

BEFORE THE  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS

Petition for Rulemaking Requesting )  
EPA Regulate Nanoscale Silver Products )  
as Pesticides; Notice of Availability )  
73 Fed. Reg. 69644 (November 19, 2008) )

EPA-HQ-OPP-2008-0650  
Regulatory Public Docket (7502P)  
Via Electronic Filing

COMMENTS OF THE NANOTECHNOLOGY INDUSTRIES ASSOCIATION  
ON THE PETITION FOR RULEMAKING FILED BY THE  
INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, ET AL.

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## EXECUTIVE SUMMARY

EPA should deny the May 1, 2008 petition filed by the International Center for Technology Assessment, *et al.* (collectively “ICTA”). ICTA requests EPA to take actions that in some cases are inconsistent with EPA’s statutory authority, in other cases are redundant of existing authority, and still others are inefficient ways of using EPA resources to facilitate compliance.

First, the Petition calls for EPA to make blanket determinations concerning nanoscale silver and other nanopesticides. This approach is inconsistent both legally and factually with the definition of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), which is the source of EPA’s jurisdiction. Simply put, not all nanoscale silver meets the definition of a pesticide, and not all nanopesticides are “new” pesticides, under FIFRA and EPA’s regulations promulgated under FIFRA. Moreover, agreeing with the ICTA and prematurely declaring that a new nanoscale substance, or a nanoscale version of a conventional substance, has no “significantly commercially valuable uses” other than its use as a pesticide could stifle innovation.

Second, the Petition calls for EPA to promulgate regulations or take other actions that are redundant and therefore unnecessary. EPA already has broad authority under FIFRA to regulate those substances that are pesticides and to require data to make possible the evaluations EPA must make to determine whether to register a particular pesticide product and, if so, under what terms and conditions. Furthermore, to the extent ICTA seeks to have EPA undertake a Programmatic Environmental Impact Statement (“PEIS”) under the National Environmental Policy Act (“NEPA”), this is unnecessary and contradicted by longstanding judicial authority concluding that EPA’s implementation of FIFRA is the functional equivalent of NEPA. To the

extent that nanoscale silver is proposed for pesticidal use, there is no need for ICTA to lecture EPA on how to adhere to its statutory obligations or established process for considering pesticide registration actions.

Finally, before contemplating a broad-scale enforcement initiative such as the one that ICTA suggests, NIA respectfully encourages the EPA to undertake additional outreach to the regulated community about how FIFRA requirements apply to consumer products made with nanoscale silver for pesticidal purposes. To the extent that the ICTA's inventory or other such lists are accurate, they suggest that some products made with nanoscale silver may be distributed by companies that are not akin to traditional pesticide companies. Some of these companies may be less familiar with FIFRA and the associated regulatory requirements, such as the conditions imposed by the treated article exemption. The Nanotechnology Industries Association ("NIA") would welcome the opportunity to work with EPA and others to facilitate this outreach.

### **INTRODUCTION**

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, NIA is an international trade association that represents diverse industries in the multi-stakeholder debate concerning nanotechnologies. NIA offers a perspective derived from the collective views and experience of its membership on regulatory standards and policy initiatives that affect the development and commercialization of nanotechnologies and nanotechnology-enabled products in the United States and abroad. NIA appreciates the opportunity to submit these comments on the ICTA's "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides" ("Petition").

As EPA noted in its request for public comments on the Petition,<sup>1</sup> ICTA requests that the Agency take several actions, including:

- “clarifying” that nanoscale silver and products containing nanoscale silver are pesticides that require registration under FIFRA;
- classifying *all* nanopesticides as new pesticides that require new registrations;
- analyzing the potential human health and environmental risks of nanoscale silver under FIFRA, the Food Quality Protection Act (“FQPA”), the Endangered Species Act (“ESA”), and NEPA;
- undertaking regulatory enforcement actions under FIFRA against existing unregistered consumer products that contain nanoscale silver;
- applying the full range of regulatory requirements to nanoscale silver pesticides for which EPA grants registration under FIFRA; and
- taking other regulatory actions under FIFRA that ICTA deems necessary to ensure the adequate regulation of nanoscale silver pesticides.

NIA recognizes the importance of the issues raised in the Petition and the effect that EPA’s decision may have on companies within the nanoscale silver value chain, as well as on companies that may seek to register nanopesticides in the future. Several NIA member companies currently produce nanoscale silver and others use it in their products. In addition, other member companies are developing, or contemplating the development of, nanopesticides for potential registration in the United States.

## **DISCUSSION**

### **1. Section 2 of FIFRA and 40 C.F.R. § 152.15 Already Provide for the Regulation of Pesticide Products on the Basis of Pesticidal Intent.**

Under the guise of seeking “clarification,” ICTA urges EPA to conclude that nanoscale silver is a pesticide (or active ingredient) and that consumer products containing nanoscale silver must be registered as pesticides. (Pet. at 30 - 42.) ICTA asserts, among other things, that

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<sup>1</sup> 73 Fed. Reg. 69,644 (Nov. 19, 2008). EPA extended the comment deadline until March  
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nanoscale silver has no other significantly commercially valuable use and consumer products containing nanoscale silver are pesticides that are ineligible for FIFRA exemptions. (Pet. at 34, 39 - 42.) EPA should deny ICTA's request because it is inconsistent both legally and factually with the definition of a pesticide in Section 2 and the evaluation criteria set out at 40 C.F.R. § 152.15.

As ICTA acknowledges, the existing regulations provide for the evaluation of pesticide products on the basis of pesticidal intent, which may be determined on the basis of the absence of other uses for the active ingredient. 40 C.F.R. § 152.15. These regulations establish that EPA determines pesticidal intent on a product-by-product basis, following a review of each product's specific claims and intended uses. Declaring that nanoscale silver and all consumer products containing nanoscale silver are pesticides that require registration is inconsistent with the product-by-product approach required by the definition of pesticide and with EPA's established regulations. It also is factually unsupported.

The existing and near-term market for nanoscale silver contradicts ICTA's assertion that nanoscale silver has no "significantly commercially valuable use." There are currently numerous commercially valuable, non-pesticidal uses of nanoscale silver. For example, some members of the electronics industry currently use nanoscale silver for the development of printed and flexible electronics, a technology that is possible because of the tiny size of the silver particles and their electrical conductivity, and not because of any pesticidal qualities that nanoscale silver may have.<sup>2</sup> Electronics manufacturers are also investigating the use of nanoscale silver in a

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20, 2009. 74 Fed. Reg. 2,072 (Jan. 14, 2009).

<sup>2</sup> *E.g.*, Press Release, PChem Associates, *High Speed, Low Temperature Nano Silver Ink Developed for Consumer Electronics* (Oct. 5, 2005), available at <http://www.nanotech->

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connective paste for semiconductors,<sup>3</sup> and scientists are experimenting with fluorescent properties of nanoscale silver applied to glass.<sup>4</sup> In addition, the use of nanoscale silver is readily available as an efficient colloidal colorant in vitreous substrates, including large-scale float glass manufacturing.<sup>5</sup> It is simply not true that nanoscale silver has no “significantly valuable commercial use” other than its use as a pesticide, in light of the diverse and expanding market for this substance.

Furthermore, some of the consumer products that ICTA lists in Appendix A to the Petition appear to be regulated under the Federal Food, Drug, and Cosmetic Act or other statutes, or potentially eligible for other exclusions or exemptions from pesticide registration requirements. Adopting ICTA’s wholesale claim that all consumer products containing nanoscale silver, or even just those listed in Appendix A, are pesticides that require registration is problematic both because some of those products are not in fact pesticides over which EPA has jurisdiction and because not all products classified as “pesticides” under FIFRA are required to be registered.

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[now.com/news.cgi?story\\_id=11891](http://www.now.com/news.cgi?story_id=11891); Martin Amberg et al., *Electromechanical Behavior of Nanoscale Silver Coatings on PET Fibers*, 5 *Plasma Processes and Polymers* 874-880 (Oct. 2008), available at <http://www3.interscience.wiley.com/journal/121450877/abstract> (discussing wearable electronics).

<sup>3</sup> J.G. Bai et al., *Low-Temperature Sintered Nanoscale Silver as a Novel Semiconductor Device-Metallized Substrate Interconnect Material*, 29 *Institute of Electrical and Electronics Engineers Transactions on Components and Packaging Technologies* 589-593 (Sept. 2006), available at [http://ieeexplore.ieee.org/xpl/freeabs\\_all.jsp?tp=&arnumber=1684182&isnumber=35464](http://ieeexplore.ieee.org/xpl/freeabs_all.jsp?tp=&arnumber=1684182&isnumber=35464).

<sup>4</sup> See, e.g., Pan Xin-Yu et al., *Fluorescence Microscopy of Nanoscale Silver Oxide Thin Films*, 20 *Chinese Phys. Lett.* 133-136 (2006).

<sup>5</sup> See, e.g., Rajala, M. et al., *An Industrial Method for Nanoparticle Synthesis with a Wide Range of Compositions*, *Rev. Adv. Mat. Sci.*, 5, pp. 493-497 (2003) and Pimenoff, J., *Nanotech Comes of Age in Glass Coatings*, *Glass Worldwide*, 8 (2006).

Lastly, granting ICTA's request also could have the unintended consequence of establishing a regulatory policy that might stifle innovation with nanoscale substances or embodiments of other emerging technologies. The fact that a nanoscale substance or other nanomaterial may currently have only pesticidal uses does not necessarily foreclose the possibility that other, non-pesticidal uses may be developed in the future. Prematurely declaring that a new nanoscale substance, or a nanoscale version of a conventional substance, has no "significantly commercially valuable uses" other than use as a pesticide could stifle innovation. Companies seeking to avoid the additional FIFRA obligations may simply limit further research and development with the regulated substance. Thus, EPA should view with caution any request for a wholesale declaration concerning the pesticidal status of a nanoscale substance or other nanomaterial. In the case of nanoscale silver, EPA should deny ICTA's requested actions because they are inconsistent with EPA's legal and regulatory authorities, and they are potentially inhibiting of technological innovation.

**2. Section 3 of FIFRA and 40 C.F.R. Parts 152, 158 and 161 Provide for a Product-by-Product Evaluation with Ample Data to Enable EPA to Determine the Similarity or Dissimilarity of a Nanopesticide to Registered Conventional Pesticides.**

The Petition seeks characterization of *all* nanopesticides as new pesticides (*i.e.*, new active ingredients), distinct from those already registered as conventional pesticides. (Pet. 42.) ICTA presumably intends this characterization to result in additional data requirements regarding nanopesticides so that EPA can review the risk-benefit balance for each nanopesticide. (Pet. at 56.) EPA should reject the request for a blanket declaration regarding the regulatory status of nanopesticides because it is inconsistent with the registration process in Section 3 and 40 C.F.R. Part 152. Moreover, EPA currently has ample authority under 40 C.F.R. Parts 158 and 161 to

require data to enable the Agency to determine whether to register a particular pesticide product and, if so, under what terms and conditions.

The assessment of the similarity or dissimilarity of a specific nanopesticide (or other pesticide) to a currently registered conventional pesticide, and the data requirements associated with that assessment, should be performed on a case-by-case basis, as EPA does with all other new pesticide products. The claims, composition, or uses of a nanopesticide may, or may not, differ from those of registered conventional pesticides. EPA should not pre-judge the regulatory status of a product simply because it contains a nanoscale version of a registered active ingredient. ICTA's request for a wholesale declaration that all nanopesticides are *per se* new pesticides requiring new registrations is inconsistent with EPA's existing authority and is simply not warranted.

**3. The Existing Registration Process Requires an Analysis of the Potential Human Health and Environmental Risks of Nanoscale Silver.**

ICTA requests that EPA use FIFRA, FQPA, ESA, and NEPA to evaluate the potential human health and environmental risk associated with nanoscale silver. (Pet. at 57 - 96.) There is no reason for ICTA to expect, or suggest, that EPA would deviate from any applicable requirements under these statutes when evaluating a registration application for a nanoscale silver pesticide. The Agency has demonstrated its ability to apply these laws as appropriate to the regulation of other emerging technologies with pesticidal applications.

To the extent that ICTA is suggesting that the current process is inadequate and seeks to impose more onerous regulatory requirements on registrants of nanoscale silver, EPA should deny the Petition. The applicable statutes, regulations, and policies provide EPA with ample authority to require the submission of data sufficient for the evaluation and management of potential effects, as well as the establishment of any necessary food tolerances.

ICTA also asserts that EPA must publish a PEIS under NEPA before creating a regulatory program for nanoscale silver or continuing to regulate nanoscale silver under the Agency's current FIFRA program. (Pet. at 93, 96.) This assertion is inconsistent with well-established law. Courts have held that the processes set out in the existing FIFRA program are "functionally equivalent" to those in NEPA, negating the need for separate NEPA reviews of EPA actions under FIFRA. *See Merrill v. Thomas*, 807 F.2d 776, 781 (9<sup>th</sup> Cir. 1986); *Env'tl. Defense Fund v. EPA*, 489 F. 2d 1247, 1254-56 (D.C. Cir. 1973). Furthermore, the denial of a citizens' petition that requests new regulations is not tantamount to the establishment of *de facto* program that would trigger the PEIS obligation. Instead of establishing a new program, the denial would merely affirm the adequacy of the existing FIFRA program for the regulation of nanopesticides.

**4. EPA's Resources Would Be Better Spent Providing Guidance Rather than Initiating Enforcement Actions.**

ICTA requests that EPA issue Stop Sale, Use or Removal Orders ("SSURO") under FIFRA Section 13(a) to manufacturers and/or distributors currently selling consumer products containing nanoscale silver, including those listed in Appendix A to the Petition. (Pet. 98.) ICTA argues that consumer products containing nanoscale silver are ineligible for FIFRA exemptions, including the treated articles exemption at 40 C.F.R. § 152.25(a). (Pet. at 39 - 42.)

NIA acknowledges that EPA has a broad range of existing enforcement authorities that enable it to proceed, as appropriate, on a case-by-case basis, against any company selling a nonexempt pesticide product without a registration under FIFRA (or committing any other FIFRA violation). These include the authority to issue SSUROs, as well as the authority under Section 14 to impose civil penalties for noncompliance or seek criminal penalties for knowing violations. However, before undertaking a broad-scale enforcement initiative such as the one

that ICTA advocates, EPA should carefully scrutinize and question ICTA's assertions about the products on that inventory, as well as the value of product inventories generally. Instead of concluding that all consumer products containing nanoscale silver are ineligible for the treated articles exemption, EPA should engage at the appropriate time in an evaluation of each product to assess its eligibility.

Furthermore, NIA respectfully suggests that, at this time, EPA's limited resources would be better spent undertaking additional outreach tailored specifically to the issues confronting the nanotechnology community before contemplating an enforcement initiative. Some products that are currently made with nanoscale silver are distributed by companies that are not akin to traditional pesticide companies and therefore may be less familiar with FIFRA and the associated regulatory requirements. EPA should educate these companies about the application of FIFRA to nanopesticides, as well as their general obligations and the eligibility of their products for exemptions under the statute. NIA would welcome the opportunity to work with EPA and others to facilitate this outreach.

For instance, the treated articles exemption may be a source of considerable confusion among consumer products companies utilizing nanopesticides or nanoscale silver for pesticidal purposes (as it has been a source of confusion for many other companies over the years). NIA therefore recommends that part of any EPA outreach effort should include disseminating guidance tailored to consumer products containing nanopesticides to explain the eligibility criteria for the treated articles exemption. It also should include an opportunity to come into compliance with the exemption (or other FIFRA requirements as part of the larger outreach effort) before EPA would initiate enforcement.

Precedent arguably exists for such an approach. For example, EPA recently issued guidance clarifying the TSCA Inventory status of carbon nanotubes (“CNTs”), as well as the premanufacture notice requirements, providing manufacturers and importers of CNTs with an opportunity to come into compliance with the guidance before EPA would initiate enforcement. *See* 73 Fed. Reg. 64946 (Oct. 31, 2008). Furthermore, EPA should consider allowing companies to continue selling or distributing versions of products that were produced on or before the date that EPA would begin to rely on the new guidance. This would avoid the potentially significant adverse economic consequences attending the interruption of supply of those products already in commerce. As EPA is aware, the Agency has concluded that it was appropriate to adopt similar measures with respect to articles treated with antimicrobials and ion-generating equipment.<sup>6</sup>

**5. EPA Should Apply the FIFRA Requirements to the Registration of Nanoscale Silver Pesticides, Including Those Protecting Confidential Business Information.**

EPA should, of course, apply FIFRA regulatory requirements to any nanoscale silver pesticides that EPA approves for registration. (Pet. 99 – 103.) Assuming that EPA determines that a particular product containing nanoscale silver is a pesticide requiring a separate registration, the Agency has ample authority available to it. ICTA does not need to instruct EPA on the available authority or the proper use of that authority. NIA assumes that EPA will continue with its current regulatory practices, evaluating each individual product for registration and determining what labeling (including determining whether nano-specific ingredient labeling is warranted), data requirements, or other conditions of use are appropriate.

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<sup>6</sup> *See* EPA PR Notice 2000-10, *Changes to ‘Effective Date and Procedures’ for PR Notice 2000-1* (Dec. 20, 2000) (regarding articles treated with antimicrobials); 72 Fed. Reg. 54039, 54040-41 (Sept. 21, 2007) (clarifying FIFRA obligations for ion-generating equipment).

NIA also rejects the Petition's assertion that it would be in the public interest under FIFRA Section 10(d) for EPA to publicly disclose for *all* nanopesticides any confidential business information ("CBI") "concerning production, distribution, sale or inventories of a pesticide that the agency receives in connection with a public proceeding to determine whether the pesticide causes unreasonable adverse effects on health or the environment." (Pet. at 103.) Section 10(d) requires a case-by-case evaluation of the necessity of disclosure of CBI under the limited circumstances described in the statute. EPA should continue, as it has in the past, to evaluate the necessity of such disclosure for a particular pesticide in light of the statutory criteria. ICTA's blanket assertion that "the dearth of information on the risk of nanotechnology [establishes that the] public interest [would be] benefited from a transparent and open dialog on the risk of any new and emerging technology such as nanotechnology" does not fulfill those criteria. *Id.*

NIA does not dispute the need for a transparent and public dialogue concerning nanotechnology. In fact, such dialogue is currently occurring in EPA's Office of Pollution Prevention and Toxics, as well as other national and international fora. However, NIA does not accept that the need for dialogue somehow provides a blanket justification for the disclosure of CBI for *all* nanopesticides.

**6. EPA Has Ample Authority to Ensure Adequate Assessment and Oversight of Nanoscale Silver Used for Pesticidal Purposes.**

ICTA recommends a number of different actions to EPA for the assessment and oversight of nanoscale silver pesticides. ICTA claims these actions are necessary for the Agency to prevent unreasonable risks to health or the environment. (Pet. at 104 – 114.) The recommendations include:

- undertaking a classification review of nanoscale silver pesticides;

- undertaking a special review of nanoscale silver pesticides;
- requiring the submission of nano-specific data from prospective registrants of nanoscale silver pesticides;
- amending the FIFRA regulations to require specific data for all nanopesticides;
- undertaking a registration review of the existing registration for silver;
- ensuring that pesticidal devices using nanoscale silver comply with FIFRA; and
- setting a tolerance for nanoscale silver under the FFDCA.

As discussed throughout these comments, FIFRA and its implementing regulations adequately govern all pesticide products, including nanopesticides. An American Bar Association group and the EPA have both separately reached this conclusion.<sup>7</sup> EPA should continue to use this authority to evaluate on a case-by-case basis the necessity of additional actions such as those ICTA identifies.

With regard to ICTA's request for additional data requirements for nanopesticides (Pet. at 107 – 108), NIA considers it premature for EPA to adopt regulations that would impose new data requirements for nanopesticides. Since 2006, the Office of Pesticide Programs has been evaluating testing requirements for nanopesticides and participating in, or following, international activities with a similar focus such as the work currently underway within the Organization for Economic Cooperation and Development (“OECD”) and the International Organization for Standardization (“ISO”). OECD and ISO are also evaluating existing testing protocols, as well as the need for additional endpoints, to assess the human health and environmental effects of nanoscale substances. These efforts will likely inform EPA's future thinking on data requirements. EPA need not and should not initiate a rulemaking to prescribe new data requirements until after the science supporting risk assessment of nanoscale substances

has been developed and peer reviewed, and appropriate harmonization has occurred at the international level.

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NIA appreciates the opportunity to provide these comments, and we look forward to further dialogue with EPA on this important matter.

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<sup>7</sup> See ABA SEER, *The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides* (May 2006); EPA, *Pesticide Issues in the Works: Nanotechnology, the Science of the Small* (July 22, 2008).