

August 17, 2011

Office of Pesticide Programs
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: Policies Concerning Pesticide Products Containing Nanoscale Materials

Docket No. EPA-HQ-OPP-2010-0197

The Environmental Working Group submits the following in response to the U.S. Environmental Protection Agency's June 17, 2011, request for comments on a proposed policy regarding nanoscale materials in pesticides.¹ EWG is a non-partisan, non-profit organization dedicated to using the power of information to protect public health and the environment. As part of that endeavor, EWG conducts original research and monitors the latest science on health effects linked to exposures to industrial chemicals.

Of particular interest to EWG is the burgeoning use of nanoscale materials in a variety of products on the market, including pesticides. EWG acknowledges the utility of nanoscale materials but remains deeply concerned by how little scientists understand their potential risks. Despite significant data gaps on the safety, fate, transport, and structural properties of nanoscale materials, what is clear from the literature is that their high surface area-to-volume ratios lead to unique chemical and/or physical properties and the potential for novel toxicity characteristics not indicated by studies of their non-nano forms.²

Accordingly, EWG believes that from a public health perspective EPA must give serious attention to these properties when evaluating the potential toxicity of pesticides containing nanoscale materials. EWG strongly backs EPA's proposal to collect information about nanoscale materials in pesticides pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).³

For more than 50 years EPA has registered pesticides with ingredients that can be considered nanoscale in nature.⁴ EPA needs to ensure that ingredient-toxicity testing is representative of nanoscale materials used in registered products. EWG also finds it imperative that EPA compile

¹ Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. 35,383 (June 17, 2011).

² E.g., Memorandum from Joseph E. Bailey, Designated Federal Official, FIFRA Sci. Advisory Panel, to Steven Bradbury, Acting Director, EPA Off. of Pesticide Programs (Jan. 26, 2010), <http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf> (meeting minutes from Nov. 3-5, 2009, on "evaluation of nanosilver and other nanometal pesticide products").

³ 7 U.S.C. §§ 136-136y.

⁴ See Bernd Nowack et al., 120 Years of Nanosilver History: Implications for Policy Makers, 45 *Envtl. Sci. & Tech.* 1177, 1179 (2011) ("The first biocidal silver product registered in the U.S. under the Federal Insecticide, Fungicide, and Rodenticide Act [] in 1954 was Algaedyn, a nanosilver product based on the patent by Moudry.").

information on particle size and toxicity testing so that it can determine the nanoscale attributes that raise toxicity concerns.

In its notice, EPA announced that it was seeking comments on which data-collecting mechanisms under FIFRA it should use to obtain risk-assessment information on nanoscale materials used in pesticides.⁵ FIFRA requires that EPA register pesticides before they can be lawfully sold and/or distributed in the United States.⁶ Before registering individual pesticides, EPA must determine that a pesticide would not cause unreasonable adverse effects on human health and the environment.⁷ FIFRA authorizes EPA to restrict a pesticide's use as necessary if it poses such a risk.⁸ FIFRA also requires EPA to re-review older pesticides on the market in light of new science and other factors, as part of the reregistration process.⁹

FIFRA's regulatory framework provides EPA with several measures for gathering information about pesticides' potential effects on public health and the environment. One measure, FIFRA Section 6(a)(2),¹⁰ allows EPA to require registrants to submit information relevant to assessing a pesticide's safety, regardless of whether EPA requested specific information.¹¹ Another measure, FIFRA Section 3(c)(2)(B),¹² allows EPA to send data call-in notices to registrants when it determines that new information is needed to assess the safety of an existing pesticide. EPA is considering both mechanisms as potential ways of obtaining information about nanoscale materials in pesticides.

EWG urges EPA to first utilize Section 6(a)(2) to obtain existing data on the nature and safety of nanoscale materials in pesticides. EWG agrees with EPA that this will be the "most efficient and expedient administrative approach" to learn more about these materials and their potential effects on public health and the environment.¹³ Importantly, Section 6(a)(2) ensures that EPA can review vital information about nanoscale materials in pesticides before they end up on the market and without having to fully anticipate every detail relevant to assessing their safety. However, EPA should subsequently use Section 3(c)(2)(B) to issue data call-in notices to registrants when outstanding data gaps prevent EPA from fully assessing the safety of such materials.

Also in the notice, EPA proposes to apply an initial presumption that nanoscale ingredients are "potentially different" from their conventional-sized counterparts when reviewing applications for pesticide registration.¹⁴ Although registrants can overcome EPA's presumption with data showing otherwise, this cautionary approach will provide the public with much-needed health protection. Further, EWG encourages EPA to require additional monitoring to assess the transport, fate, and long-term effects of nanoscale materials on human health and the

⁵ Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. at 35,384.

⁶ 7 U.S.C. § 136a.

⁷ *Id.* § 136a(a).

⁸ *Id.*

⁹ *Id.* § 136a-1.

¹⁰ *Id.* § 136d(a)(2).

¹¹ Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. 35,383, 35,386 (June 17, 2011).

¹² 7 U.S.C. § 136a(c)(2)(B).

¹³ Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. at 35,384.

¹⁴ *Id.* at 35,392.

environment.

As for specific comments, EWG would like to make the following points¹⁵:

1. EWG supports EPA's proposal to consider size-dependent properties of materials that fall outside bright-line definitions of "nano-scale" (e.g., 1- to 100-nanometer (nm) range for aggregated or agglomerated particles).¹⁶ EPA's assessments should consider the full extent of materials in pesticides that may have size-dependent toxic properties. EPA should consider larger engineered particles that have nanoscale characteristics due to etching and/or other surface modifications such as those produced by lithography and related synthesis methods. A useful starting point is provided in the U.S. Food and Drug Administration's June 2011, draft guidelines, entitled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," which considers unique size-related characteristics of particles up to 1 micron (μm).¹⁷ Drawing from these guidelines, EWG recommends that EPA consider whether engineered materials and/or their end products have "physical or chemical properties or biological effects, that are attributable to [their] dimension(s), even if these dimensions fall outside the nanoscale range" EPA describes, and even if they exceed FDA's upper-size range of 1 μm .¹⁸
2. In addition to the types of information outlined in the proposal, EPA should ask registrants to submit: (a) a complete list of tests used by registrants to assess the safety of nanoscale materials used in a pesticide, instead of just those evidencing potential adverse effects; (b) data regarding risks from occupational exposures; and (c) data on the fate and transport of nanoscale materials released into the environment, and potential risks to wildlife and the environment. EPA should compile nanoparticle characteristics, toxicity testing, production, and use and release information into a centralized database. Such a resource would help EPA more effectively assess the public health and environmental implications of registering pesticides that contain nanoscale materials.
3. Finally, EWG encourages EPA to collect information on engineered and naturally occurring nanoscale materials used in pesticides. EPA currently proposes to limit its interest to "intentionally produced" or engineered particles.¹⁹ But both man-made and naturally occurring particles may have unforeseen adverse effects on human health and the environment. To underscore why EPA's proposal is problematic on this point, EWG directs EPA's attention to a recent article in *Environmental Science & Technology* that discusses the formation of silver nanoparticles when silver ions are exposed to humic

¹⁵ Please note that EWG has signed onto the comment letter submitted by the Natural Resources Defense Council and the Environmental Defense Fund in response to EPA's proposed policy regarding nanoscale materials used in pesticides. EWG submits the comments contained herein to supplement points raised by NRDC and EDF.

¹⁶ Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. at 35,387.

¹⁷ U.S. Food & Drug Admin., Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology: Guidance for Industry (Draft Guidance) (2011), <http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm>.

¹⁸ Id.

¹⁹ Policies Concerning Products Containing Nanoscale Materials, 76 Fed. Reg. at 35,387.

acid, a common, naturally occurring substance in soil.²⁰ According to scientists, silver ions exposed to humic acid can “form detectable silver nanoparticles . . . in as little as two to four days” in a process “similar [] to how nanoparticles are synthesized in the laboratory.”²¹ Should EPA overlook information about naturally forming nanoscale materials, manufacturers using those sources in pesticides would avoid having to report information critical to evaluating their potential risks under FIFRA.

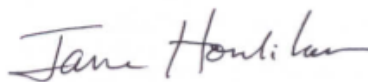
Conclusion

Despite the increasing prevalence of nanoscale materials in products on the market, scientists still have much to learn about their short- and long-term effects on public health and the environment. That is why EWG applauds EPA for proposing to collect detailed information about their use in pesticides. Armed with this data, EPA will be better situated to meet its mandate under FIFRA to assess the safety of pesticides containing nanoscale materials.

Sincerely,



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²⁰ Silver Cycle: New Evidence for Natural Synthesis of Silver Nanoparticles, Science Daily, May 12, 2011, <http://www.sciencedaily.com/releases/2011/05/110511114307.htm> (citing Nelson Akaighe et al., Humic Acid-Induced Silver Nanoparticle Formation Under Environmentally Relevant Conditions, 45 *Envtl. Sci. & Tech.* 3895 (2011)).

²¹ Id.