

**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.

I. TABLE OF CONTENTS

I. TABLE OF CONTENTS 2

II. TABLE OF AUTHORITIES 3

III. PARTIES..... 3

IV. VENUE AND JURISDICTION 5

V. CONDITIONS PRECEDENT 6

VI. FACTS 6

 A. History of Water Filters..... 6

 B. Background – Berkey is a famous American brand known for its quality water filters created and sold by Plaintiff, protected by patents and trademarks..... 8

 C. Regulatory Background - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 10

 D. After ignoring Berkey filters for decades, the EPA suddenly reinterpreted its prior rules without notice or opportunity to hear stakeholder input, to Plaintiff’s detriment..... 14

 E. The EPA changed course and began issuing SSUROs for pesticides..... 16

VII. AUTHORITIES 25

 A. General 25

 B. Administrative Procedures Act (5 U.S.C. 553)..... 25

 C. FIFRA (7 U.S.C. chap. 6 § 135–136y)..... 25

VIII. CAUSES OF ACTION 27

 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..... 27

 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. 32

 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. 33

 D. Count 4: Plaintiff seeks declaratory judgment and damages for the EPA’s violations... 35

 i. The EPA arbitrarily and capriciously designated Plaintiffs’ filters as pesticides... 35

 ii. The EPA exceeded its authority with a rule that does not comport with FIFRA. .. 36

 E. Count 5: Procedural Due Process claim against the EPA for its violation of Plaintiff’s APA rights notice and comment rights and 5th Amendment Procedural Due Process. . 38

 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. 39

 ii. The EPA violated Plaintiff’s procedural due process rights arbitrarily and capriciously, and while abusing its discretion, when issuing SSURO’s alleging Berkey Products were pesticides that must be registered without proper notice and comment based on foreign non-pesticidal claim statements..... 40

IX. APPLICATION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION..... 42

X. PRAYER 43

II. TABLE OF AUTHORITIES

CASES

Action on Smoking & Health v. C.A.B., 699 F.2d 1209, (D.C. Cir.), supplemented, 713 F.2d 795 (D.C. Cir. 1983)..... 30

Anderson v. McCarthy, No. C 16-00068 WHA, 2016 U.S. Dist. LEXIS 63671 (N.D. Cal. 2016) 27

Ass’n of Priv. Sector Colls. & Univs. v. Duncan, 681 F.3d 427, 63 (D.C. Cir. 2012)..... 32

Christopher v. SmithKline Beecham Corp., 567 U.S. 142, (2012)..... 7

Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, (1971) 5

CSX Transp., Inc. v. Surface Transp. Bd., 584 F.3d 1076, (D.C. Cir. 2009)..... 29, 32

Dep’t of Commerce v. New York, 139 S. (2019) 5

Environmental Defense Fund, Inc. v. Costle, 657 F.2d 275, 285 (D.C. Cir. 1981)..... 27

FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253, 254–55 (2012)..... 34

FCC v. Fox TV Stations, Inc., 556 U.S. 502, 515–16 (2009) 37

Hanly v. Mitchell, 460 F.2d 640, 648 (2d Cir. 1972)..... 31

Huawei Techs. USA, Inc. v. FCC, 2 F.4th 421, 447 (5th Cir. 2021)..... 29

Kollett v. Harris, 619 F.2d 134, 140 n.5 (1st Cir. 1980)..... 31

Larson v. Domestic & Foreign Com. Corp., 337 U.S. 682, (1949)..... 6

Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158, 174 (2007)..... 29

Mathews v. Eldridge, 424 U.S. 319, 333 (1976)..... 41

Medics, Inc. v. Sullivan, 766 F. Supp. 47, 53-55 (D.P.R. 1991)..... 29, 33

Mid Continent Nail Corp. v. United States, 846 F.3d 1364, 1376 (Fed. Cir. 2017) 28, 31

Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) 30

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)..... 29

Perez v. Mortg. Bankers Ass’n, 575 U.S. 92, 96 (2015)..... 30, 34

Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 414 (1971) 36

Sessions v. Dimaya, 138 S. Ct. 1204, 1212 (2018)..... 34

Sierra Club v. Marsh, 976 F.2d 763, 773 (1st Cir. 1992)..... 27

Torch Operating Co. v. Babbitt, 172 F. Supp. 2d 113 (D.D.C. 2001)..... 26

United States v. Councilman, 418 F.3d 67, 84 (1st Cir. 2005) 34

United States v. Davis, 139 S. Ct. 2319, 2325 (2019) 34

United States v. Hussein, 351 F.3d 9, 14-16 (1st Cir. 2003) 34

United States v. Irizarry, 98 F. Supp. 2d 160, 164 (D.P.R. 2000)..... 31

Victim Rights Law Ctr. v. Cardona, 552 F. Supp. 3d 104, 134 (D. Mass. 2021) 32, 39, 40, 41

Wooden v. United States, 595 U.S. 360, 142 S. Ct. 1063, 1085-86 (2022) 35

STATUTES

21 U.S.C. § 321..... 26

21 U.S.C. § 321(w) 26

21 U.S.C. § 321(x) 26

28 U.S.C. § 1331..... 5

28 U.S.C. § 1338(a) 5

28 U.S.C. § 1391(b) 6

28 U.S.C. § 2201 6, 43

28 U.S.C. § 2202..... 6, 43
 28 U.S.C. § 2412..... 6
 40 C.F.R. § 152..... 37, 38
 40 C.F.R. § 152.25..... 27
 5 U.S.C. § 553..... 5, 25, 28, 29
 5 U.S.C. § 701..... 5, 37
 5 U.S.C. § 702..... 5
 5 U.S.C. § 703..... 5
 5 U.S.C. § 704..... 5, 35, 37, 39
 5 U.S.C. § 705..... 5, 6, 37, 39
 5 U.S.C. § 706..... 5, 6, 28, 32, 33, 37, 39
 5 U.S.C. § 706(2)(A)–(B)..... 5
 7 U.S.C. § 135..... 26
 7 U.S.C. § 135e..... 11
 7 U.S.C. § 135j(a)..... 11
 7 U.S.C. § 136..... 11, 26, 33, 34, 35, 38, 44
 7 U.S.C. § 136(u)..... 18
 7 U.S.C. § 136e(a)..... 15
 7 U.S.C. § 136j(a)(1)(F)..... 14
 7 U.S.C. § 136j(a)(2)(L)..... 15
 7 U.S.C. § 136n..... 6
 7 U.S.C. § 136h..... 26
 7 U.S.C. § 136y..... 26

OTHER AUTHORITIES

41 Fed. Reg. 51065 (Nov. 19, 1976)..... 12
 E.O. 12866..... 14
 E.O. 12988..... 14
 E.O. 13563..... 14
 Comm. Rep. on Fed. Pesticide Act of 1978 (Comm. Pr. 1979)..... 38
 Remedial Restraint in Administrative Law, 117 COLUM. L. REV. 253, 275 (2017)..... 27

RULES

Fed. R. Civ. P. 65(a)..... 43
 Fed. R. Civ. P. 65(b)..... 43
 Fed. R. Civ. Pro. 57..... 6

CONSTITUTIONAL PROVISIONS

U.S. Const. amend. IX..... 42
 U.S. Const. amend. V..... 25, 28, 34, 39
 U.S. Const. amend. X..... 42

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.”¹

¹ 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.²

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.

² 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,³ 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

³ 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).⁴

33. The same website also explains 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).

34. Berkey filters were not considered a *pesticide* until 2022, but rather *pesticide devices*, because *they do not use a pesticidal substance* to kill waterborne pests in the effluent water, nor utilize a pesticide to improve the efficacy of the entire system. Instead, they trap microbiological

⁴ <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.⁵ 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.

⁵ 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 111th 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 letter⁶ 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.⁸ 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

⁶ 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.

⁷ 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.

⁸ “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 https://usepa.servicenowservices.com/ecss?id=kb_article_view&sysparm_article=KB0013400, last viewed 11/24/2023).

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.⁹ 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).

⁹ "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." (<https://www.epa.gov/compliance/pesticide-establishment-registration-and-reporting>. 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): *Bacillus atrophaeus* (Anthrax Surrogate).” Exh. B-4.

56. 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. Berkey 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**

Black¹⁰ 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.¹¹ 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

¹⁰ 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.

¹¹ 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.

62. 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.

66. 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-12.¹²

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.

¹² 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.” <https://allongeorgia.com/georgia-public-safety/epa-orders-amazon-and-ebay-to-stop-sale-of-certain-pesticide-products/> (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.

74. 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.

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

¹³ 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 5th Amendment. Lastly, the Rule of Lenity should prevent enforcement of an ever-changing 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

¹⁴ 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 (1st 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 intended 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 5th 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 9th and 10th 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 18th 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.

153. Additionally, the Tenth Amendment should guide the Court, as every state can regulate water filters if it wishes, and no federal law is necessary for such regulation. As regulation of non-

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 5th 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 Plain 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 <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
- 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