

New Nanotechnology Developments Under TSCA

Hearing no significant industry or NGO pushback, the Environmental Protection Agency seems confident about applying its recent Nanotechnology Guidance, "TSCA Inventory Status of Nanoscale Substances - General Approach" in the regulation of nanomaterials, especially carbon nanotubes (CNTs). Characterized as a case-by-case approach consistent with its historical position concerning when chemical substances are "new," the Agency's Nanotechnology Guidance actually represents a significant departure from its prior guidance. The Agency's position that different molecular formulas, different atom connectivities, different spatial arrangements of atoms and different isotopes of the same elements constitute different molecular identities for TSCA purposes is conventional enough as a restatement of prior guidance. But the Agency's view that different crystal lattices and different allotropes of the same elements constitute different chemical substances surely represents a considerable departure, which will bring most CNTs within the ambit of the Agency's New Chemicals Program.

Historically, the Agency said in advice to two different companies about silica that "different physical forms of the same chemical compositions" were not separately reportable, and industry generally understood the Agency's reference to physical forms to mean physical structures, such that different crystal lattices and different allotropes of existing chemical substances were not different molecular identities. The Agency now construes its phrase "different physical forms" simply to mean different physical attributes like particle size -- not different physical structures, like allotropes, which are newly important under the Nanotechnology Guidance for determining molecular identity. Since CNTs generally have different physical structures from the Inventory-listed forms of carbon, namely, amorphous carbon, graphite, and diamond, they will likely constitute different molecular identities and will not likely escape classification as new chemical substances.

This means that virtually every CNT will need to undergo new chemical review, and, consequently, face potential regulation under TSCA § 5(e). No doubt the Agency will develop a category of concern for CNTs, setting forth its position on exposure and risk, and will develop appropriate remedial measures for 5(e) consent orders, in connection with its review of pending PMNs for various CNTs. So PMN submitters for CNTs need to anticipate Agency concerns about exposure and risk by showing good nano-stewardship plans, which minimize potential human and environmental exposure.

Since the structural variety of CNTs is potentially infinite, EPA is likely to classify CNTs into just a few categorical listings (e.g., single-wall and multi-wall CNTs), rather than enter a plethora of different individual structural listings on the Inventory. Similarly, EPA potentially will develop a specific list of workplace, use and disposal limitations for each CNT category under TSCA § 5(e), and will rely upon follow-on SNURs to regulate all CNTs falling within these categories. At the same time, EPA will likely initiate action to bring those CNTs already on the market into the New Chemical Program, asserting that they are not entitled to rely upon any of the three carbon-based Inventory listings mentioned above. In our experience the Agency is not willing to classify multi-walled CNTs as graphite, the one Inventory listing potentially applicable to CNTs.

The Agency will likely publicize its position on CNTs widely so that companies already on the market with CNTs in reliance on the Inventory listings for amorphous carbon and graphite will recognize that they are out of compliance, stop production of their CNTs, prepare PMNs and face a potential 5(e) consent order. Presumably the Agency will afford such companies a grace period to bring themselves into compliance with the Agency's new position on CNTs, rather than seek TSCA penalties, especially since the Agency's prior guidance appeared to allow reliance on the Inventory listings of carbon and/or graphite. In short, the Agency seems poised to address CNTs aggressively under its new Nanotechnology Guidance, and the commercial impact of the Agency's new policy will emerge shortly as the first CNTs make their way through the PMN process.

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