

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

Received by
EPA Region VIII
Hearing Clerk

IN THE MATTER OF:)	
Berkey International LLC)	Docket No. FIFRA-08-2023-0038
Royal Industrial Park, B-2)	FIFRA SECTION 13(a)
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).”

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;

(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): Bacillus 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, <https://www.berkeyfilters.com/products/black-berkey-filter>:
- 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 H2O 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, <https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html>:

“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 tokarz.christine@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.
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. OTHER MATTERS

- 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.

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY REGION 8**

Date: _____

By: _____

David Cobb, Section Supervisor
Toxics and Pesticides Enforcement Section
Enforcement and Compliance Assurance Division