Client Advisory

KELLEY DRYE

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EPA Review of Nano-Silver Products Raises Significant Regulatory Issues Concerning Antimicrobial Claims and EPA, FDA, and CPSC Jurisdiction Concerning Nanotechnology Regulation

The U.S. Environmental Protection Agency ("EPA") recently published a notice announcing that it is considering a range of potential actions to regulate products containing nano-silver[1] as "pesticides" under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[2] in response to a petition filed by the International Center for Technology Assessment ("ICTA") and 13 other public interest groups.[3]

In general, the petition requests EPA to classify nano-silver as a pesticide, require formal pesticide registration of all products containing nano-silver, analyze the potential human health and environmental risks of nano-silver, and take a broad range of regulatory proceedings under FIFRA, the Food Quality Protection Act ("FQPA"), the Endangered Species Act ("ESA"), and the National Environmental Policy Act ("NEPA"), including an immediate ban on the sale of nano-silver products through the issuance of Stop Sale Use and Removal Orders ("SSURO").[4] Emphasizing the antimicrobial properties of silver and the antimicrobial nature of the nano-silver products currently being marketed in the United States, the Petitioners urge EPA to regulate nano-silver products as "pesticides" under FIFRA even where manufacturers refrain from the use of antimicrobial marketing claims (*e.g.*, "germ killing") in product labeling and advertising.[5] Notably, the petition includes information concerning 260 nano-silver containing consumer products for EPA review, including food, dietary supple-

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1 According to the National Nanotechnology Initiative ("NNI"), "nanotechnology" is the "understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications." *See* "What is Nanotechnology?" *available at* **http://www.nano.gov/html/facts/whatIsNano.html**.

2 *Petition for Rulemaking Requesting EPA Regulate Nano-scale Silver Products as Pesticides; Notice of Availability*, Fed. Reg. 69,644 (Nov. 19, 2008).

3 *ICTA's Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides*, (May 1, 2008) (the other 13 Petitioners include: the Center for Food Safety; Beyond Pesticides; Friends of the Earth; Greenpeace; the Action Group on Erosion, Technology and Concentration; the Center for Environmental Health; Silicon Valley Toxics Coalition; Institute for Agriculture and Trade Policy; Clean Production Action; Food and Water Watch; Loka Institute; the Center for the Study of Responsive Law; and Consumers Union).

4 *Id.*

5 *Id.* at 36 ("Thus, manufacturers who produce and market products containing nano-silver with 'full knowledge' of its intended uses as an anti-microbial – *even if they do not label the material as 'nano' and/or 'germ killing'* – are still properly subject to FIFRA's pesticide registration requirements.")

ments, cosmetics, drugs, and medical devices that are subject to Food and Drug Administration ("FDA") regulation under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and other products that are subject to regulation under the Consumer Product Safety Act ("CPSA"). The EPA notice requests comment on the petition by January 20, 2009.

The EPA actions requested by the petition raise significant legal and policy issues concerning the environmental, health, and safety standards governing nano-silver products and the scope of EPA, FDA and the Consumer Product Safety Commission ("CPSC") jurisdiction with respect to the regulation of nanotechnology products more generally. Manufacturers, importers, and marketers of products containing nano-silver or produced using nano-silver contact materials are encouraged to submit comments to EPA. In addition, companies that are interested in EPA, FDA, and/or CPSC nanotechnology regulatory policy should consider submitting comments in response to the EPA notice, including with respect to the jurisdictional issues presented.

EPA REGULATION OF NANO-SILVER PRODUCTS

Under FIFRA, EPA has authority to regulate "pesticides," which are defined to include "any substances or mixture of substances *intended for* preventing, destroying, repelling, or mitigating any *pest* . . ." A "pest" is defined to encompass any "form of terrestrial or aquatic plant or animal life or *virus, bacteria, or other micro-organism* (except viruses, bacteria, or other micro-organisms on or in living man or other living animals)" which EPA declares to be a "pest."[6] For purposes of determining whether a product is intended for use as a pesticide, EPA may consider (1) the seller's claims in product labeling or advertising; (2) the use of an active ingredient that has no significant commercially valuable use other than for pesticidal purposes; and (3) whether the seller has actual or constructive knowledge that a substance will be used, or is intended to be used for a pesticidal purpose.[7]

Petitioners argue that nano-silver and nano-silver products qualify as "pesticides" under FIFRA because they meet each of the three tests for pesticidal intent.[8] *First*, Petitioners point to the widespread use of antimicrobial claims in the labeling and advertising of consumer products containing nano-silver ingredients, including claims touting product benefits in combating a range of germs, bacteria, viruses, molds, fungi, and other microbes (*e.g.*, "clinically proven to fight against harmful bacteria;" "can kill and prevent all kinds of disease, germs, and microorganisms;" "long-lasting antibacterial function").[9] *Second*, Petitioners argue that because nano-silver's only commercial use is for antimicrobial purposes, the simple presence of a nano-silver ingredient or component in the product is evidence establishing the manufacturer's intent that the product be used as a pesticide.[10] *Third*, Petitioners argue that, given the antimicrobial properties of nano-silver and the circumstances surrounding the marketing of consumer products containing nano-silver, it is reasonable for EPA to determine that product sellers have actual or constructive knowledge that such products are used for pesticidal purposes.[11]

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6 7 U.S.C. § 136(t).

7 *See* 40 C.F.R. § 152.15.

8 *ICTA's Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides* (May 1, 2008) ("*ICTA Petition to EPA*") at 33.

9 *Id.*

10 *Id.* at 34.

11 *Id.*

Petitioners also argue that nano-silver and nano-silver containing products constitute "new" pesticides that are not covered by existing pesticide registrations, including risk assessments for silver, because it is well-recognized that nano-scale particles may have significantly different physical and chemical properties than their parent metals. Petitioners argue that EPA is required to make a determination that nano-silver presents no unreasonable risk of harm to human health or the environment in order to register nano-silver as a new pesticide ingredient under FIFRA.

In addition, Petitioners assert that EPA must assess the potential human health and environmental risks of nano-silver pursuant to the agency's statutory obligations under FIFRA, the FQPA, the ESA, and NEPA. Specifically, the Petitioners recommend that EPA analyze existing scientific studies on the environmental health and safety of nano-silver; assess the potential impacts of nano-silver on children and infants; ensure the protection of threatened and endangered species in connection with any EPA actions involving nano-silver; and assess the environmental impacts of any EPA actions involving nano-silver, including completing a programmatic environmental impact statement.

SCOPE OF FDA AUTHORITY TO REGULATE NANO-SILVER PRODUCTS

FDA has broad jurisdiction to regulate the safety and effectiveness of products that constitute foods, dietary supplements, cosmetics, drugs, biologicals, or medical device products within the meaning of the Federal Food Drug and Cosmetic Act,[12] including all such products containing nano-silver ingredients or components. Where antimicrobial claims in labeling or advertising represent a nano-silver product as intended for use in the "prevention" or "mitigation" of disease in man or other animals, such products would be subject to FDA regulation as "drugs" and/or "devices."[13]

The Petitioners acknowledge that "there are several classes of substances expressly excluded from regulation under FIFRA for reasons including that they are regulated by other statutes," including products "qualifying as human or animal drug products under FFDCA."[14] Petitioners nonetheless argue that, because "products incorporating nano-silver are consumer products that have already come to the market," they should not constitute "new" drug products subject to FFDCA, and should instead be regulated under FIFRA and other EPA statutes.[15] In addition, Petitioners argue that the FFDCA exclusion from FIFRA otherwise should be limited to nano-silver drug products that already have been approved by FDA under the pre-market approval process governing drug products.

Further, while acknowledging that FIFRA exempts products that are intended for use against microorganisms "in or on living humans or animals" and labeled accordingly, Petitioners argue that currently marketed nano-silver consumer products are disqualified from this exemption because of the breadth of the germ-killing benefits that are represented in marketing claims, the absence of required labeling, and other factors.[16] Arguing that EPA establishes tolerances and exemptions for specific chemicals, not products, Petitioners urge EPA to establish pesticide tolerances for nano-silver

[12] *See* 21 U.S.C. § 321(f), (g), (h), (i), (ff).

[13] 21 U.S.C. § 321(g) and (h); 40 CFR §§ 152.6 and 152.20.

[14] *ICTA Petition to EPA* at p. 39.

[15] *Id.*

[16] *Id.* at 39-41.

under FIFRA that would account for the direct and indirect exposure to humans that may occur through food (*e.g.*, health drinks and dietary supplements), food-related products (*e.g.*, food storage containers, cutting boards, cutlery, baby bottles, refrigerators, food and produce sprays), personal care products (*e.g.*, toothbrushes), hair products, and other consumer products identified in the petition.

FDA and EPA have overlapping jurisdiction with respect to the use of antimicrobials used in food production, including those that may contain nano-silver ingredients or components. As FDA has explained in its guidance for manufacturers, the respective scope of FDA and EPA jurisdiction is as follows:

- Antimicrobials used directly on processed food are regulated by FDA as food additives under Section 409 of the FFDCA and remain outside EPA jurisdiction (except for ethylene and propylene oxide use);
- Antimicrobial residues in raw agricultural commodities are regulated by EPA as pesticide chemicals under Section 408, unless the antimicrobial is used in a food processing facility, in which case the residue is a food additive regulated by FDA under Section 409;
- Antimicrobials in food packaging are regulated by FDA as food additives under Section 409, and require registration with EPA under FIFRA;
- Antimicrobials used in or on permanent/semi-permanent food-contact surfaces that are not intended to have an ongoing effect on the food-contact surface, are regulated by FDA as food additives.[17]

Without regard to these established jurisdictional boundaries, Petitioners urge EPA to "assess the safety" of nano-silver with regard to exposures occurring through food and food-related products, personal care products, and other consumer products contributing to human exposures when setting a tolerance for nano-silver.[18] Notably, ICTA submitted a Citizen Petition to FDA on May 17, 2006 requesting that the agency implement a number of regulatory policies aimed at restricting the use of "engineered nanoparticles" in food and other FDA-regulated consumer and medical products, such as food, dietary supplements, cosmetics, drugs, devices, and combination products.[19] While the ICTA petition is still pending before FDA, the FDA Nanotechnology Task Force considered the ICTA petition before issuing its report and recommendations concerning FDA regulatory policies for nanotechnology on July 25, 2007.[20] Although the FDA Task Force did not endorse any specific regulatory policies proposed by ICTA, the Task Force did recognize the need for FDA to consider "particle size" in evaluating the safety and effectiveness of nano-scale materials used in FDA-regulated products. Indeed, the Task Force recognized that the "comprehensive" nature of FDA's pre-market approval authority for food and color additives, drugs, and medical devices under the FFDCA already enables the agency to consider particle size and other distinctive features of

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[17] *See* FDA/CFSAN: Antimicrobial Food Additives – Guidance (July 1999), *available at* **http://www.cfsan.fda.gov/~dms/opa-antg.html**.

[18] *See ICTA Petition to EPA* at 112-114 and *Appendix A*.

[19] *See Petition Requesting FDA Amend its Regulations for Products Composed of Engineered Nanoparticles Generally and Sunscreen Drug Products Composed of Engineered Nanoparticles. Specifically,* Docket No. 2006P-0210 (filed May 17, 2006), *available at* **http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf** (the petition is cited in the FDA Nanotechnology Task Force Report (Jul. 23, 2007), *available at* **http://www.fda.gov/nanotechnology/taskforce/report2007.html**).

[20] *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force* (July 25, 2007), *available at* **http://www.fda.gov/nanotechnology/nano_tf.html**.

nanotechnology products on a case-by-case basis. The Task Force concluded that the FFDCA standards governing product safety and effectiveness are sufficiently broad and flexible to protect the public health, but urged FDA to issue further guidance to clarify the application of FFDCA requirements to particular categories of nanotechnology products.[21]

Since the Task Force report was issued in July 2007, FDA has requested public comment on the need for further FFDCA policy guidance.[22] FDA also has requested available data and information on the effects of nanoscale materials on quality, safety, and, where relevant, effectiveness of products subject to FDA oversight. While the deadline for the submission of public comment was October 24, 2008, we are advised that FDA is likely to consider comments submitted by companies as late as January 2009. Interested companies are encouraged to submit comments to FDA as soon as possible.

CONCLUSION

The EPA request for comments on the nano-silver petition presents an opportunity for interested companies to be engaged as EPA lays the groundwork for the Agency's regulatory and enforcement policies under FIFRA and other statutes that will govern nano-silver products and potentially nanotechnology products more generally. The petitions filed by ICTA and other groups with both EPA and FDA may motivate increased enforcement interest on the part of both agencies with respect to nano-silver and other nanotechnology products marketed with implicit, as well as explicit, antimicrobial claims.[23]

EPA's notice also could spark action from Congress and/or the CPSC to regulate nano-scale silver or nanotechnology as they are used in consumer products subject to the CPSC's jurisdiction. Congress took such a substance-specific approach earlier this year by imposing new limitations for phthalates and lead as part of the Consumer Product Safety Improvement Act. The provisions of the recent CPSC legislation could help to shape the legislation anticipated during the 111th Congress proposing far-reaching amendments to the FFDCA aimed at expanding FDA's regulatory and enforcement authority to improve the safety of foods, dietary supplements, cosmetics, drugs, biological products, and medical devices. An analysis of the extensive policy reform expected from the Obama administration is available in a Client Advisory dated November 5, 2008, available **here**.

Given the precedent-setting issues raised by the petition, companies that manufacture, distribute, or use products containing nano-silver or other nano-scale materials should consider providing comments to EPA by the January 20th deadline. Manufacturers and distributors of products containing nano-silver also should review product labels to determine if antimicrobial claims are expressed or implied, keeping in mind that the mere inclusion of nano-silver as an ingredient could indicate pesticidal intent. Moreover, companies should be aware that EPA will be examining the need for further evaluation of the potential human health and environmental risks posed by nano-scale substances, including nano-silver.

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[21] *Id.*

[22] 73 Fed. Reg. 46,022 (Aug. 7, 2008) ("The primary purpose . . . [was] to determine what factors the agency should consider in providing guidance on: (1) the information and data that may be needed to demonstrate the safety and effectiveness of FDA-regulated products containing nanoscale materials; and (2) the circumstances under which a product's regulatory status might change due to the presence or use of nanoscale materials (for example, making a device no longer exempt from 510(k) submission requirements).")

[23] Note that, earlier this year, EPA settled an enforcement action against ATEN Technology for making unregistered antimicrobial claims for keyboards and other devices with a "nano-coating."

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Kelley Drye & Warren, LLP ("KDW") has a multidisciplinary team of lawyers and government relations professionals in our Washington, D.C. office who are experienced in legal and public policy matters with respect to the regulation of nano-silver and other nanotechnology products under the laws administered by EPA, FDA, USDA, CPSC, FTC, and related state consumer protection, product liability, and insurance coverage laws.

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