

Emerging Legal and Product Stewardship Implications of Products of Nanotechnology

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ABSTRACT

The inclusion of manufactured nanomaterials in products is common today. So also are applications of nanotechnology in virtually every manufacturing sector of the economy. While the pace of technological innovation is furious, the unambiguous application of law, regulation, and policy, and the implications of nanotechnology for effective product stewardship are moving at far lesser speeds, creating uncertainty and potential commercial, legal, and business risk. It is, for example, far from clear what standards apply to various phases of a product's development, use, and end of life if the product contains nanoscale materials that are intended to enhance the product's efficacy and are expected to remain in the product after its useful life. While a host of private standards could apply, the precise application of legally enforceable standards is sometimes fluid, leaving product manufacturers and stewards in a quandary.

In addition, because the commercial value chain can be complicated, it is not always known when a product or process involves elements of nanotechnology. Suppliers often harbor legitimate expectations of confidentiality with regard to product composition or process engineering. Such expectations, however, are sometimes difficult to align with a purchaser's desire to address all aspects of product stewardship, both actual and implied. Reconciling these expectations with meaningful and thorough product stewardship can be challenging. This paper provides a brief overview of key regulatory and legal issues of which nano innovators and others should be aware.

Keywords: TSCA, PMN, nano stewardship, governance

EPA'S REGULATION OF NANOSCALE MATERIALS UNDER TSCA AND FIFRA

Nanoscale chemical substances are regulated under the Toxic Substances Control Act (TSCA). Since 2005, the U.S. Environmental Protection Agency (EPA) has received more than 170 TSCA notifications for nanoscale materials. 2015 and early 2016 saw continued steady growth in the number of these notifications consistent with prior years. EPA proposed the much anticipated TSCA Section 8(a) information rule on April 6, 2015, generally to vigorous criticism. EPA's fall 2015 Regulatory Agenda notes EPA's intention to issue a final rule in October 2016. This is both optimistic and somewhat unlikely given election year

slowdowns. If the rule is issued, it will have significant legal and commercial implications for the nano community.

Other EPA program offices are now also focusing more on nanoscale materials. Specifically, on August 4, 2015, EPA's Office of Water announced the availability of its "[Final 2014 Effluent Guidelines Program Plan](#)," which includes findings from EPA's review of engineered nanomaterials in industrial wastewater. EPA intends to monitor ongoing research on engineered nanomaterials in future annual reviews and will collect any new information as it becomes available. The takeaway here is that EPA's Water Office will continue to look for and identify evidence of nanomaterials in industrial effluent with a view toward regulating it.

On March 19, 2015, EPA responded to the International Center for Technology Assessment's 2008 petition for rulemaking requesting that EPA regulate products containing nanosilver, a widely used nanoscale material, as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and to analyze nanosilver's potential human health and environmental risks. The petition also urged EPA to prohibit the sale of nanosilver products with unapproved claims of health benefits, and to assess human health and environmental risks of nanosilver under other laws, including the Food Quality Protection Act (FQPA) and the Endangered Species Act (ESA). What impact, if any, the suit will have on EPA is unclear. EPA declined to provide the relief requested in the petition.

The Office of Pesticide Program's (OPP) May 2015 announcement that it conditionally registered a second nanosilver pesticide product, Nanosilva, was immediately the subject of a federal lawsuit in the U.S. Court of Appeals for the Ninth Circuit. The Natural Resources Defense Council (NRDC), the Center for Food Safety, and the International Center for Technology Assessment once again teamed up to sue EPA for its decision to register the product. The court has consolidated the cases. Petitioners' opening briefs were filed in mid December. In brief, they claim EPA did not support with substantial evidence their contention that Nanosilva's product would reduce the amount of silver in the environment by replacing conventional silver, and that EPA did not support its view that Nanosilva lacked sufficient time to generate all required data even though EPA required the same studies for the nanosilver registration issued to HeiQ in 2011. How the court will rule in 2016 is, of course, unclear. What is

clear is that judicial challenges to final OPP registration decisions seem inevitable.

FDA REGULATION OF NANOMATERIALS

On June 24, 2014, the U.S. Food and Drug Administration (FDA) issued three final guidances that it intends to provide “greater regulatory clarity for industry on the use of nanotechnology in FDA-regulated products.” One addresses FDA’s overall approach for all products that it regulates, while the other two provide specific guidance for the areas of cosmetics and food ingredients and food contact substances. The guidances are:

[Final Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology](#) -- The guidance outlines overarching considerations for all FDA-regulated products, identifying points to consider when determining whether a product involves the use of nanotechnology. FDA intends for it 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;

[Final Guidance for Industry: Safety of Nanomaterials in Cosmetic Products](#) -- The guidance describes FDA’s current thinking on the safety assessment of nanomaterials when used in cosmetic products and encourages manufacturers to consult with FDA on test methods and data needed to support the substantiation of a product’s safety; and

[Final Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives](#) -- The guidance alerts manufacturers to the potential impact of any significant manufacturing process change, including changes involving nanotechnology, on the safety and regulatory status of food substances. The guidance also describes considerations for determining whether a significant manufacturing process change for a food substance already in the market affects the identity, safety, or regulatory status of the food substance, potentially warranting a regulatory submission to the FDA.

On August 4, 2015, FDA announced the availability of a final guidance document entitled [Guidance for Industry: Use of Nanomaterials in Food for Animals](#). The guidance is intended to assist industry and other stakeholders in identifying potential issues related to safety or regulatory status of food for animals containing nanomaterials or otherwise involving the application of nanotechnology.

RCC NANOTECHNOLOGY INITIATIVE

In 2011, the U.S. and Canada created the Regulatory Cooperation Council (RCC) to align better their regulatory approaches in a number of areas, including nanotechnology. Based on the outcome of the nanotechnology initiative, stakeholders can expect a consistent policy approach for nanomaterials based on shared policy principles and consistent use of the nanomaterial classification scheme to identify data needs (short-term); support the use of analogue/read-across information (that is, identification of a chemical analogue to the nanomaterial in question and allocation of known characteristics from that analogue to the new nanomaterial) for risk assessment (medium- to long-term); use consistently data submitted to support risk assessments based on the framework for human health information and common assumptions for ecological fate and effects; and deploy use information to characterize exposures in risk assessments and focus information requests for new activities. The RCC has been helpful in aligning regulatory reviews, but each country maintains its own chemical management program and inconsistencies invariably arise. As most product manufacturers produce for a global economy, the lack of alignment among internal management systems will continue to inspire commercial confusion and legal jeopardy.

NANO PRODUCT INVENTORIES

While the European Commission studies implementing a European Union-wide nano product inventory, several Member States have implemented their own inventories:

French Nano Decree No. 2012-232: Under Decree No. 2012-232, companies that manufacture, import, and/or distribute a “substance with nanoparticle status” in an amount of at least 100 grams per year must submit an annual report with substance identity, quantity, and use information.

Belgium Registry: Nanomaterial substances must be registered by January 1, 2016, and mixtures containing nanomaterial substances must be registered by January 1, 2017. The following products are exempt from registration: biocides; medicinal products for human or veterinary use; products intended to come into contact with foodstuff; animal feed; and technological aid or other products that may be used for processing ingredients of agricultural origin.

Danish Registry: First reports, for the period beginning June 20, 2014, and ending June 20, 2015, were due August 30, 2015. Manufacturers and importers of products covered by other regulations, such as foodstuffs and food contact materials, animal feed, medicinal products, medical devices, cosmetics, pesticides, and waste, are not required to report.

□ Norwegian Registry: On January 9, 2013, the Norwegian Climate and Pollution Agency (Klif) posted a notice concerning the annual update of information and mandatory reporting of quantities for chemicals for 2012 to the Norwegian Product Register. The Product Register is the central register for chemical products in Norway, and there are currently approximately 25,000 products registered. According to Klif's notice, changes include adding a "NANO box" that registrants should mark if the chemical contains nanomaterials.

Other Member States, such as Sweden, Italy, and the United Kingdom, have taken a voluntary reporting approach. Still other Member States, such as Finland, oppose mandatory reporting in favor of enhanced communication strategies. The emergency of these inventories is especially challenging as they are inconsistent and misunderstood, and could pose ready made lists of products to deselect by nano detractors.

This brief regulatory update excludes a wide range of standard-setting initiatives and voluntary stewardship programs all intended to set high workplace and related standards for the manufacture, processing, use, and disposal of nanoscale chemical substances. Keeping up with these developments will continue to challenge nano stakeholders, but doing less poses considerable legal and commercial risk.