UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY, 660 Pennsylvania Avenue, SE, Suite 302 Washington, DC 20003 INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, 303 Sacramento St., 2nd Floor San Francisco, CA 94111 BEYOND PESTICIDES, 702 E Street, SE, Suite 200 Washington, DC 20003 CENTER FOR ENVIRONMENTAL HEALTH, 2201 Broadway, Suite 302 Oakland, CA 94612 CLEAN PRODUCTION ACTION, 1310 Broadway, Suite 101 Somerville, Massachusetts 02144 and INSTITUTE FOR AGRICULTURE AND TRADE POLICY, 2105 First Ave. South Minneapolis, Minnesota 55404 *Plaintiffs*, v. GINA MCCARTHY, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, 1200 Pennsylvania Avenue, NW Washington, DC 20460 *Defendants*.	**Case No.** 14-cv-2131 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** **Administrative Procedure Act Case**

INTRODUCTION

1. This is an action for declaratory and injunctive relief challenging the failure of the United States Environmental Protection Agency (EPA or the agency) to answer, as required by law, Plaintiffs' 2008 legal petition. That petition called on EPA to use its pesticide authority to regulate numerous consumer products now using novel forms of nanotechnology: nano-sized versions of silver.

2. Nanotechnology is a powerful new platform technology for taking apart and reconstructing nature at the atomic and molecular levels. Consumer products containing manufactured nanoparticles have already arrived on market shelves, and numerous pesticidal products within EPA's jurisdiction, such as antibacterial and antibiotic clothing, are now widely available. Manufactured nanomaterials have fundamentally different properties from their bulk material counterparts, and those properties create unique public health and environmental risks that require new risk assessment paradigms. Yet EPA has thus far failed to address the risks of pesticidal nanomaterials such as nano-silver-containing products.

3. Accordingly, on May 1, 2008, the Center for Food Safety, its sister nonprofit the International Center for Technology Assessment, and twelve other environmental and health nonprofit organizations filed a formal legal petition to EPA for rulemaking on this topic. *See* Ex. A. The 116-page petition, which included more than 500 pages of supporting records, was a legal, policy, and scientific blueprint for EPA's needed action, requesting, *inter alia*, that the agency classify nano-silver products as pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and require needed assessments of the public health and environmental impacts of these novel nano-pesticides under FIFRA and other applicable laws.

4. On November 19, 2008, EPA opened a public comment period in response to that

petition. Yet nearly six years later the agency has still failed to respond to Plaintiffs' 2008 Petition, a failure that violates the mandates of the Administrative Procedure Act (APA). In the interim, hundreds of new pesticidal nano-silver products have reached the market without any pesticide oversight from EPA. Accordingly, this Court should order EPA to respond to Plaintiffs' 2008 Petition without further unlawful delay.

JURISDICTION

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal question) and 1346 (United States as Defendant).

6. The relief requested is specifically authorized pursuant to 28 U.S.C. §§ 1651 (writs) and 2201 to 2202 (declaratory relief). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

7. Plaintiffs have a right to bring this action pursuant to the APA. 5 U.S.C. §§ 551-559, 702-706.

VENUE

8. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or more of the Plaintiffs reside in this District.

PARTIES

Plaintiffs

9. Plaintiff Center for Food Safety (CFS) is a Washington, District of Columbia-based nonprofit organization with offices in San Francisco, California; Portland, Oregon; and Honolulu, Hawai‘i. Founded in 1997, CFS is dedicated to addressing the environmental, economic, ethical, health, and social impacts associated with the development and commercialization of agricultural and food processing technologies, such as nanotechology,

and improving their oversight. CFS has over 600,000 members, including members in every state across the country, all of whom are vulnerable to the environmental and health risks associated with use of novel nanomaterials such as nano-silver. CFS and its members are being, and will be, adversely affected by EPA's continued failure to address those risks.

10. CFS combines multiple tools and strategies in pursuing its goals, including public education, grassroots organizing and campaigns, media, outreach, litigation, and legal petitions for rulemaking. CFS's membership action alerts also generate public education and engagement with governmental officials on issues related to addressing the health and environmental impacts of industrial agriculture, and promoting a healthier, more sustainable food system. Collectively, the dissemination of this material makes CFS an information clearinghouse for public involvement and governmental oversight of all aspects of industrial agriculture, including nanotechnology and nano-pesticides.

11. Formed in 1994, Plaintiff International Center for Technology Assessment (CTA) seeks to assist the public and policymakers in better understanding how technology affects society. To that end, CTA analyzes the economic, environmental, ethical, political, and social impacts that can result from the application of technology or technological systems, and works to improve oversight of new technologies, such as nanotechnologies like nano-silver, that pose complex and novel threats to the environment and public health.

12. CTA develops and disseminates—to members, policymakers, members of local, state, and federal government, international governmental officials, nonprofit organizations, and the general public—a wide array of educational and informational materials that address the environmental, economic, social, and public health impacts associated with the use of new technologies, such as nanotechnologies like nano-silver. CTA's materials include, but are not

limited to, reprints of news articles and agency regulatory positions, press releases, fact sheets, action alerts, electronic mail alerts, and investigative or technical reports. CTA's materials often analyze the legal and regulatory means by which federal agencies address the various economic, environmental, public health, and social impacts associated with nanotechnology.

13. Along with its function as an information clearinghouse, CTA also serves in an advocacy function to, among other things, protect public health and the environment from the impacts and risks raised by nanotechnology. Accordingly, CTA seeks to encourage full public participation in local, state, and federal policymaking and rulemaking proceedings so that public concerns over nanotechnology are duly considered and acted upon by governmental decision-making bodies.

14. Plaintiff Beyond Pesticides (BP) is a nonprofit organization headquartered in Washington, D.C., that works with allies in protecting public health and the environment to lead the transition to a world free of toxic pesticides. The founders, who established BP as a nonprofit membership organization in 1981, felt that without the existence of such an organized, national network, local, state, and national pesticide policy would become, under chemical industry pressure, increasingly unresponsive to public health and environmental concerns. BP's primary goal is to effect change through local action, assisting individuals and community-based organizations to stimulate discussion on the hazards of toxic pesticides, while providing information of safe alternatives.

15. Center for Environmental Health (CEH) is located at 2201 Broadway, Suite 302, Oakland, CA 94612. Founded in 1996, CEH is a nonprofit organization dedicated to protecting the public from environmental and consumer health hazards. CEH is committed to environmental justice, reducing the use of toxic chemicals and practices, supporting communities

in their quest for a safer environment, and promoting corporate accountability.

16. Clean Production Action (CPA) is a nonprofit organization that designs and delivers strategic solutions for the movement to green chemicals, sustainable materials, and healthy products. CPA partners with environmental organizations, public health advocates, labor unions, and progressive businesses to develop and build technical and policy support for clean production policies that promote products that are safer and cleaner across their life cycle.

17. The Institute for Agriculture and Trade Policy (IATP) is headquartered at 2105 First Avenue South, Minneapolis, Minnesota 55404, and has an office in Washington, District of Columbia. IATP is dedicated to policies and practices that support sustainable agriculture and development, healthy and safe food, and fair trade. IATP's interest in this lawsuit concerns hazards to both our rural and urban constituencies posed by the unregulated and unlabeled incorporation of nano-silver materials into a broad array of products, including agricultural chemicals.

Defendants

18. Defendant EPA coordinates federal environmental protection efforts and works closely with agencies in the development of environmental policies and initiatives. Pursuant to those responsibilities, EPA oversees pesticide registrations and use.

19. Defendant Gina McCarthy is sued in her official capacity as Administrator of the EPA. As Administrator, Ms. McCarthy has ultimate responsibility for EPA's activities and policies.

20. Ms. McCarthy and EPA are collectively referred to herein as EPA or the agency.

LEGAL BACKGROUND

Administrative Procedure Act

21. Under the APA, agencies must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). A "rule" is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4).

22. The APA requires an agency to conclude a matter presented to it, such as a legal petition, "within a reasonable time." *Id.* § 555(b). If an agency denies a petition in whole or in part, it must provide "[p]rompt notice" to the petitioner. *Id.* § 555(e).

23. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. "Agency action" is defined to include the "failure to act," *id.* § 551(13), such as the failure to respond to a legal petition.

24. Under the APA, courts "shall compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1), and "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," *id.* § 706(2)(A).

Federal Insecticide, Fungicide, and Rodenticide Act

25. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y, controls the manufacture, sale, and use of a broad range of chemicals and biological pest controls. As Congress explained, FIFRA's primary purpose is to protect human health and the environment. Pub. L. No. 92-516, 86 Stat. 973 (1972).

26. Pursuant to FIFRA, every pesticide must undergo registration with EPA before

distribution or sale. 7 U.S.C. § 136a(a). A "pesticide" is defined very broadly, to mean "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," *id.* § 136(u)(1); the term "pest" includes bacteria and other microorganisms, *id.* § 136(t).

27. FIFRA defines "pesticide" not in terms of the inherent characteristics of a particular substance but rather in terms of the *intent* underlying that substance's use. *Id.* § 136(u)(1). Under FIFRA, "[a] substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring regulation" where a manufacturer "claims, states, or implies (by labeling or otherwise) that the substance (either by itself or in combination with any other substance) can or should be used as a pesticide," 40 C.F.R. § 152.15(a); where an active ingredient has "has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance)" or "(2) use for manufacture of a pesticide," *id.* § 152.15(b); and where a manufacturer has "actual or constructive knowledge" that the substance "will be used, or is intended to be used, for a pesticidal purpose," *id.* § 152.15(c).

28. A pesticide is considered unregistered under FIFRA if its claims differ substantially from the claims made for the registered pesticide, or if its composition differs from the composition of the registered pesticide. 7 U.S.C. § 136j(a)(1)(B), (C). A new registration is required for a pesticide containing an active ingredient that has not been previously registered or used in a registered formulation. 40 C.F.R. § 152.403.

29. If a pesticide product contains an active ingredient that is already registered but that active ingredient has not previously been used in the manner proposed for the new product, the pesticide product requires a "new use" registration. *See id.* § 152.3 (defining "new use").

Food Quality Protection Act

30. Enacted in 1996, the Food Quality Protection Act (FQPA) amended the regulatory scheme set forth by FIFRA and the Federal Food Drug and Cosmetic Act for the movement of pesticides in interstate commerce. The FQPA requires EPA to reevaluate its safety standards for all existing pesticide tolerances using scientific risk factors resulting from "anticipated dietary exposure and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii). Pursuant to the FQPA, before granting a tolerance, EPA must assess the risks a pesticide poses to infants and children and "ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." *Id.* § 346a(b)(2)(C)(ii)(I).

Endangered Species Act

31. The Endangered Species Act (ESA) obligates federal agencies "to afford first priority to the declared national policy of saving endangered species." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978).

32. Under the ESA, federal agencies must "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat." 16 U.S.C. § 1536(a)(2). Thus, before engaging in an activity that may have direct or indirect effects on endangered species or their critical habitats, agencies must consult with federal wildlife agencies to evaluate the impact of that activity. *Id.*

33. The ESA's consultation provision applies to "all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas." 50 C.F.R. § 402.02. The concept of agency action has been given

broad application by courts and agencies, and it includes the promulgation of regulations, the granting of licenses, and actions directly or indirectly causing modifications to land, water, or air. *Id.*

National Environmental Policy Act

34. The National Environmental Policy Act (NEPA) is the "basic national charter for protection for the environment." 40 C.F.R. § 1500.1. NEPA is intended to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man." 42 U.S.C. § 4321. Recognizing the potential dangers of new technologies, Congress explicitly states in NEPA that "new and expanding technological advances" are activities that could threaten the environment. *Id.* § 4331(a). Consequently, Congress requires federal agencies to consider the environmental effects of a new technology by complying with the requirements of NEPA.

35. Under NEPA, federal agencies must consider the "reasonably foreseeable" effects of their proposed programs, projects, and regulations. 40 C.F.R. §§ 1502.4, 1508.7, 1508.8, 1508.18, 1508.25. Where knowledge of environmental impacts is lacking, NEPA requires "disclosure of the fact of incomplete or unavailable information; acquisition of that information if reasonably possible; and evaluation of reasonably foreseeable significant adverse impacts even in the absence of all information." National Environmental Policy Act Regulations; Incomplete or Unavailable Information, 51 Fed. Reg. 15,618, 15,520 (Apr. 25, 1986).

STATEMENT OF FACTS

Nanotechnology and Nanomaterials

36. Nanotechnology is a powerful new technology that takes apart and reconstructs nature at the atomic and molecular level. The nanoscale is exceedingly tiny; it is the world of

atoms and molecules, involving the manipulation of matter at the nanometer scale (nm), which is one billionth of a meter. By way of comparison, a red blood cell is approximately 7,000 nm wide; animal cells are generally 10,000 nm to 20,000 nm wide; a human hair is roughly 80,000 nm wide; and a sheet of paper is about 100,000 nm thick. A single nm is about as big in relation to an apple as the apple is in relation to the earth.

37. A nanoparticle or nanomaterial is a particle or manufactured substance that has at least one component at the nanoscale. Crucially, "nano" means more than just tiny manufacturing: it is well known that materials engineered or manufactured to the nanoscale exhibit radically different fundamental physical, biological, and chemical properties from bulk materials. Altered properties can include color, solubility, material strength, electric conductivity, and magnetic behavior. For example, a gold wedding ring is yellow in color, but gold nanoparticles appear red. Carbon (like graphite in pencil lead) is relatively soft; but carbon in the form of carbon nanotubes (nanoscale cylinders made of carbon atoms) is a hundred times stronger than steel. An aluminum soda can does not burn; however, aluminum nanoparticles explode when used as rocket fuel catalysts.

Nanomaterial Development and Commercialization

38. Over the last decade, governments worldwide have invested more than forty billion U.S. dollars in nanotechnology. In the United States alone, from fiscal years 2001–2009, federal agencies devoted over $10.5 billion to nanotechnology research. In 2012, the federal government maintained its lead in spending more on nanotechnology development than all other countries, with $2.1 billion of federal and state funding. However, government health and safety research is *less than four percent* of total government funding for nanotechnology research in the United States.

39. Nevertheless, although safety research is lacking, commercialization is well underway. For example, the international market for nanotechnology-related products is expected to total between $1 trillion and $2.6 trillion by 2015, and $4.4 trillion by 2018. Thousands of tons of nanomaterials are already produced each year.

40. Consequently, products containing nanomaterials continue to enter the market at a steady pace. A recent inventory identifies more than 1600 nano-products currently on the U.S. market.[1]

41. But these are only the self-identified products. Since no labeling is required, known nano-products likely represent only a small fraction of the actual commercialized applications. In fact, the NanoBusiness Alliance, an industry association representing the nanotechnology business community, estimates that thousands of nanotechnology-related products are not publicized by their manufacturers.

Nano-Silver Products

42. Within the growing field of commercialized nanotechnology, nano-silver has quickly become the most commonly used nanomaterial in consumer products and the fastest growing sector of nanomaterial commercialization. In fact, nano-silver is the most common nanomaterial identified in product descriptions.

43. EPA has acknowledged that the use of nano-silver as an antimicrobial agent is now widespread.[2] In fact, in their 2008 Petition, Plaintiffs pinpointed no fewer than 260

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[1] The Project on Emerging Nanotechnologies, *Consumer Products Inventory: An Inventory of Nanotechnology-Based Consumer Products Introduced on the Market*, http://www.nanotechproject.org/cpi/ (last visited Dec. 15, 2014).

[2] U.S. Envtl. Prot. Agency, *Research in Action: Nanosilver and Consumer Products*, http://www.epa.gov/heasd/research/nanosilver.html (last updated June 6, 2014) ("*Due to their anti-microbial activities, silver nanoparticles have been incorporated into many consumer products*. These products include dietary supplements, laundry detergents, body soap,

self-identified nano-silver consumer products. Now, on information and belief, Plaintiffs have identified *nearly 400 nano-silver products* on the market today.[3] And many more likely exist, since, as noted, there currently are no labeling requirements for nanoscale products. Further, several products were previously marketed as containing nano-silver but have since removed advertising or labeling noting that ingredient, likely to evade regulatory concerns.

44. As catalogued in the 2008 appendix and current inventory, examples of commercial nano-silver product types include:

- air and water purifiers and their replacement filters
- multipurpose, bathroom, and kitchen cleaning products
- sanitizing sprays
- children's toys, baby bottles, and infant products
- laundry detergents and fabric softeners
- food storage containers
- food/produce cleaners and cleaning sprays
- cutlery
- cutting boards
- various types of clothing, including underwear, socks, shirts, outerwear, gloves, and hats
- various fabrics and fibers
- refrigerators
- washing machines
- wet cleaning wipes
- hair care products, brushes, straighteners, and other hair appliances
- personal care products including creams, lotions, masks
- bandages
- razors and shaving accessories, including disposable razor blades
- pet accessories
- soaps
- ingestible "health" drink supplements
- pillows
- humidifiers

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toothbrushes, toothpaste, disinfectant sprays, kitchen utensils, clothing and children's toys.") (emphasis added).

[3] Ctr. for Food Safety, *Petition Appendix A: Nano-Silver Products Inventory* http://www.centerforfoodsafety.org/files/nano-silver_product_inventory-121614_66105.pdf (last visited Dec. 16, 2014).

- door handles
- computer keyboards and mouses
- printer ink
- shoe inserts
- toothbrushes
- air sanitizers
- showerhead filters
- automobile cleaning and waxing products
- powdered and liquid nano-silver in bulk form

45. The vast majority of companies that market nano-silver products emphasize the nano-silver ingredient, touting its antimicrobial and antibacterial qualities and making other sweeping medical claims, such as:

- "Antibacterial, Antibiotic effect"
- "eliminates 99.9% of bacteria, fungi and hundreds of other disease causing microorganisms by inhibiting multiplication and growth and preventing transfer"
- renders material "permanently anti-microbial and anti-fungal"
- "antibacterial effect against bacteria, yeasts, mold, and fungi"
- "kills bacteria in vitro in as little as 30 minutes, 2-5 times faster than other forms of silver"
- "when in contact with bacteria and fungus will adversely affect cellular metabolism and inhibit cell growth"
- "works against all types of bacteria and viruses, even killing antibiotic resistant strains as well as all fungal infections . . . remains potent up to 100 washes."

Nanotechnology's Novel Properties and Concomitant Risks

46. Nanoscale materials are being used in consumer products precisely because they differ from their bulk material counterparts in important properties—electrical, optical, magnetic, toxicity, chemical, photoreactive, persistence, bio-accumulation, and explosiveness, to list a few. These novel, patentable substances and their properties excite industry by creating new commercial potential. However, these properties also create unique human health and environmental risks, which require new health and safety testing paradigms.

47. As Swiss insurance giant Swiss Re explained, "Never before have the risks and opportunities of a new technology been as closely linked as they are in nanotechnology. It is

precisely those characteristics which make nanoparticles so valuable that give rise to concern regarding hazards to human beings and the environment alike."[4]

48. Specifically, nanomaterials differ in important ways from larger particles of the same materials. First, reduction in size to the nanoscale level results in an enormous increase of surface to volume ratio, giving nanoparticles a much greater surface area per unit mass compared to larger particles. Because growth and catalytic chemical reactions occur at the particle surface, this leads to increased potential for biological interaction and much more reactivity than in the same material made up of larger particles, as well as increased potential for toxicity, which can result in DNA mutation, structural damage within the cell, and even cell death.

49. Second, at the nanoscale, quantum physics come into play, potentially affecting *inter alia*, the optical, electrical, and magnetic behavior of materials.

50. Third, because of their tiny size, nanomaterials have unprecedented mobility in human bodies and the environment. Humans have evolved mechanisms of protection against environmental agents, but size is an important factor in the efficacy of these mechanisms. Exposure to manufactured nanoparticles, which have characteristics that humans have not previously encountered, presents new challenges to the normal defense mechanisms of the body's immune and inflammatory response systems.

51. For example, manufactured nanoparticles can enter the body and pass through biological membranes—*e.g.*, cell walls, cell tissue, and organs—more easily than larger particles. They readily enter the body via inhalation and ingestion. Once in the blood stream, nanomaterials can move around the body and accumulate in organs and tissues, including the brain, heart, liver, kidneys, spleen, bone marrow, and nervous system. Research highlights

[4] Swiss Re, *Nanotechnology: Small Matter, Many Unknowns* 37 (2004), *available at* http://www.denix.osd.mil/cmrmd/upload/swissrepubl04_nano_en.pdf.

nanoparticles' movement from the lungs into the blood stream; from the gastro-intestinal tract to other organs; and from the nose to the brain via olfactory nerves. Further, unlike larger particles, nanoparticles are transported within cells and taken up by cell mitochondria and the cell nucleus, where they can interfere with cell signaling and induce structural damage, including DNA damage.

52. Crucially, the consensus view of the scientific community is that the adverse effects of nanoparticles *cannot be reliably anticipated* based on comparisons to bulk versions of those particles. According to the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, "Experts are of the unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics."[5]

Nano-Silver's Health and Environmental Risks and Unknowns

53. Human exposure to nano-silver is increasingly widespread and invasive through, *e.g.*, clothing fibers, underwear, socks, lingerie, and hospital and lab gowns under various real life conditions (sweating, laundering, broken skin). Consequently, nano-silver continues to gain access to human tissues, cells, and biological molecules. However, the human health effects of the release of nano-silver remain to be investigated.

54. As an initial matter, silver itself has known harmful impacts, including high toxicity for fish, algae, crustaceans, plants, fungi, and bacteria. Consequently, EPA already regulates silver as a pesticide and requires labeling that states that silver pesticides are "toxic to

[5] European Comm'n Scientific Comm. on Emerging & Newly Identified Health Risks, *Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies* 6 (adopted Mar. 10, 2006), *available at* http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf.

fish and aquatic invertebrates."[6] Silver can bioaccumulate and persist in water sediment; it is toxic to freshwater and saltwater organisms and is particularly damaging to reproductive systems. In addition to silver's known impacts, nanoscale silver also exhibits remarkably unusual physical, chemical, and biological properties.

55. Nano-silver thus is potentially toxic to humans and other animals. Although there are major gaps in studying nano-silver's effects—*inter alia*, carcinogenicity, reproductive toxicity, mutagenicity, genotoxicity, neurotoxicity, developmental toxicity, endocrine activity, systemic toxicity, and organ effects—existing studies have shown the negative and toxic effects of nano-silver on mammalian cells. For example, in vitro (test tube) studies demonstrate that nano-silver is toxic to mammalian liver cells, stem cells, and even brain cells. An overwhelming majority of studies report that contact with nano-silver causes abnormalities in basic cell functions.

56. Nano-silver may also affect the liver, a major accumulation point of circulatory nano-silver, and may interfere with beneficial bacteria in the gut once ingested. Consequently, Nano-silver may also threaten human use of certain modern medicines, such as antibiotics. Although nano-silver effectively kills some pathogens, overexposure to silver nano-particles can cause other harmful organisms to rapidly adapt and flourish. And resistance traits can potentially be transferred to the genes of other microorganisms.

57. Nanomaterials are also entering the environment in numerous ways over their lifecycle. Some nano-silver will enter the environment directly over the course of products' use, including through washing machine waste water; laundry detergents and fabric softeners; multipurpose, bathroom, kitchen, and automobile cleaning products; soaps; cleaning and

[6] U.S. Envtl. Prot. Agency, *Registration Eligibility Document, Silver* 19 (1992), *available at* http://www.epa.gov/oppsrrd1/REDs/old_reds/silver.pdf.

sanitizing sprays and wipes; personal care products; dietary supplements; and powdered and liquid nano-silver in bulk form.

58. Other nano-silver products, including brushes, straighteners, and other hair appliances, bandages, food storage containers, pet accessories, various fabrics and fibers, razors and shaving accessories refrigerators, electronics, and other household appliances, will enter the environment at the end of their use during disposal. Still more nano-silver products, including clothing such as underwear, socks, shirts, outerwear, gloves, and hats; bedding, sheets, and pillows; and air and water purifiers and their replacement filters, will indirectly leach nano-silver into the environment over the course of their use, or during cleaning or washing.

59. Nano-silver products will continue to enter the environment through product manufacture, transport, use, and disposal pathways. Because these products are already available on market shelves across the country, nano-silver release is currently happening nationwide. Many nano-silver products are in "free" particle form (such as creams, lotions, and sprays), rather than "fixed" in a product matrix, speeding up ecosystem interactions. Even in a product matrix, nanomaterials are "highly durable" and will remain in nature long after the disposal of their host products. It is not known how quickly these materials will leech or dissolve into the environment as products are washed, broken, or thrown away.

60. Once in the environment, manufactured nanomaterials constitute a new class of non-biodegradable pollutants. The same unique mobility and toxicity concerns that apply to human health risks also apply to environmental risks. Potential impacts include, but are not limited to, mobility—reaching places larger particles cannot, and moving through aquifers and soils; the ability to absorb or bond to harmful chemicals and carry them places they would not otherwise reach; reactivity—interacting with natural substances to develop toxic compounds;

persistence in the environment; and bioaccumulation. Further, various studies have shown that plants can take up nanomaterials from soils, suggesting a potential route for nanomaterials in sewage waste to reenter to the human food chain. Plaintiffs' 2008 Petition identified numerous studies presenting these environmental red flags. *See* Ex. A at 58-70.

61. Nanomaterials' environmental persistence and potential for bioaccumulation are poorly understood. However, early studies suggest that microorganisms and plants may be able to produce, modify, and concentrate nanoparticles that can then bioaccumulate (or even biomagnify) within the food web. That is, once absorbed, nanoparticles may travel up the wild food chain to larger animals. In particular, the proliferation of nano-silver products makes it increasingly likely that threatened and endangered species and their critical habitats will be affected by the release of these materials.

62. Moreover, when released into the environment, nano-silver particles will likely threaten the beneficial bacteria that underpin ecosystem functions. Beneficial bacteria are important for the health of soil, plants, and animals. Once nano-silver is released into the environment, its biocidal activity is harmful and potentially deadly to beneficial microbes like bacteria and fungi, and may cause disturbances to critical ecosystems and ecological food webs. Some researchers suggest that nano-silver could damage bacterial cells by destroying the enzymes that transport the cell nutrient and weakening the cell membrane or cell wall. Other researchers believe nano-silver destroys the ability of the bacteria's DNA to replicate.

63. Once released, there is no way to recall nanoparticles. Consequently, the U.K. Royal Society has concluded, "[u]ntil more is known about their environmental impact we are keen that the release of nanoparticles and nanotubes in the environment is avoided as far as possible. Specifically, we recommend as a precautionary measure that factories and research

laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous and reduce them from waste streams . . . ."[7]

Plaintiffs' 2008 Petition

64. EPA is tasked with regulating the use of pesticidal products in order to protect human health and the environment. Pub. L. No. 92-516, 86 Stat. 973. As part of that responsibility, EPA must ensure that pesticides are registered under FIFRA. Nevertheless, although the agency has acknowledged that nano-silver products are pesticides under FIFRA, it so far has declined to regulate them as such.

65. In addition to failing to comply with FIFRA by declining to require registration of nano-silver products as pesticides, EPA has so far also failed to comply with mandates in the FQPA, the ESA, FIFRA, and NEPA that require consideration of the adverse impacts of pesticidal nano-silver products. Specifically, the agency has failed to evaluate the likely harms nano-silver poses to children, as required under the FQPA, 21 U.S.C. § 346a(b)(2)(A)(ii); to threatened and endangered species, as required under the ESA, 16 U.S.C. § 1536; and to the environment and human health, as required under NEPA, 40 C.F.R. §§ 1502.4, 1508.7, 1508.8, 1508.18, 1508.25, and FIFRA, 7 U.S.C. § 136a.

66. On May 1, 2008, Plaintiff submitted a legal petition for rulemaking to EPA urging the agency to remedy those failures. Specifically, the petition requested, *inter alia*, that EPA take the following actions:

> (1) Declare and classify nano-silver as a "pesticide" under FIFRA and require FIFRA registration for nano-silver products;
>
> (2) Clarify that nano-silver products require new pesticide registrations;

[7] Royal Soc'y & Royal Acad. of Eng'g, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* x (July 2004), *available at* http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf.

(3) Analyze the potential human health and environmental risks of nano-silver under FIFRA, the FQPA, the ESA, and NEPA;

(4) Take regulatory action to prohibit the illegal sale of nano-silver products with unapproved health claims;

(5) For any nano-silver product eventually approved through FIFRA registration, require, *inter alia*, labeling and post-registration notifications; and

(6) Take all other FIFRA actions necessary for adequate oversight of pesticidal nano-silver products.

67. On November 19, 2008, EPA opened a sixty-day public comment period in response to Plaintiffs' petition. Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Notice of Availability, 73 Fed. Reg. 69,644 (Nov. 19, 2008). On January 14, 2009, EPA extended the comment period on Plaintiffs' petition for another sixty days, until March 20, 2009. Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Extension of Comment Period, 74 Fed. Reg. 2072 (Jan. 14, 2009).

68. In the approximately six years since EPA opened that comment period, the agency still has not responded to Plaintiffs' 2008 Petition.

EPA's Ongoing Failure to Meaningfully Regulate Nanotechnology

69. EPA has itself recognized that nanotechnology poses novel risks, noting in its 2007 *Nanotechnology White Paper* that "special properties" can "cause some nanomaterials to pose hazards to humans and the environment."[8]

70. The agency has acknowledged that "at this point not enough information exists to assess environmental exposure for most engineered nanomaterials,"[9] and that the "fundamental

[8] U.S. Envtl. Prot. Agency, *Nanotechnology White Paper* 13–14 (Feb. 2007), *available at* http://epa.gov/ncer/nano/publications/whitepaper12022005.pdf.

[9] *Id.* at 14.

properties concerning the environmental fate of nanomaterials are not well understood."[10] EPA thus admits, "[t]here is a significant gap in our knowledge of the environmental, health, and ecological implications associated with nanotechnology."[11]

71. In June 2011, EPA issued a "[p]roposed policy statement" suggesting that it would presume that a nanoscale ingredient is "new" for purposes of FIFRA, and thus requires registration and safety testing. Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. 35,383, 35,384, 35,392, 35,393 (June 17, 2011). EPA clarified that its proposed statement on classifying nanoscale ingredients was merely a non-binding policy, and that the policy would permit the agency to waive, at its discretion, the presumption that a nano-ingredient is "new" under FIFRA. *Id.* at 35,393.

72. Several months later, in December 2011, a report by EPA's Office of Inspector General (OIG) titled *EPA Needs to Manage Nanomaterial Risks More Effectively* concluded the following: "EPA does not currently have sufficient information or processes to effectively manage the human health and environmental risks of nanomaterials. EPA has the statutory authority to regulate nanomaterials but currently lacks the environmental and human health exposure and toxicological data to do so effectively."[12]

73. Specifically, according to that OIG report,

> At the time of our review, EPA did not have sufficient information or processes to effectively manage the human health and environmental risks of nanomaterials. *EPA does not have a formal process to coordinate the dissemination and utilization of nanomaterial information or communicate nanomaterial risks*. . . . Finally, technological limitations inhibit nanomaterial detection in the environment, and a reliance on industry data impedes effective nanomaterial

[10] *Id.* at 33.
[11] *Id.* at 52.
[12] U.S. Envtl. Prot. Agency, Office of Inspector General, *EPA Needs to Manage Nanomaterial Risks More Effectively* 1 (Dec. 29, 2011), *available at* http://www.epa.gov/oig/reports/2012/20121229-12-P-0162.pdf.

> management. *If these challenges are not resolved, EPA will continue to lack assurance that it is making effective nanomaterial management decisions*.[13]

74. Nevertheless, as of the present date, EPA still has not finalized even its toothless 2011 "[p]roposed policy statement" on nano-products. *See* Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. at 35,383.

75. EPA has, however, acknowledged that it has pesticide authority over nano-silver under FIFRA—but only by bringing piecemeal enforcement actions. For example, in March 2014, EPA sent a warning letter to a company advertising nano-silver-containing food packaging as antibacterial, explaining to the company that such claims were unlawful because the product was not registered as a pesticide under FIFRA.[14] EPA also ordered various companies that had sold the product—including behemoths like Amazon, Sears, and Wal-Mart—to stop.[15]

76. Similarly, in August 2014, EPA took enforcement action against a company that advertised unregistered nano-silver shoe inserts as antibacterial, fining the company more than $200,000 for unsubstantiated claims because, under FIFRA, those products were pesticides and should have been registered before sale or distribution.[16]

77. To summarize, EPA's proposed guidance and singular enforcement actions are utterly inadequate to fulfill the agency's statutory duties with regard to protecting health and the

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[13] *Id.* at 9 (emphases added).

[14] *See* U.S. Envtl. Prot. Agency, *EPA Takes Action to Protect Public from an Illegal Nano Silver Pesticide in Food Containers; Cites NJ Company for Selling Food Containers with an Unregistered Pesticide Warns Large Retailers Not to Sell These Products* (Mar. 31, 2014), http://yosemite.epa.gov/opa/admpress.nsf/0/6469952cdbc19a4585257cac0053e637?OpenDocument.

[15] *Id.*

[16] *See* U.S. Envtl. Prot. Agency, *U.S. EPA Settles with Calif. Shoe Insert Companies for Unsubstantiated Product Claims* (Aug. 12, 2014), http://yosemite.epa.gov/opa/admpress.nsf/0/CC8BF8D3F4C6F5F385257D3200642A61.

environment from the impacts of nano-pesticides. EPA has failed to provide legal clarity regarding its oversight of these substances and the FIFRA registration duties they require; has failed to exercise its own FIFRA authority over nano-pesticides as a class, by requiring registrations and adequate pre-market testing for human health and environmental effects; has failed to undertake the data and analysis of these impacts that government and the scientific community all warn is needed. These failings are made all the more egregious given that the agency has had a legal blueprint and impetus to take regulation action before it since 2008, in the form of Plaintiffs' petition, and given that the agency is well aware that there are hundreds of nano-silver products currently commercially available.

EPA's Failure to Respond to the 2008 Petition

78. More than six years have passed since Petitioners filed their 2008 legal petition demanding that EPA use its pesticide regulation authority to regulate the hundreds of known consumer products already using nano-silver. Yet EPA still has not responded to that petition.

79. In the wake of EPA's inaction, on information and belief, hundreds of new pesticidal nano-silver products have come on the market, potentially further endangering human health and the environment.

Harm to Plaintiffs

80. EPA's unlawful delay in responding to Petitioners' 2008 Petition injures Plaintiff organizations by, *inter alia*, denying them important and urgently needed information about EPA's oversight of pesticidal nano-silver products in the form of a petition response—a response to which the petitioners are statutorily entitled under the APA. By denying Petitioners the vital and urgent information in a petition response, EPA's failure to respond to the 2008 Petition has violated Petitioners' procedural and substantive rights under the APA.

81. Additionally, EPA's failure to act on the petition directly harms Plaintiffs' concrete organizational interests by impeding their abilities as public interest nonprofit organizations to facilitate public involvement in governmental decision-making, and by foreclosing the statutory right that allows for public participation through petitions for rulemaking. As such, EPA's failure to act has effectively negated Plaintiffs' right to petition a federal agency for rulemaking under the APA.

82. Further, EPA's continued failure to respond to the 2008 Petition deprives Plaintiff organizations of a decision on the Petition's merits and, if necessary, the opportunity to seek judicial review of EPA's final decision.

83. Plaintiffs' members' concrete interests in their health and environmental protection, are being and will be adversely affected by EPA's continued failure to respond to the 2008 Petition. Specifically, Plaintiffs' members are suffering or will suffer an ongoing threat to their health, their children's health, and the health of their environment and their recreational and aesthetic interests in it, as long as EPA continues to fail to regulate pesticidal nano-silver products.

84. The requested relief will redress these harms by requiring EPA to respond to the Petition, resulting either in a response that fulfills EPA's statutory duties by protecting public health and the environment from the risks of pesticidal nano-silver products, and/or a final agency action that Plaintiffs may challenge if they disagree with the agency's response, in whole or in part. Both results would provide Plaintiff organizations with APA-mandated information, securing their procedural right to receive a timely response to a legal petition for rulemaking and safeguarding their members' interests.

CLAIM FOR RELIEF

85. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 84 *supra*.

86. EPA is an "agency" under the APA. *See* 5 U.S.C. §§ 551(1), 701(b)(1). The APA requires agencies to "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." *Id.* § 553(e); *see id.* § 551(4) (defining "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"). The APA right to petition encompasses the right to petition for a new, revised, or final rule concerning EPA oversight of nanotechnologies such as nano-silver. *See id.* §§ 551, 553(e).

87. Upon receipt of an APA petition, EPA has a duty to provide a timely response to the petitioners. *Id.* § 555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person . . ."). Such response must be substantive—*i.e.*, it must either grant or deny the petition.

88. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. Plaintiffs and their members are adversely affected by EPA's past and continued failure to respond to the 2008 Petition.

89. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1). EPA's failure to respond to and take action on the 2008 Petition constitutes unlawfully withheld and unreasonably delayed agency action.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

(1) Declaring that EPA has violated the APA by failing to provide a timely response to the 2008 Petition;

(2) Declaring that EPA continues to be in violation of the APA by failing to respond to the 2008 Petition;

(3) Ordering EPA to respond to the 2008 Petition as soon as reasonably practicable;

(4) Retaining jurisdiction of this action to ensure compliance with this Court's decree;

(5) Awarding Plaintiffs attorneys' fees and all other reasonable expenses incurred in pursuit of this action; and

(6) Granting other such relief as the Court deems just and proper.

Respectfully submitted this 16th day of December 2014,

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