
US EPA Announces March 2009 TSCA Enforcement Campaign Against Certain Carbon Nanotube Manufacturers and Importers

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On October 31, 2008, the US Environmental Protection Agency issued a formal notice both presenting the Agency's interpretation of the regulatory status of carbon nanotubes (CNTs) under the Toxic Substances Control Act (TSCA), and announcing EPA's plan to begin aggressively enforcing that interpretation, beginning in March 2009. EPA's enforcement position is that CNTs--nanoscale tubes of graphitic carbon--are *not* equivalent to graphite or carbon for TSCA purposes, and therefore it is illegal for companies to import or manufacture CNTs in any amount for non-exempt commercial purposes until after a TSCA pre-manufacture notice (PMN) for the CNT has been submitted to EPA, and the 90-day review period has expired. EPA is inviting CNT manufacturers and importers voluntarily to bring their operations into compliance with this interpretation prior to March 1, 2009, or face enhanced enforcement scrutiny. [Notice, Toxic Substances Control Act Inventory Status of Carbon Nanotubes, 73 FR 64946 \(Oct. 31, 2008\)](#).

Enforcement Risks

A more lenient enforcement response for those who come forward during this four-month "grace period" is likely, although the Notice does not so commit. Any transitional leniency by the Agency likely will not insulate CNT manufacturers and importers from private TSCA enforcement efforts under the citizen suit provisions of TSCA. And although EPA's notice is directed at importers and manufacturers, downstream commercial CNT processors and other users may also be subject to regulatory enforcement claims. TSCA §15(2). EPA's approach here is unusual. In other cases where the Agency has shifted position, it has not led with enforcement, but with public consultation on the rationale for a change and reasonable means for affected companies to conform to the new position.¹

Basis for EPA's Position Remains Unclear; Raises Questions for Other Nanomaterial Manufacturers

The absence of prior public consultation is problematic in part because it creates additional uncertainty. EPA's current Notice does not state the basis for the Agency's conclusions. It does not explain how EPA purports to define the unique "molecular identity" of a CNT that would distinguish a CNT from graphite or carbon, or *distinguish one CNT from another*. As in prior EPA policy statements

on CNTs, for example, *TSCA Inventory Status of Nanoscale Substances--General Approach*([notice of availability provided at 73 FR 4861 \(Jan. 28, 2008\)](#)), EPA's current Notice only states its legal conclusions about the material, but not how it reached them. As a result, it may be impossible for a manufacturer or importer to evaluate whether the Agency would consider its particular CNT to be "new" without a formal determination by the Agency. EPA's approach also may raise concerns for manufacturers and importers of other engineered nanoscale materials (whether or not based on carbon) that include atypically-shaped crystals, e.g., carbon fullerenes and silica and other non-carbon nanotubes.

EPA Treats All Nanotubes as Unique--For Now; Each Requires Its Own PMN

EPA has also taken the position that CNTs from different manufacturers each represent a different "chemical substance" for TSCA purposes, and therefore, each manufacturer's CNTs require their own separate PMN and 90-day review period. This interpretation is only indirectly stated by the current Notice, but it is the enforcement position the Agency has presented in recent public briefings, and is consistent with the fact that EPA has several PMNs for CNTs under review. In contrast, if all CNTs were deemed by EPA to have the same TSCA "molecular identity" (as, for example, all forms of silicon dioxide apparently are), only one PMN and one 90-day review period generally would be required for all CNTs (e.g., the [PMN and review recently completed by Swan Chemical](#)). To be sure, the Notice suggests that EPA theoretically could find the CNTs of one manufacturer to be the same substance (for TSCA purposes) as the CNTs of another, but it does not state how the Agency will make any such evaluation. EPA's rationale on these issues should be revealed, at the very least, in the course of any enforcement proceedings beginning in March 2009. See *In Re Concord Trading Co.*, EPA ALJ Docket No. TSCA-94-H-19 (Jul. 24, 1997).

TSCA Compliance Options for CNT Manufacturers, Importers and Users

The absence of any explanation of the technical basis for the positions in EPA's Notice confirms its pure enforcement purpose--to encourage voluntary submittals now and to deny companies defensive arguments that they did not have "fair notice" of EPA's interpretation. Even accepting EPA's interpretative position that CNTs generally should be considered "new" and require a PMN, the Agency has not provided enough information for any CNT manufacturer or importer to make any independent judgment about the TSCA status of its own material. Currently, the only way for a manufacturer or importer to know is to obtain (directly or indirectly) a determination from the Agency. This can be done either as a stand-alone formal request, or as part of a TSCA new chemical application.² The Notice itself is not a rule, and companies that substantively disagree with a case-specific EPA determination may be able to challenge that determination directly or, more certainly, in the defense of an enforcement action. Whether and how to make such challenges are decisions businesses should weigh carefully.

Companies planning on importing or manufacturing CNTs for commercial purposes and seeking only to conform their activities to the Agency's current enforcement position have several compliance options, including applying for and obtaining either a (1) low volume exemption, or (2) a low release-low exposure exemption (LoREX). These each have 30-day review periods, which EPA can extend as necessary. Companies also may submit a PMN, which normally has a 90-day review period, but

which is likely to be extended by EPA by at least an additional 60 days or more for a CNT submittal. All of these options entail strategic legal and business considerations.

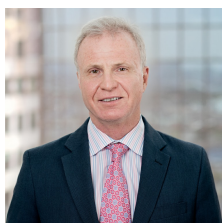
Whether under an approved PMN exemption, or in connection with a full PMN, EPA's past actions and statements suggest that it likely will require the submitter to use certain workplace and environmental exposure controls when handling CNTs. Identifying options and negotiating technically and economically appropriate measures should be a focus for manufacturers and importers. The Agency also can be expected to restrict use of the CNTs to only the uses described in the submittal, and in some instances can be expected to require a future commitment to conduct inhalation toxicity testing. These obligations may be imposed by an order, or through a significant new use rule (SNUR). EPA recently published SNURs for certain siloxane modified silica and alumina nanoparticles. [73 FR 65743, 65751 \(Nov. 5, 2008\)](#).

Companies already manufacturing or importing CNTs for commercial purposes without an EPA status determination, PMN exemption or completed PMN review have the same compliance options, but will first need to address with the Agency the status of past and ongoing operations, and any enforcement response in respect of those actions.

¹See e.g., regulatory action on the TSCA inventory status of monomer acids and derivatives, 66 FR 34193 (Jun. 27, 2001); enzymes and proteins, 69 FR 65565 (Nov. 15, 2004); and activated phosphors, 73 FR 2854 (Jan. 17, 2008). Whether EPA has the legal authority under TSCA to make the changes described in these notices has not yet been challenged or tested.

² For those CNTs that have completed the PMN process, the Agency can be expected to issue significant new use rules (SNURs). Accordingly, even if the chemical identity of your CNT is the same as one that has completed PMN review, its use may still be subject to PMN-like review under the SNUR. One can only determine if a CNT is covered by a SNUR by consulting with the Agency.

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