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EXECUTIVE SUMMARY

Legal Petition Challenges EPA's Failure to Regulate Environmental and Health Threats from Nano-Silver

On May 1, 2008, the International Center for Technology Assessment (CTA) and a coalition of consumer, health, and environmental groups filed a legal petition with the Environmental Protection Agency (EPA), demanding the agency use its pesticide regulation authority to regulate numerous consumer products now using nano-sized versions of silver. The petition is the first legal challenge to EPA's failure to regulate nanomaterials. Nano-silver is the most common commercialized nanomaterial.

Nanotechnology and Nano-silver Products have arrived

Nanotechnology takes apart and reconstructs nature at the atomic and molecular level. Nanotechnology and products containing manufactured nanomaterials have arrived and represent the crest of a product wave spanning many industries. Hundreds of consumer products composed of manufactured and engineered nanomaterials are now widely available. The largest 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.

The Products

The petitioners discovered no fewer than 260 self-identified nano-silver consumer products being sold in the U.S. The products listed in the petition's appendix include: air and water purifiers and filters; bathroom, kitchen and multipurpose cleaning sprays and wipes, children's toys, baby bottles and infant products; laundry detergents and fabric softeners; food storage containers, cutlery, and cutting boards; numerous types of clothing including underwear, socks, shirts, outerwear, gloves and hats; various fabrics and fibers; soaps, personal care and hair products; pet accessories; refrigerators and washing machines; computer hardware; ingestible "health" drink supplements; automobile products; and powdered and liquid nano-silver in bulk form. The products come from the U.S., the U.K., Canada, Korea, Japan, Taiwan, China, New Zealand, and Germany.

The nano-silver products 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.”

The Environmental and Human Health Risks of Nano-silver

The same property that makes these nanomaterials attractive to manufacturers—their highly enhanced antimicrobial action—can be highly destructive to the environment and raise serious human health concerns. Even in bulk form, silver is toxic to fish, aquatic species and microorganisms and a 2005 study found that nano-silver is approximately 45 times more toxic than standard silver. In addition, nanomaterials such as nano-silver exhibit remarkably unusual physical, chemical and biological properties, such as the ability to be harmful in new ways. Impacts are occurring through use and disposal: A 2008 study showed that washing nano-silver socks releases substantial amounts of the nano-silver into the laundry discharge water, which will ultimately reach natural waterways and ecosystems and potentially poison fish and other aquatic organisms. Another 2008 study found that releases of nano-silver destroy benign bacteria used in wastewater treatment.

Many of the nano-silver infused products are for children (baby bottles, toys, stuffed animals, and clothing) or otherwise create high human exposures (cutlery, food containers, paints, bed sheets and personal care products) despite very little study on nano-silver’s potential human health impacts. Studies have questioned whether traditional assumptions about silver’s safety are sufficient in light of the unique properties of nano-scale materials. Potential health risks from nano-silver’s widespread use also include increased bacterial and antibiotic resistance and risks created by nanomaterials’ unprecedented mobility in the body.

EPA’s Failure to Act

Concerns over nano-silver were first raised by national wastewater utilities in early 2006. Their concerns were highlighted by one then-new nano-silver product, Samsung’s Silvercare Washer, which releases silver ions into the waste stream with every wash. In response, the media reported in November 2006 that EPA would regulate nano-silver products as pesticides. One year later, EPA published a guidance covering only the Samsung washer and allowed it to remain on the market. EPA denied that this guidance was “an action to regulate nanotechnology.”

The Petition

Despite this nano-silver product explosion and its associated environmental and health risks, EPA has yet to take any meaningful regulatory action. The petitioners present both a legal blueprint and impetus to take such needed oversight action.

First, the petition calls on EPA to amend its regulations or otherwise act to clarify that nano-silver is a pesticide and those products incorporating it are pesticide products that must be registered, approved by the agency, and labeled prior to marketing. Nano-

silver meets the pesticide law's (FIFRA) definition of a pesticide because it is a highly efficient antimicrobial or antibacterial agent and is intended to be used for that purpose. 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 labeling, a potential loophole several manufacturers have already exploited.

Second, the petition calls on EPA to clarify that nano-pesticides, such as nano-silver products, are new pesticide substances that require new pesticide registrations, with nano-specific toxicity data requirements, testing and risk assessments. Nano-silver must be classified as a separate substance than macro-silver based on the nanomaterial's capacity for fundamentally unique and different properties and because nano-silver many new antimicrobial uses are not previously registered silver uses.

Third, EPA must assess the potential human health and environmental risks of nano-silver. These assessments are required by and must comply with FIFRA, as well as the Food Quality Protection Act (FQPA), the Endangered Species Act (ESA), and the National Environmental Policy Act (NEPA). As part of this assessment, EPA should analyze all existing scientific studies as well as require manufacturers to provide all necessary additional data on 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. Finally, EPA must comply with NEPA by ensuring that it assesses the environmental impacts of its actions regarding nano-silver pesticide products.

Fourth, EPA should take immediate action to prohibit the sale of nano-silver products as illegal pesticide products with unapproved health benefit claims. The nano-silver consumer products currently on market are in clear violation of FIFRA's mandates. To this end, EPA should issue Stop Sale, Use or Removal Orders or other enforcement penalties or actions to those manufacturers and/or distributors currently selling these unregistered nano-silver pesticide products.

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 with EPA the duty to prohibit, condition, or allow the manufacture and use of nanomaterials in nano-pesticides and prescribe conditions for manufacture or use. These include: requiring nano-specific ingredient and warning labeling; 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, EPA should 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 Federal Food Drug and Cosmetic Act Tolerance for nano-silver.

The full petition is available at www.icta.org and www.nanoaction.org

Relief Requested

Should EPA grant the petition, the result would be that nano-silver is classified as a new substance and nano-silver products regulated as new pesticides. That would require current and future nano-silver products to undergo mandatory EPA pre-market approval. Current products would have to be removed until and unless they received EPA approval. Approval would only occur if the agency found the products did not create an unreasonable risk to the environment. EPA would also have to assess nano-silver's potential impacts on human health, particularly on children and infants, and on the environment, particularly on endangered species and their habitat. EPA would require manufacturers to submit any needed data about the nanomaterials and current EHS unknowns to conduct its assessments. If any of the nano-silver products were approved and registered as pesticides, their use would be conditioned as necessary to protect the environment and human health, including the use of warning labeling. EPA would also amend its regulations to require nano-specific data, testing, and risk assessments for nanomaterial pesticide products.

The Petitioners

Joining the CTA petition are: the Center for Food Safety, Beyond Pesticides, Friends of the Earth, Greenpeace, ETC Group, Center for Environmental Health, Silicon Valley Toxics Coalition, Institute for Agriculture and Trade Policy, Clean Production Action, Food and Water Watch, the Loka Institute, the Center for Study of Responsive Law, and Consumers Union.

CTA

CTA is a non-profit, non-partisan organization committed to providing the public with full assessments and analyses of technological impacts on society. CTA works towards adequate oversight of nanotechnology through its Nanotechnology Project, *NanoAction*, www.nanoaction.org

CTA's uses a variety of legal and policy tools to fulfill its mission, including administrative law petitions. This is the second legal action CTA has filed on the health and environmental risks of nanotechnology: in May 2006 CTA filed a legal petition with the Food and Drug Administration (FDA), calling on that agency to address the human health and environmental risks nanomaterials in consumer products, particularly nano-cosmetics and nano-sunscreens.