

Client Alert

An informational newsletter from Goodwin Procter LLP

EPA Takes First-Ever Regulatory Actions Aimed at Potential Nanomaterial Risks

The U.S. Environmental Protection Agency (“EPA”) has taken its first clear steps to directly regulate the potential environmental, health and safety (“EHS”) risks associated with the manufacture and use of nanomaterials. EPA’s actions strongly indicate that the agency intends to start relying more on the exercise of its existing statutory authorities than on voluntary industry efforts to address these potential risks and that further regulation may be forthcoming.

Yesterday, EPA issued the first-ever “significant new use rule” (“SNUR”) for a nanoparticle under the Toxic Substances Control Act (“TSCA”). SNURs require persons to notify EPA at least 90 days before commencing the manufacture, import or processing of an “existing” chemical for any activity designated by the SNUR as a significant new use. In addition, on October 31, EPA formally put carbon nanotube (“CNT”) manufacturers on notice that it considers CNTs to be chemically different from conventional carbon compounds and therefore potentially subject to regulation as “new” chemicals under TSCA. Finally, in September, EPA designated a nanomaterial a “new” chemical under TSCA, issuing the first-ever TSCA Section 5 consent order imposing restrictions on the manufacture and use of a nanomaterial to a company proposing to develop multi-walled CNTs.

As a result of these EPA actions, companies and other entities that are currently manufacturing or importing nanomaterials must evaluate the legal implications of their activities under TSCA or risk enforcement action by EPA.

EPA’s Approach to Nanomaterials Under TSCA to Date

EPA defines “nanotechnology” as “[r]esearch and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1 - 100 nanometer range; creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size; and the ability to control or manipulate on the atomic scale.”¹ A nanometer is extremely small – one-billionth of a meter, and as the prevalence of nanoscale materials has increased (they are now used in sunscreens, cosmetics, stain-resistant coatings on clothing and even tennis rackets), so has concern about their potential EHS ramifications.

The concern is that nanomaterials, because of their small size, may be more chemically reactive, have different strength or electrical properties, or be more

mobile, than similar materials that are larger in scale. This concern has led EPA and other government agencies, from local, state and international levels, to issue “white papers,” form study groups and outline areas where research and risk assessment is needed. Such concerns have also led to private efforts to address the potential EHS risks posed by nanomaterials, most notably the “Nano Risk Framework” document announced by DuPont and the Environmental Defense Fund (“EDF”) in June 2007. (For more information about the Nano Risk Framework, see Goodwin Procter’s April 18, 2007 Client Alert titled [“Nanotechnology Risk Framework Spurs Controversy.”](#))

TSCA gives EPA broad authority to regulate chemical substances. Under TSCA, EPA maintains an Inventory of each “existing” chemical substance that is manufactured or processed in the United States. TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1). Any substance not listed on the Inventory is classified as a “new” chemical. Manufacturers or importers of a “new” chemical must submit various data to EPA in a Premanufacture Notice (“PMN”) (or qualify for an applicable exemption) at least 90 days before beginning manufacture or import, and then comply with whatever requirements EPA imposes. EPA can allow the chemical substance in question to be manufactured or imported and used without restriction, impose certain restrictions on the substance’s use, seek more data, or even completely prohibit any manufacture or use of the substance. TSCA § 5(a)(1), 15 U.S.C. § 2604(a)(1).

EPA has taken the position that in determining whether a chemical substance is a “new” or “existing” chemical for TSCA Section 5 purposes, it will look to whether the chemical substance has the same “molecular identity” as a substance already on the TSCA Inventory. *See* 73 Fed. Reg. 4861 (Jan. 28, 2008). The agency has indicated that it:

considers chemical substances to have different molecular identities for the purposes of TSCA when they ... are different allotropes of the same element, e.g., graphite (carbon atoms arranged in hexagonal sheets with each atom bonded to three other atoms in the plane of a given sheet) and diamond (carbon atoms arranged in a tetrahedral lattice with each atom bonded to four other atoms).²

The agency has indicated that in determining whether a particular nanoscale substance is a “new” or “existing” chemical under TSCA, it would not “focus on physical attributes such as particle size.”³ Under this approach, a nanomaterial would not be deemed “new” if it has the same chemical identity as an existing substance but is simply smaller in scale.

Notably, TSCA authorizes EPA to determine that a particular use of a “existing” chemical constitutes a “significant new use” of that chemical. TSCA § 5(a), 15 U.S.C. § 2604(a). EPA must make this determination through the promulgation of a regulation subject to formal public notice and comment. This regulation – the SNUR – identifies the “significant new use” of the chemical and the potential EHS risks associated with that use, based on information submitted to

EPA and imposes such limitations on its manufacture, processing, distribution and use as EPA deems appropriate. Once EPA issues a SNUR, it can regulate the “existing” chemical exactly as it would regulate the chemical as a “new” chemical, except that entities must submit a significant new use notice (“SNUN”) to EPA at least 90 days before they manufacture, import or process the chemical for that use.

EPA’s Newly Articulated Approach to Nanomaterials Under TSCA

In the first-ever action by EPA to directly regulate nanoparticles under TSCA, EPA has issued SNURs for two nanoparticles, siloxane modified silica nanoparticles (generic), and siloxane modified alumina nanoparticles (generic).⁴ Under these new regulations, companies and other entities planning to manufacture, import, or process either of these nanoparticles for generic use as an additive must give EPA at least 90 days notice before starting to do so. EPA noted that it “has concerns for lung effects” and “potential systemic effects from dermal exposure” based on the chemicals’ physical properties, as well as on test data for “analogous respirable, poorly soluble particulates.” Due to these concerns, it concluded that “without impervious gloves or a NIOSH-approved respirator,” the manufacture, process, or use of either chemical as a powder, or other than as described in information submitted to EPA, “may cause serious health effects.” In addition, EPA suggested, but did not require, that any company seeking to manufacture or use either nanoparticle undertake a 90-day inhalation toxicity test.”

EPA has also indicated that it intends to focus on CNTs in particular under TSCA. CNTs are long, thin cylinders of atomic layers of graphite that are used in a broad range of applications, from electronic components to sporting goods. They are generally classified as single-walled (i.e., consisting of a single cylindrical wall) or multi-walled (i.e., consisting of cylinders within cylinders). It has been noted that while CNTs’ “high aspect ratio (ratio of length to width) makes them an attractive structural material, their nanometer-scale diameter and needle-like shape have drawn comparisons with asbestos.”⁵ At least one recent study has suggested that long CNTs may behave like asbestos in the body, resulting in inflammation and the formation of lesions known as granulomas, which are both considered precursors to mesothelioma, a cancer of the outer lining of the lungs. The study’s authors have subsequently stated that additional research is required and clarified that their study did not address either “whether exposure to long straight carbon nanotubes will occur or, if it does, whether these fine fibres will reach the mesothelium surrounding the lungs, and go on to cause mesothelioma.”⁶ Nonetheless, some observers are now claiming that CNTs may be the “new asbestos,” and exposure to CNTs may be “ground zero” for a new wave of mesothelioma.

EPA has previously taken the position that “CNTs are *not necessarily* identical to graphite or other allotropes of carbon.”⁷ But in a Federal Register notice issued on October 31, 2008, EPA stated that it now views CNTs as having a different molecular identity as other forms of carbon. It stated that it “considers

CNTs to be chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA Inventory,” the list of “existing” chemicals already approved for use in commerce. As a result, according to the notice, EPA now “strongly recommends that persons who currently manufacture CNTs for commercial purposes determine whether their CNTs are on the TSCA Inventory and in compliance with the TSCA section 5 requirements” or face potential enforcement action starting in March 2009.⁸

Finally, EPA also issued the first-ever Contract Manufacturer Consent Order under TSCA Section 5, in September, to Thomas Swan and Co Ltd. for the manufacture of a multi-walled CNT product.⁹ The consent order requires the company to, among other things, (1) conduct a 90-day inhalation toxicity test in rats; (2) supply EPA with a one-gram sample of the CNT product and the product’s Material Safety Data Sheet; (3) submit certain characterization data within six months after commencing full manufacture; (4) require its workers to wear protective gloves and clothing shown to be impermeable, and NIOSH-approved respirators; (5) use the product only for a particular use (claimed confidential but generically identified as a “property modifier” in electronics and polymer composites); and (6) provide the product only to entities that agree to the same use restrictions and worker protection conditions. The order represents EPA’s first real exercise of its TSCA authority to address potential EHS risks posed by nanomaterials.

Practical Consequences

While EPA has previously taken the position that certain nanomaterials may be subject to TSCA regulation, it had worked with manufacturers, distributors, users and importers of nanomaterials in voluntary efforts to evaluate potential EHS risks associated with such materials, such as its Nanoscale Materials Stewardship Program (“NMSP”). (For more information about the NMSP, see Goodwin Procter’s July 25, 2007 Client Alert titled “[EPA Seeks Public Comment on Nanomaterials Proposals](#).”) The agency’s recent actions may herald a new approach that relies more on formal regulation. While the recent Federal Register notices do not mandate, for example, that all CNTs now be treated as TSCA “new” chemicals, they represent the clearest indication to date that EPA is weighing whether exercising its enforceable regulatory authorities may be a more effective approach to managing perceived nanomaterial EHS risks than voluntary industry efforts. Moreover, coming on the heels of the Thomas Swan consent order, they suggest that the agency is preparing to take a more active stance toward regulating the manufacture and use of nanomaterials.

What is clear is that companies and other entities that are currently manufacturing or importing nanomaterials must evaluate the implications of their activities under TSCA or risk enforcement action from the EPA. Specifically:

- Any companies that are planning to manufacture, process or import either of the nanoparticles covered by the newly issued SNURs need to assess

whether their planned use of the chemical may constitute a “significant new use.” If so, they must prepare and submit a SNUN to EPA at least 90 days before manufacturing, importing or processing the chemical for that use and comply with any conditions EPA imposes. Failure to take these steps may lead to enforcement action.

- Any companies that are currently manufacturing or importing CNTs, or considering doing so, need to carefully evaluate whether they can engage in these activities without submitting a PMN to EPA because failure to do so may lead to enforcement action. In some cases, it may be necessary for manufacturers or importers to negotiate a legally binding consent order with EPA regulating how a particular CNT may be manufactured, distributed and used.

¹ [EPA Nanotechnology White Paper](#) (EPA 100/B-07/001) (Feb. 2007)

² *Id.* at 3-4 (emphasis added).

³ *Id.* at 4.

⁴ 73 Fed. Reg. 65743, 65751-65752 (Nov. 5, 2008).

⁵ C. Poland, et al., “Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathology in a pilot study,” *Nature Nanotechnology* (May 20, 2008).

⁶ A. Maynard, “[Carbon Nanotubes: The New Abestos? Not If We Act Fast](#),” *see also* K. Donaldson, et al., [commentary on C. Poland article](#)

⁷ 73 Fed. Reg. 64946, 64947 (Oct. 31, 2008) (emphasis added).

⁸ *Id.*

⁹ “NANOTECH: EPA issues consent order for company planning to develop carbon nanotubes,” *Greenwire* (Oct. 10, 2008); *see also* [Swan pioneers nanomaterial controls with EPA](#) (company press release announcing consent order).

If you have any questions about the issues raised in this alert and their potential implications for your business, please contact:

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