

EPA POISED TO ADDRESS USE OF NANO-SILVER IN ANTIMICROBIAL PRODUCTS

The US Environmental Protection Agency (EPA or the Agency) announced in the Fall of 2008 that it intended to enhance oversight of innovations in nanoscale molecules that are subject to the Agency's jurisdiction under the Toxic Substances Control Act (TSCA). The EPA is now preparing to address and clarify its intentions concerning oversight of the use of nanoscale active ingredients in antimicrobial products and perhaps pesticides, generally. In May 2008, EPA received a petition requesting EPA to regulate nanoscale silver (nano-silver) products as pesticides.¹ Petitioners, the International Center for Technology Assessment (ICTA), and various other consumer groups and nonprofit organizations, requested that EPA take action on numerous issues related to the regulation of nano-silver pursuant to its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On November 19, 2008, EPA issued a notice in the Federal Register², making the petition publically available and on January 14, 2009, extended the public comment period until March 20, 2009.³

BACKGROUND

Nanotechnology is the science of manipulating matter on an atomic or molecular scale. Such matter is measured in nanometers, each of which is one billionth of a meter in length. Due to the unique properties of nanoscale materials—tiny size, increased surface area to volume ratio, and high reactivity—the applications for nanotechnology are vast and the amount of products containing nanoscale materials is continuing to grow at a rapid rate. Moreover, many of these products contain nano-silver due to its ability to act as an antimicrobial agent. While nanotechnology, and nano-silver in particular, offer significant benefits in controlling microorganisms, questions persist as to the potential risks associated with nano-silver and other nanomaterials. ICTA alleges that studies indicate that nanotechnology-based products may be harmful to beneficial bacteria, fish, and aquatic ecosystems.

Pursuant to TSCA Section 5, chemical substances manufactured in, or imported to, the US must be included on the TSCA Inventory; if a chemical substance is not on the Inventory, it is considered a "new" chemical and is subject to premanufacture

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¹ International Center for Technology Assessment, et al., "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides," <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064806c4167&disposition=attachment&contentType=pdf>.

² Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Notice of Availability, 73 *Fed. Reg.* 69644, Nov. 19, 2008.

³ Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Extension of Comment Period, 74 *Fed. Reg.* 2072, Jan. 14, 2009.

notice (PMN) requirements or must qualify pursuant to an exemption from reporting the requirements of TSCA Section 5. In October 2008, EPA issued a Federal Register notice addressing carbon nanotubes (CNTs), indicating that while carbon is a chemical substance already listed on the TSCA Inventory, the Agency views CNTs as potential new chemical substances because specific CNTs might not have the same molecular structure as graphite or other non-nanoscale allotropes of carbon.⁴ Thus, EPA has announced its intentions, effective March 1, 2009, to begin reviewing the status of CNTs in the marketplace. The Agency intends to exercise its enforcement authority to ensure that entities who manufacture or import CNTs are in compliance with the TSCA Section 5 notification requirements. Any ensuing enforcement action will certainly attract notice and could signal a more aggressive stance toward regulation of nanotechnology.

EPA regulates pesticides, including antimicrobials, pursuant to FIFRA. For purposes of FIFRA, a pesticide is defined as a product that is intended to prevent, destroy, repel, or mitigate pests. An antimicrobial product is considered to be a pesticide to the extent that it is intended to control microorganisms (i.e., bacteria, mold, mildew, and fungi) on surfaces and in the environment (i.e., other than on or in humans or animals). ICTA asserts that EPA has used its FIFRA authority to reach nano-silver only in limited circumstances. Thus, in 2006, EPA responded to concerns that a washing machine (which apparently generated or emitted silver ions) was marketed with antimicrobial claims implying or stating that it killed bacteria on clothing. Later that year, EPA expressed its intent to regulate as pesticides any products, presumably including the washing machine in question, that releases silver for antimicrobial purposes. As a result, EPA announced that products using silver, including nano-silver, for such purposes would have to be registered as pesticide products or qualify for an exemption from FIFRA. In September 2007, EPA issued a Federal Register notice to clarify its position that silver ion generating equipment will be treated as a pesticide.⁵ EPA

later noted that its policy applied without regard to whether the equipment utilized nanotechnology, and therefore, the Agency's notice did "not represent an action to regulate nanotechnology." ICTA contends EPA's action was too limited because the Agency only intends to regulate a product containing nano-silver as a pesticide if the product is promoted with "germ-killing" claims.

Notwithstanding ICTA's concerns, EPA has chosen to flex its FIFRA enforcement muscle. For example, during 2007, EPA commenced an enforcement action against ATEN Technology (ATEN), alleging that its products were labeled and marketed with explicit and implicit pesticidal claims, that ATEN's products were "pesticides" as defined by FIFRA, and that the products were sold illegally since they were not registered as pesticides. This matter was settled in February 2008, with ATEN paying a US\$208,000 fine.

SUMMARY OF PETITIONER'S REQUESTS

ICTA requests that the Agency regulate nano-silver on various levels. First, the petition requests EPA to classify nano-silver as a pesticide *per se* and to require registration of *all* products containing nano-silver. The petition notes that nano-silver infused products contain the ingredient solely for a specific, germ-killing purpose; as such, ICTA contends it is inappropriate for manufacturers to avoid FIFRA registration requirements for products containing nano-silver simply by dropping any antimicrobial claims from their labeling or marketing materials. Thus, the Agency is being requested to clarify that all nano-silver products will be regulated without regard to whether antimicrobial claims are explicitly made.

Second, ICTA seeks to have nano-silver recognized as a "new" pesticide, thus requiring registrants to provide the complete data submission traditionally needed for a new pesticide registration. Certain silver-containing products already are registered and recognized as pesticides. However, the petitioners contend that nano-silver differs significantly from its bulk form and is deserving of its own, separate risk assessment prior to registration as a pesticide.

Third, EPA is being requested to evaluate the potential risks of nano-silver, pursuant to its obligations under FIFRA and other statutes and policies. ICTA claims that the long-term

4 Toxic Substances Control Act Inventory Status of Carbon Nanotubes; Notice, 73 *Fed. Reg.* 64946, Oct. 31, 2008.

5 Pesticide Registration; Clarification for Ion-Generating Equipment; Notice, 72 *Fed. Reg.* 54039, Sept. 21, 2007.

impacts of nano-silver use are relatively unknown, and its use is now so widespread that there should be concerns about nano-silver's toxicity and the potential that its antimicrobial effects could harm beneficial bacteria necessary for the environment, wildlife, and human health.

Fourth, ICTA requests that the Agency take enforcement action against nano-silver products that are sold illegally (i.e., without FIFRA registrations). ICTA considers all products containing nano-silver to be illegal products and requests that EPA issue Stop Sale, Use, or Removal Orders to entities who currently manufacture or sell such products. The petitioners note the precedent set by the ATEN enforcement action.

Fifth, ICTA asks that EPA apply all of the FIFRA pesticide requirements to nano-silver pesticides that eventually might be registered by requiring EPA-approved labeling, a continued obligation to report any unreasonable adverse effects that nano-silver products may have on the environment and human health, and post-registration testing and data development.

Lastly, the petition requests that the Agency undertake a Special Review process pertaining to nano-silver products in order to perform a detailed risk assessment.

IMPLICATIONS

The Agency appears to be taking the petition very seriously and noted in its Federal Register announcement that the requests in the petition could have major implications. Public comments need to be received by EPA not later than March 20, 2009. As of March 13, 2009, more than 1,000 comments have been submitted.

In an appendix attached to the petition, ICTA has identified 260 products which contain nano-silver, many of which are promoted for their antimicrobial qualities. Should EPA decide to implement all of the requests made in the petition, it is likely that the products identified in the appendix will be the first items to be investigated. Accordingly, any entities that manufacture or sell the products identified should ensure that they are in compliance with FIFRA. Makers of products being promoted based on the silver content should also be prepared to respond to any actions EPA might be

anticipated to take following its consideration of the petition. The Agency's aggressive action against ATEN demonstrates that EPA has concluded it already had the means to enforce compliance with its existing policies concerning silver-containing products bearing antimicrobial claims—even without the benefit of the submitted petition.

While this petition seeks to prompt EPA to regulate nano-silver specifically as a pesticide, if the Agency implements some or all of the petitioners' requests, such action also could impact the nanotechnology industry in general. EPA's recent statements concerning its determination to enforce its interpretation of the TSCA Inventory status of CNTs, suggests the Agency is eager to continue flexing its regulatory nano-muscles. The petition provides an opportunity for an invigorated EPA to more aggressively pursue the numerous silver-containing consumer products using FIFRA. Should EPA decide to do so, the possibility of aggressive EPA regulation of nanotechnology finally might become a reality. As such, all manufacturers of products employing nanotechnology should consider whether they have a stake in the outcome of EPA's review of this petition, and provide comment to EPA while the opportunity presents itself.

We hope that you have found this client advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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