Industry Comments on EPA OPP Proposed Nanopesticide Policy

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*Presented on behalf of the **Silver Nanotechnology Working Group (SNWG)**, an industry effort intended to foster the collection of data on silver and nanotechnology in order to advance the science and public understanding of the beneficial uses of silver nanoparticles in a wide-range of consumer and industrial products.*

Presentation to the
Office on Management and Budget,
The White House
August 2010

SNWG Presentation to OMB-August 19th, 2010

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Background

The SNWG was formed in January, 2009 in direct response to both the challenges that companies were facing in registering new products containing silver nanoparticles with the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act and also increased adverse press coverage of environmental and health effects of silver nanoparticles.

The SNWG currently has five companies. Our main focus over the last 19 months has been to push EPA for a clear and reasonable regulatory path for nanoscale silver additives

We are here today to talk to you about our concerns regarding the proposed EPA Nanopesticide Policy and the use of EPA's new interpretation of the FIFRA 6 (a) (2) adverse effects policy to gain information for nanopesticide products as well as specifically for nanosilver product. In addition, we would like to provide some suggestions about how the EPA can gain the same information without using the adverse effects clause and by using their existing far-reaching regulatory authority under FIFRA.

EPA OPP Proposed NanoPesticide Policy

On April 29, 2010, EPA's Office of Pesticide Programs (OPP) introduced a new policy interpretation with regard to nanopesticides with the intent of issuing a final decision by notice in the Federal Register in June 2010:

- OPP's working definition of nanomaterial is: An ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers.
- The notice will announce a new interpretation that the presence of a nanomaterial is reportable under FIFRA 'adverse effect reporting' provision Section 6(a)(2) - applies to already registered products as well as products pending registration

- The notice will memorialize OPP's view that an active or inert ingredient would be considered "new" (FIFRA and PRIA) if it is a nanomaterial - even if the parent material is already registered.

Issues with the Proposed Policy

I. Misuse of FIFRA 6(a)2 Adverse Effects Reporting

- Section 6(a) 2 was meant to be a post-registration check on registration decisions by requiring registrants to report to EPA additional factual information about unreasonable adverse effects. It is suppose to be a means of ensuring that EPA is updated about a pesticide's risk assessment, where *tangible* evidence of some adverse effect has been discovered.

- The planned policy would require the presence of a nanomaterial in a registered pesticide to be reported under the 'unreasonable adverse effect' provision though EPA acknowledges that there is no nexus to risk.

- Invoking 6(a) 2 is not the proper method of learning additional information about a registered product when no adverse effects have been found and it is not suppose to be used for pending registrations.

II. Negative Public Perception Problems

- The new policy will unquestionably stigmatize the use of nanomaterials as commentators will equate nanomaterials with "adverse effect reports." Consumers may avoid all products because of the general belief that such products are not safe. Investors will not invest because the perception is that all nano-products are unsafe.

- In addition, the proposed nanotechnology policy promotes the perception that nanotechnology presents a common set of safety problems that can be solved through a common set of safety solutions. Such a simplification may cause decision makers and the public to confuse the experiences of one nanotech product with another nanotech product. For example, OPP may raise safety concerns regarding nanoparticles in sunscreen as a result of inhalation studies for an entirely different substance (i.e. titanium dioxide).

III. Stifle Innovation and Progress

By publishing this new policy, EPA will be endangering chemical innovation and progress. EPA has indicated that additional data requirements will be imposed on nanoscale pesticide products, but has not clarified the types of data that will be required or the regulatory path that EPA intends to take with respect to these materials. In essence the new policy constitutes an indefinite suspension of new pesticide uses of nanomaterials. This cloud of uncertainty is decreasing the incentive of potential commercialization, and creating a serious impediment to the further development of innovative technology, particularly in green chemistry. Without the incentive of potential commercialization, industry leaders will be unwilling to continue or increase investment into research and development of sustainable pesticides.

Nanomaterials are emerging as the cornerstone of sustainable pesticide development- where the "less" is more" aspect of nanomaterials provides real benefits. The use of nanoscale pesticides allows more efficient and targeted application with lower quantities of ingredients and most importantly has the potential to replace more toxic materials currently in use.

IV. Job loss

The proposed policies threaten US small business and have already resulted in lost jobs. Companies such as Dune Sciences have put their antimicrobial business on hold and staff have been let go. With such dramatic loss of time to market, it is not clear that this remains an attractive opportunity. The very first manufacturer of a nanosilver product from 1954 expects that the new policy will <u>put them out of business.</u> This will snowball as more and more nanomaterial companies and investors become discouraged from the uncertainty and cloud of adverse perception surrounding nanopesticides and nanomaterials.

V. *Institutionalize an arbitrary and unsupportable definition of nanotechnology*

> *"OPP's working definition of nanomaterial is: An ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers."*

- Size

Unfortunately, the generally accepted definition of nanotechnology—"the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications" is what the US National Nanotechnology Initiative uses—and it is one of expedience, not of science. It serves the purpose of stimulating new research and technology innovation in an exciting new area brilliantly. *But it doesn't clearly define a set of products and processes that have common and specific safety issues; and it was never intended to.*

Does it mean that something that is 101 nanometers is no longer toxic? I would suggest otherwise. It means that we need to get away from labeling things and get down to the business of hazard identification, exposure assessment and risk analysis. OPP should ultimately derive its concept of a substance's risk from the chemical and physical characteristics of a specific material, *not its size*. This definition neglects to identify hazards, assess exposures, and conduct risk analyses. Materials that are benign are already suspect, while materials that are potentially worrisome can slip through uncaught.

EPA should defer to NNI for a scientifically valid and harmonized definition. The lack of coordination with NNI is apparent, as similar definitions have been evaluated and rejected by other agencies (FDA, EPA TSCA). The proposed definition has not been validated through independent review; the EPA Scientific Advisory Panel has NOT reviewed the proposed definition.

- Intentionality

All pesticide nanomaterials are intentionally manufactured and always have been. Intentionality was originally introduced into discussions about nanomaterials in order to contrast naturally occurring nanomaterials from materials purposely generated for a specific function. However, all pesticide nanomaterials are manufactured, making the intentionality criterion inappropriate.

Nanosilver is not "new". The historic use of nanosilver is exemplified well in publicly available patent and marketing language. Specifically, numerous registrants (mainly algaecides and water filter manufacturers) reference intentionality created nanoscale particles of silver in their currently registered products. Such claims have been made for over fifty years to demonstrate enhanced product performance. Thus, given this historic use that is both well studied and well understood, nanosilver is not functionally unique from other non-suspect products and should not be treated disparately

- Mischaracterization of Nanomaterials as "new".

"The notice will memorialize OPP's view that an active or inert ingredient would be considered "new" (FIFRA and PRIA) if it is a nanomaterial - even if the parent material is already registered."

"Nanoscale silver is not new". This is cited from the p. 2-6 of the EPA Case Study, published in the Federal Register on August 13. Nanosilver, otherwise known as colloidal silver, is also not a new material. It is one of the oldest man made materials and has been used safely for decades as an antiseptic effect. Colloidal silver products with sizes ranging from 2 nm up to 50 nm, have been registered and used in the U.S. market for decades in a variety of applications, including pesticides, dietary supplements, and photography. In fact, silver has been regulated as a biocide in the United States under FIFRA since 1954. Every EPA silver registration between 1970 and 1990 was a colloidal nanosilver or nanosilver composite product. All such biocides have been subjected to a rigorous review prior to registration with the EPA to ensure that they do not pose an unreasonable risk to human health or the environment.

There are many *historic, current* and *potential* applications for silver nanoparticles: Pigments, photography, wound treatments, conductive/antistatic, catalysts, antimicrobial, etc. Silver nanoparticles are used as an *antimicrobial* (FIFRA) in textiles (*sportsclothing, socks),* medical articles & device (*plasters, wound care)* coatings (*wall paint),* plastics (*keyboards*).

The manufacturer of the very first FIFRA registered silver product from 1954 was recently told by EPA that their product would be designated as "new" under the proposed new policy and that they would have to reregister with extensive new testing – EVEN THOUGH THEY HAVE HAD NO REPORTED AVERSE EVENTS IN 50+ YEARS OF COMMERCIAL USE.

The manufacturer expects that the new policy will put them out of business.

In addition, Nano = New is a violation of **The Pesticide Registration Improvement Act (PIRA) of 2003** (renewed in 2007) that is in essence a pact between EPA and Industry to*: improve the predictability and speed of the pesticide registration process in exchange for increased fees schedule to EPA to add resources for review.*

The statutory language and definition is clear:

"New Active Ingredient. An active ingredient that is not currently contained as an active ingredient in any registered pesticide product."

- Justification for this Policy

In addition, and most important, EPA's justification for this new policy simply is not supported by modern scientific principles and the scientific understanding of nanosilver. The overwhelming peer reviewed scientific evidence is that silver, including nanosilver is rendered innocuous to all life forms long before it comes into contact with ecosystems. Nanosilver cannot even exist as discrete particles except in artificial sterile environments that are subjected to ultrasonic vibration or some other technology to break up agglomerations.

The justification is based on generic "Potential Human Health Concerns", generic "Potential Environmental Concerns", though no adverse environmental health effects from the use of commercial nanomaterials have been documented.

OPPs decision to introduce broad new regulation based on unsupported generalities and theoretical risks contradicts the measured and scientifically grounded 'case-by-case' approach to risk assessment supported by the 20+ agencies coordinated under the National Nanotechnology Initiative.

Alternative Methods of Obtaining Information

While we understand and fully support EPA's interest in obtaining information about the possible presence of nanoscale materials in a pesticide formulation, we respectively suggest that there are alternatives, which could fulfill the same goal with far less negative impacts of the proposed approach and would begin to establish a long term strategy for regulating nanomaterials.

- EPA could modify the information that it requires to obtain pesticide registration or registration reviews. For instance EPA could require that applications for pesticide products include information on active ingredient and inert ingredient particle size and distribution. Additionally, EPA can pursue modifying its Part 158 requirements to obtain this information without the adverse effects label. By focusing on methods that systematically obtain information from a particular category that is of real interest, EPA can avoid haphazard collection of only the information that registrants happen to obtain (including information that has no risk implications). In this way EPA can also avoid the stigma associated with a policy that implies that all nanotechnology may be associated with adverse effects.

- EPA should consider **its regulatory authority as outlined by the American Bar Association in "The Adequacy of FIFRA to Regulate Nanotechnology Based Pesticides."** This is a very important document that clearly shows a regulatory pathway on how to regulate nanopesticides. For example, where

a registrant of a conventional pesticide applies for registration of a nano version of that pesticide, an application for an amended registration of the corresponding macro pesticide under FIFRA Section 3C (7) and 40 C.F. R., Section 152.44 of FIFRA might be appropriate. An amended registration application could be required to provide additional information specific to the nanopesticide's risks and benefits.

- To perform the statutorily-mandated risk assessment for a nanopesticide, EPA needs information on the potential risks and benefits of the nanopesticide. Under FIFRA Section 3, EPA may obtain the necessary data from prospective registrants, new registrants. Under FIFRA, the EPA can ensure that the Agency has all the data on the specific nanopesticide necessary to perform its risk assessment.

FIFRA offers ample statutory authority to regulate nanopesticides. This authority covers the entire scope of regulatory interest, from pre-registration research and development, to registration, through post-registration marketing and use. **EPA's most powerful tool for controlling the potential risks posed by nanopesticides is the registration requirement.**

Registration provides EPA the opportunity to prohibit, condition, or allow the manufacture and use of nanopesticides and prescribes the conditions of that manufacture or use. The registration requirement in FIFRA Section 3 is backed up by strong enforcement powers that EPA can exercise over unregistered pesticides under Sections 12, 13, 14, 19. EPA's authority to regulate nanopesticides under FIFRA continues post-registration as well. After a period of years, reregistration is required under FIFRA Section 3(g) and 4. Nanopesticide registrants remain under an obligation to notify the Agency of adverse effects discovered **after registration** under FIFRA 6(a) 2. If EPA should determine that the balance of risk and benefits of a nanopesticide has shifted since its original risk assessment, the Agency has a variety of tools to halt further use of the nanopesticide under FIFRA Sections 12, 13, 14, and 19.

Recommendations

In summary, I would like to propose the following:

EPA OPP should suspend or rescind the proposed Nanopesticide Policy pending the following activity:

- Use the pesticide reregistration process outlined under FIFRA to gain information about the current and historical uses of intentional and unintentional nanomaterials in pesticide products. This data should be included in any risk assessment conducted by EPA and considered during policy making.

- EPA should seriously consider the alternative approaches that do not rely on arbitrary definitions and the stigma of 'adverse effects' reporting that have been outlined in "The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides, American Bar Association, Section of Environment, Energy, and Resources, May 2006."

- Finally, the EPA should commission a study on the green chemistry benefits of nanomaterials, including analyzing the relative risks and benefits to the implementing the regulations.

Until EPA fully considers and understands the job losses, economic burden, negative impact on green chemistry and innovation, and the stigma to nanotechnology development and the chemical industry in general, the proposed policy should be indefinitely delayed or completely rescinded. If the proposed EPA policy on nanomaterials is not rescinded, the nanomaterials industry will be indefinitely trapped in a bureaucratic loop resulting in continued job losses, compromising US leadership in nanomaterials innovation