INSTITUTE FOR AGRICULTURE AND TRADE POLICY

Pesticides; Policies Concerning Products Containing Nanoscale Materials:
Opportunity for Public Comment
Docket ID: EPA-HQ-OPP-2010-0197
76 Federal Register 35383 (June 17, 2011)

The Institute for Agriculture and Trade Policy (IATP) is a 501(c)(3) nongovernmental organization, headquartered in Minneapolis, MN with an office in Washington, DC. Our mission states, "The Institute for Agriculture and Trade Policy works locally and globally at the intersection of policy and practice to ensure fair and sustainable food, farm and trade systems." To carry out this mission, with regards to nanotechnology, IATP engages in research and advocacy activities in the United States and internationally. IATP is a member of the Nanotechnology Working Group of the Transatlantic Consumer Dialogue, which meets at least annually with U.S. and EU officials, mostly recently in June in Brussels, to discuss TACD resolutions and regulatory cooperation challenges. IATP joined the International Center for Technology Assessment et al petition of May 2008 to the Environmental Protection Agency to regulate nanosilver as a pesticide.[1] IATP reports and comments periodically on nanotechnology regulatory issues, most recently with a report titled "Racing Ahead: U.S. Agri-nanotechnology in the Absence of Regulation."[2]

IATP is pleased to have the opportunity to comment on EPA's draft guidance on the submission of data and information about nanomaterials and particularly Engineered Nano-scale Materials (ENMs) in pesticide products, both those already EPA-registered for commercial use and those that are in the research and development phase. This expression of pleasure is not a pro forma statement. Prior to the release of the draft guidance, the aforementioned co-petitioners to EPA had discussed whether to initiate legal action to attempt to compel release of the draft guidance, and otherwise motivate the Agency to respond. Those discussions were made known to the Office of Management and Budget during a January 2011 meeting several co-petitioners had with OMB staff to find out why OMB had not approved the draft guidance for release for comment.[3]

The undue delay in releasing the draft guidance for comment should now prompt expedited regulatory action, since, "EPA now has information suggesting that there are other pesticide products currently registered and in the marketplace that contain nanosilver as an ingredient" (Federal Register 35389). Just on the basis of the scientific information summarized in reports by the National Institute of Occupational Safety and Health and the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, both cited in the draft guidance (FR 35388), expedited action on already-commercialized nano-pesticides is warranted. The exposure of farmers and farm workers to ENMs in pesticides, whether through inhalation or through the skin, and the bioaccumulation of ENMs in species along the food chain present potential public and environmental health risks. Recall of those pesticides with ENMs already in the marketplace and safety assessment of them based on pesticide manufacturer information and independent information submitted to EPA are urgently needed first steps towards regulation of ENMs in pesticide products.

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General comment

IATP strongly supports the following summary statement: "It is EPA's view that FIFRA [Federal Insecticide Fungicide and Rodenticide Act] section 6(a)(2) is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach."[4] Section 6(a)(2), as noted in the draft guidance, requires the holders of permits to commercialize a pesticide (registrant) to submit environmental health and safety (EHS) information about their products even if not specifically requested by the Agency (FR 35386) and after registration for a pesticide's use has been granted. This statutory provision, together with EPA's history of regulatory interpretation, gives clear guidance to industry to provide peer-reviewed studies, company data and other information to enable EPA to determine whether a pesticide product with ENMs meets the "unreasonable adverse effects on the environment" risk/benefit standard.

IATP wishes to commend EPA for the clarity of the draft guidance and for its courage in releasing it for comment when the Agency's budget and indeed, its mission, are under attack by anti-regulatory elements of industry and the United States Congress. However, prior EPA guidance for industry to submit product information voluntarily has seldom resulted in adequate industry cooperation to enable EPA to fulfill its statutory obligations. The recent report by the EPA's Office of the Inspector General on industry response to voluntary guidance about industrial chemicals affecting children's health[5] does not bode well for cooperation with the draft voluntary guidance on ENMs in pesticide products. According to the Inspector General, "[p]rogrammatic effectiveness was hampered by industry partners who chose not to voluntarily collect and submit information, and EPA's decision not to exercise its regulatory authorities under the Toxic Substance Control Act (TSCA) to compel data collection."[6] As a result of industry's failure to cooperate, and EPA's failure, under the previous administration, to use its statutory powers to compel information submission and to renew the pilot program to protect children from toxic substances, children continue to be exposed to an unreasonable risk of harm from industry chemicals.

An industry decision not to submit information on ENMs and an EPA decision not to compel submission in the event of inadequate industry response would be detrimental to public and environmental health for at least two reasons. First, the ubiquity of pesticides and of pesticide residues on our fruits, vegetables, grains and oilseeds, now incorporating ENMs, presents the opportunity for a very broad and adverse public and environmental health impact. In addition to the estimated 888 million pounds of pesticides applied annually in the United States[7], EPA should now track the kinds and amounts of ENMs incorporated into pesticides. However, there is very great uncertainty about the amounts of U.S. production of nano-silver and other likely ENMs in pesticides, because such production information is among the many kinds that industry classifies, unchallenged by competent authorities, as Confidential Business Information (CBI). For example, one academic study attempting to estimate annual U.S. production for the most commonly used ENMs concluded that degree of uncertainty was its most prominent finding, since, e.g., the nano-silver estimate ranged from 2.8 to 20 tons.[8] In order for EPA to estimate credibly the exposure of the public and the environment to ENMs in pesticides, the Agency will have to collect annual production data for ENMs in pesticide products, as well as toxicological data and information to characterize the properties of ENMs comprehensively. Such data should not, once aggregated by the Agency, be granted CBI status, but should be available in a public registry.

Second, if this voluntary guidance fails to elicit the extent of industry cooperation necessary for EPA to fulfill its obligations under FIFRA and PRIA, and EPA does not compel industry to produce the required information on ENMs in registered and/or prospective pesticide products, it will set a terrible precedent for nanotechnology regulation. If EPA's non-prejudicial draft guidance cannot elicit industry cooperation and subsequently EPA did not compel submission of information required for pre-market safety assessment, other federal agencies likewise might decline to compel industry to submit information on ENMs relevant to carrying out their statutory duties. If agencies refuse to use their statutory authorities, industry effectively would direct nanotechnology regulatory policy and practice. Such a possibility is in no way authorized by the June 9, 2011 memo on nanotechnologies from the presidential Office of Science and Technology Policy, the Office of Management and Budget and the Office of the U.S. Trade Representative to remind all highly ranked federal officials that they are to "protect public health, safety and the environment while promoting economic growth, innovation, competitiveness, exports and job-creation."[9] EPA has the statutory mandate and regulatory competence to "protect public health, safety and the environment," but not to ensure the achievement of economic objectives.

Responses to questions posed in the draft guidance

> *In view of the Agency's goal of identifying what nanoscale materials are in products so that EPA can determine whether it needs additional information to evaluate the products' safety under FIFRA, should EPA change the description of a "nanoscale material"?*

EPA's description of "nanomaterials" should be tiered in such a way as to outline a science-justified size range for nanomaterials and major categories of characteristics to guide industry's reporting to the Agency. Although EPA's description of "nanoscale material" for the purpose of this draft guidance does not constitute a formal legal definition of ENMs, IATP urges the Agency to adopt a description that incorporates the widest consensus based on the best science. The elements of this description should harmonize with those of other jurisdictions, most prominently that of the European Union, which is most advanced in agreeing on a regulatory definition of nanomaterials. The European Commission proposed a regulatory definition of ENMs in its draft Recommendation of October 2010. IATP, as a member of the Transatlantic Consumers Dialogue supports that draft Recommendation, except that TACD proposes an upper size boundary of 300 nanometers.[10]

TACD's variance from the Commission's draft recommendation is based on the general principle that the size dimension of the regulatory definition, like other definitional aspects, should be based on consensus about possible hazards of ENMs identified in peer-reviewed articles that point to particle size as one hazard factor. For example, research on polystyrene beads of 240 nm that cross the human placental barrier with potential airway inflammation in newborns would justify a higher upper size boundary for the ENM definition.[11] IATP agrees with the Commission that the nanomaterials definition should cover natural and incidental nanomaterials, as well as ENMs, and agglomerates, aggregates and structured particles, as well as individual particles.[12] The Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) advised the inclusion of natural and incidental nanomaterials in its justification for a definition of "nanomaterial" because of the use of naturally occurring nanomaterials in the production of ENMs and because of the incidental nanomaterials that could result in the process of manufacturing ENMs.[13] Even though the primary target of EPA's information collection are

ENMs, the inclusion of naturally occurring and incidental nanomaterials in the description of what information the EPA requests in its final guidance would enable the reporting of information that might help the EPA understand unintentional environmental and public health effects resulting from the interaction of ENMs with a pesticide product, either during product production or application.

Given the well-documented tendency of nanoparticles to aggregate and agglomerate, we believe that the EPA should include aggregates and agglomerates in its description of nanomaterials. Because characteristics and properties vary greatly according to the material manufactured at the nanoscale, the list of characteristics that EPA would request in final guidance should be described as indicative, rather than an exhaustive list.

> *Should the reporting requirement apply to ingredients in pesticides that contain any amount of a nanoscale material, or should the requirement apply only if an ingredient contains more than a specified percentage (e.g. 10%) of nanoscale material? If the latter, what should the specified percentage be and why?*

Because the surface to mass ratio of ENMs is exponentially greater than that of counterpart macro-material ingredients, a specified percentage ingredient reporting guideline for ENMs will be of little use in determining whether a pesticide product with ENMs will comply with the statutory requirement for registration. Furthermore, the reaction of one active ENM and/or ENM compounds may vary from one pesticide product to another, so the utility of a specified reporting guideline for any given ENM will likely be of little help to EPA. IATP believes that the registrant or applicant for registration should report to EPA whether the ENM or ENMs incorporated into a pesticide product are inert or active ingredients and to show the scientific basis for this determination.

> *How should the reporting requirement apply to a pesticide manufacturer who purchases ingredients that may contain nanoscale material?*

This is an excellent question to which IATP does not have a comprehensive answer. Until U.S. federal agencies have a registry of nanomaterial manufacturers and an agreed protocol for tracing back the origin of ENMs incorporated into pesticide products and other products, it will be very difficult for pesticide manufacturers to determine the origin of any inadvertently incorporated ingredients containing either incidental nanomaterials or ENMs. Applicants for registration of new pesticide products incorporating ENMs likely will know the origin of the ENMs employed, and certainly, if those ENMs are custom designed for a specific pesticide product. But if manufacturers of registered products have any cause to believe that a change in ingredients and/or ingredient supplier may result in the inadvertent incorporation of ENMs in their pesticide products, EPA should advise those registrants to request that their ingredient supplier test for ENMs and report the results of testing to both the registrant and EPA.

> *If a pesticide is identified as containing a particular nanoscale material, what would be the most useful next steps to inform EPA's understanding of potential risks associated with the pesticide? Are there tests that could provide useful information toward an understanding of risk that would be common to all nanoscale materials, or should the data requirements necessarily be compound- and situation specific?*

The draft guidance states, "EPA now has information suggesting there are other pesticide products currently registered and in the marketplace that contain nanosilver as an active ingredient" (FR 35388). EPA should require that registrants provide documentation that the registered pesticide in which nanosilver has been incorporated without EPA approval is no longer commercialized. The manufacturer may then apply to have EPA register the pesticide unconditionally. Given what is known about the toxicity for aquatic organisms exposed to very low quantities of silver[14] and the lack of *in* situ knowledge about the public and environmental health effects of nanosilver in pesticides, IATP does not believe that conditional registrations, with their lower documentation requirements, are appropriate for applications to commercialize pesticides with ENMs. We share the concern of the National Resources Defense Council that "conditional registrations, representing two-thirds of current product registrations, have been overused, possibly as a way for registrants to gain rapid market access while delaying, or even avoiding, the data requirements for product registration."[15]

According to investigators for the United Kingdom's House of Lords, "toxicologists agree that the persistent nanoparticles, especially those that are non-biologically degradable, inorganic, the inorganic metal oxides and metals, are the particles that pose the most risk."[16] Since draft guidance states that EPA anticipates that nanosilver and carbon nanotubes will be the most frequent ENMs employed in pesticides, these inorganic and bio-accumulative substances should be priorities for EPA's regulatory concern. EPA should require of applicants for registration the kinds of studies and data it requires for pesticides without ENMs, e.g., acute and chronic toxicity, and reproductive toxicity. IATP is unaware of nanotechnology specific *a priori* tests that can be used to characterize risks for all nanoscale materials.

The rule of thumb that the dose of a toxic substance determines exposure to a toxin will be difficult to apply to an ENM compound of small volume but exponentially larger bio-availability. Fortunately, toxicologists have begun to develop nanotechnology-appropriate metrics to measure the toxicity of both low and high bio-persistent ENMs: "In general, toxicologists express doses by mass. However, given the extremely low mass of nanoparticles and increasing doubts about the usefulness of mass as a metric, other metrics have been proposed, i.e. [nano] particle number and particle surface area" to measure dose response.[17] EPA should consult with toxicologists outside the Agency, in addition to those on the FIFRA Scientific Advisory Panel, about which of the nano-specific metrics are most appropriate for use in evaluating information about ENMs used in applicants' pesticide products.

> *What kinds of information should EPA accept as demonstrating that a pesticide product containing a nanoscale ingredient is identically or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects, and that approving the registration in the manner proposed would not significantly increase of any unreasonable adverse effect on the environment?*

Only information from peer-reviewed scientific publications with well-enforced conflict of interest policies should be accepted by EPA from registrants making this claim of substantial equivalence to a currently registered pesticide. Information claimed by the applicant to be Confidential Business Information (CBI) should not be allowed to validate a substantial equivalence claim. The Agency should not consider as CBI any information already available in patents granted to the registrant, and documentation in support of the patent application, for the pesticide product for which registration is sought. Patent application documentation as well

as the grant of patent should be included in the applicant's submission of information to the Agency.

> *When choosing an approach for obtaining needed data, how should EPA weigh considerations relating to the need to update its safety evaluations of currently marketed pesticides in a timely manner, the goal of ensuring marketplace equity, and the interest in minimizing the burdens on regulated entities?*

IATP believes that EPA can update its safety evaluations of currently marketed products with ENMs under its Registration Review Program without significantly burdening regulated entities. In our opinion, due to resource and statutory constraints (e.g., FIFRA's prohibition of mandatory reporting to the EPA of information about the volume, kinds and practices of pesticides applied), EPA is able to review each registered pesticide just once every 15 years (FR 35386). Since peer-reviewed science about the human and environmental health effects of a registered pesticide's use evolves at a greater pace than a once in 15 year or less frequent review, EPA's request for information about registered pesticides, with or without ENMs, to update safe evaluations is not an undue burden on regulated entities.

IATP was unaware that EPA has a statutory duty to ensure "marketplace equity," but assumes that such a duty is subordinate to the statutory obligation to prevent "unreasonable adverse effects on the environment." EPA must not discriminate against the registration of one pesticide product in favor of another, if both have provided sufficient information to enable the Agency to evaluate whether the product in question meets statutory requirements. However, in the case of ENMs incorporated into a registered pesticide without Agency approval, IATP believes that all unauthorized "nano-pesticides" should be withdrawn from commerce while the Agency reviews the applications for their registration as new pesticide products (their grants of patent already testify as to their novelty). Applying this measure to all manufacturers of pesticides with ENMs will ensure that no one manufacturer will gain commercial advantage during the regulatory review and pre-market safety assessment period.

Given the likelihood that manufacturers could charge EPA with violating the "goal of marketplace equity" in reviewing a specific hazard or exposure of its registered pesticide, not identical to that in other "nano-pesticides," IATP does not recommend use of the Special Review Program for evaluating the safety of registered pesticides with ENMs. We believe that information collected from registrants under FIFRA section 6(a)(2) plus information obtained independently by the Agency will enable a timely decision on applications concerning registered pesticides with ENMs. Then the Agency will be able to review applications for registration of wholly new pesticides with ENMs.

Conclusion

IATP wishes to thank the Agency for this opportunity to comment on the draft guidance and looks forward to responding to further requests for comment as the Agency begins to regulate pesticides with ENMs.

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[1] http://www.nanoaction.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf

[2] http://www.iatp.org/documents/racing-ahead-us-agri-nanotechnology-in-the-absence-of-regulation

[3] Bridget Di Cosmo, "Activists Hint at Suit to Force Action on EPA's Stalled 'Nano' Pesticides Plan," *Risk Policy Report: Inside EPA*, January 28, 2011.

[4] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0197-0001, p. 35385.

[5] Gabby Fekete et al, "EPA's Voluntary Chemical Evaluation Program Did Not Achieve Children's Health Goal," Office of the Inspector General, Environmental Protection Agency, July 21, 2011. http://www.epa.gov/oig/reports/2011/20110721-11-P-0379.pdf

[6] Ibid., "At a glance," 1.

[7] http://www.whatsonmyfood.org/

[8] Christine Ogilvie Hendren et al., "Estimating Production Data for Five Engineered Nanomaterials As a Basis for Exposure Assessment," Environmental Science and Technology, March 10, 2011, 2564 and Table 2, 2566. http://pubs.acs.org/doi/pdfplus/10.1021/es103300g

[9] "Memorandum for the Heads of Executive Departments and Agencies: Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials" Office of Science and Technology Policy, Office of Management and Budget and Office of the United States Trade Representative, June 9, 2011, 1. http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf

[10] "Resolution on the need for a mandatory reporting scheme and invetory for nanomaterials contained in consumer products," Transatlantic Consumer Dialogue, June 29, 2011, 4. http://tacd.org/index.php?option=com_docman&task=cat_view&gid=75&Itemid=40

[11] Peter Wick et al., "Barrier Capacity of Human Placenta for Nanosized Materials," *Environmental Health Perspectives*, Vol. 118:3 (March 2010), 1.

[12] "Draft Recommendation on the definition of the term "nanomaterial," European Commission, October 2010, paragraphs 9 and 11.

[13] "Scientific basis for the definition of the term "nanomaterial," Scientific Committee on Emerging and Newly Identified Health Risks, Directorate General of Health and Consumer Protection, European Commission, December 8, 2010, 24. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

[14] Ibid., 3.

[15] "Comments from the Natural Resources Defense Council on the proposed conditional registration of a pesticide product HeiQ AGS-20, containing nanosilver," September 10, 2010, 2. http://xa.yimg.com/kq/groups/20183530/768776433/name/NRDC%20nanosilver%20CR%20Docket%20ID%20EPA-HQ-OPP-2009-1012.pdf

[16] House of Lords Science and Technology Committee, "Nanotechnologies and Food," Volume I, January 2010, 26.

[17] Günter Oberdörster, "Concepts of Nanotoxicology," NanoAgri 2010, April 2010, 3. http://www.nanoagri2010.com/fao_mini_papers_extra_files.pdf