- (I) the submission date;
- (II) the electronic portal tracking number assigned to the application at the time of the submission of the application to the electronic submission portal;
- (III) the type of regulatory action, as defined by statute or guidance document, and the specific label action;
  - (IV) the status of the action;
  - (V) the due date;
  - (VI) the reason for the outcome; and
  - (VII) the completion date, if applicable.

## (iii) Screening process

Data for the initial content screens and preliminary technical screens that are completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

- (I) the number of applications successfully passing each type of screen;
- (II) the number of applications that failed the screening process for each type of screen;
- (III) the number of notifications issued by the Administrator under subsection (f)(4)(B)(ii)(II);
- (IV) the number of notifications issued by the Administrator under subsection (f)(4)(B)(ii)(I) and the number of applications resulting in a rejection; and
- (V) the number of notifications issued under section 152.105 of title 40, Code of Federal Regulations (or successor regulations), and to the extent practicable, the reasons for that issuance.

#### (iv) Staffing

Data on the staffing relating to work covered under the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act, organized by registering division, including—

- (I) the number of new hires and personnel departures;
- (II) the number of full-time equivalents at the end of each fiscal year:
- (III) the number of full-time equivalents working on registration review activities; and
- (IV) the number of full-time equivalents working on registrant submissions not covered by subsection (b)(3)(B).

### (C) Publication

The Administrator shall publish each report under subparagraph (A)—

- (i) on the website of the Environmental Protection Agency; and
- (ii) by such other methods as the Administrator determines to be the most effective for efficiently disseminating the report.

#### (2) Information technology

#### (A) System

Not later than 1 year after December 29, 2022, the Administrator shall establish an information technology system that—

- (i) includes all registering divisions in the Office of Pesticide Programs:
- (ii) provides a real-time, accurate, tracking system for all regulatory submissions to the Office of Pesticide Programs;
- (iii) provides a  $\frac{4}{}$  real-time, accessible information  $\frac{4}{}$  that provides each applicant confidential, online access to the status and progress of the regulatory submissions of the applicant; and
  - (iv) updates the electronic submission portal—

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- (I) to ensure that label reviews are limited to current label changes, to the maximum extent practicable;
  - (II) to automate, to the extent practicable, minor, low risk regulatory actions; and
  - (III) to allow self-certification of certain regulatory actions, as determined by the Administrator.

## (B) Access to registration data and decisions

The Administrator shall implement efforts to expand existing, and develop new, information technology tools and databases to improve access by Environmental Protection Agency employees to data used to fulfill registrations, and public access to information about regulatory decisionmaking tools, including opportunities for—

- (i) analysis of the impact of submitted studies on Environmental Protection Agency assessments and decisions:
  - (ii) facilitation of read-across or computational model development to help fill information gaps;
- (iii) tracking and reporting submission and decision metrics relating to the use and acceptance of test methods; and
- (iv) drafting and publication of policies communicating Environmental Protection Agency acceptance of novel technologies or approaches.

## (I) Savings clause

Nothing in this section affects any other duties, obligations, or authorities established by any other section of this subchapter, including the right to judicial review of duties, obligations, or authorities established by any other section of this subchapter.

## (m) Termination of effectiveness

## (1) In general

Except as provided in paragraph (2), the authority provided by this section terminates on September 30, 2027.

## (2) Phase out

## (A) Fiscal year 2028

During fiscal year 2028, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 40 percent below the level in effect on September 30, 2027.

## (B) Fiscal year 2029

During fiscal year 2029, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 70 percent below the level in effect on September 30, 2027.

## (C) September 30, 2029

Effective September 30, 2029, the requirement to pay and collect registration service fees terminates.

## (D) Decision review periods

## (i) Pending applications

In the case of an application received under this section before September 30, 2027, the application shall be reviewed in accordance with subsection (f).

## (ii) New applications

In the case of an application received under this section on or after September 30, 2027, subsection (f) shall not apply to the application.

(June 25, 1947, ch. 125, §33, as added Pub. L. 108–199, div. G, title V, §501(f)(2), Jan. 23, 2004, 118 Stat. 422; amended Pub. L. 110–94, §5, Oct. 9, 2007, 121 Stat. 1002; Pub. L. 110–193, §1(a), Mar. 6, 2008, 122 Stat. 649; Pub. L. 112–177, §2(a)(2)(B), (b), Sept. 28, 2012, 126 Stat. 1328, 1330; Pub. L. 116–8, §§5, 6, Mar. 8, 2019, 133 Stat. 487, 491; Pub. L. 117–328, div. HH, title VI, §§705, 706, Dec. 29, 2022, 136 Stat. 6008, 6018.)

## **EDITORIAL NOTES**

## REFERENCES IN TEXT

The effective date of the Pesticide Registration Improvement Act of 2003, and the effective date of this section, referred to in text, is the effective date of section 501 of Pub. L. 108–199, which is the

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date that is 60 days after Jan. 23, 2004, unless otherwise provided, see section 501(h) of Pub. L. 108–199, set out as an Effective Date of 2004 Amendment note under section 136a of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2)(B)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seg.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Paragraph (3), referred to in subsec. (b)(6)(A), probably should be a reference to paragraph (3) (B). Amendment by section 705(a)(1)(B) of Pub. L. 117-328 substituting "paragraph (3)(B)" for "paragraph (3)" wherever appearing in subsec. (b) was followed by the general amendment of subsec. (b)(6)(A) by section 705(a)(1)(D)(i) of Pub. L. 117-328, which contained the reference to paragraph (3).

Section 2 of Public Law 89-106, referred to in subsec. (b)(7)(E)(i), was formerly classified to secton 450i of this title prior to editorial reclassification and renumbering as section 3157 of this title.

The Endangered Species Act of 1973, referred to in subsec. (c)(3)(B)(i), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified principally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

The Pesticide Registration Improvement Act of 2022, referred to in subsecs. (c)(3)(C)(ii)(I), (iii)(I) (aa)(BB) and (k)(1)(A)(iv), (B)(iv), is title VI (§701 et seq.) of div. HH of Pub. L. 117–328, Dec. 29, 2022, 136 Stat. 5996. For complete classification of this Act to the Code, see Short Title of 2022 Amendment note set out under section 136 of this title and Tables.

The effective date of the Pesticide Registration Improvement Extension Act of 2018, referred to in subsec. (e), means the effective date of Pub. L. 116-8, which was approved Mar. 8, 2019.

The effective date of the Pesticide Registration Improvement Act of 2022, referred to in subsec. (f)(1), means the effective date of title VI of div. HH of Pub. L. 117-263, which was approved Dec. 29, 2022.

The Chief Financial Officers Act of 1990, referred to in subsec. (h)(1)(A), is Pub. L. 101–576, Nov. 15, 1990, 104 Stat. 2838. For complete classification of this Act to the Code, see Short Title of 1990 Amendment note set out under section 501 of Title 31, Money and Finance, and Tables.

The Government Management Reform Act of 1994, referred to in subsec. (h)(1)(B), is Pub. L. 103-356, Oct. 13, 1994, 108 Stat. 3410. For complete classification of this Act to the Code, see Short Title of 1994 Amendment note set out under section 3301 of Title 31, Money and Finance, and Tables.

Two years after enactment, referred to in subsec. (k)(1)(B)(i)(XIX), means two years after the enactment of section 136a(f)(5) of this title, as enacted by Pub. L. 117–328, which was approved Dec. 29, 2022.

## **PRIOR PROVISIONS**

A prior section 33 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

#### **AMENDMENTS**

2022—Subsec. (b). Pub. L. 117-328, §705(a)(1)(B), substituted "paragraph (3)(B)" for "paragraph (3)" wherever appearing. Subsec. (b)(6)(A) was subsequently amended generally by Pub. L. 117-328, §705(a)(1)(D)(i), after which "paragraph (3)" appeared in text.

Subsec. (b)(2)(E)(iii). Pub. L. 117–328, §705(a)(1)(A), substituted "on completion of, where appropriate, the initial screening of the contents of the application or the preliminary technical screening" for "after review".

Subsec. (b)(3). Pub. L. 117–328, §705(a)(1)(C), designated existing provisions as subpar. (B), inserted heading, and added subpar. (A).

Subsec. (b)(3)(B). Pub. L. 117-328, §706, added subpar. (B) and struck out former subpar. (B), as designated by section 705(a)(1)(C) of Pub. L. 117-263, which set out the schedule of covered applications and other actions and their registration service fees.

Subsec. (b)(6)(A), (B), Pub. L. 117–328, \$705(a)(1)(D), which directed amendment of subpars, (A) and (B) "to read as follows" but did not include subpar, designations or headings, was executed by amending the text only and retaining the existing designations and headings, to reflect the probable intent of Congress. Prior to amendment, subpars. (A) and (B) related to fee adjustment

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between Oct. 1, 2019, and Sept. 30, 2021, and an additional fee adjustment starting on Oct. 1, 2021.

Subsec. (b)(7)(A). Pub. L. 117–328, §705(a)(1)(E), substituted "(including a Gold Seal letter and a Certificate of Establishment)" for "(commonly referred to as a Gold Seal letter)".

Subsec. (c)(3)(B), (C). Pub. L. 117–328, §705(b)(1), added subpars. (B) and (C) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows:

- "(i) IN GENERAL.—For each of fiscal years 2013 through 2023, the Administrator shall use approximately 1/17 of the amount in the Fund (but not less than \$1,000,000) to enhance scientific and regulatory activities relating to worker protection, with an emphasis on field-worker populations in the United States.
- "(ii) Partnership grants.—Of the amounts in the Fund, the Administrator shall use for partnership grants, for each of fiscal years 2013 through 2023, \$500,000.
- "(iii) Pesticide safety education program.—Of the amounts in the Fund, the Administrator shall use \$500,000 for each of fiscal years 2013 through 2023 to carry out the pesticide safety education program."

Subsec. (c)(4)(B), (C). Pub. L. 117–328, §705(b)(2), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (d)(2). Pub. L. 117–328, §705(c), struck out "(as in existence in fiscal year 2012)" after "for the functions" and substituted "\$166,000,000." for "the amount of appropriations for covered functions for fiscal year 2012 (excluding the amount of any fees appropriated for the fiscal year)."

Subsec. (e). Pub. L. 117–328, §705(d), substituted "Reforms to reduce decision time review periods and prevent double payment of registration fees" for "Reforms to reduce decision time review periods" in subsec. heading, designated existing provisions as par. (1) and inserted par. heading, and added par. (2).

Subsec. (f). Pub. L. 117–328, §705(a)(2), substituted "subsection (b)(3)(B)" for "subsection (b)(3)" wherever appearing.

Subsec. (f)(1). Pub. L. 117–328, §705(e)(1), substituted "Pesticide Registration Improvement Act of 2022" for "Pesticide Registration Improvement Extension Act of 2018".

Subsec. (f)(4)(B)(i)(III). Pub. L. 117–328, §705(e)(2)(A)(i), added subcl. (III).

Subsec. (f)(4)(B)(iii). Pub. L. 117–328, §705(e)(2)(A)(ii), inserted "automate the process, to the maximum extent practicable, and" before "determine" in introductory provisions.

Subsec. (f)(4)(B)(iv). Pub. L. 117–328, §705(e)(2)(A)(iii), struck out determine if after shall in introductory provisions, inserted determine if at beginning of subcls. (I) and (II), and added subcls. (III) to (VI).

Subsec. (f)(4)(E). Pub. L. 117–328, §705(e)(2)(B), added subpar. (E) and struck out former subpar. (E). Prior to amendment, text read as follows: "In the case of a covered pesticide registration application listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency, the decision time review period begins on the date that is 30 days after the effective date of the Pesticide Registration Improvement Act of 2003."

Subsec. (f)(5). Pub. L. 117–328, §705(e)(3), added par. (5) and struck out former par. (5). Prior to amendment, text read as follows: "The Administrator and the applicant may mutually agree in writing to extend a decision time review period under this subsection."

Subsec. (k). Pub. L. 117–328, §705(f), added subsec. (k) and struck out former subsec. (k) which related to publication of annual reports and submission of another report to Congress.

Subsec. (m). Pub. L. 117–328, §705(g)(1), substituted "2027" for "2023" wherever appearing. Subsec. (m)(2)(A). Pub. L. 117–328, §705(g)(2)(A), substituted "2028" for "2024" in heading and text

Subsec. (m)(2)(B), (C). Pub. L. 117–328, §705(g)(2)(B), substituted "2029" for "2025" in heading and text.

**2019**—Subsec. (b)(2). Pub. L. 116–8, §5(a)(1)(A), struck out "pesticide registration" after "Covered" in heading.

Subsec. (b)(2)(A). Pub. L. 116–8, §5(a)(1)(B), inserted "or for any other action covered by a table specified in paragraph (3)" after "Pesticide Registration Improvement Act of 2003".

Subsec. (b)(3). Pub. L. 116–8, §6, amended par. (3) generally. Prior to amendment, par. (3) related to schedule of covered applications and registration service fees.

Subsec. (b)(5). Pub. L. 116–8, §5(a)(2), substituted "covered applications" for "pesticide registration applications" in heading and "covered application" for "pesticide registration

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application" in two places in text.

Subsec. (b)(6)(A). Pub. L. 116–8, §5(a)(3)(A), struck out "pesticide registration" after "Effective for a covered" and substituted "October 1, 2019, and ending on September 30, 2021" for "October 1, 2013, and ending on September 30, 2015".

Subsec. (b)(6)(B). Pub. L. 116–8, §5(a)(3)(B), struck out "pesticide registration" after "Effective for a covered" and substituted "2021" for "2015" in two places.

Subsec. (b)(6)(C). Pub. L. 116–8, §5(a)(3)(C), substituted "service fee schedules revised pursuant to this paragraph" for "revised registration service fee schedules".

Subsec. (b)(7)(A). Pub. L. 116–8, §5(a)(4)(A), substituted "covered application" for "covered pesticide registration" and inserted before period at end ", except that no waiver or fee reduction shall be provided in connection with a request for a letter of certification (commonly referred to as a Gold Seal letter)".

Subsec. (b)(7)(F)(i). Pub. L. 116–8,  $\S5(a)(4)(B)$ , struck out "pesticide registration" after "for a covered".

Subsec. (b)(8)(A). Pub. L. 116–8, §5(a)(5)(A), struck out "pesticide registration" after "a covered".

Subsec. (b)(8)(i). Pub. L. 116–8, §5(a)(5)(B), struck out "pesticide registration" after "If a covered".

Subsec. (b)(8)(C)(i). Pub. L. 116–8,  $\S5(a)(5)(C)(i)$ , substituted "case of a covered" for "case of a pesticide registration".

Subsec. (b)(8)(C)(ii)(I). Pub. L. 116–8, §5(a)(5)(C)(ii), substituted "covered" for "pesticide registration".

Subsec. (c)(3)(B). Pub. L. 116–8, §5(b)(1), inserted ", partnership grants, and pesticide safety education" after "Worker protection" in heading.

Subsec. (c)(3)(B)(i). Pub. L. 116–8, §5(b)(2), substituted "2023" for "2017" and inserted before period at end ", with an emphasis on field-worker populations in the United States".

Subsec. (c)(3)(B)(ii). Pub. L. 116-8, §5(b)(3), substituted "2023" for "2017".

Subsec. (c)(3)(B)(iii). Pub. L. 116-8, §5(b)(4), substituted "2023" for "2017".

Subsec. (e). Pub. L. 116–8, §5(c), substituted "Pesticide Registration Improvement Extension Act of 2018" for "Pesticide Registration Improvement Extension Act of 2012" and inserted at end "Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process."

Subsec. (f)(1). Pub. L. 116–8, §5(d)(1), substituted "Pesticide Registration Improvement Extension Act of 2018" for "Pesticide Registration Improvement Extension Act of 2012" and inserted "or for any other action covered by a table specified in subsection (b)(3)" after "covered pesticide registration actions".

Subsec. (f)(3)(C). Pub. L. 116–8, §5(d)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: "covered pesticide registration applications listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency."

Subsec. (f)(4)(A). Pub. L. 116–8, §5(d)(3), substituted "a covered application" for "a pesticide registration application" and "the covered application" for "the covered pesticide registration application".

Subsec. (k)(1). Pub. L. 116-8, §5(e)(1), substituted "2023" for "2017".

Subsec. (k)(2)(D)(i). Pub. L. 116–8, §5(e)(2)(A), added cl. (i) and struck out former cl. (i) which read as follows: "the number of pesticides or pesticide cases reviewed;".

Subsec. (k)(2)(G)(i). Pub. L. 116–8,  $\S5(e)(2)(B)(i)$ , substituted "paragraphs (4) and (5) of section 136a–1(k) of this title" for "section 136a–1(k)(4) of this title" and "such paragraphs" for "that section".

Subsec. (k)(2)(G)(ii) to (vii). Pub. L. 116–8, §5(e)(2)(B)(ii)–(iv), added cl. (ii), redesignated cl. (vii) as (iii), and struck out former cls. (ii) to (vi) which read as follows:

"(ii) implementing systems for the electronic tracking of registration submissions by December 31, 2013.

"(iii) implementing a system for tracking the status of conditional registrations, including making nonconfidential information related to the conditional registrations publicly available by December 31, 2013;

"(iv) implementing enhancements to the endangered species knowledge database, including making nonconfidential information related to the database publicly available;

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"(v) implementing the capability to electronically submit and review labels submitted with registration actions:

(vi) acquiring and implementing the capability to electronically assess and evaluate confidential statements of formula submitted with registration actions by December 31, 2014; and".

Subsec. (k)(2)(K) to (O). Pub. L. 116–8, §5(e)(2)(C)–(E), added subpars. (K) to (O).

Subsec. (m)(1). Pub. L. 116-8, §5(f)(1), substituted "2023" for "2017".

Subsec. (m)(2)(A). Pub. L. 116–8, §5(f)(2)(A), in heading, substituted "Fiscal year 2024" for "Fiscal year 2018" and in text, substituted "2024" for "2018" and "2023" for "2017".

Subsec. (m)(2)(B). Pub. L. 116–8, §5(f)(2)(B), in heading, substituted "Fiscal year 2025" for "Fiscal vear 2019" and in text, substituted "2025" for "2019" and "2023" for "2017".

Subsec. (m)(2)(C). Pub. L. 116–8, §5(f)(2)(C), substituted "2025" for "2019" in heading and text. Subsec. (m)(2)(D). Pub. L. 116-8, §5(f)(2)(D), substituted "2023" for "2017" in cls. (i) and (ii).

2012—Subsec. (b)(3). Pub. L. 112–177, §2(b)(1)(A), added par. (3) and struck out former par. (3)

which related to schedule of covered applications and registration service fees. Subsec. (b)(6)(A). Pub. L. 112–177, §2(b)(1)(B)(i), substituted "October 1, 2013" for "October 1,

2008" and "September 30, 2015" for "September 30, 2010". Subsec. (b)(6)(B). Pub. L. 112-177, §2(b)(1)(B)(ii), substituted "October 1, 2015" for "October 1,

2010" and "September 30, 2015" for "September 30, 2010". Subsec. (b)(7)(F)(i). Pub. L. 112–177, §2(a)(2)(B)(i), substituted "section 136a–1 (i)(1)(E)(ii)" for

"section 136a-1(i)(5)(E)(ii)".

Subsec. (b)(7)(F)(ii). Pub. L. 112–177, §2(a)(2)(B)(i), (ii), substituted "section 136a–1 (i)(1)(E)(ii)" for "section 136a-1(i)(5)(E)(ii)" in subcl. (I) and "section 136a-1(i)(1)(E)(ii)(I)(bb)" for "136a-1(i)(5) (E)(ii)(I)(bb)" in subcl. (II).

Subsec. (b)(7)(F)(iv)(I). Pub. L. 112–177, §2(a)(2)(B)(i), substituted "section 136a–1 (i)(1)(E)(ii)" for "section 136a-1(i)(5)(E)(ii)".

Subsec. (b)(7)(F)(iv)(II). Pub. L. 112–177, §2(a)(2)(B)(ii), (iii), substituted "applicable" for applicable.", "revenue" for "revenues", and "section 136a–1(i)(1)(E)(ii)(I)(bb)" for "section 136a– 1(i)(5)(E)(ii)(I)(bb)".

Subsec. (b)(8)(C)(ii)(III). Pub. L. 112–177, §2(b)(1)(C), added subcl. (III).

Subsec. (c)(3)(B)(i). Pub. L. 112-177, §2(b)(2)(A), substituted "2013 through 2017" for "2008 through 2012".

Subsec. (c)(3)(B)(ii). Pub. L. 112–177, §2(b)(2)(B), substituted "grants, for each of fiscal years 2013 through 2017, \$500,000." for "grants-

"(I) for each of fiscal years 2008 and 2009, \$750,000; and

"(II) for each of fiscal years 2010 through 2012, \$500,000."

Subsec. (c)(3)(B)(iii). Pub. L. 112–177, §2(b)(2)(C), substituted "2013 through 2017" for "2008 through 2012".

Subsec. (d)(2). Pub. L. 112–177, §2(b)(3)(A), substituted "2012" for "2002" in two places.

Subsec. (d)(4), (5). Pub. L. 112–177, §2(b)(3)(B), (C), redesignated par. (5) as (4) and struck out former par. (4). Prior to amendment, text of par. (4) read as follows: "The requirements of paragraph (2) shall have been considered to have been met for any fiscal year if the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2002) of the Office of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) is not more than 3 percent below the amount of appropriations for covered functions for fiscal year 2002 (excluding the amount of any fees appropriated for the fiscal year)."

Subsec. (e). Pub. L. 112–177, §2(b)(4), substituted "Pesticide Registration Improvement Extension Act of 2012" for "Pesticide Registration Improvement Act of 2003".

Subsec. (f)(1). Pub. L. 112–177, §2(b)(5)(A), substituted "Pesticide Registration Improvement Extension Act of 2012, the Administrator shall make publicly available for "Pesticide Registration Improvement Renewal Act, the Administrator shall publish in the Federal Register".

Subsec. (f)(2). Pub. L. 112-177, §2(b)(5)(B), substituted "provided under subsection (b)(3)." for appearing in the Congressional Record on pages S10409 through S10411, dated July 31, 2007."

Subsec. (f)(4)(A). Pub. L. 112–177, §2(b)(5)(C)(i), inserted "and fee" before period at end.

Subsec. (f)(4)(B). Pub. L. 112–177, §2(b)(5)(C)(ii)(I), substituted "Initial content and preliminary technical screenings" for "Completeness of application" in heading.

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Subsec. (f)(4)(B)(i). Pub. L. 112–177, §2(b)(5)(C)(ii)(I), (II), substituted "Screenings" for "In general" in cl. heading, designated existing provisions as subcl. (I) and inserted subcl. heading, and added subcl. (II).

Subsec. (f)(4)(B)(ii). Pub. L. 112–177, §2(b)(5)(C)(ii)(III), added cl. (ii) and struck out former cl. (ii). Prior to amendment, text read as follows: "If the Administrator determines under clause (i) that the application does not pass the initial screening and cannot be corrected within the 21-day period, the Administrator shall reject the application not later than 10 days after making the determination."

Subsec. (f)(4)(B)(iii). Pub. L. 112–177, §2(b)(5)(C)(ii)(IV), inserted "initial content" before "screening" in heading, "content" before "screening" in introductory provisions, and substituted "appears to contain" for "contains" in subcl. (II).

Subsec. (f)(4)(B)(iv). Pub. L. 112–177, §2(b)(5)(C)(ii)(V), added cl. (iv).

Subsec. (k)(1). Pub. L. 112–177, §2(b)(6)(A), substituted "March 1, 2017" for "March 1, 2014".

Subsec. (k)(2)(A)(viii). Pub. L. 112–177, §2(b)(6)(B)(i), added cl. (viii).

Subsec. (k)(2)(G) to (J). Pub. L. 112–177, §2(b)(6)(B)(ii)–(iv), added subpars. (G) to (J).

Subsec. (k)(4). Pub. L. 112–177, §2(b)(6)(C), added par. (4).

Subsec. (m)(1). Pub. L. 112-177, §2(b)(7)(A), substituted "2017" for "2012".

Subsec. (m)(2)(A). Pub. L. 112–177, §2(b)(7)(B)(i), substituted "2018" for "2013" in heading and "2018," for "2013," and "September 30, 2017" for "September 30, 2012" in text.

Subsec. (m)(2)(B). Pub. L. 112–177, §2(b)(7)(B)(ii), substituted "2019" for "2014" in heading and "2019," for "2014," and "September 30, 2017" for "September 30, 2012" in text.

Subsec. (m)(2)(C). Pub. L. 112–177, §2(b)(7)(B)(iii), substituted "2019" for "2014" in heading and "September 30, 2019" for "September 30, 2014" in text.

Subsec. (m)(2)(D). Pub. L. 112–177, §2(b)(7)(B)(iv), substituted "2017" for "2012" in cls. (i) and (ii). **2008**—Subsec. (b)(7)(D)(i). Pub. L. 110–193, §1(a)(1)(A)(i), added cl. (i) and struck out former cl.

(i). Prior to amendment, text read as follows: "The Administrator may waive or reduce a registration service fee for an application for minor uses for a pesticide."

Subsec. (b)(7)(D)(ii). Pub. L. 110–193, §1(a)(1)(A)(ii), inserted "or exemption" after "waiver".

Subsec. (b)(7)(E). Pub. L. 110–193, §1(a)(1)(B)(ii), substituted "exempt an application from the registration service fee" for "waive the registration service fee for an application" in introductory provisions.

Pub. L. 110–193, §1(a)(1)(B)(i), substituted "exemption" for "waiver" in heading.

Subsec. (b)(7)(E)(ii). Pub. L. 110–193, §1(a)(1)(B)(iii), substituted "exemption" for "waiver".

Subsec. (m)(2)(A), (B). Pub. L. 110–193, §1(a)(2), substituted "2012" for "2008".

**2007**—Subsec. (b)(2)(C)(ii). Pub. L. 110–94, §5(a)(1), added cl. (ii) and struck out former cl. (ii) which read as follows: "a request for a waiver from or reduction of the registration service fee."

Subsec. (b)(2)(D) to (H). Pub. L. 110-94, §5(a)(2), added subpars. (D) to (H).

Subsec. (b)(3)(A). Pub. L. 110–94, §5(b)(1)(A), substituted "Pesticide Registration Improvement Renewal Act" for "Pesticide Registration Improvement Act of 2003".

Subsec. (b)(3)(B). Pub. L. 110–94, §5(b)(1)(B), substituted "S10409 through S10411, dated July 31, 2007." for "S11631 through S11633, dated September 17, 2003."

Subsec. (b)(6). Pub. L. 110–94, §5(b)(2), added par. (6) and struck out former par. (6). Prior to amendment, text of par. (6) read as follows: "Effective for a covered pesticide registration application received on or after October 1, 2005, the Administrator shall—

"(A) increase by 5 percent the service fee payable for the application under paragraph (3); and

"(B) publish in the Federal Register the revised registration service fee schedule."

Subsec. (b)(7)(F)(ii). Pub. L. 110–94, §5(c)(1), substituted "75 percent" for "all" in introductory provisions.

Subsec. (b)(7)(F)(iv)(II). Pub. L. 110–94, §5(c)(2), substituted "75 percent of the applicable." for "all".

Subsec. (b)(8)(A). Pub. L. 110–94, §5(d), substituted "25 percent." for "10 percent".

Subsec. (c)(1)(B). Pub. L. 110-94, §5(e)(1), substituted "paragraph (5)" for "paragraph (4)".

Subsec. (c)(3)(B). Pub. L. 110–94, §5(e)(2)(A), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: "For each of fiscal years 2004 through 2008, the Administrator shall use approximately 1/17 of the amount in the Fund (but not more than \$1,000,000, and not less than \$750,000, for any fiscal year) to enhance current scientific and regulatory activities related to worker protection."

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Subsec. (c)(3)(C). Pub. L. 110–94, §5(e)(2)(B), struck out subpar. (C). Text read as follows: "For each of fiscal years 2004 and 2005, the Administrator shall use approximately 1/34 of the amount in the Fund (but not to exceed \$500,000 for any fiscal year) for the review and evaluation of new inert ingredients."

Subsec. (c)(5). Pub. L. 110–94, §5(e)(3), designated existing provisions as subpar. (A), inserted heading, redesignated former subpars. (A) to (C) as cls. (i) to (iii), respectively, of subpar. (A) and added subpar. (B).

Subsec. (d)(2). Pub. L. 110–94, §5(f), which directed substitution of "Registration" for "For fiscal years 2004, 2005 and 2006 only, registration", was executed by making the substitution for text which contained a comma after "2005" to reflect the probable intent of Congress.

Subsec. (f)(1). Pub. L. 110–94, §5(g)(1), substituted "Pesticide Registration Improvement Renewal Act" for "Pesticide Registration Improvement Act of 2003".

Subsec. (f)(2). Pub. L. 110–94, §5(g)(2), substituted "S10409 through S10411, dated July 31, 2007." for "S11631 through S11633, dated September 17, 2003."

Subsec. (f)(4)(B). Pub. L. 110–94, §5(g)(3), added subpar. (B) and struck out former subpar. (B) which provided criteria for determining completeness of pesticide registration applications.

Subsec. (k)(1). Pub. L. 110-94, §5(h)(1), substituted "March 1, 2014" for "March 1, 2009".

Subsec. (k)(2)(A)(ii) to (v). Pub. L. 110–94, §5(h)(2)(A)(i), (ii), added cls. (ii) to (iv) and

redesignated former cl. (ii) as (v). Former cls. (iii) and (iv) redesignated (vi) and (vii), respectively.

Subsec. (k)(2)(A)(vi). Pub. L. 110–94,  $\S5(h)(2)(A)(i)$ , (iii), redesignated cl. (iii) as (vi) and added subcls. (IV) and (V).

Subsec. (k)(2)(A)(vii). Pub. L. 110–94, §5(h)(2)(A)(i), redesignated cl. (iv) as (vii).

Subsec. (k)(2)(D) to (F). Pub. L. 110–94, §5(h)(2)(B)–(D), added subpars. (D) to (F).

Subsec. (m)(1). Pub. L. 110-94, §5(i)(1), substituted "2012" for "2008".

Subsec. (m)(2)(A). Pub. L. 110–94, §5(i)(2)(A), substituted "2013" for "2009" in heading and text.

Subsec. (m)(2)(B), (C). Pub. L. 110–94, §5(i)(2)(B), substituted "2014" for "2010" in headings and text.

Subsec. (m)(2)(D). Pub. L. 110–94, §5(i)(2)(C), substituted "2012" for "2008" in two places.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 2012 AMENDMENT**

Amendment by Pub. L. 112–177 effective Oct. 1, 2012, see section 2(c) of Pub. L. 112–177, set out as a note under section 136a–1 of this title.

## **EFFECTIVE DATE OF 2008 AMENDMENT**

Pub. L. 110–193, §1(b), Mar. 6, 2008, 122 Stat. 650, provided that: "The amendments made by subsection (a) [amending this section] take effect on October 1, 2007."

## **EFFECTIVE DATE OF 2007 AMENDMENT**

Amendment by Pub. L. 110–94 effective Oct. 1, 2007, see section 6 of Pub. L. 110–94, set out as a note under section 136a of this title.

#### **EFFECTIVE DATE**

Section effective on the date that is 60 days after Jan. 23, 2004, except as otherwise provided, see section 501(h) of Pub. L. 108–199, set out as an Effective Date of 2004 Amendment note under section 136a of this title.

## IMPLEMENTATION DATES WITH RESPECT TO FEES

Increases in registration service fees specified in this section, as amended by title VI of div. HH of Pub. L. 117–328, not effective until 60 days after Dec. 29, 2022, regardless of whether this section specifies such increases to be effective for fiscal year 2023, see section 708(a)(1) of Pub. L. 117–328, set out in a note under section 136a–1 of this title.

## EXTENSION OF LIMITATIONS ON FEE AMOUNTS AND USAGE OF FEES

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Subsection (c)(3)(B) of this section to continue in effect through Sept. 30, 2018, see section 401(a) of Pub. L. 115–141, formerly set out as a note under section 136a–1 of this title.

Pub. L. 115–141, div. M, title IV, §401(b)(2), Mar. 23, 2018, 132 Stat. 1050, extended the authority provided by this section until Sept. 30, 2018.

- <sup>1</sup> See References in Text note below.
- <sup>2</sup> So in original. The period probably should not appear.
- <sup>3</sup> So in original. There is no item (bb).
- <sup>4</sup> So in original.

## §136x. Severability

If any provision of this subchapter or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this subchapter which can be given effect without regard to the invalid provision or application, and to this end the provisions of this subchapter are severable. (June 25, 1947, ch. 125, §34, formerly §26, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 998; renumbered §30, Pub. L. 95–396, §24(1), Sept. 30, 1978, 92 Stat. 836; renumbered §33, Pub. L. 104–170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §34, Pub. L. 108–199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

#### **EDITORIAL NOTES**

## **PRIOR PROVISIONS**

A prior section 34 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

#### **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

## §136y. Authorization of appropriations

There is authorized to be appropriated to carry out this subchapter (other than section 136u(a) of this title)— (1) \$83,000,000 for fiscal year 1989, of which not more than \$13,735,500 shall be available for research under this subchapter;

- (2) \$95,000,000 for fiscal year 1990, of which not more than \$14,343,600 shall be available for research under this subchapter; and
- (3) \$95,000,000 for fiscal year 1991, of which not more than \$14,978,200 shall be available for research under this subchapter.

(June 25, 1947, ch. 125, §35, formerly §27, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 998; amended Pub. L. 94–51, July 2, 1975, 89 Stat. 257; Pub. L. 94–109, Oct. 10, 1975, 89 Stat. 571; Pub. L. 94–140, §3, Nov. 28, 1975, 89 Stat. 752; renumbered §31 and amended Pub. L. 95–396, §§24(1), 25, Sept. 30, 1978, 92 Stat. 836, 838; Pub. L. 96–539, §3, Dec. 17, 1980, 94 Stat. 3195; Pub. L. 98–201, §2, Dec. 2, 1983, 97 Stat. 1380; Pub. L. 99–198, title XVII, §1768, Dec. 23, 1985, 99 Stat. 1656; Pub. L. 100–532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679; renumbered §34, Pub. L. 104–170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §35, Pub. L. 108–199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

## **EDITORIAL NOTES**

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## CODIFICATION

Another section 1768 of Pub. L. 99–198 enacted sections 154a and 159 and amended sections 151, 154, and 157 of Title 21, Food and Drugs.

## **AMENDMENTS**

- 1988—Pub. L. 100–532 amended section generally. Prior to amendment, section read as follows: "There is authorized to be appropriated to carry out this subchapter for the period beginning October 1, 1985, and ending September 30, 1986, \$68,604,200 of which not more than \$11,993,100 shall be available for research under this subchapter."
- 1985—Pub. L. 99–198 substituted provisions authorizing appropriations of \$68,604,200 for fiscal year 1986 of which not more than \$11,993,100 shall be available for research for former provisions which had authorized appropriations for fiscal years 1973 through 1984.
- **1983**—Pub. L. 98–201 authorized necessary appropriations for period beginning Oct. 1, 1983, and ending Sept. 30, 1984, not in excess of \$64,200,000.
- **1980**—Pub. L. 96–539 inserted provisions authorizing appropriations for period beginning Oct. 1, 1979, and ending Sept. 30, 1980, and for period beginning Oct. 1, 1980, and ending Sept. 30, 1981.
- **1978**—Pub. L. 95–396, §25, substituted appropriations authorization of \$46,636,000 for period beginning Oct. 1, 1976, and ending Sept. 30, 1977, for prior authorization of \$23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977, and authorized appropriations of \$54,500,000 for period beginning Oct. 1, 1977, and ending Sept. 30, 1978, and such sums as may be necessary, limited to \$70,000,000, for period beginning Oct. 1, 1978, and ending Sept. 30, 1979.
- **1975**—Pub. L. 94–140 authorized appropriation of \$47,868,000 to carry out provisions of this subchapter for period beginning Oct. 1, 1975, and ending Sept. 30, 1976, and \$23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977.
- Pub. L. 94–109 inserted provisions authorizing appropriation of \$5,983,500 for period beginning Oct. 1, 1975 and ending Nov. 15, 1975.
- Pub. L. 94–51 authorized appropriation of \$11,967,000 to carry out provisions of this subchapter for period beginning July 1, 1975, and ending Sept. 30, 1975.

#### STATUTORY NOTES AND RELATED SUBSIDIARIES

## **EFFECTIVE DATE OF 1988 AMENDMENT**

Pub. L. 100–532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679, provided that amendment made by Pub. L. 100–532 is effective Oct. 1, 1988.

## **EFFECTIVE DATE**

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

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Office of the Secretary

# MEDICAL CARE OF U.S. EMPLOYEES OVERSEAS AND THEIR DEPENDENTS

Special Reimbursement Rates

Pursuant to the authority provided in 24 U.S.C. 34, as implemented by Executive Order No. 11116, August 5, 1963, special reimbursement rates for medical care of U.S. employees overseas and their dependents were put into effect on January 1, 1964. Because of increases in the cost of providing medical care, changes in international economic conditions, and improvements in the Federal Employees Health Benefits Program such blanket rates are no longer valid and are in need of revision. Pursuant to the authority delegated to the Secretary of Defense by Executive Order No. 11609, July 22, 1971, as amended, the special reimbursement rates for medical care provided to employes of the United States, and their dependents by hospitals and dispensaries overseas are revised as follows:

For inpatient care, of employees of the United States who are not citizens of the United States and their dependents (This rate is now paid by employees who are citi-

zens) \$168.00 per day.

For each outpatient treatment, examination, or consulation of employees of the United States and their dependents rate is now paid by employees in the United States) \$20.00 per visit.

(The revised reimbursement rates provided above become effective April 1, 1977, except where local union contracts or agreements with foreign governments are in effect which incorporate the old rates of reimbursement. The contracts and agreements will be honored until expiration. Requests for special rates due to unusual circumstances shall be submitted by overseas commanders to the Assistant Secretary of Defense (Comptroller) for review and approval.

> MAURICE W. ROCHE, Director, Correspondence and Directives OASD (Comptroller).

NOVEMBER 15, 1976. [FR Doc.76-34149 Filed 11-18-76;8:45 am]

#### Office of the Secretary DEFENSE INTELLIGENCE AGENCY SCIENTIFIC ADVISORY COMMITTEE

Closed Meeting

Pursuant to the provisions of Subsection (d) of Section 10 of Public Law 92-463, as amended by Pub. L. 94-409, notice is hereby given that a closed meeting of a Panel of the DIA Scientific Advisory Committee will be held as follows:

Thursday, 16 December 1976, Pomponio Plaza, Rosslyn, VA.

The entire meeting commencing at 0830 hours is devoted to the discussion of classified information as defined in Section 552(b) (1), Title 5 of the U.S. Code and therefore will be closed to the public. The Panel will receive briefings and participate in discussions relative to the Defense Intelligence Agency's assesserations, and capabilities.

Dated: November 16, 1976.

MAURICE W. ROCHE. Director, Correspondence and Directives, OASD (Comptroller).

[FR Doc.76-34187 Filed 11-18-76;8:45 am]

#### **ENVIRONMENTAL PROTECTION AGENCY**

[FRL 646-3; OPP-33000/478 & 479]

#### RECEIPT OF APPLICATION FOR PESTICIDE REGISTRATION

Data to be Considered in Support of **Applications** 

On November 19, 1973, the Environmental Protection Agency (EPA) published in the Federal Register (39 FR 31862) its interim policy with respect to the administration of section 3(c) (1) (D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended ("Interim Policy Statement"). On January 22, 1976, EPA published in the Feb-ERAL REGISTER a document entitled "Registration of a Pesticide Product-Consideration of Data by the Administrator in Support of an Application" (41 FR 3339). This document described the changes in the Agency's procedures for implementing section 3(c)(1)(D) FIFRA, as set out in the Interim Policy Statement, which were effectuated by the enactment of the recent amendments to FIFRA on November 28, 1975 (Pub. L. 94-140), and the new regulations governing the registration and re-registration of pesticides which became effective on August 4, 1975 (40 CFR Part 162).

Pursuant to the procedures set forth these Federal Register documents, EPA hereby gives notice of the applications for pesticide registration listed below. In some cases these applications have recently been received; in other cases, applications have been amended by the submission of additional supporting data, the election of a new method of support, or the submission of new "offer

to pay" statements.

In the case of all applications, the labeling furnished by the applicant for the product will be available for inspection at the Environmental Protection Agency, Room 209, East Tower, 401 M Street, SW., Washington, DC 20460. In the case of applications subject to the new section 3 regulations, and applications not subject to the new section 3 regulations which utilize either the 2(a) or 2(b) method of support specified in the Interim Policy Statement, all data citations submitted or referenced by the applicant in support of the application will be made available for inspection at the above address. This information (proposed labeling and, where applicable, data citations) will also be supplied by mail, upon request. However, such a request should be made only when circumstances make it inconvenient for the inspection to be made at the Agency offices.

Any person who (a) is or has been an applicant, (b) believes that data he de-

ments of foreign military equipment, op- veloped and submitted to ERA on or after January 1, 1970, is being used to support an application described in this notice, (c) desires to assert a claim under section 3(c)(1)(D) for such use of his data, and (d) wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data or the status of such data under section 10 must notify the Administrator and the applicant named in the notice in the Federal Register of his claim by certified mail. Notification to the Administrator should be addressed to the Product Control Branch, Registration Division (WH-567), Office of Pesticide Environmental Protection Programs. Agency, 401 M St. SW, Washington DC 20460. Every such claimant must include. at a minimum, the information listed in the Interim Policy Statement of November 19, 1973.

Specific questions concerning applications made to the Agency should be addressed to the designated Product Manager (PM), Registration Division (WH-567). Office of Pesticide Programs, at the above address, or by telephone as follows:

PM 11, 12, & 13-202/755-9315 PM 21 & 22—202/426-2454 PM 24—202/755-2196 PM 31-202/426-2635 PM 33-202/755-9041 PM 15, 16, & 17-202/426-9425 PM 23-202/755-1397 PM 25-202/426-2632 PM 32-202/426-9486 PM 34-202/426-9490

The Interim Policy Statement requires that claims for compensation be filed on or before January 18, 1977. With the exception of 2(c) applications not subject to the new section 3 regulations, and for which a sixty-day hold period for claims is provided, EPA will not delay any registration pending the assertion of claims for compensation or the determination of reasonable compensation. Inquiries and assertions that data relied upon are subject to protection under Section 10 of FIFRA, as amended, should be made on or before December 20, 1976.

Dated: November 15, 1970.

JOHN B. RITCH, Jr., Director. Registration Division.

APPLICATIONS RECEIVED (OPP-33000/478) EPA Reg. No. 275-21. Chemical Division, Abbott Laboratories, 14th and Sheridan Rd., North Chicago IL 60064. AMICAL-48. Active Ingredients: Dilodomethyl paratolyl sulfone 95%. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 352-GIN, E. I. Du Pont De Nemours & Co., Inc., Biochemicals Dept., Wilmington DE 19898, LANNATE D METH-OMYL INSECTICIDE DUST. Active Ingredients: Methomyl (S-methyl N-[ (methylcarbamoyl)oxy]thioacetimidate) 2%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM12

EPA File Symbol 352-GIR. E. I. Du Pont De Nemours & Co., Inc. LANNATE 5-D METH-OMYL INSECTICIDE DUST. Active Ingredients: Methomyl (S-methyl N-[methylcarbamoyl) oxy]thioacitimidate 5%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM12

EPA Reg. No. 499-160. Whitmire Research, Inc., 3568 Tree Court Industrial Blvd., St. Louis MO 63122. NO. 110 AEROSOL GENERATOR. Active Ingredients: (5-Benzyl-3-furyl) methyl 2,2-dimethyl - 3-(2 - methylpropenyl) cyclopropane carboxylate 1.000%. Method of Support: Application proceeds under 2(a) of interim policy. Republished: Added uses. PM17

EPA Reg. No. 961-277. Lebanon Chemical Corp., PO Box 180, Lebanon PA 17042. LEB-ANON TURF FUNGICIDE. Active Ingredients: Chlorothalonii (Tetrachloroisophthalonitrile) 5.0%. Method of Support: Application proceds under 2(b) of interim

policy. Application for reregistration. PM21
EPA Reg. No. 1526-428. Arizona Agrochemical Co., PO Box 21537, Phoenix AZ 85036.
AGRO-CHEM BRAND MALATHION 5
DUST. Active Ingredients: Malathion 5.00%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM16.
EPA File Symbol 1763-E. Fields Point Chem-

ical, Inc., PO Box 2095, Edgewood Station, Providence RI 02905. SODIUM HYPO-CHLORITE SOLUTION FOR INDUSTRIAL USE ONLY. Active Ingredients: Sodium Hypochlorite 10.5%. Method of Support: Application proceeds under 2 (c) of interim policy, Application for reregistration. PM34.

EPA Reg. No. 2290-38. The Terre Co. of New Jersey, Inc., 1 Samson St., Saddle Brook NJ 07662. DURSBAN LAWN INSECTICIDE GRANULES FOR PROFESSIONAL USE ONLY. Active Ingredients: Chlorpyrifos (O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) phosphorothioate) 2.32%. Method of Support: Application proceeds under 2(b) of interim policy. Republished: Revised offer to pay statement submitted, Added use and new method of support. PM12

EPA Reg. No. 3125-122. Chemagro Corp., PO
Box 4913, Kansas City MO 64120. BAYGON
SPRAY CONCENTRATE INSECTICIDE.
Active Ingredients: O-Isopropoxyphenyl
Methylcarbamate 17.0%. Method of Support: Application proceeds under 2(b) of
interim policy. Application for reregistration. PM12

EPA Reg. No. 3125-146. Chemagro Corp. BAYGON 70% WEITABLE POWDER INSECTICIDE. Active Ingredients: 2-(1-Methylethoxy) phenol methylcarbamate 70%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. Republished: added use.

EPA Reg. No. 3125-156. Chemagro Corp. BAYGON 70% WETTABLE POWDER INSECTICIDE. Active Ingredients: 2-(1-Methylethoxy) phenol methylcarbamate 70.0%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. Republished: Added uses.

EPA Reg. No. 3125-214. Chemagro Corp. BAYGON 1.5 EMULSIFIABLE INSECTICIDE. Active Ingredients: 2-(1-Methylethoxy) phenol methylcarbamate 13.9%. Method of Support: Application procedes under 2(b) of interim policy. Application for reregistration. PM12

EPA File Symbol 3298-EI. Murd Co., 1945 Philip St., Philadelphia PA 19122. ZURD RESIDUAL CRAWLING INSECT KILLER. Active Ingredients: o-isopropoxyphenyl methylcarbamate 1.0%; Petroleum distillate 84.0%. Method of Support: Application proceeds under 2(c) of interim policy. Republished: Revised offer to pay statement submitted. PM12

EPA Reg. No. 6720-59. Southern Mill Creek Products Co., Inc., PO Box 1096, Tampa FL 33601. DURSBAN 2E INSECTICIDE. Active Ingredients: Chiorpyrifos (O.O-diethyl O-(3.5.6-trichloro-2-pyridyl) phosphorothioate) 23.5%; Aromatic petroleum derivative solvent 14.9%; Xylene 54.9%. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA File Symbol 6962-UU. Madison Bionics, 11250 W. Addison St., Franklin Park II. 60131. CHEMPLEX. Active Ingredients: nalkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethylbenzyl ammonium chlorides 1.6%; n-alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 1.6%; Sodium carbonate 3.0%; Tetrasodium ethylene diamine tetraccetate 1.0%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 7296-RU. Gem City Chemicals, Inc., 1287 Air City Ave., Dayton OH 45404. CUPRI-PELS POOL WINTERIZER. Active Ingredients: Copper Sulfate (Pentahydrate) Copper as Metallic (25.2%) 99%. Method of Support: Application proceeds under 2(b) of interim policy. PM22

EPA File Symbol 8329-RN. Clark Outdoor Spraying Co., Inc., 7N570 Garden Ave., Roselle II. 60172. CLARKE SKEETER SLUGS. Active Ingredients: Chlorpyrifos (O,Odiethyl O-(3.5,6-trichloro-2-pyridyl) phosphorothioate 1.0%. Method of Support: Application proceeds under 2(b) of interim policy. PM12

EPA Reg. No. 8590-252. Agway, Inc., Fertilizer-Chemical Div., Box 1333, Syracuse NY 13201. AGWAY LAWN SHIELD CRAB-GRASS KILLER WITH TUPERSAN. Active Ingredients: Siduron [1-(2-methylcyclohexyl)-3-phenylurea] 6.15%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration, PM25

EPA File Symbol 8730-RR. Herculite Protective Fabrics Corp., A Subsidiary of Health-Chem Corp., 1107 Broadway, New York NY 10010. INSECTAPE. Active Ingredients: 2-(1-Methylethoxy) phenol methylcarbamate 10.0%. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 8959-EN. Applied Biochemists, Inc., 5300 W. County Line Rd., Mequon WI 53092. CUTRINE-PLUS II ALGAECIDE. Active Ingredients: Copper as elemental 10.88%. Method of Support: Application proceeds under 2(c) of interim policy. PM24

EPA File Symbol 11661-R. Hot Bug Organic Pesticides Sales & Services, PO Box 8274. Long Beach CA 90808. HOT BUG PESTI-CIDE KILLS ADULT SPIDER MITES, SALT MARSH LARVAE. Active Ingredients: Borax 2.09%. Method of Support: Application proceeds under 2(a) of interim policy. PM16

EPA File Symbol 11661-E. Hot Bug Organic Pesticides Sales & Services. HOT BUG PES-TICIDE KILLS COCKROACHES. Active Ingredients: Borax 3.28%. Method of Support: Application proceeds under 2(a) of

interim policy. PM16
EPA File Symbol 11661-L. Hot Bug Organic
Pesticide Sales & Services. HOT BUG PESTICIDE KILLS HOUSEFLIES, MOSQUITIOS. Active Ingredients: Borax 3,28%.
Method of Support; Application proceeds
under 2(a) of interim policy. PM16

EPA File Symbol 11687-OG. Transvaal, Inc., Suite 3200, Clark Tower, 5100 Poplar Ave., Memphis TN 38137. TRANSVAAL WEED-RHAP MCPA-6-A. Active Ingredients: Dimethylamine salt of 2-methyl-4-chlorophenoxyacetic acid 75.0%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

EPA File Symbol 15749-E. Vermillion Chemical Service, Inc., 1306 Charity St., Abbeville, LA 70510. VERMILLON Q.A.C. Active Ingredients: n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 5%; n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 15749-G. Vermillion Chemical Service, Inc. V.C. ALGA-WAY. Active Ingredients: n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 5%; n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 20954-A. Zoecon Corp., 975 California Ave., Puloatta CA 94304. STAR-BAR BLOCK IGR CATTLE SUPPLEMENT. Active Ingredients: methoprene [Isopropyl (E,E)-11-methoxy-3, 7-11-trimethyl-2, 4dodecadlenoate] 0.01%. Method of Support: Application proceeds under 2(b) of interim policy. PM17

port: Application proceeds under 2(b) of interim policy. PM17

EPA Reg. No. 27586-1. U.S. Forest Service, (1205-B LRPE), 14th & Independence Ave., SW, Washington DC 20250, TM BIOCONTROL-1 BIOLOGICAL INSECTICIDE FOR THE DOUGLAS-FIR TUSSOCK MOTH. Active Ingredients: (Polyhedral inclusion bodies of Douglas-fir tussock moth nucleopolyhedrosis virus) 3.5%. Method of Support: Application proceeds under 2(a) of interim policy. PM17

EPA Reg. 34429-4. American Chemical Corp., PO Box 296, Buyamon PR 00619. SUPER KILLER PRESSURIZED SPRAY. Active Ingredients: Petroleum distillates 68.054%; N-Octyl bicycloheptane dicarboximide 0.840%; Technical Piperonyl Butoxide 0.504%; Pyrethrins 0.252%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA Reg. No. 36531-4. The Friar Co., 4440 Fifth St. Rd., PO Box 109, Lavalette WV 25535. SHILLELAGH 211. Active Ingredients: Didecyl dimethyl ammonium chloride 50%; Isopropyl alcohol 20%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 36636-R. Perc Serv., Inc., 2235 Chestnut St., Oakland CA 94607. PSI MILDEW CONTROL. Active Ingredients; Didecyl dimethyl ammonium chloride 40%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 38053-E. Leo Ind., Inc., 1750 W. 75th Pl., Chicago IL 60620. LEO QUAT 450 NP DISINFECTANT CLEANER, MINT. Active Ingredients: n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 2.25%; n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 2.25%; Sodium Carbonate 3.00%; Tetrasodium ethylenediamine tetraacetate 1.00%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 38515-R. Dabco, 3402 Dean St., Naples FL 33940, DABCO, Active Ingredients: Sodium Hypochlorite 9.2%. Method of Support: Application proceeds under 2(b) of interim policy. PM34

EPA File Symbol 38621-R. Foster Manufacturing, Inc., 1577 First St., Coachella CA 92236. EAGLE METHYL BROMIDE. Active Ingredients: Methyl Bromide 99.75%; Chloropicrin 0.25%. Method of Support: Application proceeds under 2(b) of interim policy. PM11

EPA File Symbol 39508-R. New Mexico Dept. of Agriculture, PO Box 3189, Las Cruces NM 88003. M-44 CYANIDE CAPSULES. Active Ingredients: Sodium Cyanide 88.78%. Method of Support: Application proceeds under 2(b) of interim policy.

APPLICATIONS RECEIVED (OPP-33000/479)

EPA Reg. No. 239-2337. Chevron Chemical Co. Ortho Div., 940 Hensley St., Richmond CA 94804, ORTHO CRAB GRASS PREVENTER PLUS LAWN FOOD 19-3-3. Active Ingredi-S-(0,0-diisopropylphosphorodithioents: ate) ester of N-(2-mercaptoethyl) benzenesulfonamide 4.35%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA Reg. No. 239-2338. Chevron Chemical Co. ORTHO CRAB GRASS PREVENTER PLUS LAWN AND DICHONDRA FOOD: Active Ingredients: S-(0,0-disopropyl phosphorodithioate) ester of N-(2-mercaptoethyl) benzenesulfonamide 5.2%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA File Symbol 323-LG. J. I. Holcomb Mfg. Co., 4415 Euclid Ave., Cleveland OH 44103. HOLCOMB SWIMMING POOL ALGAE-CIDE. Active Ingredients: Alkyl Dimethyl Benzyl Ammonium Chloride (C14 60%, C12 C16 15%) 10%. Method of Support: Application proceeds under 2(b) of interim

policy, PM24 EPA File Symbol 323-LU, J. I. Holcomb Mfg. Co. LIQUID SANITIZER. Active Ingredients: Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chlorides 1.28%; Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chlorides 1.28%; Sodium carbonate 2.00% Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA Reg. No. 449-227. Techne Corp., c/o Regulatory Affairs Dept., Farmland Ind., Inc., P.O. Box 7305, Kansas City MO 64116. TECHNE LAWN GUARD. Active Ingredients: Dimethyl tetrachloroterephthalate (Dacthal (R)) 1.75%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

EPA File Symbol 464-LUR. Dow Chemical Co., P.O. Box 1706, Midland MI 48640. TOR-DON 5K PELLETS HERBICIDE. Active Ingredients: Picloram (4-amino-3,5,6-trichloropicolinic acid) potassium salt 5.8%. Method of Support: Application proceeds under 2(b) of interim policy. PM25

EPA Reg. No. 524-80. Monsanto Co., Agricultural Products, 800 N. Lindbergh Blvd., St. Louis MO 63166. MCP AMINE. Active Ingredients: Dimethylamine salt of 2-Methyl-4-Chlorophenoxyacetic acid 52.0%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

File Symbol 524-GEE, Monsanto Co. MCP AMINE. Active Ingredients: Di-methylamine sale of 2-Methyl-4-Chloro-phenoxyacetic acid 52.0%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistra-tion, PM23

EPA Reg. No. 538-11. O. M. Scott & Sons, Marrysville OH 43040, SCOTTS HALTS BRAND CRABGRASS PREVENTER. Active Ingredients: S-(0,0-Diisopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide 11%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA Reg. No. 538-26. O. M. Scott & Sons. SCOTTS PROTURF BRAND. Active Ingredients: S-(0,0-Diisoprophyl phosphorodithioate) ester of N-(2-Mercaptoethyl)

of interim policy. Application for reregistration, PM25

EPA Reg. No. 538-37. O. M. Scott & Sons. SCOTTS PROTURF BRAND 28-0-7 FER-TILIZER WITH WEEDGRASS VENTER. Active Ingredients: S-(0,0-Di-isopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide 9.00%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA Reg. No. 538-53. O. M. Scott & Sons. SCOTTS SUPER HALTS PLUS BRAND CRABGRASS PREVENTER PLUS LAWN FERTILIZER. Active Ingredients: S-(0.0-Diisopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide 4.60%. Method of Support: Application proceeds under 2(b) of interim policy. Ap-

plication for reregistration. PM25
EPA Reg. No. 538-58. O. M. Scott & Sons.
TURF BUILDER PLUS HALTS CRABGRASS PREVENTER PLUS LAWN FER-TILIZER. Active Ingredients: S-(0,0-Di-isopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide 5.60%. Method of Support: Application proceeds under 2(b) of interim policy. Ap-

plication for reregistration. PM25 EPA Reg. No. 538-177. O. M. Scott & Sons. SUPER TURF BUILDER PLUS HALTS CRABGRASS PREVENTER PLUS LAWN FERTILIZER. Active Ingredients: S-(0,0-Diisopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide fonamide 5.75%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA Reg. No. 538-129. O. M. Scott & Sons. SCOTTS PROTURF BRAND 32-4-4. Active Ingredients: S-(0.0-Diisopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide 5.20%. Method of Support: Application proceeds under 2(b) of Interim policy. Application for reregistration. PM25

tration PMZ6

EPA Reg. No. 538-137. O. M. Scott & Sons.
SCOTTS PROTURF (R) BRAND 26-0-12.
Active Ingredients: S-(0,0-Disopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl (Benzenesulfonamide 7.80%. captoethyl (Benzenesulfonamide 7.80%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA Reg. No. 554-60. Agsco, Inc., P.O. Box 458, Grand Folks ND 58201, MCP AMIME HERBICIDE. Active Ingredients: Di-methylamine Salt of 2-Methyl-4-chlorophenoxyacetic acid 52.47%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

EPA Reg. No. 554-123. Agsco, Inc. AGSCO MA HERBICIDE. Active Ingredients: Diethanolamine Salt of 2-Methyl-4-chlorophenoxyacetic acid 62.33%. Method of Support: Application proceeds under 2(b) of in-terim policy. Application for registration.

EPA Reg. No. 554-125. Agsco, Inc. AGSCO MXL HERBICIDE. Active Ingredients: 2-Methyl-4-chlorophenoxyacetic acid Iso-octyl ester 75.08%. Method of Support: Application proceeds under 2(b) of interim

policy. Application for reregistration. PM23 EPA File Symbol 900-RRR. Chemical Service, Div. of American Chemmate Corp., Howard & West Sts., Baltimore MD 21230, CREAMY BACTERIOSTATIC CLEANER. Active In-gredients: Ammonium Oxalate 1.30%; 2,2'-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4'-Trichloro-2'hydroxydiphenylether 0.10%; Ammonium Ortho Phenylphenate 0.05%. Method of Support: Application proceeds under 2(b) of interim policy. PM32

benzenesulfonamide 8.50%. Method of EPA File Symbol 900-RRE. Chemical Service, Support: Application proceeds under 2(b) CREME-BRITE BACTERIOSTATIC BACTERIOSTATIC CREME-BRITE BACTERIOSTATIC CLEANER. Active Ingredients: Am-monium Oxalate 1.30%; 2.2\*-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4'- Trichloro - 2'- hydroxydiphenylether 0.10%: Ammonium Ortho Phenylphenate 0.05%. Method of Support: Application proceeds under 2(b) of interim policy.

> EPA File Symbol 900-RRG. Chemical Service LEMON BACTERIOSTATIC CREME CLEANER. Active Ingredients: Ammonium Oxalate 1.30%; 2,2'-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4'-Trichloro-2'-hydroxydiphenylether 0.10%; Ammonium Ortho Phenylphenate 0.05% Method of Support: Application proceeds

under 2(b) of interim policy PM32
PA Reg. No. 904-146. B. G. Pratt Div.,
Gabrial Chemicals Ltd., 204 21st Ave.,
Paterson NJ 07509. PRATT DANDELION DESTROYER, Active Ingredients; Dimethylamine salt of Dicamba (3,6-dichloro-oanisic acid) 3.43%; Dimethylamine salts of Related Acids 0.55%; Dimethylamine salt of 2.4-Dichlorophenoxyacetic acid 17.22%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

EPA Reg. No. 904-195. B. G. Pratt Div. PRATT TURF HERBICIDE 10,000. Active Ingredients: Dimethylamine salt of 2,4-dichloro-phenoxyacetic acid 12.88%; Dimethyl-amine salt of 2-(2-methyl-4-chlorophe-noxy) propionic acid 5.84%; Dimethyla-mine salt of Dicamba (3,6-dichloro-o-anisic acid) 1.34%. Method of Support: Application proceeds under 2(b) of interim policy Application for reregistration. PM23

[FR Doc.76-34121 Filed 11-18-76;8:45 am]

[FRL 646-4; OPP-33000/480]

#### RECEIPT OF APPLICATION FOR PESTICIDE REGISTRATION

#### Data To Be Considered In Support of **Applications**

On November 19, 1973, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (39 FR 31862) its interim policy with respect to the administration of section 3(c)(1) (D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended ("Interim Policy Statement"). On January 22, 1976, EPA published in the FEDERAL REGISTER a document entitled "Registration of a Pesticide Product-Consideration of Data by the Administrator in Support of an Application" (41 FR 3339). This document described the changes in the Agency's procedures for implementing section 3(c) (1) (D) of FIFRA, as set out in the Interim Policy Statement, which were effectuated by the enactment of the recent amendments to FIFRA on November 28, 1975 (Pub. L. 94-140), and the new regulations governing the registration and re-registration of pesticides which became effective on August 4, 1975 (40 CFR Part 162)

Pursuant to the procedures set forth in these Federal Register documents, EPA hereby gives notice of the applications for pesticide registration listed below. In some cases these applications have recently been received; in other cases, applications have been amended by the submission of additional supporting data,

the election of a new method of support, or the submission of new "offer to pay" statements.

In the case of all applications, the labeling furnished by the applicant for the product will be available for inspection at the Environmental Protection Agency, Room 209, East Tower, 401 M Street, SW., Washington DC 20460, In the case of applications subject to the new section 3 regulations, and applications not subject to the new section 3 regulations which utilize either the 2(a) or 2(b) method of support specified in the Interim Policy Statement, all data citations submitted or referenced by the applicant in support of the application will be made available for inspection at the above address. This information (proposed labeling and, where applicable, data citations) will also be supplied by mail, upon request. However, such a request should be made only when circumstances make it inconvenient for the inspection to be made at the Agency

Any person who (a) is or has been an applicant, (b) believes that data be developed and submitted to EPA on or after January 1, 1970, is being used to support an application described in this notice. (c) desires to assert a claim under section 3(c) (1) (D) for such use of his data, and (d) wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data or the status of such data under section 10 must notify the Administrator and the applicant named in the notice in the FEDERAL REGISTER of his claim by certified mail. Notification to the Administrator should be addressed to the Product Control Branch, Registration Division (WH-567), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington DC 20460. Every such claimant must include, at a minimum, the information listed in the Interim Policy Statement of November 19, 1973.

Specific questions concerning applications made to the Agency should be addressed to the designated Product Manager (PM), Registration Division (WH-567), Office of Pesticide Programs, at the above address, or by telephone as follows:

PM 11, 12, and 13—202/755-9315 PM 21 and 22—202/426-2454 PM 24—202/755-2196 PM 31—202/426-2635 PM 33—202/755-9041 PM 15, 16, and 17—202/426-9425 PM 23—202/755-1397 PM 25—202/426-2632 PM 32—202/426-9486 PM 34—202/426-9486 PM 34—202/426-9490

The Interim Policy Statement requires that claims for compensation be filed on or before January 18, 1976. With the exception of 2(c) applications not subject to the new section 3 regulations, and for which a sixty-day hold period for claims is provided, EPA will not delay any registration pending the assertion of claims for compensation or the determination of reasonable compensation. Inquiries and

assertions that data relied upon are subject to protection under section 10 of FIFRA, as amended, should be made on or before December 20, 1976.

Dated: November 11, 1976.

John B. Ritch, Jr., Director, Registration Division.

APPLICATIONS RECEIVED (OPP-33000/480)

EPA Reg. No. 602-87. Raiston Purina Co., Checkerboard Square, St. Louis MO 63188. PURINA MALATHION DUST. Active Ingredients: Malathion 4%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM16

EPA Reg. No. 602-227. Ralston Purina Co. PURINA HOG AND CATTLE DUSTING POWDER. Active Ingredients: Malathion 4%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM16

EPA File Symbol 1266-RTR. Malter International, Inc., PO Box 6099, New Orleans, LA 70114. KNOX OUT II INSECTICIDE SPRAY, Active Ingredients: (5-Bensyl-3-furyl) methyl 2,2-dimethyl-3-(2-methyl-propenyl) cyclopropanecarboxylate 0.250%; Related compounds 0.034%. Method of Support: Application proceeds under 2(b) of interim policy, PM17

EPA Reg. No. 1598-90, FCX, Inc., 121 E. Davie St., PO Box 2419, Raleigh, NC 27602, FER-BAM NO. 10 DUST FUNGICIDE, Active Ingredients: Ferbam (ferric dimethyl dithiocarbamate) 11.4%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration, PM21

EFA Reg. No. 1685-45. State Chemical Manufacturing Co., 3100 Hamilton Ave., Cleveland, OH 44114. STATE FORMULA 219
SURE-KIL SELECTIVE WEED KILLER.
Active Ingredients: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid 26.75%, Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

EPA Reg. No. 1990-147. Farmland Industries, Inc., c/o Regulatory Affairs Dept., PO Box 7305, Kansas City, MO 64116. CO-OP BIG 3 LAWN FERTILIZER. Active Ingredients; Dimethyl ester of tetrachioroterephathalic acid 1.25%. Method of Support: Application proceeds under 2(b) of Interim policy. Application for reregistration. PM23

EPA Reg. No. 2124-192. W. R. Grace & Co., Agricultural Chemicals, Box 277, Memphis, TN 38101. NACO MALATHION 4 DUST, Active Ingredients: O.O-Dimethyl Dithiophosphate of Diethyl Mercaptosuccinate (Malathion) 4%. Method of Support: Application proceeds under 2(b) of Interim policy. Application for reregistration. PM16

policy. Application for reregistration. PM16
EPA Reg. No. 2124-404. W. R. Grace & Co.
NACO MALATHION 25% WETTABLE
POWDER, Active Ingredients: O,O-Dimethyl Dithiophosphate of Diethyl Mercaptosuccinate (Malathion) 25.0%. Method
of Support: Application proceeds under
2(b) of interim policy. Application for reregistration. PM16

EPA Reg. No. 2124-588. W. R. Grace & Co. NACO MALATHION 5 DUST. Active Ingredients: O,O-Dimethyl Dithiophosphate of Diethyl Mercaptosuccinate (Malathion) 5.00%. Method of Support: Application proceeds under 2(b) of Interim policy. Application for reregistration. PM16

EPA Reg. No. 2136-27. J. L. Hoffman Co., Inc., 1415 Court St., Allentown PA 18102. HOFF-MAN'S LOUSE KILLER. Active Ingredients: Maiathion (O,O-Dimethyl Dithiophosphate of Diethyl Mercaptosuccinate) 4%; Sulfur 20%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM16

EPA Reg. No. 2136-28. J. L. Hoffman Co., Inc. HOFFMAN'S MALATHION 4 DUST. Active Ingredients: Malathion (O.O-Dimethyl Dithiophosphate of Diethyl Mercaptosuccinate) 4%. Method of Support: Application proceeds under 2(b) of Interim policy Application for reregistration. PM16

EPA Reg. No. 2459-181. Stevens Industries, Inc., Box 272, Dawson GA 31742, MASTER BRAND 5% MALATHION DUST. Active Ingredients; Malathion 5%, Method of Support; Application proceeds under 2(b) of interim policy. Application for reregistration, PM16

EPA Reg. No. 2491-139. Koos, Inc., 4500 13th St., Kenosha WI 53140. HOLIDAY CRABGRASS PREVENTER. Active ingredients: Dimethyl ester of Tetrachloroterephthalic Acid 5.75%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM23

EPA File Symbol 3160-UR. Davis Manufacturing Co., Inc., 1023 Morales St., San Antonio TX 78206. DACIDE CONCENTRATE 5776. Active Ingredients: n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 5%; n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA Reg. No. 3743-64. Southern Agricultural Chemicals, Inc., PO Box 527, Kingstree SC 29556, 4% MALATHION DUST WITH SUL-FUR. Active Ingredients: Malathion 4%; Sulfur 18%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration, PM16

EPA Reg. No. 3770-188. Economy Products Co., Inc., PO Box 427, Shenandoah IA 51601, MBC NON-SELECTIVE GRANULAR HERBICIDE CONTROLS BROADLEAF AND GRASSY WEEDS. Active Ingredients: Sodium Chlorate (NaClo.) 30%; Sodium Metaborate Tetrahydrate Na-B<sub>2</sub>O, 4H-O) 68%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM25

EPA Reg. No. 5602-17. Hub States Corp., 2000 N. Illinois St., Indianapolis IN 46204. MALATHION 5% DUST. Active Ingredients: Malathion (O,O-dimethyl dithiophosphate of diethyl mercaptosuccinate) 5.0%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration, PM16

EPA File Symbol 5813-RI. The Clorox Co., PO Box 493, Pleasanton CA 94566, CLOROX DISINFECTANT CLEANER. Active Ingredients: Sodium dichloro-s-triazinetrione Dihydrate 3.00%; Trisodium phosphate, anhydrous 9.71%. Method of Support: Application proceeds under 2(a) of interim policy. PM34

EPA File Symbol 6378-EA. Lab Automated Chemicals, Div. of American Chemmate Corp., Howard & West Sts., Baltimore MD 21230. LAB BRITE-CREME. Active Ingredients: Ammonium Oxalate 1.30%; 2,2'-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4'-Trichloro-2'-hydroxydiphenylether 0.10%; Ammonium Ortho Phenylphenate 0.05%. Method of Support: Application proceeds under 2(b) of interim policy PM32.

of interim policy. PM32
EPA File Symbol 6720-EAT. Southern Mill
Creek Products Co., Inc., Box 1096, Tampa
FL 33601. SMCP SBP-1382 2% CONCENTRATE. Active Ingredients; (5-Benzyl-3furyl)methyl 2,2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate 2,000%.
Method of Support: Application proceeds
under 2(b) of interim policy. PM17

EPA Reg. No. 6735-201. Tide Products, Inc., Box 1020, Edinburg TX 78533. TIDE MALA-THION 5 DUST. Active Ingredients: Malathion (0,0-dimethyl dithiophosphate of diethyl mercaptosuccinate) 5%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregis-tration PM16

EPA File Symbol 6962-LR. Madison Bionics, 11250 W. Addision St., Franklin Park, IL 60131. PROPER. Active Ingredients: Am-monium Oxalate 1.30%; 2,2'-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4' - Trichloro-2' - hydroxydiphenylether 0.10%; Ammonium Ortho Phenylphenate 0.05%. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 6962-LE. Madison Bionics. DISINFECTANT 4045. Active Ingredients: Isopropanol 15.00%; Potassium orthophenylphenate 4.40%; Potassium o-benzylp-chlorophenate 4.05%; Tetrasodium ethylenediamine tetrascetate 1.60%, Method of Support: Application proceeds under 2(a) of interim policy. PM32

EPA File Symbol 8075-A. Allen Chemical Co. 3235 N. W. 37th St., Miami FL 33142. ALCO TOWER BIOCIDE #13. Active Ingredients: Disodium cyanodithiomidocarbonate 3.68%; Potassium N-methyldithiocarba-mate 5.07%. Method of Support: Application proceeds under 2(b) of interim policy.

[FR Doc.76-34122 Filed 11 18-76;8:45 am]

#### [FRL 646-5]

#### PEST CONTRAL DEVICES AND DEVICE **PRODUCERS**

#### Consolidation and Clarification of Requirements

#### I. PURPOSE

· Requirements applicable to pest control devices and device producers have been set forth in various regulations promulgated pursuant to the Federal Insecticide, Fungicide, and Roden-ticide Act, as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136 et seq.) ("FIFRA" or "the Act"). The purpose of this notice is to provide a consolidation and clarification of all such requirements. .

#### II. DEFINITIONS

At section 2(h) of FIFRA (7 U.S.C. 136 (h)) the term "device" is defined to mean:

\* \* \* any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separtely therefrom.

To more clearly identify the types of products to which the requirements discussed in this Notice apply, the term "device" must be contrasted with the term "pesticide," which is defined at section 2(u) of FIFRA to mean:

\* \* \* any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any sub-stance or mixture of substances intended for use as plant regulator, defoliant, or desic-

Thus, if an article uses physical or mechanical means to trap, destroy, repeal, or mitigate any plant or animal life declared to be a pest at 40 CFR 162.14, it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide.

#### III. DEVICES SUBJECT TO THE ACT

Section 25(c)(4) of FIFRA (7 U.S.C. 136w(c)(4)) provides that the Administrator may specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) (7 U.S.C. 136(q)(1)) or section 7 (7 U.S.C. 136e) of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act. On July 3, 1975, the Administrator promulgated regulations (40 F.R. 28242) amending 40 CFR Part 162 pursuant to this authority. 40 CFR 162.15 now provides that devices as defined in FIFRA section 2(h) are subject to the requirements of FIFRA section 2(q) (1) (A)-(G) and to those provisions of FIFRA section 7 which are necessary to effectuate the purposes of FIFRA with respect to devices.

The preamble to these regulations at 40 F.R. 28266 declared that to effectuate the purposes of the Act, devices subject to sections 2(q) (1) and 7 include but are not limited to:

(A) Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides). and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites; (B) certain high frequency sound generators, carbide cannons, folls, and rotating devices, for which claims are made to repel birds; (C) black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and (D) mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

The preamble further specifies those instruments declared to be of a character unnecessary to be subject to this Act in order to carry out the purposes of the Act. These include:

(1) Those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and

(2) Those which operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps

Section 8 of FIFRA (7 U.S.C. 136f) provides for such record-keeping and record inspection requirements as the Administrator determines necessary for effective enforcement of the Act. Section 17 specifies the requirements to be placed on the import and export of devices. In neither of these sections is there a provision that the Administrator declare those classes of devices subject to these sections of the Act; and in the attendant regulations, no specification is made. For purposes of enforcement, the Agency will consider those classes of devices declared to be subject to regulation under section 25(c) (4) of the Act as subject to regulation under sections 8 and 17 as well.

#### IV. SUMMARY OF FIFRA PROVISIONS APPLICABLE TO DEVICES

Any instrument declared to be a device under 40 CFR 162.15 is, upon introduction into channels of trade, subject to the provisions discussed below. Those provisions of the amended FIFRA which pertain to devices are in many respects similar to those under the 1947 FIFRA (61 Stat. 163; 7 U.S.C. 135-135k). In both Acts the Agency is authorized to inspect records showing the delivery, movement, or holding of devices (7 U.S.C. 135c, 136f); to obtain samples of any device in the marketplace (7 U.S.C. 135d, 136g); to seize any misbranded device (7 U.S.C. 135g, 136k); to initiate criminal proceedings against any person violating any provision of the Act (7 U.S.C. 135f, 136l); and, in cooperation with the Secretary of the Treasury, to sample, examine, and detain any imported device which violates the provisions of the Act (7 U.S.C. 135h 136o)

The differences in the provisions of the two Acts with respect to requirements applicable to devices, lie primarily in the greater specification of jurisdiction and regulatory requirements provided by the 1972 amendments. For example, while a device, unlike a pesticide, is not subject to the section 3 registration requirement of FIFRA, section 12 of the Act makes clear the intent of the Act that subject devices and persons dealing with devices be held responsible for those obligations. other than registration, that are imposed by the Act. Jurisdiction to regulate devices is expanded to intra- as well as interstate commerce (7 U.S.C. 136j(a) (1)). Similarly, section 9(a) of the amended FIFRA specifies that entry for the purpose of inspecting and obtaining samples of devices "packaged, labeled, and released for shipment is permitted into "any establishment or other place where \* \* \* devices are held for distribution or sale (7 U.S.C. 136g(a)).
With respect to affirmative regulatory

requirements, section 2(q)(1) of the amended FIFRA expands the definition of misbranding as it applies to devices subject to the Act (7 U.S.C. 136(q)(1)). Section 7 of the amended FIFRA is totally new, requiring the registration of establishments which produce devices declared subject to the Act (7 U.S.C. 136e). In addition to the provisions of the Act allowing the inspection of records kept by producers and distributors of devices, section 8(a) of the amended FIFRA requires producers of devices subject to the Act to maintain such books and records as the Administrator requires by regulation (7 U.S.C. 136f(a)). Finally, section 17(a) of FIFRA, as amended, specifically imposes the same recordkeeping requirements on producers of devices intended for export by making such producers subject to the require-

ments of section 8.

V. ELABORATION OF SPECIFIC REQUIRE-MENTS APPLICABLE TO DEVICES

A. Section 2(q) (1), Misbranding Provisions (7 U.S.C. 136(q) (1)). With promulgation of the regulations at 40 CFR 162.15, which invoked the authority of section 25(c) (4) to specify devices subject to sections 2(q) and 7 of the Act, the labeling requirements of the 1947 FIFRA to which devices had been subject were expanded (7 U.S.C. 135(z) (1)). Those misbranding provisions of section 2(q) (1) of the amended FIFRA which the Administrator has made applicable to devices are listed at 40 CFR Part 162.15(b). In summary, a device will be subject to enforcement action if

2(q) (1) (A): Its labeling bears any statements, designs, or graphic representations relative thereto or to its ingredients which are false or misleading in any particular;

2(q)(1)(B): Its packaging or wrapping fails to conform with standards established pursuant to section 25(c)(3) (Such standards have not, as of this date, been issued by the Administrator; at such time as they are, the question of their applicability to devices will be addressed):

devices will be addressed);
2(q)(1)(C): It is an imitation of, or is offered for sale under the name of another device;

2(q)(1)(D): Its label fails to bear the establishment number;

2(q)(1)(E): Required information is not prominently displayed on the label;

2(q)(1)(F): It lacks adequate directions for use: or

for use; or 2(q)(1)(G): It lacks an adequate warning or caution statement.

40 CFR 162.10(a) (5) provides an interpretation of what the term "false and misleading" may include in the context of FIFRA section 2(q) (1) (A) misbranding:

A false or misleading statement concerning the composition of the product; A false or misleading statement concern-

A false or misleading statement concerning the effectiveness of the product;

A false or misleading statement about the value of the product for purposes other than as a device;

A falle or misleading comparison with other devices:

Any statement directly or indirectly implying that the device is recommended or endorsed by any agency of the Federal Government:

A true statement used in such a way as to give a false or misleading impression to the purchaser;

Label disclaimers which negate or detract from labeling statements required under the Act and regulations; or

Non-numerical and/or comparative statements on the safety of the product.

B. Section 7, Registration of Establishments (7 U.S.C. 136e). On November 6, 1973, regulations (40 CFR Part 167) for the implementation of section 7, Registration of Establishments, were published in the Federal Registers (38 F.R. 30557). The scope of the requirements is set forth at § 167.2(a): "All establishments, as defined in this part, which produce any pesticide or device subject to the provisions of this section, must be registered pursuant to the requirements of these regulations - "At § 167.1(k) the term "device" is defined as "- any device or class of devices as defined by the Act and determined by the Administrator

pursuant to section 25(c) to be subject to the provisions of section 7 of the Act."

Section 7 imposes three basic requirements: (1) Registration of device-producing establishments, (2) labeling which reflects the EPA establishment in umber assigned to the establishment in which the device was produced, and (3) submission of annual production reports.

All establishments in which devices subject to the Act are produced must be registered with the Environmental Protection Agency as producing establishments. This includes foreign establishments in which devices shipped to the United States are produced, as well as establishments located in the United States which produce devices for export.

To register establishments, producers should obtain from an EPA regional office the Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8). The applications require such information as the name and address of the company headquarters and the names and addresses of all device-producing establishments owned and operated by the company. This application must be submitted to the regional office on or before January 18, 1976. Upon receipt of a completed application, the regional office shall register each establishment listed and shall assign each establishment an EPA establishment number. This EPA establishment number must be displayed on all devices released for shipment by the establishment after 90 days after the producer is notified of the assigned number.

The production reports (EPA Form 3540-16) must be submitted to the regional office within thirty days after notification of registration and by February 1 each year thereafter.

C. Section 8, Books and Records (7 U.S.C. 136f). On September 18, 1974, regulations (40 CFR Part 169) for the implementation of section 8, Books and Records, were published in the FEDERAL REGISTER (39 F.R. 33512). Pursuant to the authority of section 8(a) of the Act, these regulations (at 40 CFR 162.2) specify those records pertaining to development, testing, production, holding, and distribution, which all producers of devices declared subject to the Act are required to maintain and submit to inspection. These requirements apply to domestic and foreign persons producing devices for sale and distribution in the United States and to domestic producers who export devices.

Specifically, producers of devices subject to the Act are required to maintain the following records:

169.2(b): Records showing the brand names and quantities of devices produced. These records shall be retained for two years.

169.2(c): Records showing the following information regarding the receipt of devices: (1) Brand name of device, (2) Name and address of shipper, (3) Name of delivering carrier, (4) Date received, and (5) Quantities received.

These records shall be retained for two years.

169.2(d): Records showing the following information regarding the shipment of devices: (1) Brand name of device, (2) Name and address of the consignee, (3) Name of originating carrier, (4) Date shipped or delivered for shipment, and (5) Quantities shipped or delivered for shipment.

These records shall be retained for two years.

169.2(e): Inventory records with respect to the types and amounts of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

169.2(h): In the case of devices intended solely for export to any foreign country, copies of the specifications or directions of the foreign purchaser for the production of the devices. These records shall be retained for two years after expiration of the contract.

Pursuant to the authority of section 8(b) of the Act, 40 CFR 169.3(b) requires that distributors, carriers, dealers or other persons who sell or deliver (or offer to sell or deliver) devices declared subject to the Act, allow inspection of the records they have pertaining to the following:

(1) The delivery or holding of the device and quantity held; (2) Date of shipment and receipt; (3) Name and address of consignee and consignor; and (4) Any guarantees received pursuant to section 12(b) (1).

D. Section 17, Imports and Exports (7 U.S.C. 1360). On August 1, 1975, regulations (19 CFR Part 12.1) for the implementation of section 17, Imports and Exports, were published in the FEDERAL REG-ISTER (40 FR 32321). These regulations require that devices produced by foreign manufacturers and imported into the United States comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, available at any EPA office) for review and determination as to whether the shipment should be sampled and/or permitted entry into the United States. The Act also provides that samples may be collected and examined and that shipments may be permitted entry. detained until brought into compliance, destroyed, or re-exported.

With respect to devices produced in this country for export, section 17(a) of the FIFRA as amended requires that such devices must be prepared or packed in accordance with the specifications or directions of the foreign purchaser and that producers of such devices must maintain books and records pursuant to section 8(a).

#### VI. ENFORCEMENT AUTHORITIES

Section 9(a) (7 U.S.C. 136(g) (a)) of the Act authorizes officers of the Agency to inspect any establishment or other place where a device is held for distribution or sale in order to obtain a sample of the device as packaged, labeled and released for shipment, and samples of any containers or labeling for the device. Officers of the Agency are also authorized

to inspect books and records required to be maintained under section 8(a) and copies of records which are available under section 8(b).

Pursuant to section 12(a)(2)(B) of the Act, it is unlawful for any person to refuse to keep or to permit inspection of books and records, or to refuse to permit inspection of an establishment. Pursuant to section 12(a) (1) (F) of the Act, it is unlawful to sell or distribute any device which is misbranded. Finally, pursuant to section 12(a)(2)(L) of the Act, it is unlawful to violate any provision of sec-

Upon a finding of any unlawful act, the Administrator may assess a civil penalty pursuant to section 14(a) of the Act or initiate criminal proceedings pursuant to section 14(b) of the Act. If, upon inspection or tests, a device is believed to be in violation of the Act, or if it is believed that a device is intended to be distributed or sold in violation of the Act, a Stop Sale, Use or Removal Order may be issued pursuant to section 13(a). Additionally, section 13(b) authorizes in rem seizure proceedings in a federal district court against any device which is misbranded or which, when used in accordance with the requirements imposed under the Act causes unreasonable adverse effects upon the environment. Finally, the Administrator may seek injunctive relief pursuant to section 16(c) to prevent and restrain violations of the

#### VII. PUBLIC COMMENT

The Administrative Procedure Act (5 U.S.C. 533(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." EPA has determined that this Notice falls within this exemption from the requirement to solocit public comment. Nonetheless, interested persons may submit written comments regarding the policy set forth in this Notice to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: November 8, 1976. STANLEY W. LEGRO. Assistant Administrator for Enforcement.

[FR Doc.76-34119 Filed 11-18-76;8:45 am]

[FRL 646-2; OPP-30114A]

#### PESTICIDE PROGRAMS

Approval of Application to Register Pesticide Product Containing A New Active Ingredient and Waiver of Data

On April 21, 1976, the Environmental Protection Agency (EPA) gave notice (41 FR 16692) that the United States Forest Service (USFS), 1205-B (RPE), 14th and Independence Ave. SW. Washington, D.C. 20250, had filed an application with the EPA to register the pesticide product TM BIOCONTROL-1 containing 3.5 percent of the active ingredient polyhedral inclusion bodies of Douglas Fir Tussock Moth nucleopolyhedrosis virus which was not previously registered at the time of submission. The application received from the USFS proposed that the product be used in aerial application to control Douglas Fir Tussock Moth and that the product be classified for general use. PM17.

Having considered the evidence submitted by USFS in their application for registration and the data submitted in support thereof, the Administrator has made a written finding pursuant to the regulations (40 CFR 180.6(a)(3)) with respect to whether such properties of TM Biocontrol-1 are fundamentally different from the factors considered by EPA in establishing the data requirements set forth in the Registration Guidelines. Although the Guidelines were published as proposed rules in the FEDERAL REGISTER on June 25, 1975 (40 FR 26802), and have not as yet been promulgated in their final form, the basic data requirements set forth in the proposed Guidelines represent the data currently considered necessary to support the registration of a pesticide product. Accordingly, the notification of data waiver will apply to the supporting data now required by the Agency and set forth in the proposed Guidelines.

The Administrator has found that the submission of certain data is not necessary for determining whether TM Biocontrol-1 will generally cause unreasonable adverse effects on man or the environment. Specifically, the following required data have been waived by the Administrator for the polyhedral inclusion bodies of the nucleopolyhedrosis virus of the Douglas Fir Tussock Moth:

- 1, Avian 8-day dietary LC<sub>m</sub> study utilizing a native upland game bird, preferably bobwhite quail.
- 2. Acute LC<sub>sc</sub> studies to 96 hours on a native cold and warm water species of fish, preferably utilizing trout and bluegill sun-
- 3. Acute aquatic invertebrate LC, to 48 hours, preferably utilizing daphnia sp.

The primary basis of this waiver is due to the natural presence of the nucleopolyhedrosis virus in the environment and its role in bringing about the collapse of epizootic Douglas Fir Tussock Moth populations. During outbreaks of the Tussock Moth, large amounts of this virus are naturally released into the environment, Moreover, data presented by the registrant demonstrate that a much greater amount of this virus is released naturally into the environment through the collapse of Douglas Fir Tussock Moth populations than is released through the application of this product as a suppression measure.

Finally, it should be noted that this product can be used against only one pest, the Douglas Fir Tussock Moth, and that infestations of this pest are cyclic in nature: the maximum use of this product would likely be once in 6 to 10 years, and therefore exposure of fish and wildlife to this product would be minimal. Because the data submitted by the registrant have adequately demonstrated that this product is fundamentally different from the products for which the fish and wildlife testing requirements were designed, a waiver of the data listed above is both appropriate and acceptable.

This application was approved August 11, 1976, and the product has been assigned the EPA Registration No. 27586-1. Notice of registration is given in accordance with the regulations (40 CFR 180.7(d)(2)) for the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751, 7 U.S.C. 136(a) et sea.).

Test data and other information submitted in support of this registration as well as such other scientific information deemed relevant to the registration decision, except for such material protected by section 3(c)(1)(D) and section (10) of FIFRA, will be available for public inspection in the office of the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, Room EB-31, East Tower, 401 M St., Washington, D.C. 20460.

It is suggested that persons interested in viewing these data notify the Information Coordination Section, either by letter at the above address or by telephone at 202/426-2690, prior to visiting the EPA Headquarters Office so that clearance procedures may be instituted and the appropriate data made available for review purposes pursuant to the regulations for section 3(c) (2) of FIFRA (40 CFR 162,7(f)).

Dated: November 15, 1976.

EDWIN L. JOHNSON. Deputy Assistant, Administration for Pesticides Program.

[FR Doc.76-34120 Filed 11-18-76:8:45 am]

[PRL 647-2; OPP-30000/9]

#### PESTICIDE PROGRAMS

Intent to Process Pesticide Products for Reregistration-Sperm Whale Oil

The Deputy Assistant Administrator. Office of Pesticide Programs, Environmental Protection Agency (EPA) has determined that the use of pesticide products containing sperm whale oil which has already been stockpiled does not result in fatality to members of endangered species; accordingly, such product registrations will be returned to the Registration Division, Office of Pesticide Programs, for processing according to normal reregistration and classification procedures.

I. Regulatory provisions. On July 3. 1975 (40 FR 28242), EPA promulgated regulations (40 CFR 162) for the registration, reregistration, and classification of pesticides, pursuant to Section 3 of the Federal Insecticide, Fungicide and

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Registration Division
Office of Pesticide Program
Criteria and Standards Division
Office of Drinking Water

GUIDE STANDARD AND PROTOCOL FOR TESTING MICROBIOLOGICAL WATER PURIFIERS

Report of Task Force Submitted April, 1986 Revised April, 1987

Exhibit C-3, pg.2 of 36.

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## PREFACE

The task force began deliberations in July, 1984 and submitted its initial report in April, 1986. The task force included a broad multi-disciplinary group of experts representing the interest areas of academic and governmental research, product evaluation, development and testing, manufacturer's product registration, and governmental enforcement.

The report was provided for public comments in May, 1986. A review subcommittee was constituted to prepare a response to the public comments and to revise the report, as herewith submitted. Additional revision has been provided in response to review by the Scientific Advisory Panel (Federal Insecticide, Fungicide, and Rodenticide Act).

The recommended guide standard and testing protocol was developed to be useful in a number of ways, not only for governmental but also for industrial and consumer purposes:

- as a basic framework, starting point for the testing and evaluation of microbiological water purifiers for EPA registration;
- as a guide to the acceptance of water treatment units for compliance with Safe Drinking Water Act requirements where point of use units may be needed temporarily to treat a contaminated public water supply or for emergency situations, but not for use in extreme overseas situations or for the conversion of waste water to micro-biologically potable water;
- as a testing guide to manufacturers wishing to have their units considered as microbiological water purifiers, whether registered or not, and for the evaluation of such testing data;
- as a guide to consumers regarding what they can expect from microbiological water purifiers tested according to this standard and protocol;
- to assist in the research and development of microbiological treatment units for possible military applications.

I want to thank the expert members of the task force for their participation in this work and particularly the chairmen of three work groups:

Charles Gerba:

Microbiological Challenges

Richard Tobin:

Physical, Chemical and Operational Challenges

Frank A. Bell, Jr.:

Testing Protocol

Stephen A. Schaub, Ph.D.

Chairman

U.S. Army Medical Bioengineering Research and Development Laboratory

## **SECTION 1 - GENERAL**

#### 1.1 Introduction

The subject of microbiological purification for waters of unknown microbiological quality repeatedly presents itself to a variety of governmental and non-governmental agencies, consumer groups, manufacturers and others. Examples of possible application of such purification capabilities include:

- backpackers and campers
- non-standard military requirements
- floods and other natural disasters
- foreign travel and stations (however, not for extreme contamination situations outside of the U.S.)
- contaminated individual sources, wells and springs (however, not for the conversion of waste water to microbiologically potable water)
- motor homes and trailers

Batch methods of water purification based on chlorine and iodine disinfection or boiling are well known, but many situations and personal choice call for the consideration of water treatment equipment. Federal agencies specifically involved in responding to questions and problems relating to microbiological purifier equipment include:

Registration Division, Office of Pesticide Programs (OPP), Environmental Protection Agency (EPA): registration of microbiological purifiers (using chemicals);

Compliance Monitoring Staff, EPA: control of microbiological purifier device claims (non-registerable products such as ultraviolet units, ozonators, chloride generators, other);

U.S. Army Medical Bioengineering Research and Development Laboratory (USAMBRDL), U.S. Army Natick Research and Development Center and other Army and military agencies: research and development for possible field applications;

Criteria and Standards Division, Office of Drinking Water (ODW), EPA: Consideration of point-of-use technology as acceptable technology under the Primary Drinking Water Regulations; consumer information and service;

Drinking Water Research, Water Engineering Research Laboratory (WERL), EPA; responsible for water treatment technology research;

Microbiology Branch, Health Effects Research Laboratory (HERL), EPA; responsible for study of health effects related to drinking water filters.

A number of representatives of the above mentioned agencies provided excellent participation in the task force to develop microbiological testing protocols for water purifiers. Major participation was also provided by the following:

- a technical representative from the Water Quality Association;
- a technical representative from the Environmental Health Center,
   Department of Health and Welfare of Canada; and
- an associate professor (microbiology) from the University of Arizona.

## 1.2 Basic Principles

- 1.2.1 <u>Definitions</u>: As set forth in EPA Enforcement Strategy and as supported by a Federal Trade Commission (FTC) decision (FTC v. Sibco Products Co., Inc. et al., Nov. 22, 1965), a unit, in order to be called a microbilogical water purifier, must remove, kill or inactivate all types of disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts so as to render the processed water safe for drinking. Therefore, to qualify, a microbiological water purifier must treat or remove all types of challenge organisms to most specified standards.
- 1.2.2 General Guide: The standard and protocol will be a general guide and, in some cases, may present only the minimum features and framework for testing. While basic features of the standard and protocol have been tested, it was not feasible to conduct full-fledges testing for all possible types of units. Consequently, protocol users should include pretesting of their units in a testing rig, including the sampling techniques to be used. Where users of the protocol find good reason to alter or add to the guide in order to meet specific operational problems, to use an alternate organism or laboratory procedure, or to respond to innovative treatment units without decreasing the level of testing or altering the intent of the protocol, they should feel free to do so. For example, the OPP Registration Division might find it necessary to amend the guide somewhat for different types of treatment units. Another example would be ultraviolet (U.V.) units, which may have specific requirements in addition to the guide protocol.
- 1.2.3 <u>Performance-Based</u>: The standard will be performance-based, utilizing realistic worst case challenges and test conditions and shall result in water quality equivalent to that of a public water supply meeting the microbiological requirements and intent of the National Primary Drinking Water Regulations.
- 1.2.4 <u>Exceptions</u> A microbiological water purifier must remove, kill or inactivate all types of pathogenic organisms if claims are made for any organism. However, an exception for limited claim may be allowed for units removing specific organisms to serve a definable environmental need (i.e., cyst reduction units which can be used on otherwise disinfected and microbiologically safe drinking water, such as a disinfected but unfiltered surface water containing cysts. Such units are not be called microbiological water purifiers and should not be used as sole treatment for an untreated raw water.)
- 1.2.5 Not to Cover non-Microbiological Reduction Claims: The treatment of water to achieve specific chemical removal from water or other non-microbiological claims will not be a part of this standard. National Sanitation Foundation (NSF) Standards 42 (Aesthetic Effects) and 53 (Health Effects) provide partial guides for chemical removal and other claims testing.
- 1.2.6 Construction and Informational Exclusions: While the standard recommends safe responsible construction of units with non-toxic materials for optimum operation, all such items and associated operational considerations are excluded as being beyond the scope of the standard. Included in the exclusion are materials of construction, electrical and safety aspects, design and construction details, operational instructions and information, and mechanical performance testing.
- 1.2.7 <u>Research Needs Excluded</u>: The guide standard and protocol must represent a practical testing program and not include research recommendations. For example, consideration of mutant organisms or differentiation between injured and dead organism would be research items at this time and not appropriate for including in the standard.

- 1.2.8 Not To Consider Sabotage: Esoteric problems which could be presented by a variety of hypothetical terrorist (or wartime) situations, would provide an unnecessary complication, and are not appropriate for inclusion in the standard.
- 1.2.9 <u>Continuity</u>: The guide standard and protocol will be a living document, subject to revision and updating with the onset of new technology and knowledge. It is recommended that the responsible authorities for registration and drinking water quality review potential needs every two to three years and reconvene the task force upon need or upon request from the water quality industry, to review and update the standard and testing protocol.

#### 1.3 Treatment Units Coverage

- 1.3.1 <u>Universe of Possible Treatment Units</u> A review of treatment units that might be considered as microbiological purifiers discloses a number of different types covering treatment principles ranging from filtration and chemical disinfection to ultraviolet light radiation.
- 1.3.2 <u>Coverage of This Standard</u>: In view of the limited technical data available and in order to expedite the work of the task force, the initial coverage is limited, on a priority basis, to three basic types of microbiological water purifiers or active components with their principal means of action as follows:
  - 1.3.2.1 Ceramic Filtration Candles or Units (may or may not contain a chemical bacteriostatic agent): filtration, and adsorption, and chemical anti-microbial activity if a chemical is included.
  - 1.3.2.2 Halogenated Resins and Units: chemical disinfection and possible filtration. (Note: While not included in this guide standard, halogen products for disinfection or systems using halogen addition and fine filtration may be tested using many of its elements, i.e., test water parameters, microbiological challenge and reduction requirements, analytical techniques and other pertinent elements.)
  - 1.3.2.3 Ultraviolet (UV) Units: UV irradiation with possible add-on treatment for adsorption and filtration, (not applicable to UV units for treating potable water from public water supply systems).
- 1.3.3 Application of Principles to Other Units: While only three types of units are covered in this standard, the principles and approaches outlined should provide an initial guide for the testing of any of a number of other types of units and/or systems for the microbiological purification of contaminated water.

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## SECTION 2: PERFORMANCE REQUIREMENTS

## 2.1 Microbiological Water Purifier

In order to make the claim of "microbiological water purifier," units must be tested and demonstrated to meet the microbiological reduction requirements of Table 1 according to the test procedures described in Section 3 for the specific type of unit involved.

#### 2.2 Chemical Health Limits

Where silver or some other pesticidal chemical is used in a unit, that chemical concentration in the effluent water must meet any National Primary Drinking Water Maximum Contaminant Level (MCL), additional Federal guidance or otherwise be demonstrated not to constitute a threat to health from consumption or contact where no MCL exists.

## 2.3 Stability of Pesticidal Chemical

Where a pesticidal chemical is used in the treatment unit, the stability of the chemical for disinfectant effectiveness should be sufficient for the potential shelf life and the projected use life of the unit based on manufacturer's data. Where stability cannot be assured from historical data and information, additional tests will be required.

#### 2.4 Performance Limitations

#### 2.4.1 Effective Lifetime

The manufacturer must provide an explicit indication or assurance of the unit's effective use lifetime to warn the consumer of potential diminished treatment capability either through

- a. Having the unit terminate discharge of treated water, or
- Sounding an alarm, or
- c. Providing single, explicit instructions for servicing or replacing units within the recommended use life (measurable in terms of volume throughput, specific time frame or other appropriate method).

### 2.4.2 <u>Limitation on Use of Iodine</u>

EPA policy initially developed in 1973 and reaffirmed in 1982 (memo of March 3, 1982 from J. A. Cotruvo to G. A. Jones, subject: "Policy on lodine Disinfection") is that iodine disinfection is acceptable for short-term or limited or emergency use but that it is not recommended for long-term or routine community water supply application where iodine-containing species may remain in the drinking water.

TABLE 1

## MICROBIOLOGICAL REDUCTION REQUIREMENTS

Klebsiella terrigena, a common coliform, was selected as the challenge organism to represent the coliform group. Poliovirus 1 (LSc) and rotavirus (Wa oe SA-11) are common environmental viruses and show resistance to different treatment processes, thereby providing good challenges for the virus group. Giardia was selected as the cyst challenge representative because of its widespread disease impact and its resistance to chemical disinfection. The use of 4-6 micron particles or beads for testing the occlusion filtration of cysts has been demonstrated to be an accurate and practical substitute for the use of live cyst challenges. It is included as an option where disinfection or other active processes are not involved.

Organism	Influent Challenge	Minimum Required Reduction	
		Log	%
Bacteria: Klebsiella terrigena (ATCC-33257	10 <sup>7</sup> /100 mL	6	99.9999
Virus: a. Poliovirus 1 (LSc) (ATCC-VR-59 and, b. Rotavirus (Wa or SA-11) (ATCC-VR-899 or VR-2018)	1 x 10 <sup>7</sup> /L 1 x 10 <sup>7</sup> /L	4	99.99**
Cyst (Protozoan): Giardia*** a: Giardia muris or Giardia lamblia or	10 <sup>6</sup> /L	3	99.9
b. As an option for units or components based on occlusion filtration: particles or spheres, 4-6 microns	10 <sup>7</sup> /L	3	99.9

(Testing according to National Sanitation Foundation Standard 53 for cyst reduction will be acceptable)

- \* The influent challenges may constitute greater concentrations than would be anticipated in source waters, but these are necessary to properly test, analyze, and quantitatively determine the indicated log reductions.
- Virus types are to be mixed in roughly equal 1 x 10<sup>7</sup>/L concentrations and a joint 4 log reduction will be acceptable
- It should be noted that new data and information with respect to cysts (i.e., Cryptosporidium or others) may in the future necessitate a review of the organism of choice and of the challenge and reduction requirements.

# SECTION 3. MICROBIOLOGICAL WATER PURIFIER TEST PROCEDURES

## 3.1 PURPOSE

These test are performed on ceramic filtration candles or units, halogentated resins and units and ultraviolet (UV) units in order to substantiate their microbiological removal capabilities over the effective use life of the purifier as defined in Table 1 and, where a pesticidal chemical is used, to determine that said chemical is not present in the effluent at excessive levels (see Section 3.5.3.4.

## 3.2 Apparatus

Three production units of a type are to be tested, simultaneously, if feasible, otherwise, in a manner as similar to that as possible.

Design of the testing rig must parallel and simulate projected field use conditions. For plumbed-in units a guide for design of the test rig may be taken from "Figure 1: Test Apparatus-Schematic" (p. A-2 of Standard Number 53 "Drinking Water Treatment Units—Health Effects," National Sanitation Foundation). Otherwise, the test rig must be designed to simulate field use conditions (worst case) for the unit to be tested.

## 3.3 Test Waters - Non-Microbiological Parameters

In addition to the microbiological influent challenges, the various test waters will be constituted with chemical and physical characteristics as follows:

#### 3.3.1 Test Water #1 (General Test Water)

This water is intended for the normal non-stressed (non-challenge) phase of testing for all units and shall have specific characteristics which may easily be obtained by the adjustment of many public system tap waters, as follows:

- (a) It shall be free of any chlorine or other disinfectant residual:
- (b) pH 6.5 8..5;
- (c) Total Organic Carbon (TOC) 0.1 - 5.0 mg/L;
- (d) Turbidity 0.1 5 NTU;
- (e) Temperature 20°C ± 5°C; and
- (f) Total Dissolved Solids (TDS) 50 500 mg/L

#### 3.3.2 Test Water #2 (Challenge Test Water/Halogen Disinfection)

This water is intended for the stressed challenge phase of testing where units involve halogen disinfectants (halogen resins or other units) and shall have the following specific characteristics:

a. Free of chlorine or other disinfectant residual:

- b. (1) pH 9.0 ± .2, and
- (2) for iodine-based units a pH of 5.0 ± .2 (current information indicates that the low pH will be the most severe test for virus reduction by iodine disinfection):
- c. Total Organic Carbon (TOC) not less that 10 mg/L;
- d. Turbidity not less than 30 NTU;
- e. Temperature 4°C ± .1°C; and
- f. Total Dissolved Solids (TDS) 1,500 mg/L ± 150 mg/L.

# 3.3.3 Test Water #3 (Challenge Test Water/Ceramic Candle or Units With or Without Silver Impregnation)

This water is intended for the stressed challenge phase of testing for the indicated units but not for such units when impregnated with a halogen disinfectant (for the latter, use Test Water #2). It shall have the following specific characteristics:

- a. It shall be free of any chlorine or other disinfectant residual;
- b. pH 9.0 ± .2;
- c. Total Organic Carbon (TOC) not less than 10 mg/L;
- d. Turbidity not less than 30 NTU;
- Temperature 4°C ± 1°C; and
- f. Total Dissolved Solids (TDS) 1500 mg/L ± 150 mg/L.

#### 3.3.4 Test Water #4 (Challenge Test Water for Ultraviolet Units)

This water is intended for the stressed phase of testing for UV units and shall have the following specific characteristics:

- a. Free of chlorine or other disinfectant residual;
- b. pH 6.5 8.5;
- Total Organic Carbon (TOC) not less than 10 mg/L;
- d. Turbidity not less than 30 NTU;
- Temperature 4°C ± 1°C;
- f. Total Dissolved Solids (TDS) --1500 mg/L ± 150 mg/L
- g. Color U.V. Absorption (absorption at 254 nm) Sufficient parahydroxybenzoic acid (PHBH) to be just below the trigger point of the warning alarm on the U.V. unit. ([Note that Section 3.5.1.1 provides an alternative of adjusting the U.V. lamp electronically, especially when the U.V. lamp is preceded by activated carbon treatment.]

## 3.3.5 Test Water #5 (Leaching Test Water for Units Containing Silver)

This water is intended for stressed leaching tests of units containing silver to assure that excess levels of silver will not be leached into the drinking water. It shall have the following specific characteristics:

- a. Free of chlorine or other disinfectant residual;
- **b.**  $pH 5.0 \pm 0.2$ ;
- c. Total Organic Carbon (TOC) approximately 1.0 mg/L;
- d. Turbidity 0.1 5NTU;
- e. Temperature 20°C ± 5°C; and
- f. Total Dissolved Solids (TDS) -- 100 mg/L

## 3.3.6 Recommended Materials for Adjusting Test Water Characteristics

- a. pH; inorganic acids or bases (i.e., HCl, NaOH);
- b. Total Organic Carbon (TOC): humic acids;
- c. Turbidity: A.C. Fine Test Dust (Part No. 1543094)
  from: A.C. Spark Plug Division
  General Motors Corporation
  1300 North Dort Highway
  Flint, MI 48556;
- d. Total Dissolved Solids (TDS): sea salts, Sigma Chemical CO., S9883 (St. Louis, MO) or another equivalent source of TDS:
- e. Color U.V. Absorption: p-hydroxybenzoic acid (grade: general purpose reagent).

## 3.4 Analytical Methods

#### 3.4.1 Microbiological Methods

Methods in this section are considered "state-of-the-art" at the time of its preparation and subsequent improvements should be expected. Methods used for microbiological analyses should be compatible with and equal to or better than those given below.

#### 3.4.1.1 Bacterial Tests:

- Chosen Organism: Klebsiella terrigena (ATCC-33257);
- b. Method of Production: The test organism will be prepared by overnight growth in nutrient broth or equivalent to obtain the organism in the stationary growth phase [Reference: Asburg, E.D., 1983, Methods of Testing Sanitizers and Bacteriostatic Substances; in <u>Disinfection, Sterilization and Preservation</u> (Seymour S. Block, ed.), pp. 964-980]. The organism will be collected by centrifugation and washed three times in phosphate buffered saline before use. Alternatively, the organisms may be grown overnight on nutrient agar

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slants or equivalent and washed from the slants with phosphate buffered saline. The suspensions should be filtered through sterile Whatman Number 2 filter paper (or equivalent) to remove any bacterial clumps. New batches of organisms must be prepared daily for use in challenge testing.

- c. State of organism: Organisms in the stationary growth phase and suspended in phosphate buffered saline will be used.
- d. Assay Techniques: Assay may be by the spread plate, pour plate or membrane filter technique on nutrient agar, M.F.C. or m-Endo medium (<u>Standard Methods for the Examination of Water and Wastewater</u>, 16<sup>th</sup> edition, 1985, APHA),. Each sample dilution will be assayed in triplicate.

#### 3.4.1.2 Virus Tests:

- a. Chosen Organism: Poliovirus type 1 (LSc) (ATCC-VR-59), and Rotavirus Strain SA-11 (ATCC-VR-899) or WA (ATCC-VR-2018).
- b. Method of Production: All stocks should be grown by a method described by Smith and Gerba (1982, in <u>Methods in Environmental Virology</u>, pp. 15-47) and purified by the procedure of Sharp, et al. (1975, Appl. Microbiol., 29:94-101), or similar procedure (Berman and Hoff, 1984, Appl. Environ. Microbiol., 48:317-323), as these methods will produce largely monodispersed virion particles.
- c. State of the Organism: Preparation procedure will largely produce monodispersed particles.
- d. Assay Techniques: Poliovirus type 1 may be grown in the BGM, MA-104 or other cell line which will support the growth of this virus. The rotaviruses are best grown in the MA-104 cell line. Since both viruses can be assayed on the MA-104 cell line a challenge test may consist of equal amounts of both viruses as a mixture (i.e., the mixture must contain at least 1.0 x 10<sup>7</sup>/mL of each virus). Assays may be as plaque forming units (PFU) or as immunofluorescence foci (IF) (Smith and Gerba, 1982, in Methods in Environmental Virology, pp. 15-47). Each dilution will be assayed in triplicate.

#### 3.4.1.3 Cyst Tests:

#### a. Chosen Organism:

- Giardia lamblia or the related organism, Giardia muris, may be used as the challenge cyst.
- 2. Where filtration is involved, tests with 4-6 micron spheres or particles have been found to be satisfactory and may be used as a substitute for tests of occlusion using live organisms (see Table 1) <u>Spheres or particles may only be used to evaluate filtration of efficacy</u>. Disinfection efficacy can only be evaluated with the use of viable Giardia cysts.

- b. Method of Production: Giardia muris may be produced in laboratory mice and Giardia lamblia may be produced in Mongolian gergils; inactivation results based on excystation measurements correlate well with animal infectivity results.
- c. State of the Organism: Organisms may be separated from fecal material by the procedure described by Sauch (1984, Appl. Environ. Microbiol., 48: 454-455) or by the procedure described by Bingham, et al, (1979, Esp. Parasitol., 47: 284-291).
- d. Assay Techniques: Cysts are first reconsentrated (500 mL., minimum sample size) according to the method of Rice, Hoff and Schaefer (1982, Appl. Environ. Microbiol. 43: 250-251). The excystation method described by Schaefer, et al. (1984, Trans., Royal Soc. Of Trop. Med. & Hyg. 78: 795-800) shall be used to evaluate Giardia muris cyst viability. For Giardia lamblia cysts, the excystation method described by Bingham and Meyer (1979, Nature, 277:301-302) or Rice and Schaefer (1981, J. Clin. Microbiol., 14: 709-710) shall be used. Cyst viability may also be determined by an assay method involving the counting of trophozoites as well as intact cysts (Bingham, et al., 1979, Exp. Parasitol., 47: 284-291).

## 3.4.2 Chemical and Physical Methods

All physical and chemical analyses shall be conducted in accordance with procedures in <u>Standard Methods for the Examination of Water and Wastewater</u>, 18<sup>th</sup> Edition, American Public Health Association, or equivalent.

#### 3.5 Test Procedures

#### 3.5.1 Procedure - Plumbed-in Units

- a. (1) Install three production units of a type as shown in Figure 1 and condition each unit prior to the start of the test in accordance with the manufacturer's instructions with the test water without the addition of the test contaminant. Measure the flow rate through each unit. The unit shall be tested at the maximum system pressure of 60 psig static and flow rate will not be artificially controlled.
  - (2) Test waters shall have the defined characteristics continuously except for test waters 2, 3 and 4 with respect to turbidity. The background non-sampling turbidity level will be maintained at 0.1-5 NTU but the turbidity shall be increased to the challenge level of not less than 30 NTU in the following manner:
    - in the "on" period(s) prior to the sampling "on" period.
    - in the sampling "on" period when the sample actually will be taken. (Note at least 10 unit void volumes of the 30 NTU water shall pass through the unit prior to actual sampling so as to provide adequate seasoning and uniformity before sample collection.)
- b. (1) Use appropriate techniques of dilution and insure continual mixing to prepare a challenge solution containing the bacterial contaminant. Then

spike test water continuously with the influent concentration specified in Table 1.

(2) Use appropriate technique to prepare concentrated virus and *Giardia* suspensions. Feed these suspensions into the influent stress so as to achieve the influent concentrations specified in Table 1 in the following manner:

- in the "on" period(s) prior to the sampling "on" period.
- in the sampling "on" period when the sample actually will be taken. [Note: at least 10 unit void volumes of seeded water shall pass through the unit prior to sampling so as to provide adequate seasoning and uniformity before sample collection.]
- c. Purge the system of the uncontaminated water with a sufficient flow of contaminated test water. Start an operating cycle of 10 percent on, 90 percent off with a 15 to 40 minute cycle (Example: 3 minutes on, 27 minutes off) with the contaminated test water. This cycle shall be continued for not more than 16 hours per day (minimum daily rest period of 8 hours). The total program shall extend to 100% of estimated volume capacity for halogenated resins or units and for 10 ½ days for ceramic candles or units and for U. V. units.
- d. Sampling: Samples of influent and effluent water at the specified sampling points shall be collected as shown below for the various units; these are minimum sampling plans which may be increased in number by the investigator. All samples shall be collected in duplicate from the following water during the sampling "on" portion of the cycle and they shall be one "unit void volume" in quantity (or of appropriate quantity for analysis) and represent worse case challenge conditions. Effluent samples shall usually be collected near the middle of the sampling "on" period (or the whole volume during one "on" period) except for samples following the specified "stagnation" periods, for which sampling shall be conducted on the first water volume out of the unit. Each sample will be taken in duplicate and shall be retained and appropriately preserved, if required, for chemical or microbiological analysis in the event verification is required. (For units where the volume of a single "on" period is insufficient for the required analysis, samples from successive "on" periods may be accumulated until a sufficient volume has been collected.)

# 1(a). Sampling Plan: Halogenated Resins or Units (Non-iodine Based)

Test Point (% of Estimated Capacity)	Test Water	Influent Background	Tests Active Agent/ Residual	Microbiological
Start	General	×	×	X
25%			X	X
50%			×	X
After 48 hours stagnation			Х	Х
60%	Challenge pH		×	X
75%	9.0 ± 0.2		×	X
After 48 hours stagnation			×	x
100%			X	X

1(b). Sampling Plan: lodinated Resins or Units

Test Point (% of Estimated Capacity)	Test Water	Influent Background	Tests Active Agent/ Residual	Microbiological
Start	General	×	x	x
25%			×	X
50%			×	X
After 48 hours stagnation			X	X
60%	Challenge pH		×	х
75%	9.0 ± 0.2		×	x
After 48 hours stagnation			X	x
90%	Challenge pH		×	х
100%	5.0 ± 0.2			
After 48 hours stagnation				

# 2. Sampling Plan: Ceramic Candles or Units and U.V. Units

Test		Tests
Water	Influent Background	Microbiological
General	x	x
		x
		x
		х
Challenge		x
		×
		x
		x
	Water General	Water Influent Background  General X

(Note: all days are "running days" and exclude stagnation periods. When the units contain silver, a leaching test shall be conducted as shown in Section 3.5.1.a and silver residual will be measured at each microbiological sampling point.

e. Leaching Tests for Silverized Units: Where the unit contains silver, additional tests utilizing Test Water #5 will be conducted as follows:

	Tes	ts
Test Point	Influent Background	Silver/Residual
Start	x	X
Day 2		X
After 48 hours stagnation		x

# f. Alternate Sampling Plans:

- Since some laboratories may find it inconvenient to test some units on a 16 hour on/8 hour off cycle, two alternates are recognized:
- --- go to a shorter operational day but lengthen the days of test proportionally.

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- use up to 20 percent "on"/80 percent "off for a proportionally shorter operational day
- Sampling points must be appropriately adjusted in any alternate sampling plan.
- g. Application of Test Waters:

The application of test waters is designed to provide information on performance under both normal and stressed conditions; it should be the same or equivalent to the following:

(a) Halogenated Resins or Units (Non-iodine based) –

First 50% of test period:

Test Water 1 (General)

Last 50% of test period:

Test Water 2 (Challenge)

 $(pH - 9.0 \pm 0.2)$ 

(b) Iodinated Resins or Units-

First 50% of test period:

Test Water 1 (General)

Next 25% of test period

Test Water 2 (Challenge)

 $(pH - 9.0 \pm 0.2)$ 

Last 25% of test period:

Test Water 2 (Challenge)

(but with pH -  $5.0 \pm 0.2$ )

Ceramic Candles or Units –

First 6 days of testing:

Test Water 1 (General)

Last 4-1/2 days of testing:

Test Water 3 (Challenge)

Ultraviolet (U.V.) Units –

First 6 days of testing:

Test Water 1 (General)

Last 4 1/2 days of testing:

Test Water 3 (Challenge)

- h. Analyses and Monitoring:
  - Microbiological sampling and analysis shall be conducted of the specified influent and effluent sampling points during each indicated sampling period.
  - Test Water Monitoring: The specified parameters of the various test waters (see Section 3.3) will be measured and recorded at each microbiological sampling point; the specified parameters will be measured at least once in non-sampling days when the units are being operated.

- Background chemical analyses of influent water shall be conducted at least once at the start of each test period to determine the concentration of the U.S. EPA primary inorganic contaminants, secondary contaminants and routine water parameters, not otherwise covered in the described test waters.
- 4. In addition, quality assurance testing shall be conducted for the seed bacteria under environmental conditions on the first and last days of testing to make sure that there is no significant change over the test day. Populations will be measured (for example, as dispersed in the supply tank) at the beginning and end of the test day to detect possible incidental effects such as proliferation, die-off, adsorption to surfaces, etc. Relatively stable bacterial seed populations are essential to an acceptable test program.
- When a unit contains a halogen or silver, the active agent residual will be measured in the effluent at each microbiological test (sampling) point.
- Silver will additionally be measured three times in the effluent as specified in Section 3.5.1.e.
- Neutralization of Disinfection Activity: Immediately after collection, each test sample must be treated to neutralize any residual disinfectant. For Halogen-and silver-based disinfectants this may be done by addition of thioglycollate-thiosulfate neutralizer solution (Chambers, et al., J. Amer. Water Works Assoc., 54: 208-216, 1962). This solution should be prepared daily. All results are invalid unless samples are neutralized immediately upon collection.
- j. Special Provisions for Ceramic Candles or Units:
  - Provisions for slow flow: Ceramic units may be subject to clogging and greatly reduced flow over the test period. An attempt should be made to maintain manufacturer rated or claimed flow rates, but even at reduced flows the sampling program set forth in Section 3.5.1.1.d.2 shall be maintained.
  - 2. Cleaning of ceramic units: Units should be cleaned according to manufacturer's directions. Two cleanings should occur during the period of test (in order to prove the unit's durability through the cleaning procedure). However, near the time of microbiological sampling, the units should not be cleaned until after the sampling. Further, no anti-microbial chemical (for cleaning or sanitizing) may be applied to the units during the test period unless the manufacturer specifies the same as part of routine maintenance.
- k. Halogenated units or U.V. units with mechanical filtration processes separate from the microbiological disinfection components shall have the mechanical filtration components replaced or serviced when significant flow reduction (clogging) occurs in accordance with the manufacturer's instructions in order to maintain the test flow rate. Units with non-removable mechanical filtration components will be run until flow is below that considered acceptable for consumer convenience. (If premature clogging presents a problem, some specialized units may require a customized test plan.)
  - 1. Special Provisions for Ultraviolet (U.V.) Units:
    - The units will be adequately challenged by the prescribed test waters; consequently they will be operated at normal intensity. However, where the U.V. treatment component is preceded by activated carbon treatment, the output of the U.V. lamp shall be adjusted electronically,

such as by reducing the current to the lamp or other appropriate means., to be just above the alarm point. This option shall be available for use under other U.V. configurations, at the choice of the persons responsible for testing, as an alternative to the use of the U.V. absorbent, p-hydroxybenzoic acid.

- Fail/safe: Units will provide and will be tested for fail/safe warnings in the event of water quality changes or equipment failures which may interfere with its microbiological purification function.
- Cleaning: Manufacturer's guidance with respect to cleaning will be followed.

# 3.5.2 <u>Procedure: Non-Plumbed Units</u>

- a. General The basic procedures given in Section 3.5.1 shall be used with necessary adaptations to allow for the specific design of the unit. In any event, the testing procedures shall provide a test challenge equivalent to those for plumbed-in units.
- b. Test conditions and apparatus should be adapted to reflect proposed or actual use conditions in consultation with the manufacturer, including flow rate and number of people to be served per day. In some cases variable flow or other non-standard conditions may be necessary to reflect a worst-case test.

#### 3.5.3 Acceptance and Records

3.5.3.1 To quality as a microbiological water purifier, three production units of a type must continuously meet or exceed the reduction requirements of Table 1, within allowable measurement tolerances for not more than ten percent of influent/effluent sample parts, defined as follows:

Virus:

one order of magnitude

Bacteria:

one order of magnitude

Cysts:

one/half order of magnitude

The geometric mean of all microbiological reductions must meet or exceed the requirements of Table 1. An example is given as follows:

- Unit: iodinated resin.
- Number of sample pairs over the completed test program: 10 per unit 3 units = 30.
- Number of allowable sample pairs where log reduction is insufficient:
   10% of 30 = 3 sample pairs.
- Allowable minimum log reductions in these 3 pairs:
  - Bacteria 5 log

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- Virus 3 log
- cyst 2½ log
- Conclusion: If the geometric mean of all reductions meets or exceeds the requirements of Table 1, the indicated insufficient sample pairs will be allowed.
- 3.5.3.2 Records: All pertinent procedures and data shall be recorded in a standard format and retained for possible review until the report of results has been completely accepted by review authorities, in no case for less than a year.
- 3.5.3.3 Scaling up or down: Where a manufacturer has several similar units using the same basic technology and parallel construction and operation, it may sometimes be appropriate to allow the test of one unit to be considered representative of others. Where any serious doubt exists, all units of various sizes may require testing. A "rule of three" is suggested as a matter of judgment. Scaling up to three times larger or one-third, based on the size of either the test unit or of its operative element, may be allowed. However, for UV units, any size scale-up must be accompanied by a parallel increase in radiation dose.
- 3.5.3.4 Where silver or some other chemical is used in the unit, concentrations in the effluent water must meet any National Primary Drinking Water Maximum Contaminant Level (MCL), additional Federal guidelines, or otherwise not constitute a threat to health where no MCL exists.

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# APPENDIX A

# SUMMARY FOR BASIS OF STANDARDS AND TEST WATER PARAMETERS

# A: Microbiological Reduction Requirements

# Bacteria

Current standards for the microbiological safety of drinking water are based on the presence of coliform bacteria of which *Klebsiella* is a member. Members of the genus *Klebsiella* are also potential pathogens of man (Vlassof, 1977). *Klebsiella terrigena* is designated as the test organism since it is commonly found in surface waters (Izard, et al., 1981)

Experience with the use of coliform bacteria to estimate the presence of enteric bacterial pathogens in drinking water as performed over the last 75 years indicates a high degree of reliability. Required testing of more than one bacterial pathogen appears unjustified since viral and *Giardia* testing will be required. Enteric viruses and *Giardia* are known to be more resistant to common disinfectants than enteric bacterial pathogens and viruses are more resistant to removal by treatments such as filtration. Thus, any treatment which would give a good removal of both virus and *Giardia* pathogens would most likely reduce enteric bacteria below levels considered infectious (Jarroll, et al., 1981; Liu, et al., 1971).

The concentration of coliform bacteria in raw sewage is approximately 109/100 .mL. Concentrations in polluted stream waters have been found to exceed  $10^5$  per 100 mL (Culp, et al., 1978, Table 10.

Based on the over 10<sup>5</sup>/100 ml concentrations observed in highly polluted stream water and a target effluent concentration of less than 1/100 mL, a 6 log reduction is recommended.

# 2. Virus

In the United States concentrations of enteroviruses are estimated to range from 10<sup>3</sup>-10<sup>4</sup>/liter in raw sewage (Farrah and Schaub, 1971). Based on this observation it is estimated that natural waters contaminated with raw sewage may contain from 10<sup>1</sup> to 10<sup>2</sup> enteric viruses per liter.

There are currently no standards for viruses in drinking water in the United States. However, EPA has proposed a non-enforceable health-based recommended maximum contaminant level (RMCL) of zero for viruses (EPA, 1985). Several individuals and organizations have developed guidelines for the presence of viruses in drinking water and various experts have proposed standards (WHO, 1979, 1984; Berg, 1971; Melnick, 1976). It has generally been felt that drinking water should be free of infectious virus since even one virus is potentially infectious and suggested standards are largely based on technological limits of our detection methodology. Guidelines suggested by the World Health Organization (1984) and others recommend that volumes to be tested be in the order of 100-1,000 liters and that viruses be absent in these volumes.

Assuming a target effluent level of less than one virus in 100 liters of water and a concentration of 10<sup>4</sup> enteric viruses in 100 liters of sewage-contaminated waters, the water purifier units should achieve at least 4 logs of virus removal.

The relative resistance of enteric viruses to different disinfectants varies greatly among the enteric viruses and even among members of the same group (i.e., enteroviruses). For example, while f2 coliphage is one of the most resistant viruses to inactivation by chlorine it is one of the most susceptible to inactivation by ozone (Harakeh and Butler, 1984). Ionic conditions and pH can also affect the relative resistance of different viruses to a disinfectant (Englebrecht, et al., 1980). On this basis it is felt that more than one enteric virus should be tested to ensure the efficacy of any disinfection system. Poliovirus type 1 (Strain LSc) was chosen as one of the test viruses because it has been extensively used in disinfection and environmental studies as representative of the enterovirus family. It is recognized that it is not the most resistant virus to inactivation to chlorine, but is still resistant enough to serve as a useful indicator. Rotavirus is selected as the second test enteric virus since it represents another group of enteric viruses in nucleic acid composition and size. It is also a major cause of viral gastroenteritis and has been documented as a cause of waterborne gastroenteritis (Gerba, et al., 1985). The human rotavirus or the similar Simian rotavirus may be used in the test procedure. A net 4-log reduction for a joint challenge of 1 x 107/L each for poliovirus and rotavirus is recommended.

# Cysts (Protozoan)

Over the past several years, giardiasis has consistently been one of the most frequently reported waterborne diseases transmitted by drinking water in the United States (Craun, 1984). EPA has proposed a RMCL of zero for *Giardia* (EPA, 1985).. Its occurrence has generally been associated with treatment deficiencies including either inadequate or not filtration. *Giardia* has not been known to occur from drinking water produced by well-operated filtration treatment plants. De Walle, et al. (1984), in a study of filtration treatment plant efficiencies, cited percent removals for *Giardia* in pilot plant tests as follows:

- rapid filtration with coagulation-sedimentation; 96.6-99.9%;
- direct filtration with coagulation: 95.9-99.9%

From this research and from the lack of *Giardia* cases in systems where adequate filtration exists, a 3-log (99.9%) reduction requirement is considered to be conservative and to provide a comparable level of protection for water purifiers to a well-operated filtration treatment plant.

Data on environmental levels for cysts in natural waters is limited because of the difficulties of sampling and analysis. Unpublished data indicate very low levels from less than 1/L to less than 10/L. Here a 3-log reduction would provide an effluent of less than 1/100 L, comparable to the recommended virus reduction requirements.

Either Giardia lamblia or the related organism, Giardia muris, which is reported to be a satisfactory test organism (Hoff, et al., 1985), may be used as the challenge organism. Tests will be conducted with a challenge of 10<sup>6</sup> organisms per liter for a 3-log reduction.

Where the treatment unit or component for cysts is based on the principle of occlusion filtration alone, testing for a 3-log reduction of 4-6 micron particle or spheres (National Sanitation Foundation Standard 53, as an example) is acceptable. Difficulties in the cyst production and measurement technologies by lesser-equipped laboratories may require the use of such alternative tests where applicable.

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# B. Microbiological Purifier Test Procedures

# Test Waters

- a. The general test water (test water #1) is designed for the normal, non-stressed phase of testing with characteristics that may easily be obtained by the adjustment of many public system tap waters.
- Test water #2 is intended for the stressed phase of testing where units involve halogen disinfectants.
  - 1) Since the disinfection activity of some halogens falls with a rising pH, it is important to stress test at an elected pH. The recommended level of 9.0 ± 0.2, while exceeding the recommended secondary level (Environmental Protection Agency, 1984) is still within a range seen in some natural waters (Environmental Protection Agency, 1976). However, for iodine-based units, a second stressful condition is provided a pH of 5.0 ± 0.2 since current information indicates that the disinfection activity of iodine falls with a low pH (National Research Council, 1980). While beneath the recommended secondary level (Environmental Protection Agency, 1984) a pH of 5.0 is not unusual in natural-waters (Environmental Protection Agency, 1976).
  - Organic matter as total organic carbon (TOC) is known to interfere with halogen disinfection. While this TOC is higher than levels in many natural waters, the designated concentration of 10 mg/L is cited as typical in stream waters (Culp/Wesner/Culp, 1978).
  - 3) High concentrations of turbidity can shield microorganisms and interfere with disinfection. While the recommended level of not less than 30 NTU is in the range of turbidities seen in secondary wastewater effluents, this level is also found in many surface waters, especially during periods of heavy rainfall and snow melt (Culp/Wesner/Culp, 1978).
  - 4) Studies with Giardia cysts have shown decreasing halogen disinfection activity with lower temperatures (Jarroll, et al., 1980); 4° C, a common low temperature in many natural waters, is recommended for the stress test.
  - 5) The amount of dissolved solids (TDS) may impact the disinfection effectiveness of units that rely on displaceable or exchange elements by displacement of halogens or resins, or it may interfere with adsorptive processes. While TDS levels of 10,000 mg/L are considered unusable for drinking, many supplies with over 2,000 mg/L are used for potable purposes (Environmental Protection Agency, 1984) The recommended level of 1,500 mg/L represents a realistic stress challenge.
- c. Test water #3 is intended for the stressed phase of testing of ceramic filtration candles or units with or without silver impregnation
  - Since viruses are typically eluted from adsorbing media at high pHs (Environmental Protection Agency, 1978) it may be concluded that a high pH will provide the most stressful testing for a ceramic-type unit; consequently, the high natural water pH of 9.0 is recommended.

- Expert opinion also holds that organic material will interfere with adsorption of viruses. Thus, a high total organic carbon level of not less than 10 mg/L is recommended.
- 3) Turbidity may enhance the entrapment and removal of microorganisms but it also may stimulate "short-circuiting" through some units. A turbidity level of 30 NTU will provide stress at time of sampling but the non-sampling level of 0.1-5 NTU will allow routine operation of units.
- 4) Expert opinion was that low water temperatures and high TDS would most likely interfere with virus reduction by adsorption; consequently, a 4° C temperature and 1,500 mg/L TDS are recommended.
- d. Test water #4 is intended for the stressed phase of testing for ultraviolet (UV) units.
  - In general, high TOC, turbidity and TDS and low temperature are considered most stressful for UV, and the indicated challenge levels are the same as for test water #2.
  - 2) The pH is not critical and may range from 6.5 to 8.5.
  - 3) In order to test the UV units at their most vulnerable stage of operation, a color challenge (light absorption at 254 nm) is to be maintained at a level where UV light intensity is just above the unit's low intensity warning alarm point. However, an alternate to the absorption challenge is provided through adjusting the light intensity output of the UV lamp electronically by reducing current to the lamp, or other appropriate means, to be just above the alarm point; this approach would be particularly necessary where the UV lamp is preceded by activated carbon treatment.
- e. Test water #5 is intended for the stressed leaching tests of units containing silver. Low pH, TOC, turbidity, and TDS and higher temperature are felt to be the characteristics associated with increased leachability. The recommended pH of 5 ± .2, while being beneath the recommended secondary range of 6.5-8.5 (Environmental Protection Agency, 1984) is still found in some natural waters.

#### Test Procedures

The plan for testing and sampling is designed to reveal unit performance under both "normal" and "stressed" operating conditions. The Stressed phase would utilize a set of water quality and operating conditions to give the units a realistic worst case challenge. Testing plans for a specific model might involve modifications to the recommended plan; more samples could be taken and analyzed; more units could be studied. The principle of demonstrating adequate performance even under realistic worst case conditions should be maintained and the final selected test procedures should be agreed as between investigators and reviewers or regulators.

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While some aspects of the testing procedures have been utilized in actual experiments, the proposed protocol has not been verified or utilized in actual experiments, the proposed protocol has not been verified or utilized for the various units that may be considered. Consequently, investigators and users of this protocol may find reasons to alter some aspects through their practical experience; needed changes should be discussed and cleared with involved reviewers/regulators.

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# APPENDIX B

# LIST OF PARTICIPANTS: TASK FORCE ON GUIDE STANDARD AND PROTOCOL

# FOR TESTING MICROBIOLOGICAL WATER PURIFIERS

- Stephen A., Schaub, Chairman U.S. Army Medical Bioengineering Research and Development Laboratory (USAMBRDL), Fort Detrick, Maryland 21701, FTS: 8/935-7207 – Comm: 301/663-7207.
- Frank A. Bell, Jr., Secretary Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, Washington, D.C. 20460. Phone: 202/382-3027.
- Paul Berger, Ph.D. Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, Washington, D.C. 20460, Phone: 202/382-3039.
- Art Castillo Disinfectants Branch, Office of Pesticide Programs (TS-767C), Environmental Protection Agency, Washington, D.C. 20460, Phone: 703/557-3965.
- Ruth Douglas –Disinfectants Branch, Office of Pesticide Programs (TS-767C), Environmental Protection Agency, Washington, D.C. 20460. Phone: 703/557-3675.
- Al Dufour Microbiology Branch, Health Effects Research Laboratory, Environmental Protection Agency, 26 W. St. Clair Street, Cincinnati, Ohio 45268, Phone: FTS: 8/684-7870 Comm. 513/569-7870.
- Ed Geldreich Chief, Microbiological Treatment Branch, Water Engineering Research Laboratory, Environmental Protection Agency, 26 W. St. Clair Street, Cincinnati, Ohio 45268, Phone: FTS: 8/684-7232 Comm: 513/569-7232.
- Charles Gerba Associate Professor, Department of Microbiology and Immunology, University of Arizona, Tucson, Arizona 85721, Phone: 602/621-6906.
- John Hoff Microbiological Treatment Branch, Water Engineering Research Laboratory, Environmental Protection Agency, 26 W. St. Clair Street, Cincinnati, Ohio 45268, Phone: FTS 8/684-7331 Comm:513/569-7331
- Art Kaplan U. S. Army, Natick R&D Center, Attn: STRNC-YE, Natick, Massachusetts 01760-5020, Phone: 617/651-5525 (5526).
- Bala Krishnan Office of Research and Development (RD-681) Environmental Protection Agency, Washington, D.C. 20460, Phone: 202/382-2583.
- John Lee Disinfectants Branch, Office of Pesticide Programs (TS-767C) Environmental Protection Agency, Washington, D.C. 20460. Phone: 703/557-3663.

- Dorothy Portner Disinfectants Branch, Office of Pesticide Programs (TS-767-C), Environmental Protection Agency, Washington, D.C. 20460. Phone 703/557-0484...
- Don Reasoner Microbiological Treatment Branch, Water Engineering Research Laboratory, Environmental Protection Agency, 26 W. St. Clair Street, Cincinnati, Ohio 45268, Phone: FTS: 8/684-7234 – Comm. 513/569-7234.
- P. Regunathan (Regu) Everpure, Inc., 660 N. Blackhawk Drive, Westmont, Illinois 60559, Phone: 312/654-4000.
- David Stangel Policy and Analysis Branch, Office of Compliance Monitoring, Environmental Protection Agency, Washington, D.C., Phone: 202/382-7845.
- Richard Tobin Monitoring and Criteria Division, Environmental Health Center, Department of Health and Welfare of Canada, Tunney's Pasture, Ottawa, Ontario, K1A 0L2, Canada, Phone: 613/990-8982.

# APPENDIX C

# RESPONSE BY REVIEW SUBCOMMITTEE\* TO PUBLIC COMMENTS ON GUIDE STANDARD AND PROTOCOL FOR TESTING MICROBIOLOGICAL WATER PURIFIERS

A. Recommendation for the use of Giardia lamblia cysts as a replacement for Giardia muris cysts as the protozoan cyst test organisms.

# Recommendation:

The subcommittee concurs with the recommendation and further endorses the use of *Giardia lamblia* as the preferred cyst test for evaluation of all treatment units and devices. Obviously the use of the protozoan organisms of actual health concern in testing is the most desirable. Anyone finding the *Giardia lamblia* strain feasible for testing and cost-effective to work with is encouraged to use same instead of *Giardia muris*.

B. Substitution of 4-6 micron bead of particle tests as an alternate option instead of the Giardia cysts for evaluating devices that rely strictly on occlusion filtration for microbiological removal: Several commenters criticized the use of beads or particles (e.g., A. C. fine dust) and recommended only use of live Giardia cysts for performance tests.

#### Discussion

The subcommittee recognizes and favors the use of the natural human parasite, *Giardia lamblia*, but was not aware of any convincing scientific data which would disallow the optional use of testing with beads or particles for units or devices using only occlusion filtration to remove microorganisms. Previous development of the national Sanitation Standard (NSF) 53 (1982) requirement for cyst reduction (using 4-6 micron particles as cyst models) was based on engineering and scientific opinion and experimental evidence at that time. Specifically, Logsdon<sup>(1)</sup> used radioactive cyst models in the initial phase of a study of removal efficiencies for diatomaceous earth filters; subsequent experiments with *Giardia muris* cysts confirmed the efficacy of the diatomaceous earth filters. Further studies by Hendricks <sup>(2)</sup> and DeWalle<sup>(3)</sup> with *Giardia lamblia* cysts also showed comparable reduction efficiencies for diatomaceous earth filters.

Subsequently confirmatory parallel testing results have been developed vis-a-vis 4-6 micron particles as compared to *Giardia lamblia* cysts. Specifically, two units listed by NSF for cyst reduction (using 4-6 micron particles)<sup>(4)</sup> have also been tested and listed for 100% efficiency reduction (using *Giardia lamblia* cysts) by Hibler<sup>(5)</sup>:

<sup>\*</sup>S. A. Schaub; F. A. Bell, Jr..; P. Berger; C. Gerba; J. Hoff; P. Regunathan; and R. Tobin. (Includes additional revision pursuant to Scientific Advisory Panel review (Federal Insecticide, Fungicide, and Rodenticide Act)

- Everpure Model QC 4-SC
- (2) Royal Doulton Model F303.

Again we prefer the use of the human pathogen, *Giardia lamblia*; however, no experimental data has been provided regarding the lack of validity or of failure in previous tests utilizing beads or particles of 4-6 microns. In most cases the bacterial or viral challenges to occlusion filters will represent a greater problem in terms of microbiological reduction requirements than will cysts. Therefore, without substantiation of deficiencies, the use of 4-6 micron beads or particles is considered to be as feasible as the use of live cysts for routine performance testing of water filtration (occlusion devices.

### Recommendation:

Recommend retaining the optional use of 4-6 micron particles or beads for cyst reduction testing in occlusion filtration devices only.

### References

- (1) Logsdon, G. s., et al. Alternative Filtration Methods for Removal of <u>Giardia</u> Cysts and Cyst Models, JAWWA, February, 1981.
- (2) Logsdon, G. S., Hendricks, D. W., et al. Control of Giardia Cysts by Filtration. The Laboratory's Role, presented AWWA Water Quality Technology Conference, December 6, 1983.
- (3) De Walle, et al. Removal of Giardia lamblia Cysts by Drinking Water Treatment Plants, Grant NO. R806127, Report to Drinking Water Research Division, U.S. EPA (ORD/MERL), Cincinnati, Ohio.
- (4) National Sanitation Foundation, 1986, Listing of Drinking Water Treatment Units, Standard 53. May 21, 1986.
- (5) Hibler, C. P. 1984. An Evaluation of Filters in the Removal of *Giardia lamblia*. Water Technology, July, 1984, pp. 34-36.
- C. Alternate assay techniques for cyst tests (Jensen): Proposed alterations in cyst tests include a different method for separating cysts from fecal material and an assay method involving the counting of trophozoites as well as intact cysts. Both alterations have been used by Bingham, et al. (1979, Exp. Parasitol., 47:284-291).

#### Recommendation

These alterations appear to be reasonable laboratory procedures, supported by a peerreviewed article and will be included in the Report as options for possible development and use by interested laboratories.

D. The use of pour plate techniques as an option for Klebsiella terrigena bacterial analyses.

#### Recommendation:

The pour plate technique adds a heat stress factor to the bacteria which constitutes a possible deficiency. However, it is a recognized standard method and probably will not adversely

affect the Klebsiella terrigena. Consequently, it will be added to the Report as one of the acceptable techniques

E. Option of using Escherichia coli in lieu of Klebsiella terrigena for the bacterial tests

#### Discussion:

Appendix A, Section A.1. of the Guide Standards and Protocol sets forth the basis for selection of *K. terrigena* as the test bacteria. The selection was made along pragmatic lines emphasizing the occurrence of *K. terrigena* in surface waters and that it would represent the enteric bacteria. It was also pointed out that the tests with virus and *Giardia* were expected to be more severe than the bacterial tests. For comprehensiveness, bacterial tests were included in the protocol but were not felt to be as crucial as the virus and *Giardia* tests.

*E.coli*, or any number of other generally accepted indicator bacteria, could be used for the test program if they were shown to have good testing and survival characteristics (equivalent to *K. terrigena*) by the interested research laboratory.

### Recommendation:

The intent of the Guide Standard and Protocol is to provide a base-line program subject to modification when properly supported by an interested laboratory. Consequently, any laboratory could propose and with proper support (demonstrating challenge and test equivalency to *K. terrigena*) use *Escherichia coli* or one of the other enteric bacteria. This idea will be included in revised wording in Section 1.2.2, "General Guide.""

F. Performance requirements for Giardia cysts and virus in relation to the EPA-Recommended Maximum Contamination levels (RMCLs) of zero.

# Discussion:

The RMCLs of zero for *Giardia* and viruses which have been proposed by EPA are health goals. The are not enforceable standards since to assure the presence of "<u>no</u> organisms" would require an infinite sample. The rationale for the recommended performance requirements for *Giardia* cysts and virus is set forth in Sections A.2 and A.3 of Appendix A. We feel that these requirements together with the application of realistic worst case test conditions will provide a conservative test for units resulting in treated effluent water equivalent to that of a public water supply meeting the microbiological requirements and intent of the National Primary Drinking Water Regulations.

### Recommendation:

Retain recommended performance (log reduction) requirements for cyst and virus reduction.

G. Rotavirus and its proposed assay: One commenter states that the rotavirus tests are impractical because Amirtharajah (1966, JAWWA, 78:3:34-49) cites "no satisfactory culture procedure available for analysis of these pathogens and, therefore, monitoring would not be feasible."

#### Discussion:

Section 3.4.1.2, "Virus Tests" of the Report, presents means for culturing and assaying rotaviruses. The means for doing the rotavirus tests are available and are practical for application in the <u>laboratory</u>. Dr. Amirtharajah was referring to the field collection,

identification in the presence of a wide variety of microorganisms, and quantification as not being "satisfactory." Laboratory analysis of rotaviruses is practical but their field monitoring may not yet be feasible.

Further, the selection of both poliovirus and rotavirus as test viruses was necessitated by the fact that the surface adsorptive properties and disinfection resistance of the various enteric viruses have been shown to differ significantly by virus group and by strains of a specific virus. While all enteric viruses and their strains could not be economically tested, it was determined by the task force that at least two distinctly different virus types should be tested to achieve some idea of the diversity of removal by the various types of water purifiers. Polio and rota viruses have distinctly different physical and chemical characteristics representative of the viruses of concern. Polioviruses are small single stranded RNA viruses with generally good adsorptive properties to surfaces and filter media while rotaviruses are over twice as large, are double stranded RNA and in some studies have been found to possess less potential for adsorption onto surfaces or filter media. These two viruses also have been demonstrated to have somewhat different disinfection kinetics.

# Recommendation:

Retain the rotavirus test requirements.

H. Definition of microbiological water purifier: One general comment requested redefinition based on "lack of any virus removal" requirement in the EPA primary drinking water regulations, so that no virus reduction requirement should be included. Also, it was claimed that the separation of purifiers from non-purifiers would be a "disservice to consumers and other users."

#### Discussion:

Virus are recognized in the EPA regulations vis-a-vis a proposed recommended maximum contaminant level of zero. Since virus monitoring for compliance with a possible MCL is not yet feasible, a treatment requirement is necessary. Virus control will be considered in the Safe Drinking Water Act filtration and disinfection treatment regulations. The reduction of viruses by treatment is discussed by Amirtharajah (1986, JAWWA, 78:3:34-49).

With respect to consumers and other users, we feel that the current definition is appropriate and necessary. The average consumer cannot be expected to know the difference between viruses, bacteria and cysts, or when a raw water will or will not contain any of these organisms. In order to protect the average consumer, the subject units either alone or with supplementary treatment, should be able to cope with all of the specified organisms.

#### Recommendation:

Retain the current definition for microbiological water purifier.

- Coverage of units: Several comments related to the coverage of units. These questions are addressed individually as follows:
  - Ultraviolet units that are used for supplemental treatment of water from public water system taps should not be covered. We agree that such units are not covered and parenthetical language has been included in Section 1.3.2.3 to clarify this point.

- 2. A special status should be given to units which remove Giardia and bacteria but not virus. Specifically, the meaning of Section 1.2.4, "Exceptions," was addressed. The "Exceptions" section was specifically developed to relate to the problem of public water systems having disinfection but no filtration on a surface supply. Cysts alone have been found to survive disinfection treatment and could be present in such treated waters. In this case an effective cyst filter serves an independent, beneficial purpose and should not be required to be a microbiological water purifier. However, such a unit should not be used as sole treatment for untreated raw water. Additional parenthetical language has been added to Section 1.2.4.
- The entire treatment unit or system should be tested, not just a single component. We agree but believe that it is sufficiently clear without providing additional language.
- 4. The protocol should be expanded to cover units for the reduction of TCE, EDB and other chemical pollutants. We felt that the introduction of non-microbiological claims to the standard would make it large, unwieldy and duplicative of an existing third-party standards and testing program (see Section 1.2.5).
- J. Alleged preference of National Sanitation Foundation (NSF) over other laboratories for conducting the microbiological water purifier testing protocol. The comment indicated that we were giving NSF preferential treatment "to the detriment of other laboratories well qualified to perform the required protocol."

#### Discussion

We have made appropriate references to existing standards (#42 and #53) developed by the NSF standards development process. Standard 53, the health effects standard, was developed by broadly based Drinking Water Treatment Units Committee, including representatives from local, State and Federal health and environmental agencies, universities, professional and technical associations, as well as water quality industry representatives. It was adopted in 1982 and the only test from it utilized in our Report has been substantiated as described in Part B of this "Response."

Nowhere in our report have wee advocated NSF (or any other laboratory) as the prime or only laboratory for implementing "the required protocol."

#### Recommendation:

No action needed.

K. Instruction concerning effective lifetime. One comment described an alternate means for determining lifetime where a ceramic unit is "brushed" to renew its utility and is gradually reduced in diameter. A gauge is provided to measure diameter and to determine when replacement is needed.

# Recommendation:

Where a manufacturer provides a satisfactory "other" means of determining lifetime, this should be accepted. Appropriate words have been added to Section 2.4.1.C.

L. Ceramic candles should not be cleaned during testing because some consumers would not clean them and this would provide the "worst case test." One comment asserted this point.

### Discussion:

There is some truth to this proposition. However, the other approach may also have validity. Frequent brushing may reduce filtration efficiency. In any event, where a manufacturer prescribes filter cleaning and how to do it, and provides a gauge to determine lifetime, we feel the testing program is bound to follow the manufacturer's directions.

# Recommendation:

No change needed.

M. Scaling up or down. One comment points out that one or more manufacturers may vary size of treatment units by increasing or decreasing the number of operative units rather than the size of the operative unit. The comment suggests allowing scaling based on size of operative unit.

### Recommendation:

We agree with the comment and have added clarifying words to Section 3.5.3.3

N. Turbidity level of "not less than 30 NTU" for ceramic candles or units. One comment states that "Such levels are impossible to utilize in testing mechanical filtration devices which will clog entirely or require such frequent brushing as to render the test impossible as a practical matter."

#### Discussion

We recognized the potential "clogging problems" in Section 3.5.1.a(2) where the 30 NTU water is only to be applied immediately before and during each sampling event; the non-sampling turbidity level, which will be applied over 90% of the "on" time, is currently set at not less than 10 NTU.

Turbidity levels of 30 NTU are commonly found in surface waters during heavy rainfall or snow melt. Treatment units may be used under these circumstances, so this challenge level should be retained. However, most usage will occur under background conditions so the non-sampling turbidity levels should be 0.1-5 NTU.

#### Recommendations:

- (1) Retain sampling turbidity level of not less than 30 NTU, and
- (2) Change non-sampling turbidity level to 0.1-5 NTU. Appropriate wording changes have been introduced in Section 3.5.1.a(2) and in Appendix A, Section B.
- O. Chlorine in test water #5. One comment asserts that chlorine "tends to increase silver ion leaching activity" and that a high chlorine level should be included in the silver leaching test; but no reference or evidence, however, is provided to back this assertion.

February 23, 2023

# Pesticide Registration Notice (PR Notice) 2023-01

# NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, REGISTRANTS AND APPLICATORS OF PESTICIDE PRODUCTS

**ATTENTION:** Persons Responsible for Public Health Programs and Those Responsible for

Registration of Pesticide Products

SUBJECT: Lists of Pests of Significant Public Health Importance – Revised 2023

This notice updates and replaces PR Notice 2002-1, which identifies pests of significant public health importance. Section 28(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the United States Environmental Protection Agency (EPA), in coordination with the United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA), to identify pests of significant public health importance and to develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to combat and control such pests of public health importance.

The lists were first published in 2002, fulfilling the requirement of FIFRA section to identify pests of significant public health importance. EPA, HHS and USDA believe that pests, diseases, and control techniques have changed since 2002. The lists provide an interagency baseline for the federal government and the public to begin any discussions on government regulation and control of disease or vectors of disease agents. EPA makes this information available, in part, to establish a platform for stakeholders, such as public health departments or pesticide registrants to prioritize their workloads and resource allocations. The Office of Pesticide Programs, EPA, coordinated the review by experts in public health and/or pesticide use patterns to compile these lists. No person is required to take any action in response to this notice.

The publication of these lists do not affect the regulatory status of any pesticide registration, pesticide registration exemption under FIFRA section 25(b), pesticide device, or application for registration of any pesticide product or device. These lists do not, by itself, determine whether a pesticide product might be considered a "public health pesticide" as that term is used in FIFRA. That term is defined in FIFRA section 2(nn); determining whether any specific pesticide is a public health pesticide is beyond the scope of this PR Notice.

The Agency has determined that the lists of pests of significant public health importance required under FIFRA section 28(d) can be established independently of the definition of "public health pesticide" in section 2(nn). EPA is interpreting the term "significant public health importance" broadly, to include pests that pose a widely recognized risk to considerable numbers of people.

# I. BACKGROUND

FIFRA section 28(d) charges EPA with identifying "pests of significant public health importance." FIFRA section 2(t) defines the term "pest" as meaning:

(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organism on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1).

Pursuant to the authorization in the second part of this definition, EPA has broadly declared that the term pest includes all members of each of the categories of organisms identified in FIFRA section 2(t) in circumstances where they are deleterious to man or the environment, except for the organisms specifically excluded by the definition (See 40 CFR 152.5).

# II. THE LISTS

EPA has determined that the pests identified in the Appendix are pests of significant public health importance as that term is used in FIFRA section 28(d). Although these lists are derived in large part from review of the pesticide/pest combinations for which efficacy (product performance) data are generally required to be submitted and reviewed prior to registration; in no way should this be interpreted to mean that EPA has or would base any regulatory action solely on these lists. EPA is publishing these lists separate from any statutory or regulatory conclusions which may be associated with public health pesticides. Additionally, these lists do not account for unanticipated nomenclature changes and/or novel pests. A brief description of the pests and their potential impact on the public's health each is provided below:

<u>Arthropods</u>. The listed arthropods may cause asthma or trigger allergies, contaminate food, irritate skin, cause direct injury, or carry agents causing diseases such as Lyme disease, epidemic typhus, trench fever, epidemic relapsing fever, malaria, encephalitis (St. Louis, Eastern, Western, West Nile and LaCrosse), yellow fever, dengue fever and many others.

<u>Vertebrates</u>. The listed organisms have the potential for direct human injury and can act as disease reservoirs for rabies and other diseases. The rats and mice include those that spread rodent-borne diseases and contaminate food for human consumption.

Microorganisms and acellular particles. This category includes listed bacteria, fungi, protozoans, viruses, virusoids, and prions. The microorganisms and acellular particles listed in this category cause diseases such as COVID-19, cholera, meningitis, Legionnaire's Disease and many others.

As with the original 2002 lists (PR Notice 2002-1)<sup>1</sup>, these lists identify the pests that EPA, HHS and USDA currently consider to be of significant public health importance. As deemed necessary, the Agency will update the lists of pests of significant public health importance. Also, EPA notes that the listings in the "Public Health Importance/Possible Clinical Significance" column are not exhaustive and can vary in their presence and severity (up to and including death) based on a variety of situation specific factors.

<sup>&</sup>lt;sup>1</sup> https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf

Interested parties are invited to petition the Agency regarding the amendment of these lists. This petition should include the common use name and scientific name of the pest, and a rationale regarding the public health threat posed by this pest. These petitions can be sent to the contact under **Part V. For Additional Information**.

# III. USE OF THE LISTS OF PESTS OF SIGNIFICANT PUBLIC HEALTH IMPORTANCE BY THE AGENCY

The Agency will use the lists of pests of significant public health importance to:

- 1. Fulfill the requirements set forth in FIFRA section 28(d)
- 2. Together with other federal agencies, develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to control pests of public health importance
- 3. To identify pests that might warrant additional scrutiny and analyses of benefits before changing, restricting or eliminating a use to control a pest of public health significance

# IV. WHAT REGISTRANTS SHOULD DO

Registrants do not need to do anything in response to this notice.

# V. FOR ADDITIONAL INFORMATION

If you have questions regarding this PR Notice, please contact one of the following individuals:

Name: Susan Jennings phone: (706) 355-8574

e-mail: jennings.susan@epa.gov

You may also mail a written inquiry to EPA using the following address:

U.S. Environmental Protection Agency Office of Pesticide Programs (Mailcode 7505M) 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

# VI. Signature

This PR Notice is digitally signed today, February 23, 2023.

MICHAEL
GOODIS

Digitally signed by MICHAEL
GOODIS
Date: 2023.02.23 14:25:50 -05'00'

Michael Goodis,

Acting Director, Office of Pesticide Programs.

# **Appendix**

# Appendix to PR Notice 2023-01 (02/23/2023)

Arthropod Pests	. 2
Vertebrate Pests	. 7
Microorganisms	11

Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
ARACHNIDS		
Ixodida		
Soft Ticks	Argasidae	
	Ornithodoros turicata	
Relapsing fever ticks (and	Ornithodoros hermsi	Tick-borne relapsing fever
allied species)	Ornithodoros parkeri	
Hard Ticks	Ixodidae	
American dog tick	Dermacentor variabilis	Rocky Mountain spotted fever, Tularemia, tick paralysis,
Rocky Mountain wood tick	Dermacentor andersoni	Colorado tick fever, Rocky Mountain spotted fever, Tularemia, tick paralysis,
Pacific Coast tick	Dermacentor occidentalis	Pacific Coast tick fever
Western blacklegged tick	Ixodes pacificus	Anaplasmosis, <i>Borrelia miyamotoi</i> disease, Lyme disease
Blacklegged tick (deer tick)	Ixodes scapularis	Anaplasmosis, <i>Borrelia miyamotoi</i> disease, Lyme disease, Babesiosis, Powassan encephalitis
Brown dog tick	Rhipicephalus sanguineus	Rocky Mountain spotted fever
Lone star tick	Amblyomma americanum	Ehrlichiosis, Bourbon virus disease, Heartland virus disease, Alpha-gal syndrome (red meat allergy)
Gulf Coast tick	Amblyomma maculatum	Rickettsia parkeri rickettsiosis
Trombidiformes		
Chigger mites	Trombiculidae	
Common chiggers	Eutrombicula spp.	Dermatitis with risk of secondary infection
Follicle mites	Demodicidae	
Dog follicle mite	Demodex canis	Scabies
	Demodex brevis	Roseacea, Demodicosis,
Human follicle mites	Demodex folliculorum	Demodicidosis, eye infections
Sarcoptiformes		
Dust Mites	Pyroglyphidae	
American house dust mite	Dermatophagoides farina	Allergic reaction Asthma
European house dust mite	Chorioptes pteronyssinus	Allergic reaction, Asthma
Itch Mites	Sarcopidae	
Scabies mite	Sarcoptes scabiei	Scabies

Arthropod Pests			
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance	
Araneae			
Spiders			
Widow spiders, including: Southern black widow Northern black widow Western black widow Brown widow	Latrodectus mactans Latrodectus variolus Latrodectus hesperus Latrodectus geometricus	Venomous bite	
Recluse spiders, including: Brown recluse	Loxosceles reclusa		
Scorpiones			
Scorpions			
	Centruroides sculpturatus		
Bark scorpions	Centruroides exilicauda	Venomous sting	
	Centruroides vittatus		
Chilopoda			
Centipedes			
House centipede	Scutigera coleoptrata	Venomous bite	
Florida blue centipede	Hemiscolopendra marginata		
Scolopendra centipedes	Scolopendra spp.		
INSECTS			
Blattodea			
Cockroaches			
American cockroach	Periplaneta americana		
Australian cockroach	Periplaneta australasiae		
Brown cockroach	Periplaneta brunnea	Allergic reaction, asthma,	
Smokybrown cockroach	Periplaneta fuliginosa	Salmonellosis, <i>E. coli</i> infection,	
Brownbanded cockroach	Supella longipalpa	hepatitis	
German cockroach	Blattella germanica		
Oriental cockroach	Blatta orientalis		
<b>Anoplura</b> Sucking lice			
Body louse (cootie)	Pediculus humanus humanus	Epidemic typhus, epidemic	
Head louse	Pediculus humanus capitis	relapsing fever, Trench fever,	
Crab louse (crabs)	Phthirus pubis	dermatitis with risk of secondar infection	

Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Heteroptera		
True bugs		
Bed bug	Cimex lectularis	Bites, allergic reactions
Tropical bed bug	Cimex hemipterus	Bites, affergic reactions
Masked hunter	Reduvius personatus	Chagas disease, allergic reactions
Large kissing bug	Triatoma rubrofasciata	
Bloodsucking conenose	Triatoma sanguisuga	Chagas disease, allergic reactions
Western bloodsucking conenose	Triatoma protracta	-Chagas disease, aneigic reactions
Diptera		
Horse & Deer Flies		
Horse flies	Tabanus spp.	Painful Bite, allergic reactions, mechanical transmission of anthrax
Deer flies	Chrysops spp.	Painful Bite, allergic reactions, Tularemia
Calyptrate Flies		
House fly	Musca domestica	Salmonellosis, Shigella,
Stable fly	Stomoxys calcitrans	dysentery, myiasis, allergic
Little house fly	Fannia canicularis	reactions
Horse bot fly	Gasterophilus intestinalis	
Nose bot fly	Gasterophilus haemorrhoidalis	Ocular myiasis, cutaneous
Torsalo (human bot fly)	Dermatobia hominus	-myiasis
Sheep ked	Melophagus ovinus	Myiasis
Flesh flies	Sarcophagidae, including Sarcophaga and Wohlfahrtia spp.	Myiasis, mechanical vector of pathogens
Blow flies	Calliphoridae, including <i>Phaenicia</i> and <i>Calliphora</i> spp.	Myiasis, mechanical vector of pathogens
Screwworm	Cochliomyia hominivorax	- Myiasis
Secondary screwworm	Cochliomyia macellaria	INITYIASIS

Arthropod Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Biting Midges and Sand Flies		
"No-See-Ums"		
Punkies	Culicoides spp., Leptoconops	Dermatitis with risk of secondary
Biting midges	-spp.	infection, allergic reactions
Sand flies	Lutzomyia spp., Phlebotomus spp.	Dermatitis with risk of secondary infection, American dermal leishmaniasis
Black flies	Simuliidae; includes Simulium	River blindness, dermatitis with
Black gnats	and <i>Prosimulium</i> spp.	risk of secondary infection, painful bite, allergic reactions
Mosquitoes	Culicidae	
		Viral diseases, such as:
Mosquito species that vector disease	Aedes spp. Culex spp. Culiseta spp. Ochlerotatus spp. Anopheles spp. Psorophora spp. Coquillettidia spp. Mansonia spp.	West Nile, St. Louis encephalitis Eastern equine encephalitis, Western equine encephalitis, Venezuelan equine encephalitis, LaCrosse, Jamestown Canyon, Cache Valley virus disease, Dengue fever, Yellow fever, Malaria, Zika, Chikungunya, Japanese encephalitis  (note: not all diseases are vectored by every genera)
Siphonaptera		
Fleas		
Cat flea	Ctenocephalides felis	Bartonella, Murine typhus, tapeworm infection, dermatitis
Dog flea	Ctenocephalides canis	with a risk of secondary infection, allergic reactions, painful bite
Human flea	Pulex irritans	Dermatitis with risk of secondary infection, allergic reactions, painful bite
Sticktight flea	Echidnophaga gallinacea	
Oriental rat flea	Xenopsylla cheopis	Bubonic plague, Murine plague
Chigoe	Tunga penetrans	(endemic typhus), Dermatitis with
Other fleas	Oropsylla spp. Thrassis spp. Ceratophyllus gallinae	risk of secondary infection, allergic reactions, painful bite

Arthropod Pests				
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance		
Hymenoptera				
Stinging Wasps, Bees, & An	nts			
Yellowjackets	Vespula spp.			
European hornet	Vespa crabro			
Bald-faced hornet	Dolichovespula maculata	Painful stings, allergic reactions		
Paper wasps	Polistes spp.			
Thread-waisted wasps (including mud daubers)	Sphecidae: Various species			
Ants	Formicidae			
Pharaoh ant	Monomorium pharaonis	Feed on wounds		
Fire ants, including: Southern fire ant Tropical fire ant Red imported fire ant Black imported fire ant European fire ant	Solenopsis spp. Solenopsis xyloni Solenopsis geminata Solenopsis invicta, Solenopsis richteri Myrmica rubra	Painful stings, allergic reactions		
Harvester ants	Pogonomyrmex spp.	Painful stings, allergic reactions		
Bees	Apidae			
Africanized honey bee	Apis mellifera scutellata	Painful stings, allergic reactions		

Vertebrate Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Reptiles		
Rattlesnakes	Crotalus spp.	
Copperhead and cottonmouth snakes	Agkistrodon spp.	Direct injury, venomous bites
Coral snakes	Micrurus spp.	
Brown tree snake	Boiga irregularis	
Fish		
Great white shark	Carcharodon carcharias	
Tiger shark	Galeocerdo cuvier	
Bull shark	Carcharhinus leucas	Direct Injury
Asian carps	Cyprinus spp. Ctenopharyngodon spp. Hypophthalmichthys spp.	Direct injury
Birds		
Geese	Subfamily Anserinae	
Mute swan	Cygus olor	
Gulls	Subfamily Larinae	
Coot	Fulica americana	
Rock dove (domestic pigeon)	Columba livia	
Cliff swallow	Petrochelidon pyrrhonota	
Barn swallow	Hirundo rustica	
House (English) sparrow	Passer domesticus	Histoplasmosis, cryptococcosis, psittacosis, avian influenza, direct
American crow	Corvus brachyrhynchos	injury, bird strike at airports
Fish crow	Corvus ossifragus	1
European starling	Sturnus vulgaris	
House finch	Cardodacus purpureus	
Blackbirds	Family Icteridae	
Common raven	Corvus corax	
Chihuahuan raven	Corvus cryptoleucus	
Black vulture	Cathartes aura	
Turkey vulture	Coragyps atratus	

Vertebrate Pests				
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance		
Mammals				
Bats				
Big brown bat	Eptesicus fuscus			
Little brown bat	Myotis lucifugus	Rabies, histoplasmosis,		
Brazilian (Mexican) free-tailed bat	Tadarida brasiliensis	salmonellosis, yersiniosis, Nipah virus, Ebola virus, SARS		
Big eared bat	Corynorhinus townsendii	coronavirus		
Common vampire bat	Desmodus rotundus			
Mice				
House mouse	Mus musculus			
Deer mouse	Peromyscus maniculatus	Hantavirus, salmonellosis,		
Cotton mouse	Peromyscus gossypinus	tularemia, leptospirosis,		
White-footed mouse (White-footed deer mouse)	Peromyscus leucopus	lymphocytic chorio-meningitis, rat bite fever, other diseases, allergy and asthma triggers from		
Eastern harvest mouse	Reithrodontomys humuli	urine/hair/dander		
Golden mouse	Ochrotomys nuttalli			
Rats				
Norway rat	Rattus norvegicus			
Roof rat	Rattus rattus			
Polynesian rat	Rattus exulans	Leptospirosis, plague, rat bite		
Cotton rats	Sigmodon spp.	fever, salmonellosis, tularemia,		
Mexican woodrat	Neotoma mexicana	lymphocytic chorio-meningitis,		
Southern plains woodrat	Neotoma micropus	direct injury, allergy and asthma triggers from urine/hair/dander		
White-throated woodrat	Neotoma albigula			

Vertebrate Pests			
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance	
Squirrels			
Flying squirrels	Glaucomys spp.	Sylvatic typhus, leptospirosis	
Ground squirrels and prairie dogs	Urocitellus spp., Spermophilus spp., Ictidomys spp., Poliocitellus spp., Cynomys spp., Xerospermophilus spp., Callospermophilus spp., Otospermopjilus spp., Ammospermophilus spp.	Plague, tularemia	
Tree squirrels and	Sciurus spp., Tamias spp.,		
chipmunks	Eutamias spp., Tamiasciurus spp.	I antognirogis, galmonallogis	
Woodchuck	Marmota monax	Leptospirosis, salmonellosis, tularemia, rabies, direct injury	
Yellow-bellied marmot	Marmota flaviventris	— tularemia, rables, direct injury	
Other Mammals			
Bears	Family Ursidae	Toxoplasmosis, brucellosis, trichinellosis, direct injury	
Coyote	Canis latrans		
Arctic fox	Alopex lagopus		
Gray fox	Urocyon cinereoargenteus	Rabies, canine distemper virus,	
Red fox	Vulpes vulpes	leptospirosis, direct injury	
Gray wolf	Canis lupus		
Wild (feral) dog	Canis lupus familiaris		
Wild (feral) cat	Felis catus	Toxoplasmosis, rabies, direct injury	
Wild (feral) horse	Equus caballus	Rabies, leptospirosis, salmonellosis, campylobacterosis, cryptosporidiosis, direct injury	
Wild (feral) swine Javelina (collared peccary)	Sus scrofa Dicotyles tajacu	Leptospirosis, brucellosis, <i>E. coli</i> infection, salmonellosis, toxoplasmosis, rabies, swine influenza viruses, trichinosis, giardiasis, cryptosporidiosis, direct injury	
Deer and elk	Family Cervidae	Leptospirosis, salmonellosis, chlamydiosis, campylobacterosis, cryptosporidiosis, giardiasis, direct injury	
American bison	Bison bison	Brucellosis, direct injury	
Mongooses	Family Herpestidae	Leptospirosis, direct injury	

Vertebrate Pests		
Pest	Scientific Name	Public Health Importance/ Possible Clinical Significance
Other Mammals (con	itinued)	
Mountain lion (cougar)	Puma concolor	Toxoplasmosis, plague, rabies, direct injury
Nutria	Myocastor coypus	Tuberculosis, septicemia, rabies, leptospirosis
Porcupine	Erethizon dorsatum	Rabies, tularemia, direct injury
North American beaver	Castor canadensis	Giardiasis, leptospirosis, hantavirus, direct injury, waterway impoundment that can lead to life-threatening flooding
Badger	Taxidea taxus	Rabies, direct injury
Muskrat	Ondatra zibethicus	Leptospirosis, tularemia
Striped skunk	Mephitis mephitis	Leptospirosis, tularemia, direct injury
Spotted skunk	Spilogale putorius	
Raccoon	Procyon lotor	
Rabbits	Family Leporidae	Cryptosporidoisis, tularemia, rabbit hemorrhagic fever
Virginia opossum	Didelphis virginiana	Leptospirosis, tularemia, direct injury
Nine-banded armadille	o Dasypus novemcinctus	Leprosy, Chagas disease

Microorganisms			
Taxonomic Name	Public Health Importance		
(Organism or Particle Type)	(Possible Clinical Significance)		
Bacteria			
Spirochetes			
Borrelia spp.	Lyme disease, <i>Borrelia miyamotoi</i> disease, tick-borne relapsing fever		
Leptospira spp.	Leptospirosis		
Treponema spp.	Syphilis, yaws, pinta		
Gram-Negative Bacteria – aerobic rods and cocci			
Campylobacter spp.	Enteritis, abscesses,		
Pseudomonas spp.	Septicemia, abscesses, respiratory and urinary infections, bacteremia		
Stenotrophomonas spp.	Respiratory infections, urinary tract infections		
Burkholderia spp.	Endocarditis, septicemia, wound infections		
Legionella spp.	Legionnaires' Disease, pneumonia		
Neisseria spp.	Meningitis, gonorrhea, urinary tract infections		
Elizabethkingia spp. (Chryseobacterium - Flavobacteria spp.)	Nosocomial infection, meningitis, septicemia		
Bordetella spp.	Whooping cough		
Brucella spp.	Brucellosis, undulant fever		
Moraxella spp.	Conjunctivitis		
Acinetobacter spp.	Nosocomial infections		
Aeromonas spp.	Gastroenteritis, wound, septicemia		
Haemophilus spp.	Bronchitis, sinusitis, otitis, septicemia, venereal disease		
Chromobacterium spp.	Pyogenic infections, septicemia		
Gram-Negative Bacteria –facultatively anaero			
Vibrio spp.	Cholera, gastroenteritis, septicemia, ear infections		
Plesiomonas spp.	Gastroenteritis		
Pasteurella spp.	Meningitis, arthritis, otitis, septicemia, sinusitis, encephalitis		
Actinobacillus spp.	Pneumonia, bronchitis, septicemia, sinusitis		
Bacteroide spp.	Diarrhea, intra-abdominal abscesses, peritoneal infections, inflammatory bowel disease, anaerobic bacteremia, colon cancer		
Cardiobacterium spp.	Endocarditis		
Gardnerella spp.	Vaginitis		
Eikenella spp.	Sinusitis, pulmonary infections, arthritis, endocarditis, pancreatic abscesses		

Microorganisms	
Taxonomic Name	Public Health Importance
(Organism or Particle Type)	(Possible Clinical Significance)
Enteric Bacteria	
Escherichia spp.	Urinary tract infections, septicemia, diarrhea, hemorrhagic colitis
Shigella spp.	Dysentery, diarrhea
Salmonella spp.	Gastroenteritis, septicemia, bacteremia, arthritis, typhoid fever, enterocolitis, gallbladder infection
Citrobacter spp.	Opportunistic infections, neonatal meningitis
Klebsiella spp.	Pneumoniae, infant diarrhea and urinary tract infection
Enterobacter spp./Other related species	Wound infection, nosocomial infections, urinary tract infections, gastroenteritis
Hafnia spp.	Opportunistic infections
Proteus spp.	Urinary tract infections, infant diarrhea, respiratory infections
Serratia spp.	Cystitis, bloodstream and central nervous system infections
Providencia spp.	Nosocomial infections, urinary tract infections, burn wound infections
Morganella spp.	Bacteremia, respiratory/urinary tract infections, wound infections
Yersinia spp.	Gastroenteritis, wound infections, septicemia
Gram-Negative, Anaerobic, Straight, Curved, a	
Bacterioides spp.	Periodontal disease, bacteremia
Fusobacterium spp.	Abscesses
Rickettsia and Chlamydia – obligate, intrace	llular parasites
Rickettsia—Rod-shaped bacteria or Coccobacilli, Gram-Negative, Non-motile, Most transmitted by arthropods	
Rickettsia spp.	Rickettsialpox, Rocky Mountain spotted fever, <i>Rickettsia parkeri</i> rickettsiosis, Pacific Coast tick fever
Anaplasma spp.	Anaplasmosis
Ehrlichia spp.	Ehrlichiosis
Coxiella spp.	Q fever
Chlamydia -coccoid bacteria, Gram-negative, r	non-motile
Chlamydia spp.	Trachoma (blindness), nongonococcal urethritis, lymphoma venereum, pneumonia
Mycoplasma spp.	Pneumonia, urogenital tract infections
Úreaplasma spp.	Urogenital tract infections

Microorganisms		
Taxonomic Name	Public Health Importance	
(Organism or Particle Type)	(Possible Clinical Significance)	
Gram-Positive Cocci		
	Cellulitis, boils, carbuncles, impetigo, toxic	
Staphylococcus spp.	shock syndrome, bacteremia, endocarditis,	
	meningitis, pneumonia, osteomyelitis	
Coagulase-negative <i>Staphylococcus</i> spp.	Bacteremia, endocarditis, peritonitis,	
Coagulase-negative Stuphytococcus spp.	genitourinary tract infections	
Group A <i>Streptococci</i> spp.	Pharyngitis, tonsillitis, sinusitis, arthritis,	
Group A streptococci spp.	rheumatic fever, scarlet fever, impetigo	
Group B <i>Streptococci</i> spp.	Neonatal disease, pneumonia, septicemia,	
Group B streptococci spp.	meningitis, endocarditis	
Group C Streptococci spp.	Pneumonia, pharyngitis, endocarditis,	
Group & Streptococci spp.	meningitis	
Enterococcus spp.	Wound infections, bacteremia, endocarditis,	
Ziner coccens app.	meningitis	
Additional <i>Streptococci</i> spp.	Pneumonia, otitis media, bacteremia,	
1 11	meningitis	
Endospore-forming Gram-positive rods and co		
Bacillus spp.	Anthrax, gastroenteritis	
Clostridioides spp.	Pseudomembranous colitis	
Clostridium spp.	Tetanus, botulism, gangrene	
Non-Endospore forming Gram-Positive Rods		
Listeria spp.	Food poisoning, abscess, abortion, meningitis	
Erysipelothrix spp.	Erysipeloid, arthritis, endocarditis	
Irregular, non-endospore forming, Gram-posit		
Corynebacterium spp.	Diphtheria	
	Actinomyces-granulomatous, ocular	
Actinomyces spp.	infections, caries, periodontal disease,	
	intrauterine infection	
Propionibacterium spp.	Acne	
Mycobacterium spp.	Tuberculosis, pulmonary disease, cutaneous	
7	abscesses, post-operative wound infections	
Actinomycetes—Irregular, non-endospore forming, Gram-positive		
Nocardia spp.	Cutaneous/subcutaneous infections,	
DI I	nocardiosis, mycetoma	
Rhodococcus spp.	Opportunist pathogens	
Streptomyces spp.	Actinomycetoma	
Actinomadura spp.		

Microorganisms	
Taxonomic Name	Public Health Importance
(Organism or Particle Type)	(Possible Clinical Significance)
Fungi	
Rhizopus spp.	
Rhizomucor spp.	
Absidia spp.	
Mucor spp.	
Cunninghamella spp.	Opportunistic infectionsMucormycosis
Mortierella spp.	
Saksenaea spp.	
Apophysomyces spp.	
	Pneumonia, endocarditis, urinary tract
Penicillium spp.	infections
~	Candidiasis, thrush, iatrogenic infections,
Candida spp.	Genitourinary tract infections
	Disseminated skin lesions in patients with
Fusarium spp.	leukemia
	Local lesions in paranasal sinuses,
Pseudalleschericia spp.	disseminated in kidney, thyroid, brain, heart
Cryptococcus spp.	Meningitis
Trichosporon spp.	Trichosporonosis
Epidermophyton spp.	Tinea cruris, tinea pedis
Malassezia spp.	Tinea versicolor
Exophiala spp.	Tinea nigra palmaris
Емориши эрр.	Athlete's foot, tinea pedis, tinea corporis,
Trichophyton spp.	tinea pedis, tinea barbae, tinea cruris, tinea
Trenophyton spp.	capitis, tinea favosa
Microsporum spp.	Tinea capitis
Pneumocystis spp.	Pneumonia Pneumonia
Histoplasma spp.	Histoplasmosis
Coccidioides spp.	Coccidioidomycosis
Paracoccidioides spp.	Paracoccidioidomycosis
Blastomyces spp.	Blastomycosis
Sporothrix spp.	Sporotrichosis
	Aspergillosis, pneumonia, ear infections,
Aspergillus spp.	food-borne intoxication (aflatoxin)
Stachybotrys spp. / Memnoniella spp.	Allergic reactions
Protozoans	1 Mergie reactions
Amoebas	
Entamoeba spp.	Amoebic dysentery
Naegleria spp.	Meningoencephalitis
	Keratitis, chronic granulomatous amoebic
Acanthamoeba spp.	encephalitis
	oncophanas

Microorganisms	
Taxonomic Name	Public Health Importance
(Organism or Particle Type)	(Possible Clinical Significance)
Flagellates	
Giardia spp.	Dysentery
Trichomonas spp.	Urethritis, vaginitis
Ciliates	
Balantidium spp.	Dysentery
Sporozoans	
Babesia spp.	Babesiosis
Cryptosporidium spp.	Diarrhea
Cyclospora spp.	Food poisoning
Toxoplasma spp.	Toxoplasmosis
Isospora spp.	Watery diarrhea, abdominal pain/cramping, vomiting, fever
Viruses	, , , , , , , , , , , , , , , , , , ,
Adenoviruses (Infectious canine hepatitis	Bronchitis, pneumonia, diarrhea,
virus)	conjunctivitis, fever, bladder inflammation
Alphaviruses (Eastern equine encephalitis	Fever, headache, joint swelling, pain,
virus, chikungunya virus)	seizures, neurocognitive symptoms
Papillomaviruses (HPV),	Cancers, papilloma, warts
Polyomaviruses (simian vacuolating virus, Simian Virus 40, BK virus)	Usually asymptomatic, hemorrhagic cystitis,
Herpesviruses (herpes simplex viruses, varicella-zoster virus, cytomegalovirus, Epstein-Barr virus)	Shingles, chicken pox, fever, sore throat, swollen glands, hepatitis
Parvoviruses (parvovirus B19, canine parvovirus)	Fifth disease, rash, rhinitis, headache, painful joints
Poxviruses (smallpox virus, cow pox virus, sheep pox virus, monkey pox, vaccinia virus, molluscum contagiosum)	Lesions, skin nodules, disseminated rash
Picornaviruses (poliovirus, rhinovirus, coxsackie virus, enterovirus, hepatovirus, cardiovirus)	Hand, foot, and mouth disease, viral meningitis, myocarditis, acute flaccid paralysis, inflammatory muscle disease, stomach pain, nausea
Reoviruses (rotavirus)	Acute necrotizing encephalopathy, vomiting, diarrhea, abdominal pain
Caliciviruses (norovirus)	Diarrhea, vomiting, stomach pain
Togoviruses (rubella virus, alphavirus)	German measles, rash, sore throat
Flaviviruses (dengue virus, hepatitis C virus, yellow fever virus, Zika virus, West Nile virus, Powassan virus, tick-borne encephalitis virus)	Fever, headache, neurological symptoms, nausea, vomiting, rash, aches, pains, bleeding from nose or gums
Orthomyxoviruses (influenza viruses, Thogotovirus)	Fever, child, cough, sore throat, rhinitis

Microorganisms		
Taxonomic Name	Public Health Importance	
(Organism or Particle Type)	(Possible Clinical Significance)	
Viruses (continued)		
Paramyxoviruses (measles virus, measles virus, respiratory syncytial virus (RSV), canine distemper virus)	High fever, coryza, conjunctivitis, coughing, wheezing,	
Bunyaviruses (California encephalitis virus, hantavirus, Crimean-Congo hemorrhagic fever)	Fever, fatigue, muscle aches, vomiting, diarrhea, lethargy, shortness of breath	
Rhabdoviruses (rabies virus)	Flu-like symptoms, weakness, fever, headache	
Filoviruses (Ebola virus, Marburg virus)	Muscle pains, fatigue, diarrhea, unexplained bleeding or bruising	
Coronaviruses (coronavirus, SARS-CoV, MERS-CoV)	Rhinitis, cough, sore throat, fever, fatigue, difficulty breathing	
Astroviruses (astrovirus)	Vomiting, diarrhea	
Retroviruses (HIV)	Night sweats, continual fevers, extreme fatigue, prolonged swelling of lymph glands, immune deficiency (i.e., AIDS)	
Hepeviruses (Hepatitis E virus)	Nausea, jaundice, liver failure	
Hepadnaviruses (Hepatitis B virus)	Fever, vomiting, nausea, dark urine, jaundice	
Arenaviruses (Lymphocytic choriomeningitis virus (LCMV), Lujo Hemorrhagic Fever (LHF) virus, Sabia Virus, Lassa virus)	Meningitis, encephalitis, hydrocephalus, rash on face and trunk, respiratory distress, circulatory issues	
Prions		
TSEs (transmissible spongiform encephalopathies)	Gerstmann-Straussler-Scheinker Syndrome, fatal familial insomnia, kuru, Creutzfeldt-Jakob Disease, bovine spongiform encephalopathy, scrapie, transmissible mink encephalopathy, feline spongiform encephalopathy, ungulate spongiform encephalopathy, chronic wasting disease	

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### Pesticide Registration

 $CONTACT\ US\ {\it https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration}\$ 

## Pesticide Registration Manual: Chapter 13 - Devices

### In this chapter:

- Devices Introduction
- How to Obtain a Device Determination from EPA
- Devices Subject to Regulation
- Devices Not Subject to Regulation
- Requirements for a Device Subject to Regulation
  - Registration Not Required
  - Production Requirements
  - Labeling Requirements
  - Device Efficacy
  - Child-Resistant Packaging
- Import and Export of Devices
- Contacts for Additional Information
- References Cited in Chapter 13

### **Devices - Introduction**

This chapter describes how EPA regulates pesticidal devices and clarifies which types of devices are subject to regulatory oversight and what requirements apply to them.

In 1976, EPA issued a Federal Register Notice concerning the regulatory status of devices <a href="https://epa.gov/pesticide-registration/pest-registration/

### Registration Manual Table of Contents

Pesticides Registration Manual Home Page

<https://epa.gov/pesticideregistration/pesticide-registrationmanual>

Introduction <a href="https://epa.gov">https://epa.gov</a> /pesticide-registration/pesticideregistration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <a href="https://epa.gov">https://epa.gov</a> /pesticide-registration/how-register-pesticide-guideapplicants-new-process>

control-devices-and-device-producers-1976-federal-register-notice». In that notice, EPA also explained its interpretation of the distinction between a "pesticide" and a "device." More information can be found on the EPA's Pest Control Devices and Device Producers: 1976 Federal Register Notice webpage <a href="https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice">https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notices</a>.

FIFRA defines a device as any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom. Refer to FIFRA section 2(h) <a href="https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a>.

In general, if an article is an instrument or contrivance that uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 152.5, it is considered to be a device and subject to regulation under FIFRA. However, devices are not subject to the registration requirements that apply to pesticides and pesticide products under FIFRA section 3. Further information can be found on EPA's Pest Control Devices Webpage. <a href="https://epa.gov/pesticides/pesticide-devices-guide-consumers">https://epa.gov/pesticides/pesticide-devices-guide-consumers></a>

If a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3. Also, if such a product is sold with any substance that functions as a precursor for creation of a pesticidal substance, the entire product is generally considered to be a pesticide and subject to registration under FIFRA section 3.

If the product is an instrument or contrivance and claims to control pests through physical or mechanical means, the product is considered to be a device, unless it is a firearm.

Distinctions among devices, pesticides, and pesticide

- Requirements for Pesticide Registration and Registrant Obligations
  - <https://epa.gov/pesticideregistration/pesticideregistration-manual-chapter1-overview-requirementspesticide>
- Registering a Pesticide
   Product < https://epa.gov</p>
   /pesticide-registration
   /pesticide-registration-manual-chapter-2-registering-pesticide-product>
- 3. Additional
  Considerations for
  Biopesticide Products
  <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations</a>
- 4. Additional
  Considerations for
  Antimicrobial Products
  <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations</a>
- Registration Fees
   https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>

application equipment can be illustrated by comparing products that are outwardly similar but are treated differently under FIFRA. For example, a bait station that is sold by itself to be used in conjunction with other products in the control of insects or rodents is considered to be pesticide application equipment and is not directly regulated under FIFRA, although the labels for registered pesticide products may require them to be used in bait stations in some or all applications.

If the same design of bait station is sold with toxic bait in it (or packaged with it for use in it), the entire product is considered a "pesticide product" and is regulated and labeled as such. If the bait station is sold with a sticky trap inside it (or is packaged with sticky traps that are to be placed inside it), the entire product is a device, and is regulated under FIFRA because it achieves pest control by physical means.

## 6. Amending a Registered Pesticide Product

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide></a>

## 7. Notifications and Minor Formulation Amendments

<https://epa.gov/pesticideregistration/pesticideregistration-manual-chapter7-notifications-and-minorformulation>

### 8. Inert Ingredients

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients></a>

## 9. SupplementalDistribution of aRegistered Pesticide

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered">https://epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registration-registration-pesticide-registration-manual-chapter-9-supplemental-distribution-registration-r

## 10. Data Compensation Requirements

<https://epa.gov/pesticideregistration/pesticideregistration-manual-chapter10-data-compensationrequirements>

### 11. Tolerance Petitions

<https://epa.gov/pesticideregistration/pesticideregistration-manual-chapter11-tolerance-petitions>

12. Applying for an Experimental Use

Permit <a href="https://epa.gov">https://epa.gov</a>
/pesticide-registration
/pesticide-registrationmanual-chapter-12-applyingexperimental-use-permit>

### 13. Devices

14. How to Obtain an EPA
Establishment Number

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or-">https://epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or-</a>

15. Submitting Data and Confidential Business Information

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential">https://epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential></a>

16. Transfer of Product
Registrations and Data

Rights <a href="https://epa.gov">https://epa.gov</a>
/pesticide-registration
/pesticide-registrationmanual-chapter-16-transferproduct-registrations-and>

17. State Regulatory
Authority <a href="https://epa.gov">https://epa.gov</a>
/pesticide-registration
/pesticide-registrationmanual-chapter-17-stateregulatory-authority>

## 18. Other Federal or State Agency Requirements

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency">https://epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

## 19. How to Obtain Publications

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications">https://epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>

## 20. Forms and How to Obtain Them

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them</a>

### 21. Directions for Submitting Applications and Contacting EPA

<a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications">https://epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications></a>

### **Appendices**

 Appendix A: Guidance Documents

<https://epa.gov/pesticideregistration/pesticideregistration-manual-appendixguidance-documents>

- Appendix B: Examples of Registrant Documents
  - <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents">https://epa.gov/pesticide-registration-manual-appendix-b-examples-registrant-documents></a>
- Appendix C: Pesticide
   Forms Overview Table
   https://epa.gov/pesticide registration/pesticide registration-manual-appendix c-pesticide-forms-overview table>
- Appendix D: Examples
   of Completed Forms
   <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0">https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0</a>>
- Pesticidal devices must be produced in an EPA registered pesticide-producing establishment. It is important to note that EPA establishment numbers, which are required for devices, are not the same as EPA pesticide registration numbers required for pesticide products. Obtaining an establishment number <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or</a> is an administrative process, completed upon request to the EPA. In contrast, obtaining an EPA pesticide registration requires a fee for review of product specific data and is a longer process.
- EPA establishment numbers are composed of a company number, followed by a 2-letter U.S. State or 3-letter Country abbreviation, followed by the unique facility number (e.g., xxxx-PA-xx; xxxxx-CHN-xxxx)
- EPA Registration Numbers are composed of a company number followed by a product number (e.g., xxxxx-xxxx). For registered distributor products, the company number and product number are followed by the distributor company number (e.g., xxxxx-xx-xxxx)

• See Chapter 14 <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or">epa-company-or</a> for information on how to register a pesticide-producing establishment. Devices are also subject to certain labeling requirements. Refer to FIFRA section 2(q)(1) <a href="https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a> and 40 CFR Part 156.

# How to Obtain a Device Determination from EPA

If you are uncertain about whether your product requires EPA registration as a pesticide, you may request a determination from EPA. If you would like a determination from EPA as to whether your product is considered a pesticidal device, please submit a request to the Agency using PRIA code M009. The cost is \$2,482\* and the timeframe is 4 months. Please submit the following information with your request:

- Submit 8570-1 application form (select "miscellaneous" and provide an explanation in the space provided);
- Submit a cover letter on company letterhead requesting a device determination and include as much of the following information as possible:
  - Your EPA issued company number;
  - The complete brand names of the product;
  - Complete copy of the label for the product, and a statement of all claims to be made for the product, including all written, printed, or broadcast claims made for the product;
  - o Directions for use and warnings or cautionary statements;
  - All material distributed with the product;
  - A detailed written description of how the product works to kill, destroy, repel, or mitigate a pest;
  - Starting material inputs or ingredients or specifications used in the operation of the product. Ingredients in the product must be identified by common name and CAS number if applicable;
  - Schematic diagram or detailed engineering drawings, diagrams, flow diagrams or patent(s) application information. Note: if a patent(s) has been issued, please include copies;
  - Photographs of the product from all sides, including digital copies available upon request; and
  - Comparisons to current industry products;
- Provide proof of payment;

Once all of the submitted information is reviewed by the Agency, a determination letter will be issued to the applicant within the 4-month PRIA timeframe.

\*There are provisions for waiving up to 75% of the fee if you qualify as a small business (waiver information is also on the website <a href="https://epa.gov/pria-fees/pria-fee-waivers-small-businesses">https://epa.gov/pria-fees/pria-fee-waivers-small-businesses</a>). The fee waiver application must be submitted with the registration application.

Fees may be reduced under some circumstances <a href="https://epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula">https://epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula</a>.

If you have questions, please contact us at OPP\_FIFRA\_Jurisdictional\_Issues@epa.gov.

## **Devices Subject to Regulation**

In a *Federal Register* notice published on November 19, 1976 (Pest Control Devices and Device Producers <a href="https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice">https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice>>, EPA stated that devices subject to FIFRA section 2(q)(1) and section 7 include, but are not limited to:

- certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances), and ultrasonic devices for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites;
- certain high frequency sound generators, carbide cannons, foils, and rotating devices for which claims are made to repel birds;
- black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper for which claims are made to kill or entrap certain insects; and
- mole thumpers, sound repellents, foils, and rotating devices for which claims are made to repel certain mammals.

Since that notice was issued, EPA has determined that products of the following types also fall within the definition of device:

- products that are claimed to control pests via **electromagnetic and/or electrical emissions** (e.g., hand held bug zappers, eletric flea combs);
- products that are claimed to control burrowing animals via product-caused subterranean explosions; and
- products that work via principles indicated in the 1976 Federal Register Notice for one category of pest but are claimed to control pests of different types (e.g., sticky traps for rodents (without attractants), light or laser repellents for birds, etc.).

**Important Note**: In applying the definition of "device" in FIFRA section 2(h), EPA examines each individual product on a case-by-case basis. For instance, the public should be aware that EPA has reviewed a number of individual products that claim to provide pest control through the use of electromagnetic radiation and has found these products to be devices within the meaning of section 2(h). In addition, EPA has found that a silver ion generating washing machine marketed with claims that

odor causing bacteria will be killed on laundry must be registered as a pesticide. Read more about regulation of ion generating equipment <a href="https://epa.gov/pesticide-registration/pesticide-registration-clarification-ion-generating-equipment">https://epa.gov/pesticide-registration/pesticide-registration-clarification-ion-generating-equipment</a>.

## **Devices Not Subject to Regulation**

The November 19, 1976, Federal Register Notice Pest Control Devices and Device Producers <a href="https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice">https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice</a> also provided examples of those types of devices that are not subject to regulation under FIFRA:

- devices that depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself; and
- devices that operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mousetraps, fly swatters, tillage equipment for weed control, and fish traps.

# Requirements for a Device Subject to Regulation

### **Registration Not Required**

A device is not required to be registered under FIFRA section 3. However, devices are subject to certain requirements of FIFRA as specified in 40 CFR 152.500 .

### **Production Requirements**

Pesticidal devices must be produced in a registered pesticide-producing establishment. Refer to 40 CFR 152.500(b)(2). See Chapter 14 <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or</a> for information on registering a site.

### **Labeling Requirements**

Devices are subject to the labeling requirements of FIFRA section 2(q)(1) and 40 CFR Part 156. These requirements are summarized below.

**Misbranding** - Under FIFRA section 2(q)(1) a device is considered to be misbranded and subject to enforcement action if:

- the labeling bears any statements, designs, or graphic representations that are false or misleading (see 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3) (as of 2010, such standards have yet to be established for devices);
- it is an imitation of, or is offered for sale under the name of another device;
- the label fails to bear the establishment number of the establishment where it was produced;
- any required information is not prominently displayed on the label;
- it lacks adequate directions for use; or
- it lacks an adequate warning or caution statement.

### **Device Efficacy**

Unlike registrants of pesticide products, FIFRA does not require device producers to submit any data concerning either safety or efficacy of a device prior to distribution or sale. This is particularly important to note for antimicrobial pesticide devices that claim to disinfect, sanitize, and/or sterilize items or ambient air. Because microbial pests are not visible to the naked eye, users of such devices generally cannot evaluate the actual performance of the device. The device may be "misbranded" if labels, labeling, and/or websites for devices including general or specific efficacy claims include any statement, design, or graphic representation that is "false or misleading in any particular." Distribution or sale of a misbranded device is prohibited under FIFRA. Therefore, every producer or seller of devices is responsible for ensuring that these products perform as claimed, and that such performance claims are not misleading to the intended user.

Also, please note that some state laws have requirements for devices in addition to those imposed by FIFRA. Some state governments require registration of devices, including submission and review of efficacy data and labeling, before a device can be sold or distributed in that state. Therefore, compliance with FIFRA's requirements does not ensure that a device can be legally sold in those states. Click the link below for a contact list of state lead agencies.

http://npic.orst.edu/reg/state\_agencies.html <a href="http://npic.orst.edu/reg/state\_agencies.html">http://npic.orst.edu/reg/state\_agencies.html</a>

### **Child-Resistant Packaging**

Devices are subject to child-resistant packaging (CRP) requirements when they meet certain toxicity and use criteria. For information concerning CRP requirements, see:

- Child-Resistant Packaging for Pesticides <a href="https://epa.gov/pesticide-registration/child-resistant-packaging-pesticides">https://epa.gov/pesticide-registration/child-resistant-packaging-pesticides</a>
- EPA regulations on child-resistant packaging -- 40 CFR 157.20 157.36

Child-resistant packaging is defined as packaging designed or constructed to be significantly difficult for children less than five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly. 40 CFR 157.21(b).

## **Import and Export of Devices**

Please refer to FIFRA section 17 <a href="https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a> for information concerning import and export requirements for devices. U.S. Customs regulations at 19 CFR 12.1(b) related to the implementation of FIFRA section 17 require, in part, that devices produced by foreign manufacturers and imported into the U.S. comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices <a href="https://epa.gov/compliance/importing-and-exporting-pesticides-and-devices">https://epa.gov/compliance/importing-and-exporting-pesticides-and-devices</a> (EPA Form 3540-1) for review and determination as to whether the shipment should be sampled and/or permitted entry into the U.S.

FIFRA section 17 states that no device produced solely for export to any foreign country shall be deemed in violation of FIFRA when prepared or packaged to the specifications or directions of the foreign producer, except that producers of such devices are subject to labeling requirements and certain misbranding restrictions found in sections 2(p) and 2(q) of FIFRA.

In addition, producers of devices are subject to record keeping and inspection requirements in accordance with section 8 of FIFRA <a href="https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a>.

## **Contacts for Additional Information**

If you have any questions concerning regulatory requirements for devices that are not subject to registration, please contact:

OPP\_FIFRA\_Jurisdictional\_Issues@epa.gov

## **References Cited in Chapter 13**

Refer to Chapter 19 <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications">https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications</a> for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 152 Pesticide registration and classification procedures
- Part 153 Statement of policies and interpretations
- Part 156 Labeling requirements for pesticides and devices
- Part 157 Packaging requirements for pesticides and devices
- Part 167 Registration of pesticide-producing establishments, submission of pesticide reports, and labeling
- Part 169 Books and records of pesticide production and distribution

Federal Insecticide, Fungicide, and Rodenticide Act <a href="https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 Definitions
- Section 3 Registration of pesticides
- Section 7 Registration of establishments
- Section 8 Books and records
- Section 9 Inspection of establishments, etc.
- Section 12 Unlawful acts
- Section 13 Stop sale, use, removal, and seizure
- Section 14 Penalties
- Section 17 Imports and exports
- Section 25 Child-resistant packaging

Federal Register Notice, Pest Control Devices and Device Producers <a href="https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice">https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice</a>, (41 FR 51065), November 19, 1976

Pesticide Registration Home <a href="https://epa.gov/pesticide-registration">https://epa.gov/pesticide-registration</a>

About Pesticide Registration <a href="https://epa.gov/pesticide-registration/about-pesticide-registration">https://epa.gov/pesticide-registration</a>

Electronic Submission of Applications <a href="https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications">https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications</a>

Pesticide Registration Manual <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual">https://epa.gov/pesticide-registration/pesticide-registration-manual</a>

Fees and Waivers <a href="https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers">https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers</a>

Registration Information by Type of Pesticide <a href="https://epa.gov/pesticide-registration/registration-information-type-pesticide">https://epa.gov/pesticide-registration/registration-information-type-pesticide></a>

- Antimicrobial Registration <a href="https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration">https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration</a>
- Biopesticide Registration <a href="https://epa.gov/pesticide-registration/biopesticide-registration">https://epa.gov/pesticide-registration/biopesticide-registration</a>
- $Conventional \ Registration \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration|| \verb|-https://epa.gov/pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration/conventional-pesticide-registration-pesticide-registra$
- Inert Ingredient Regulation <a href="https://epa.gov/pesticide-registration/inert-ingredients-regulation">https://epa.gov/pesticide-registration/inert-ingredients-regulation</a>

Requirements and Guidance <a href="https://epa.gov/pesticide-registration/registration-requirements-and-guidance">https://epa.gov/pesticide-registration/registration-requirements-and-guidance</a>

- Data <a href="https://epa.gov/pesticide-registration/data-requirements-pesticide-registration">https://epa.gov/pesticide-registration/data-requirements-pesticide-registration</a>
- Forms <a href="Forms">- Forms</a> <a href="Forms">- Form
- Labeling <a href="https://epa.gov/pesticide-registration/labeling-requirements">https://epa.gov/pesticide-registration/labeling-requirements</a>

Contact Us <a href="https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration">https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration</a> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON MARCH 1, 2023



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<a href="https://epa.gov/accessibility/epa-accessibility-statement">https://epa-accessibility-statement</a>

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<a href="https://epa.gov/web-policies-and-procedures/epa-disclaimers">https://epa.gov/web-policies-and-procedures/epa-disclaimers</a>

### Contracting

<a href="https://epa.gov/contracts">https://epa.gov/contracts</a>

### EPA www Web Snapshot

<a href="https://epa.gov/utilities">https://epa.gov/utilities</a> /wwwepagov-snapshots>

**Grants** <a href="https://epa.gov/grants">https://epa.gov/grants</a>

### **No FEAR Act Data**

<a href="https://epa.gov">https://epa.gov</a>
/ocr/whistleblowerprotections-epa-and-how-theyrelate-non-disclosureagreements-signed-epa>

### **Plain Writing**

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### **Pesticides**

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# Pesticide Devices: A Guide for Consumers

This guide for consumers explains key facts about pesticidal devices (called devices in this document) and how they differ from registered pesticide products. Device producers and those seeking more information may also wish to consult the Pesticide Registration Manual - Chapter 13 - Devices <a href="https://epa.gov/pesticide-registration/pesticide-registration-">https://epa.gov/pesticide-registration/pesticide-registration-</a>

### On this page:

• What is a Device?

manual-chapter-13-devices>.

- The differences between pesticide devices and pesticide products and how they are regulated
- Products commonly mistaken as devices
- Recognizing a device by reading the label
- Understanding what EPA has reviewed on a device label and advertising
- Related information
- Examples of regulated pesticide devices
- Additional device information

## Additional Information

COVID-19
 Compliance
 Advisory for UV
 Light Devices
 <a href="https://epa.gov">https://epa.gov</a>

/compliance /compliance-advisoryepa-regulations-aboutuv-lights-claim-kill-or-

be-effective-against>

State regulation of devices

## What is a Device?

Devices are instruments or contrivances intended to control pests, often through physical or mechanical means like filtration, UV light, or electricity. According to FIFRA, a device is:

> "any instrument or contrivance (other than a firearm) [that] is intended for trapping, destroying, repelling, or mitigating any pest . . . "

This definition excludes equipment used for applying pesticides when sold separately from the pesticides themselves. Generally, a device is not considered a pesticide when the pesticidal substance and the device are sold separately. Pesticides are substances or mixtures of substances that are intended to prevent, destroy, repel, or mitigate pests, such as insecticides, fungicides, rodenticides, antimicrobials (e.g., disinfectants),

- EPA Letter on
   Generic Efficacy
   Claims for UV
   Lights
   <a href="https://epa.gov">https://epa.gov</a>
   /safepestcontrol/epaletter-nationalelectricalmanufacturers-association-genericefficacy-claims-uv>
- Office of Research and Development COVID-19 Webinar on UVC Lights
   <a href="https://epa.gov">https://epa.gov</a>
   /emergency-response-research/covid-19-uv-c-devices-and-methods-surface-disinfection-webinar>

herbicides, and many pest repellents and attractants. (Pesticides can also be plant regulators or nitrogen stabilizers.) Application equipment is an article used for the application of pesticides. Such equipment may be part of a pesticide product if sold or distributed with a pesticide. For Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) <a href="https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act">https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act</a> and regulatory definitions, see FIFRA §§ 2(h), 2(u), 40 C.F.R. § 152.3 <a href="https://www.ecfr.gov/current/title-40/chapter-i/subchapter-e/part-152/subpart-a/section-152.3">https://www.ecfr.gov/current/title-40/chapter-i/subchapter-e/part-152/subpart-a/section-152.3</a> ("pesticide product"), and 41 Fed. Reg. 51,065 (Nov. 19, 1976) <a href="https://archives.federalregister.gov/issue\_slice/1976/11">https://archives.federalregister.gov/issue\_slice/1976/11</a> /19/51061-51067.pdf>.

Under FIFRA, EPA regulates both pesticides and devices. How a particular product is regulated depends on whether it is a pesticide or a device; the product's specific claims,

intended use, design, and function; and whether the product is used or sold/distributed with a pesticide or a precursor substance.

# The Differences Between How Devices and Pesticides Work and How They Are Regulated

To better understand the key differences between devices, pesticides, and application equipment, below is a general discussion of how each type of product is regulated.

### **Pesticides and Pesticide Products**

*Key Feature:* A substance or mixture of substances that is intended to destroy, repel, prevent, or mitigate a pest.

*Examples:* Insecticides, fungicides, rodenticides, antimicrobials (e.g., disinfectants), herbicides, and many pest repellants and attractants (e.g., substances that attract pests to lessen their impact, such as by attracting pests to a trap).

• For more information on the types of products that may be pesticides, please see Types of Pesticide Ingredients <a href="https://epa.gov/ingredients-used-pesticide-products/types-pesticide-ingredients">https://epa.gov/ingredients-used-pesticide-products/types-pesticide-ingredients</a>.

How EPA Regulates: "Registration" (FIFRA § 3)—a premarket review of the product.

It is generally unlawful to sell or distribute a pesticide that is not registered by EPA.
 Therefore, most pesticide products must be registered by EPA unless they qualify for an exemption (see, e.g., 40 C.F.R. § 152.25 <a href="https://www.ecfr.gov/current/title-40/chapter-i/subchapter-e/part-152/subpart-b/section-152.25">https://www.ecfr.gov/current/title-40/chapter-i/subchapter-e/part-152/subpart-b/section-152.25</a>). Please see the Pesticide Registration Manual <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual">https://epa.gov/pesticide-registration/pesticide-registration-manual</a> for more information.

### **Devices**

*Key Feature:* an instrument or contrivance, generally working by physical means (e.g., electricity, light, or other mechanical or physical means) and not containing a

substance or mixture of substances, that is intended to trap, destroy, repel, or mitigate a pest.

*Examples:* UV lights, water and air filters not treated with a pesticidal substance, ultrasonic devices, replacement parts (e.g., bulbs) for devices that are themselves intended for pesticidal purposes.

Pesticides v. Devices: Some products commonly mistaken for devices that are actually pesticides include:

- Pesticide products in liquid, dust, or coating form are generally pesticides and not devices because they are not an "instrument or contrivance."
  - o For pesticidal coating products, EPA considers cleaning as physically removing dirt and organic matter from surfaces primarily using soap or detergents. While most cleaning products do not need to be registered with EPA, registration is required for any cleaning product that claims to kill viruses or bacteria that cause human illness. Additionally, products that are impregnated with ingredients that claim to be "self-cleaning" are generally not exempt from EPA regulation.
- Pesticide products for controlling microorganisms that generate metal ions
   <a href="https://epa.gov/pesticide-registration/pesticide-registration-clarification-ion-generating-equipment">https://epa.gov/pesticide-registration/pesticide-registration-clarification-ion-generating-equipment</a>, such as silver, are generally pesticides and not devices because they contain a pesticidal substance.
- An apparatus sold with a substance (e.g., salt) that is used to generate a pesticide are generally pesticides, not devices.

Pesticidal Devices v. Medical Devices: The Food and Drug Administration (FDA)

<a href="https://www.fda.gov/"><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href="https://www.fda.gov/">https://www.fda.gov/</a><a href=

How EPA Regulates: "Misbranding" (FIFRA § 2(q), 40 C.F.R. pt. 156), which generally means that the label or labeling is deficient in some way.

• For products regulated as devices, there is no required premarket review. Unlike pesticides, FIFRA does not require registration of devices. However, EPA does still regulate these products with some limited exceptions including devices that depend more upon the performance of the user than the performance of the device itself to be effective (such as flyswatters); and devices that trap vertebrate animals (such as mouse snap traps, raccoon cages, and bear traps).

# Products Commonly Mistaken as Devices

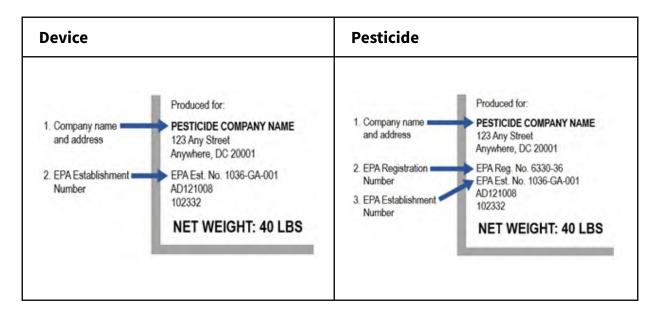
**Combination products:** Where a product that would otherwise be a device also incorporates a pesticidal substance, it may be considered a pesticide product. For example, a filter that physically traps microbial pests (generally a device) would be an antimicrobial pesticide product if it also incorporated a pesticidal substance that kills those pests to improve the efficacy of the entire system.

**Firearms:** FIFRA excludes firearms from the device definition. For example, a rifle used to control feral hogs is not a device. The U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) <a href="https://www.atf.gov/">https://www.atf.gov/</a> (not EPA) regulates firearms.

Pesticide Application Equipment: Equipment used to apply a pesticide is often sold separately from or packaged with a pesticide. Such equipment serves as a delivery mechanism for the pesticide. Application equipment is not a device. Application equipment that is sold or distributed with the pesticide is generally registered along with the pesticide as part of the pesticide product, per 40 C.F.R. § 152.3 <a href="https://www.ecfr.gov/current/title-40/chapter-i/subchapter-e/part-152/subpart-a/section-152.3">https://www.ecfr.gov/current/title-40/chapter-i/subchapter-e/part-152/subpart-a/section-152.3</a>. For example, a sprayer for a lawn herbicide that is sold with a registered herbicide (e.g., a full-size container, a sample) must be included in the herbicide registration. Pesticide application equipment that is sold and distributed separately from the pesticide itself is neither a device nor part of a pesticide product. For example, if the same sprayer for a lawn herbicide were sold and distributed separately from the registered herbicide, it would not be regulated by EPA.

# Recognizing a Device by Reading the Label

Establishment Number on the label (associated with the location where the device is produced). It will not include an EPA Registration Number, which would only be found on registered pesticide products. Registered pesticide products will include an EPA Establishment Number and an EPA Registration Number. Pesticide products undergo a thorough review of data supporting the registration, including product performance (efficacy) studies.



## Understanding What EPA Has Reviewed on a Device Label and Advertising

As noted above, FIFRA does not require devices to undergo premarket review and registration before being sold and distributed, as it does for pesticides. Generally, device manufacturers, sellers, and distributors do not submit their claims or efficacy and safety data to EPA (for approval or otherwise) before selling or distributing a device.

However, EPA does regulate devices and may find that some devices are misbranded

(FIFRA § 2(q), 40 C.F.R. pt. 156) upon review at import or in the marketplace. Misbranding issues with device labels and labeling may include:

- Missing Establishment Number: Devices must be produced in an EPA-registered establishment and the final establishment number must be visible on the outer packaging of the device. An EPA establishment number on device packaging does
   NOT indicate that the product has been reviewed for safety or efficacy by EPA, nor does it imply EPA product approval, registration, certification, or endorsement.
- Missing Directions for Use: Devices must include directions for use, allowing the user to properly operate the product.
- False or Misleading Claims: Devices may not include "false or misleading claims" on their labels or labeling. A claim about the effectiveness or safety of devices that cannot be supported by the company's scientific data could be an example of a false or misleading claim. Device manufacturers, sellers, and/or distributors are responsible for maintaining records and data to support their claims.

Consumers can report a device that appears misbranded on EPA's website for all environmental violations <a href="https://echo.epa.gov/report-environmental-violations">https://echo.epa.gov/report-environmental-violations</a>.

## **Related Information**

EPA recommends that consumers use devices consistent with any precautionary language and directions for use. In addition, EPA recommends that consumers should contact the manufacturer or seller of the device directly with any questions regarding the proper use of the product

## **Examples of Regulated Devices**

**Devices EPA Regulates with Examples of Uses** 

Devices EPA Regulates with Examples of Uses	
	Claim to kill, inactivate, or suppress growth of microorganisms such as fungi, bacteria or viruses. They may also be used to attract insects or kill plant pathogens (e.g., powdery mildew on strawberries).
Ultraviolet Light Units	Water and air treatment units
	Antimicrobial lamps
	Individual water purification devices
	See: Additional Device Information below

### **Devices EPA Regulates with Examples of Uses**

Claim to reduce microorganisms, unqualified organic contaminants, unqualified allergens or purify the air. These products may filter the air, generate substances, or both.

- Air filters that make pesticidal claims (see additional information below)
- UV lights (see additional information below)
- Air purifiers
- Ozone generators
- Plasma generators
- Bipolar ionization generators (see additional information below)
- Photocatalytic air treatment device (see additional information below)

## Air Purifiers, Filters or Air Treatment Devices

Combinations of the types of products in this category

Products that create ions from the air are generally regulated as devices, unless they contain or are sold with a pesticidal substance or have a pesticidal coating or film causing the pesticidal effect.

Air treatment products that do not claim to purify the air or kill pests are regulated by the U.S. Consumer Product Safety Commission

<a href="https://www.cpsc.gov/>">https://www.cpsc.gov/>">.

Note: HEPA filters that limit claims to particle size and do not claim to purify the air or mitigate microorganisms are generally not regulated under FIFRA.

Devices EPA Regulates with Examples of Uses	
See: Additional Device Information below	

### **Devices EPA Regulates with Examples of Uses**

Claim to kill, inactivate, or suppress growth of microorganisms, including fungi, algae, bacteria, or viruses.

Generally, EPA considers these generators to be devices.

However, if the generator is sold or distributed (e.g., transported to another location for use) with a substance (e.g., salt) or the output solutions, the generator may be part of a pesticide product.

Hypochlorous Acid Generators (includeing electrolyzed water) On September 14, 2022, EPA issued an exemption for residues <a href="https://www.federalregister.gov/documents/2022/09/14/2022-19799/hypochlorous-acid-exemption-from-the-requirement-of-a-tolerance">https://www.federalregister.gov/documents/2022/09/14/2022-19799/hypochlorous-acid-exemption-from-the-requirement-of-a-tolerance</a> of the antimicrobial pesticide ingredient hypochlorous acid from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places.

Note: Electrolyzed water is another name for hypochlorous acid <a href="https://www.regulations.gov/docket/epa-hq-opp-2020-0244/document">https://www.regulations.gov/docket/epa-hq-opp-2020-0244/document</a>. As EPA has assessed hypochlorous acid and determined the potential for adverse effects, EPA recommends that electrolyzed water generated by these devices not be ingested or applied to the human body <a href="https://epa.gov/coronavirus/can-disinfectant-products-be-used-people">https://epa.gov/coronavirus/can-disinfectant-products-be-used-people</a>.

See: Additional Device Information below.

### **Devices EPA Regulates with Examples of Uses**

Claim to kill, inactivate, or suppress growth of fungi, algae, bacteria, viruses, or cysts.

- Certain drinking water filter units. The filter in such a unit removes microbial pests by physical or mechanical means. However, if the unit contains any substance intended to disinfect the water, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed.
- Certain pool and spa electrolysis units. Such units also must not be sold or distributed with or contain a pesticidal substance intended to disinfect the water, unless registered.
- Ozonation units (gaseous or aqueous)
- Ozone bubble generation technology
- Algal bloom treatment units must not be sold/distributed with a substance unless registered.

Note: Water filters that limit claims to taste, odor, or sediment and do not claim to purify water or mitigate microorganisms are generally not considered pesticidal devices and thus are not regulated under FIFRA.

### Water Purifiers or Water Treatment Units

	Claim to kill or entrap insects and similar pests
	through physical means, which can include UV
	light or ozone.
	Black-light traps
	<ul> <li>Bug zappers, including hand-held or racquet-</li> </ul>
Insect Devices	type bug zappers
	<ul><li>Insect traps</li></ul>
	<ul> <li>Fly ribbons/fly paper/sticky traps (without an</li> </ul>
	attractant)
	<ul><li>Glue boards (without an attractant)</li></ul>
	Electric flea combs
	Claim to control subterranean animals via carbor
	monoxide generation or subterranean explosion
Gopher and Rodent	when sold or distributed without a substance. If
Control Systems	sold with a substance, registration is required.
	<ul> <li>Carbon monoxide generators</li> </ul>
	<ul> <li>Subterranean explosive devices</li> </ul>

Devices EPA Regulates with Examples of Uses	
	Claim to repel pests such as birds, mice, and underground animals.
	<ul> <li>Carbide cannons: a device that emits a loud boom or blast at around 125 decibels</li> </ul>
	<ul> <li>Rotating devices: devices with rotating arms</li> </ul>
	<ul> <li>High frequency (ultrasonic) sound generators</li> </ul>
Sound, Airwave, and	<ul> <li>Mole thumpers</li> </ul>
<b>Vibration Generators</b>	<ul> <li>Pinwheel vibrators</li> </ul>
	<ul> <li>Non-lethal bear (or other pest) sound-based deterrents (not regulated by the ATF as a firearm)</li> </ul>
Gamma Irradiation Units	Claim to treat insects, mold, and other microorganisms on raw agricultural commodities and other inanimate objects. These are regulated under FIFRA unless they are otherwise exempt.

## **Additional Device Information**

**UV lights and filters:** UV lights or certain filters that make pesticidal claims are examples of EPA-regulated devices, provided that they do not contain or are not sold with a substance intended to elicit the pesticidal effect. Examples of pesticidal substances could include silver, zinc or copper. See EPA's Compliance Advisory on UV Lights <a href="https://epa.gov/compliance/compliance-advisory-epa-regulations-about-uv-lights-claim-kill-or-be-effective-against">https://epa.gov/compliance/compliance-advisory-epa-regulations-about-uv-lights-claim-kill-or-be-effective-against</a> and EPA's webpage on Consumer Products Treated with Pesticides <a href="https://epa.gov/safepestcontrol/consumer-products-treated-pesticides">https://epa.gov/safepestcontrol/consumer-products-treated-pesticides</a>. See EPA's research on UV lights <a href="https://epa.gov/emergency-response-research/covid-19-uv-c-devices-and-methods-surface-">https://epa.gov/emergency-response-research/covid-19-uv-c-devices-and-methods-surface-</a>

disinfection-webinar>.

**Devices that generate a substance:** Generally, products that generate a substance (through physical means), such as ozone or hypochlorous acid/electrolyzed water generators, are considered devices and do not require EPA registration unless they are sold with or contain a substance. However, if a company provides a service using a device that contains a substance (e.g., hypochlorous acid generator used as part of a sanitization service), this may be considered sale or distribution of a pesticide. Consumers should ask companies who are applying a pesticidal solution generated onsite for the product's EPA registration number.

**Note:** An unregistered output solution generated by a device that is a pesticide cannot be sold or distributed without violating FIFRA. An example of distribution would include providing the output substance from the device (with or without payment) to a neighbor or friend.

• **Photocatalytic Products:** At this time, photocatalytic air and surface treatment products that use materials with photocatalytic properties (e.g., titanium dioxide) to generate reactive oxygen species may be pesticides.

**Note:** EPA has previously determined that photocatalytic products in liquid, dust, or coating form are pesticides, not devices, because these products contain a substance and are not an instrument or contrivance. These products would likely require a FIFRA Section 3 registration as a pesticide. Please see the Pesticide Registration Manual <a href="https://epa.gov/pesticide-registration/pesticide-registration-manual">https://epa.gov/pesticide-registration/pesticide-registration-manual</a> for more information on pesticide registration.

Bipolar Ionization Devices: Bipolar ionization (also called needlepoint bipolar ionization) is a technology that can be used in heating, ventilation, and air conditioning (HVAC) systems or portable air purifiers to generate positively and negatively charged particles. These products may be considered devices unless there is a pesticidal substance integral to the product's performance sold with and used in the ion generation process.

Bipolar ionization has the potential to generate ozone and other potentially harmful by-products indoors unless specific precautions are taken in the product design and maintenance. To avoid such byproducts from use of bipolar ionization

devices, EPA recommends using a device that meets UL 2998 standard certification (Environmental Claim Validation Procedure (ECVP) for Zero Ozone Emissions from Air Cleaners). Please see additional information on Bipolar ionization and COVID-19 <a href="https://epa.gov/coronavirus/can-air-cleaning-devices-use-bipolar-ionization-including-portable-air-cleaners-and">https://epa.gov/coronavirus/can-air-cleaning-devices-use-bipolar-ionization-including-portable-air-cleaners-and</a>.

**Electromagnetic and/or Electrical Devices:** Products claiming to control pests via electromagnetic and/or electrical means (e.g., ultrasonic insect and rodent repellers, hand-held bug zappers, electric flea combs) are devices, provided that that the product is not sold with a pesticidal substance.

Ozone-generating and certain UV light devices may generate unintentional ozone. Claims that ozone generating devices are safe and effective for controlling indoor air pollution—and the potential threat to human health from high concentrations of ozone—prompted EPA and other federal agencies to publicly address the use of such devices. Please see additional information on Ozone Generators that are Sold as Air Cleaners <a href="https://epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners">https://epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners</a>.

## **State Regulation of Devices**

Some states have regulatory requirements for devices in addition to those imposed by FIFRA. Some states require registration of devices, including submission and review of efficacy data and labeling before a device can be sold or distributed in that state. Therefore, compliance with EPA's FIFRA requirements does not ensure that a device can be legally sold in those states. See the American Association of Pest Control Officials (AAPCO) <a href="https://aapco.org/2015/07/28/resources-2/">https://aapco.org/2015/07/28/resources-2/</a> website for a list of state lead agencies.

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International Activities Related to Pesticides <a href="https://epa.gov/pesticides/international-">https://epa.gov/pesticides/international-</a> activities-related-pesticides>

Pest Control and Pesticide Safety for Consumers <a href="https://epa.gov/safepestcontrol">https://epa.gov/safepestcontrol</a>

Pesticide Registration <a href="https://epa.gov/pesticide-registration">https://epa.gov/pesticide-registration</a>

Contact Us <a href="https://epa.gov/pesticides/forms/contact-us-about-pesticides">https://epa.gov/pesticides/forms/contact-us-about-pesticides> to ask a question,</a> provide feedback, or report a problem.

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