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Client Alert 08-097

Citizen Petition for Regulation of Nano-Silver: A Potential Gold Mine for Enhanced Federal Regulation

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In response to the influx of products engineered using nano-silver in the consumer marketplace, the International Center for Technology Assessment (“CTA”), in conjunction with a number of other consumer groups, filed a self-styled *Petition For Rulemaking To The United States Environmental Protection Agency* (“Petition”) on May 1, 2008. The Petition, citing to the rulemaking provisions of the Federal Administrative Procedure Act (“APA”) and other statutes, calls for the review and control of some 260 nano-silver products, most specifically through the regulatory process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). In the Petition, CTA claims “nanomaterials present serious toxicity risks for human health and ecosystems” and asserts that “nano-silver has quickly become the most commonly used nanomaterial in consumer products.” The scattershot but substantiated approach of the Petition, combined with its prior administrative filings, and recent Environmental Protection Agency (“EPA”) enforcement and rulemaking actions, could well lead to future federal efforts to control nano-silver products.

Prior CTA Filing and EPA Control Efforts

Both the EPA and the U.S. Food and Drug Administration (“FDA”) have been alerted to the potential public health concern related to nanoproducts. Similar to its petition to the EPA, CTA filed a petition with the FDA on May 17, 2006, requesting the FDA amend its regulations for products composed of engineered nanoparticles, including sunscreen drug products. Such petitions for rulemaking are not uncommon at FDA, which has a formal process for their consideration (unlike EPA, which essentially treats such petitions on an *ad hoc* basis). This petition remains under review by the FDA, which to date has issued no regulations or guidance documents on the use of nanoparticles in FDA-regulated products, such as drugs, devices, foods, dietary supplements, and cosmetics. The pending FDA petition, along with the EPA Petition, could accelerate FDA regulatory action with respect to products specifically containing silver components, which continue to endure a long history of medical skepticism.

The Petition filed with EPA also makes significant note of the Agency’s own efforts, albeit limited at this stage, of controlling nano-silver products. Importantly, CTA’s petition to the EPA was filed following the February 27, 2008 EPA Region IX Consent Agreement with Southern California technology company, ATEN Technology, Inc., requiring payment of a fine of \$208,000 in connection with the sale of its nanoproducts. The EPA found that ATEN Technology, Inc. violated FIFRA: (1) by making unverified claims that the nano-silver coating it uses in the manufacture of its computer keyboards and mouse accessories eliminates pathogens and kills bacteria, and (2) by failing to register each of its nanoproducts as pesticides as required under FIFRA.

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Earlier, in 2006, EPA had reacted to concerns voiced by trade association National Association of Clean Water Agencies and Tri-TAC that many household products used pesticides, including nano-silver, for their claimed antimicrobial purposes. Products that released “silver ions” as disinfectants, such as washing machines, were targeted for EPA data collection and regulatory control. The ultimate *Federal Register* notice September 21, 2007, was cited as important for at least requiring registration for producers of certain equipment that generated silver ions for “express pesticidal purposes.”

The Petitioners’ Requests

The petitioners have requested the EPA to take a number of regulatory actions regarding nano-silver. First, petitioners insist that the Agency classify nano-silver as a pesticide. Second, petitioners request that the EPA require that manufacturers register nano-silver according to the FIFRA pesticide regulations. Third, petitioners urge the Agency to undertake extensive evaluation of the human health and environmental risks of nano-silver as required by FIFRA and other laws, including the Food Quality Protection Act (“FQPA”), the Endangered Species Act (“ESA”), and the National Environmental Policy Act (“NEPA”). Fourth, the consumer groups demand the EPA’s immediate prohibition of the sale of nano-silver as an unregistered pesticide product. Fifth, if the Agency does approve nano-silver products as pesticides, petitioners request that the EPA apply its pesticide regulations to any registered nano-silver products. Sixth, the petitioner urges that the EPA undertake any other reviews necessary (including a Special Review or a registration review) to ensure proper regulation of nano-silver as a pesticide. In addition to regulating nano-size silver products, the petitioner requests that the EPA conduct a review of the bulk silver pesticide products registered with the EPA that have not been reviewed by the EPA since 1993.

Importantly, CTA has attached to its EPA Petition a list of companies selling nano-silver products, presumably to encourage the EPA to investigate these companies for potential violations of FIFRA. Given the informal nature of EPA rulemaking consideration, as well as its immediate prior enforcement action, this attachment may provide the most immediately viable basis for Agency compliance actions.

Potential EPA Actions and Possible Cautionary Steps

The EPA may take several potential actions that could affect companies selling nano-silver products. Most obviously, EPA could elect to initiate formal rulemaking, which could take several forms, as well as enforcement action. First, the EPA can conduct the registration review process to reevaluate the registrations for the active ingredient silver. Alternatively, the Agency can undertake the new registration process to require the registration of nano-silver as a new pesticide or as a new use of an old pesticide. Either on its own or at the request of any interested person, the EPA may also undertake the Special Review process to determine whether to initiate procedures to cancel, deny or reclassify a pesticide registration when uses of the product cause unreasonable adverse effects on the environment. Finally, the EPA can take enforcement action against companies that illegally sell nano-silver products without EPA approval in violation of the FIFRA prohibition against the sale of unregistered pesticides.

The EPA has indicated, informally, that it has already begun to investigate the use of nano-silver products by companies listed in the attachment to the Petition. Such Agency reviews could lead to enforcement actions similar to those initiated against ATEN Technology, Inc. Companies that sell nanoproducts in the United States, particularly if they appear on the appendix to the CTA Petition, should review FIFRA requirements to ensure their understanding of and compliance with FIFRA.

Companies should also monitor the EPA and the *Federal Register* for opportunities to impact any future proposed rulemaking(s). In fact, potentially affected companies should also closely follow the EPA and FDA progress regarding their consideration of the CTA respective petitions. It is likely—but probably not well publicized—

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that federal agencies will permit “interested party” comments regarding such petitions. These petitions might be made directly, or through a representative trade association. Companies should also study how the EPA is enforcing noncompliances with FIFRA regarding nano-silver products. The Agency has already provided a “marker” regarding how it intends to proceed in such matters.

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