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FEDERAL AGENCIES SIGNAL SHIFTS IN REGULATING MANUFACTURED NANOMATERIALS

by
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Two lawsuits recently filed in federal court highlight the ongoing challenges of regulating manufactured nanomaterials ("MNMs") and indicate that the federal government may be changing its approach. Both the Food and Drug Administration ("FDA") and the Environmental Protection Agency ("EPA") have recently stated that they may revise existing product approval processes to require evaluation of risks specifically associated with MNMs. Clarification of testing and data requirements for MNMs has the potential to reduce uncertainty costs in the regulatory process. In the meantime, however, the continuing absence of a regulatory definition for "nanotechnology" makes it difficult to know what products might be subject to new scrutiny. In addition, a failure to coordinate efforts or harmonize new rules with international standards may only increase uncertainty if regulators reach different conclusions about what products are subject to "nanospecific" requirements.

Late last year, several nonprofit groups filed an action against FDA in the Northern District of California to compel a response to a citizen petition they submitted in 2006. *See Int'l Ctr. For Tech. Assessment v. Hamburg*, No. 3:11-cv-06592-MEJ (N.D. Cal. Dec. 21, 2011). The petition asked the agency to issue new regulations specifically directed at MNMs—including new definitions of "nanotechnology," "nanomaterial," and "engineered nanoparticle"; a formal advisory opinion explaining FDA's position on MNMs in products regulated by FDA; and "nano-specific" testing and labeling rules—and to prohibit marketing of sunscreens containing nanoparticles until new rules are implemented. *See* Docket No. FDA-2006-P-0213. The suit is still pending. On April 20, 2012, however, FDA issued a detailed response to the 2006 citizen petition. The agency granted the petitioners' request to reopen the administrative record for its ongoing proceeding to develop safety and efficacy standards for MNMs in sunscreens. But it denied the remaining requests, explaining that FDA "has already undertaken many steps, and plans further actions, to help ensure the safe use of nanotechnology in FDA-regulated products." Docket No. FDA-2006-P-0213-0003 (Apr. 20, 2012).

FDA addressed some of the issues raised in the citizen petition in its 2007 Nanotechnology Task Force Report. More recently, in June 2011, FDA issued draft guidance "intended to help industry and others identify when they should consider potential implications for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology in FDA-regulated products." Docket No. FDA-2010-D-0530-0002 (June 15, 2011). Although the agency still has not settled on formal definitions of "nanotechnology" and related terms, this development signals the beginnings of a departure from the Task Force recommendation that FDA "take into account the potential importance of material size"

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without adopting "formal, fixed definitions." The draft guidance indicates that an ongoing public comment process may inform the development of regulatory definitions. Finally, concurrent with its response to the citizen petition on April 20, FDA issued two new draft guidance documents for specific classes of products. The agency provided recommendations to producers of food ingredients and food product substances about when nano-related changes to manufacturing processes may affect a product's regulatory status. The second draft guidance document, concerning cosmetics, sheds light on the agency's current approach to evaluating the safety of products that incorporate MNMs. Like the 2011 draft guidance, neither document provides a definition of "nanotechnology."

Meanwhile, the Natural Resources Defense Council ("NRDC") has challenged EPA's recent decision to grant conditional registration to a pesticide containing nanosilver in the U.S. Court of Appeals for the Ninth Circuit, even as the administrative record demonstrates that the agency is strengthening its approach. *Natural Res. Def. Council v. E.P.A.*, No. 12-70268 (9th Cir. Jan. 26, 2012). AGS-20, which is manufactured by the Swiss company HeiQ Materials AG, is intended to be incorporated into textiles to suppress bacterial growth. It was conditionally approved after a three-year agency review process that included consultation with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel ("SAP") and a public comment period. HeiQ originally sought a "me too" registration—a fast-track process for products that are identical or substantially similar in composition to a registered product. However, after SAP advised that the toxicity of nanosilver might be higher than other forms of silver, EPA required HeiQ to reclassify its application as seeking approval of a "new active ingredient," thus subjecting it to increased data requirements.

EPA issued the final Decision Document on December 1, 2011 after responding to public comments on a draft version. The order emphasized that standard EPA test guidelines for evaluating risks and benefits of pesticide products "have not been adapted generally for use with nanoscale particles" and will "require revision going forward." Accordingly, "future applicants for products containing nanoscale materials should consult with EPA prior to performing any tests." EPA Decision Document: Conditional Registration of HeiQ AGS-20 as a Materials Preservative in Textiles 5 (Dec. 1, 2011).

EPA explained that because it had not decided what types of data would be required to assess nanoscale materials before requiring HeiQ to reclassify its application, it would allow HeiQ to market the product while submitting additional data to EPA over a four-year period. NRDC has challenged this decision under FIFRA section 16(b), which allows "any person who will be adversely affected" by an administrative order following a "public hearing" to challenge the validity of the order in the U.S. courts of appeals. *See* 7 U.S.C. § 136n (2006). Because courts have interpreted "public hearing" to include public comment periods, NRDC's standing likely derives from its comments on the draft Decision Document. *See, e.g.*, *United Farm Workers of Am. v. E.P.A.*, 592 F.3d 1080, 1082 (9th Cir. 2010).

Industry members will face several challenges as both agencies work to take account of scientific developments. First, MNM producers risk being subject to costly, duplicative testing requirements if they do not consult with the relevant agency before developing testing protocols for products that may contain nanomaterials. In the pesticide registration context, the absence of EPA guidance similar to the FDA draft guidance may make it difficult to tell when such a conversation is necessary. Second, the courts' broad interpretation of section 16(b) may lead to increased litigation costs if pesticide producers are forced to intervene in lawsuits challenging registration, as HeiQ has done in the Ninth Circuit case. Finally, increased regulatory focus on particle size as contributing to risk factors will likely lead to intensified data submission requirements during the premarket stage in both the food and drug and pesticide realms.

Going forward, producers can participate in the ongoing FDA comment process. Where possible, they should emphasize to both agencies that national and international consistency in setting regulatory standards for MNMs is necessary to bring innovative technologies to market while ensuring public confidence.

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