

Environmental and Toxic Tort ADVISORY

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EPA Trend Toward Nanomaterial Regulation Accelerates

Although the number of nanomaterial-containing and nanomaterial-enabled products available in the marketplace has grown substantially in recent years, federal agencies have generally been slow to regulate nanoparticles differently than other chemical substances. Nonetheless, significant efforts to evaluate—and ultimately regulate—nanotechnology’s potential health and environmental risks are now underway at multiple levels. In particular, the U.S. Environmental Protection Agency’s (EPA) trend toward assessment and limitation of nanomaterial risks via the Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.*, (TSCA) is quickly emerging as the hottest area for nano-specific regulation at the federal level.

Three recent signals suggest that EPA’s steady march toward more direct regulation of nanotechnology under the TSCA framework is accelerating. First, EPA recently proposed “significant new use rules” requiring protective equipment and clothing, among other things, for companies manufacturing, importing, or processing carbon nanotubes (CNTs). Second, EPA may soon require manufacturers and processors of CNTs, nanoscale clays, and nanoscale alumina to conduct health effects testing and report the results to EPA. Finally, EPA has expressed a desire to implement potentially broad-ranging nanomaterial environmental and health effects reporting requirements.

Proposed “Significant New Use Rules” For Carbon Nanotubes

In November 2009, EPA proposed Significant New Use Rules (SNURs) for both multi- and single-walled CNTs. See 74 Fed. Reg. 57430-36 (Nov. 6, 2009). According to EPA’s published notice, the agency believes that both generically-identified classes of CNTs “may cause lung effects,” as well as “health effects via dermal exposure.” Citing a purported “lack of data on the potential health risks” posed by CNT exposures, EPA proposes designating the manufacture, import, or processing of CNTs without the use of NIOSH-approved full-face respirators and protective clothing as a “significant new use” of nanotubes under TSCA Section 5. From an environmental perspective, EPA also proposes designating CNT releases to waters of the United States as a “significant new use.” EPA’s proposed rule further contemplates several new recordkeeping requirements for CNT manufacturers, importers, and processors, including, for example, mandatory maintenance of certain CNT production records, personal protective equipment program documents, and water discharge compliance information.

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If adopted, EPA's proposed rules will essentially require businesses to either (i) use EPA-prescribed protective equipment and clothing, or (ii) provide advance notice to EPA and submit information on production volumes, production byproducts, expected exposure estimates and disposal methods. Likewise, CNT discharges to water would require at least 90 days' advance notice and similar data submissions. In either scenario, the notifying business could be forced to conduct new EPA-mandated toxicity tests and submit the results.

Presumably, EPA would respond to these notices by prohibiting, restricting, or otherwise limiting CNT manufacture/use wherever it can articulate a "reasonable basis" for concluding that nanotubes present risks of injury to human health or the environment. As a practical matter, complying with EPA-specified protective equipment requirements and eliminating all possible CNT discharges to water will be the only sure-fire way for CNT manufacturers, importers, and processors to avoid onerous EPA intervention.

Possible Mandatory Nanomaterial Health Effects Testing Under TSCA Section 4

As significant as EPA's efforts to regulate CNT use via SNURs may be, the agency's most recent Semiannual Regulatory Agenda (released December 7, 2009, and available at <http://www.regulations.gov/>) demonstrates that EPA interest in nanoparticle health risks extends even further. Per the Agenda, EPA has identified a need "to determine the health effects" of not only multi-walled CNTs, but also nano-sized clays and alumina. (See pp. 261-62.) EPA intends to develop such health effects information via TSCA Section 4, which authorizes EPA to require chemical manufacturers and processors to test substances using EPA-dictated protocols and submit the resulting data for review.

According to the Agenda, EPA hopes to promulgate the new test rule by November 2010. Although many questions about the specific contours of any new testing requirements remain unanswered (including the specific nanoparticles potentially subject to the new rule), the agency believes that the mandatory test results "would assist EPA in understanding the health effects" of these substances. Further, EPA has indicated that the results could support subsequent regulatory efforts to "manage/minimize any potential risk and exposure[s]." Companies manufacturing or processing CNTs, nanoclays, and nanoscale alumina should monitor further developments and consider submitting formal comments on any proposed new rule.

Anticipated Nanomaterial Reporting Requirements Under TSCA Section 8

Even more broadly, EPA's latest Agenda indicates that EPA is currently "developing a proposal to establish reporting requirements for certain nanoscale materials" under TSCA Section 8. (See p. 264.) Although a new Section 8 rule would not impose new testing requirements, it would presumably require nanoparticle manufacturers to submit existing data on "environmental and health effects" in accordance with 15 U.S.C. § 2607(a)(2)(E). According to EPA, mandatory

reporting requirements would also require the submission of such information as production volumes, manufacturing and processing methods, exposure and release details, and health and safety data.

Again, nanomaterial manufacturers should stay vigilant as events unfold. If implemented, the anticipated Section 8 rule would potentially lay the groundwork for further EPA action under TSCA to reduce purported nanomaterial-related risks to human health or the environment. Although the EPA's Agenda does not indicate the specific nanoparticles that new Section 8 reporting requirements would target, CNTs, nanoclays, and alumina are obvious candidates in light of the possible Section 4 rule described above. EPA has also previously identified fullerenes, cerium oxide, nanosilver, titanium dioxide, and zero-valent iron as materials of ongoing interest. See, e.g., Alston & Bird's October 5, 2009, client advisory (available at http://www.alston.com/elu_nano/).

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