



International Center for Technology Assessment

Date: September 10, 2012

To: Mr. Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
Environmental Protection Agency

From: Jaydee Hanson
Policy Director

RE: Nano-Silver Pesticide Registration Review EPA-HQ-OPP-2011-0370

While we are glad that the EPA is finally reviewing the registration of some of the commercial products containing nano-silver, we urge the EPA to respond to our 2008 petition on nano-silver. ⁱ In that petition we call on the EPA to use its powers to take such products off the market as we argued that, these products are now being illegally sold as pesticides. In the last four (4) years, the EPA has only taken action on two nano-silver products illegally on the market. ⁱⁱ The International Center for Technology Assessment (ICTA) found in 2008 that there were already over 260 nano-silver products on the market, ranging from household appliances and cleaners to clothing, cutlery and children's toys to personal care products and coated electronics. We now estimate that there are more than 600 nano-silver consumer products. Most of these products are still on the market. Yet, as the ICTA legal petition argues, this unique substance may be highly destructive to natural environments and raises serious human health concerns.

Please note that we also have filed an amicus brief ⁱⁱⁱ in a case challenging the EPA conditional registration of HeiQ AGS-20 intended for use as a preservative in textile products (EPA Reg. Nos. 85249-1 and 85249-2.) We have requested that the 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 EPA is correct in arguing that there are many areas of environmental health and risk data that are missing for nano-silver. On June 17, 2011 in its Federal Register notice, EPA proposed using two different legal authorities contained in the Federal Insecticide and Rodenticide Act (FIFRA) to obtain information about nanopesticidal products. We agree with the EPA view that FIFRA section 6(a)(2) is the "most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides." This section requires pesticide permit

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holders wanting to commercialize a pesticide to submit environmental health and safety data about their product without waiting for the agency's request for the data, both before and after the pesticide is approved. This approach is clear and places the responsibility on the registrant to report all data that would help the agency meet its requirement to determine whether a product meets the no "unreasonable adverse effects on the environment" standard. Our organization and many other non-governmental groups supported using this approach that was reportedly the preferred approach for EPA. We note that despite thousands of individuals and dozens of organizations having supported this approach to gather needed data on the EPA docket EPA-HQ-OPP-2010-0197-0150, the EPA is now using the Data Call In (DCI) approach from FIFRA 3(c)(2)(B). While a Data Call in approach can be used as an interim step while the EPA finalizes regulations for an approach the would require registrants to submit health and safety data about their products, both before and after a pesticide is approved, a Data Call In should not be used instead of section 6(a) (2) as now seems the case. If a decision has been made not to proceed with issuing regulations under section 6(a) (2), EPA should say so explicitly.

The Data Call In approach has only resulted in four companies identifying their products as containing nano-silver and the EPA has identified on its own only one additional company. This is a shockingly small number of companies given the large number of companies marketing their products as containing nano-silver.

A review of the literature related to nano-silver and its possible effects on human and environmental health suggests to us that there is not adequate research to make definitive judgments in many areas.

We support the EPA efforts to get more data on:

1. Human health effects, especially material released from treated textiles that accesses long term effects on the lungs, liver, kidneys, blood, and reproductive organs. The EPA should require a dietary risk assessment given the use of nano-silver in ways that will get into drinking water supplies and in dental treatments. The use of nanosilver treated fabrics can pose a long-term problem when infants are exposed to nano-silver and the EPA should require data to assess the likely exposure that infants would face in residential, daycare, and other settings. Specific data on carcinogenicity, mutagenicity, reproductive toxicity, developmental and neurodevelopmental toxicity, endocrine activity and acute toxicity are needed. The currently available data in all of these areas are lacking or insufficient for the EPA to make adequate judgments on the human health effects of these substances.
2. Occupational exposure is a special category related to human health effects. Workers could face the highest levels of exposure and special studies that focus on the effects of handling nano-silver in its various forms should be designed and required of registrants. Requiring data on the systemic toxicity, skin sensitization, skin irritation/corrosivity, eye

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irritation/corrosivity, and respiratory sensitivity are especially needed for worker safety. Few data are presently available for any nano-silver applications in these areas.

3. Environmental Fate & Eco-toxicity. The scientific advisory panel (SAP) review of nano-silver warned that the toxicity of nano-silver might be different from and higher than other forms of silver. We support their recommendation that the existing data requirements for antimicrobial pesticides might need to be changed to accommodate data appropriate for assessing the fate, degradation, metabolism, mobility, dissipation, and accumulation of nano-silver. Moreover, the EPA should require specific data on the kinds of nano-silver and the formulations of nano-silver being used in an application.

The EPA should seek specific data on: 1. Particle size (we support the FDA approach of asking for data on particles up to 1000nm), 2. Structure—amorphous vs. crystalline, 3. Mobility, 4 bioavailability, 5. Agglomeration/aggregation, 6. Chemical composition, 7. Purity, 8. Shape, 9. Surface area, 10. surface charge, 11. Surface chemistry, and 12. Assessing whether the characterization was done in the relevant media.

Tests need to address: Acute aquatic toxicity, chronic aquatic toxicity, persistence in the environment, bioaccumulation, Reactivity, and Flammability unless data are presented that support the exclusion of one of these test areas. Bulk silver testing or silver ion testing cannot be used as a surrogate for testing of the actual nano-silver formulation being used by the manufacturer.

4. Confidential Business Information (CBI) should not be used to shield the description of the way the product was produced, or the formulation process or the production process. The intellectual property provisions of patent law should be sufficient to protect a company's interests. No health or safety data should be hidden under CBI.

ⁱ International Center for Technology Assessment, et al., Petition to the EPA for Rulemaking Requesting EPA to Regulate Nano-silver Products as Pesticides. May 1, 2008. Available at: http://www.icta.org/files/2011/12/CTA_nano-silver-petition_final_5_1_08.pdf (last accessed Sept. 10, 2012.)



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ii “U.S. EPA fines Southern California technology company \$208,000 for “nano coating” pesticide claims on computer peripherals”, EPA press release March 5, 2008. Available at:

<http://yosemite.epa.gov/opa/admpress.nsf/0/16a190492f2f25d585257403005c2851>

“Hefty fine for So Cal Company’s untested “nano” claims”, EPA press release Dec. 15, 2010, Available at:

<http://yosemite.epa.gov/opa/admpress.nsf/6427a6b7538955c585257359003f0230/3db62e7e695b684a852577fa005948dc!OpenDocument>

iii 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. Natural Resources Defense Council, Inc., Petitioner, v. United States Environmental Protection Agency, Respondent. Review of an order of the U.S. Environmental Protection Agency. United States Court of Appeals for Ninth Circuit, 2012, Case No. 12-70268 available at <http://www.icta.org/files/2012/04/21-2-Nano-Silver-Amicus-Brief.pdf> (last accessed Sept. 10, 2012)

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