Case No. 12-70268

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC.,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

REVIEW
of an order of the U.S. Environmental Protection Agency

BRIEF OF *AMICI CURIAE* INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, CENTER FOR FOOD SAFETY, FRIENDS OF THE EARTH, BEYOND PESTICIDES, CENTER FOR ENVIRONMENTAL HEALTH, INSTITUTE FOR AGRICULTURE AND TRADE POLICY

IN SUPPORT OF PETITIONERS SEEKING REVIEW

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Dated: April 23, 2012

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CORPORATE DISCLOSURE STATEMENT

Amici, International Center for Technology Assessment, Center for Food Safety, Friends of the Earth, Beyond Pesticides, Center for Environmental Health, and Institute for Agriculture and Trade Policy, are all non-profit corporations, have no parent corporations, and do not issue stock.

Respectfully Submitted,

Dated: April 23, 2012

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INTERESTS OF THE *AMICI CURIAE*

Amici are non-profit, public interest organizations whose missions' center on the protection of the environment and public health. Each actively works on the issues of nanotechnology and nanomaterials, including nano-silver pesticides, and nanomaterials' concomitant environmental, health and socioeconomic impacts.[1] To that end, the *Amici* have produced ground-breaking reports and other public and policy maker education materials on various aspects of nanotechnology; they have program areas ensconced in tracking nanotechnology's commercial and scientific development; they have staff dedicated to improving the oversight and consumer awareness of nanotechnology; and they have thousands of members interested and concerned about the infusion of nanomaterials in commerce, such as nano-silver pesticide products. Finally, when necessary, *Amici* are currently signatories and plaintiffs to other legal actions challenging various aspects of nanomaterial oversight, or the absence thereof, including that of nano-silver pesticides.

As stakeholders whose interests and memberships will be harmed by the release of HeiQ Materials AG (HeiQ) nano-silver pesticide products, as well as by the regulatory precedent the U.S. Environmental Protection Agency (EPA)'s action

[1] Pursuant to Rule 29(c)(5) of the Federal Rules of Appellate Procedure, *Amici* state that (a) no party's counsel authored the brief in whole or in part; (b) no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and (c) no person—other than *Amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

sets more broadly for U.S. oversight of nanotechnology, nanomaterials and nano-silver pesticides, *Amici* have a strong interest in presenting their concerns regarding the conditional registration of HeiQ, as well as offering the Court the broader "nano-world" perspective surrounding this specific approval action.

Amicus International Center for Technology Assessment (ICTA) is a Washington, D.C. based non-profit which assists the public and policy makers in better understanding how new technologies affect society. ICTA has a specific nanotechnology project, NanoAction, with 22,000 members. Among other publications and actions, in 2006 ICTA spearheaded the first *Principles for the Oversight of Nanotechnologies and Nanomaterials*, now joined by more than a hundred organizations and labor unions across the globe.[2] ICTA also drafted and filed the first-ever legal actions on the health and environmental risks of nanomaterials, legal petitions with the Food and Drug Administration (in 2006)[3] and with EPA (in 2008), respectively. The EPA petition deals specifically with nano-silver pesticides such as the one at issue in this case (hereafter ICTA Nano-

[2] ICTA, *Principles for the Oversight of Nanotechnologies and Nanomaterials* (2007), *available at* http://www.icta.org/files/2012/04/080112_ICTA_rev1.pdf (last visited Apr. 21, 2012).

[3] ICTA *et al.*, *Petition Requesting FDA Amend Its Regulations for Products Composed of Nanomaterals* (2006), Docket No. FDA-2006-P-0213-0003, *available at* http://www.centerforfoodsafety.org/wp-content/uploads/2011/12/2006-Nano-FDA-petition.pdf (last visited Apr. 21, 2012).

Silver Petition).[4] In these actions ICTA is joined by many of the other *Amici*. ICTA also joined Petitioner NRDC's comments opposing EPA's proposed conditional registration of HeiQ's pesticide product AGS-20.

ICTA's sister organization, *Amicus* Center for Food Safety (CFS) is a non-profit organization with over 200,000 members nationwide and offices in Washington, D.C., San Francisco, California, and Portland, Oregon. CFS addresses the environmental, health, and economic impacts of agriculture and food processing technologies, including nanomaterials, pesticides, and nano-pesticides.

Amicus Beyond Pesticides is a Washington, D.C. based non-profit organization that works to protect public health and the environment by encouraging a transition beyond the use of pesticides.[5] Beyond Pesticides is a signatory to ICTA's legal petition on nano-silver.

Amicus Center for Environmental Health (CEH) is a California-based non-profit dedicated to protecting the public from environmental and consumer health

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[4] ICTA *et al.*, *Petition For Rulemaking Requesting EPA Regulate Nano-Silver Products As Pesticides* (2008), Docket No. EPA-HQ-OPP-20080650, *available at* http://www.icta.org/files/2011/12/CTA_nano-silver-petition__final_5_1_08.pdf (last visited April 21, 2012); *see also ICTA Nano-Silver Petition Executive Summary*, *available at* http://www.icta.org/files/2011/12/CTA_nano-silver_executive_summary_5_1_08.pdf (last visited Apr. 21, 2012); *ICTA Petition Nano-Silver Pesticide Product Appendix*, *available at* http://www.icta.org/files/2011/12/CTA-Petition-Appendix-A_nano-silver_product_inventory1.pdf (last visited Apr. 21, 2012).

[5] Beyond Pesticides, Nanosilver, http://www.beyondpesticides.org/antibacterial/nano.htm (last visited Apr. 21, 2012).

hazards, including pesticides. CEH is a signatory to ICTA's petition on nano-silver.

Amicus Friends of the Earth (FoE), is an international public interest organization with offices in Washington, D.C. and California that seeks to create a more healthy, just world. FoE has published numerous reports on the impacts of nanotechnology, including on nano-silver, and product inventories of nano consumer products.[6] FoE joined ICTA's petition on nano-silver.

Amicus Institute for Agriculture and Trade Policy (IATP) is a non-profit organization with offices in Washington, D.C. and Minneapolis, Minnesota that works to promote fair, healthy and sustainable food, farm and trade systems. IATP has published reports on U.S. nanotechnology oversight,[7] and is a signatory to ICTA's petition on nano-silver.

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[6] FoE, Nanotechnology, http://www.foe.org/projects/food-and-technology/nanotechnology (last visited Apr. 22,2012; *see also* FoE *Nano-Silver: Policy Failure Puts Public Health At Risk* (2011), *available at* http://libcloud.s3.amazonaws.com/93/e2/8/549/NanoSilverUS.pdf (last visited Apr. 21, 2012); FoE, *Nano & Biocidal Silver* (2009), *available at* http://nano.foe.org.au/sites/default/files/Nanosilver%20Report%202009.pdf (last visited Apr. 21, 2012).

[7] IATP, *Racing Ahead: U.S. Agri-Nanotechnology in the Absence of Regulation* (2011), *available at* http://www.iatp.org/files/2011.6.29%20AgriNanotech%20SS.pdf (last visited Apr. 21, 2012).

SUMMARY OF ARGUMENT

Nanotechnology is a powerful new set of platform technologies for observing, taking apart, and reconstructing nature at the atomic and molecular level. Most people tend to think of nanotechnology only in the future tense. If they know anything about it, people tend to conjure tiny nano-robots, mini-self-assemblers, nano-drug vectors, or something of the like. Similarly, when picturing nanotechnology's risks, minds immediately conjure images of nanotechnology pioneer Eric K. Drexler's now-infamous "Grey Goo" scenario,[8] or the predatory nano-swarms of fiction writer Michael Crichton's *Prey*.[9]

Nanotechnology's current reality, however, is equally compelling, but a bit more down to earth: Consumer products containing manufactured nanomaterials have already arrived on market shelves and comprise a product wave spanning many technologies. Nano-silver is the largest sector of these products, with hundreds of nano-silver products commercially available, although total numbers are unknown, since no labeling is required. These nano-silver products are properly defined and should be regulated as pesticides by EPA, since their only, intended use is as an anti-bacterial, anti-microbial agent, i.e., to kill pests. Polls show that most of the public is still unaware of the presence of these new materials in their products and their potential risks.

[8] Eric Drexler, *Engines of Creation* (Anchor Books 1986).
[9] Michael Crichton, *Prey* (2003).

Private industry and governments are spending billions on product development, because "nano" means more than just tiny, a billionth of a meter in scale; it is best understood to mean materials that have the capacity to be fundamentally different, with new chemical, physical, and biological properties that cannot be predicted from the properties of their larger material counterparts.

Yet the same new properties that so excite industry—tiny size, vastly increased surface area to volume ratio, high reactivity—can result in new risks to human health and the environment. These risks essentially take two forms: increased potential toxicity and unprecedented mobility for a manufactured material. The risks of this new materials field are exacerbated by the fact that: 1) federal agencies are only spending little on risk research relative to federal investments in nanomaterial product development; and 2) oversight lags considerably behind commercialization, and with agencies approaching the issue, if at all, in piecemeal fashion.

Amici provide this broader context in requesting this Court set aside EPA's unprecedented decision to conditionally register the nano-silver pesticide products HeiQ AGS-20 and HEiQ AGS-20 (AGS-20) as unsupported by substantial evidence. EPA has failed to show that the conditional registration will not cause any "unreasonable adverse effect" on human health and the environment. The limited studies to this point have raised significant red flags about nano-silver. The

agency entirely failed to consider the aggregate exposure to consumers and the environment from the hundreds of other nano-silver pesticide products. Given the risk red flags, significant scientific unknowns, and lack of public awareness surrounding nanomaterials such as AGS-20, the agency's conditional approval is also contrary to the public interest.

Finally, as opposed to this piecemeal conditional approval, in which the agency has permitted commercial use to continue despite acknowledging significant unknowns regarding impacts, EPA has a ready-made blueprint and legal impetus for responsible and lawful oversight of nano-silver pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): *Amici*'s 2008 nano-silver petition, which the agency has never answered. The 116-page petition, supported by a 500-page scientific record and a product appendix documenting over 260 nano-silver pesticide products, requests that the agency take a number of regulatory steps to adequately protect health and the environment from these new materials, including: classifying them as a class of new pesticides; requiring manufactures to submit new pesticide registrations, with nano-specific toxicity data requirements, testing, risk assessments, and labeling; completing analyses of their impacts pursuant to FIRFA, as well as the Food Quality Protection Act (FQPA), the Endangered Species Act (ESA), and the National Environmental

Policy Act (NEPA); and halting the current sales of all nano-silver pesticides until and unless they undergo new pesticide registration.

For these reasons, Amici respectfully request this Court set the conditional registration aside.

ARGUMENT

I. NANOTECHNOLOGY AND NANOMATERIALS: THE FUTURE IS NOW

Nano 101

The nanoscale refers to nanometer (nm) measurement, which equals one billionth of a meter. This scale is exceedingly tiny for a manufactured material. To illustrate, a red blood cell is approximately 7,000 nm wide, human hair is roughly 80,000 nm wide, and a sheet of paper is about 100,000 nm thick.

However, the key to understanding nanotechnology and nanomaterials is that "nano" does not mean merely tiny; it is best understood to mean materials that have the capacity to be fundamentally different. It is well known that materials engineered or manufactured to the nano-scale exhibit different fundamental physical, biological, and chemical properties from bulk materials. The U.S. National Nanotechnology Initiative (NNI), the federal body that coordinates nanotechnology research and development between federal agencies, defines nanotechnology as "the understanding and control of matter at dimensions of

roughly 1 to 100 nanometers, where unique phenomena enable novel applications."[10]

This radical reduction in size means that previously familiar materials may behave very differently than their larger bulk or macro form. Altered properties can include color, solubility, material strength, electric conductivity, and magnetic behavior. For example, carbon (e.g., graphite in pencil lead) is relatively soft, but carbon nanotubes (nano-scale cylinders made of carbon atoms) are a hundred times stronger than steel. An aluminum soda can does not burn, yet aluminum nanoparticles explode when used as rocket fuel catalysts. A 2006 National Geographic article perhaps described this phenomenon best:

> Nanotechnology matters because familiar materials begin to develop odd properties when they're nanosize. Tear a piece of aluminum foil into tiny strips, and it will still behave like aluminum—even after the strips have become so small that you need a microscope to see them. But keep chopping them smaller, and at some point—20 to 30 nanometers, in this case—the pieces can explode.
>
> …
>
> It's like you shrink a cat and keep shrinking it, and then at some point, all at once, it turns into a dog.[11]

[10] U.S. Nat'l Nanotechnology Initiative, http://www.nano.gov (last visited Apr. 21, 2012) (emphasis added).

[11] Jennifer Kahn, *Nano's Big Future*, Nat'l Geographic, June 2006, *available at* http://ngm.nationalgeographic.com/2006/06/nanotechnology/kahn-text (last visited Apr. 21, 2012) (emphasis added).

Although scientists are not completely sure what enables nanomaterials' novel properties, one reason is that a different realm of physics, quantum physics, comes into play at the nano-scale.[12] 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 mass compared to larger particles.[13] For example, a gram of nanoparticles has a surface area of a thousand square meters. 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.[14] This enormous increase in surface area can change relatively inert substances into highly reactive ones. A material can then melt faster, absorb more, or simply become more explosive.

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[12] Nanotechnology Now, Nanotechnology Basics, http://www.nanotech-now.com/basics.htm (last visited Apr. 21, 2012).

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

[14] *See, e.g.*, European Commission (EC), 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 Sept. 28-29, 2005), http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003.pdf (last visited Apr. 21, 2012).; *see also* Warheit, D.D., *Nanoparticles: Health impacts?*, 7 Materials Today 32-35 (2004).

Commercialization

Nanomaterials' new properties have led to billions of dollars in product research and development, a gold rush on patents,[15] and over the past half-dozen years, an explosion of products in many fields. Thousands of tons of nanomaterials are already being produced each year.[16] The nanotechnology industry generated approximately $225 billion in product sales in 2009,[17] and according to EPA, by 2015 "consumer products with nanotechnology applications will value $1 trillion on the world market."[18] The U.S. invested around $16.5 billion in public funds between 2001 and 2012.[19] Some commentators predict that by 2014, fifteen percent of all goods manufactured globally will involve nanotechnology.[20]

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[15] *See generally* Raj Bawa *et al.*, *The Nanotechology Patent 'Gold Rush'*, 10 J. Intell. Prop. Rts. 426-433 (2005) *available at* http://nopr.niscair.res.in/bitstream/123456789/3675/1/JIPR%2010(5)%20426-433.pdf (last visited Apr. 21, 2012).

[16] *See*, *e.g.*, The Royal Soc'y and the Royal Acad. of Eng'g, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* 26-27 & tbl. 4.1 (July 2004), *available at* http://www.nanotec.org.uk/finalReport.htm (last visited Apr. 21, 2012) (hereafter Royal Soc'y).

[17] Nat'l Research Council, *A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials* 3 (Nat'l Academies Press 2012).

[18] EPA, *Types of Nanomaterials Under Investigation by the EPA*, *available at* http://www.epa.gov/nanoscience/quickfinder/nanomaterials.htm (last visited Apr, 21, 2012).

[19] U.S. Nat'l Nanotechnology Initiative, *NNI Budget*, http://www.nano.gov/about-nni/what/funding (last visited Apr, 21, 2012).

[20] Clarence Davies, Woodrow Wilson Int'l Ctr. for Scholars, *EPA and Nanotechnology: Oversight for the 21st Century* 32 (2007) (citing Lux Research,

According to the Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies (PEN), which maintains a registry of self-labeled products containing nanomaterials, there are over 1,300 such products in the consumer sector alone, over 300 of which are nano-silver products.[21] Currently available consumer products incorporating nanotechnology 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. [22]

Since no labeling or government registration is currently required, these self-labeled products are likely only the tip of the iceberg. The Wilson Center estimates that there are three to four new nanotech products hitting the market every week.[23]

The Nanotech Report iii (4th. ed. 2006), *available at* http://www.nanotechproject.org/process/assets/files/2698/197_nanoepa_pen9.pdf (last visited Apr. 21, 2012).

[21] *See* Project on Emerging Nanotechnologies, Woodrow Wilson Int'l Ctr. for Scholars, *Nanotechnology Consumer Product Database Analysis, available at* http://www.nanotechproject.org/inventories/consumer/analysis_draft/ (last visited Apr. 21, 2012).

[22] *See id.*

[23] Press Release, Project on Emerging Nanotechnologies, Woodrow Wilson Int'l Ctr. for Scholars, *New Nanotech Products Hitting the Market at the Rate of 3-4*

Despite this commercial explosion, consumer awareness of the use of nanotechnology remains low, with 70% of poll respondents indicating they had heard very little or nothing at all about it.[24]

Risks

The same new properties that so excite industry—tiny size, vastly increased surface area to volume ratio, high reactivity—can result in new risks to human health and the environment. Swiss insurance giant Swiss Re noted: "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."[25] These risks essentially take two forms: increased potential toxicity and unprecedented mobility for a manufactured material.

First, nanoparticles' exceptionally large relative surface area creates increased surface reactivity and enhanced toxicity potential, which cannot be

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Per Week (Apr. 24, 2008), *available at* http://www.nanotechproject.org/process/assets/files/6697/pen_press_release_080422.pdf (last visited Apr. 21, 2012).

[24] Project on Emerging Nanotechnologies, Woodrow Wilson Int'l Ctr. for Scholars, *Poll Reveals Public Awareness of Nanotech Stuck at Low Level*, http://www.nanotechproject.org/news/archive/poll_reveals_public_awareness_nanotech/ (last visited Apr. 21, 2012).

[25] Swiss Re, *Nanotechnology-Small Matter, Many Unknowns* 37 (2004), *available at* http://www.asse.org/nanotechnology/pdfs/govupdate_02-3-05_nanosafety.pdf (last visited Apr. 21, 2012).

accurately predicated from larger material cousins.[26] As the European Commission's (EC) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) explained:

> "[e]xperts are of unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics."[27]

The U.K. Royal Society and the Royal Academy of Engineering similarly emphasized, "[f]ree 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."[28] And the Institute of Occupational Medicine concluded, "Because of their size and the ways they are used, they 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."[29]

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[26] Andre Nel *et al*., *Toxic Potential of Materials at the Nanolevel*, 311 Science 622-23 (2006).
[27] EC, SCENIHR, *Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies*, *supra* note 14, at 6, 32.
[28] Royal Society, *supra* note 16, at 49.
[29] C. L. Tran *et al., A Scoping Study to Identify Hazard Data Needs for Addressing the Risks Presented by Nanoparticles and Nanotubes*, Institute of Occupational Medicine 34 (2005), *available at*

Scientists have yet to determine even what physicochemical properties will be most important in determining ecological and toxicological properties of nanomaterials.[30] 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. 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."[31] Nanotoxicology is an emerging field in its own right, requiring new paradigms of predictive toxicology, which are only now being delineated. *But see* Excerpts of Record (ER) 21 (EPA Decision Document[32]) (EPA relying solely on mass as its risk metric for AGS-20 despite being "aware" that

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http://randd.defra.gov.uk/Document.aspx?Document=CB01072_3060_FRP.doc (last visited Apr. 21, 2012).

[30] A. Maynard *et al.*, *Safe Handling of Nanotechnology*, 444 Nature 267-69 (Nov. 2006); G. Oberdorster *et al*., *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113(7) Envtl. Health Perspectives 823-39 (2005).

[31] Andrew Maynard, *Nanotechnology: The Next Big Thing, or Much Ado about Nothing?*, 51 Annals of Occupational Hygiene 1-12, 7 (2006), *available at* http://annhyg.oxfordjournals.org/content/51/1/1.full.pdf+html (last visited Apr. 21, 2012).

[32] EPA, Decision Document: Conditional Registration of HeiQ AGS-20 as a Materials Preservative in Textiles (Dec. 1, 2011) (ER 1 – 72).

"metrics other than mass (such as particle number or surface area) may be more suitable for assessing nanoparticle risks").[33]

Second, due to their tiny size, nanomaterials have unprecedented mobility for a manufactured material.[34] They are more easily taken up by the human body and can cross biological membranes, cells, tissues, and organs more efficiently than larger particles.[35] Once in the blood stream, nanomaterials can circulate throughout the body and can be taken up by the organs and tissues including the brain, liver, heart, kidneys, spleen, bone marrow, and nervous system.[36] In addition, unlike larger particles, nanoparticles are transported within cells and taken up by cell mitochondria and the cell nucleus, where they can interfere with cell signaling, induce major structural damage and result in DNA mutation.[37] EPA has voiced its concerns regarding nanomaterials' ability to be absorbed into the

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[33] A. Nel *et al.*, *Toxic Potential of Materials at the Nanolevel*, 311 *Science* 622-627 (2006); A. Maynard *et al.*, *supra* note 30.
[34] Hoet *et al.*, *Nanoparticles-known and unknown health risks*, 2 Journal of Nanobiotechnology 12 (2004); Swiss Re, *supra* note 25, at 7.
[35] *See, e.g.*, Holsapple *et al.*, *Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs*, 88 Toxicological Sciences 12 (2005).
[36] Oberdorster *et al.*, *supra* note 30.
[37] Li, N., *Ultrafine particulate pollutants induce oxidative stress and mitochondrial damage*, 111 Environ. Health Perspectives 455-60 (2003).

body and cross the blood brain barrier, as well as the high durability and reactivity of some nanomaterials.[38]

As little as is known about nanomaterials' health impacts, even less is known about their environmental impacts.[39] Yet nanomaterials are already entering the environment, through manufacturing, transport, use and disposal. Once loose in nature, these nanomaterials represent a new class of manufactured pollutants. Nanomaterials' unique chemical and physical characteristics create foreseeable environmental risks, including potentially toxic interactions and compounds, absorption and/or transportation of pollutants (pursuant to which other contaminants could "hitch a ride"), unknown durability or bioaccumulation, and the ability to reach places larger particles cannot.[40] There is preliminary evidence that some nanoparticles could have a negative impact on algae and plants, and

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[38] W. Jordan, Office of Pesticide Programs, EPA, *Nanotechnology and Pestcides* 8-9 (2010), *available at* http://www.epa.gov/pesticides/ppdc/2010/april2010/session1-nanotec.pdf (last visited Apr. 21, 2012).

[39] Nanotechnology Working Group, EPA Science Policy Council, EPA *Nanotechnology White Paper* 33 (2007) ("The fundamental properties concerning the environmental fate of nanomaterials are not well understood, as there are few available studies on the environmental fate of nanomaterials."), *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf (last visited Apr. 21, 2012).

[40] *See* ICTA Nano-Silver Petition, *supra* note 4, at 87-92 (and citations therein); *see also* EPA, White Paper, *supra* note 39, at 33-40; V. Colvin, Director of the Ctr. for Biological and Envtl. Nanotechnology, Rice Univ., *Responsible Nanotechnology: Looking Beyond the Good News*, EurekAlert! (2002) http://www.eurekalert.org/context.php?context=nano&show=essays&essaydate=1102 (last visited Apr. 21, 2012).

impair the function or reproductive cycles of bacteria and fungi, which play a key role in nutrient cycling that underpins ecosystem function. [41] Despite rapid commercialization, many potential risks remain untested and regulators lack cost-effective field measuring, monitoring and control technologies. *See, e.g.*, ER 9-10.[42]

Many specific examples of these potential risks to human health and the environment are documented in the 2008 ICTA Petition seeking EPA regulation of nano-silver pesticide products and its accompanying record. *See* ICTA Nano-Silver Petition at 59-72, 83-85, & 87-92 (and citations therein).

Finally, despite the known potential risks of nanomaterials, very little environmental and health risk research is being undertaken to further identify and evaluate such risks: government funding of environmental, health and safety research is woefully underfunded, on average receiving just 4.5% of the total NNI funding.[43] Further, government oversight has lagged far behind commercialization, and generally as of yet has failed to make the regulatory

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[41] Navarro, Enrique *et al.*, *Environmental Behaviour and Ecotoxicity of Engineered Nanoparticles to Algae, Plants and Fungi*, 17 Ecotoxicology 372–386 (2008).
[42] EPA, White Paper, *supra* note 39, at 40-41.
[43] U.S. Nat'l Nanotechnology Initiative , White House Office of Science and Technology Policy, *NNI Budget* (2012), *available at* http://www.nano.gov/about-nni/what/funding (last visited Apr. 22, 2012); *see also* U.S. Nat'l Nanotechnology Initiative, White House Office of Science and Technology Policy, National Nanotechnology Initiative Investments V. 1 (2012), *available at* http://nanodashboard.nano.gov/ (last visited Apr. 22, 2012).

adjustments necessary to account for nanomaterials' new challenges.[44] This case is a microcosm of that larger problem.

II. EPA'S UNPRECEDENTED DECISION TO CONDITIONALLY REGISTER A NANO-SILVER PESTICIDE IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE AND IS CONTRARY TO THE PUBLIC INTEREST

Before granting a pesticide registration, EPA must determine that the pesticide will not cause any "unreasonable adverse effect" on human health and the environment, and that the use of the pesticide is "in the public interest." 7 U.S.C. §§ 136a(c)(7)(C), 136(bb). EPA's findings on both were not supported by substantial evidence. *See, e.g.*, *Northwest Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1079 (9th Cir. 1989) (FIFRA decision reviewed for substantial evidence).

Aggregate Exposures

First, EPA ignored aggregate exposures from other nano-silver pesticide products. *See* Pet'r's Br. at 31-36. Nano-silver has quickly become the most commonly used nanomaterial in consumer products and the fastest growing sector

[44] *See, e.g.*, Government Accountability Office (GAO), *Nanotechnology: Nanomaterials Are Widely in Commerce, but EPA Faces Challenges in Regulating Risk* (May 2010), *available at* http://www.gao.gov/new.items/d10549.pdf http://www.gao.gov/new.items/d10549.pdf (last visited Apr. 21, 2012); Davies, Woodrow Wilson Int'l Ctr. for Scholars, *EPA and Nanotechnology: Oversight for the 21st Century* (2007) *available at* http://www.nanotechproject.org/file_download/files/Nano&EPA_PEN9.pdf (last visited Apr. 21, 2012); IATP, *supra* note 7.

of nanomaterial commercialization. The use of nano-silver as an antimicrobial agent is now widespread, with a wide variety of consumer and industrial products. *Amici*'s 2008 petition included a 60-page product appendix with no fewer than 260 self-identified nano-silver products, including:

> 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; and powdered and liquid nano-silver in bulk form.[45]

EPA has been aware of these products since at least 2008, when it received *Amici*'s petition. The petition appendix listed the products, giving their name, product type, company, country of origin, website, and marketing claims, among other information.[46]

[45] ICTA Nano-Silver Petition, Product Appendix, *supra* note 4. A recent search of the Wilson Center's Inventory found it to now have over 300 products listing nano-silver as a component. *See supra* note 23.
[46] *See* ICTA Nano-Silver Petition, *supra* note 4.

EPA's registering AGS-20 while intentionally turning a blind eye to other nano-silver pesticides currently on the market is contrary to its obligations under FIFRA. *See, e.g., Mayes v Massanari*, 276 F.3d 453, 459 (9th Cir. 2001) ("Whether substantial evidence supports a finding is determined from the record as a whole, with the court weighing both the evidence that supports and the evidence that detracts from [EPA's] conclusion."). The agency is legally obligated to adopt a consistent policy with regard to nano-silver products, because nano-silver is a pesticide requiring registration. These other nano-silver products, like AGS-20, are properly classified as "pesticides" since the only purpose of the infused nano-silver is to fight bacteria, i.e., prevent pests. Nano-silver thus meets the definition of a pesticide. 7 U.S.C. § 136(a)(1); 40 C.F.R. § 153.125 (defining "pesticide" broadly to be "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.").[47]

[47] EPA has elsewhere concluded another company's nano-silver coated mouses and keyboards were pesticides unlawfully marketed and sold without registration. *See In the Matter of: ATEN Technology, Inc. d/b/a IOGEAR, Inc.*, Docket No, FIFRA-09-2008-0003, *Consent Agreement and Final Order Pursuant to Sections 22.13 and 22.18*, at 2-4 (Feb. 28, 2008) (EPA action explaining FIFRA definition of pesticide and concluding that nano-silver coated electronics were pesticides pursuant to 7 U.S.C. § 136(u)). Further, in 2010, EPA fined Monterey Park, Calif based Kinetic Solutions $82,400 for selling unregistered nano-silver misbranded pesticides and making unproven claims about their effectiveness. EPA, *Hefty Fine for "Nano" Pesticide Violations* (December 2010), http://epa.gov/region9/newsletter/dec2010/nano-silver.html (last visited Apr. 21, 2012). In so doing, EPA noted: "Products that kill or repel bacteria or germs are considered pesticides, and must be registered with the EPA prior to distribution or

Manufacturers' intended use for nano-silver is an important factor as well. 40 C.F.R. § 152.15; *see also In re Chemco Indus., Inc., I.F.&R*, 1984 WL 50057, at *4-5 ("A substance shall be considered a pesticide by the intent of the manufacturer, seller or distributor, as expressed or implied via labeling claims and recommendations, or in advertising material."). The nano-silver products all make broad claims about the power of their nano-silver ingredients, such as: "eliminates 99% of bacteria"; renders material "permanently anti-microbial and anti-fungal"; "kills approximately 650 kinds of harmful germs and viruses" and "kills bacteria in as little as 30 minutes, 2-5 times faster than other forms of silver." *See* ICTA Nano-Silver Petition at 40-41 and Product Appendix. Thus, industry labeling and other claims, the lack of any other commercially valuable use, and manufacturers' actual and constructive knowledge that nano-silver is used with a pesticidal purpose, *see* ICTA Nano-Silver Petition at 32-38, supports the conclusion that these nano-silver products are pesticides.

EPA acknowledged other aggregate nano-silver exposures are likely to be significant, *see* ER 114, yet then inexplicably failed to account for them in its health assessment. Similarly, as with aggregate exposures to people, EPA acknowledged but failed to account for aggregate

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sale. According to EPA, the Nano Silver Pre Filter is a pesticide and was not registered as such as required by federal law EPA will not register a pesticide until it has been tested to show that it will not pose an unreasonable risk when used according to the directions." *Id.*

environmental exposures from other sources of nano-silver. *See* ER 45. These failings are all the more egregious in light of the fact the agency had significant information about these products, many of which were discussed in *Amici*'s petition and its supporting record. To the extent the agency needed further information, FIFRA provides ample authority for the agency to seek that data. 7 U.S.C. § 136a(c)(2)(A)-(B); 7 U.S.C. § 136d(a)(2); 40 C.F.R. § 152.11; 40 C.F.R. § 159.152(a); 40 C.F.R. § 159.195(a). *See* ICTA Nano-Silver Petition at 99-109.

Further, as the Petitioner explains, EPA also failed to assess the potential risks specifically to younger children and infants. Pet'r's Br. at 19-29. However a plethora of the nano-silver products are likely to be in contact with infants, as the inventory details; these products include, *inter alia*, nano-silver infused baby milk bottles and bottle cleaners; children's toys and stuffed animals; baby textile softener; baby mugs; baby toothbrushes; infant teething toys; strollers; cutlery; brushes; various clothing; personal care products; pillows; humidifiers; soaps; detergents; and cleaning products. *See* ICTA Nano-Silver Petition Product Appendix; *see also* ICTA Nano-Silver Petition at 13-15.

Without including such acknowledged increased aggregate exposure and cumulative risk, the agency's determination failed to ensure that the

registration will not cause any "unreasonable adverse effect" on the environment or health and is plainly contrary to the public interest.

Lack of Data and Red Flags

EPA's conditional registration of AGS-20 is also unlawful because nano-silver poses unreasonable risks to human health and the environment. Data explained in Amici's 2008 Petition, *see* ICTA Nano-Silver Petition at 59-95 (and citations therein), indicate significant potential for adverse effects from the use of nano-silver. The unreasonableness of the risks posed by nano-silver pesticides are further underscored by the dearth of health and safety data in the record.

As with nanomaterials most generally, there is a lack of research on the human health and environmental safety of nano-silver.[48] In its 2009 Report, EPA's FIFRA Scientific Advisory Panel (SAP) specifically acknowledged "data gaps about potential exposures and hazards related to nanosilver are broad," noting that "there is very little information about nanosilver in the environment related to fate, transport and transformation."[49] EPA's Decision Document admits that there are

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[48] *See, e.g.*, Stebounova *et al*., *Nanosilver induces minimal lung toxicity or inflammation in a subacute murine inhalation model*, 8 Particle and Fibre Toxicology 5 (2011) (expressing concern that little is known about the environmental and health consequences of exposure to nano-silver); *available at* http://www.particleandfibretoxicology.com/content/8/1/5 (last visited Apr. 21, 2012);

[49] SAP, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Evaluation of the Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products* at 9 (2009); *available at*

"uncertainties" regarding consumer and occupational risk assessment, ER 27, 36, pointing out the many gaps in scientific knowledge with regard to nano-silver's effects on health and the environment. These gaps include:

- no dermal toxicity studies and no agency guideline or scientific literature studies conducted in animals for the *in vivo* dermal absorption of nano-silver;
- no studies in the scientific literature that investigate the neurotoxicity of nano-silver in mammals;
- no studies in the scientific literature that investigate the chronic toxicity or carcinogenicity of nano-silver;
- no studies in the scientific literature that investigate the reproductive or developmental toxicity of nano-silver in mammals;
- no pharmacokinetic data on nano-silver;
- no studies establishing toxicity over all life stages or evaluating all potential effects; and
- insufficient information on aggregate exposures to other nano-silvers currently in the market place.

See ER16-19, 35. Yet the absence of data cannot replace the agency's burden to show, based on substantial evidence, that there will be no unreasonable impacts on the environment. 7 U.S.C. § 136a(c)(7)(C).

Studies have raised significant red flags about nano-silver pesticides. *See* ICTA Nano-Silver Petition at 59-95 (and citations therein). As with some other nanomaterials, due to its small size, the toxicity of nano-silver is greater than that

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http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf (2009 SAP Report) (last visited Apr. 21, 2012).

of silver in bulk form; furthermore, nano-silver is more toxic then other metal nanoparticles.[50] The EPA's SAP concluded:

> Nanoscale particles including nanosilver have been shown to be capable of penetrating biological barriers such as cell membranes and can enter into the cells themselves. Nanoparticles are able to attach to cell membranes, producing changes in membrane permeability, redox cycling in the cytosol, intracellular radical accumulation, and dissipation of the proton motive force for ATP synthesis. Each of these has been reported as a possible mechanism for nanoparticle toxicity. Evidence from scanning transmission electron microscopy also shows that smaller particles (< 10 nm) may enter the cell directly to inhibit microbial growth.[51]

Among documented potential harms to human health, *in vitro* (test tube) studies demonstrate that nano-silver is toxic to mammalian liver cells,[52] stem cells[53] and even brain cells.[54] One 2009 study discovered that absorption of nano-silver may

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[50] Braydich-Stolle, L *et al*., *In Vitro Cytotoxicity of Nanoparticles in Mammalian Germline Stem Cells*, 88(2) Toxicological Sciences 412–419 (2005).

[51] FIFRA Scientific Advisory Panel Meeting, SAP Minutes No. 2010-01, *Evaluation of the Hazard and Exposure Associated with Nanosilver and Other Nanometal Pestcide Products*, (Nov. 3-5, 2009) (internal citations omitted).

[52] Hussain, S.M. *et al., In Vitro Toxicity of Nanoparticles in BRL 3A Rat Liver Cells*, 19 Toxicology in Vitro 975–983 (2005).

[53] Braydich-Stolle, L *et al., supra* note 50.

[54] Hussain, S.M *et al., The Interaction of Manganese Nanoparticles with PC-12 Cells Induces Dopamine Depletion*, 92(2) Toxocological Sciences 456–63 (2006); *see also* Bar-Ilan O., *et al*., *Toxicity Assessments of Multisized Gold and Silver Nanoparticles in Zebrafish Embryos*, 5 Small 1897-1910 (2009); Soto K., *et al*., *Cytotoxic Effects of Aggregated Nanomaterials*, 3 Acta Biomaterialia 351-358 (2007); Soto K., *et al*., *Comparative In Vitro Cytotoxicity Assessment of Some Manufactured Nanoparticulate Materials Characterized by Transmission Electron Microscopy*, 7 Journal of Nanoparticle Research 145-169 (2005); *and* AshaRani P., *et al*., *Cytotoxicity and Genotoxicity of Silver Nanoparticles in Human Cells*, 3 Acs Nano, 279-290 (2009); *see also* ICTA Nano-Silver Petition, *supra* note 4, at 59-72.

interfere with the replication of DNA molecules, potentially creating genetic mutations.[55] Two other studies have demonstrated that exposure to nano-silver can reduce mitochondrial function.[56] The number of diseases associated with mitochondrial malfunction is increasing and includes Parkinson's, Alzheimer's and Huntington's disease.[57]

Beyond the issue of toxicity, nano-silver may also create a public health burden by producing antimicrobial resistance.[58] As with antibiotics, the overuse of nano-silver may promote resistance to this important antimicrobial and potentially other antimicrobials.

Nano-silver is also toxic to a variety of aquatic and terrestrial organisms.[59] Even in its bulk form, silver is extremely toxic to fish and other aquatic species.[60] At the nano-scale, however, nano-silver can be many times more toxic.[61] Swiss

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[55] Wenjuan Yang *et al.*, *Food storage material silver nanoparticles interfere with DNA replication fidelity and bind with DNA*, 20:8 Nanotechnology 85-102 (2009).
[56] Hussain *et al.*, *supra* note 52; Hussain *et al.*, *supra* note 54.
[57] Schapira *et al.*, *Mitochondrial disease*, 368 (9529) Lancet 70-82 (2006).
[58] *See generally* FoE, *Nano-silver: policy failure puts public health at risk*, *supra* note 6.
[59] *See* FoE, *Nano & Biocidal Silver* (2009), *supra* note 6, at 15-18, 20-24 (and citations therein).
[60] Hogstrand *et al.*, *The Toxicity of Silver to Marine Fish*, 4th International Conference Proceedings: Transport, Fate, and Effect of Silver in the Environment 109-112 (1996); *see also* ICTA Nano-Silver Petition, *supra* note 4, at 59-60 (and citations therein).
[61] Marambio-Jones *et al.*, *A Review of the Antibacterial Effects of Silver Nanomaterials and the Potential Implications for Human Health and the Environment*, 12 J. Nanopart Res 1531-51 (2010); Wijnhoven *et al.*, *Nano-silver* –

researchers recently modeled the environmental concentrations of several commercially available nanomaterials and predicted that nano-silver emissions may already pose risks to aquatic organisms.[62] *See also* ER 42 (concluding that exposure to AGS-20 nanosilver "may result in adverse effects to aquatic species").

Further, the same property that makes these nanoparticles attractive to manufacturers—their highly enhanced antimicrobial properties—can be highly destructive to ecosystems, by threatening the bacteria-dependent processes that underpin these natural systems. [63] Microorganisms are the foundation of all ecosystems and provide key environmental services ranging from primary productivity to nutrient cycling and waste decomposition. Early studies show that nano-silver can reduce the activities of microbes employed in treating wastewater.[64] Widespread use of household products that release nano-silver into the sewage system could adversely affect waterways, exacerbated by the inability

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a review of available data and knowledge gaps in human and environmental risk assessment, 3 (2) Nanotoxiocology 109-138 (2009).

[62] Gottschalk *et al.*, *Possibilities and limitations of modeling environmental exposure to engineered nanomaterials by probabilistic material flow analysis*, 29 Envion Toxicology and Chemistry 1036-48 (2010).

[63] *See* ICTA Nano-Silver Petition, *supra* note 4, at 67-68.

[64] Choi *et al.*, *The Inhibitory Effect of Silver Nanoparticles, Silver Iosn, and Silver Chloride on Microbial Growth*, 42 Water Research 3066-74 (2008); Nanowerk, *Too Much Technology May Be Killing Beneficial Bacteria* (2008), http://www.nanowerk.com/news/newsid=5520.php (last visited Apr. 21, 2012).

of public utilities and water treatment plants to properly treat the substance.[65] Increased nano-silver concentrations in treatment-plant discharges could lead to adverse effects such as bioaccumulation in fish and the killing of aquatic life.[66] Another potential post-treatment harm is the spreading of sewage sludge and the decomposition of nano-silver in landfills, whereby nano-silver can contaminate agricultural fields.[67]

In 2009, as a result of these and other potential adverse impacts on the environment, EMERGNANO, the first global review of environmental, health, and safety studies examining the risks of nanotechnology exposure, found that there is "sufficient evidence to suggest that silver nanoparticles may be harmful to the environment and therefore the use of the precautionary principle should be considered in this case."[68]

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[65] Letter from Ken Kirk, Executive Director, Nat'l Ass'n of Clean Water Agencies, to Stephen Johnson, Administrator, EPA (February 14, 2006), *available at* http://archive.nacwa.org/www.nacwa.org/getfile7128.html?fn=2006-02-14agltr.pdf (last visited Apr. 21, 2012); Benn, T. M., *et al. Nanoparticle silver released into water from commercially available sock fabrics*, 42 (11) Environmental Science & Technology 4133-4139 (2008).

[66] *See* ICTA Nano-Silver Petition, *supra* note 4, at 69, 63, 83-84 (and citations therein).

[67] 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 Env't 396-409 (2008).

[68] Aitken R, Hankin S, *et al.*, *EMERGNANO: A Review of Completed and Near Completed Environmental, Health and Safety Research on Nanomaterials and Nanotechnology* 146 (2009), *available at*

III. EPA HAS A BLUEPRINT FOR PROPER OVERSIGHT OF NANO-PESTICIDES, INCLUDING NANO-SILVER PESTICIDES, AND SHOULD HAVE ACTED IN ACCORDANCE WITH IT.

Despite the nano-silver product explosion and its associated environmental and health risks, EPA has yet to take any meaningful regulatory action. Yet over four years ago, *Amici* presented both a blueprint and legal impetus to take such needed oversight action. Instead of approving an unprecedented conditional registration for one nano-silver pesticide, EPA should have taken programmatic oversight action for all nano-silver products. As explained in *Amici*'s petition, such action must include, *inter alia*:

- Clarifying that all nano-silver products are pesticides that must undergo FIFRA registration before commercialization, *see* ICTA Nano-Silver Petition at 30-42;
- Clarifying that nano-silver pesticide are new pesticide substances that require new pesticide registrations, with nano-specific data requirements, testing, risk assessments, conditions for use, post-registration notification of adverse impacts and disclosure of all information concerning environmental and health effects, *id*. at 42-56, 99-114.
- Assessing the potential human health and environmental risks of nano-silver. These assessments are required by and must comply with FIFRA, as well as the FQPA, the ESA, and NEPA, *id.* at 57-96;
- Taking immediate action to stop the sale of current nano-silver products as illegal pesticide products with unapproved health benefit claims, *id.* at 96-99.

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http://nanotech.law.asu.edu/Documents/2010/06/CB0409_7911_FRP_466_1948.pdf.

CONCLUSION

AGS-20 is not just any pesticide that EPA has conditionally regulated, while simultaneously acknowledging it lacked critical data. Nanomaterials represent a new class of materials, materials for which the scientific community universally has concluded can act in fundamentally new ways, ways that experts are just starting to understand. Nano-silver pesticides are the first regulatory precedent for these materials, as well as the leading product type. If there was ever time for caution, in furtherance of the public interest, it should have been here. The agency instead placed of its imprimatur on business as usual, a decision even more egregious given that the agency has known about the nanomaterial and nano-silver pesticide product commercialization onslaught, its unknowns and red flags, and has a blueprint for responsible regulation. The Court should set the registration aside.

Respectfully Submitted,

Dated: April 23, 2012

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CERTIFICATE OF COMPLIANCE WITH RULES 29(d), 32(a)

1. With respect to the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B), this brief contains 6,997 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2003 in 14-point Times New Roman.

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CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2012, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Some of the participants in the case are not registered CM/ECF users. I have mailed the brief by first-class mail, postage prepaid, to the following non-CM/ECF participant:

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