
Imminent EPA Determination May Impose New Costs, Regulatory Burdens and Enforcement Risk on the Nanotech Materials Industry

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The Environmental Protection Agency soon may answer in part one of the questions that nanotech material manufacturers and investors have been watching closely—whether EPA will require industry to treat nanoscale materials as "new" under environmental laws, even in instances where the same material (albeit not in nanoscale particles) has been present in the chain of commerce for many years. Such a decision could have immediate consequences for the nanotech materials sector and will insert the Agency firmly into the nanotech development process. EPA is poised to rule on this issue in respect to carbon nanotubes. We understand a decision by EPA is imminent; we will report further as soon as any decision issues.

Pre-Manufacture Review Required under TSCA

Subject to certain exemptions, the Toxic Substances Control Act (TSCA) requires chemical manufacturers and importers to submit a pre-manufacture notification (PMN) to EPA prior to manufacturing a "new" chemical substance—i.e., any substance of a "particular molecular identity" that (subject to certain exemptions) is not already listed on EPA's inventory of chemicals in commerce (the TSCA Inventory). Preparing a PMN is a time-consuming and costly undertaking and includes submitting physical data regarding the substance; circumstances of anticipated use, exposure and release; and known health effects information. After PMN submittal, EPA has 90 days to complete a screening risk assessment and to either allow the substance to be manufactured and used without conditions, or to limit manufacture or use (usually by negotiated consent order). Manufacturing or importing a substance that has not completed such review (and is not otherwise exempt) is a violation of law.

Recently, EPA and others have questioned whether the various manufactured nanoparticles (e.g., quantum dots, core dots, nanotubes, nanowires, nanoropes, fullerenes, etc.) of a given substance have the same "particular molecular identity" as macroscale versions of such substances that may be listed on the TSCA Inventory—and, therefore, whether manufacturers and importers of the nanoparticle forms are (or were) required to complete the PMN review process (or qualify under an exemption) prior to commencing manufacture or import. Such regulatory concerns seem misplaced

where the nanoparticle represents only smaller than typical agglomerations of listed substances, but may raise a more substantial question where the molecular structure of the manufactured nanoparticle is arguably distinct from other versions of the same substance.

For example, although carbon nanotubes (CNTs) have the same chemical formula as graphite, carbon and diamond (i.e., composed entirely of carbon), CNTs arguably possess a distinct arrangement of carbon atoms different from graphite or other forms of carbon. In an enforcement context, EPA might take the position that this difference represents a unique "molecular identity" and, therefore, that a PMN (or exemption) is required prior to manufacture or import. Indeed, a casual review of Material Safety Data Sheets for various CNTs available through chemical supply houses indicates that different firms have identified CNTs with a range of different Chemical Abstract Service Registry (CAS) numbers—including those of graphite and carbon. In at least one case, the manufacturer reported that there is no applicable CAS number.

EPA Poised to Rule Whether Carbon Nanotubes Require Pre-Manufacture Review

One carbon nanotube manufacturer or importer has put this question to the test by submitting to EPA a TSCA low-volume exemption (LVE) application for a single wall carbon nanotube (SWCNT). If EPA determines that the SWCNT is "covered" by an existing TSCA Inventory listing (e.g., for carbon), the LVE application would be denied (as unnecessary). On the other hand, if EPA grants the application (with or without conditions), this would suggest the Agency's formal determination that SWCNTs are not covered by any existing Inventory listing, and—by extension—that until a SWCNT is listed on the Inventory (i.e., by submission of a PMN and commencement of manufacture after EPA review), all SWCNT manufacturers must qualify for an exemption to the PMN requirement. Based on application submittal dates, EPA action on the LVE application is expected very shortly.

EPA action on the pending nanotube LVE application—including the imposition of any conditions—may signal a change in EPA policy or interpretation that may have financial, operational and enforcement consequences. What enforcement risk will exist for those businesses that have acted in a way that now may be inconsistent with EPA's position? What does any such decision imply for manufacturers of nanomaterials other than SWCNTs? The importance of these questions suggests that wider industry and research community input is in order before policy is made. And, given the novelty of these issues and the current regulatory uncertainty, EPA should, as a policy matter, give only future effect to any statutory interpretations made in this context. Agency enforcement officials have at times, however, treated analogous interpretations as applicable retrospectively, subject only to Agency enforcement discretion. To best protect their interests, current CNT (and other nanoparticle) manufacturers and importers should review their TSCA compliance position in advance of EPA action.