



Silver Nanotechnology Working Group

A Program of The Silver Research Consortium LLC

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May 25, 2010

Steve Owens, Assistant Administrator
Office of Chemical Safety And Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Response to Pending Federal Register Policy Applicable to
Nanotechnology

Dear Mr. Owens:

On behalf of the Silver Nanotechnology Working Group (SNWG), we are writing to express our concern regarding the pending proposed Office of Pesticide Programs (OPP) interpretation concerning the regulation of nanoscale pesticide products. This new interpretation — which, among other deficiencies, includes an unsupported and arbitrary definition of “nanomaterial” and ignores decades of historical safety data — represents a major and damaging change in policy by the U.S. Environmental Protection Agency (EPA). In fact, this change in policy runs contrary to the core themes of the EPA as expressed under this Administration – decisions based on science, transparency in the regulatory process, and following the rule of law. As a result, this pending policy will threaten not only the nanosilver industry, but all nano-related industries. Based on the recent presentation given by William Jordan, Senior Policy Advisor at OPP, to the Pesticide Program Dialogue Committee (PPDC), the SNWG is concerned that the policy will:

- Institutionalize an arbitrary definition of nanotechnology;

- Contradict the statutory language and purpose of section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA or the Act);
- Improperly characterize nanosilver as a “new” pesticide;
- Stifle innovation without any benefit to human health and/or the environment; and
- Promote a negative public perception regarding nanotechnology as a whole.

For these reasons, and as elaborated in further detail below, we urge you to consider these concerns prior to the release of the pending policy.

I. The New Policy Institutionalizes an Arbitrary Definition.

OPP’s proposed working definition of “nanomaterial” — an ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers (nm) — is arbitrary. The definition contains subjective and unscientific criteria that are inappropriate to serve as the basis for regulation; specifically, it includes the arbitrary size threshold of approximately 100 nm and the imprecise concept of intentionality.

Stakeholders in the nanosciences have long argued that the 100 nm description is not an appropriate basis for regulatory definition. By arbitrarily drawing a line at 100 nm, the regulation focuses too heavily on size rather than the underlying properties of the underlying material. The definition ignores the interaction between the product and the biology, and has no scientific basis. The definition neglects to identify hazards, assess exposures, and conduct risk analyses. Materials that are benign are automatically suspect, while materials that are potentially worrisome can slip through uncaught. Applying the prefix ‘nano’ to any material between 1 and 100 nm does not render that material harmful; any more than a 101 nm or 150 nm material is safe. OPP should ultimately derive its concept of a substance’s risk from the chemical and physical characteristics of a specific material, not its size.

The inclusion of intentionality, conversely, casts doubt on the objectivity of OPP’s definition. Intentionality was originally introduced into discussions about nanomaterials in order to contrast naturally occurring nanomaterials, such as carbon nanoparticle emissions from combustion, from manufactured nanomaterials, such as carbon nanotubes. However, all pesticide nanomaterials are manufactured, making the intentionality criterion inappropriate. By applying such a criterion, a manufacturer that

either neglects to characterize the material or claims that the nanoscale particles were unintended may be able to bypass FIFRA regulation.

Alternatively, OPP's use of the subjective concept of intentionality to define nanomaterials improperly permits OPP to ignore the evidence of benign nanomaterials that call into question the hazard generalizations that form the basis of the overall policy. For example, as will be discussed in more depth below, colloidal nanosilver has been safely and effectively registered under FIFRA for more than 50 years. However, this historical counter-data is absent from the Agency's discussion of the hazards of nanomaterials. It appears that instead of using the extensive data for risk assessment purposes, OPP has ignored the data by labeling it as "unintentionally produced." OPP should not sideline important scientific data in order to artificially support its policy position.

II. The New Policy Contradicts the Articulated Purpose of § 6(a)(2).

As indicated by Mr. Jordan to the PPDC, the pending proposed policy also announces a new interpretation of regulations under FIFRA § 6(a)(2), where the presence of nanoscale material in any registered pesticide is considered reportable as an unreasonable adverse effect. This change would apply to already registered products as well as products pending registration. This policy was justified as the result of studies that raised concerns that nanoscale materials "may potentially affect human health and the environment adversely."

EPA's planned interpretation of the statute, however, is clearly at odds with the language and purpose of FIFRA § 6(a)(2). First, the language of the statute clearly differentiates between the information needed to obtain a registration and that needed to maintain the registration. Section 6(a)(2) was designed as a method of maintaining the safety that previously had been ascertained as part of the registration application. The language clearly covered only the requirement of submitting new, additional information that specifically demonstrated some form of adverse effects. If the information was not new, or if it did not demonstrate any adverse effects, the information did not fall under the statutory reporting requirement. As noted by the plain language of the provision itself:

"If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator."

FIFRA § 6(a)(2) (emphasis added). Indeed, the statute was meant to be a post-registration check on pesticides, to provide a window on the real world and an after-the-fact check on registration decisions by requiring registrants to report to EPA additional factual information about unreasonable adverse effects. The application process itself was supposed to be the initial evaluation regarding any known risks to health or the environment that may result from the registration.¹ In fact, EPA recognized the limits of section 6(a)(2) in applying post-registration only and included a regulatory provision to ensure that adverse effects information prior to registration were, in fact, submitted.² Section 6(a)(2), conversely, is supposed 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.³

Invoking § 6(a)(2) is not the proper method of learning additional information about a registered product when no adverse effects have been found. It would require too much conjecture into the possible effects. Moreover, EPA already has a history of eliminating §6(a)(2) reporting requirements where the harms would be too speculative.⁴ Specifically, EPA

¹ Reporting Requirements for Risk/Benefit Information, *Final Rule*, 62 FED. REG. 49,370 (Sept. 19, 1997) (“The standard for determining whether an application should be granted is found in FIFRA section 3(c)(5), which provides that in order to grant a registration, EPA must find that . . . the product will perform its intended function without causing unreasonable adverse effects on the environment. . . . Thus, a critical aspect of determining whether or not a pesticide should be granted a registration is an evaluation of whether the benefits associated with the use of a pesticide exceed the risks associated with such use.”) (emphasis added).

² See 40 C.F.R. § 15.25(f)(3): “An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.” (emphasis added).

³ 62 FED. REG. at 49,370 (“Section 6(a)(2) provides an important function by assuring that a previous Agency decision to register a pesticide remains a correct one, and that a registered pesticide can in fact be used without posing unreasonable adverse effects to human health and the environment. . . . Section 6(a)(2) recognizes that registrants may come into the possession of important information that was not anticipated by the Agency, and that without the submission of such information by registrants, EPA would remain without it. . . . Thus, section 6(a)(2) serves to provide an important ongoing check on the correctness of the original decision to register a pesticide.”) (emphasis added).

⁴ See EPA, Pesticide Registration Notice 98-4, Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants (August 4, 1998). A group of trade organizations representing registrants petitioned EPA to eliminate the requirement that they report incidents where a person ‘may suffer a delayed or chronic adverse effect in the future.’ Registrants expressed concern that this would require them to report whenever someone thought he or she might later get sick. EPA agreed to

issued guidance regarding this section that confirmed that the Agency intended for § 6(a)(2) reporting to be required only where a distinct incident had occurred showing that use of the pesticide resulted in adverse effects. Thus, EPA has shown a concern with ensuring that reporting occurs where adverse effects are clearly known; the only “[e]xceptions to incident reporting include those situations in which the registrant has facts that *clearly establish* that the adverse effect did not or will not occur, or that exposure to a pesticide did not occur.”⁵

III. The New Policy Improperly Categories Nanosilver as a “New” Material.

EPA’s decision to declare all products containing nanomaterials as “new,” despite decades of historical EPA-registered use, is a drastic and unwarranted action. This policy will be create a major impediment to continued success the nanotech industry and will severely impact an embryonic manufacturing industry that is capable of employing a significant number of Americans.

Nanosilver, otherwise known as colloidal silver,⁶ is not a new material. Nanosilver is one of the oldest man-made materials, and has been used safely for decades, if not centuries, for its antiseptic effect. For example, Greeks used silver vessels for drinking water storage. Colloidal silver products, with sizes ranging from approximately 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

eliminate this requirement, and issued this pesticide registrant notice (Pesticide Registrant Notice 98-4) eliminating the requirement on August 4, 1998. The Notice stated that, beginning on the effective date of the regulations of August 17, 1998, the Agency eliminated for all registrants the requirement to report incidents in which a registrant has been informed that a person or non-target organism may suffer a delayed or chronic adverse effect in the future. The elimination of the requirement was to remain in effect for at least one year and for any further period until the Agency provides written notice to registrants that the requirement has been reinstated.

⁵ Pesticide Registration Notice 98-3, Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants, (April 3, 1998) (emphasis added).

⁶ “Colloidal” silver is often used as a term to refer to microscopic silver in suspension. Such silver is at the nanoscale and is equivalent to nanosilver as presented recently to the SAP. See SNWG “Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Oxide Pesticide Products,” Presentation to Scientific Advisory Panel (November 4th, 2009); <http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480a52512&disposition=attachment&contentType=pdf>

nanosilver or nanosilver-composite product.⁷ All such biocides have already been subjected to rigorous review prior to registration with EPA to ensure that they do not pose an unreasonable risk to human health or the environment.

Cary Lea produced the earliest known rational synthesis of nanosilver in 1889. Throughout the early 1900s, nanoscale silver was used as the basis for colloidal science, which focused on the synthesis and characterization of extremely small particles. Rigorous scientific methods adequately characterized colloidal metals as having nanoscale dimensions. Studies conducted in 1969 verified that Carey Lea colloidal silver consisted of metallic silver particles sized between 7 and 10 nm, well within the range of the current definition of nanomaterials.

Colloidal nanosilver was widely used as a topical disinfectant throughout the early 20th century until antibiotics were introduced in the market. This form of nanosilver found other widespread consumer use in the intervening decades, including as an algacide for drinking water purification systems and in swimming pools. Over the last twenty years, nanosilver has been used without causing harm in numerous medical applications—including directly on wounds and broken skin—and in engineered articles such as textiles, coatings, and plastics. The long history of low impact is due to the demonstrated tendency of silver particles to be strongly passivated by ubiquitous natural environmental complexing agents, such as sulfur, chlorides, phosphate, and dust.

In addition to ignoring decades of historical record of safe use of colloidal nanosilver materials, the decision to declare nanosilver, and indeed all nanomaterials, as a “new” material also confuses the toxicological nature of nano- and bulk silver. OPP has mistakenly conflated general “nano” related issues with issues specific to nanosilver, particularly with respect to the toxicity profile of nanosilver. An EPA Science Advisory Panel incorrectly assumed that available silver toxicity data relates to *bulk* silver. However, historical toxicological data for colloidal nanosilver has actually been used to inform hazard assumptions for bulk silver, not the reverse. Moreover, nanosilver is typically embedded within polymer substrates. Any antimicrobial action is believed to arise from the generation of silver ions, which is the identical mechanism of all EPA-registered silver products, such as silver salts, silver glasses, and silver zeolites, which will not be subject to this new regulation. The historic use of nanosilver is exemplified well in publicly available patent and marketing language. Specifically, numerous registrants (mainly algacides and water filter manufacturers) reference intentionality created nanoscale particles of silver in their currently

⁷ EPA did not register a non-nanosilver product until 1994.

registered products. Such claims have been made for over fifty years to demonstrate enhanced product performance. Given this historic basis and current 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.

In addition, EPA's justification for this new policy simply is not supported by modern scientific principles and the scientific understanding of nanosilver. In fact, review of the literature and scientific evidence offered in support of the new policy leads to the conclusion that the determination is based on irrelevant if not totally flawed science. The overwhelming peer reviewed scientific evidence is that silver, including nanosilver is rendered innocuous to all life forms long before it comes in 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.

With decades of scientific research supporting the safety of nanosilver and its inability to exist outside of artificial environments, it clearly does not present any new risks that merit new oversight. EPA already has examined, and deemed safe, nanosilver materials when it examined silver colloids. Both common sense and EPA's commitment to scientific discipline should dictate EPA taking the history of safe nanosilver use into account when considering the risk profile of nanosilver materials and making rational regulatory choices.

IV. The New Policy Will Stifle Innovation

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. This cloud of uncertainty is creating a serious impediment to the further development of innovative technology, particular in green chemistry. In particular, nanomaterials are emerging as a cornerstone of sustainable pesticide development. However, without a clear regulatory path for nanoscale pesticides, commercialization of the products is not possible. Without the incentive of potential commercialization, industry leaders will be unwilling to continue or increase investment into research and development of sustainable pesticides.

V. The New Policy Promotes a Negative Public Perception of Nanotechnology

OPP's proposed definition perpetuates an unjustifiable alarmism about the potential hazards of nanotechnology. OPP should be basing its policies on proven science, and addressing risks and hazards in an objective manner. 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 set of safety solutions. Such a simplification may cause decision makers and the public to conflate the experiences of one nanotech product with other nanotech. 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). Similarly, because of the policy interpretation that all nanomaterials are subject to FIFRA § 6(a)(2)'s adverse effects reporting, consumers may avoid all nanotech products because of a general belief that such products are not safe.

Nanotech itself is safety-neutral. How the technology is applied determines its safety much more than the technology itself. OPP should be addressing the safe handling, use, and disposal of specific nanotech materials through its proposed policy, not issuing sweeping pronouncements of hazard that distract from useful discussion of the relative safety profiles of nanomaterials based on scientific evidence. EPA already took a step in that direction when looking at the unique properties of carbon nanotubes through OPP's sister office – the Office of Pollution Prevention and Toxic Substances. Specifically, in late 2009, OPPT issued a Federal Register notice regarding the potential need to file Premanufacture Notices (PMNs) under section 5 of the Toxic Substances Control Act (TSCA) for carbon nanotubes due to their unique properties. Such a focused approach was appropriate for the particular substance, but not for the technology as a whole. As a result, we would urge EPA to continue the scientifically-justified approach of reviewing nanomaterials individually and not attempt to blanket an entire class of technology with the same broad brush stroke. Such action makes no more sense than classifying all metals as identical.

Based on the foregoing statements, the SNWG recommends that EPA take the following action in lieu of the current approach planned in the pending federal register notice:

- Use the pesticide reregistration process 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 policymaking.

- Commission a study on the green chemistry benefits of nanomaterials, including analyzing the relative risks and benefits prior to implementing the regulations.
- Reconsider any definition of nanomaterials that involves the arbitrary 100 nm threshold. EPA should instead consider using its existing regulatory authority as outlined by the American Bar Association in *The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides*, Section of the Environment, Energy, and Resources (May 2006).

We look forward to working with the Agency on these important and timely matters. Please feel free to contact us with any questions or comments.

Sincerely

A handwritten signature in cursive script, appearing to read "Rosalind Volpe".

Rosalind Volpe, D.PH
Executive Director
Silver Nanotechnology Working Group

cc: Travis Earles, Office of Science and Technology Policy, White House
Steve Bradbury, Office of Pesticide Programs, U.S. EPA
William Jordan, Office of Pesticide Programs, U.S. EPA