International Center for Technology Assessment

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CITIZEN PETITION FOR RULEMAKING TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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et al.,

Petitioners,

Filed With:

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Docket Number _____

PETITION FOR RULEMAKING REQUESTING EPA REGULATE NANO-SILVER PRODUCTS AS PESTICIDES

Introduction

Nanotechnology and products containing manufactured and engineered nanomaterials have arrived and represent the crest of a product wave spanning many industries. A rapidly expanding universe of products containing nanomaterials is currently widely available, being

sold to the public and disposed of into the environment. These new materials can have fundamentally different properties from their bulk material counterparts–properties that also create unique human health and environmental risks–which create new oversight challenges for the regulatory agencies charged with protecting public health and the environment. A large and increasing percentage of the currently known commercial nanomaterial products are infused with forms of nanoparticle silver ("nano-silver") for its nano-enhanced ability to kill microorganisms and bacteria. While the risks of nano-silver to the environment and human health are not well understood, existing studies have indicated cause for concern, such as harmful impacts on fish and aquatic ecosystems, potential interference with beneficial bacteria in our bodies and the environment, and the potential development of more virulent harmful bacteria.

EPA has recognized that its oversight of materials pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") will include the oversight of pesticide products containing nanomaterials ("nano-pesticides"). Despite the explosion of nano-silver products on the market implicating that jurisdiction, the agency has yet to take any meaningful steps pursuant to FIFRA or other applicable statutes to address the human health and environmental impact challenges created by nanomaterials generally or nano-silver products specifically. While not conventional agricultural pesticides, these nano-silver products meet FIFRA's definition of pesticides as substances intended to kill pests such as microorganisms. EPA's Region 9 office recently took action against a manufacturer of a nano-silver product for FIFRA violations, a precedent-setting action that strongly supports the legal arguments outlined in this petition on a broader scale. Petitioners call on EPA to immediately take the steps necessary to properly regulate nano-silver products as pesticides pursuant to FIFRA and other applicable statutes. This legal petition provides both the blueprint and the legal impetus to take such regulatory actions.

Accordingly, pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,[1] the Administrative Procedure Act ("APA"),[2] and EPA's FIFRA-implementing regulations,[3] the undersigned submit this citizen petition for rulemaking and collateral relief pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551 et seq., the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136w et seq., the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 et seq., the Food Quality Protection Act ("FQPA"), 21 U.S.C. §§ 346 et seq., the Endangered Species Act ("ESA"), 16 U.S.C. §§ 1531 et seq., and the National Environmental Policy Act ("NEPA"), 42 U.S.C. §§ 4321 et seq.

ACTIONS REQUESTED

PETITIONERS REQUEST THAT THE EPA ADMINISTRATOR UNDERTAKE THE FOLLOWING ACTIONS:

I. Classify Nano-silver As a Pesticide and Require the Registration of Nano-silver Products as Pesticides

II. Determine That Nano-silver is a New Pesticide That Requires a New Pesticide Registration

III. Analyze the Potential Human Health and Environmental Risks of Nano-silver

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[1] U.S. Const., amend. I. ("Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances."). The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. United Mine Workers of Am., Dist. 12 v. Illinois State Bar Ass'n, 389 U.S. 217, 222 (1967). It shares the "preferred place" accorded in our system of government to the First Amendment freedoms, and has a sanctity and a sanction not permitting dubious intrusions. Thomas v. Collins, 323 U.S. 516, 530 (1945). "Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger." Id. The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. United States v. Cruikshank, 92 U.S. (2 Otto) 542, 552 (1875).

[2] 5 U.S.C. § 553(e) (2005) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.").

[3] See e.g., 40 C.F.R. Chapter I, Subchapter E Pesticide Programs.; 40 C.F.R. § 152.40 (application for new registration of a pesticide product); id. § 154.10 (petition to begin Special Review process); id. Part 158 (pesticide class-specific changes to data requirements); id. § 158.5(data requirements for petition to establish tolerance under FFDCA 408) Part 158 (pesticide class-specific changes to data requirements); 21 U.S.C. § 346a(d) (petition for setting tolerance).

A. *Pursuant to FIFRA, Analyze the Potential Human Health and Environmental Impacts as Part of the Nano-silver Pesticide Registration Process*

B. *Pursuant to the FQPA, Assess the Potential Impacts of Nano-silver Exposures on Infants and Children and Ensure that No Harm Will Result From Aggregate Exposures*

C. *Compliance with the ESA, Including Undertaking Consultation Procedures In Accordance with ESA § 7 for Any EPA Actions, Activities, or Programs Impacting Nano-silver Oversight*

D. *Compliance with NEPA, Including Assessing the Human Health and Environmental Impacts of EPA's Current and Future Actions or Programs Regarding Nano-silver, Including Completing a Programmatic Environmental Impact Statement*

IV. Take Regulatory Actions against the Class of Nano-silver Products Illegally Sold Without EPA FIFRA Approval, Including Issuing Stop Sale, Use or Removal Orders for Illegal and Unlabeled Nano-silver Pesticide Products

V. If any Nano-silver Pesticide Registration is Approved, Apply and/or Amend to Specifically Apply the FIFRA Pesticide Requirements to the Class of Nano-silver Pesticides, Including

1. *Labeling*
2. *Post-Registration Notification of Adverse Effects*
3. *Post-Registration Testing and New Data Development*
4. *Conditional Registration*
5. *Confidential Business Information*

VI. Take Other EPA FIFRA Actions Necessary for Adequate Oversight of Nano-silver Pesticides, Including:

1. *Undertaking a Classification Review of Nano-silver Pesticides*
2. *Undertaking a Special Review of Nano-silver Pesticides*
3. *Requiring the Submission of Nano-specific Data from Nano-silver Registrants*
4. *Amending FIFRA Regulations to Require Nano-Specific Data*
5. *Registration Review of Existing Bulk Silver Pesticide Registration*
6. *Regulate Nano-silver Devices*
7. *Set a Pesticide Tolerance for Nano-silver*

PETITIONERS

Petitioner **The International Center for Technology Assessment** ("CTA") is located at 660 Pennsylvania Ave., S.E., Suite 302, Washington, DC 20003. Formed in 1994, CTA seeks to assist the public and policy makers in better understanding how technology affects society. CTA is a non-profit organization devoted to analyzing the economic, environmental, ethical, political, and social impacts that can result from the application of technology or technological systems. CTA works towards adequate oversight of nanotechnology through its Nanotechnology Project, *NanoAction*.

Petitioner **The Center for Food Safety** ("CFS") is located at 660 Pennsylvania Ave., S.E., Suite 302, Washington, DC 20003 and 2601 Mission Street, Suite 803, San Francisco, CA 94110. CFS is a non-profit public interest and environmental advocacy membership organization established in 1997 by its sister organization, International Center for Technology Assessment, for the purpose of challenging harmful food production technologies and promoting sustainable alternatives.

Petitioner **Beyond Pesticides** is located at 701 E Street, SE, Suite 200, Washington, DC 20003. Founded in 1981, Beyond Pesticides is a non-profit membership organization that serves a nationwide network and works to reduce threats to human health and environmental quality from the use of hazardous pesticides. Beyond Pesticides' primary goal is to educate and advocate for the adoption safe pest management practices and products.

Petitioner **Friends of the Earth** ("FOE") is located at 1717 Massachusetts Avenue, NW, Suite 600, Washington, DC 20036. FOE is a non-profit organization that seeks to create a more healthy, just world. FOE is the U.S. voice of Friends of the Earth International, the world's

largest federation of democratically elected grassroots environmental groups, located in 70 countries.

Petitioner **Greenpeace** is located at 702 H Street, N.W. Suite 300, Washington, D.C. 20001. Greenpeace was founded in 1971 and has 250,000 members in the U.S. and 2.5 million worldwide. Greenpeace is an independent campaigning organization that uses peaceful direct action and creative communication to expose global environmental problems and promote solutions that are essential to a green and peaceful future.

Petitioner **The Action Group on Erosion, Technology and Concentration** ("ETC Group") is an international civil society organization headquartered in Canada, with offices in the USA and Mexico. ETC Group is dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights. To this end, ETC Group supports socially responsible developments in technologies useful to the poor and marginalized, and it addresses governance issues affecting the international community. ETC Group also monitors the ownership and control of technologies and the consolidation of corporate power.

Petitioner **Center for Environmental Health** ("CEH") is located at 528 61st Street, Suite A, Oakland, CA 94609. Founded in 1996, CEH is a non-profit 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 corporate accountability.

Petitioner **Silicon Valley Toxics Coalition** ("SVTC") is located at 760 North First Street, San Jose CA, 95112. SVTC is a diverse grassroots coalition that engages in research, advocacy, and organizing around the environmental and human health problems caused by the rapid growth of the high-tech electronics industry. SVTC is interested in incorporating a precautionary

approach and the appropriate regulatory structure to emerging technologies, such as nanotechnology, that have the potential for tremendous good as well as devastating harm to human health and the environment.

Petitioner **Institute for Agriculture and Trade Policy** ("IATP") is headquartered at 2105 First Avenue South, Minneapolis, Minnesota 55404, and has an office in Geneva, Switzerland. IATP is dedicated to policies and practices that support sustainable agriculture and development, healthy and safe food, and fair trade. IATP's interest in the petition 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.

Petitioner **Clean Production Action** ("CPA") is a non-profit organization registered in the US. CPA's 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 the use of products that are safer and cleaner across their life cycle.

Petitioner **Food & Water Watch** is a national non-profit public interest consumer organization, based in Washington, D.C. that works to ensure safe food and clean water. FWW has worked on many emerging technologies that impact our food supply, by educating consumers, the media, and policymakers about the impact on the food system and public health and by calling for appropriate regulation.

Petitioner **Loka Institute** is located at 736 Bonita Dr., South Pasadena, California 91030. The Loka Institute was founded as a 501(c)3 non-profit organization in 1996 to advocate for

making research, science and technology responsive to democratically-decided social and environmental concerns.

Petitioner **The Center for the Study of Responsive Law** ("CSRL") is located in Washington, DC and contacted at P.O. Box 19367, Washington, DC 20036. CSRL is a non-profit organization that supports and conducts a wide variety of research and educational projects to encourage the political, economic and social institutions of this country to be more aware of the needs of the citizen-consumer. The Center serves to empower citizens, guard the environment, protect consumers and monitor worker health and safety issues.

Petitioner **Consumers Union** is an independent, nonprofit testing, and information organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants.

FACTUAL BACKGROUND

Nanotechnology

Nanotechnology is a powerful new platform technology for taking apart and reconstructing nature at the atomic and molecular level.[4] The nano-scale is exceedingly tiny; it

[4]The National Nanotechnology Initiative (NNI) defines nanotechnology as

> the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.

is the world of atoms and molecules, involving the manipulation of matter at the nanometer scale (nm), one billionth of a meter.[5] "Nano" means more than just tiny manufacturing: It is well-known that materials engineered or manufactured to the nano-scale exhibit radically different fundamental physical, biological, and chemical properties from bulk materials.[6]

One reason for these fundamentally different properties is that quantum physics comes into play at the nano-scale.[7] Another is that the reduction in size to the nano-scale results in an enormous increase of surface to volume ratio, giving nanoparticles a much greater surface area per unit of mass compared to larger particles.[8] Because growth and catalytic chemical reactions occur at the particle surface, a given mass of nanoparticles will have an increased potential for biological interaction and be much more reactive than the same mass made up of larger particles, thus enhancing intrinsic toxicity.[9] This enormous increase in surface area can change relatively inert substances into highly reactive ones. A material in nano-scale form can then melt faster, absorb more, or simply become more explosive.

Thus, to say that a substance is "nano" does not merely mean that it is tiny, a billionth of a meter in scale; rather, the prefix is best understood to also mean that a substance has the capacity to act in fundamentally different ways. Altered properties can include color, solubility,

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National Nanotechnology Initiative, Factsheet: What Is Nanotechnology?, http://www.nano.gov/html/facts/whatIsNano.html; 15 U.S.C. 7501-7509; Id. § 7509 (definitions).

[5] For illustration, a hydrogen atom is about .1 nm. A DNA molecule, which carries genetic information in the cell nucleus, is about 2.5 nm long. A human hair is huge by comparison, about 50,000 nm thick; the head of a pin is about 1 million nm across. A sugar molecule, which measures about 1 nm, is about as big in relation to an apple as the apple is in relation to the earth.

[6] National Nanotechnology Initiative, *What is Nanotechnology?*, at http://www.nano.gov/html/facts/whatIsNano.html.

[7] Nanotechnology Now, *Nanotechnology Basics*, at http://www.nanotech-now.com/basics.htm.

[8] See, e.g., Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622 (2006). For example, a gram of nanoparticles has a surface area of a thousand square meters.

[9] See, e.g., European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*, adopted September 28-29, 2005; Warheit, D.D., *Nanoparticles: Health impacts?*, 7 MATERIALS TODAY 32-35 (2004).

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 (nano-scale 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.

The Human Health and Environmental Risks of Nanomaterials

Just as the size and chemical characteristics of engineered nanoparticles can give them unique properties, those same new properties—tiny size, vastly increased surface area to volume ratio, high reactivity— can also create unique and unpredictable human health and environmental risks.[10] Swiss Insurance giant Swiss Re noted that, "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."[11] A growing number of peer-reviewed scientific studies have demonstrated the potential for nanomaterials to present serious toxicity risks for human health and ecosystems.[12] Manufactured nanomaterials move excessively through the environment and have the potential to enter living cells and the environment in ways their larger counterparts do not. For example, the human body absorbs nanomaterials more readily than larger sized particles and nanoparticles cross biological membranes that larger sized particles normally cannot, such as the blood-brain barrier. In addition, research has shown that

[10] See, e.g., Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622-27, 622, 623 Fig. 1 (2006); see generally Florini et al., *Nanotechnology: Getting It Right the First Time*, 3 NANOTECHNOLOGY L. & BUS. 38, 41-43 (2006).
[11] Swiss Re, *Nanotechnology-Small Matter, Many Unknowns*, (2004), at 17.
[12] See infra pp. 57-95 and accompanying footnotes.

many types of nanomaterials can be toxic to human tissue and cell cultures, resulting in increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death.[13]

Once loose in nature, these nanomaterials represent a new class of manufactured non-biodegradable pollutants. Nanomaterials' unique chemical and physical characteristics create foreseeable environmental risks, including potentially toxic interactions or compounds, absorption and/or transportation of pollutants, durability or bioaccumulation, and unprecedented mobility for a manufactured material.[14] Because of their tiny size, nanomaterials may be highly mobile and travel further than larger particles in soil and water. Because nanoparticles tend to be more reactive than larger particles, interactions with substances present in the soil could lead to new and possibly toxic compounds. Environmental impact studies have raised some red flags, including dangers from nano-silver to aquatic life; however, despite rapid nanomaterial commercialization, many potential risks remain dangerously untested due to the government's failure to prioritize and adequately fund environmental impact research.[15] In addition, nanomaterials' unique chemical and physical characteristics create foreseeable, yet unexplored, risks. For example, nanoparticles are the subject of vigorous drug research because of their ability to carry and deliver drugs to specific targets. But this same transport propensity could give nanoparticles the ability to carry toxic chemicals present in the environment.

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[13] See generally International Ctr. for Technology Assessment, "Petition Requesting FDA Amend its Regulations for Products Composed of Engineered Nanoparticles Generally and Sunscreen Drug Products Composed of Engineered Nanoparticles Specifically," Docket No. 2006P-0210 (filed May 17, 2006), available at http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf

[14] See generally pp. 86-91 infra and accompanying footnotes.

[15] Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Press Release, *Nanotechnology Development Suffers from Lack of Risk Research Plan, Inadequate Funding & Leadership*, September 21, 2006, at http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.item&news_id=201894

Nanomaterials in Consumer Products: The Future Is Now

Nanotechnology and its material creations are no longer future predictions; they have arrived. Funding is astronomical: global nanotech research and development (R&D) is estimated at around $9 billion, with $1 trillion in U.S. dollars globally estimated by 2015.[16] Investments in federally funded nanotechnology activities coordinated through the National Nanotechnology Initiative (NNI) were approximately $1.3 billion in 2006, and about $2 billion annually of R&D investment is currently being spent by non-federal sectors such as states, academia, and private industry. State governments spent an estimated $400 million on facilities and research aimed at the development of local nanotechnology industries in 2004. Unfortunately, only a paucity of this robust federal funding--4% of the NNI's FY07 budget--was earmarked for environmental health and safety (EHS) research.[17] Other non-governmental estimates put the EHS funding number as actually closer to 1%.[18]

Nanotechnology commercialization is moving forward at lightning speed. Thousands of tons of nanomaterials are already being produced each year.[19] Many materials can be engineered into nanomaterials or nanoparticles with the most common being silver, carbon, zinc, silica, titanium dioxide, gold, and iron.[20] Consumer products containing nanomaterials have been in, and continue to enter, the market at a steady pace. According to Lux Research's 2006

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[16] See, e.g., Lux Research, *The Nanotech Report, 4th Edition*, 2006, http://luxresearchinc.com/TNR4_TOC.pdf

[17] See, e.g., International Center for Technology Assessment, *Congressional Letter on NNI 2006 Budget*, available at http://www.icta.org/doc/nano%20approp%20letter_Feb_2006.pdf

[18] Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Press Release, *Nanotechnology Development Suffers from Lack of Risk Research Plan, Inadequate Funding & Leadership*, September 21, 2006, at http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.item&news_id=201894

[19] See, e.g., The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, July 2004, pp. 26-27 & Table 4.1, available at http://www.nanotec.org.uk/finalReport.htm (hereafter Royal Society Report).

[20] Lloyd's of London, Risks: Lloyd's Emerging Risks Team Report, *Nanotechnology Recent Developments, Risks and Opportunities*, at 10, 2007.

Nanotechnology Report, more than $32 billion in products incorporating nanotechnology were sold last year, more than double the previous year.[21] Lux predicts that by 2014, $2.6 trillion in manufactured products will be nano-products, 15% of total global manufacturing.

The only publicly available nanomaterial product inventory shows approximately 600 currently available on U.S. market shelves.[22] Since its launch in early 2006 the database shows an addition of about one new product every working day.[23] The nano-products found include: paints, coatings for numerous products, sunscreens, medical devices, sporting goods, cosmetics, stain-resistant clothing, supplements, nanoceuticals, and vitamins, food and food packaging, kitchen and cooking ware, light emitting diodes used in computers, cell phones, and digital cameras, film and photo development products, automotive electronics, automotive exteriors, batteries, fuel additives, and tires, computer accessories, children's toys and pacifiers, laundry detergent and fabric softeners, personal hygiene products, cleaning agents, air conditioning units, pet products, jewelry, bedding and furniture, lubricants and foams, waxes, MP3 players and other electronics.[24] But because there are no labeling requirements for products containing nanomaterials, the total number and range of nano-products is unknown.

Nano-silver Products

Nano-silver has quickly become the most commonly used nanomaterial in consumer products and the fastest growing sector of nanomaterial commercialization. The use of nano-silver as an antimicrobial agent is now widespread, with a wide variety of products now on market shelves. The petitioners discovered no fewer than 260 self-identified nano-silver

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[21] See, e.g., Lux Research, 2006, http://luxresearchinc.com/TNR4_TOC.pdf
[22] The Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, *Nanotechnology Consumer Products Inventory*, available at http://www.nanotechproject.org/consumerproducts
[23] March 2006: over 200 products; December 2007: 600 products.
[24] Id.

consumer products, which are listed in Appendix A. These are just the products that are self-identified and many more likely exist since there are currently no labeling requirements. In addition, several of the products were previously marketed as containing nano-silver but have removed advertising or labeling noting that ingredient.[25]

The numerous nano-silver products found 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
- numerous 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
- door handles
- computer keyboards and mouses
- printer ink
- shoe inserts
- toothbrushes
- air sanitizers
- showerhead filters
- automobile cleaning and waxing products

[25] See pp. 36-37 infra.

- powdered and liquid nano-silver in bulk form[26]

The nano-silver products' countries of origin include the U.S., U.K, Canada, Korea, Japan, Taiwan, China, New Zealand, and Germany.[27] The vast majority of the companies market their nano-silver products putting emphasis on the nano-silver ingredient, touting its antimicrobial and antibacterial qualities, as well as making other sweeping medical claims, including:

- "Antibacterial, Antibiotic effect"
- "eliminates 99.9% of bacteria, fungi and hundreds of other disease causing microorganisms by inhibiting multiplication and growth and preventing transfer"
- "long lasting antibacterial function"
- renders material "permanently anti-microbial and anti-fungal"
- "eliminates the growth of one-celled organisms (such as bacteria and viruses) by deactivating the organism's oxygen metabolism enzymes"
- "antibacterial effect against bacteria, yeasts, mould, and fungi"
- "clinically proven to fight against harmful bacteria"
- "lasting antiseptic that can exterminate bacteria in a short time"
- "can kill and prevent all kinds of disease germs and microorganisms"
- "is proven to kill over 99% of bacteria including MRSA"
- "kills bacteria in vitro in as little as 30 minutes, 2-5 times faster than other forms of silver"
- "kills approximately 650 kinds of harmful germs and viruses with a germ resistance rate of 99.9%"
- "control air free from bacteria, virus, germs, fungus, or even A.I. (Avian Influenza)"
- "can kill and prevent all kinds of disease germs and microorganisms"
- "naturally kills most of bacteria, mold, and germs . . . sterilization benefits for over 650 types of bacteria like "E. coli, S. Aureus, Pneumococcus, Salmonella, Typhus, Vibria, Cholerae, etc."
- "natural bacteriostat"
- "instant knockdown of bacteria & virus"
- "deactivate enzymes and proteins of bacteria from surviving on the surface of the product
- "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."
- "sterilizes bacteria of over 650 species."

[26] See Appendix A.
[27] Id.

- "sterilize up to 99.9% of harmful bacteria, such as colon bacilli, salmonella, yellow staphylococcus, pseudomonas aeruginosa and salmonella enteritidis."[28]

Nano-silver Risks

Simultaneously with this product explosion, research has mounted to indicate that nano-silver materials pose serious risks to human health and the environment.[29] Even in its bulk form, silver is extremely toxic to fish and other aquatic species.[30] At the nano-scale, nano-silver can be many times more toxic.[31] Because nanoparticles of silver have a greater surface area than larger particles of silver, nano-silver is more chemically reactive and more readily ionized than silver in larger particle form.[32] Nano-silver therefore has greater antibacterial and toxic effects compared to larger silver particles partly because it is more readily converted to silver ions. There is also preliminary evidence that nano-silver can exert effective antibacterial action at a considerably lower concentration than that of silver ions, suggesting that the antibacterial properties and toxicity of nano-silver are not explained only by its chemical composition and by the production of silver ions alone.[33]

While the long-term potential impacts of widespread nano-silver use and disposal are unknown, an increasing number of studies have raised warnings regarding potential toxic effects on human health and the environment.[34] Recent research found that washing nano-silver impregnated clothing caused substantial amounts of nano-silver to leech into the discharge wastewater and eventually into the environment.[35]

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[28] See Appendix A.
[29] See pp. 58-72, 74-76, 82-84 & 86-91 infra and accompanying footnotes.
[30] See infra pp. 59-60, 82-84 and accompanying footnotes.
[31] See infra pp. 58-59, 60-62, 82-83 and accompanying footnotes.
[32] Id.
[33] See note 29 supra.
[34] See pp. 55-68, 80-86 infra and accompanying footnotes.
[35] See infra pp. 66-67 and accompanying footnotes.

At the nano-scale, silver exhibits remarkably unusual physical, chemical and biological properties.[36] Physical characteristics of nanomaterials, such as shape, size, and surface properties, can exert a toxic effect that goes beyond their chemical composition.[37] Research has demonstrated that nano-silver produce reactive oxygen species (ROS), resulting in oxidative stress toxicity; ROS production is a key mechanism for nanomaterials toxicity. Nano-silver can cause toxicity at a cellular level in mammals and other organisms and has the potential to disrupt key cellular functions.[38] Environmental release and accumulation of nanosilver can also have negative impacts on beneficial bacteria important for soil, plant, and animal health.[39]

Studies have also shown that nanosilver may potentially compromise our ability to control harmful bacteria by creating increased antibiotic resistance which may have an overall negative impact on human health.[40] The powerful antibacterial and toxic effects of nano-silver are of significant concern given that the burgeoning use of nano-silver in disinfectants and other consumer products is likely to result in both human and environmental systems facing greater overall exposures.

PROCEDURAL HISTORY

EPA's Stated Positions on Nanotechnology and Nanomaterials, including Nanosilver

Based on the National Nanotechnology Initiative's ("NNI") definition, EPA has informally defined nanotechnology as

> research and technology development at the atomic, molecular, or macromolecular levels using a length scale of approximately one to one hundred

[36] See infra pp. 8-10, 42-46, 49-51, 87-91 and accompanying footnotes.
[37] Id.
[38] See infra pp. 60-73 and accompanying footnotes.
[39] See infra pp. 66-69 and accompanying footnotes.
[40] See infra pp. 64-66 and accompanying footnotes.

> nanometers in any dimension; the creation and use of structures, devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale.[41]

In its 2007 "White Paper" on nanotechnology, EPA notes that nanomaterials' "special properties" can "cause some nanomaterials to pose hazards to humans and the environment, under specific conditions."[42] EPA believes that "at this point not enough information exists to assess environmental exposure for most engineered nanomaterials"[43] and that "the fundamental properties concerning the environmental fate of nanomaterials are not well understood."[44] There are numerous sources of potential direct and indirect nanomaterial release into the environment, including, *inter alia*, "releases resulting from the use and disposal of consumer products containing nanoscale materials."[45] The "high durability and reactivity of some nanomaterials raise issues of their fate in the environment."[46] Many nanoparticles in current products are non-biodegradable materials (such as metal oxides used in sunscreens) and are not expected to biodegrade.[47] EPA has noted that "the use of nanomaterials in the environment may result in novel by-products or degradates that also may pose risks."[48] EPA has also noted that "nanomaterials may affect aquatic or terrestrial organisms differently than larger particles of the same materials."[49] In general, EPA acknowledges that "there is a significant gap in our

[41] Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 5, (February 2007).
[42] Id. at 13-14.
[43] Id. at 14.
[44] Id. at 33.
[45] Id. at 33.
[46] Id. at 14.
[47] Id. at 36.
[48] Id. at 58.
[49] Id.

knowledge of the environmental, health, and ecological implications associated with nanotechnology."[50]

With regards to "current intentionally produced" nanomaterials, EPA White Paper specifically lists as one category that expressly includes nano-silver:

> (2) Metal-based materials. These nanomaterials include quantum dots, nanogold, **nanosilver** and metal oxides, such as titanium dioxide.[51]

In addition, the EPA White Paper lists examples of products that "use nanotechnology and nanomaterials," that include "wound dressing," "antibacterial socks," "antimicrobial pillows," and "antimicrobial refrigerator,"[52] which are all nano-silver products.[53]

EPA's Stated Position on FIFRA Authority and Pesticide Products Containing Nanomaterials

EPA has recognized that nanotechnology and nanomaterials do and will impact various statutory regimes under its authority, including FIFRA.[54] Specifically with regard to its statutory authority pursuant to FIFRA, EPA has said

> Pesticide products containing nanomaterials will be subject to FIFRA's review and registration requirements. In addition, to the extent that the use of pesticide products containing nanomaterials results in residues in food, the resulting residues require the establishment of a tolerance (maximum allowed residue limit) under the Federal Food, Drug, and Cosmetic Act. [55]

EPA has further stated that in response to the "rapid emergence" of nano-pesticides, the Office of Pesticide Programs (OPP) is currently studying the issue in order to develop policy and evaluating its FIFRA regulatory authority for nano-pesticides:

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[50] Id. at 52.
[51] Id. at 8 (emphasis added).
[52] Id. at 11 Table 1.
[53] See Appendix A.
[54] EPA, Nanotechnology, at http://es.epa.gov/ncer/nano/ EPA, Science Policy Council, *Nanotechnology White Paper*, February 2007, at http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf (hereafter EPA White Paper).
[55] EPA White Paper, supra note 41 at 66.

> [M]embers of the pesticide industry have engaged the Office of Pesticide Programs (OPP) regarding licensing/registration requirements for pesticide products that make use of nanotechnology. In response to the rapid emergence of these products, OPP is forming a largely intra-office workgroup to consider potential exposure and risks to human health and the ecological environment that might be associated with the use of nano-pesticides. Specifically, the workgroup will consider whether or not existing data are sufficient to support additional yet undefined testing. The workgroup will consider the exposure and hazard profiles associated with these new nano-pesticides on a case-by-case basis and ensure consistent review and regulation across the program.[56]

In the interim, voluntary "pre-submission conferences" between companies manufacturing pesticides using nanotechnology and Agency staff are being held.[57] EPA's Office of Pesticide Programs has declined further requests to discuss its ongoing efforts to develop policies for pesticides designed with nanotechnologies.[58]

Concerns Raised over the Samsung Silvercare™ Washing Machine

In early 2006, EPA received letters from both the National Association of Clean Water Agencies (NACWA) and Tri-TAC, a technical advisory group for Publicly Owned Treatment Works in California, expressing concern with the growing number of household products that use pesticides such as nano-silver for general antimicrobial purposes.[59] Both entities pointed out that the silver ions released by the Silver Care washing machine can be highly toxic to aquatic organisms such as plankton,[60] and have the potential to bioaccumulate in some aquatic species.[61]

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[56] Id. at 20.; see also Pat Phibbs, *Pesticides: Firms Making Nanoengineered Pesticides Urged to Meet with EPA Staff on Data Needs*, DAILY ENVIRONMENT REPORT, May 15, 2006, at A-6.
[57] *Id*.
[58] Pat Phibbs, *Pesticides: Firms Making Nanoengineered Pesticides Urged to Meet with EPA Staff on Data Needs*, DAILY ENVIRONMENT REPORT, May 15, 2006, at A-6.
[59] Letter from Ken Kirk, Executive Director, National Association of Clean Water Agencies, to Stephen Johnson, Administrator, Environmental Protection Agency (February 14, 2006); Letter from Chuck Weir, Chair, Tri-TAC, to James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency (January 27, 2006); Letter from Tobi Jones, Assistant Director, Registration and Health Evaluation Division, Department of Pesticide Regulation, California Environmental Protection Agency, to Chuck Weir, Chair, Tri-TAC (February 22, 2006).
[60] Pat Phibbs and Tripp Baltz, *Pesticides: Examining Use of Nanoscale Silver in Washing Machines as Possible Pesticide*, DAILY ENVIRONMENT REPORT, May 15, 2006, at A-5 - A-6 (quoting Phil Bobel, who works with Tri-TAC).

Widespread use of household products that release silver ions into the sewage system could greatly increase silver concentrations in influents and effluents and adversely affect the nation's waterways.[62] Both entities recommended that EPA require pesticide registration for products using "silver ions" as disinfectants, including washing machines.[63] Both entities also requested that EPA request data regarding wash cycle volumes and silver ion concentrations when registering the Samsung Silver Care Washing Machine.[64]

In its March 10, 2006, response to the letters, EPA stated that the issue was being reevaluated, and it anticipated it would have a decision "within the next few weeks."[65] On May 9, 2006, EPA clarified that it was still examining the question "but does not know when it will make a decision."[66]

EPA November 21, 2006 Announcement

In response to the public concern and calls for action, on November 21, 2006, the media reported that EPA would regulate the nanosilver products used to kill bacteria as a pesticide.[67]

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[61] Letter from Ken Kirk, Executive Director, National Association of Clean Water Agencies, to Stephen Johnson, Administrator, Environmental Protection Agency (February 14, 2006); Letter from Chuck Weir, Chair, Tri-TAC, to James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency (January 27, 2006).
[62] *Id.*; Pat Phibbs and Tripp Baltz, *Pesticides: Examining Use of Nanoscale Silver in Washing Machines as Possible Pesticide*, DAILY ENVIRONMENT REPORT, May 15, 2006, at A-5 - A-6 (quoting Phil Bobel, who works with Tri-TAC).
[63] Letter from Ken Kirk, Executive Director, National Association of Clean Water Agencies, to Stephen Johnson, Administrator, Environmental Protection Agency (February 14, 2006).
[64] Letter from Ken Kirk, Executive Director, National Association of Clean Water Agencies, to Stephen Johnson, Administrator, Environmental Protection Agency (February 14, 2006); Letter from Chuck Weir, Chair, Tri-TAC, to James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency (January 27, 2006).
[65] Letter from James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency, to Ken Kirk, Executive Director, National Association of Clean Water Agencies (March 10, 2006); Letter from James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency, to Chuck Weir, Chair, Tri-TAC (February 17, 2006).
[66] Pat Phibbs and Tripp Baltz, *Pesticides: Examining Use of Nanoscale Silver in Washing Machines as Possible Pesticide*, DAILY ENVIRONMENT REPORT, May 15, 2006, at A-5 - A-6 (quoting Agency spokeswoman Enesta Jones).
[67] Pat Phibbs, *EPA to Regulate Nanoscale Silver Used in Washing Machines to Kill Bacteria*, Daily Environment, at A-6, BNA, November 21, 2006.

The Washington Post, in a front page article entitled, *EPA to Regulate Nanoproducts Sold as Germ-killing*, explained

> The Environmental Protection Agency has decided to regulate a large class of consumer items made with microscopic 'nanoparticles' of silver, part of a new but increasingly widespread technology that may pose unanticipated risks, a government official said yesterday.[68]

Thus, "companies using nanoscale silver as a pesticide will have to register their product or seek an exemption from federal pesticide rules."[69] As reported, the then-forthcoming EPA action would address the Samsung Washing Machine –reversing its decision to be classified as a "device" and classifying it as a "pesticide" – but would also apply to the broader universe of nano-silver products.[70] EPA spokeswoman Enesta Jones was reported as saying that,

> As for the increasing number of other products that incorporate silver to fight microbes, such as air sanitizers and food-storage containers, Jones said that they will have to be registered or meet a registration exemption if they make pesticide claims.[71]

While the announcement was not limited to the Samsung Washer, it was limited in scope: according to EPA officials, this "large class" of products would be limited only to those nano-silver products advertised as "germ-killing" or the like, and not to those who dropped or did not include such anti-microbial marketing claims.[72]

The Federal Register (FR) notice proposing the new rule was said to be coming "soon."[73]

The EPA September 21, 2007 Federal Register Notice

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[68] Rick Weiss, *EPA to Regulate Nanoproducts Sold as Germ-killing*, Wash Post, A01, November 23, 2007.
[69] Phibbs, supra note 60.
[70] Id.
[71] Id.
[72] Weiss, supra note 68.
[73] Id.

Nearly a year later, on September 21, 2007 EPA finally issued the long-awaited FR notice, entitled "Pesticide Registration; Clarification for Ion-Generating Equipment."[74] EPA summarized its purpose and scope:

> [The notice] clarifies the Agency's position on the distinction between devices and pesticides with regard to ion-generating equipment and explains why such equipment will now be regulated as a pesticide. 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. [75]

Generally speaking, the FR notice was opaque in its language (i.e., "silver ion generating equipment,") described by one well-known technology reporter as "Washington mumbo jumbo, translated into English, means that Samsung's SilverCare washing machines are covered by pesticide regulations because Samsung claims they kill germs by injecting 100 quadrillion silver ions into each wash load. "[76]

The notice's purpose was stated to: "alert manufacturers of the Agency's determination;" assure that the Agency "will work to identify the information needed to apply to register the machine as a pesticide;" and to "give those products currently out of compliance time to obtain registration."[77] EPA opened a docket, EPA-HQ-OPP-2007-0949, for affected parties to submit information. Producers of the equipment can continue to sell or distribute the equipment as long as they file registration papers by March 23, 2009.[78]

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[74] See 72 Fed. Reg. 54039 (September 21, 2007).
[75] EPA, Pesticides: Topical & Chemical Fact Sheets, *Pesticide Registration: Clarification for Ion Generating Equipment*, at http://www.epa.gov/oppad001/ion_gen_equip.htm (last visited October 16, 2007).
[76] Barnaby J. Feder, *Samsung's Nanotech Washer Must Follow Bug-Spray Rules*, New York Times *Bits* Blog, September 26, 2007, at http://bits.blogs.nytimes.com/2007/09/26/samsungs-washers-regulated-as-a-pesticide/.
[77] Id.
[78] 72 Fed. Reg. 54039, 54041.

The products covered by the notice are cabined to "ion generators that incorporate a substance (e.g., silver or copper) in the form of an electrode, and pass a current through the electrode to release ions of that substance for the purpose of preventing, destroying, repelling, or mitigating a pest (e.g., bacteria or algae)."[79] Crucially, the notice gave no reference to EPA's oversight of nanotechnology, nanomaterials, or nano-silver ingredients; in fact, it did not contain the prefix "nano" anywhere. Instead, the Agency gave this one-paragraph explanation of that omission on its website:

> While recent press articles have referred to the silver ion generating washing machine as a product of nanotechnology, EPA has not yet received any information that suggests that this product uses nanotechnology. EPA will evaluate any applications to register this type of equipment according to the same regulatory standards as any other pesticide. The notice does not represent an action to regulate nanotechnology.[80]

EPA's statement that it "has not yet received any information" on the nano-aspects of the Samsung Silvercare™ washer defies rationality given that Samsung itself touts its use of nanotechnology on its website, entitled the "Silver Nano Health System" and pictures the washer, among other products.[81]

Finally, in the FR notice no mention is given to the rest of the existing fleet of nano-silver products (besides the "ion generating" equipment) or any proposed action by the agency regarding it, contrary to reports of the quotes from EPA officials in the November 2006 announcement. Nowhere does the notice request information about such products or in any way solicit comment from interested parties or the public on the regulation of nano-silver products.

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[79] 72 Fed. Reg. 54039, 54040 ("Because these items incorporate a substance or substances that accomplish their pesticidal function, such items are considered pesticides for purposes of FIFRA, and must be registered prior to sale or distribution.").
[80] EPA, Pesticides: Topical & Chemical Fact Sheets, *Pesticide Registration: Clarification for Ion Generating Equipment*, at http://www.epa.gov/oppad001/ion_gen_equip.htm (last visited October 16, 2007).
[81] Samsung, *Silver Nano Health System*, at http://www.samsung.com/ph/silvernano/.

Further communications between petitioners (in an attempt to get further clarification regarding the notice) and an agency official noted that

> The point that was being made was that this notice will not address or represent an action to regulate nanotechnology. It is also pointed out that the Agency at some time in the future may set criteria (in addition to particle size) for determining whether technology would qualify as nanotechnology and until such criteria are established Samsung's claims may or may not be upheld.[82]

However neither the September 21, 2007 FR notice or anything on EPA's website giving further explanation included such notice of any future criteria-setting process.

The February 27, 2008 Consent Agreement Between EPA Region 9 and ATEN Technology, Inc.

On February 27, 2008, EPA's Region 9 office settled an action against a California corporation that manufacturers a nano-silver product for violations of FIFRA.[83] EPA fined the technology company ATEN Technology, Inc., of Irvine, Calif., acting for its subsidiary IOGEAR $208,000 for "nano coating" pesticide claims on its computer peripherals, for selling unregistered pesticides and for making unproven claims about their effectiveness.[84] The IOGEAR products at issue were: wireless laser mouse with nano-silver shield coating, laser travel mouse with nano-silver coating technology, and wireless RF keyboard and mouse combinations. After being contacted by EPA, IOGEAR stopped making claims that their computer peripherals protect against germs.[85] In its complaint EPA alleged that:

1) the IOGEAR electronic equipment with "nano shield coating" was labeled containing pesticidal claims;

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[82] September 25, 2007 Email from Melba S. Morrow, D.V.M., Special Assistant to the Director, Antimicrobials Division, Office of Pesticide Programs, Environmental Protection Agency to Jaydee Hanson, Policy Analyst, ICTA (on file with author).

[83] In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc., Docket # FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18* (February 27, 2008).

[84] Nanowerk News, *EPA fines technology company $208,000 for 'nano coating' pesticide claims on computer peripherals*, March 7, 2008, at http://www.nanowerk.com/news/newsid=4857.php

[85] Id.

2) in the marketing of the products, that IOGEAR had made both "implicit and explicit public health and pesticidal claims," including claims that the nano coating has "mechanisms to deactivate enzymes and proteins to prevent bacteria from surviving on the surface of the product" and "the compound has been tested and proven effective against various bacteria."

3) that "each of the nano products is a 'pesticide' as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u). Each of the nano products is not a registered pesticide";

4) and that in 2007 IOGEAR had distributed or sold the nano products on 40 separate occasions, in violation of 7 U.S.C. § 136j(a)(1)(A).[86]

In giving its authority to take this enforcement action EPA explained its relevant FIFRA authority, including, *inter alia*, the definition of a pesticide and that it is unlawful to distribute or sell unregistered pesticides.[87] Thus EPA charged that IOGEAR violated the law by failing to register its products as pesticides prior to distribution and sale as well as making health claims about its products that were unsubstantiated. IOGEAR neither admitted or denied EPA's allegations but consented to the all the conditions of the final order and settlement, waived the right to appeal it, and agreed to pay a fine of $208,000.[88]

As explained in detail in the legal argument section below, the legal bases and analyses by EPA in this IOGEAR enforcement action is precisely the legal argument petitioners herein present regarding the regulatory status of nano-silver products as illegal, unregistered pesticides as well as EPA's FIFRA authority over these products. This precedent-setting enforcement action by EPA strongly supports petitioners' position and highlights the urgency of this matter. Unfortunately press accounts noted that EPA is not making any concerted effort in this area nor does EPA have a new strategy for dealing with these products.[89]

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[86] In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc., Docket # FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18* (February 27, 2008), at p.4.
[87] Id. at 2-3.
[88] Id. at 5-6.
[89] Lacey, *First-Time Fine May Signal New FIFRA Nano Enforcement Effort*, INSIDE EPA, March 14, 2008.

Accordingly, petitioners hereby file this legal petition with EPA in order to, *inter alia*, address the reasonably foreseeable adverse human health and environmental consequences caused by the explosion of nano-silver products on the market that the agency has thus far avoided, and to call on the agency to take the actions required to fulfill its statutory duties of protecting public health and environmental welfare.

EPA ACTIONS REQUESTED REGARGING NANO-SILVER PRODUCTS

Summary of Actions Requested

There are currently at least 260 consumer products in the marketplace that contain nano-silver, which either expressly make pesticidal claims or imply pesticidal effectiveness -- none of which are currently registered with EPA. First, EPA should classify nano-silver as a pesticide and require manufacturers to register nano-silver pesticides pursuant to FIFRA's pesticide regulations. As explained in Section I below, nano-silver products meet the FIFRA definition of a pesticide because nano-silver is a highly efficient antimicrobial or antibacterial agent and is intended to be used for that purpose. Further, EPA should clarify that pesticidal intent and public health claims can be both implicit and explicit and that manufacturers cannot avoid pesticide classification simply by stripping their products of labelling.

Second, EPA should clarify that nano-pesticides, such as nano-silver products, are new pesticide substances that require new pesticide registrations, with nano-specific toxicity testing and risk assessment. As explained in Section II, nano-silver is not covered under previous registrations for bulk silver because nano-silver should be classified as a separate substance than silver based on nanomaterials' capacity for fundamentally unique and different properties and because nano-silver's many new antimicrobial uses are not previously registered silver uses.

Third, EPA must assess the potential human health and environmental risks of nano-silver. As explained in Section III below, these assessments are required by and must comply with the FIFRA, the Food Quality Protection Act (FQPA), the Endangered Species Act (ESA), and the National Environmental Policy Act (NEPA). Pursuant to FIFRA, in order to assess nano-silver pesticides EPA must assess whether nano-silver presents "any unreasonable risk to

man or the environment." As part of this assessment, EPA should analyze all existing scientific studies as well as require manufacturers to provide all necessary additional data on the EHS unknowns of nano-silver. Pursuant to FQPA, EPA must assess the potential impacts of nano-silver on children and infants and ensure that no harm will result from aggregate exposures. Additionally, EPA must ensure that its activities regarding nano-silver comply with the ESA and the protection of endangered and threatened species, including ESA Section 7 Consultation requirements. Finally, EPA must comply with NEPA by ensuring that it assesses the environmental impacts of its actions regarding nano-silver pesticide products, including completing a programmatic environmental impact statement.

Fourth, EPA should take immediate action to prohibit the sale of nano-silver products as illegal pesticide products with unapproved health benefit claims. If a nano-pesticide is unregistered, it may not be distributed or sold in the United States.[90] Similarly, distribution and sale of registered nano-pesticides is prohibited if it is distributed, sold, or used in a manner that departs from the conditions of EPA's approval. This includes: pesticidal claims substantially different from those approved with registration;[91] a composition different than that reviewed in the registration;[92] adulteration;[93] or a use inconsistent with labeling.[94] The nano-silver consumer products currently on market are in clear violation of FIFRA's mandates. To this end, as explained in Section IV below, EPA should issue Stop Sale, Use or Removal Orders ("SSURO") or other enforcement penalties or actions to those manufacturers and/or distributors currently selling these unregistered nano-silver pesticide products.

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[90] This prohibition is subject to certain exceptions for R&D and exports. 7 U.S.C. §§ 136j(a)(1)(A), 136o(a).
[91] 7 U.S.C. § 136j(a)(1)(B).
[92] 7 U.S.C. § 136j(a)(1)(C).
[93] 7 U.S.C. § 136j(a)(1)(E).
[94] 7 U.S.C. § 136j(a)(2)(G).

Fifth, should EPA, after rigorous assessment, approve any nano-silver products as pesticides, the agency must fully apply its pesticide regulations to any registered nano-silver pesticides. FIFRA's pesticide registration requirement instills EPA with the duty to prohibit, condition, or allow the manufacture and use of nanomaterials in nano-pesticides and prescribe conditions for manufacture or use. As explained in Section V, these include, *inter alia*: requiring nano-specific ingredient and warning labelling; applying conditional registration; applying requirements for post-registration notification of adverse impacts; applying post-registration testing and new data development; and requiring the disclosure of all information concerning environmental and health effects, including "confidential business information."

Finally, as explained in Section VI, EPA should also use its FIFRA authority to further review the potential impacts of nano-silver, including: undertaking either a Classification Review or a Special Review of nano-silver pesticides; amending the FIFRA regulations to require the submission of nanomaterial and/or nano-silver specific data; completing a registration review of existing silver pesticides; regulation of nano-silver pesticide devices; and the setting of a FFDCA Tolerance for nano-silver.

I. Nano-silver and Nano-silver Products Are Pesticides Requiring FIFRA Registration

EPA should clarify that nano-silver and nano-silver products are pesticides requiring registration under FIFRA because nano-silver is a highly efficient pest killer and is incorporated into the products with the intent of using its nano-enhanced antimicrobial properties.

A. The Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")

The Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")[95] is the federal regulatory scheme for the manufacture, labeling, sale, and application of pesticides.[96] FIFRA controls the manufacture, sale, and use of a broad range of chemicals and biological pest controls, as well as substances to control plant growth.[97] Although first passed in 1947 to ensure product efficacy and accurate labeling,[98] Congress significantly overhauled it in 1972 through the Federal Environmental Pesticide Control Act to shift the regulatory focus to protection of human health and the environment.[99]

Every pesticide chemical to be sold in the United States must be registered with EPA before it can be distributed or sold.[100] If a substance is found to have "unreasonably adverse effects on the environment," it cannot be registered and brought to market.[101] Accordingly, the Agency must conduct a cost-benefit analysis, balancing the risk of allowing a pesticide to be registered and sold in the market with any potentially harmful effects.[102]

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[95] 7 U.S.C. §§ 136-136y et seq.

[96] The Federal Food, Drug, and Cosmetic Act (FFDCA) also regulates pesticides in a number of ways. In particular the FFDCA requires EPA to establish a "tolerance" for each ingredient of a pesticide used in connection with food or animal feed. 21 U.S.C. § 346a. In addition, various other laws and regulations governing chemical substances such as the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2692, Hazardous Materials Transportation Act, 49 U.S.C. §§ 5101-5127, and the Occupational Safety and Health Act Hazard Communication Standard, 29 C.F.R. § 1910.1200, may apply to pesticides.

[97] 7 U.S.C. § 136u. It also includes more limited authority over mechanical pest control devices, including FIFRA labeling and establishment registration requirements. 7 U.S.C. §§ 136(h), 136w(c)(4); 40 C.F.R. § 152.500(a).

[98] Pub. L. No. 80-104, 61 Stat. 163 (1947).

[99] Pub. L. No. 92-516, 86 Stat. 973 (1972); see also Alexandra B. Klass, Bees, Trees, Preemption and Nuisance: A New Path to Resolving Pesticide Land Use Disputes, 32 Ecology L.Q. 763, 771 (2005).

[100] 7 U.S.C. § 136a(a).

[101] No Spray Coalition, Inc. v. City of New York, 351 F.3d 602, 604-05 (2d. Cir. 2003) (citing 7 U.S.C. § 136a(c)(5)(D).

[102] Peter J. Martinez, Damon L. Worden, Luke M. Jones, Jason S. Juceam, Environmental Crimes, 43 Am. Crim. L. Rev. 381, 452 n.540 (2006).

B. Nano-Silver is a Pesticide under the FIFRA Definition of Pesticides

Pursuant to section 2(u) of FIFRA, a pesticide is defined as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."[103] A "pest" is in turn defined as

> **Pest**: (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest pursuant to 7 U.S.C. 136w(c)(1).[104]

The pesticide's "active ingredient" is the ingredient which "will prevent, destroy, repel, or mitigate" pests.[105] Nano-silver is the ingredient in these nanomaterial products infused to fight bacteria, i.e., prevent pests. Therefore, nano-silver meets the definition of a pesticide and/or the active ingredient in a pesticide.[106]

C. The Intent of Nano-Silver Demonstrates that it is a Pesticide

Nano-silver is a pesticide because its intended use is as a pesticide. As noted above, the FIFRA definition of pesticide hinges on the intent: FIFRA defines "pesticide" not in terms of the inherent characteristics of particular substances but rather in terms of the *intent* underlying the use of a substance.[107] EPA's FIFRA-implementing regulations elaborates on intent as the statutory touchstone, providing that a pesticide is "any substance (or mixture of substances)

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[103] 7 U.S.C. § 136(u)(1); 40 C.F.R. § 152.3.
[104] 7 U.S.C. § 136(t); 40 C.F.R. § 152.5. In addition, the Agency Administrator is authorized, after notice and the opportunity for hearing, to declare as a pest any form of plant or animal life (excluding man and any other bacteria, virus, and micro-organism on or in living man or other animals) that is injurious to human health or the environment. 7 U.S.C. § 136w(c)(1); 40 C.F.R. § 152.5.
[105] 7 U.S.C. § 136(a)(1); 40 C.F.R. § 153.125.
[106] EPA has concluded that one company's nano-silver coated mouses and keyboards were pesticides. See In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc., Docket # FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18* (February 27, 2008) at 2-4 (EPA action explaining FIFRA definition of pesticide and concluding that nano-silver coated electronics were pesticides pursuant to 7 U.S.C. § 136(u)).
[107] 7 U.S.C. § 136(u)(1) (emphasis added); Office of Prevention, Pesticides & Toxic Substances, Environmental Protection Agency, Label Review Manual, p. 2-4 (3d ed. 2003).

intended for a pesticidal purpose."[108] The regulations give three factors for determining "intent" i.e., whether "a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring regulation:"

> A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring regulation, if:
>
> (a) The person who distributes or sells the substance claims or implies (by labeling or otherwise):
>
> 1) That the substance [] can or should be used as a pesticide; or
> 2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
>
> (b) The substance contains one or more active ingredient and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose [], (2) use for manufacture of a pesticide; or
>
> (c) The person distributing or selling the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.[109]

Any one of these factors could be sufficient to show intent; in the case of nano-silver products, all of the factors are present. First, the manufacturers of these nano-silver products claim – indeed they proudly tout, by product labeling and/or other advertising -- the highly efficient germ-killing propensities of the nano-silver ingredients in their products. These claims include, *inter alia*, various statements that the nano-silver ingredients have a "*long lasting antibacterial function*;" or renders material "*permanently anti-microbial and anti-fungal*"; or "*kills approximately 650 kinds of harmful germs and viruses with a germ resistance rate of 99.9%.*" See generally supra p. 14-15 and Appendix A infra. According to well-established precedent, labeling or advertising

[108] 40 C.F.R. § 152.15.
[109] 40 C.F.R. § 152.15.

material recommending a product for use against a pest may be clear evidence of that intent.[110]

Second, nano-silver is specifically and solely used for its anti-microbial properties. Research has shown no other "significantly commercially valuable use."

Third, the manufacturers have both actual and constructive knowledge that the nano-silver is infused in said product for a pesticidal purpose. For every nano-silver product listed in the attached appendix and chart,[111] the product description clearly emphasizes its ability to kill, eliminate, curb, prevent or reduce the growth of microorganisms such as fungus and bacteria. These nano-silver product descriptions include: "*can kill and prevent all kinds of disease germs and microorganisms*"; "*natural bacteriostat*"; "*deactivate enzymes and proteins of bacteria from surviving on the surface of the product*"; "*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*"; "*kills bacteria in vitro in as little as 30 minutes, 2-5 times faster than other forms of silver*"; and so forth. See supra pp. 13-14 and Appendix A infra. These representations and their variants alone are sufficient under the definition of intent provided in the FIFRA-implementing regulations.[112] In addition, these product descriptions make it impossible for manufacturers and distributors to deny they did not have actual or constructive knowledge the substance was to be used, or was intended to be used, for

[110] See In re Chemco Indus., Inc., I.F.&R.,1984 WL 50057, *4-5 (EPA Jan. 24, 1984); see also In re Myers, I.F.&R., 1980 WL 19379, *5 (EPA July 31, 1980) ("The intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant sources.") (citing United States v. 216 Bottles, 409 F.2d 734, 739 (2d. Cir. 1969)).
[111] See Appendix A.
[112] 40 C.F.R. § 152.15(a)

pesticidal purposes.[113] The nano-silver product descriptions and the manufacturers' and distributors' actual knowledge that these products would be used as pesticides clearly demonstrate intent as defined in the FIFRA-implementing regulations.

D. Intent Showing Pesticidal Purpose Is Not Limited to Only Product Labeling

EPA should clarify that intent can be shown by means far broader than just labeling. As the factors above illustrate, "a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring regulation" for reasons including "claims or implies (by labeling *or otherwise*) that the substance can or should be used as a pesticide."[114] In addition, intent can be shown by the active ingredient having "insignificant commercial value as anything else besides a pesticide."[115] Finally, intent can be showing by the "active or constructive knowledge" of the manufacturer that the substance "will be used or is intended to be used for a pesticidal purpose."[116]

At least one Federal Circuit Court of Appeals applies an objective standard to determine intent in the FIFRA context, asking whether the company could expect a reasonable consumer to use the product against pests.[117] "Industry claims and general public knowledge can make a product pesticidal notwithstanding the lack of express pesticidal claims by the producer itself."[118] Accordingly, the general advertising of nano-silver specifically as a germ-killer,[119] creates public knowledge that leads a consumer knowledge and expectation that nano-silver product is an anti-

[113] 40 C.F.R. § 152.15(c).
[114] 40 C.F.R. § 152.15(a) (emphasis added).
[115] Id. 152.15(b).
[116] 40 CFR § 152.15(c).
[117] N.Jonas & Co. vs. EPA, 666 F.2d 829, 833 (3d Cir. 1981) ("In determining intent objectively, the inquiry cannot be restricted to a product's label and to the producer's representations. Industry claims and general public knowledge can make a product pesticidal notwithstanding the lack of express pesticidal claims by the producer itself. Labeling, industry representations, advertising materials, effectiveness and the collectivity of all the circumstances are therefore relevant.").
[118] Id.
[119] See Appendix A.

microbial agent, not withstanding any lack of specific germ-killing advertizing on said specific nano-silver product. The appendix includes more than 260 products that contain nano-silver, of which nearly all include some reference to nano-silver's germ-fighting propensity in the manufacturer's advertizing and/or the product's labeling.

Subsequently EPA has incorporated that objective standard into its regulations: "EPA believes that a producer who sells a product with full knowledge of its intended pesticidal use should be held responsible for its regulation."[120] Thus, manufacturers who produce and market products containing nano-silver with "full knowledge" of its intended uses as an anti-microbial – *even if they do not label the material as "nano" and/or "germ killing"*–are still properly subject to FIFRA's pesticide registration requirements.[121]

EPA must clarify that a pesticide classification is not solely based on a product's labeling.[122] This distinction is crucial, as early reports of EPA's planned action on nano-silver products from November 2006 quoted EPA officials erroneously claiming (or erroneously quoted as claiming) that only products marketed or advertised as anti-microbial or germ killing will have to be regulated, providing a huge loophole for companies that drop anti-microbial claims from their nano-silver products.[123] This potential loophole has been exploited: in response to EPA's anticipated proposed action regarding nano-silver, several nano-silver product

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[120] See Pesticide Registration Procedures, Pesticide Data Requirements, 53 Fed Reg 15952, 15954 (May 4, 1988) (codified at 40 C.F.R. § 152.15(c)); see also Clarification of Treated Articles Exemption, 63 Fed. Reg. 19256, 19257 (April 17, 1998) (discussing 40 C.F.R. § 152.25) (""The Agency has consistently interpreted and applied this rule to prohibit *implied* or explicit public health claims for unregistered products, and continues to regard any public health claims as not consistent with the provisions of the rule.") (emphasis added).

[121] See, e.g., N.Jonas & Co., 666 F.2d at 833 ("In determining intent objectively, the inquiry cannot be restricted to a product's label and to the producer's representations.").

[122] See In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc., Docket # FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18* (February 27, 2008) at 4 (EPA alleging that IOGEAR had made "both implicit and explicit public health claims and pesticidal claims"), 3 (unregistered pesticide products may not be marketed if, *inter alia*, they make any "implied or explicit public health claims").

[123] Weiss, supra note 68.

manufacturers removed their nano-specific labeling. For example, The Sharper Image's *FresherLonger™ Miracle Food Storage* containers were previously marketed with an entire section entitled "*The Silver Nanoparticle Miracle*," noting that the food storage containers were "infused with antibacterial silver nanoparticles" that were "25nm in diameter" and "created by advanced nanotechnology."[124] The nano-silver ingredient was "anti-germ, anti-mold, and anti-fungus" and "compared to regular containers … reduced the growth of microorganisms by over 98 percent."[125] After EPA's November 2006 announcement, Sharper Image stripped its website and all its print and online advertising of any claims to either nano-silver ingredients or that ingredient's biocide activity.[126] Another U.S. company, Pure Plushy, also dropped its claims to be selling toys and stuffed animals made using nanoparticles of 25nm of silver for their antimicrobial effects.[127] Appendix A includes other products previously marketed as nano and/or anti-microbial which are no longer so marketed.[128]

EPA should clarify that manufacturers such as Sharper Image and others cannot purposely evade EPA purview by disclaiming its previous advertising or intentionally misrepresenting its products' ingredients. Manufacturers who produce and market products containing nano-silver with "full knowledge" of its intended uses as an antimicrobial –even if they do not label the material as "nano" or do not label the nano-silver's intended antimicrobial

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[124] http://web.archive.org/web/20060208021530/http:/www.sharperimage.com/us/en/catalog/productdetails/sku__ZN020

[125] Id.

[126] Compare, FresherLonger™ Miracle Food Storage Containers, http://www.sharperimage.com/us/en/catalog/productdetails/sku__ZN020 with FresherLonger™ Miracle Food Storage Containers, http://web.archive.org/web/20060208021530/http:/www.sharperimage.com/us/en/catalog/productdetails/sku__ZN020

[127] Andrew Maynard, SafeNano Community Blog, *Benny the Bear and the Case of the Disappearing nanoparticles*, December 15, 2007, at http://community.safenano.org/blogs/andrew_maynard/archive/2007/12/15/benny-the-bear-and-the-case-of-the-disappearing-nanoparticles.aspx

[128] See Appendix A.

effects–are still properly subject to FIFRA's pesticide registration requirements and must be regulated by EPA as such.[129]

E. Nano-silver Products Fit into the Category of Antimicrobial Pesticides

FIFRA also defines one particular subset of pesticides as "antimicrobial pesticides:"

> **Antimicrobial Pesticide**: a pesticide intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.[130]

Thus, an antimicrobial pesticide is one meant either to affect the growth or development of microbiological organisms or to protect inanimate objects, industrial processes, or chemical substances from contamination from such organisms.[131] Common antimicrobial products include disinfectants for medical and household surfaces including floors, walls, linens, and other surfaces, sanitizers for food contact products such as dishes and cooking utensils and non-food contact products such as carpet cleaners and laundry additives.[132] The nano-silver products listed in Appendix A easily fall within this pesticides definition subset, as products include: floor, wall, and other surface cleaners, cutlery and food contact substances, laundry additives and so on, all intended to "reduce, or mitigate growth or development of microbiological organisms" and/or "protect

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[129] See In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc., Docket # FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18* (February 27, 2008) at 4 (EPA alleging that IOGEAR had made "both implicit and explicit public health claims and pesticidal claims").

[130] 7 U.S.C. § 136(mm). Products excluded from this definition include wood preservatives or antifouling paint products, an agricultural fungicide, or an aquatic herbicide. However, the term "antimicrobial pesticide" does include any other chemical sterilant (other than for use with critical devices), disinfectant product, industrial microbiocide product, or preservative product not excluded above. Id.

[131] EPA, Pesticides: Topical & Chemical Fact Sheets, Antimicrobial Pesticide Products, at www.epa.gov/pesticides/factsheets/antimic.htm

[132] Id.

inanimate objects … or other substances … from contamination … caused by bacteria, viruses, fungi…."[133] Accordingly, the logical fit of the nano-silver products in this subset of pesticides further buttresses the conclusion that these products are pesticides and must be regulated as such.

F. Limited FIFRA Pesticide Exemptions Do not Apply to Nano-Silver

Finally, there are several exemptions or exclusions from the FIFRA pesticide definition and accompanying regulations relevant to the nano-silver determination. As discussed below, the nano-silver consumer products do not qualify for these limited regulatory exceptions.

First, there are several classes of substances expressly excluded from regulation by FIFRA for reasons including that they are regulated by other statutes, like those products qualifying as human or animal drug products under FFDCA.[134] The products incorporating nano-silver are consumer products that have come to market already and not new drug products classified and subject to pre-market review by FDA. However any nano-silver drug products approved by FDA pursuant to its drug approval process would be exempt from EPA FIFRA pesticide regulations.

Second, FIFRA also exempts products intended for use only against microorganisms, internal parasites, or nematodes in or on living humans or animals and labeled accordingly.[135] The nano-silver consumer products in Appendix A are not so limited in the scope of their pesticidal intent, nor are they so labeled.

[133] See Appendix A.
[134] See 40 C.F.R. §§ 152.6, 152.20.
[135] 40 C.F.R. § 152.8.

Third, some products are exempted from FIFRA regulation because they are not "deemed to be used for a pesticidal effect."[136] This exemption has an explicit lists three types of products exempted which includes, *inter alia*, deodorizers, bleaches, and cleaning agents.[137] This is relevant since several of the nano-silver products currently on market are cleaning agents. See Appendix A. However this exemption expressly does not apply if "a pesticidal claim is made on their labeling or in connection with their sale and distribution."[138] Thus, any nano-silver cleaning agent products would be disqualified by their express labeling and/or advertizing as antibacterial agents. See Appendix A (listing products and advertizing claims).

Finally, some pesticide-treated articles or substances are exempted from FIFRA regulation, if several prerequisites are met.[139] One such class is pesticide "treated" articles. As EPA recognizes

> many products (e.g. cutting boards . . .) are being treated with antimicrobial pesticides. Antimicrobial pesticides are substances or mixtures of substances used to destroy or limit the growth of microorganisms, whether bacteria, viruses or fungi – many of which are harmful – on inanimate objects and surfaces.[140]

"Treated articles" refers to the products treated with an antimicrobial pesticide to protect the article itself.[141] The pesticide is usually added to the treated articles during manufacture or added

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[136] 40 C.F.R. § 152.10.

[137] 40 C.F.R. § 152.10(a). The complete list of exempted products under this section:

> The following types of products or articles are not considered to be pesticides unless a pesticidal claim is made on their labeling or in connection with their sale and distribution:
> (a) Deodorizers, bleaches, and cleaning agents;
> (b) Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly;
> (c) Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints to trees.

Id.

[138] 40 C.F.R. § 152.10.

[139] 40 C.F.R. § 152.25.

[140] EPA, Pesticides: Topical & Chemical Fact Sheets, Consumer Products Treated with Pesticides, at www.epa.gov/pesticides/factsheets/treatart.htm

[141] Id.

after manufacture but before use.[142] Such pesticide-treated products can be exempt from FIFRA registration, but only if

1) the pesticide is added only to protect the article itself; and
2) the pesticide added to the treated article "is registered for such use."[143]

Nano-silver consumer products such as those listed in Appendix A do not qualify for this exemption. As to the latter requirement, nano-silver itself is not registered as a pesticide, for these current uses or any other uses for that matter. As to the former, as detailed in the Appendix, the nano-silver products make express claims to protection from bacteria or germs beyond and separate from just the protection of the incorporating product itself. As EPA notes: "Any pesticide-treated product that is not registered by EPA must not make public health claims, such as 'fights germs, provides antibacterial protection, or controls fungus."[144] Many of these nano-silver products do make exactly such beyond product and/or public health claims, including but not limited to "*can kill and prevent all kinds of disease germs and microorganisms*"; provides "*antibacterial effect against bacteria, yeasts, mould, and fungi"; "kills approximately 650 kinds of harmful germs and viruses*"; "*fights against cross infection of super bugs such as MRSA*"; "*natural antibiotic that can kill and prevent infections"; "kills athlete's foot germs and staphylococcus*", "*nanosilver coated foils have been scientifically proven to reduce redness and irritation*"; and so forth. See Appendix A.

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[142] Id.

[143] 40 C.F.R. § 152.25(a). Examples include paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insects or fungus infestation. See also EPA, Pesticides: Topical & Chemical Fact Sheets, Consumer Products Treated with Pesticides, at www.epa.gov/pesticides/factsheets/treatart.htm

[144] EPA, Pesticides: Topical & Chemical Fact Sheets, Consumer Products Treated with Pesticides, at www.epa.gov/pesticides/factsheets/treatart.htm

EPA further clarified the interpretation of Section 125.25(a) (the Treated Article Exemption) in Federal Register notice,[145] stating that unregistered products may be marketed only provided that

> (1) no implied or explicit health claims of any kind are made;
>
> (2) the claims concerning the presence of a pesticide in the treated article are limited to protection of the treated article only;
>
> (3) when such claims involve antibacterial properties, (a) the words "antibacterial," "antimicrobial," or "germicidal," or related terms, are not part of the name of the product, and (b) the permissible claims are qualified by statements indicating that the presence of the antibacterial properties does not protect users or others against disease and that users should follow prudent hygienic measures, i.e., cleaning and washing the article;
>
> (4) the pesticide in a treated article is present only as a result of using a pesticide product which is registered under FIFRA and labeled for use in treating the article in question.[146]

As explained above, these conditions are not met and the limited exemption for treated articles does not apply for the nano-silver pesticides.[147]

II. Nano-silver Is a New Pesticide That Requires New Pesticide Registrations

Next, EPA should classify nanomaterial pesticides such as nano-silver pesticides as new pesticides that require new pesticide registrations. The risk assessment for nanomaterials is different from that larger particle substances and must include a nanotoxicology assessment assessing physicochemical characteristics and factors not otherwise assessed. The safety of nanomaterials cannot be reliably predicted or derived from the known toxicity of the bulk

[145] Clarification of Treated Article Exemption, 63 Fed. Reg. 19256 (April 17, 1998).
[146] Id. at 19257.
[147] See In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc., Docket # FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18* (February 27, 2008) at 3-4 (explaining the Treated Article Exemption before alleging that the IOGEAR nano-silver coated electronics were illegal unregistered pesticides).

material. Further, the claims, composition, and new uses of these nano-silver pesticides are very different from bulk material counterpart pesticides. Finally, the conclusion that nanomaterials—including nano-silver—are distinct and new substances is supported by their patentability, a legal standard which requires, *inter alia*, non-obviousness and novelty.

A. Nano-pesticides Require New Pesticide Registrations

Under FIFRA, a pesticide is considered unregistered if, *inter alia*, 1) its claims differ substantially from the claims made for the registered pesticide, or 2) if its composition differs from the composition of the registered pesticide.[148] In general, claims for nano-pesticides will and do differ from those made for conventional pesticides because nanotechnology allows for many new applications. Nano-silver pesticides and their claims, as discussed infra, are one example. A new registration is required for a pesticide containing an active ingredient that has not been previously registered or used in a registered formulation.[149] Thus, nano-pesticides are not covered by existing registrations of conventional pesticides.

The unique characteristics of nano-pesticides result in different risks and benefits than any macro-scale versions. Product chemistry, toxicology, and other information submitted for macro versions pursuant to 40 C.F.R. Part 158 C & D do not apply to nanomaterials. "Composition" includes the identity of both active and inert ingredients and their ratios. Given the unique characteristics of nanomaterials, nano-pesticides do not have the same composition as bulk material, macro versions.[150] *In short, EPA must employ a different risk assessment based on the actual characteristics of the nano-pesticide.* Any previous analysis/balance of risks and

[148] 7 U.S.C. § 136j(a)(1)(B) & (C).
[149] 40 C.F.R. § 152.403 (new chemical registration review).
[150] See, e.g., Reut Snir, *Regulating Risks of Nanotechnologies for Water Treatment*, 38 ENVT'L L. REPORTER 10233, 10244-46 (2008); James Chen et al., ABA-SEER, The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides (2006), at 11, available at http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf

benefits and appropriate control measures for a conventional pesticide containing a macro-ingredient of the same nanomaterial is different, because of the nano-specific properties, the "nano-ness" of the nanomaterial.

Further, under FIFRA § 3(c)(5)(D), registration decisions depend in the main on EPA's determination that a pesticide "will not generally cause unreasonable adverse effects on the environment."[151] To comply with FIFRA, EPA must weigh the *precise* benefits and risks of individual pesticides and determine under what conditions a pesticide may be registered, if any. Key factors in this determination are the claims and composition of the pesticide. Since the balancing of risks and benefits of a nano-pesticide is different from a corresponding conventional pesticide containing a bulk material ingredient of the same substance, EPA must require a new registration for the nano-pesticide.[152] Substitution of a nanoscale ingredient for a macro counterpart constitutes a change in composition *per se* requiring new registration.

"Experts are overwhelmingly of the opinion that the adverse effects of nanoparticles cannot be reliably predicted or derived from the known toxicity of the bulk material."[153] For example, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded: "Experts are of the *unanimous* opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of

[151] 7 U.S.C. § 136a(a), (c)(5)(C)-(D).

[152] See also Reut Snir, *Regulating Risks of Nanotechnologies for Water Treatment*, 38 ENVT'L L. REPORTER 10233, 10244-45 (2008); James Chen et al., ABA-SEER, The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides (2006), at 11-12, available at http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf Where a registrant of a conventional pesticide applies for registration of a nano-pesticide, an amended registration may be appropriate. 40 C.F.R. § 152.44, provided it is required to provide additional information specific to the nano-pesticide's risks and benefits.

[153] The Allianz Group and the Organisation for Economic Co-operation and Development (OECD), *Small Sizes that Matter: Opportunities and risks of Nanotechnologies*, (June 3, 2005) at § 6.4, at 30.

macroscopic size, which obey the laws of classical physics."[154] Similarly, the U.K. Royal Society and the Royal Academy of Engineering emphasized: "Free particles in the nanometre size range do raise health, environmental, and safety concerns and their toxicology *cannot be inferred* from that of particles of the same chemical at a larger size."[155] And finally, the British Institute for Occupational Medicine similarly concluded:

> Because of their size and the ways they are used, they [engineered nanomaterials] have specific physical-chemical properties and therefore may behave differently from their parent materials when released and interact differently with living systems. *It is accepted, therefore, that it is not possible to infer the safety of nanomaterials by using information derived from the bulk parent material.*[156]

Toxicology normally correlates health risks with the mass to which an individual is exposed, resulting in an accumulated mass as an internal dose/exposure. However, the biological activity of nanoparticles is likely to depend on physicochemical characteristics that are not routinely considered in toxicity screening studies.[157] There are many more factors affecting the toxicological potential of nanoscale materials, up to at least sixteen in fact, including: size, surface area, surface charge, solubility, shape or physical dimensions, surface coatings, chemical composition, and aggregation potential- a "far cry from the two or three usually measured."[158] Size is one of many factors, but is crucial: The relevance of the nano-size is that unlike larger particles, we cannot predict the toxicity of nanomaterials from the known properties of larger

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[154] European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*, at 6 (adopted September 28-29, 2005) (emphasis added); id. at 34.
[155] See, e.g., The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, 2004, supra note 19, at 49 (emphasis added).
[156] Tran et al., *A Scoping Study to Identify Hazard Data Needs For Addressing The Risks Presented By Nanoparticles and Nanotubes*, INSTITUTE OF OCCUPATIONAL MEDICINE Research Report (December 2005), at 34 (emphasis added).
[157] European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*, at 6 (adopted September 28-29, 2005), at 32; Nuala Moran, *Nanomedicine lacks recognition in Europe*, 24 NATURE BIOTECHNOLOGY, No. 2 (February 2006).
[158] Andrew Maynard, *Nanotechnology: The Next Big Thing, or Much Ado about Nothing?*, at 7 ANNALS OF OCCUPATIONAL HYGIENE, 7 September 2006.

substances. Unless EPA requires a thorough manufacturer testing and investigation of all these variables and then applies a subsequent agency assessment to that submitted data, it cannot properly assess the toxicity of nano-pesticides or assure their safety.

In fact, nanotoxicology is an emerging field in its own right, underscoring the differences of nanomaterial toxicity. In an agenda-setting 2006 article in *Nature*, fourteen international nanotechnology scientists put forth nanotechnology's five "grand challenges," which included the urgent need to develop methods for assessing nano-toxicity.[159] Two recently published articles suggest new paradigms of predictive toxicology for engineered nanoparticle testing.[160] EPA should develop a basic screening framework to guide its testing and data-submission requirements, such as the tiered approach that would start with non-cellular tests to establish particle reactivity, followed by in vitro and in vivo tests for exposure pathways that are relevant to a chemical's anticipated use patterns and lifecycle.[161]

B. Nano-silver Pesticides Require New Chemical Pesticide Registrations Because They are Substances With New Compositions and Claims that Require New, Nano-specific Risk Assessments

Nano-silver exemplifies why nano-pesticides require new pesticide registration. Silver is already registered as a pesticide.[162] It is registered for use in water filter systems as a bacteria inhibitor (90% of use) and in swimming pools as an algicide (3% of use).[163] As of its 1993-94 Re-registration, there were 80 pesticide products registered with silver as an active ingredient.[164] The nano-silver products being used as antimicrobials in consumer applications and appliances

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[159] Maynard et al., *Safe Handling of Nanotechnology*, NATURE, November 16, 2006.
[160] Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622 (2006); Oberdorster et al., *Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy*, 2 PARTICLE AND FIBRE TOXICOLOGY 8, at 1.0 (2005).
[161] Id.
[162] See EPA, Silver Reregistration Eligibility Document (RED), June 1993.
[163] Id. at p.1.
[164] Id. at p. 2.

differ substantially in both uses and claims from these registered silver pesticides. The nano-silver product explosion has included a broad swath of industries and products including much more than water filtration systems and swimming pools; these new nano-silver products include, but are not limited to, various cleaning and sanitizing products, food storage containers, toiletries, clothing, home appliances, air filters, medical supplies, dietary supplements, and powdered and liquid nano-silver in bulk form. See Appendix A.

These new nano-silver products also differ in the breadth of their product claims, which are much broader than previously-registered silver pesticide products. Silver pesticides are limited to claims as water-based bacteria inhibitors and algicides. In contrast, these new nano-silver products' claims include: "*control air free from bacteria, virus, germs, fungus, or even A.I. (Avian Influenza)*"; *"kills approximately 650 kinds of harmful germs and viruses with a germ resistance rate of 99.9%"*; "*is proven to kill over 99% of bacteria including MRSA*"; "*sterilize up to 99.9% of harmful bacteria, such as colon bacilli, salmonella, yellow staphylococcus, pseudomonas aeruginosa an salmonella enteritidis"*; "*can kill and prevent all kinds of disease germs and microorganisms*"; renders material "*permanently anti-microbial and anti-fungal*"; and so forth. See Appendix A.

Further, the risk assessment needed for nano-silver is wholly different. Exposures are substantially increased and varied. For example, in the 1993 Silver RED, EPA notes that "residential exposure" to silver pesticides was expected at only "very low levels" through the silver drinking water filters and by swimming in treated pools.[165] The Re-registration document lists as "currently registered" uses of silver as only two types: "aquatic non-food residential

[165] EPA, Silver RED, supra note 162 at 3, Appendix A.

(swimming pool systems) and indoor food uses (human drinking water systems).[166] About 90% of the 80 registered silver pesticides are basteriostatic water filters; 7% are media which contain silver for actual filter housing; and 3% are algicides.[167] The sudden appearance of nano-silver consumer products dramatically increases exposure potential and levels as well as the routes of exposure. See Appendix A. These new uses include household cleaners, sprays and wipes, personal care products and soaps, children's toys and bottles, food storage containers and cutlery, clothing and fabrics, and so forth.

Similarly, in the Silver RED, EPA concluded that there were not unreasonable adverse effects to the environment from silver because the exposure from silver pesticides used in swimming pools and drinking water systems would be discharged into municipal water systems and treated.[168] The broad range of new nano-silver products encompasses many environmental discharge and exposure routes, creating a very different environmental risk and exposure assessment. See Appendix A. Moreover, public utility and water treatment experts have already warned EPA of their concerns about nano-silver's potential negative environmental impacts and their inability to adequately treat that substance.[169]

Finally, as discussed, at the nano-scale silver exhibits remarkably unusual physical, chemical and biological properties.[170] Taking into account their unique physicochemical properties, it is likely that nano-silver possesses unique toxicity mechanisms.[171] For example, nano-silver may deplete the antioxidant defense mechanism, which leads to ROS accumulation

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[166] EPA, Silver RED, supra note 162 at 4.
[167] Id.
[168] EPA, Silver RED, supra note 162 at 4.
[169] Letter from Ken Kirk, Executive Director, National Association of Clean Water Agencies, to Stephen Johnson, Administrator, Environmental Protection Agency (February 14, 2006); Letter from Chuck Weir, Chair, Tri-TAC, to James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency (January 27, 2006).
[170] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12 (2008).
[171] Id. at 8.

and can initiate the destruction of mitochondria and eventually cell death.[172] In addition, damage to cell membranes appears to be another part of nano-silver's mechanism of cytotoxicity.[173] There is also preliminary evidence that the nano-silver can exert effective antibacterial action at a considerably lower concentration than silver ions, i.e, is a "far more efficient" conveyer of antibacterial effects.[174] This suggests that the antibacterial properties and toxicity of nano-silver are not explained only by its chemical composition and the production of silver ions alone. As with other nanomaterials, nano-silver will require a nano-specific toxicity assessment.

C. Nano-silver Pesticides Require New Chemical Pesticide Registrations Because Nano-silver is Patented for its Novelty

The U.S. legal patent framework also strongly supports the conclusion that engineered and manufactured nanomaterials generally–and nano-silver specifically–are novel substances, for which manufacturers should be classified and regulated as new products, in this case, new pesticides. As such, nano-silver requires a separate risk assessment and FIFRA registration process. Many of the manufacturers of these nano-silver pesticide products, regulated by EPA, have applied for and received patents for their products and/or the nano-silver in them, a legal and commercial reality that belies any claim that the engineered nanomaterials are not wholly unique substances which must be classified as new substances and new pesticides.

1. Patent Law Requires Novelty

By law, the issuance of a patent requires a determination of novelty and nonobviousness,[175] and claims for novel disclosures are assigned one or more patent classifications. The applicant must demonstrate that the invention is novel, non-obvious, and

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[172] Id.
[173] Id.
[174] Lok et al., *Proteomoic analysis of the mode of antibacterial action of silver nanoparticles*, 5 J. PROTEAME RES. 916-924 (2007).
[175] 35 U.S.C. §§ 102-103.

useful.[176] It is well-established patent case law that a mere change in size, scale, or dimensions of a known composition are not alone sufficient to establish novelty and nonobviousness and render new material patentable.[177] As early as 1928, the legal principle was well established that a "mere difference in dimension cannot add novelty" to a claimed new product.[178] Courts have since consistently held that the mere scaling of a prior art, capable of being scaled, would not establish patentability in a claim over that prior art.[179] The United States Court of Appeals for the Federal Circuit held that when the only difference between the prior art and its claims was a recitation of relative dimensions of the claimed device, and a device having the claimed relative dimensions would not "exhibit qualitatively different phenomena" from the prior art, the claimed invention was not patentably distinct from the prior art.[180] Thus, whether a nanomaterial is patentable turns on whether the nanomaterial or nanoparticle exhibits "qualitatively different phenomena" than that of its bulk material counterpart.[181]

Nanomaterials meet this threshold because matter behaves uniquely when manufactured or engineered to the nano-scale: nano means more than merely tiny, a billionth of a meter in scale.[182] Rather, it is best understood to mean substances having the capacity to be fundamentally different. "The nano-scale is not just another step toward miniaturization, but a

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[176] 35 U.S.C. §§ 101-103.
[177] Application of Troiel, 274 F.2d 944, 949 (C.C.P.A. 1960) ("It is well established that the mere change of the relative size of the co-acting members of a known combination will not endow an otherwise unpatentable combination with patentability.").
[178] King Ventilating Co. v. St. James Ventilating Co., 26 F.2d 357, 359 (8th Cir. 1928).
[179] In re Rinehart, 531 F.2d 1048, 1053 (C.C.P.A. 1976); see also U.S. Indus., Inc., v. Norton Co., 210 U.S.P.Q. 94, 104 (N.D.N.Y. 1980) (holding that "mere changes of proportions of a known composition with a resultant increase in strength, size, etc., is generally deemed insufficient to constitute patentability, such changes, though useful, being only of degree rather than kind.").
[180] Gardner v. TEC Sys., Inc., 725 F.2d 1338, 1346 (Fed. Cir. 1984).
[181] See id. at 1345-46 (noting that dimensional limitations do not inherently distinguish the subsequent version from the prior art).
[182] See, e.g., pp. 8-11, 44-46 supra.

qualitatively new scale."[183] Taking advantage of quantum physics, nanotechnology companies have and are continuing to engineer materials that have entirely new properties never before identified in nature, and patenting them in the U.S and other countries.

Recognizing this, in August of 2004, the United States Patent and Trademark Office (USPTO) created an art collection of Nanotechnology, Class 977, in response to the desire to gather in one place all published US Patents and US PreGrant Publications (US PGPUBs) that claim subject matter related to nanotechnology.[184] In December of 2005, the USPTO revised the nanotechnology patent classification, replacing one comprehensive digest with 263 new subclasses for cross-referencing all nano-related patents. Class 977, which establishes the definitions and cross-references for these patents, has a two pronged definition of "nanostructures," a necessary ingredient of all patents for which the class provides disclosures,[185] to be an atomic, molecular, or macromolecular structure that both: 1) "has at least one physical dimension of approximately 1-100 nanometers;" and 2) "*possess[] a special property, provides a*

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[183] Nat'l Sci. Found., *Societal Implications of Nanoscience and Nanotech*. at 1 (Mihail C. Roco & Sims Bainbridge eds., 2001), http://www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf

[184]Patent office Classification Definitions, Class 977, Nanotechnology, (November 2005), available at http://www.uspto.gov/web/patents/classification/uspc977/defs977.htm#C977S000000.

[185] Id. The definition of nanotechnology as a class includes "nanostructures" and their chemical compositions, devices that include at least one nanostructure, mathematical algorithms for modeling confiurations or properties of nanostructures, or specified uses of nanostructure.

Patent Class 977, Nanotechnology, Section I - Class Definition, reads:

> i. Nanostructure and chemical compositions of nanostructure;
> ii. Device that include at least one nanostructure;
> iii. Mathematical algorithms, e.g., computer software, etc., specifically adapted for modeling configurations or properties of nanostructure;
> iv. Methods or apparatus for making, detecting, analyzing, or treating nanostructure; and
> v. Specified particular uses of nanostructure.
>
> As used above, the term "nanostructure" is defined to mean an atomic, molecular, or macromolecular structure that:
> (a) Has at least one physical dimension of approximately 1-100 nanometers; and
> (b) Possesses a special property, provides a special function, or produces a special effect that is uniquely attributable to the structure's nanoscale physical size.

special function, or produces a special effect that is uniquely attributable to the structure's nanoscale physical size."[186] Thus, to be included in USPTO Class 977, a patent must not simply be a reduction in size of an existing element or particle; rather, that new size must alter the original substance creating a unique effect or property that is only possible at the nanoscale. The classification class notes on Class 977 are even more explicit, clarifying that

> Special properties and functionalities should be interpreted broadly, and are defined as those properties and functionalities that are significant, distinctive, non-nominal, noteworthy, or unique as a result of the nanoscale dimension. In general, differences in properties and functionalities that constitute *mere differences of scale are insufficient* to warrant inclusion of the subject matter in Class 977.[187]

2. Nanotechnology Patents Demonstrate the Novelty of Nano-Materials

The President's Council of Advisors on Science and Technology (PCAST) reported in May 2005 that the Patent Office issued over 8,600 "nanotechnology-related" patents in 2003, an increase of 50% from 2000 (compared to about 4% for patents in all technology fields).[188] More discrete surveys have found at least 5,000 nanotechnology patents as of March 2006, with the number of patents growing by over 30% every year since 2000.[189] The "gold rush" for patents on the building blocks of the platform technology continues unabated.[190] Claims include composition of matter claims (claims to nanomaterials themselves, nanotubes, nanowires, and nanoparticles), device, apparatus, or system claims (claims to electrical, mechanical, and optical

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[186] Id.
[187] U.S. Patent Class 977, Nanotechnology, Classification Definitions, Note (3), available at http://www.uspto.gov/web/patents/classification/uspc977/defs977.htm#C977S000000 (emphasis added);
[188] President's Council of Advisors on Science and Technology (PCAST), *The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel*, at 15-17 & fig. 4, May 2005, available at http://www.nano.gov//FINAL_PCAST_NANO_REPORT.pdf ; Julie A. Burger et al., *Nanotechnology and the Intellectual Property Landscape,* Chapter 14, p.3, NANOSCALE: ISSUES AND PERSPECTIVES FOR THE NANO CENTURY, ED. NIGEL CAMERON ET AL., (Wiley Pub. 2007).
[189] Nanowerk, *The patent land grab in nanotechnology continues unabated, creating problems down the road*, Marcy 30, 2006, at www.nanowerk.com/spotlight/spotid=386.php
[190] See, e.g., Charles Choi, *NanoWorld: Nano Patents in Conflict*, WASH. TIMES, April 25, 2005.

devices incorporating nanomaterials), and method claims (claims to processes for synthesizing nanomaterials or constructing devices or systems).

3. Nano-silver Patents Demonstrate the Novelty of Nano-Silver Products

Many of these nanotechnology patents are for nano-silver products. An enumerated search of currently-held patents disclosed a number of relevant nano-silver material, formulation, and use patents and patent applications including, *inter alia*,

- U.S. Patent 6,379,712, Yan, et al., April 30, 2002: *Nanosilver-containing antibacterial and antifungal granules and methods for preparing and using the same*

- U.S. Patent 6,979,491, Yan, et al., December 27, 2005: *Antimicrobial yarn having nanosilver particles and methods for manufacturing the same* – "The present invention provides a yarn with antimicrobial effects. The antimicrobial antifungal effect of the yarn is derived from nanosilver particles (diameter between 1 and 100 nm) which are adhered to the yarn."

- U.S. Patent Application 20050287112: *Antibacterial paint containing nano silver particles and coating methods using the same* – December 29, 2005 Kwon, Kyuk-Min; Samsung Electronics – Assignee. An antibacterial paint containing 30 ppm of nano silver particles on a surface. Nano silver particles have a diameter of 5 nm. "Nano technology, as used herein, refers to a technology wherein a material, such as silver, is fabricated into nano-scale particles…. This is based on new phenomena which appear when crystal grain size of a material, such as metal or ceramic, become smaller than 100 nm and which is difficult to explain by conventional theories. It is known in the art that nano silver particles have antibacterial properties."

- U.S. Patent Application 20020051823 (5/2/2002): *Nanosilver-containing antibacterial and antifungal granules and methods for preparing and using the same*

- U.S. Patent Application 20030185889 (10/2/2003): *Colloidal nanosilver solution and method for making same* – "The present invention provides a colloidal nanosilver solution which contains nanosilver particles having diameters between 1 nm and 100 nm."

- U.S. Patent Application 20040135480 (7/15/2004): *Refrigerator with an inner case containing nanosilver particles*

- U.S. Patent Application 20050152992 (7/14/2005): *Antimicrobial surface preparation and method for producing the same* – "The antimicrobial surface preparation of claim 1

wherein said particles of silver have a size between about 5 nanometers and about 100 nanometers on average."

- U.S. Patent Application 20060243675 (11/2/2006): *Novel composite for inhibiting algae growth and use thereof* – "A composite for inhibiting algae growth comprising of a polypore base carrier and a nano-metal mixture coated on a carrier . . . . The composite of claim 4, wherein the nano-metal is nanosilver."

- U.S. Patent Application 20060272542 (12/7/2006): *Nanosilver as a biocide in building materials*.

- U.S. Patent Application 20070256560 (11/8/2007): *Silver nanoparticle-containing polymer film for facilitated olefin transport and method for the fabrication thereof*

The patents and patent claims above belie any argument that manufactured nano-silver particles and materials are not wholly new substances with their novel properties; specifically in the case of nano-silver, that nano-silver pesticides are substantially different from other pesticides made without them. If these substances were the same as their bulk material counterparts (silver pesticides), they would not be patentable, as they would be unable to meet patent law standards for novelty.

D. "New Use" Would Also Require Registration of Nano-silver Pesticides

If a pesticide product to be registered contains an active ingredient that is already registered, but has not previously been used in the manner proposed for the new product, it requires a "new use" registration.[191] For the above reasons, petitioners firmly believe nano-silver is a new active ingredient of a new pesticide that requires its own separate pesticide registration process that accounts for the nano-specific risk assessments, toxicology, and exposures discussed above. However, even if the agency comes to the mistaken conclusion that nano-silver is the equivalent of silver for FIFRA registration purposes, EPA must still act, because nano-silver is a "new use" of previously registered silver pesticides.

[191] See generally *Pesticide Regulation Deskbook*, ENVIRONMENTAL LAW REPORTER, 24-25 (2000).

The definition of a "new use" of a pesticide product is:

> New use, when used with respect to a product containing a particular active ingredient, means:
>
> (1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food additive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act;
> (2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or
> (3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.[192]

In this case, nano-silver pesticide products meet all three of the possible ways of creating a new use. First, nano-silver requires the establishment of a tolerance, see Section VI(E) infra, and no tolerance has been set. Second, many unregistered nano-silver products have uses that have the capacity to impact aquatic, terrestrial, and outdoor environments, as discussed infra Section III(A), (C), & (D). Neither nano-silver, nor silver, is registered for such use. And third, nano-silver pesticide products are resulting in new use patterns, with significant increases and new routes of exposure to man and other organisms. See supra & Appendix A.

A pesticide's use is required to be included in the mandatory statement that must accompany the registration.[193] When the use is being changed, or a new use is being added, the registration must be updated if the manufacturer wants to avoid selling an illegal and misbranded product.[194] The registration amendment process[195] is similar to the registration of a new pesticide, requiring a statement, and supporting data, except certain data may be re-used from the initial registration.[196] EPA may also need new data to evaluate the potential effects of the

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[192] 40 C.F.R. § 152.3.
[193] *See* 7 U.S.C. §136a(c)(1)(C), §136a(c)(1)(E).
[194] 7 U.S.C. §136(q)(1)(F) & 7 U.S.C. §136(q)(2)(B).
[195] 40 C.F.R. §152.44.
[196] *See* 7 U.S.C. §136a(c)(1)(F).

pesticide in the new use application. EPA can conditionally register a pesticide for a new use only if it determines, *inter alia*, that the applicant has submitted "satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment."[197]

E. Conclusion: Nano-Silver is a New Pesticide

In summary, nanomaterial pesticide products such as nano-silver products are new pesticides. They have new claims and compositions, requiring new risk assessments. Pesticides comprised of engineered or manufactured nano-silver cannot be considered safe and/or to not have an "unreasonable risk to man or the environment,"[198] based on the testing or previous approvals of macro-silver pesticide counterparts. Rather, EPA must require safety information specifically addressing the new dangers presented by these new novel substances. EPA must analyze their nano-specific potential for "unreasonable adverse effects on the environment," as discussed in section III infra. Moreover, consistent legal treatment of nano-pesticides with established patent law necessitates that EPA's pesticide regulatory regime treat nano-pesticides as new pesticides for which manufacturers must complete new and separate pesticide applications. Finally, even if EPA erroneously concludes that silver and nano-silver are the same active ingredient, new use registrations are required for nano-silver pesticides because of the broad swath of new uses of nano-silver pesticide products.

[197] 7 U.S.C. § 136a(c)(7)(B).
[198] 7 U.S.C. § 136(bb).

III. EPA Must Analyze the Potential Environmental and Human Health Risks of Nano-silver Pursuant to EPA's Statutory Obligations under FIFRA, FQPA, ESA, and NEPA

Next, EPA must assess the potential human health and environmental risks of nano-silver. These assessments are required by and must comply with FIFRA, the Food Quality Protection Act (FQPA), the Endangered Species Act (ESA), and the National Environmental Policy Act (NEPA). Pursuant to FIFRA, in order to assess nano-silver pesticides EPA must assess whether nano-silver presents "any unreasonable risk to man or the environment." As part of this assessment, EPA should analyze all existing scientific studies as well as require manufacturers to provide all necessary additional data on the environmental, human health and safety ("EHS") unknowns of nano-silver. Pursuant to FQPA, EPA must assess the potential impacts of nano-silver on children and infants and ensure that no harm will result from aggregate exposures. Additionally, EPA must ensure that its activities regarding nano-silver comply with the ESA and the protection of endangered and threatened species, including ESA Section 7 Consultation requirements. Finally, EPA must comply with NEPA by ensuring that it assesses the environmental impacts of its actions regarding nanomaterial and/or nano-silver pesticide products, including completing a programmatic environmental impact statement.

A. As Part of the FIFRA Pesticide Registration Process, EPA Must Analyze the Potential Human Health and Environmental Risks of Nano-silver

1. The FIFRA Pesticide Registration Standard: Unreasonable Adverse Effects on the Environment

EPA can register a pesticide if, in conjunction with any restrictions that it may place on the use of the pesticide, *inter alia*, the expected use of the product will not cause unreasonable environmental harm.[199] FIFRA defines "unreasonable adverse effects on the environment" as

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under The Federal Food, Drug and Cosmetic Act 21 U.S.C. § 346a relating to tolerances and exemptions for pesticide chemical residues.[200]

The "environment" is defined broadly to include the "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."[201] Thus, as part of the registration process, EPA must assess whether nano-silver specifically creates an unreasonable risk to man or the environment. EPA acknowledges as it must that, "some of the same special properties that make nanomaterials useful are also properties that may cause some nanomaterials to pose hazards to humans and the environment, under specific conditions."[202]

2. *Nano-Silver May Pose Unreasonable Risk to Humans and the Environment*

While the long-term potential impacts of widespread nano-silver use and disposal are unknown, its use as an antimicrobial agent is now widespread including in numerous products such as sprays, liquids, gels, cleaning agents, food containers, clothing, and appliances.[203] These nano-silver products are in direct human contact and direct and/or are indirectly released into the

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[199] 7 U.S.C. § 136a(c)(5); see also Montana Pole & Treating Plant v. I.F. Laucks & Co., 775 F. Supp. 1339, 1343 (D. Mont. 1991) ("Under FIFRA, the EPA is required to register a pesticide if it determines (1) the pesticide's labeling and other materials comply with FIFRA's requirements; and (2) the pesticide, when used properly, will perform its intended purpose without unreasonable adverse effects on the environment.").

[200] 7 U.S.C. § 136(bb).

[201] 7 U.S.C. § 136(j).

[202] Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 13, (February 2007)

[203] See Appendix A.

environment. Simultaneously, concerns have been mounting that nano-silver particles pose an unacceptable toxicity risk to human health and the environment.[204] While silver in it's larger forms is already known to be toxic, the dramatically increased surface area of nano-silver enhances that toxic propensity. Existing research has shown that nano-silver is toxic at a cellular level in mammals and other organisms and has the potential to disrupt key cellular functions.[205] Negative impacts can be expected on beneficial bacteria important for soil, plant, and animal health.[206] Studies have also shown that the widespread use of nano-silver may compromise our ability to control harmful bacteria by creating increased antibiotic resistance.[207] The petition summarizes these issues below.

i. Silver Poses Adverse Environmental Impacts

Even in non-nano form silver is extremely toxic to fish,[208] algae, crustaceans, plants, fungi,[209] and bacteria (especially nitrogen fixing heterotrophic and soil forming chemolithotrophic).[210] As noted above, EPA already regulates silver as a pesticide[211] and requires labeling that states silver pesticides are "highly toxic to fish and aquatic invertebrates."[212] Silver also inhibits microbial growth at concentrations far below that of other

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[204] See, e.g., Lloyd's of London, Risks: Lloyd's Emerging Risks Team Report, *Nanotechnology Recent Developments, Risks and Opportunities*, 2007.
[205] See infra pp. 62-64 and accompanying footnotes.
[206] See infra pp. 66-70 and accompanying footnotes.
[207] See infra pp. 64-66 and accompanying footnotes.
[208] Hogstrand et al., *The toxicity of silver to marine fish*, at 109-112 in Andren, Anders W.; Bober, Thomas W. (ed.) THE 4TH INTERNATIONAL CONFERENCE PROCEEDINGS: TRANSPORT, FATE AND EFFECTS OF SILVER IN THE ENVIRONMENT (1996).
[209] Eisler, R. *A review of silver hazards to plants and animals*, 143-44 in (1996)., pp. 143-144 in Andren, Anders W.; Bober, Thomas W. (ed.) THE 4TH INTERNATIONAL CONFERENCE PROCEEDINGS: TRANSPORT, FATE AND EFFECTS OF SILVER IN THE ENVIRONMENT (1996).
[210] Albright et al., *Sub-lethal effects of several metallic salt-organic compound combinations upon heterotrophic microflora of a natural water*. 8 WATER RES 101-105 (1974).
[211] EPA, R.E.D., supra note 162 at 4.
[212] Brown et al., *Assessing Toxicant Effects in a Complex Estuary: A Case Study of Effects of Silver on Reproduction in the Bivalve, Potamocorbula Amurensis, in San Francisco Bay,* 9 HUMAN AND ECOLOGICAL RISK ASSESSMENT 95, at 117 (2003)

heavy metals.[213] It can also bioaccumulate and persist in water sediment. Silver is toxic to both freshwater and saltwater organisms and is particularly damaging to reproductive systems. In a study of the bivalves, *Potamocorbula amurensis* and *Macoma balthica*, silver presence resulted in a decreased level of reproductive rates. The highest levels of silver were synonymous with the lowest levels of reproductivity.[214] Other studies have shown that silver accumulates in the liver, gills, kidneys and blood plasma of fish causing circulatory failure and ion regulation disruption.[215] Silver can also accumulate in invertebrates and will thus be passed on to different organism when consumed.[216] Silver exposure via direct uptake and trophic transfer can be toxic to zooplankton, a primary food source for developing larvae and fish.[217]

ii. The Nano-Enhanced Toxic Properties And Toxicity Mechanisms of Nano-Silver

In addition to silver's known impacts, nano-scale silver exhibits remarkably unusual physical, chemical and biological properties.[218] The extremely high reactivity and very small mass of nanomaterials means that nanomaterials can be toxic at far lesser weights than bulk materials. Their small size confers greater particle mobility in the environment and in the body. EPA has noted: "Nanoscale materials are typically more reactive than larger particles of the same

[213] Braydich-Stolle et al., *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells* 88 (2) TOXICOLOGICAL SCIENCES 412-19 (2005).
[214] Brown et al., *Assessing Toxicant Effects in a Complex Estuary: A Case Study of Effects of Silver on Reproduction in the Bivalve, Potamocorbula Amurensis, in San Francisco Bay,* 9 HUMAN AND ECOLOGICAL RISK ASSESSMENT 95, at 116 (2003)
[215] Wood et al., *Bioavailability, Physiology and Toxicology of Silver in Freshwater Fish: Implications for Water Quality Criteria,* PROCEEDINGS OF THE 5TH INTERNATIONAL CONFERENCE ON THE TRANSPORT, FATE AND EFFECTS OF SILVER IN THE ENVIRONMENT 205, at 206-207, (1997); Dethloff et al. *Effects of Sodium Chloride on Chronic Silver Toxicity to Early Life Stages of Rainbow Trout (Oncorhynchus Mykiss)*, 26 ENV. TOX. CHEM. 1717, at 1722-1723 (2007).
[216] Fisher et al. *Trophic Transfer of Silver to Marine Herbivores: A Review of Recent Studies,* 17 ENV TOX CHEM 562 (1998).
[217] Hook et al., *Sublethal Effects of Silver in Zooplankton: Importance of Exposure Pathways and Implications for Toxicity Testing*, 20(3) ENVIRON TOXICOL AND CHEMISTRY 568-74 (2000).
[218] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12 (2008).

material. *This is true especially for metals and metal oxides*."[219] The smaller a particle, the greater its surface area to volume ratio and the higher its chemical reactivity and biological activity.[220] The increased chemical reactivity of nanoparticles results in increased production of reactive oxygen species (ROS), including free radicals.[221] ROS production has been found in a diverse range of nanomaterials including carbon fullerenes, carbon nanotubes, and nanoparticle metal oxides.[222] ROS and free radical production is one of the primary mechanisms of nanoparticle toxicity and may result in oxidative stress, inflammation, and consequent damage to proteins, membranes, and DNA.[223] Size is therefore a key factor in determining the potential toxicity of a particle. Other factors influencing toxicity include shape, chemical composition, surface structure, surface charge, aggregation, and solubility.[224]

As with many nanomaterials, the toxicity of nano-silver is greater than that of silver in bulk form; furthermore, nano-silver is considerably more toxic then other metal nanoparticles.[225] At the very small nanometer size the particles' surface area is exponentially large comparative to its volume. The comparatively large surface area of nanoparticles increases their reactivity, which in many instances also increases toxicity. For example, one study showed that the interaction with the HIV-I virus is highly size dependent, with silver nanoparticles in the 1-10nm

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[219] EPA White Paper, supra note 41 at 38.
[220] Institute of Occupational Medicine for the Health and Safety Executive, *Nanoparticles: An occupational hygiene review* (2004).
[221] Nel A et al., *Toxic potential of materials at the nanolevel* 311 SCIENCE 622-627 (2006).
[222] Oberdörster G et al., *Nanotoxicology: an emerging discipline from studies of ultrafine particles*, 113 (7) ENVIRONMENTAL HEALTH PERSPECTIVES 823-839 (2005).
[223] Nel A et al., *Toxic potential of materials at the nanolevel* 311 SCIENCE 622-627 (2006).
[224] Nel A et al., *Toxic potential of materials at the nanolevel* 311 SCIENCE 622-627 (2006).
[225] Braydich-Stolle, L et al., *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells*, 88(2): TOXOCOLOGICAL SCIENCES 412–419 (2005).

range exclusively attaching to the virus and consequently inhibiting it from binding to hosts cells.[226]

Moreover, because nano-silver has a greater surface area than larger particles of silver, nano-silver is more chemically reactive and more readily ionized than silver in larger particle form. Nano-silver therefore has greater antibacterial and toxic effects compared to larger silver particles partly because it is more readily converted to silver ions, which are extremely toxic to fish and other aquatic species.[227]

There is also preliminary evidence that the nano-silver can exert effective antibacterial action at a considerably lower concentration than silver ions.[228] This suggests that the antibacterial properties and toxicity of nano-silver are not explained only by its chemical composition and the production of ions alone. Physical characteristics of nanomaterials, such as their size, shape, and surface properties, can exert a toxic effect that goes beyond that associated with their chemical composition.[229] For example one study demonstrated that nano-silver produces reactive oxygen species (ROS) and this can result in oxidative stress-mediated toxicity.[230] Production of ROS, highly reactive molecules which include free radicals, can interfere with cellular metabolism, cause inflammation, and damage proteins, membranes and DNA. ROS production is a key mechanism of nanomaterials' toxicity.[231]

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[226]Jose Luis Elechiguerra et al., *Interaction of silver nanoparticles with HIV-1*, JOURNAL OF NANOBIOTECHNOLOGY 3:6 (2005), at http://www.jnanobiotechnology.com/content/3/1/6

[227]Hogstrand et al., *The Acute and Chronic Toxicity of Silver to Marine Fish,* Proceedings of the 5th International Conference on the Transport, Fate and Effects of Silver In the Environment, 317-324 (1997).

[228] Lok et al., *Proteomoic analysis of the mode of antibacterial action of silver nanoparticles*, 5 J. PROTEAME RES. 916-924 (2007).

[229] Brunner et al., *In Vitro Cytotoxicity of Oxide Nanoparticles: Comparison to Asbestos, Silica, and the Effect of Particle Solubility*, 40 ENVIRON SCI TECHNOL 4247-81 (2006).

[230] Hussain, S.M. et al., *In vitro toxicity of nanoparticles in BRL 3A rat liver cells*, 19 TOXICOLOGY IN VITRO 975–983 (2005).

[231] See, e.g., Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622-27 (2006).

iii. Studies Show Nano-silver is Toxic to Mammalian Cells and Zebra fish

Numerous studies have shown not only the mobility of nano-silver but also the negative and toxic effects of nano-silver on mammalian cells. *In vitro* (test tube) studies demonstrate that nano-silver is toxic to mammalian liver cells,[232] stem cells[233] and even brain cells.[234] An overwhelming majority of studies reported abnormalities in basic cell functions as a result of nano-silver contact.[235] One study demonstrated the mobility of inhaled nano-silver after it concentrated in the lungs of rats and then followed systematic pathways throughout the body to enter the kidney, brain and heart.[236] In another study, C18-4 germline stem cells from mice exposed to nano-silver underwent dramatic structure changes and apoptosis, a form of cell self-destruction.[237] Silver carbonate had no significant cytotoxic effect on mitochondrial and cell functions while nano-silver caused extreme toxicity and reduced mitochondrial function and cell viability.[238]

Other studies confirmed that cells treated with nano-silver had decreased mitochondrial function and additionally reported that cells shrank and developed irregular shapes.[239]

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[232]Hussain, S.M. et al., *In vitro toxicity of nanoparticles in BRL 3A rat liver cells*, 19 TOXICOLOGY IN VITRO 975–983 (2005).
[233]Braydich-Stolle, L et al., *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells*, 88(2): TOXOCOLOGICAL SCIENCES 412–419 (2005).
[234]Hussain, S.M et al., *The Interaction of Manganese Nanoparticles with PC-12 Cells Induces Dopamine Depletion*, 92(2) TOXOCOLOGICAL SCIENCES 456–63 (2006).
[235]Hussain et al. *In Vitro Toxicity of Nanoparticles in BRL 3A Rat Liver Cells*, 19 TOXICOLOGY IN VITRO 977-978, (2005); Stolle et al. *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells,* 88 TOXICOLOGICAL SCIENCES 412 (2005).
[236] Health & Safety Laboratory, *Health & Safety Executive NanoAlert Service,* http://www.hse.gov.uk/horizons/nanotech/nanoalert001.pdf , December 2006 at p.26.
[237]Stolle et al. *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells,* 88 TOXICOLOGICAL SCIENCES 412, 414 (2005).
[238]Id.
[239]Hussain et al. *The Interaction of Manganese Nanoparticles with PC-12 Cells Induces Dopamine Depletion,* 92 TOXICOLOGICAL SCIENCES 456, at 460 (2006); Hussain et al. *In Vitro Toxicity of Nanoparticles in BRL 3A Rat Liver Cells*, 19 TOXICOLOGY IN VITRO 977-978, (2005).

Additional research showed that nano-silver agglomerated in cell cytoplasm and fully permeated cell membranes.[240]

Similar studies performed on zebra fish demonstrated that nano-silver could diffuse into developing embryos and affect embryonic development.[241] Zebra fish are commonly used in human drug studies because their protein sequences are similar to humans.[242] Such similarities indicate the potential risks for human embryonic development if exposed to nano-silver. In all studies nano-silver was the most toxic and damaging when tested against several other metal nanoparticles.[243]

Similarly, a study investigating the cytotoxicity of silver nanoparticles in mammalian germline stem cells showed that silver nanoparticles were more toxic than other metal oxides. [244] The authors of the study also pointed out that while silver nanoparticles are proposed to be used as antimicrobial agents in bone cement or other implantable devices, they may in fact be toxic to the bone-lining cells and other tissues.[245] Silver nanoparticles significantly reduced mitochondrial function and interfered with cell metabolism leading to cell leakage. Furthermore, the significant toxicity of silver nanoparticles on mammalian germline stem cells (mice testes) indicates the potential of these particles to interfere in general with the male reproductive system. These findings are of significant practical implications because nano-silver is now available via a

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[240]Skebo et al. *Assessment of Metal Nanoparticle Agglomeration, Uptake, and Interaction Using High-Illuminating System,*26 INTERNATIONAL JOURNAL OF TOXICOLOGY 135 (2007).
[241]Lee et al. *In Vivo Imaging of Transport and Biocompatibility of Single Silver Nanoparticles in Early Development of Zebrafish Embryos,* 1 ACS NANO 133, 141 (2007).
[242]Id. at 134.
[243]Hussain et al. *The Interaction of Manganese Nanoparticles with PC-12 Cells Induces Dopamine Depletion,* 92 TOXICOLOGICAL SCIENCES 456, at 460 (2006); Hussain et al. *In Vitro Toxicity of Nanoparticles in BRL 3A Rat Liver Cells*, 19 TOXICOLOGY IN VITRO 977-978, (2005); Stolle et al. *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells,* 88 TOXICOLOGICAL SCIENCES, (2005) at 418; Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 7 (2008).
[244]Braydich-Stolle, L et al., *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells*, 88(2): TOXOCOLOGICAL SCIENCES 412–419 (2005).
[245]Id.

variety of commercialized products, including contraceptive devices and maternal hygiene items. Fertility problems may occur.[246] These studies establish the risk and toxicity of nano-silver in mammalian animals and denote the possible hazards of nano-silver in humans.

iv. Human Health: Nano-silver Promotes Bacterial and Antibiotic Resistance

Nano-silver poses a unique threat to humans in the form of bacterial and antibiotic resistance. Nano-silver is an antimicrobial biocide that can kill or inhibit the growth of microbes.[247] Certain harmful bacteria may become resistant against nano-silver. In addition, because of the type of resistance mechanism developed, the harmful bacteria could develop resistance to 50% of currently used antibiotics.[248]

Silver resistance genes have been found in some large plasmids (a small ring of genetic material) that also carry several genes that encode for antibiotic resistance. Carrying plasmids is energy intensive so bacteria may lose plasmids that are unnecessary. Yet, with increased silver exposure, bacteria are encouraged to retain plasmids with silver and antibiotic resistant genes, increasing the potential for antibiotic resistance.[249]

"Silver can …constitute a part of selective pressure and may actively contribute to the spread of antibiotic resistance. Silver resistance associated with antibiotic resistance has been observed in isolated bacteria from birds and in salmonella spp." [250] It can also be induced under laboratory conditions, and "is most easily developed in bacteria with already documented resistance mechanisms to antibiotics, such as methicillin-resistant *Staphylococcus aureus*

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[246] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 7 (2008).
[247] See generally Sass, Jennifer. *Nanotechnology's Invisible Threat: Small Science, Big Consequences,* NRDC, at 3 (May 2007).
[248] Melhus, A, *Silver threatens the use of antibiotics*, Unpublished manuscript, (on file with author) (2007).
[249] Melhus, A, *Silver threatens the use of antibiotics*, Unpublished manuscript, (on file with author) (2007).
[250] Id.

(MRSA), vancomycin- resistant enterococci (VRE), enterobacteria with production of extended spectrum beta-lactamases (ESBL), multiresistant *Pseudomonas aeruginosa*."

Thomas O'Brien of Harvard Medical School states that, "antimicrobial-resistance genes and their genetic vectors, once evolved in bacteria of any kind anywhere, can spread indirectly through the world's interconnecting commensal, environmental, and pathogenic bacterial populations to other kinds of bacteria anywhere."[251] The widespread introduction of nano-silver into consumer products could thus contribute significantly to the spread of antibiotic resistance throughout the world. Uncertainties about silver and resistance prompted Swedish pharmacies to stop selling band-aids containing silver in April 2006.[252]

v. Environmental Impacts: Environmental Exposures and Impacts on Beneficial Bacteria

As a powerful bactericide, when released into the environment nano-silver particles threaten bacteria-dependent processes that underpin ecosystem functions. The release of nano-silver from consumer products into the environment is inevitable after products degrade and/or are thrown away. Exposures will also come from use: a recent study[253] by Arizona State scientists found that socks impregnated with nano-silver released substantial amounts of the nano-silver when washed in both nanoparticle and ionic forms.[254] The study suggested that nano-silver could travel through a wastewater treatment system and enter natural waterways to

[251] O'Brien, Thomas F., *Emergence, Spread, and Environmental Effect of Antimicrobial Resistance: How Use of an Antimicrobial Anywhere Can Increase Resistance to Any Antimicrobial Anywhere Else,* 34 (Suppl 3) CID S78, (2002).
[252] Sandquist, Anna, *Swedish Pharmacies Ban Silver Band-Aids,* 3 MILJOAKTUELLT April 2006.
[253] Benn and Westerhoff, *Nanoparticle Silver Released in Water from Commercially Available Sock Fabrics*, Arizona State University, presentation for EMPA nanoECO conference, Ascona, Switzerland, March 3, 2008; forthcoming in ENVIRONMENTAL SCIENCE & TECHNOLOGY.
[254] Rachel Petkewich, *Toxic Socks: Silver nanoparticles intended to control odor release in the wash*, CHEMICAL AND ENGINEERING NEWS, April 7, 2008.

impact aquatic organisms.[255] The study was the first to examine how nanomaterials are released during laundering from commercially available clothing.[256] As discussed infra, nanomaterials can be extremely mobile and can travel large distances in air and water which could have impacts in areas far away from their area of release.[257]

Beneficial bacteria are important for soil, plant and animal health.[258] Once these nanomaterials are released into the environment, their 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.[259] 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.[260] Other researchers believe nano-silver destroys the ability of the bacteria's DNA to replicate. [261]

A recent study provided one example of nano-silver's damage to beneficial bacteria: a 2008 University of Missouri study has found that nano-silver also may destroy benign bacteria that are used to remove ammonia from wastewater treatment systems.[262] The study's authors

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[255] ScienceDaily, As Nanotechnology Goes Mainstream, 'Toxic Socks' Raise Concerns; Unknown Risks from Nanosilver Cited, April 7, 2008, at http://www.sciencedaily.com/releases/2008/04/080406175050.htm

[256] Id.

[257] See infra pp. 89-90 and accompanying footnotes

[258] For example, bacteria form symbiotic relationships with all animals from insects to humans. Many of these bacteria aid their animal hosts to digest food, others perform more unusual functions. Antibiotic-producing bacteria protect the European beewolf (wasp) from pathogenic fungal infestation. Light- producing bacteria help the Hawaiian squid to camouflage itself from predators.

[259] It is nano-silver particles' increased surface area that is credited with enabling the highly effective destruction of bacteria and other microbes. The actual mechanism by which nano-silver particles interfere with bacteria is as unknown.

[260] In their study of *E. coli* bacteria, Sondi and Salopek-Sondi found that nanosilver damaged and pitted the bacteria's cell walls and accumulated in the cell wall, leading to increased cell permeability and ultimately cell death. Soni, I.and Salopek-Bondi, B, *Silver nanoparticles as antimicrobial agent: a case study on E.coli as a model for Gram negative bacteria*, 275(1) J.COLLOID INTERFACE SCIENCE 1770-82 (2004). *E. coli* is often used as a model for gram negative bacteria, suggesting that these results could be more broadly relevant.

[261] Berger, M. (2007), *Stabilizing antimicrobial nanosilver on a natural porous plant material*, Nanowerk, January 18, 2007, at http://www.nanowerk.com/spotlight/spotid=1276.php.

[262] Choi et al., *The inhibitory effects of silver nanoparticles, silver ions, and silver chloride on microbial growth*, WATER RESEARCH (2008), doi:10.1016/j.watres.2008.02.021

summarized: "that silver nanoparticles are extremely toxic. The nanoparticles destroy the benign species of bacteria that are used for wastewater treatment. It basically halts the reproduction activity of the good bacteria."[263] Further, the study concluded that nano-silver generates more highly reactive oxygen species than do larger forms of silver inhibit bacterial growth. This outcome could impact the use of wastewater treatment "sludge" as land-application fertilizer, which is common practice. If high levels of nano-silver are present in the sludge, soil used to grow food crops may be harmed.[264] The study concluded that "the results of nano-silver toxicity to environmentally sensitive nitrifying microorganisms suggest that stringent regulations of [nano-silver] entering [wastewater] are necessary."[265]

Nano-silver coatings have also been implicated in adverse environmental impacts which, "may result in enhanced interactions with bacteria, algae, and other microorganisms in the environment, and may result in bioaccumulation and possibly biomagnifications up the food chain."[266]

vi. Environmental Impacts: Soil

While limited scientific studies on the microbiological effects of nano-silver in soil systems have been conducted,[267] it is well-established that silver in its bulk form inhibits microbial growth in soils and has the ability to disrupt denitrification processes.[268] Denitrification is a bacteria-driven process, where nitrates are converted to nitrogen gas in some

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[263] *Too much technology may be killing beneficial bacteria*, Nanowerk, April 29, 2008, at http://www.nanowerk.com/news/newsid=5520.php
[264] Id.
[265] Choi et al., *The inhibitory effects of silver nanoparticles, silver ions, and silver chloride on microbial growth*, WATER RESEARCH (2008), doi:10.1016/j.watres.2008.02.021, at 8.
[266] Mowat et al., *Nanotechnology and the Water Market: Applications and Health Effects*.
[267] Senjen, Rye, *Nanosilver- a threat to water, soil and human health?,* Friends of the Earth Australia, March (2007).
[268] Throback et al., *Silver (Ag+) reduces denitrification and induces enrichment of novel nirK genotypes in soil,* 270 FEMS MICROBIOL LETT 189, (2007); Finnsson, A. et al., *Two Approaches to Prevent Bio Film in Modern Household Washing Machines,* at 10 (June 2006) (on file with author).

soils, wetlands and other wet environments. For example, denitrification bacteria play an important role in removing nitrate from water contaminated by excessive fertilizer use. Denitrification is also important because excess nitrates reduce plant productivity, can result in eutrophication in rivers, lakes and marine ecosystems, and are a drinking water pollutant.

In situ studies have demonstrated that silver, even in larger particle form, inhibits microbial growth at concentrations below that of other heavy metals.[269] It is especially toxic to heterotrophic (ammonifying/ nitrogen fixing) and chemolithotrophic bacteria. Chemolithotropic bacteria belong to the lithotropic family of microbes and consume inorganic material. These organisms liberate many crucial nutrients, and are essential in the formation of soil.[270]

vii. Environmental Impacts: Bioaccumulation

The persistence of nanomaterials and their potential for bioaccumulation is 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) along the food chain.[271] Once absorbed the nanoparticles may travel up the food chain to larger animals in a similar way to mercury. Mercury is a toxic pollutant that concentrates in marine ecosystems and has the well-known and documented ability to bioaccumulate and biomagnify at all trophic levels in the food web. Mercury is absorbed by micro-organisms which are then consumed by larger organisms. This allows the chemical to continue to be passed along the food chain and in the process increasing in concentration. In large animals, birds and humans mercury concentrations can reach toxic concentrations and may cause birth defects, neurological

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[269] Murata et al. (2005), *as cited by* Throwback et al., *Silver (Ag(+)) reduces denitrification and induces enrichment of novel nirK genotypes in soil*, FEMS MICROBIOL LETT. (Jan 2007).

[270] http://soils.usda.gov/sqi/concepts/soil_biology/bacteria.html

[271] Tran C, Donaldson K et al., *A scoping study to identify hazard data needs for addressing the risks presented by nanoparticles and nanotubes* Research Report. Institute of Occupational Medicine, Edinburgh (2005).

disorders and death. The deadly effects of mercury were first discovered and publicized in Minimata, Japan, after causing severe disabilities and death among people eating seafood contaminated through industrial mercury discharge, which had accumulated through the food chain.[272] Given how mercury has negatively affected the environment and human health in the past, the potential biological magnification caused through mass manufacturing and disposal of nanomaterials, such as nano-silver, are a definitive possibility that must be investigated and if found to occur addressed. The impact of nanomaterial exposure on plant growth also remains largely uninvestigated; however, high levels of exposure to nanoscale aluminium have been found to stunt root growth in five plant species.[273] No such studies have been performed on silver nanoparticles.

The NACWA and Tri-Tac letters to EPA pointed out that widespread use of household products like the Samsung washing machine will increase the release of nano-silver into sanitary sewer systems.[274] This in turn will greatly increase nano-silver concentrations in treatment-plant discharges, leading to adverse effects, such as bioaccumulation in fish and the killing of aquatic life. It is also possible that nanoparticles, persistent organic pollutants, and other hazardous metals may form associations and spread together, thereby amplifying their toxicity.[275]

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[272]Booth et al., *Mercury, Food Webs, and Marine Mammals: Implications of Diet and Climate Change for Human Health.* 113(5) ENVIRONMENTAL HEALTH PERSPECTIVES 521–526 (2005) at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1257541

[273]Yang L et al., *Particle surface characteristics may play an important role in phytotoxicity of alumina nanoparticles*, 158 (2) TOXICOL LETT. 122-32 (2005).

[274]Letter from Ken Kirk, Executive Director, National Association of Clean Water Agencies, to Stephen Johnson, Administrator, Environmental Protection Agency (February 14, 2006) (on file with author); Letter from Chuck Weir, Chair, Tri-TAC, to James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency (January 27, 2006) (on file with author).

[275]Tang, H.; Wang, D.; Ge, X., *Environmental nano-pollutans and aquatic micro-interfacial processes*, 50(12), WATER SCI TECHNOL 103-9(2004).

viii. Human Health: Nano-Silver May Adversely Impacts Human through Ingestion and othe Unknown Exposures

Very little attention has been given to the study of nano-silver's potential human health impacts, such as their entry portals into the human body, biodistribution, potential to accumulate in organs as well as their potential interactions with tissues, cells and molecules and their relevant toxicological implications.[276] As discussed above, exposure to nano-silver in the body is becoming increasingly widespread and invasive. Consequently, nano-silver has gained an increasing access to tissues, cells, and biological molecules within the human body.[277] At least one study has noted that the traditional assumptions about silver being only a minimal health risk may not be alone sufficient because "once reaching the nano-scale, certain materials do exhibit significant toxicity to mammalian cells even if they are biochemically inert and biocompatible in bulk size," like carbon.[278]

Ingestion of colloidal silver (a suspension of silver in microparticles and/ or nanoparticles in a gelatinous base) has been linked to neurological problems, kidney damage, stomach upset, headaches, fatigue, and skin irritation. [279] One study demonstrated that silver atoms present in drinking water for purification purposes can accumulate in the cerebellum "which is critical for the motor coordination and functional efficiency of the locomotion system", and oxidative muscle tissue, including the hearts, of rats. The study exposed rats to silver concentrations three times *lower* than the World Health Organization maximum level for drinking water

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[276] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 2 (2008).
[277] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 2 (2008).
[278] Id.
[279] White JM, Powell AM, Brady K, *Severe generalized argyria secondary to ingestion of colloidal silver protein*, 28(3) Clinical and Experimental Dermatology 254-56 (2003); Hori K, Martin TG, Rainey P, *Believe it or not--silver still poisons!*, 44(5) VETERINARY AND HUMAN TOXICOLOGY 291-292 (2002).

disinfection.[280] Considering the growing number of nano-silver water purification systems on the market and the demonstrated ability of silver to pass the blood brain barrier like nanoparticles, this study shows the potential for nano-silver to create similar effects.[281]

One product, a nano-silver coated dressing- Acticoat (Smith & Nephew, Inc.), has generated concern after a previously healthy teenager developed symptoms of hepatotoxicity and argyria symptoms as well as elevated liver enzymes and silver levels in plasma and urine.[282] Six days after treatment the patient developed grayish discoloration with blueish-lips (argyia) and elevated serum aspartate aminotransferase, alanine aminotransferase, and γ-galactosyl transferase without elevation of bilirubin, lactate dehydrogenase, or cholinesterase. The patient had elevated urinary (28 µg/kg) and serum (107 µg/kg) silver levels. Cessation of the nanoscale silver treatment resulted in an immediate decrease of the clinical signs of hepatotoxicity, argyria, and serum and urinary silver; however, serum and urinary levels of silver (42 and 2.3 µg/kg, respectively) were still elevated at 7 weeks.[283]

ix. Additional Research is Needed

One recent study specifically examined the potential of nano-silver coated consumer products to cause environmental damage in freshwater aquatic and terrestrial ecosystems.[284] Noting that there is strong growth potential in the number of nano-silver products in the near future, Blaser et. al conclude that by 2010 nearly 15% of all silver emissions in Europe will be

[280]Rungby, J., *An experimental study on silver in the nervous system and on aspects of its general cellular toxicity*. 37DANISH MED. BULL., 442-449 (1990); Pelkonen et al., *Accumulation of silver from drinking water into cerebellum and musculus soleus in mice*, 186 TOXICOLOGY, 151-157 (2003).
[281]Lloyd's of London, Risks: Lloyd's Emerging Risks Team Report, *Nanotechnology Recent Developments, Risks and Opportunities*, at 15, 2007.
[282] Trop et al. *Silver-Coated Dressing Acticoat Caused Raised Liver Enzymes and Argyria-like Symptoms in Burn Patient,* 60 JOURNAL OF TRAUMA-INJURY INFECTION & CRITICAL CARE 648 (2006).
[283] Id.
[284]Blaser et al., *Estimation of cumulative aquatic exposure and risk due to silver: contribution of nano-functionalized plastics and textiles*, 390 SCIENCE OF THE TOTAL ENVIRONMENT 396-409 (2008).

released from biocidal nano-silver products. The study specifically recognizes the prevalence of nano-silver particles imbedded into plastic matrixes and the ability of these plastics to break down in water over time. Additionally, the researchers raise concerns over nano-silver contamination in agricultural fields due to the spreading of sewage sludge and the potential for nano-silver products to decompose in landfills. The study strongly recommends additional research to examine "not only the aquatic exposure to silver from biocidal plastics and textiles…but also the impact on terrestrial ecosystems."[285]

3. Human Health and Environmental Impact Unknowns: EPA Should Require Additional Data from Manufacturers

The approval of a pesticide is contingent on an agency determination that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5), including, *inter alia*, the determination that the product will not cause unreasonable adverse effects on the environment.[286] If more data is necessary, EPA should require manufacturers provide it. To perform its statutorily-mandated risk assessment for a pesticide, EPA needs information on the potential risks and benefits of a pesticide. While existing studies show potential risks regarding nanomaterials and nano-silver, there are also many still-unexplored potential human health and environmental impacts that must be "imperatively answered before people rush to indulge in the nano-silver boom."[287]

"If information required generally is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data

[285] Id. at 407.
[286] 40 C.F.R. § 152.112; 7 U.S.C. § 136a(c)(5)(D).
[287] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 2 (2008).

requirements will be imposed."[288] Therefore, to ensure it has all the data it needs on nano-silver to perform the risk assessments, EPA should require the necessary data from prospective registrants for nano-silver products.[289]

B. PURSUANT TO THE FQPA, EPA MUST ASSESS THE POTENTIAL IMPACTS OF NANO-SILVER ON INFANTS AND CHILDREN AND ENSURE THAT NO HARM WILL RESULT FROM AGGREGATE EXPOSURES

1. EPA Must Apply The Food Quality Protection Act to Nano-Silver Products

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 ("FFDCA") for the movement of pesticides in interstate commerce.[290] 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."[291] 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."[292]

Among the FQPA requirements for tolerance level reassessment was a mandate for EPA to "apply a presumptive 'tenfold margin of safety in order to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'"[293] The EPA Administrator may deviate from the tenfold factor only if, on the basis of reliable scientific data, such deviation is safe to infants and children.[294]

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[288] 40 C.F.R. § 158.75(a).
[289] 7 U.S.C. § 136a.
[290] New York v. EPA, 350 F. Supp. 2d 429, 432 (S.D.N.Y. 2004); Croplife Am. v. EPA, 329 F.3d 876, 879 (D.C. Cir. 2003) (FQPA "substantially revised" and rewrote most of the FFDCA method for setting tolerances).
[291] Croplife, 329 F.3d at 879 (quoting 21 U.S.C. § 346(b)(2)(A)(ii)).
[292] 21 U.S.C. § 346a(b)(2)(C)(ii)(I).
[293] New York, 350 F. Supp. 2d at 432 (quoting 21 U.S.C. § 346a(b)(2)(C)); Am. Farm Bureau v. EPA, 121 F. Supp. 2d 84, 89 (D.C. Cir. 2000); NRDC v. Johnson, 461 F.3d 164, 168 (2d Cir. 2006) (noting new requirements

2. EPA Must Assess the Health Risks of Nano-silver on Infants and Children and Set an Exposure Tolerance

Before setting a tolerance for nano-silver, see Section VI(E) infra, 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.[295] Exposures include both dietary exposures and all other exposures for which there is reliable information."[296] EPA must "apply a presumptive 'tenfold margin of safety in order to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children'" for nano-silver.[297]

The importance of the agency's application of, and compliance with, the FQPA's standards for child safety is underscored by the plethora of nano-silver children and infant products currently on market. As listed in Appendix A, these products include: children's stuffed animals and toys, strollers, baby bottle cleaner, baby textile softener, baby mug, infant teething toy, and baby milk bottle. See Appendix A. In addition, it is foreseeable that many household nano-silver products will also increase exponentially pre-natal, infant, and baby nano-silver exposures. As listed in Appendix A, these nano-silver products include: dietary supplements, bed sheets and pillows, bandages, soaps and personal care products, food storage containers, cutlery and cooking utensils, clothing, filters, washing machines and refrigerators, paints, sprays, cleaners, and bulk and powdered and liquid nano-silver in bulk form. See Appendix A. Healthcare and hygiene spray products containing nano-silver have entered daily

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pertaining to the safety of several major subgroups of individuals); Physicians Comm. For Responsible Medicine v. EPA, 451 F. Supp. 2d 223, 226 (D.D.C. 2006) ("In other words, the pesticide manufacturer must show that the pesticide is ten times safer than the typical exposure limits for adults").

[294] New York, 350 F. Supp. 2d at 432.

[295] 21 U.S.C. § 346a(b)(2)(C)(ii)(I).

[296] Croplife, 329 F.3d at 879 (quoting 21 U.S.C. § 346(b)(2)(A)(ii)).

[297] See notes 288-89 supra.

use, raising concern of respiratory entry and potential effects.[298] These nano-silver products create dietary and skin exposures to infants and children that must be assessed.

With regard to nanomaterials generally, a growing number of peer-reviewed scientific studies have demonstrated both the potential for nanomaterials to present serious toxicity risks for human health[299] and the capacity for nanomaterials to penetrate the skin in at least some circumstances.[300] Research has shown that many types of nanomaterials can be toxic to human tissue and cell cultures, resulting in increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death.[301] Nanomaterials' small size confers greater particle mobility both in the environment and in the body.[302] Potential health concerns from nano-silver were addressed above, supra Section III(A)(2), and include *inter alia*, nano-silver toxicity and bacterial and antibiotic resistance concerns, as well as numerous unknowns. These include respiratory impacts from inhalation, as studies have noted the potential for nano-silver, like other nanomaterials, once inside the lungs, to "serve as an efficient facilitator of generation of radicals and ROS" due to their "enormous surface area."[303] Transdermal penetration for some

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[298] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 3 (2008).

[299] For overviews of the emerging field of nanotoxicology, see Oberdörster G et al., *Nanotoxicology: an emerging discipline from studies of ultrafine particles*, 113(7) ENVIRONMENTAL HEALTH PERSPECTIVES 823-839 (2005); Oberdörster G, Maynard A, Donaldson K, Castranova V, Fitzpatrick J, Ausman K, Carter J, Karn B, Kreyling W, Lai D, Olin S, Monteiro-Riviere N, Warheit D, and Yang H, *Principles for characterising the potential human health effects from exposure to nanomaterials: elements of a screening strategy*, 2:8 PARTICLE AND FIBER TOXICOLOGY (2005); Hoet P, Bruske-Holfeld I and Salata O, *Nanomaterials – known and unknown health risks* 2 JOURNAL OF NANOBIOTECHNOLOGY 12 (2004).

[300] See, e.g., Ryman-Rasmussen J, Riviere J, Monteiro-Riviere N, *Penetration of intact skin by quantum dots with diverse physicochemical properties*, 91 TOXICOLOGICAL SCIENCES (1):159-165 (2006); Tinkle S, Antonini J, Roberts J, Salmen R, DePree K, Adkins E, *Skin as a route of exposure and sensitisation in chronic beryllium disease*, 111 ENVIRONMENTAL HEALTH PERSPECTIVES 1202-1208 (2003).

[301] Oberdörster G, Maynard A, Donaldson K, Castranova V, Fitzpatrick J, Ausman K, Carter J, Karn B, Kreyling W, Lai D, Olin S, Monteiro-Riviere N, Warheit D, and Yang H, *Principles for characterising the potential human health effects from exposure to nanomaterials: elements of a screening strategy*, 2:8 PARTICLE AND FIBER TOXICOLOGY (2005).

[302] Chen and Schluesener, *Nanosilver: A nanoproduct in medical application*, 176 TOXICOLOGY LETTERS 1-12, 3 (2008).

[303] Id.

nanomaterials (titanium dioxide, quantum dots) has been observed in studies, but there is no data for nano-silver.[304] The release of nano-silver from clothing fibers, underwear, socks, lingerie, hospital and lab gowns, under various real life conditions (sweating, laundering, broken skin) remains to be investigated.[305] "Dermal toxicity is still a topic of dispute and concern."[306] Other potential impacts include impacts on the liver, a major accumulation point of circulatory nano-silver[307] and interference with beneficial bacteria in the gut once ingested.[308]

In sum, in setting a nano-silver tolerance EPA must set a 10-fold margin of safety in setting the nano-silver tolerance and ensure that there is a reasonable certainty that no harm will result from aggregate exposure.

C. ANY EPA ACTIVITIES OR PROGRAMS REGARDING NANO-SILVER OVERSIGHT MUST COMPLY WITH ESA, INCLUDING NANO-SILVER PESTICIDE REGISTRATION, REQUIRE ESA SECTION 7 CONSULTATION

1. The Endangered Species Act (ESA)

The ESA obligates federal agencies "to afford first priority to the declared national policy of saving endangered species."[309] To that end, the ESA contains numerous substantive and procedural provisions designed to protect species listed as threatened or endangered under the Act.

One such provision, Section 7, requires federal agencies to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of [endangered or threatened species] or result in the destruction or adverse

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[304] Id. at 5.
[305] Id.
[306] Id
[307] Id at 7.
[308] Lloyd's of London, Risks: Lloyd's Emerging Risks Team Report, *Nanotechnology Recent Developments, Risks and Opportunities*, at 15, 2007.
[309] Tenn. Valley Auth. v. Hill, 437 U.S. 153, 185 (1978).

modification of [critical] habitat."[310] Thus, before engaging in any type of activity that may have direct or indirect effects on endangered species or critical habitat, agencies must "consult" either the Fish and Wildlife Service ("FWS") or the National Marine Fisheries Service (NMFS) in order to evaluate the impact of such agency action.[311] FWS regulations implementing section §7(a)(2) state that such formal or informal consultation must be initiated whenever an agency determines its action may affect a listed species, and that ongoing actions must be re-evaluated when species that may be affect by those actions are listed.[312]

The Act's consultation provision applies to "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."[313] The concept of agency action has been given broad application by the courts and agency regulations, including the promulgation of regulations, the granting of licenses, and actions directly or indirectly causing modifications to land, water, or air.[314] Other examples of activities include the creation of interim management strategies,[315] and ongoing activities and projects.[316] EPA must comply with ESA when acting under FIFRA. "FIFRA does not exempt EPA from complying with ESA requirements when EPA registers pesticides. Indeed, a pesticide registration that runs against the clear mandates of the ESA will most likely cause an unreasonable adverse effect on the environment under FIFRA."[317]

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[310] 16 U.S.C. § 1536
[311] 16 U.S.C. § 1536(a)(2).
[312] 50 C.F.R. §§ 402.14, 402.16.
[313] 50 C.F.R. § 402.02.
[314] 50 C.F.R. § 402.02.
[315] Lane Cty Audubon Soc'y v. Jamison, 958 F.2d 290 (9th Cir. 1992).
[316] Klamath Water Users Protective Ass'n v. Patterson, 191 F.3d 1115 (9th Cir. 1999).
[317] Defenders of Wildlife v. EPA, 882 F.2d 1294, 1299 (8th Cir. 1989).

FWS regulations under the ESA require agencies to review their action "at the earliest possible time to determine whether any action may affect listed species."[318] The threshold for the requirement to make the determination of whether a particular agency action may affect a listed species is triggered where "an endangered or threatened species may be present in the area of the proposed action."[319]

2. ESA applies to agency actions taken pursuant to FIFRA and EPA Must Comply with ESA Section 7 With Regard to Nano-Silver

Any "agency action" EPA takes with regard to nano-silver triggers Section 7 Consultation procedures. This includes oversight programs, and ongoing activities and pesticide projects. [320] EPA should now, "at the earliest possible time" consult with the applicable wildlife agency to determine whether its actions regarding nano-silver may affect listed species.[321]

FIFRA does not exempt EPA from compliance with the ESA's requirements with regard to pesticides.[322] Rather, the statute's mandates apply to agency actions taken pursuant to FIFRA, including pesticide registrations and rescissions. In Washington Toxics Coalition v. EPA, EPA argued that it was bound to follow only the provisions of FIFRA concerning the registration of 54 pesticide active ingredients that plaintiff environmental coalitions argued might harm endangered or threatened salmon in the waters of the Pacific Northwest.[323] EPA argued that the ESA's Section 7 Consultation requirements did not confer independent responsibilities on EPA. The Ninth Circuit disagreed, holding that EPA was not relieved of its obligations to comply with

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[318] 50 C.F.R. § 402.14(a).
[319] City of Sausalito v. O'Neill, 386 F.3d 1186, 1215 (9th Cir. 2004); Pacific Rivers Council v. Thomas, 30 F.3d 1050, 1055 (9th Cir. 1994) (agency actions 'may affect' the protected salmon where "the plans set forth criteria for harvesting resources within the salmon's habitat").
[320] Klamath Water Users Protective Ass'n v. Patterson, 191 F.3d 1115 (9th Cir. 1999).
[321] 50 C.F.R. § 402.14(a).
[322] Wash. Toxics Coal. v. EPA, 413 F.3d 1024, 1032 (9th Cir. 2005); Defenders of Wildlife v. EPA, 882 F. 2d 1294, 1299 (8th Cir. 1989).
[323] Wash. Toxics Coal, 413 F.3d at 1028; see also Defenders of Wildlife v. EPA, 882 F.2d 1294 (8th Cir. 1989) (EPA's continued registration of strychnine pesticides effected a taking of endangered species).

the ESA by its compliance with FIFRA: "We agree with the Eighth Circuit that even though EPA registers pesticides under FIFRA, it must also comply with the ESA when threatened or endangered species are affected."[324] EPA was required to engage in ESA Section 7 consultation with the National Marine Fisheries Service (NFMS, now NOAA Fisheries) before engaging in pesticide registration. Further, EPA's obligation to comply with the ESA is "continuing" since the agency retains ongoing authority to register pesticides, alter registrations for reasons that include environmental concerns, and cancel registrations.[325]

3. Nano-silver Causes Adverse Environmental Exposures

The proliferation of nano-silver products makes it increasing likely that protected species and their critical habitat may be affected by the increasing release of these materials. The nano-silver products listed in Appendix A create numerous foreseeable direct and indirect environmental exposures. Some nano-silver products will enter the environment directly over the course of the products' use, including: washing machine waste water, laundry detergents and fabric softeners, multipurpose, bathroom, kitchen, and automobile cleaning products, soaps, cleaning and sanitizing sprays and wipes, personal care products, dietary supplements, and powdered and liquid nano-silver in bulk form. See Appendix A. Other nano-silver products will enter the environment at the end of their use during disposal, 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.

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[324] Id. at 1032 ("The statutes at issue in this case similarly have different but complementary purposes. FIFRA utilizes a cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide, taking into account the economic, social, and environmental costs and benefits of a pesticide's use. *Headwaters, Inc.,* 243 F.3d at 532. In contrast, the ESA affords endangered species the "highest of priorities" in assessing risks and benefits. Tennessee Valley Auth. v. Hill, 437 U.S. 153, 174 (1978). The reasoning of our case law therefore leads us to conclude that an agency cannot escape its obligation to comply with the ESA merely because it is bound to comply with another statute that has consistent, complementary objectives.") .

[325] Id. at 1033.

Id. Still other nano-silver products will indirectly leach nano-silver into the environment over the course of their use and cleaning and/or washing including numerous types of clothing such as underwear, socks, shirts, outerwear, gloves and hats, bedding, sheets, and pillows, and air and water purifiers and their replacement filters. Id. A recent study[326] by Arizona State scientists found that socks impregnated with nano-silver released substantial amounts of the nano-silver when washed in both nanoparticle and ionic forms.[327] The study suggested that nano-silver could travel through a wastewater treatment system and enter natural waterways to impact aquatic organisms.[328] The study was the first to examine how nanomaterials are released during laundering from commercially available clothing.[329]

These products will continue to enter the environment through product manufacture, transport, use, and disposal pathways. Because these products are household consumer products available on market shelves across the country, nano-silver environmental disposals and releases will occur nationwide. Many of the nano-silver products are in "free" particle form (such as creams, lotions, sprays), rather than "fixed" in a product matrix, speeding up ecosystem interactions. Even if they are in a product matrix nanomaterials are "highly durable" and will remain in nature long after the disposal of their host products.[330] It is unknown how quickly these materials will leech or dissolve into the environment as the product is washed, broken, or thrown away. These disposals will lead to greater environmental exposures by natural systems

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[326] Benn and Westerhoff, *Nanoparticle Silver Released in Water from Commercially Available Sock Fabrics*, Arizona State University, presentation for EMPA nanoECO conference, Ascona, Switzerland, March 3, 2008; forthcoming in ENVIRONMENTAL SCIENCE & TECHNOLOGY.

[327] Rachel Petkewich, *Toxic Socks: Silver nanoparticles intended to control odor release in the wash*, CHEMICAL AND ENGINEERING NEWS, April 7, 2008.

[328] ScienceDaily, *As Nanotechnology Goes Mainstream, 'Toxic Socks' Raise Concerns; Unknown Risks from Nanosilver Cited*, April 7, 2008, at http://www.sciencedaily.com/releases/2008/04/080406175050.htm

[329] Id.

[330] Andrew Maynard, *Nanotechnology: A Research Strategy for Addressing Risk*, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, at 12 (July 2006).

than those of larger discarded materials since nanoparticles have the ability to reach places that larger particles cannot. Because of their tiny size, nanoparticles move with great speed through aquifers and soils and settle more slowly than larger particles. In addition, because of their large surface area, nanoparticles provide a large and active surface for interacting with and absorbing other materials. The foreseeable result will be a large and quickly increasing aggregate environmental exposure of protected species and their habitat to nano-silver discharges.

4. Nano-silver Causes Environmental Impacts and Potentially Impacts Protected Species

In addition to the potential environmental impacts discussed *infra*, many protected species are potentially impacted by the nano-silver product explosion. For example, it is well-established that silver in larger forms is highly toxic to fish, aquatic invertebrates and estuarine organisms.[331] Products containing silver are not to be applied to marine/estuary environments or oil fields. As explained above, among other nano-specific properties, nano-silver's exponentially increased surface area makes it even more dangerous to these species. Nano-silver therefore has greater antibacterial and toxic effects compared to larger silver particles partly because it is more readily converted to silver ions. There is also preliminary evidence that the nano-silver can exert effective antibacterial action at a considerably lower concentration than silver ions.[332] This suggests that the antibacterial properties and toxicity of nano-silver are not explained only by their chemical composition and the production of ions alone. As EPA has noted, "nanomaterials may affect aquatic or terrestrial organisms differently than larger particles

[331] EPA, Silver RED, supra note 162 at 4.
[332] Lok et al., *Proteomoic analysis of the mode of antibacterial action of silver nanoparticles*, 5 J. PROTEAME RES. 916-924 (2007).

of the same materials" and that "the use of nanomaterials in the environment may result in novel by-products or degradates that also may pose risks."[333]

There are 139 listed species of ESA-protected fish (65 Threatened and 74 Endangered) potentially negatively impacted by widespread nano-silver releases and individual and cumulative exposures.[334] Similarly, there are 70 listed species of protected claims (8 Threatened and 62 Endangered), and 22 listed species of protected crustaceans (3 Threatened and 19 Endangered) also potentially negatively impacted by nano-silver releases and exposures.[335] Finally, there are at least 10 water-based protected reptiles (6 Threatened and 4 Endangered) and 15 water-based mammals (4 Threatened and 11 Endangered) potentially negatively impacted by nano-silver releases and exposures.[336]

Unfortunately, despite rapid nanomaterial commercialization, many potential environmental risks of nanomaterials such as nano-silver remain dangerously untested due to the failure to prioritize relevant research and paucity of funding for environmental impact research. However some extrapolations from the known risks of silver are helpful to show potential risks to species. It is well-known that silver is among the most toxic metals for aquatic organisms.[337] The highly toxic levels generally have been considered to result from the presence of the free silver ion in water.[338] Because nano-silver has a greater surface area than larger particles of silver, nano-silver is more chemically reactive and more readily ionized than silver in larger particle form. Nano-silver therefore has greater antibacterial and toxic effects compared to larger

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[333] EPA White Paper, supra note 41 at 58.
[334] See http://www.fws.gov/endangered/wildlife.html#Species
[335] Id.
[336] See http://www.fws.gov/endangered/wildlife.html#Species
[337] Fisher et al., *Trophic Transfer of Silver to Marine Herbivores: A Review of Recent Studies*, 17 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 562-571 (1998).
[338] Call et al., Toxicity *of Silver in Water and Sediment To the Freshwater Amphipod Hyallella Azteca*, 25 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 1802-08 (2006).

silver particles, partly because it is more readily converted to silver ions. Thus, 139 federally protected species of fish, as well as other protected aquatic species, are potentially at risk from widespread and cumulative nano-silver releases.

Free silver ions are extremely toxic to fish.[339] For example, studies have shown the severe toxicity of silver to juvenile rainbow trout,[340] a fish closely related to several endangered members of the *Salmonidae* family (trout and salmon). The *Salmonidae* family includes numerous distinct population segments of pacific salmon (Chinook, Sockeye, Chum, and Coho), atlantic salmon, and trout (steelhead, bull, gila, cutthroat and others), collectively representing at least 40 different federally protected fish species,[341] with critical habitats from coast to coast.

Silver is also toxic to aquatic invertebrates[342] such as sea urchins[343] and amphipods.[344] Studies have shown that the young life stages of numerous marine and estuarine life forms such as mollusks (e.g, clams, snails) and crustacean (e.g., lobsters) are highly susceptible to silver toxicity.[345] There are 75 federally protected members of the snail species,[346] 70 different protected clam species,[347] five members of the amphipod family,[348] and four members of the crayfish family.[349]

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[339]Hogstrand et al., *The Acute and Chronic Toxicity of Silver to Marine Fish,* Proceedings of the 5th International Conference on the Transport, Fate and Effects of Silver In the Environment, 317-324 (1997).
[340] Naddy et al., *Effects of Sodium Chloride on Chronic Silver Toxicity to Early Life Stages of Rainbow Trout*, 26 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 1717-25 (2007).
[341] http://ecos.fws.gov/tess_public/SpeciesReport.do?groups=E&listingType=L&mapstatus=1
[342]Naddy et al., *Chronic Toxicity of silver nitrate to Ceriodaphnia dubia and Daphnia magna, and potential mitigating factors*, 84 AQUATIC TOXICOLOGY 1-10 (2007).
[343]Ward et al., *Chronic Toxicity of Silver to the Sea Urchin*, 25 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 1568-73 (2006).
[344] Call et al., Toxicity *of Silver in Water and Sediment To the Freshwater Amphipod Hyallella Azteca*, 25 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 1802-08 (2006).
[345] Luoma et al., *Fate, Bioavailability, and Toxicity of Silver in Estuarine Environments*, 31 MARINE POLLUTION BULLETIN 44-54, Table 1 (1995).
[346] http://ecos.fws.gov/tess_public/SpeciesReport.do?groups=G&listingType=L&mapstatus=1
[347] Idhttp://ecos.fws.gov/tess_public/SpeciesReport.do?groups=F&listingType=L&mapstatus=1
[348] http://ecos.fws.gov/tess_public/SpeciesReport.do?groups=K&listingType=L&mapstatus=1
[349] http://ecos.fws.gov/tess_public/SpeciesReport.do?groups=K&listingType=L&mapstatus=1

Additionally, low levels of silver when ingested can be toxic to both marine and freshwater zooplankton.[350] These are important components of marine and freshwater food webs since they are the primary grazers in many ecosystems and are often the major food source for developing larvae and fish.[351] Contaminant impacts on these animals are important because they can affect food web structures by altering the grazing on phytoplankton communities and affecting the food supply of predators and/or impact the critical habitat of protected species.

4. Conclusions Made for Bulk Silver Are Not Sufficient To Protect Species from Nano-Silver Releases

Conclusions of potential species' safety and/or the lack of a need for ESA consultation with regard to bulk silver are inadequate for nano-silver releases. First, as explained above, nanomaterials such as nano-silver require a specific nanotoxicology analysis; a bulk materials toxicity assessment is not alone sufficient.[352] In addition, the nano-silver product explosion is creating a vastly increased aggregate environmental exposure than previous releases of bulk silver. One reason that EPA concluded, in the 1993 Silver Re-registration Eligibility Document, that it did not expect "unreasonable adverse effects" on aquatic organisms from silver was because only "*little exposure* to fish and aquatic invertebrates is expected from these uses" and that "the agency does not expect unreasonable adverse effects *from these uses*."[353] In contrast, nano-silver products are creating many more opportunities for exposure from increased and different uses/products, as listed above and in Appendix A. Thus, EPA's 1993 conclusion of no unreasonable adverse effects is inadequate for a plethora of 2008 products of nano-silver.

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[350] Fisher et al., *Silver Accumulation and Toxicity in Marine and Freshwater Zooplankton*, PROCEEDINGS OF THE 5TH ANNUAL CONFERENCE ON THE TRANSPORT, FATE, AND EFFECTS OF SILVER IN THE ENVIRONMENT, pp. 265-274 (1999).
[351] Hook et al., *Sublethal Effects of Silver in Zooplankton: Importance of Exposure Pathways and Implications for Toxicity Testing*, 20 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 568-574 (2001).
[352] See pp. 9-11, 43-46 supra and accompanying footnotes.
[353] EPA, Silver RED, supra note 162 at 17 (emphases added).

Moreover, because nano-silver has a greater surface area than larger particles of silver, nano-silver is more chemically reactive and more readily ionized than silver in larger particle form. Nano-silver therefore has greater antibacterial and toxic effects compared to larger silver particles partly because it is more readily converted to silver ions, which are extremely toxic to varied protected species.

There is also preliminary evidence that nano-silver can exert effective antibacterial action at a considerably lower concentration than silver ions.[354] This suggests that the antibacterial properties and toxicity of nano-silver are not explained by its chemical composition and the production of ions alone. Physical characteristics of nanomaterials, such as their size, shape, and surface properties, can exert a toxic effect that goes beyond that associated with their chemical composition.[355] For example one study demonstrated that nano-silver produces reactive oxygen species (ROS) and this can result in oxidative stress-mediated toxicity.[356] Production of ROS, highly reactive molecules which include free radicals, can interfere with cellular metabolism, cause inflammation, and damage proteins, membranes and DNA. ROS production is a key mechanism for nanomaterials' toxicity.[357]

5. EPA Must Comply with ESA Requirements

Accordingly, EPA must act as soon as possible to protect endangered and threatened species by complying with the ESA, including *inter alia* by consulting with the appropriate wildlife agency about the impacts on protected species of EPA's oversight actions, including *inter alia* any pesticide registration or classification decisions, for nano-silver.

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[354] Lok et al., *Proteomoic analysis of the mode of antibacterial action of silver nanoparticles*, 5 J. PROTEAME RES. 916-924 (2007).
[355] Brunner et al., *In Vitro Cytotoxicity of Oxide Nanoparticles: Comparison to Asbestos, Silica, and the Effect of Particle Solubility*, 40 ENVIRON SCI TECHNOL 4247-81 (2006).
[356] Hussain, S.M. et al., *In vitro toxicity of nanoparticles in BRL 3A rat liver cells*, 19 TOXICOLOGY IN VITRO 975–983 (2005).
[357] See, e.g., Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622-27 (2006).

D. EPA MUST COMPLY WITH THE NATIONAL ENVIRONMENTAL POLICY ACT (NEPA) TO ASSESS THE ENVIRONMENTAL IMPACTS OF EPA'S DECISIONS REGARDING NANO-PESTICIDES AND/OR NANO-SILVER PESTICIDE PRODUCTS, INCLUDING COMPLETING A PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT (PEIS)

1. The National Environmental Policy Act

The National Environmental Policy Act ("NEPA") is the "basic national charter for protection for the environment."[358] 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."[359] Agency NEPA duties are not "inherently flexible."[360] Recognizing the effects of new technologies on the environment, Congress explicitly states in NEPA that "new and expanding technological advances" are activities that could threaten the environment.[361] Thus, in order to understand and control the effects of new technologies like nanotechnology, Congress requires federal agencies to consider the environmental effects of new technology by complying with the requirements of NEPA.

2. The Potential Environmental Impacts of Nanomaterials, Including Nano-Silver

This Section hereby incorporates the above Sections' discussions of the potential environmental impacts of nano-silver pesticides. See supra pp. 57-73, 79-85 and accompanying footnotes. In addition, summarized below is more general information on the potential environmental impacts of nanomaterials. Engineered and manufactured nanomaterials are entering the natural environment throughout their lifecycle: via manufacturing, transportation,

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[358] 40 C.F.R. § 1500.1.
[359] 42 U.S.C. § 4321.
[360] Calvert Cliffs Coordinating Comm. Inc. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109, 115 (D.C. Cir. 1971). In fact, "[c]onsideration of administrative difficulty, delay or economic cost will not suffice to strip the section of its fundamental importance." Id.
[361] 42 U.S.C. § 4331(a). In the legislative history, Congress expressed its concern with "[a] growing technological power * * * far outstripping man's capacity to understand and ability to control its impact on the environment." Found. on Economic Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1985) quoting S. Rep. No. 91-296 (1969).

use, disposal, and/or intentional introduction.[362] All of these lifecycle stages present possible environmental impacts and are potential foci of a comprehensive NEPA impacts assessment.[363]

Nanomaterials' unique chemical and physical properties can create reasonably foreseeable environmental risks. Nanomaterials' potential health and ecological impacts could occur as a result of direct and/or new routes of exposure; the toxicity of the materials themselves; and alterations or byproducts from interactions with other compounds and the environment over time.[364] Cumulative exposures with other manufactured nanomaterials as well as bulk-scale pollutants could also create impacts.[365] Once loose in nature manufactured nanomaterials represent a new class of non-biodegradable pollutants.

Toxicity: Studies assessing the role of size on toxicity have generally found that nanoparticles are more toxic than larger particles of the same substance.[366] Other studies have shown that some nanoparticles are toxic in ways that cannot be attributed to particle size alone.[367] Scientists have yet to determine what physicochemical properties will be most important in determining ecological and toxicological properties of nanomaterials.[368]

There is an emerging literature on the ecotoxicity of nanomaterials. Given all the unknowns about nanomaterials, researchers have focused on the traits that make nanomaterials

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[362] The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, July 2004, pp. 37 Fig. 5.1, 46, available at http://www.nanotec.org.uk/finalReport.htm.
[363] See, e.g., Environmental Protection Agency, *Draft Nanomaterials Research Strategy (NRS)*, January 24, 2008, at 22, available at http://es.epa.gov/ncer/nano/publications/nano_strategy_012408.pdf ; J. Michael Davis, *How to Assess the Risks of Nanotechnology: Learning from Past Experience*, 7 JOURNAL OF NANOSCI AND NANOTECHNOLOGY, 402, 406-07 (2007).
[364] See, e.g., Environmental Protection Agency, *Draft Nanomaterials Research Strategy (NRS)*, January 24, 2008, at 2, 38, available at http://es.epa.gov/ncer/nano/publications/nano_strategy_012408.pdf
[365] Id.
[366]Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, supra note 41, at 54 (February 2007).
[367] Id.
[368]See, e.g., Maynard et al., *Safe Handling of Nanotechnology*, Vol 444 NATURE 267-69 (November 16, 2006); Oberdorster et al., *Nanotoxicology: an emerging discipline evolving from studies of ultrafine particles*, 113 ENVIRON HEALTH PERSPECT 823-839 (2005).

attractive for applications in industry and medicine—their ability to enter cells and carry other materials as well as a slew of other behaviors that make nanomaterials potentially damaging for humans and the environment. A number of studies have shown respiratory toxicity of various types of nanoparticles in small mammals.[369] These mammalian studies raise concerns that some nanomaterials may also be toxic to wildlife. EPA noted that "nanomaterials may affect aquatic or terrestrial organisms differently than larger particles of the same materials."[370] Several studies on the effects of various nanomaterials on fish and aquatic species have shown potentially negative impacts.[371] Significant lipid peroxidation was found in the brains of fish (largemouth bass) after exposure to carbon fullerenes, demonstrating the toxic effects of these nanoparticles on aquatic and possibly other organisms.[372] This is especially important given that this fish species is seen as a model for defining ecotoxicological effects. Studies on fullerenes have shown other potential impacts on aquatic ecosystems.[373] Similarly studies on various nanomaterials currently in use commercially have shown potential negative impacts on fish and aquatic organisms, e.g. carbon nanotubes,[374] copper nanoparticles,[375] titanium dioxide nanoparticles,[376] and silver nanoparticles.[377]

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[369]Handy et al., *Toxic effects of nanoparticles and nanomaterials: implications for public health, risk assessment, and the public perception of nanotechnology*, 9 HEALTH, RISK AND SOCIETY 125-144 (2007).
[370] Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 58, (February 2007).
[371] Handy et al., *Ecotoxicity of nanomaterials to fish: Challenges for ecotoxicity testing*, 3 INTEGRATED ENVIRONMENTAL ASSESSMENT AND MANAGEMENT 458-60 (2007).
[372] Oberdorster et al., *Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENVIRONMENTAL HEALTH PERSPECTIVES 10 (2004).
[373] Fortner et al., *C60 in water: Nanocrystal formation and microbial response*, 39 ENVIRON SCI & TECH 4307-16 (2005); Rick Weiss, *Nanoparticles Toxic in Aquatic Habitat, Study Says*, WASH. POST (March 29, 2004) at A2; Press Release Rice University's Center for Biological and Environmental Nanotechnology, *CBEN: Buckyball aggregates are soluble, antibacterial*, (June 22, 2005), available at http://www.eurekalert.org/pub_releases/2005-06/ru-cba062205.php; Geoff Brumfiel, *A Little Knowledge . . .*, Vol 424 NATURE 246 (July 17, 2003); Sayes C. et al., *The differential cytotoxicity of water-soluble fullerenes*, 4 NANOTECHNOLOGY LETTERS 1881-87 (2004).
[374] Smith et al., *Toxicity of single walled carbon nanotubes to rainbow trout: respiratory toxicity, organ pathologies, and other physiological effects*, 82 AQUAT. TOXICOL. 94-109 (2007);

There is little research thus far on impacts of nanomaterials on plants, for instance in terms of bioaccumulation. One study found that engineered nanoparticles of aluminum oxide slowed the growth of roots in at least five species of plants.[378] Nanoparticles also can be "taken up" by bacteria, creating a means of potential bioaccumulation up the food chain.[379]

Mobility and Durability: Because of their tiny size nanomaterials may be highly mobile and travel further than larger particles in soil and water, which could foreseeably create environmental impacts.[380] Initial studies on potential remediation uses indicate that nanoparticles of iron can travel with groundwater over a distance of twenty meters and remain reactive for up to two months.[381] Early studies on the effects of nanomaterial exposure to biological systems have shown a high mobility in organisms or cells.[382] The translocatory potential of nanomaterials that makes them commercially attractive for drug delivery could cause unintended consequences as nanomaterials are released into natural systems.

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[375]Griffitt et al., *Exposure to Copper Nanoparticles Causes Gill Injury and Acute Lethality in Zebrafish (Danio rerio)*, 41 ENVIRON. SCI. TECHNOL., 8178–8186 (2007).
[376] Federici, *Toxicity of titanium dioxide nanoparticles to rainbow trout (Oncorhynchus mykiss): Gill injury, oxidative stress, and other physiological effects.,* AQUAT TOXICOL. 2007 Jul 25; : 17727975 (P,S,E,B,D); Zhang et al., *Enhanced bioaccumulation of cadmium in carp in the presence of titanium dioxide nanoparticles*, 67 CHEMOSPHERE 160-67 (2007).
[377] Lee et al, *In Vivo Imaging of Transport and Biocompatibility of Single Silver Nanoparticles in Early Development of Zebrafish Embryos*, ACS Nano, 1(2), 133–143 (2007).
[378] Watts, D., *Particle Surface Characteristics May Play an Important Role in Phytotoxicity of Alumina Nanoparticles*, 158 TOXICOLOGY LETTERS 122-132 (2005); *Study Shows Nanoparticles Could Damage Plant Life*, SCIENCEDAILY (November 22, 2005), available at http://www.sciencedaily.com/releases/2005/11/051122210910.htm.
[379]Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 36, (February 2007).
[380] Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 34, (February 2007).
[381] Zhang et al., *Nanoscale Iron Particles for environmental remediation: An overview*, 5 JOURNAL OF NANOPARTICLE RESEARCH 323-332 (2003).
[382]See, e.g., Limbach et al., *Oxide nanoparticle uptake in human lung fibroblasts: Effects of particle size, agglomeration, and diffusion at low concentrations*, 39 ENVIRON. SCI. TECHNOL. 9370-9376 (2005); Rothen-Rutishauser et al., *Interaction of fine particles and nanoparticles with red blood cells visualized with advanced microscopic techniques*, 40 ENVIRON. SCI. TECHNOL. 4353-4359 (2006); Geiser, et al., *Ultrafine particles cross cellular membranes by nonphagocytic mechanisms in lungs and in cultured cells*, 113 ENVIRON. HEALTH PERSPECT. 1555-1560 (2005).

Little is known about the potential of biodegradation of nanoparticles and mechanisms will depend on the nature of the material. The "high durability and reactivity of some nanomaterials raise issues of their fate in the environment."[383] Many nanoparticles in current products are non-biodegradable materials (such as metal oxides used in sunscreens).[384]

Interactions and Transport of Pollutants: Possible interactions between nanoparticles and harmful environmental chemicals may lead to unique exposures and impacts. Because nanoparticles tend to be more reactive than larger particles, interactions with substances present in the soil could lead to new and possibly toxic compounds. EPA has noted that "the use of nanomaterials in the environment may result in novel by-products or degradates that also may pose risks."[385] Many nanomaterial products (such as cosmetics and sunscreens) consist of "free" nanoparticles not fixed in a product matrix which will speed up their interaction in the environment.

Nanoparticles are the subject of vigorous drug research because of their ability to carry and deliver drugs to specific targets.[386] This same transport propensity could give nanoparticles the ability to carry toxic chemicals present in the environment. Natural and accidentally-created ultrafine particles can similarly carry toxic chemicals such as hydrocarbons and metals which can then damage natural systems.[387] The large surface area, crystalline structure and reactivity of

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[383] Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 14, (February 2007).
[384] Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 36, (February 2007).
[385]Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 58, (February 2007).
[386] See, e.g., Chavanpatil et al., *Nanoparticles for cellular drug delivery: mechanisms and factors influencing delivery*, 6 J. Nanosci. NANOTECHNOL 2651-2663 (2006).
[387] See, e.g., Penn et al., *Combustion-derived ultrafine particles transport organic toxicants to target respiratory cells,* 113 ENVIRON HEALTH PERSPECTIVES 956-79 (2005); Gutierrez-Castillo et al., *Effect of chemical composition on the induction of DNA damage by urban airborne particulate matter*, 47 ENVIRON MOL MUTAGEN 199-211 (2006); Schwarze et al., *Particulate matter properties and health effects: consistency of epidemiological and toxicological studies*, 25 HUM EXP TOXICOL 559-79 (2006).

some nanoparticles may facilitate transport of toxic pollutants in the environment.[388] Moreover, recent research has discovered a possible "trojan horse"-like toxicity mechanism of nanoparticles, which could carry harmful metals into cells.[389] Once inside the cell, the metal ions can leach from the nanoparticle and create oxidative stress.[390]

3. EPA's NEPA responsibilities

To accomplish NEPA's purposes, all federal agencies are required to prepare a "detailed statement"–known as an Environmental Impact Statement (EIS)– regarding all "major federal actions significantly affecting the quality of the human environment . . ."[391] To determine whether an EIS is required, federal agencies must prepare an Environmental Assessment (EA), that provides sufficient evidence and analysis to support the agency's determination on whether a proposed action will significantly affect the environment.[392] In addition to environmental concerns, the proposed action's possible direct, indirect, and cumulative impacts on public health must be reviewed if they are linked to its environmental impacts.[393]

Beyond just assessing the impacts of particular project-related actions, EPA is also required to assess the broader impacts of its programmatic actions and to consider alternative program approaches. A programmatic EIS (PEIS) is called for under the CEQ NEPA regulations, which define a "Federal action" broadly to include, in pertinent part, when there is:

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[388] Zhang et al., *Environmental Technologies at the nanoscales,* 37 ENVIRON SCI. TECHNOL. 102A-108A (2003).
[389] Limbach et al., *Exposure of Engineered Nanoparticles to Human Lung Epithelial Cells: Influence of Chemical Composition and Catalytic Activity on Oxidative Stress*, 41 ENVIRON. SCI. TECHNOL. 4158-4163 (2007).
[390] Id.
[391] 42 U.S.C. § 4332(c). The EIS must describe (1) the "environmental impact of the proposed action," (2) any "adverse environmental effects which cannot be avoided should the proposal be implemented," (3) "alternatives to the proposed action," (4) "the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity," and (5) any "irreversible or irretrievable commitment of resources which would be involved in the proposed action should it be implemented." Id.
[392] 40 C.F.R. §§ 1501.4(b), 1508.9.
[393] 40 C.F.R. § 1508.8; Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 106 (1983)(explaining that "NEPA requires an EIS to disclose the significant health, socioeconomic, and cumulative consequences of the environmental impact of a proposed action").

> Adoption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic or connected agency decisions allocating agency resources to implement a specific statutory program or executive directive.[394]

If EPA grants this petition and enacts new regulations, or amends existing regulations with an aim at regulating nano-silver products, or adopts an official policy in another form, such programmatic regulatory action would necessitate a PEIS if the action "significantly affects the quality of the human environment."[395] Moreover, an agency "program" or "proposal" that exists in fact, but is not necessarily expressly declared by the agency, also requires a PEIS.[396] Accordingly, if EPA declines to enact or amend its regulations, but instead continues acting pursuant to a "de facto" nano-silver regulatory policy, such concerted action would also necessitate a PEIS.

At least one Court has said that EPA does not need to prepare an EIS before it can register a pesticide.[397] That said, the registration and labeling of a pesticide under FIFRA does not exempt an agency from its general NEPA obligations.[398] A pesticide registration under

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[394]40 C.F.R. § 1508.18(b)(3) (defining "Federal action"). CEQ's "Question 24a" is instructive here as it addresses programmatic compliance on the topic of: "When are EISs required on policies, plans or programs?" It provides:

> An EIS mst be prepared if an agency proposes to implement a specific policy, to adopt a plan for a group of related actions, or to implement a specific statutory program or executive directive. In addition, the adoption of official policy in the form of rules, regulations, and interpretations pursuant to . . . formal documents establishing governmental or agency policy which will substantially alter agency programs, could require an EIS . . . . It should be noted that a proposal may exist in fact as well as by agency declaration that one exists.

46 Fed. Reg. 18026, 18033 (Forty Most Asked Questions Concerning CEQ's NEPA Regulations) (Question and Answer 24(a)).

[395] 21 C.F.R. § 25.22(b).

[396] See 40 C.F.R. § 1508.23 (Defining "Proposal" to include that a "proposal may exist in fact as well as by agency declaration that one exists").

[397]Merrill v. Thomas, 807 F.2d 776 (9th Cir. 1986).

[398]42 U.S.C. § 4332; Oregon Envtl. Council v. Kunzman, 714 F.2d 901, 905 (9th Cir. 1983); Save Our Ecosystems v. Clark, 747 F.2d 1240, 1248 (9th Cir. 1984).

FIFRA does not require the same examination of environmental concerns that an agency is required to make under NEPA.[399]

5. EPA regulatory action or program regarding nano-silver and nanotechnology is "significant" and requires a PEIS

CEQ's implementing regulations list factors to determine whether a Federal action, such as EPA's pesticide regulatory approach to nanotechnology and nanomaterials, is "significant," which include:

> -- The degree to which the proposed action affects public health or safety
>
> -- The degree to which the effects on the quality of the human environment are likely to be highly controversial
>
> -- The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks
>
> -- [t]he degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.[400]

In this case, all the above factors are present. First, given the unprecedented environmental and human health risks of nanomaterials, EPA regulatory actions or programs (or inaction) for nano-silver will greatly affect public health and safety. The petition discusses the significant risks nano-silver poses to public health and safety and the environment. These nano-silver pesticide products being released into the environment are under EPA's FIRFA jurisdiction, and represent the highest percentage of known nanomaterial consumer products currently on markets and being disposed into the environment.[401]

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[399] Save Our Ecosystems, 747 F.2d at 1248; Washington Toxics Coal. v. EPA, 413 F.3d 1024, 1032 (9th Cir. 2005).
[400] 40 C.F.R. § 1508.27(b)(2),(4),(5),(6) & (9). The Supreme Court has held that CEQ's NEPA implementing regulations are entitled to substantial deference by the courts. Andrus v. Sierra Club, 442 U.S. 347, 358 (1979); Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 372 (1989). FDA has expressly adopted CEQ's "significantly" definition in its own NEPA regulations. 21 C.F.R. § 25.5(a)(19).
[401] The Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, *Nanotechnology Consumer Products Inventory*, available at http://www.nanotechproject.org/consumerproducts

Second, EPA's current general stance is that it has "no information" regarding nano-silver pesticide products.[402] Yet this petition includes an appendix with over 260 such products, over 100 pages and 400 footnotes providing information publicly available. Further, EPA's Region IX has taken an enforcement action against one nano-silver product manufacturer for violating FIFRA, using the same statutory provisions and statutory authority outlined in this petition. Still, EPA has also limited any proposed action to the "ions" of the Samsung Washing Machine, without even mentioning nanotechnology or nanomaterials. This is at odds with the scientific studies on nanomaterials regarding their fundamentally unique properties and risks. Thus, the agency's regulatory stance, if not corrected, is highly controversial at best and grossly negligent at worst.

Third, due to the paucity of research funding on the environmental and health impacts of nanomaterials, the possible effects on the human environment are highly uncertain;[403] given the fundamental differences of engineered nanoparticles from bulk materials, those risks are also quite unique.[404] The nano-ness created capacity for fundamentally different properties and the associated unknowns about potential adverse environmental and health impacts of nanotechnology apply to both nanomaterial writ large as well as nano-silver specifically.

Finally, no U.S. regulatory agency has enacted regulations governing the release and marketing of nanomaterials. However, EPA has acknowledged that products containing nanomaterials such as nano-silver are currently available to consumers and fall under its pesticide

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[402] See notes 75-82 and accompanying text supra.
[403] EPA White Paper, supra note 41, at 35 ("The fundamental properties concerning the environmental fate of nanomaterials are not well understood [], as their are few available studies on the environmental fate of nanomaterials.) (footnote omitted).
[404] See id. at 35-44 (discussing, *inter alia*, the different behavior of nanoparticles in water and soil, the inability to meaningfully predict the biodegradation, bioavailability, or bioaccumulation of nanomaterials, and the inability of existing methods to detect or track nanomaterials in the environment).

regulation. Accordingly, EPA's pesticide regulatory and/or policy stance on nanopesticides and nano-silver regulation is significant and precedential.

The "presence of one or more of these factors should result in an agency decision to prepare an EIS."[405] In this case, at least four factors are present.[406] Accordingly, NEPA requires EPA to conduct a PEIS before enacting, adopting, or amending its regulations to create a regulatory program for nano-silver pesticide regulation, and before continuing to act under its regulatory program on nano-silver pesticide regulation.[407]

IV. EPA Must Take Immediate Action to Prohibit the Sale of the Class of Illegal Nano-silver Pesticide Products with Unapproved Health Claims

A. Both Nano-silver as an Active Ingredient and Nano-silver Products are Illegal Pesticide Products

Under the above statutory and regulatory framework, the nano-silver infused consumer and household products are illegal pesticides that require registration.[408] The products easily meet the FIFRA definition of pesticides, even a specific subset of antimicrobial pesticides.[409] The products are intended for such use. Their labeling illegally connotes a germ-killing propensity without registration.[410] Even if unlabeled or if such labeling is stripped, the nano-silver products are pesticides because manufacturers have actual knowledge of the nano-silver's germ killing powers and advertising has created a reasonable expectation of that use from industry-wide ads on other nano-silver products.[411] The nano-silver pesticide used to treat many consumer items is not registered for use in the items or use (or registered at all for any use).

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[405] Public Service Co. of Colo. v. Andrus, 825 F. Supp. 1483, 1495 (D. Idaho 1993); See Friends of the Earth, Inc. v. U.S. Army Corp of Eng'rs, 109 F. Supp. 2d 30, 43 (D. D.C. 2000).
[406] See 40 C.F.R. § 1508.27(b)(2),(4),(5),(6) & (9).
[407] Id. §§ 1502.4(c)(3), 1508.18(b)(1).
[408] See supra pp. 30-42.
[409] See pp. 30-38 supra and accompanying footnotes.
[410] See supra pp. 14-15, 32-34.
[411] Id. at 34-37.

EPA itself lists several types of common "illegal pesticides," including antimicrobial products used in households:

> Many common household products, ranging from cleansers to cutting boards, claim to protect against bacteria. Such claims are illegal unless the product is registered with EPA or the claim only applies to protecting the item itself from damage by microorganisms, not to provide any additional health benefits. In addition, the pesticide used to treat the item must be registered for use in or on the treated item.[412]

In this case, the nano-silver pesticide products are not registered, and the widespread claims made include various other additional health benefits besides protecting the product itself. These claims include claims like "*sterilization benefits for over 650 types of bacteria like "E. coli, S. Aureus, Pneumococcus, Salmonella, Typhus, Vibria, Cholerae, etc*."; "*kills bacteria in vitro in as little as 30 minutes, 2-5 times faster than other forms of silver*"; "*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*"; and "*sterilize up to 99.9% of harmful bacteria, such as colon bacilli, salmonella, yellow staphylococcus, pseudomonas aeruginosa an salmonella enteritidis*." See Appendix A. Further, nano-silver itself is not registered for use on the items or any items for that matter. Thus, the claims and products are clearly illegal.

B. EPA Must Act to Stop the Sale of Illegal Nano-silver Pesticides by All Means Possible, Including the Issuance of Stop Sale, Use or Removal Orders

With express limited exemptions, no pesticide products may be distributed or sold if not registered.[413] EPA's statement on "illegal pesticides" notes:

> EPA is concerned about these claims because, in addition to being unlawful, they are also potentially harmful to the public (e.g., if people believe that a product has a self-sanitizing quality, they may become lax in their hygiene practices). Practicing standard hygiene practices has been proven to prevent the transmission

[412]EPA, Illegal Pesticide Products, at www.epa.gov/pesticides/health/illegalproducts/index.htm
[413]40 C.F.R. §§ 152.15, 152.42 (application for new registration must be approved before product may be legally distributed or sold).

> of harmful microorganisms and, therefore, reduce the possibility of public health risk.
>
> In response to the marketing of unregistered pesticide-treated products with illegal, unsubstantiated public health claims, EPA has acted quickly and decisively to prohibit sales of such products. It will continue to be the Agency's policy to take action against companies that make such illegal claims.[414]

In accordance with the mandates of FIFRA and EPA's own regulations and policies, petitioners call on EPA to act "quickly and decisively" to prohibit the sale of these nano-silver products and take further actions it deems necessary against the companies making these illegal claims.

To that end, EPA should issue Stop Sale, Use or Removal Orders ("SSURO") to those manufacturers and/or distributors currently selling these unregistered nano-silver pesticide products. EPA may issue a stop sale, use or removal order (SSURO) under FIFRA § 13(a) to any person who owns, controls, or has custody of a pesticide or device that EPA has reason to believe, *inter alia*, is in violation of any FIFRA provision or has been or is intended to be distributed or sold in violation of FIFRA.[415] EPA may issue such orders based on only a reasonable belief of a FIFRA violation. According to the EPA's FIFRA Enforcement Response Policy, a SSURO must be issued for a number of instances, including

> a pesticide for which there is reason to believe that there is a potential hazard to man or the environment because: (1) *they are not registered* or are so over-formulated, under-formulated or adulterated as to present a serious health hazard . . .[416]

[414]EPA, Pesticides: Topical & Chemical Fact Sheets, Consumer Products Treated with Pesticides, at www.epa.gov/pesticides/factsheets/treatart.htm
[415]7 U.S.C. § 136k(a).
[416]U.S. EPA, Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (July 2, 1990) (FIFRA ERP) at 6 (emphasis added).

EPA should issue stop sale orders to the manufacturers of nano-silver products not properly registered as pesticides. Appendix A lists many of these illegal pesticide products and their manufacturers.

Finally, as discussed above, there is already precedent for such actions: EPA's recent consent agreement with ATEN Technology fining that company for unlawfully marketing and selling unregistered nano-silver pesticide products.[417]

V. If Any Nano-silver Pesticide Registration is Approved, EPA Must Apply the EPA Pesticide Requirements To Nano-silver Pesticides, Including Requiring Labeling and Post-Registration Notification Requirements

If approved, EPA must insure that nano-silver pesticides abide by all pesticide requirements. The pesticide registration requirements provide EPA authority to require the generation of data necessary for risk assessment on nano-pesticides; to prohibit the use of a nano-pesticide that is determined to present unreasonable adverse effects to human health or the environment; and to condition the use of nano-pesticides to ensure that it does not present the threat of unreasonable adverse effects. Accordingly, when making registration decisions, EPA should impose appropriate restrictions on the registration of a nano-silver pesticide in order to prevent it from causing unreasonable adverse effects. These restrictions include but are not limited to: Registration for general use or restricted use under FIFRA Section 3(d) and 40 C.F.R. Part 152, Subpart I; Labeling restrictions under FIFRA Section 3(c)(5)(B) and 40 C.F.R. Part 156. (including the use of personal protective equipment, disposal restrictions, use restrictions, etc.); Tolerances under the FFDCA Section 408 and 40 C.F.R. Part 180; Worker protection standards under FIFRA Section 25(a) and 40 C.F.R. Part 170; and Packaging standards under

[417] See pp. 25-26 supra and accompanying footnotes.

FIFRA Section 25(c)(3) and 40 C.F.R. Part 157. Further, the pesticide registration requirement is supported by strong enforcement powers that can be exercised over unregistered pesticides under FIFRA §§ 12, 13, 14, & 19. Finally, in addition to information required to be submitted under § 3(c)(2)(B), registrants are under a continuing obligation under FIFRA § 6(a)(2) to submit factual information regarding unreasonable adverse effects on the environment of the pesticide whenever the registrant has such information. 7 U.S.C. § 136d(a)(2).; 40 C.F.R. § 152.125.

A. EPA Must Require Labeling of Nano-Silver Products

Registered pesticides must have EPA-approved labels, including a proper ingredient statement, directions for use, classification for restricted use, and hazard and precautionary statements.[418] In addition, all other written, printed, or graphic matter accompanying the pesticide or any other such matter to which the label or literature accompanying the pesticide refers must conform to EPA requirements.[419] Warnings and precautionary statements include statements for environmental risks,[420] such as those to non-target organisms.[421] For example, silver pesticides must carry a label stating:

> the pesticide [silver] is toxic to fish and aquatic invertebrates.
>
> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit….[422]

Current nano-silver pesticide products are in violation of FIFRA for their commercial sale without proper labeling. EPA must require a unique identifier to be commonly understood to designate a nano-formulation; these products need to be labeled as containing nano-silver,

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[418] 40 C.F.R. § 156.10.
[419] 7 U.S.C. § 136(p)(1-2).
[420] 40 C.F.R. § 156.80.
[421] 40 C.F.R. § 156.85.
[422] EPA, Silver RED, supra note 162 at 5.

including any nano-specific environmental precautionary statements; and any other limitations the agency saw appropriate to mandate.

B. EPA Must Require Post-Registration Notification of Adverse Effects

Registration of nano-silver pesticides places upon registrants a continuing obligation to report to EPA any new factual information the registrant learns about unreasonable adverse effects on the environment from the pesticide.[423] This includes information from scientific studies, including toxicological, ecological, and human epidemiological and exposure studies.[424] Any study that suggests a pesticide may present greater risks than previously known is reportable. In addition, registrants must provide information they know or should know that EPA might regard as raising concerns about the continued registration of the pesticide or about the terms or conditions of the registration.[425]

This post-registration notification requirement is especially crucial for emerging technologies and materials such as nanotechnologies, with rapid commercialization happening ahead of EHS research. Significant health, safety and environmental impact information on nanomaterials and nano-silver will continue to appear. EPA must require nano-silver pesticide registrants to timely provide all information related to unreasonable adverse effects on the environment from nano-silver.

Further, this post-registration reporting obligation includes information related to a class of pesticides, not just individual pesticides.[426] EPA has previously tailored post-registration reporting requirements for certain types or classes of pesticides, such as plant-incorporated

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[423] 7 U.S.C. § 136d(a)(2); 40 C.F.R. § 159.152(a); 40 C.F.R. Part 159 (specifying the kinds of information required to be submitted).
[424] 40 C.F.R. §§ 159.155(a)(1), (3); 159.165; 159.170.
[425] 40 C.F.R. § 159.195(a).
[426] See PR Notice 98-3, "Guidance on Final FIFRA Section 6(A)(2) Regulations for Pesticide Product Registrants" (Apr. 3, 1998), § X, available at http://www.epa.gov/opppmsd1/PR_Notices/pr98-3.pdf.

protectants[427] and specifically singled out genetically-engineered microbial pesticides on their duty to report adverse effects.[428] EPA should undertake similar actions for nanomaterial and/or nano-silver pesticides as well, to ensure the agency timely receives all pertinent data on the impacts of these new materials in order to best inform its oversight actions.

C. EPA Must Require Post-Registration Testing and New Data Development

EPA should also require nano-silver registrants to develop new data post-registration. EPA can require post-registration testing of nanopesticides under FIFRA § 3(c)(2)(B) and 4. EPA has the authority to require registrants conduct new studies whenever EPA determines such data is "required to maintain in effect an existing registration of a pesticide."[429] As new scientific data on nano-silver emerges EPA should use its authority to ensure FIFRA's standards are maintained. In addition, EPA should require, as part of reregistration, submission of missing or inadequate data.[430]

D. Conditional Registration

When EPA does not have enough data to make an unconditional registration decision it may conditionally register a pesticide.[431] Most new pesticide registrations are conditional.[432] EPA can conditionally register a pesticide for a time period sufficient to allow the generation and submission of additional data.[433] Because of the many unknowns about nanomaterials and nano-silver specifically, EPA should use its conditional registration authority.

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[427] 40 C.F.R. § 174.71
[428] 51 Fed. Reg. 23313, 23320 (June 26, 1986).
[429] 7 U.S.C. § 136a(c)(2)(B).
[430] 7 U.S.C. §136a-1(d)(3).
[431] 7 U.S.C. § 136a(c)(7).
[432] 40 C.F.R. § 152.111
[433] 136a(c)(7)(C).

E. Disclosure of Confidential Business Information is in the Public Interest

All information concerning the environmental or health effects of a registered pesticide or its ingredients is available for public disclosure.[434] Data submitted with registrations must be made part of the public record and be available for public inspection.[435] In addition, EPA may disclose confidential business information (CBI) concerning production, distribution, sale, or inventories of a pesticide in connection with a public proceeding to determine whether the pesticide causes unreasonable adverse effects on health or the environment, if EPA finds such disclosure is necessary in the public interest.[436] In the case of nanotechnology, nanomaterials, and nano-silver products, disclosure of claimed CBI is in the public interest because of the dearth of information on the risks of nanotechnology. The public interest is benefited from a transparent and open dialog on the risks of any new and emerging technology such as nanotechnology. Here, nano-silver product information would substantially enhance and inform the public interest and EPA should require the disclosure of such information with regard to nano-silver pesticide products.

VI. Other EPA Actions Requested for Adequate Assessment and Oversight of Nano-silver Pursuant to FIFRA

FIFRA grants EPA general authority to prescribe regulations to carry out the provisions of the Act,[437] and separate sections of FIFRA include more specific grants of rulemaking authority.[438] EPA thus has broad powers under FIFRA to make regulatory changes as it sees necessary to protect public heath and the environment from the potential dangers of nano-

[434] 7 U.S.C. § 136h(d)(1).
[435] 40 C.F.R. §152.119
[436] 7 U.S.C. § 136h(d)(2).
[437] 7 U.S.C. § 136w(a)(1).
[438] See, e.g., 7 U.S.C. § 136a(c)(2)(A)(registration data guidelines shall be revised from time to time); § 136f(a) (regulations for recordkeeping requirements necessary for effective enforcement).

pesticides, including nano-silver products. Accordingly, in addition to the above delineated agency actions, EPA should also use all other relevant FIFRA oversight mechanisms to adequately address the potential environmental and human health impacts of nano-silver and determine whether nano-silver presents an unreasonable risk to man or the environment.

A. EPA should Undertake a Classification Review of Nano-silver Pesticides

EPA should undertake a classification review of nano-silver pesticides. Pursuant to its classification procedure regulations, EPA may, by regulation, prescribe classification restrictions relating, *inter alia*, to a pesticide product's composition, labeling, packaging, uses, or distribution and sale.[439] EPA may identify "a group of products having common characteristics or uses and may classify for restricted use same or all of the products or uses included in that group."[440] Such a group can be comprised of products that:

> (1) Contain the same active ingredients.
> (2) Contain the same active ingredients in a particular concentration range, formulation type, or combination of concentration range and formulation type.
> (3) Have uses in common.
> (4) Have other characteristics, such as toxicity, flammability, or physical properties, in common.[441]

Thus, EPA can conduct a classification review of such a group of products with the same active ingredient, same usage, or same characteristics in common if it deems such review necessary to avoid unreasonable adverse affects on the environment.[442] All of the nano-silver products have the same active ingredient (nano-silver), in the same concentration range

[439] 40 C.F.R. § 152.160.
[440] 40 C.F.R. § 152.164.
[441] Id. § 152.164(a).
[442] 40 C.F.R. § 152.164(a)-(b).

(nanoscale), for the same or similar use (antimicrobial effects). In this case, the environmental impacts of nano-silver and existing unknowns warrant such a classification review.[443]

Classification reviews are often conducted as part of a review of an application for a new registration of a product containing an active ingredient not contained in any currently registered product.[444] Nano-silver is not registered for use and is a new active ingredient. If the EPA determines that a product or one or more of its uses should be classified for restricted use, it can do so by regulation.[445]

B. EPA Should Undertake a Special Review of Nano-silver Pesticides

Alternatively, EPA should undertake the Special Review process for nano-silver pesticide products.[446] The purpose of Special Reviews is for the agency to determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because that product may cause unreasonable adverse effects on the environment under FIFRA sections 3(c)(6) and 6.[447] The Special Review procedures expressly note that even though EPA is taking review action, the burden of persuasion that a pesticide is entitled to registration remains on the pesticide product manufacturer/applicant.[448]

The EPA Administrator may conduct a Special Review of a pesticide use for a broad array of reasons, including, *inter alia*:

> (3) May result in residues in the environment of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.

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[443] See supra pp. 58-91.
[444] 40 C.F.R. § 152.164(b)(1).
[445] 40 C.F.R. § 152.164(c)(1).
[446] 40 C.F.R. §§ 154.1-154.35
[447] 40 C.F.R. § 154.1
[448] 40 C.F.R. § 154.5.

> (4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.
>
> (5) May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any endangered or threatened species.
>
> [and the catch-all provision]
>
> (6) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.[449]

Nano-silver poses environmental risks pertaining to one or more of these types of risks sufficient to conduct a Special Review.[450] Nano-silver aimed at killing bacteria and microorganisms in or on consumer products, homes, and other goods, when released into the environment pose dangers to non-target species such as fish and other aquatic species. These residues may exceed levels toxic to such organisms. In addition, many of these fish and aquatic species may be federally protected as endangered or listed species. See Section III(C) infra. The current Fish and Wildlife Service (FWS) protected species listing counts at least 258 protected relevant fish or other aquatic species, including 139 threatened or endangered fish, 70 threatened or endangered clams, and 22 threatened or endangered crustaceans, and 25 reptiles or mammals.[451] Given the widespread usage and potential disposal routes, nano-silver releases could also result in the destruction or adverse modification of these species' habitat. Finally, nano-silver releases may pose other risks to humans or the environment, see supra, of sufficient magnitude to merit a determination.

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[449] 40 C.F.R. § 154.7(a).
[450] See supra pp. 58-91 and accompanying footnotes
[451] See Appendix C; http://www.fws.gov/endangered/wildlife.html#Species

As part of the Special Review of nano-silver the Administrator should, among other duties, open a public docket for comments,[452] request a Scientific Advisory Panel hold a public meeting to review the scientific issues related to the Special Review,[453] hold hearings,[454] and meetings with interested parties.[455]

C. EPA should Require the Submission of Nano-specific Data from Prospective Nano-Silver Registrants

EPA should require the necessary data from prospective registrants for nano-silver products. EPA must ensure it has all the data it needs on nano-silver necessary to perform its risk assessments. Where data does not exist, EPA must require its development.[456] The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.[457] Data needs include, *inter alia*, data on physical and chemical characteristics of a pesticide active ingredient, wildlife and aquatic organism data, environmental fate data, mobility studies, accumulation studies, and hazards to nontarget organisms.[458] To perform its statutorily-mandated risk assessment for a pesticide, EPA needs information on the potential risks and benefits of a pesticide. There are many unknowns currently about potential the human health and environmental impact of nanomaterials, including nano-silver. "If information required generally is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements <u>will be imposed</u>."[459]

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[452] 40 C.F.R. § 154.15, 154.26,
[453] 40 C.F.R. § 154.25(d).
[454] 40 C.F.R. § 154.29.
[455] 40 C.F.R. § 154.27.
[456] 40 C.F.R. § 152.111
[457] 40 C.F.R. § 158.130
[458] <u>Id.</u>
[459] 40 C.F.R. § 158.75(a).

D. EPA should Amend FIFRA Regulations to Require Nanomaterial and/or Nano-silver Specific Data

To account for the unique challenges of nanomaterials and nano-pesticides, including nano-silver products, EPA should amend its regulations to require nano-specific data for nano-pesticides.[460] The data requirements are intended to generate the data necessary to address concerns. FIFRA section 25(a) instructs EPA to "take into account the difference in concept and usage between various classes of pesticides [] and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, non-agricultural, and public health pesticides."[461] Accordingly, FIFRA gives EPA the ability to make regulatory data requirements for specific types of pesticide products.[462]

Current data requirements for product composition, certified limits, and physical and chemical characteristics do not address information regarding some of the key unique properties of nanomaterials.[463] For example the regulations do not require either identifying or testing the surface area, shape, or aggregation of particles, all of which can modify cellular uptake, protein binding, translocation, and the potential for injury. Further the regulations define threshold limits by mass concentration rather than surface area.[464]

There is well established precedent for actions amending data requirements for specific types of pesticide products. For example, EPA has promulgated regulations that apply specifically to testing of genetically modified microbial pesticides.[465] The data requirements for this category of pesticides differ from those typically required for other types of pesticides.

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[460] 40 C.F.R. Part 158 (Data Requirements).
[461] 7 U.S.C. § 136w(a).
[462] 40 C.F.R. § 158.1.
[463] See 7 U.S.C. § 136a(c)(2)(A); 40 C.F.R. Part 158.
[464] 40 C.F.R. § 158.175(b).
[465] 40 C.F.R. §§ 172.43-.59

E. EPA should Undertake Registration Review of Existing Bulk Silver Pesticide Registration

A registration review decision is "the Agency's determination whether a pesticide meets, or does not meet the standard for registration under FIFRA."[466] "Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment."[467] Silver last re-registered in 1993.[468] Since then, nanotechnology has come of age and a fleet of nano-silver products have come to market and thus entered the natural environment.[469] "At any time, the Agency may undertake any other review of a pesticide under FIFRA, irrespective of the pesticide's past, ongoing scheduled, or not yet scheduled registration review."[470]

EPA should undertake a registration review for its existing pesticide registrations for the active ingredient silver, in order to take in account and properly analyze the new scientific issues of nanotechnology and nano-silver. This review is needed not only because of the new scientific challenges and risks created by nanotechnology and nanomaterials but also the new nanomaterial uses and nanomaterial products, and nanomaterial created routes of exposure for humans and the environment.

As part of the silver registration review EPA should issue a data call-in notice under FIFRA Section 3(c)(2)(B) to gather the nano-specific health and safety and exposure data necessary to conduct the registration review.[471] Additionally, as part of the registration review process, EPA should: open a public docket;[472] "assess changes since the pesticide's last review;"

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[466] 40 C.F.R. § 155.57
[467] 40 C.F.R. § 155.40(a)(1).
[468] Silver Re-registration Eligibility Document (RED), 1993.
[469] See, e.g., supra pp. 11-14, 66-67, 89-90
[470] 40 C.F.R. § 1555.40(c)(1).
[471] 40 C.F.R. § 155.48, 155.53(b)(1); 7 U.S.C. 136a(c)(2)(B)
[472] 40 C.F.R. § 155.50.

"consider whether any new data or information on the pesticide … warrant conducting new risk assessment or a new risk/benefit assessment;" and "conduct new assessments as needed."[473] Any proposed findings, revised or new risk assessments, risk mitigation measures, and/or labeling changes must be subject to public notice and comment.[474]

F. EPA should Ensure that Nano-silver Pesticide Devices Comply with FIFRA

Some nano-silver products may qualify as a pesticide device in addition to (or instead of) classification as a pesticide. A pesticide device is defined as

> **Pesticide Device**: any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals).[475]

In general, an article is a device if it uses physical or mechanical means (as opposed to chemical or biological agent) to control a pest. Some of the nano-silver products in Appendix A contain not only nano-silver intended to prevent and destroy pests, but also a mechanism such as a filter, coating, or other process where the product itself is intended to trap or mitigate pests.[476] The possible "co-packs" not only contain nano-silver, but also are items capable of trapping or repelling the microorganisms that come into contact with them.

Nano-silver products properly classified as devices are still subject to FIFRA regulation. Devices are subject to FIFRA labeling requirements.[477] They are also subject to establishment registration requirements, record requirements, inspection requirements,

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[473] 40 C.F.R. § 155.53(a)-(b).
[474] 40 C.F.R. §§ 155.53(c), 155.58.
[475] 7 U.S.C. § 136(h); 40 C.F.R. Part 152, Subpart Z (Devices).
[476] 7 U.S.C. § 136(h).
[477] 7 U.S.C. § 136w(c)(4); 40 C.F.R. § 152.500(b)(1), Part 156 (labeling requirements); 7 U.S.C. § 136(q)(1) (misbranded definition).

import and export requirements, and child-resistant packaging requirements.[478] Devices are subject to FIFRA's violation, enforcement and penalty provisions.[479]

Accordingly, if EPA determines that one or more of the nanosilver products are properly classified as pesticide devices rather than pesticides, the agency should ensure each complies with FIFRA's pesticide device requirements, including accurate labeling.

G. EPA should Set a FFDCA Tolerance for Nano-silver

1. Pesticide Tolerances and Exemptions

In addition to direct oversight and regulation of pesticides, EPA regulates pesticide residues in food and animal feed. EPA cannot register a pesticide under FIFRA until the applicant has obtained the necessary tolerance or exemption under the FFDCA. Under § 301, FFDCA prohibits the shipment in interstate commerce of "adulterated food."[480] Under FFDCA § 402(a)(2)(B), a food is considered adulterated if "it bears or contains a pesticide chemical residue that is unsafe" within the meaning of § 408(a).[481] Section 408(a) provides that a pesticide is "unsafe" (and the food containing it adulterated) unless EPA has established a tolerance for the pesticide and the pesticide residue is within that tolerance; or EPA has exempted the pesticide from the requirement for a tolerance.[482] No food containing any pesticide residue can be introduced into commerce unless the amount of the pesticide residue is within the prescribed tolerance.[483]

[478] 40 C.F.R. §§ 152.500(b); 7 U.S.C. §§ 136e (registration and reporting of establishments), 136f (books and records), 136g (inspection of establishments), 136o (imports and exports), 136w(c)(3) (child-resistant packaging).
[479] 40 C.F.R. §§ 152.500(b); 7 U.S.C. §§ 136j (unlawful acts), 136k (stop sale, use, removal, and seizure), 136l (penalties).
[480] 21 U.S.C. § 331.
[481] 21 U.S.C. § 342(a)(2)(B).
[482] 21 U.S.C. § 346a(a)(1).
[483] 21 U.S.C. § 331(a)-(c).

A "tolerance" is the maximum level of a pesticide residue that may be present in food or animal feed;[484] it is established by substantial testing demonstrating that it meets statutory standards for safety.[485] The statutory standard of "Safe" is defined as a "reasonable certainty that no harm will result from the aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposure for which there is reliable information."[486] Section 408 of the FFDCA and its regulations layout the procedures for the establishment of a tolerance and factors to be considered by the agency, which can be begun with the filing of a petition to establish a tolerance.[487]

Alternatively to a tolerance, EPA can register a pesticide if an applicant obtains an "exemption" from the tolerance requirement if EPA determines that there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."[488] However such an exemption would be arbitrary and capricious given the information provided in this petition.

2. In Order to Register Nano-silver Pesticides EPA Must Set a Nano-silver Tolerance

EPA establishes tolerances and exemptions for specific chemicals not products.[489] Silver is not registered for use on food or feed crops or for use on processed commodities.[490] There is no tolerance for silver or exemptions from the requirements of a tolerance. In the Silver RED, EPA concluded that "Silver is a natural element and trace amounts are normally present in the human diet." EPA further concluded that only "minimal dietary exposure may result from the

[484] 21 U.S.C. § 346a.
[485] Id. 346a(b)(2)(A).
[486] Id. § 346a(b)(2)(A)(ii).
[487] Id. § 346a(d)(1).
[488] Id. § 346a(c)(2)(A).
[489] 40 C.F.R. § 152.112(g).
[490] EPA, Silver RED, supra note 161 at 3.

use of silver in human drinking water systems. EPA does not anticipate that dietary exposure to these low levels of silver will be associated with any significant degree of risk."[491]

In sharp contrast, the recent explosion of nanosilver consumer products presents much higher human exposures. See Appendix A. These exposures are dietary through colloidal silver "health" drinks. Pesticides can reach food or feed several different ways, including by the migration of pesticidal chemicals from containers or processing equipment. Nano-silver is being used in a number of food-related products, including storage containers, cutting boards, cutlery, baby bottles, refrigerators, food and produce spray cleaners, toothbrushes, and dietary supplements. See Appendix A. While the nano-silver is in a "fixed" matrix in some products, it is unknown how and if they will migrate to food. Given their close proximity to food by many different products it seems likely that they the nano-silver particles will cause aggregate contamination and ingestion by the public, creating an internal build-up of the nanomaterial within the body before the toxicological effects of the nanomaterial are fully known. For example, the effect of organs storing nano-silver over a long period of time is unknown. Nano-silver could also interfere with beneficial bacteria in the gut.

Moreover, these nano-silver exposures are also occurring as skin-contact exposures. The statutory standard of "Safe" is defined as a "reasonable certainty that no harm will result from the aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposure for which there is reliable information."[492] Many nano-silver products will create direct and indirect skin exposures. These nano-silver products include personal care products, hair products, soaps, various cleaning products, detergents and softeners, clothing, pillows, bandages, and shaving accessories. See Appendix A. Nano-silver clothing in

[491] Id.
[492] 21 U.S.C. § 346a(b)(2)(A)(ii).

particular will be in direct contact with skin over prolonged periods of time. EPA must assess the safety of these materials with regard to these exposures as well when setting a tolerance for nano-silver.

CONCLUSION

EPA has said that "in response to the marketing of unregistered pesticide-treated products with illegal, unsubstantiated public health claims, EPA has acted quickly and decisively to prohibit sales of such products. It will continue to be the Agency's policy to take action against companies that make such illegal claims."[493] Yet with one recent exception EPA has not acted to prohibit the widespread sale of illegal nano-silver pesticide products, including products with false and misleading claims. Instead, EPA has taken action only with regard to a limited category of these substances ("ion machines") while still permitting them to remain on market and expressly denied that its action in any way was related to nanotechnology or nanomaterials.

Petitioners urge EPA to act to remedy these failings in a timely fashion. EPA has jurisdiction over and a continuing statutory obligation to regulate nano-silver pesticide products. EPA has set precedent already for this with its action and consent agreement with IOGEAR Inc. Yet EPA has thus far denied its actions are even nanotech-related, or that oversight measures are needed to account for nanomaterials' regulatory and testing challenges, including those of nano-silver pesticide products. In general, there is currently a vacuum of regulation in the field of nanotechnology and nanomaterials. Industry has no guidance regarding the classification of these nano-silver products.[494] This legal petition provides both the blueprint for EPA's needed regulatory actions with regard to nano-silver and the legal impetus to take those actions. In

[493] www.epa.gov/pesticides/factsheets/treatart.htm
[494] See, e.g., Feder, *New Device for Germophobes Runs Into Old Law*, NEW YORK TIMES, March 6, 2008.

addition, FIFRA grants EPA general authority to prescribe regulations to carry out the provisions of the Act,[495] and separate sections of FIFRA include more specific grants of rulemaking authority.[496] EPA thus has broad powers under FIFRA to amend its regulations as it sees necessary to protect public heath and the environment from the potential dangers of nano-silver.

Specifically, petitioners requests EPA take the following actions with regard to nano-silver pesticides:

PETITIONERS REQUEST THAT THE EPA ADMINISTRATOR UNDERTAKE THE FOLLOWING ACTIONS:

I. Classify Nano-silver As a Pesticide and Require the Registration of Nano-silver Products as Pesticides

II. Determine That Nano-silver is a New Pesticide That Requires a New Pesticide Registration

III. Analyze the Potential Human Health and Environmental Risks of Nano-silver

A. Pursuant to FIFRA, Analyze the Potential Human Health and Environmental Impacts as Part of the Nano-silver Pesticide Registration Process

B. Pursuant to the FQPA, Assess the Potential Impacts of Nano-silver Exposures on Infants and Children and Ensure that No Harm Will Result From Aggregate Exposures

C. Compliance with the ESA, Including Undertaking Consultation Procedures In Accordance with ESA § 7 for Any EPA Actions, Activities, or Programs Impacting Nano-silver Oversight

D. Compliance with NEPA, Including Assessing the Human Health and Environmental Impacts of EPA's Current and Future Actions or Programs Regarding Nano-silver, Including Completing a Programmatic Environmental Impact Statement

IV. Take Regulatory Actions against the Class of Nano-silver Products Illegally Sold Without EPA FIFRA Approval, Including Issuing Stop Sale, Use or Removal Orders for Illegal and Unlabeled Nano-silver Pesticide Products

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[495] 7 U.S.C. § 136w(a)(1).

[496] See, e.g., 7 U.S.C. § 136a(c)(2)(A)(registration data guidelines shall be revised from time to time); § 136f(a) (regulations for recordkeeping requirements necessary for effective enforcement).

V. If any Nano-silver Pesticide Registration is Approved, Apply and/or Amend to Specifically Apply the FIFRA Pesticide Requirements to the Class of Nano-silver Pesticides, Including

1. *Labeling*
2. *Post-Registration Notification of Adverse Effects*
3. *Post-Registration Testing and New Data Development*
4. *Conditional Registration*
5. *Confidential Business Information*

VI. Take Other EPA FIFRA Actions Necessary for Adequate Oversight of Nano-silver Pesticides, Including:

1. *Undertaking a Classification Review of Nano-silver Pesticides*
2. *Undertaking a Special Review of Nano-silver Pesticides*
3. *Requiring the Submission of Nano-specific Data from Nano-silver Registrants*
4. *Amending FIFRA Regulations to Require Nano-Specific Data*
5. *Registration Review of Existing Bulk Silver Pesticide Registration*
6. *Regulate Nano-silver Devices*
7. *Set a Pesticide Tolerance for Nano-silver*

In accordance with the APA, petitioners request that EPA provide an answer to this petition within a reasonable time.[497]

Respectfully submitted,

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[497] 5 U.S.C. § 555(b) ("[W]ithin a reasonable time, each agency shall proceed to conclude a matter presented to it.") id.. § 706(1) (The reviewing court shall … compel agency action unlawfully withheld or unreasonably delayed."); 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 made in connection with any agency proceeding.").