

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS - FORT WORTH DIVISION

JAMES SHEPHERD,
Trustee for the James B. Shepherd Trust, and
NEW MILLENNIUM CONCEPTS, LTD.,
Plaintiffs,

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CIVIL CAUSE NO.
4:23-cv-826

v.

ENVIRONMENTAL PROTECTION AGENCY,
MICHAEL S. REGAN, Administrator, CHRISTINE
TOKARZ, DAVID COBB, CAROL KEMKER, and
KERIEMA NEWMAN, in their personal capacities
Defendants.

JURY TRIAL DEMANDED

PLAINTIFFS’ ORIGINAL COMPLAINT,
APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY
INJUNCTION AGAINST THE ENVIRONMENTAL PROTECTION AGENCY

Plaintiffs James Shepherd and New Millennium Concepts, Ltd. come now to file suit against the Environmental Protection Agency for its violations of the Administrative Procedures Act and due process involving Berkey water filters.

To summarize, the public has relied on Berkey water filters without incident or regulation by the EPA for 25 years. The EPA only this year decided that its 2007 rule requiring registration of electric ion-generating devices requires registration of Berkey’s gravity-fed non-electric filters. The EPA changed directions only in 2022, when without notice, it demanded Plaintiffs register their mechanical filter products as a “pesticide device” and then recently as a “pesticide” without authority and without complying with the EPA’s rule-making process.

The EPA’s failure to operate using plain language and follow EPA guidelines has caused Plaintiffs devastating damage. Plaintiffs seek to enjoin the EPA from enforcing pesticide registration requirements against Plaintiffs’ filter systems, and a declaration that the classification of Berkey filters as a pesticide is arbitrary, capricious, and an abuse of discretion.

I. PARTIES

1. Plaintiff James “Jim” Shepherd is the trustee of the James B. Shepherd trust (“JBS Trust”), a Texas Trust, the beneficiaries of which own equitable title to the majority partnership interest in New Millennium Concepts, Ltd. (“NMCL”) and hold legal title to intellectual property licensed to NMCL and which issues licenses to other entities to manufacture and sell Berkey water filtration products. Parties may serve Shepherd through the undersigned counsel.
2. Plaintiff New Millennium Concepts, Ltd. (“NMCL”) is a Texas-registered limited partnership. NMCL’s primary place of business has been in Bedford, Texas, though it is currently relocating to Arlington, Texas (both are in the Northern District of Texas). Parties may serve NMCL through its attorney of record, the undersigned. NMCL contracts with other entities to sell Berkey-branded water filter systems based on intellectual property licensed to it by the JBS Trust.
3. 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.
4. 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.
5. Defendants Christine Tokarz, David Cobb, Carol Kemker, and Keriema Newman are all EPA personnel sued personally 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).

II. VENUE AND JURISDICTION

6. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), which provides jurisdiction based on federal questions.

7. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the Administrative Procedures Act, 5 U.S.C. §§ 553, 701–06. 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, 159 Oil & Gas Rep. 896, 2001 U.S. Dist. LEXIS 18417 (D.D.C. 2001).

8. The Administrative Procedure Act (“APA”) gives courts 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.” 5 U.S.C. § 706(2)(A)–(B). Indeed, the APA creates a “basic presumption of judicial review.” *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2567 (2019).

9. This Court has jurisdiction to grant preliminary relief pursuant to the APA. 5 U.S.C. § 705 (“[T]he reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.”).

10. This Court has jurisdiction to grant declaratory relief, pursuant to 28 U.S.C. § 2201, and additional relief pursuant to 28 U.S.C. § 2202.

11. 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.

12. This Court has jurisdiction to issue equitable relief to enjoin ultra vires agency action. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

13. This case seeks declaratory relief, injunctive relief, damages, and other appropriate relief under 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.

14. Plaintiff seeks attorney fees under the Equal Access to Justice Act, 28 USC § 2412.

15. Venue is proper in the Northern District of Texas 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 Plaintiffs have been damaged in this district.

16. Plaintiffs have standing under the right of review provided in the APA at 5 U.S.C.S. § 702, 7 U.S.C. Ch. 6 §136n(b), and “basic presumption of judicial review [for] one ‘suffering legal wrong because of agency action.’” *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020).

17. Plaintiffs here complain of unnoticed change of water filter regulation by the EPA and seek review in federal district court to obtain redress, as approved by the Supreme Court in *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 142 (2012) (“Agencies should provide regulated parties fair warning of the conduct a regulation prohibits or requires. Indeed, it would result in precisely the kind of ‘unfair surprise’ against which the Supreme Court’s cases have long warned.”)

III. CONDITIONS PRECEDENT

18. 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.

IV. FACTS

A. History of Water Filters.

19. 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

20. 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.

21. 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.

22. 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

23. 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.

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.

² Mays, Larry, A brief history of water filtration/sedimentation, *Water Science & Tech: Water Supply*, V.13.3, 2013.

24. 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.

25. 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.

26. Based on this history, Plaintiffs assert that residents of the colonies during the founding of the United States used gravity-fed mechanical water filters routinely. 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.

B. Background – Berkey is a famous American brand known for its quality water filters.

27. More than two decades ago, the JBS Trust licensed New Millennium Concepts, Ltd (“NMCL”) to commercialize its gravity-fed filter elements and began marketing filter systems under the Berkey trademark.

28. Berkey International, LLC is a Puerto Rico based manufacturer of Berkey filtration systems, which holds a license from the JBS Trust to manufacture Berkey filtration systems which include Berkey filter elements, the subject of the EPA's concerns. Exh. A.

29. New Millennium Concepts, Ltd (“NMCL”) has an exclusive license from the JBS Trust to market Berkey Water Filtration products. NMCL has its principal place of business in Arlington, TX. This complaint jointly refers to NMCL and Berkey Int’l as “Berkey.” Exh. A.

30. NMCL’s signature product is its Black Berkey Filters. Black Berkey filters employ proprietary, trade-secret technology in gravity-fed filters which employ microscopic pores to mechanically trap and eliminate contaminants from water. Berkey distributes its filters to authorized retailers. Exh. A.

31. NMCL is a longstanding American company that has been marketing proprietary Berkey water filters and other water-related products since 1998.

32. During NMCL’s 25-year existence, the EPA never sought to enforce FIFRA regulations against Berkey products until 2022. Exh. A. As explained more fully below, Congress created FIFRA to regulate agricultural products. Exhibit C-1. EPA guidelines specifically state that mechanical filter construction warrants regulation only as a device, and not a pesticide. Exh. C-4.

33. Unfortunately, numerous unauthorized retailers and knock-offs of Berkey’s products abound; all attempting to benefit from Berkey’s reputation for excellent, reliable products. Berkey struggles with knock-off filters because a knock-off competitor can build filter systems using mundane carbon filters constructed to fit into the Berkey filter system as a form-and-fit replacement, but not a “function” replacement, being made with different materials. The knock-off filters are designed to imitate the appearance of Black Berkey filters but utilize cheap and ineffective materials compared to the components of authentic Berkey filters. In this way, purveyors of knock-off and imitation 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 knock-off filters. Exh. A.

34. To Plaintiffs' knowledge, the EPA has not engaged in enforcement actions against any unauthorized sellers of Berkey knock-offs making or implying false function claims, but is singling out genuine products offered by Berkey, a longstanding American brand known for its quality and performance.

35. The EPA is applying its regulations and enforcement actions unevenly, focusing on Berkey while neglecting unauthorized knock-off and counterfeit manufacturers. The EPA's actions are destructive to Berkey and reward low-value knock-offs and counterfeit filters, as these low-quality filters do not perform as well and such products are typically made overseas by manufacturers who are very difficult to identify and thus can operate without fear of being sued in the United States.

36. The end result of the EPA's recent actions is to make the market less safe for American consumers. Exh. A.

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

37. 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 (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.

38. In 2000, the EPA adopted a "Treated Articles Exemption to Antimicrobial Pesticides" policy, announced by a 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.

39. On September 21, 2007, the EPA issued a Federal Register Notice that clarified the Agency's position on the distinction between devices and pesticides, specifically regarding ion-

generating equipment incorporating silver. The EPA's website described the new rule as "The Agency has now determined that these machines will be regulated as pesticides if the machines contain silver or other substances, and *if they generate ions of those substances for express pesticidal purposes.*" (italics added for emphasis).³ Exh. C-3.

40. The EPA's formal 2007 Federal Register Notice of Clarification included a notice to presumably warn those who would be responsible for following its dictates that included this verbiage: "You may be affected by this action if you sell or distribute ion-generating equipment that uses electrodes to emit chemical substances for pesticidal purposes." The Notice also explains in detail that water filters had been considered devices and not pesticides since 1976, and that at that time, ion-generating equipment was not known to the EPA.⁴ Exh. C-4.

41. The natural reading of the 2007 Notice was that the EPA was now regulating devices which employ a power source that creates a voltage between two incorporated electrodes to create ions deliberately for pesticidal purposes. The Notice explains its purpose:

In September 2005, Agency staff advised a manufacturer that washing machines utilizing silver electrodes to produce silver ions for the pesticidal purpose of killing germs are considered devices rather than pesticides, and do not require registration. However, the Agency has since determined that under the statutory interpretation set out in the 1976 policy statement, such ion-generating equipment would require registration as a pesticide under FIFRA. This notice provides additional clarification of the Agency's longstanding position, and gives the regulated community time to come into compliance with the requirements of FIFRA.

Exh. C-4. Thus, the 2007 Notice has no bearing on non-electrical water filters.

³ Pesticide Registration: Clarification for Ion Generating Equipment, Environmental Prot. Agency (Sept. 21, 2007), <https://www.epa.gov/pesticide-registration/pesticide-registration-clarification-ion-generating-equipment> (accessed July 26, 2023).

⁴ Pesticide Registration; Clarification for Ion-Generating Equipment, 72 Fed. Reg. 54039, 54040 (Sep. 21, 2007), <https://www.govinfo.gov/content/pkg/FR-2007-09-21/html/E7-18591.htm> (last accessed on July 26, 2023).

42. The EPA's Pesticide Registration Manual⁵ states:

"In general, if an article is an instrument or contrivance that uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 152.5, it is considered to be a device and subject to regulation under FIFRA. However, devices are not subject to the registration requirements that apply to pesticides and pesticide products under FIFRA section 3. Further information can be found on EPA's Pest Control Devices Webpage.

If a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3.

Exh. C-7.

43. Gravity-fed filtering is commonly available to the public from innumerable sources. Few filters are registered with the EPA even as devices. The EPA only in 2022 demanded that Berkey manufacturers register their establishments as required by FIFRA for pesticide devices. Exh. A.

44. The Administrative Procedures Act generally requires agencies to include information for interested parties on how to make comments, but makes an exception for interpretative rules, which the 2007 Notice claimed to be. 5 U.S.C. § 553(b). However, the Notice indicated only that it was directed to those manufacturing machines that have electrodes used by a device to generate ions, and does not suggest that makers of gravity-fed water filters which have no electrical component should expect the Notice to impact their operations. Exh. A, C-4.

45. If the 2007 Notice was merely an interpretative rule and thus bypassed the rule-making process of notice and consideration of stakeholders and their input, then it could not have substantively changed the duties of those governed. In 2007, the Notice impacted only electrical devices which used a power source to create ions; under the new interpretation, the EPA seems to be stating that any device that contains a metal is a pesticide that must be registered.

⁵ <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices> (maintained online, last revised March 1, 2023; last accessed July 29, 2023).

D. After ignoring Berkey filters for decades, the EPA suddenly reversed its prior rules without notice or opportunity to accept stakeholder input, to Plaintiffs' detriment.

46. Around April 28, 2022, the Environmental Protection Agency stopped an inbound NMCL container at customs to conduct an EPA inspection. To address the matter, NMCL's shipper, Charles Shayer, set up a call on for May 3, 2022, with Christine Tokarz, a Region 8 EPA inspector.

47. On May 1, 2022, 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.

48. 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 NMCL's 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.

49. On or about May 4, 2022, Shepherd learned that the EPA had begun requiring EPA establishment numbers for water filter manufacturers, including Berkey manufacturing facilities, and 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.

50. Around this same time, Shepherd learned from businesses contacts that the EPA may be targeting water filter manufacturers making virus removal claims and perhaps pathogenic bacteria removal claims, and reinterpreting their regulations, though neither he nor any of his manufacturers were aware of any formal change to the relevant law. Further, those same enforcement actions

indicated to Shepherd that the EPA may now consider outdoor water filters that can filter raw untreated water and remove waterborne pathogens to be pesticides, though the filters did not use electrodes to generate ions. Exh. A.

51. About May 5, 2022, Tokarz issued an EPA Close Out letter which stated, “Under FIFRA section 7, all pesticide devices sold or distributed in the United States must be produced in a registered establishment. 7 U.S.C. §§ 136e(a), 136j(a)(2)(L). A pesticide device is defined as any instrument or contrivance that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life” the EPA “Reinterpretation” of the rule. Exh. B-2 (Tokarz Close Out Letter), Exh. C-1.⁶ At no point has Tokarz explained why the EPA, which has been aware of Berkey products for 25 years, never required any sort of registration until 2022.

52. In May of 2022, to try to mollify Tokarz and the EPA, NMCL requested an EPA establishment number for Texado, Ltd., its third-party distribution center. The EPA issued Establishment No. 101921-CO-1 shortly thereafter and communicated that development to Tokarz in support of NMCL’s position that it was compliant with the new demand for Berkey filters to be treated as a pesticide device, as the establishment number was now being posted on the outside of the box for each Berkey filtration system that they manufactured. Tokarz denied that these actions satisfied FIFRA. About June 8, 2022, NMCL filed a 30-day report making NMCL compliant with the EPA’s requests pertaining to Pesticide Devices. Exhibit A, B-3 (Email Thread discussing NMCL 30-day Report, Texado Establishment Number).

53. After the EPA’s demands for pesticide device compliance, NMCL verified that all its claims were accurate according to the test data for removing waterborne pathogens. Exh. A.

⁶ 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.

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

54. James Enterprises sells Berkey products while doing business as Berkey Filters. During an EPA inspection of its facilities on November 22, 2022, the staff of James Enterprises noted that the EPA took note of language on products that suggested pesticide claims. EPA inspector Tokarz mentioned to the James Enterprises staff, “that NMCL mentions that their filters remove viruses and that the EPA is cracking down on virus claims because of COVID-19,” and “that the EPA had stepped up its enforcement efforts, particularly in regard to anti-microbial devices.” Because of the inspection, NMCL again checked all its virus removal claims and testing to verify that no misleading or fraudulent contaminant-removal claims were being made and found that all claims could be verified by third-party lab tests. Exh. A.

55. 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).

56. On or about December 27, 2022, 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 monthly afterward to Christine Tokarz. Exh. B-4. This was the first SSURO alleging that Berkey water filter systems were unregistered, misbranded pesticides. Exh. A.

57. This was an unfair surprise in which EPA did not provide any sort of explanation, notice, or guidance before issuing the order. Exh. A. The SSURO states 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.

58. To Plaintiffs’ knowledge, at no point has any Berkey-authorized entity claimed that the silver in their products is intended to be used for any purpose other than to protect the filter itself.

59. Though the SSURO to James Enterprises recognizes that the mention of silver is in the context of protecting the filter at para. 26, para. 27 concludes “These claims indicate that **Berkey Black⁷ 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).”

60. The conclusory statement does not mention what “substance or mixture of substances” in Berkey’s filter constitute pesticides. The drafter of the SSURO appears to latch onto the presence of silver and leap to the unwarranted definition of pesticide, ignoring the purpose of said silver. The statement in para. 26 explains the silver’s presence as it is explained on 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.

61. 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 “pesticide devices” and were not “pesticides,” making them exempt from registration. Exh. A.

⁷ The term “Berkey Black” is a name used by knock-off filter marketers to sell fake Black Berkey filters. Troublingly, “Berkey Black” was used a dozen times in the SSURO.

62. In mid-January of 2023, NMCL and James Enterprises agreed that, rather than arguing with the EPA whether Black Berkey products were a pesticide or pesticide device, Berkey products would change their status to that of a treated article and remove all testing references and statements that could be construed to indicate that the filters could remove waterborne pathogens. Exh. A. James Enterprises and NMCL thereafter changed their websites to remove all waterborne pathogen removal claims. Exh. A.

63. Undeterred by any communication with NMCL or affiliated businesses, Tokarz has continued to target Berkey sellers and issued multiple SSUROs, all of them based on allegations that Berkey products are unregistered, misbranded pesticides.

64. 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.

65. On March 3, 2023, David Cobb issued an SSURO, Docket Number: FIFRA-08-2023-0015, to Fritz Wellness, a Berkey dealer and required 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, misbranded pesticides. Exh. B-7. Again, the knock-off filter name “Berkey Black” was used in the SSURO. Exh. A, B-7.

66. On March 6, 2023, David Cobb issued an 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, misbranded pesticides. Exh. A, B-8.

67. 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, misbranded pesticides and required a monthly report to Sherrie Kinard. Exh. B-9. Again, the knock-off filter name “Berkey Black” was used in the SSURO.

68. 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 misbranded pesticides. Exh. B-10. Again, the knock off 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.

69. On May 8, 2023, David Cobb issued an SSURO, Docket No. FIFRA-08-2023-0038, to Berkey Int’l (a.k.a. Vendor A), a manufacturer for NMCL, which alleged that Berkey Int’l violated FIFRA by selling Black Berkey Filter Products, which the EPA considered to be unregistered, misbranded pesticides. Exh. B-11. Berkey Int’l is in region 2, and not region 8; Berkey Intl. has never been contacted by EPA region 2. Again, the SSURO uses the knock-off filter name “Berkey Black”, and required Berkey Int’l to send monthly reports to Tokarz. Exh. B-11.

70. 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 them to submit to the EPA for approval. Exh. A. Thereafter, JE submitted multiple iterations to the EPA. Each was rejected for minor changes that could have been communicated to JE during the EPA phone discussion in May of 2022, the EPA inspection in November 22, 2022, or any number of email communications. Exh. A, B-13 (“Rejected Packaging Proposals”).

71. 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.

72. 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 they believed Berkey products violated FIFRA. Exh. A, B-12.⁸

73. At all times during these events, EPA agent Tokarz has been an inspector in Region 8.

74. NMCL has been in business for more than twenty-five years and has always rigorously complied with EPA environmental regulations. NMCL has periodically hired EPA consultants to review its websites and claims and to ensure that NMCL complied with EPA regulations. Exh. A.

75. Since May of 2022, NMCL has complied with exempt treated device regulations as the EPA suddenly decided to require, by obtaining and then attaching establishment numbers to its products. NMCL has completed its reporting requirements and verified its advertising claims for accuracy. NMCL has been and remains in compliance with treated article regulations. Exh. A.

76. During early 2023, NMCL and JE modified their websites to change the status of Berkey water filter products to treated articles. NMCL repackaged the Black Berkey Filters with

⁸ 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).

packaging that did not make any waterborne pathogen removal claims for U.S. sales, and all the un-repackaged filters were marked for international export. Exh. A.

77. On or about July 12, 2023, NMCL agents conferenced with EPA Inspector Tokarz. Tokarz stated that NMCL continues to make pesticide claims about Berkey products. NMCL has slowly come to realize, based on the many rejections of packaging proposed to NMCL in the Rejected Packaging Proposals, the phone conversations rejecting even an image of a lake that Berkey has used for many years, Tokarz and her allies at the EPA will never allow Berkey to sell its filters without registration, even if Berkey just sold a boxed filter and provided no specification to consumers, because consumers know that Berkey is a water filter that has a reputation for reducing contaminants in water, and Berkey will never escape that reputation.

78. Berkey Int'l has \$38,500,000 in wholesale inventory that it is unable to manufacture and sell. Storage costs are approximately \$63,000 per month. More than 500 jobs have been lost and more are imperiled by the irrational decision to creatively interpret a rule about electric ion-generating washing machines into an excuse to put a long-time proven manufacturer of reliable water filters out of business. NMCL has never been part 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 all of that, while also encouraging low grade knock-offs and counterfeit filters to fill the market gap with cut-rate products. If a member of the public is damaged by such filters, redress is more difficult than if they were damaged by a Black Berkey filter, as the sourcing for knock-off 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 they are almost always produced outside the US, where seeking redress for damage is almost impossible. Exh. A.

V. AUTHORITIES

A. Administrative Procedures Act (5 U.S.C. 553)

79. The holy codex of the administrative state is the Administrative Procedure Act (“APA”), which outlines the general 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. 5 U.S.C. § 553.

80. To change the rights and duties of interested parties, an agency must promulgate rules by notice and comment rulemaking. 5 U.S.C. § 553. However, Section 553 provides for exceptions to notice and comment rulemaking, for example, interpretive rules. *Id.* The condition on using this exception for notice and comment rule making is that it cannot change the rights and duties of interested parties that would be subject to the rule and it cannot use mandatory language.

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

81. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was passed by Congress in the early 20th Century to regulate agricultural pesticides

82. Products of interest to the EPA under FIFRA can be loosely categorized as pesticides, pesticidal devices, and treated articles.

83. 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. § 136u.

84. FIFRA defines “pesticide device” as:

as “. . . any instrument or contrivance . . . which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life[.],” and “pesticide” in § 136(u) as “. . . (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer[.]” FIFRA requires that all manufacturers of pesticides register those pesticides with the Environmental Protection Agency.

7 U.S.C. § 136h.

85. 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.

86. For a broad judicial discussion of these categories, see generally, *Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 U.S. Dist. LEXIS 63671 (N.D. Cal. 2016) (denying a motion to dismiss and describing pesticide-coated seeds as “pesticidal devices” as opposed to “pesticides”).

VI. CAUSES OF ACTION

87. Through this suit, Plaintiffs bring against Defendants three counts for breaching the restrictions that the Constitution and Congress have placed upon the Defendants.

88. For Plaintiff, vacatur of the Final Rule would remedy the harms that flow therefrom. Indeed, in this Circuit, for APA violations that are unlawful, the default—and appropriate—remedy is vacatur. *See Data Mktg. P’ship, LP v. U.S. Dep’t of Lab.*, 45 F.4th 846, 859–60 (5th Cir. 2022) (“The ordinary practice is to vacate unlawful agency action.”) (quoting *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019)). For example, “nearly every logical outgrowth violation leads to vacatur.” Nicholas Bagley, *Remedial Restraint in Administrative Law*, 117 COLUM. L. REV. 253, 275 (2017). Alternatively, if the EPA’s reinterpretation of FIFRA

were to stand, declaratory and injunctive relief declaring the reinterpretation of silver as a pesticide under the FIFRA unconstitutional and enjoining the Agencies from enforcing the same would remedy the harms that flow from the EPA's enforcement action predicated on its reinterpretation.

A. Count 1: Violation of the APA 5 U.S.C. § 706 Plaintiff seeks vacatur of the EPA's Regulation for Failure to Observe Legally Required Procedures.

89. As the reviewing court in this case, under 5 U.S.C. § 706(2)(D), “[t]he reviewing court shall . . . hold unlawful and set aside any action, findings, and conclusions found to be . . . without observance of procedure required by law[.]”

90. The APA's rulemaking requirements include a mandate for federal agencies to provide the public with a meaningful opportunity to comment on the elements of a rule and the materials that form the basis for the rule. *See, e.g.,* 5 U.S.C. § 553(c); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1404 (9th Cir. 1995) (“The purpose of the notice and comment requirement is to provide for meaningful public participation in the rule-making process.”).

91. 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).

92. 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 Tex. Ass’n of Mfrs. v. U.S. Consumer Prod. Safety Comm’n*, 989 F.3d 368, 382 (5th Cir. 2021).

93. 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.” *Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 447 (5th Cir. 2021) (cleaned up).

94. Here, nothing in the Agencies’ application of FIFRA to water filters or its explanation thereof “gave [any] indication that [the agency] was contemplating a potential change” as drastic as reinterpreting guidance that previously dealt with electronically stimulated ionization to now apply to the presence of inert silver in water filters. *See Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1376 (Fed. Cir. 2017).

95. Due to the substantial discrepancy between the Final Rule from 2007, and its recent reinterpretation and application of the rule against Plaintiff, the public were denied the chance to comment on the substance of the latter. That denial violates the APA and warrants vacatur of the Final Rule. *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).

i. Relief Requested

Plaintiffs respectfully request the following relief:

- I. Holding unlawful and setting aside the EPA’s Reinterpretation of “Pesticide” as applicable to inert silver in a water filter.
- II. Vacatur of the Reinterpretation.

B. Count 2: Plaintiff seeks vacatur of the EPA’s reinterpretation of the rule governing pesticides because it is Arbitrary, Capricious, and Not in Accordance with Law.

96. 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[.]” The Final Rule is arbitrary, capricious, and not in accordance with law.

97. The APA requires federal agencies, including Defendants, to (a) give general notice of proposed rulemaking in the Federal Register and thereafter (b)“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).

98. An agency action is not reasonable if the agency “entirely failed to consider an important aspect of the problem[.]” *See Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

99. “An agency must 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).

100. “An agency need not respond to every comment, but it must respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments.” *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).

101. The House and Senate reports with regard to this provision state that “the agency must analyze and consider all relevant matter presented.” S. Rep. No. 752, 796 Cong., 1st Sess. 15 (Nov. 19, 1945); H. Rep. No. 1980, 79th Cong., 1st Sess. 25 (May 3, 1946) “[Public] participation . . . in the rule-making process is essential in order to permit administrative agencies to inform themselves. . . .” Report submitted by Pat McCarran, Chairman, U.S. Senate Committee on the Judiciary, Administrative Procedure Act, Legislative History 1944–46, 79th Cong. (July 26, 1946).

102. “[I]t is ‘arbitrary or capricious’ for an agency not to take into account all relevant factors in making its determination.” *Hanly v. Mitchell*, 460 F.2d 640, 648 (2d Cir. 1972).

103. 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 Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 630 (5th Cir. 2001).

104. The Final Rule implemented in 2007 clearly did not contemplate application to inert silver as a pesticide, thus the public was unable to address comments to the Final Rule during the Proposed Rule comment phase and the EPA cannot possibly have addressed comments that were never made.

105. On information and belief, a full review of the record in this case will evidence that the EPA failed to adequately consider the full extent of novel interpretation of the Final Rule as applied to inert silver's effect on the public and the filter industry writ large and failed to adequately consider the financial impact on business because the industry lacks requisite notice to comment on the rule as recently interpreted.

i. Relief Requested

Plaintiffs respectfully request the following relief:

- I. Holding unlawful and setting aside the EPA's Reinterpretation of "Pesticide" as applicable to inert silver in a water filter.
- II. Vacatur of the Reinterpretation.

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.

106. "No person shall . . . be deprived of life, liberty, or property, without due process of law."
U.S. CONST. AMEND. V.

107. Agency regulations bear the "force and effect of law." *Perez*, 575 U.S. at 96 (quoting *Chrysler Corp.*, 441 U.S. at 302–03).

108. 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).

109. “A law is unconstitutionally vague if people of common intelligence must guess at its meaning and differ as to its application.” *Shamloo v. Miss. State Bd. of Trustees of Insts. of Higher Learning*, 620 F.2d 516, 523 (5th Cir. 1980).

110. 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).

111. 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).

112. The 2007 Rule uses vague phraseology, specifically “*generate ions of those substances for express pesticidal purposes.*” As discussed above, this is unduly vague for the manufacturers who are attempting good faith compliance with the law if this statement covers electrical and nonelectrical mechanisms. It is not remotely clear, what devices fall within the ambit of this language if nonelectrical effects fall within its scope.

113. The law is thus unduly vague and would violate the void for vagueness doctrine necessitating vacatur.

ii. Relief Requested

Plaintiffs respectfully request the following relief:

- I. Holding unlawful and setting aside the EPA’s Reinterpretation of “Pesticide” as applicable to inert silver in a water filter.
- II. Vacatur of the Reinterpretation.

D. Plaintiff seeks vacatur for violation of the APA 5 U.S.C. § 706 and violation of the U.S. Constitution U.S. Const. Art. I, Separation of Powers and the Delegation Doctrine.

114. Article I, Section 1 of the U.S. Constitution provides: “All legislative Powers herein granted shall be vested in a Congress of the United States.”

115. Article I, Section 3 of the U.S. Constitution directs that the president “shall take Care that the Laws be faithfully executed[.]”

116. A “fundamental precept” of “another strand of [] separation-of-powers jurisprudence, the delegation doctrine,” “is that the lawmaking function belongs to Congress, U.S. CONST. ART. I, § 1, and may not be conveyed to another branch or entity.” *Loving v. United States*, 517 U.S. 748, 758 (1996).

117. “Even before the birth of this country, separation of powers was known to be a defense against tyranny,” and “it remains a basic principle of our constitutional scheme that one branch of the Government may not intrude upon the central prerogatives of another.” *Id.* at 756–57.

118. “‘The fundamental precept of the delegation doctrine is that the lawmaking function belongs to Congress[.]’” *Brackeen v. Haaland*, 994 F.3d 249, 420 (5th Cir. 2021) (quoting *Loving*, 517 U.S. at 758).

119. As the Fifth Circuit has noted, “the Constitution’s first substantive word” places all lawmaking power in Congress and therefore “Congress’s statutes define the scope of agencies’ power.” *Forrest Gen Hosp. v. Azar*, 926 F.3d 221, 228 (5th Cir. 2019).

120. Government actions, including agency rules, “are ‘legislative’ if they have ‘the purpose and effect of altering the legal rights, duties, and relations of persons . . . outside the legislative branch.’” *Jarkesy v. SEC*, 34 F.4th 446, 461 (5th Cir. 2022) (quoting *INS v. Chada*, 462 U.S. 919, 952 (1983)).

121. Congress may not “abdicate or [] transfer to others the essential legislative functions with which it is thus vested.” *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935).

122. Neither the president nor his subordinates, therefore, may exercise, Congress’ legislative power to declare entirely “what circumstances . . . should be forbidden” by law. *Panama Refining Co. v. Ryan*, 293 U.S. 388, 418–19 (1935).

123. The EPA’s novel interpretation, by re-writing and significantly expanding the definition of “pesticide,” exercised legislative powers.

124. A violation of the Constitution is always a violation of the APA. 5 U.S.C. § 706(2)(B).

125. Thus, the EPA violated the APA by exercising legislative powers.

126. The EPA’s claim it is acting within delegated authority is false because it is not a reasonable construction of statutory terms.

127. The Supreme Court has “reaffirm[ed] the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate.” *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 328 (2014).

128. The EPA, therefore, “cannot manufacture statutory ambiguity with semantics to enlarge their congressionally mandated border.” *Tex. Pipeline Ass’n v. FERC*, 661 F.3d 258, 264 (5th Cir. 2011); *id.* (“Ambiguity is a creature not of definitional possibilities but of statutory context.”) (quoting *Brown v. Gardner*, 513 U.S. 115, 118 (1994)). 176. Further, an agency cannot create implicit questions “left unresolved” in a statute, “merely because a statute’s ‘authors did not have the forethought expressly to contradict any creative contortion that may later be constructed to expand or prune its scope.’” *Calix v. Lynch*, 784 F.3d 1000, 1005 (5th Cir. 2015) (quoting *Moore v. Hannon Food Serv. Inc.*, 317 F.3d 489, 497 (5th Cir. 2003)).

129. Delegation must be express; courts cannot “presume that a power is delegated if Congress does not expressly withhold it, as then agencies would enjoy virtually limitless hegemony, a result

plainly out of keeping with Chevron and quite likely with the Constitution as well.” *Contender Farms, L.L.P. v U.S. Dep’t of Agric.*, 779 F.3d 258, 269 (5th Cir. 2015) (internal citation omitted); *see also Gulf Fishermens Ass’n v. Nat’l Marine Fisheries Serv.*, 968 F.3d 454, 461 (5th Cir. 2020), as revised (Aug. 4, 2020).

130. Congress cannot delegate authority to an agency absent an “intelligible principle” to guide and limit the delegation. *See Jarkesy*, 34 F.4th at 460–61 (citing *Mistretta v. United States*, 276 U.S. 394, 409 (1989)).

131. There was no delegation to the EPA to more broadly define “pesticide” to exceed the limits of its congressionally established authority, nor is there any intelligible principle by which such authority could have been delegated.

132. The EPA reinterpretation is therefore unconstitutional under the non-delegation doctrine, and thus was passed in violation of the APA.

133. The reinterpretation is not merely a regulatory change that allows the EPA to enforce FIFRA. The reinterpretation would give the EPA new power over new items that are not contemplated nor regulated under federal law. This rulemaking constitutes an executive branch agency making new law in violation of the Delegation Doctrine as established by the structure of the U.S. Constitution and Elucidated by the U.S. Supreme Court.

iii. Relief Requested

Plaintiffs respectfully request the following relief:

- I. Holding unlawful and setting aside the EPA’s Reinterpretation of “Pesticide” as applicable to inert silver in a water filter.
- II. Vacatur of the Reinterpretation.

E. Count 5: Plaintiff seeks vacatur for violation of the U.S. Constitution U.S. Const. Art. I, Take Care Clause.

134. Article I, Section 1 of the U.S. Constitution provides: “All legislative Powers herein granted shall be vested in a Congress of the United States.”

135. Article I, Section 7, Clauses 2 and 3 of the U.S. Constitution require that “Every Bill” shall be passed by both the House of Representatives and the Senate and signed by the President “before it [may] become a Law.”

136. Article II, Section 3 of the U.S. Constitution directs that the President “shall take Care that the Laws be faithfully executed[.]”

137. A violation of the Constitution is always a violation of the APA. *See* 5 U.S.C. § 706(2)(B).

138. “In the framework of our Constitution, the President’s power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker.” *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 587 (1952).

139. The Executive Branch cannot create new policies to be enforced with the force of federal law in the guise of enforcing a congressional enactment. *Id.* at 587–88 (“The President’s order does not direct that a congressional policy be executed in a manner prescribed by Congress—it directs that a presidential policy be executed in a manner prescribed by the President.”); *see Kendall v. U.S. ex rel. Stokes*, 37 U.S. (12 Pet.) 524, 613 (1838) (rejecting the notion that “the obligation imposed on the President to see the laws faithfully executed, implies a power to forbid their execution”).

140. “[W]here Congress pass[es] a law for the guidance and government of the executive, in m[at]ters properly concerning the executive department, it belongs to the President to take care that this law be faithfully executed[.]” *Kendall*, 37 U.S. 524 at (1838).

141. “The Supreme Court has also invoked the Take Care Clause as the textual source of the President’s duty to abide by and enforce the laws enacted by Congress—that is, as the instantiation of the President’s duty to respect legislative supremacy and not to act *contra legem*.” Jack Goldsmith & John F. Manning, *The Protean Take Care Clause*, 164 U. PA. L. REV. 1835, 1848 (2016).

142. “Separate opinions by members of the *Youngstown* majority expressed a like sentiment about the Take Care Clause—that it obliges the President to respect the means and ends of statutory policy power specified by Congress. In his famous concurrence, Justice Jackson wrote that the clause confers on the President ‘a governmental authority that reaches so far as there is law,’ thereby ‘signify[ing] . . . that ours is a government of laws, not of men, and that we submit ourselves to rulers only if under rules.’” *Id.* at 1849–50.

143. “To similar effect, Justice Frankfurter quoted Justice Holmes for the proposition that ‘[t]he duty of the President to see that the laws be executed is a duty that does not go beyond the laws or require him to achieve more than Congress sees fit to leave within his power.’ Likewise, in Justice Douglas’s words, any authority conferred by the clause ‘starts and ends with the laws Congress has enacted.’” *Id.* at 1850.

144. The EPA’s reinterpretation is not a faithful execution of congressionally enacted law. Instead, it is an executive-created law offered under the guise of enforcing FIFRA. But it is not truly based on a reasonable reading of any ambiguous passage in the text of the law. It violates the prohibition on Executive law making and further violates the President’s duty to ensure faithful execution of the law. And because the reinterpretation violates the Constitution, it was not legitimately passed under the APA and should be subject to vacatur.

iv. Relief Requested

Plaintiffs respectfully request the following relief:

- I. Holding unlawful and setting aside the EPA’s Reinterpretation of “Pesticide” as applicable to inert silver in a water filter.
- II. Vacatur of the Reinterpretation.

F. Count 6: Plaintiffs seek declaratory judgment and damages for the EPA's violations.

v. Claim 1: The EPA arbitrarily and capriciously designated Plaintiffs' filters as pesticides.

145. Plaintiffs claim here that the EPA violated the APA by arbitrarily and capriciously designating Black Berkey water filters as pesticides with no basis in any record of facts.

146. 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.

147. 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 flipped its adjudication of the issue in the record of available data it considered, courts view that decision as arbitrary and capricious. *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515–16 (2009).

148. 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. This type of flip 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 a 2007 interpretative rule concerning ion-generating electrodes, which are not present in Berkey filters. Therefore, the EPA's determination that Berkey filters are pesticides is arbitrary and capricious and the EPA is in violation of 5 U.S.C. § 704–706. The EPA's violations have substantially injured Plaintiffs and require damages, declaratory judgment, and injunctive relief to restore Plaintiffs to the rightful position.

vi. Claim 2: The EPA exceeded statutory authority to find that Berkey Filters are pesticides.

149. Plaintiffs claim 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.

150. As discussed at 5 U.S.C. § 701, *et. seq.*, the APA allows an interested party to challenge final agency actions for exceeding 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 numerous or 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.

151. 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.

152. 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, 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).

153. 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 DDTs 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.

154. Further, the EPA has promulgated regulations to define certain innocuous products that would otherwise be pesticides that are excepted from registration. 40 C.F.R. § 152.25. Some examples include embalming fluids, castor oil, pheromone traps, and peppermint oil. *Id.* None of these excepted pesticides even remotely resemble a water filter.

155. Hence, the EPA’s attempt to force Berkey to register its water filters as pesticides exceeds the bounds of the congressionally granted authority found in FIFRA. 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 for purposes of FIFRA and the EPA. 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. Therefore, the EPA is in violation of 5 U.S.C. § 704–06. The EPA’s violations have substantially injured

Plaintiffs and require damages, declaratory judgment, and injunctive relief to restore Plaintiffs to their rightful position.

- vii. Claim 3: The EPA's ion generating interpretive rule does not impact Berkey filters and any requirement to register non-electric water filters based thereon is invalid.

156. The EPA claims in part that Black Berkey filter elements are pesticides because of a September 2007 interpretive rule announcing that devices that generate silver ions for a pesticidal purpose are pesticides and must be registered as such. This rule does not give the EPA the authority to do as it has done and is invalid against Black Berkey Filters.

157. To change the rights and duties of interested parties, an agency must promulgate rules by notice and comment rulemaking. 5 U.S.C. § 553. However, Section 553 provides for exceptions to notice and comment rulemaking, e.g., interpretive rules. *Id.* The condition on using this exception for notice and comment rule-making is that it cannot change the rights and duties of interested parties that would be subject to the rule and it cannot use mandatory language. The 2007 notice clarifying the EPA's position states just that: it is a clarification. Pesticide Registration; Clarification for Ion-Generating Equipment, 72 Fed. Reg. 54039, 54040 (Sep. 21, 2007).

158. Further, the notice for notice-and-comment rule-making must include information for interested parties on how to make comments. 5 U.S.C. § 553(b). The notice published in the federal register contained no language describing how to make public comments. This points to the fact that this was an interpretive rule and not a notice-and-comment rule, therefore not binding on Plaintiffs.

159. Further, even if this was a notice and comment rule, the notice failed because it did not give any water filter element manufacturers adequate notice that they would be subject to the rule. In the "Does this Action Apply to Me?" section, the EPA denoted that the rule is intended to apply to manufactures of "ion-generating equipment that uses electrodes to emit chemical substances

for pesticidal purposes." Pesticide Registration; Clarification for Ion-Generating Equipment, 72 Fed. Reg. 54039, 54040 (Sep. 21, 2007). Even though it provides some caveat that the description was intended to be exhaustive, there is no way the manufacturer of a passive mechanical water filter element would place itself in the same category as washing machine manufacturers. Therefore, because the notice is insufficient, the EPA cannot use the rule, regardless of its status as interpretive or notice and comment, to require Plaintiffs to register their water filter elements.

viii. Relief Requested

160. Plaintiffs respectfully request the following relief:

- a. a declaratory judgment pursuant to 28 U.S.C. § 2201 that the EPA violated the APA when it acted arbitrarily and capriciously in attempting to require Plaintiffs to register their Black Berkey Water Filters as pesticides;
- b. a declaratory judgment pursuant to 28 U.S.C. § 2201 that the EPA violated the APA when it exceeded its statutory authority under FIFRA by attempting to require Plaintiffs to register their Black Berkey Water Filters as pesticides;
- c. a declaratory judgment pursuant to 28 U.S.C. § 2201 that the EPA's Sep. 27, 2007 notice concerning silver ion generating devices is an interpretive rule and does not constitute a rule requiring water filter element manufacturers to register their filters as pesticides;
- d. a Temporary Restraining Order, preliminary, and permanent injunctive relief pursuant to 28 U.S.C. § 2202 enjoining the EPA from enforcing FIFRA pesticide registration requirements against Berkey Water Filters;
- e. general damages, special for lost market share and lost 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' actions, 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.

G. Count 7: Procedural *Due Process* claim against the EPA for its violation of Plaintiffs' 14th Amendment Procedural Due Process rights.

161. The EPA violated Plaintiff's procedural due process by failing to provide notice or opportunity to be heard when arbitrarily and capriciously relabeling Berkey products from "pesticide devices" to "pesticides" without explanation or guidance. Berkey Products' and Plaintiffs' good name, reputation, and integrity were damaged by EPA's lack of explanation and cooperation with Plaintiffs in issuing a stop order for Berkey Products with no rational explanation.

162. The arbitrary and capricious procedures of the EPA involved no notice or opportunity to be heard for Plaintiffs 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.

- i. The EPA failed to follow the APA by denying notice and comment before simply concluding that Berkey filters are no longer pesticide devices, but pesticides themselves.

163. As noted above, the EPA provided no notice or opportunity to be heard when in May 2022 it labeled Berkey Products as "pesticide devices", then seven months later without explanation or published guidance, relabeled Berkey Products as "pesticides." Plaintiffs received no explanation of the EPA's reinterpretation of Berkey Products, nor even a notice, let alone an opportunity to be heard. Because of EPA's relabeling, the EPA issued multiple stop orders for Berkey Products in December 2022, which resulted in a 50% decrease in market share of Black Berkey elements and a 90% decrease in market share of Big Berkey filtration systems.

164. The EPA shut Plaintiffs 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; Plaintiffs suffered harm to their product's reputation and good name, resulting in 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 knock-off and counterfeit filters which are abundantly available and completely ignored by the EPA.

165. The EPA did not satisfy notice and comment rulemaking requirements and violated Plaintiff's procedural due process rights by not providing notice or an opportunity to be heard. Plaintiffs will continue to suffer extreme hardship in having to spend valuable time and money to both clear their good name and comply with whatever irrational requirements the EPA arbitrarily adopts next.

- ii. The EPA violated Plaintiffs' procedural due process rights, arbitrarily and capriciously, and while abusing its discretion, when alleging Berkey Products were pesticides that must be registered without proper notice and comment.

166. The EPA reclassified Berkey Products as a pesticide without notice, opportunity to be heard, guidance, or properly followed notice and comment rulemaking, resulting in harm to Plaintiffs' good name and reputation. This was a violation of Plaintiffs' procedural due process rights. *See Mullane v. C. Hanover Bank & Tr. Co.*, 339 U.S. 306, 314 (1950), *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976).

167. 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.

168. 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.* Plaintiffs' private interest to be free of wrongful interference in the operations of their business and needless damage to their professional reputation is at stake, and was erroneously deprived by the EPA 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.

169. After nearly 25 years of production without EPA interference, Berkey discovered that an obscure rule had been reinterpreted by the EPA to apply to Plaintiffs and that Plaintiff have thus been rendered non-compliant with rules of which they were previously unaware. The Court should declare that the EPA acted arbitrarily and capriciously, did not satisfy notice and comment rulemaking requirements under the APA, and violated Plaintiffs' procedural due process rights. The Court should further enjoin the EPA from enforcing the stop order against Berkey Products.

iii. Relief Requested

170. As to Claim 2 of this Complaint, Plaintiffs respectfully request the following relief:

- a. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA violated Plaintiffs procedural due process rights by failing to meet APA and Constitutional requirements when changing the rights and duties of the Plaintiffs as to their Black Berkey Water Filters;
- b. temporary Restraining Order, preliminary, and permanent injunctive relief pursuant to 28 U.S.C. § 2202 enjoining the EPA from enforcing FIFRA pesticide registration requirements against Berkey Water Filters;
- c. 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' actions, or in the alternative, nominal damages should other damages be unavailable;
- d. attorney's fees and costs of court because of this action; and
- e. such other and further relief that the Court deems just and proper.

H. Count 3: Regulation of Gravity-Fed Mechanical Water Filters by Federal Agencies is Unconstitutional under the Ninth and Tenth Amendments.

i. Early American citizens freely filtered water using analogically similar filters to Berkey's.

171. As detailed in the fact section above, early citizens of this country had access to and used gravity-fed mechanical filters without seeking permission from any government. Plaintiffs assert that any attempt by the federal government to regulate such devices would have been rejected, as the administrative state was more than a century into the future, and potable water was not generally provided by government systems.

172. Plaintiffs assert that, contrary to the several SSUROs issued by Tokarz in connection with Berkey filters, an establishment constructing mere devices that do not employ substances as pesticides is not required to seek establishment numbers and be regulated by the EPA. Because the federal government has not passed a law requiring that action, Plaintiffs assert that they are not required to pretend otherwise in order to buy peace with rogue EPA actors.

ii. The Tenth Amendment should protect Berkey from the EPA/Tokarz's overreach.

173. If, however, this Court sees in FIFRA a requirement for ordinary mechanical filters to be regulated, then Plaintiffs assert that FIFRA is unconstitutional, at least as applied to their products. Plaintiffs' issues may not be as grand as the overreach discussed in *Nat'l Fed'n of Indep. Bus. v. DOL, OSHA*, 142 S. Ct. 661 (2022), where the Supreme Court stopped OSHA's effort to force vaccination on every employee of more than 100 employers, but the difference is in quantity, not quality, as the plaintiffs in both cases cited the Tenth Amendment to argue that the agency in question had overstepped its boundaries.

iii. The Ninth Amendment should protect Berkey from the EPA/Tokarz's interpretation.

174. Additionally, Plaintiffs assert that, because citizens in the early years of the United States enjoyed unfettered ability to use mechanical filter products without regulatory interference, any ambiguity in the EPA's authority should be answered by the Ninth Amendment's command to recognize that rights enjoyed by its citizens at the time of the Bill of Rights' adoption should be protected until, at the very least, a clearly expressed curtailing statute is passed by Congress.

175. If the Ninth Amendment means anything at all, it should require courts to interpret vague regulations away from restricting common freedoms enjoyed when the Bill of Rights was adopted, rather than deferring to state agencies which rarely know boundaries. Plaintiffs recognize that water filters which use exotic processes and chemical treatments that did not exist when the Bill of Rights was passed may not enjoy the protection of historical use, but certainly every water filter that uses a gravity-fed element comprising a porous medium to capture contaminants should be protected from government interference.

iv. Relief Requested

176. As to Claim 3 of this Complaint, Plaintiffs respectfully request the following relief:

- a. a declaratory judgment pursuant to the Tenth Amendment and 28 U.S.C. § 2201 that the EPA cannot require Berkey's manufacturers and distributors to register with the EPA merely on the basis that they are manufacturing or selling mechanical filters, such as Berkey products, which do not utilize pesticides to kill pathogens in the water;
- b. a declaratory judgment pursuant to the Ninth Amendment and 28 U.S.C. § 2201 that the EPA cannot interpret FIFRA such that Berkey water filters must comply with EPA's registration process, as FIFRA does not clearly require non-electric, mechanically operating filters to be governed by the EPA, and further, Berkey filters are not pesticides;
- c. economic damages, attorney fees, costs, and all other relief to which plaintiffs are entitled.

**VII. APPLICATION FOR TEMPORARY RESTRAINING ORDER,
PRELIMINARY, AND PERMANENT INJUNCTION**

A. Plaintiffs request a Temporary Restraining Order.

177. Because of the drastic and irreparable injury that Plaintiffs are currently suffering and the inadequacy of legal remedies, Plaintiffs seek a temporary restraining order preventing enforcement of the EPA's determination that Berkey filters are pesticides and the SSUROs subject of this suit.

178. A party seeking a temporary restraining order must demonstrate by a clear showing: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable harm if the injunction is not granted; (3) that the threatened injury to the movant outweighs any harm to the nonmovant that may result from the injunction; and (4) that the injunction will not undermine the public interest. *See Smith v. Tarrant County College Dist.*, 670 F. Supp. 2d 534, 537 (N.D. Tex. 2009). Plaintiffs allege that these elements are met, as follows.

i. There is a significant threat of irreparable harm to Plaintiffs if the TRO is not granted.

179. Plaintiffs suffered a real injury when the EPA issued a stop sale order to Berkey International. Specifically, Plaintiffs' distributors have questioned, with some merit, whether Berkey has long term stability and viability given the EPA's campaign to make it jump through ever more ridiculous hoops. Exh. A.

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

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

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

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

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

184. Because of the EPA's SSUROs, Berkey Int'l has \$38,500,000 in wholesale inventory that it is unable to manufacture or sell. Storage costs exceed \$63,000 per month. Exh. A.

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

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

187. Plaintiff Shepherd understands that Berkey filtration systems have had the same attrition on other platforms such as Walmart.com, Ebay.com, etc.

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

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

190. NMCL has offered its customers the option of utilizing third party ceramic filters, in lieu of Black Berkey filters, for over 25 years in the following systems: *Travel Berkey Water Filters*, *Big Berkey Water Filters*, *Royal Berkey Water Filters*, *Imperial Berkey Water Filters*, and *Crown Berkey Water Filters*. Yet, the EPA has indicated that going forward, it would likely not allow the use of the Berkey trademark in association with NMCL's filters, which would shut down sales of wholly unobjectionable ceramic filters that are not as issue. Exh. A.

191. The EPA's SSUROs have left NMCL in a state of confusion. As previously mentioned on or about February 3rd, 2023, the EPA issued an SSURO to Vendor B, an OEM manufacturer for NMCL and on or about May 8, 2023, Tokarz (Region 8) issued an SSURO in a different region (Region 2) on Berkey Int'l (Vendor A).

192. On or about May 26, 2023, Region 4 of the EPA terminated the Stop Sale order on Vendor B allowing it to manufacture and sell Berkey filter products as treated articles, including the Travel Berkey, Big Berkey, Light Berkey, Royal Berkey, Imperial Berkey, Crown Berkey and Black Berkey elements. However, the SSURO on Berkey Int'l remains in effect, preventing it from manufacturing and selling those same products as treated articles. This places NMCL in a precarious position where it can purchase and market Black Berkey Products and Systems from one of its OEM manufacturers in Region 4 while at the same time it is prohibited from purchasing or selling those same products from another OEM manufacturer in Region 2.

193. No adequate legal remedy exists to make Plaintiffs whole. Again, the EPA's campaign against Berkey filters has directly caused Plaintiff massive losses to market share, to sales revenue,

to brand and reputation, and of new customers while being drowned with massive irrecoverable business expenses. No one can honestly contest these are real injuries, yet each injury is of a nature that cannot be measured accurately in monetary terms to place the Plaintiffs in the rightful position. Therefore, the legal remedy of traditional compensatory damages is inadequate to remedy Plaintiffs' injuries, requiring this Court to grant equitable relief in the form of a temporary injunction to prevent irreparable harm before this Court holds an evidentiary hearing on Plaintiffs' petition for a preliminary injunction.

ii. The Defendants suffer no hardship if this Court grants the TRO.

194. Defendants suffer no hardship from a temporary restraining order. Berkey has sold its trade secret Black Berkey Filters on the market for two decades without an issue. Defendants considered Plaintiffs to be a manufacturer of pesticide devices, not pesticides, up until late 2022, when, without adequate explanation, they suddenly reversed course. When this Court grants the temporary restraining order, the EPA will suffer no prejudice in its investigation and its enforcement efforts against legitimate pesticides will continue unabated as FIFRA mandates.

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

196. To state the situation another way, the EPA is not capable of stopping the knock-offs and counterfeits, which are available on multiple global sources. The choice before the EPA and this Court is whether the EPA can shut down Berkey and prevent quality tested products from being offered for sale, so the void in the marketplace can be filled by untested knock-offs and counterfeits.⁹

⁹ See, e.g., https://www.alibaba.com/product-detail/BB9-2-Black-Purification-Element-Water_1600431948291.html?spm=a2700.galleryofferlist.normal_offer.d_title.1d8a114eJp7Mbk (July 27, 2023).

iii. Plaintiffs will suffer extreme hardship if this Court does not grant the TRO.

197. By contrast, Plaintiffs will suffer extreme hardship if this Courts refuses to grant the TRO. Plaintiffs face irreparable market share loss, sales revenue loss, brand and reputational loss, and loss of new customers while being drowned with massive irrecoverable legal and business expenses, damage to brand and reputation, and the continuing loss of new customers.

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

iv. This Court suffers no hardship if it grants the injunction.

199. This Court will suffer no hardship when it grants the preliminary injunction. This Court will need only minimal supervision, if at all, to ensure that the injunction is effective in preventing irreparable harm. Once the injunction is issued, there is no reason to believe the EPA will not comply, thus no action will be needed from this Court. Therefore, there is no hardship to this Court to issue the injunction.

v. Plaintiffs will likely succeed on the merits.

200. Plaintiffs have adequately shown that the EPA's actions are arbitrary and capricious, and the result of an abuse of discretion, as no colorable argument exists to say that Berkey filters employ electrodes to generate ions. Plaintiffs have adequately shown that the EPA violated the APA and the procedural due process rights of Plaintiffs.

vi. The public interest advises this Court to grant the TRO.

201. Public interest demands that administrative states all over the country properly comply with constitutional and statutory bounds. Public interest does not support arbitrary, capricious, or abusive agency actions taken without notice, comment, guidance, or explanation. No reasonable person wants government agencies to have carte blanche authority to change their own interpretations of the rules without warning or notice to affected parties.

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

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

vii. Bond

204. Because the restraining order would place so little burden on the Defendants and provide such great relief to the Plaintiffs, Plaintiffs request this court set the bond at \$100, if at all.

B. Plaintiffs seek a Preliminary Injunction and Permanent Injunction.

205. Because of the drastic and irreparable injury that Plaintiffs will suffer before trial and the inadequacy of legal remedies, Plaintiffs seek a preliminary injunction, based on the reasons stated supra.¹⁰ Additionally, Plaintiffs pray for a permanent injunction after trial to enjoin the EPA's illegal action.¹¹

¹⁰ See *Smith v. Tarrant County College Dist.*, 670 F. Supp. 2d 534 (N.D. Tex. 2009).

¹¹ See *id.*

VIII. PRAYER

Plaintiffs pray that this Court issue citations so that Plaintiffs may serve Defendants with a summons to appear and answer. Upon trial and final judgment of this Court, Plaintiffs pray this Court award the following:

- a. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA exceeded its statutory authority under FIFRA when it attempted to require Plaintiffs to register their Black Berkey Water Filters as pesticides;
- b. a declaratory judgment pursuant to 28 U.S.C. § 2201 that EPA violated Plaintiffs procedural due process rights by failing to meet APA and constitutional requirements when changing the rights and duties of the Plaintiffs as to their Berkey Water Filters;
- c. temporary restraining order, preliminary, and permanent injunctive relief pursuant to 28 U.S.C. § 2202 enjoining the EPA from enforcing FIFRA pesticide registration requirements against Berkey Water Filters;
- d. a declaratory judgment pursuant to 28 U.S.C. § 2201 that the EPA's Sep. 27, 2007 notice concerning silver ion generating devices is an interpretive rule and does not constitute a rule requiring water filter element manufacturers to register their filter elements as pesticides;
- 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' ultra vires actions in their personal capacity, 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.

Dated August 3, 2023,

Respectfully submitted,

/s/Warren V. Norred

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Counsel for Plaintiffs

ATTACHMENTS:

Exhibit A: Declaration of Jim Shepard

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: Federal Register September 21, 2007

C-3: EPA Website Introduction to 2007 Federal Reg. Notice of Clarification

C-4: 2007 Federal Reg. Notice of Clarification

C-5: EPA Guide Standard and Protocol for Testing Microbiological Water Purifiers

C-6: PR 2023-1, Lists of Pests of Significant Public Health Importance – Revised 2023

C-7: 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-8: Pesticide Device: A Guide to Consumers

CERTIFICATE OF SERVICE

I certify that on Wednesday, August 9, 2023, I electronically filed this proceeding with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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The Honorable Merrick B. Garland
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