

USEPA: Regulating Nanotechnology

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As part of its recent efforts to address growing concerns over the health and safety of nanomaterials and the general absence of regulation over nanotechnology, USEPA promulgated, on May 6, 2011, a final significant new use rule (SNUR) under the Toxic Substances Control Act (TSCA), Section 5(a)(2), for the chemical substance generically identified as multi-walled carbon nanotubes (CNT). This is the third SNUR issued by USEPA for nanomaterials. The multi-walled CNTs subject to the May 6 SNUR were originally the focus of a premanufacture notice (PMN), P-08-199, submitted to USEPA pursuant to TSCA, Section 5. The final May 6 SNUR was initially proposed by USEPA in February 2010. However, the comment period for the rule was re-opened and extended in July 2010 in order to address public comment and to add information to the docket. The rule became effective June 6, 2011.

Pursuant to the May 6 final SNUR, any person intending to manufacture, import, or process multi-walled CNTs for a use that is designated as a “significant new use” by the rule must submit a significant new use notice to USEPA at least 90 days prior to commencing that manufacture, import or processing. A significant new use is one that is different from those multi-walled CNT uses described in PMN P-08-199, which include use as an additive/filler for polymer composites and as support media for industrial catalysts. A significant new use is also one that may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified for the substance that, in the case of multi-walled CNTs, include possible lung effects, immunotoxicity, and mutagenicity from exposure.

USEPA has also drafted a rule under Section 8(a) of TSCA requiring manufacturers of nanoscale substances, who have not already made formal detailed submissions to USEPA, to submit, for USEPA’s review, detailed environmental, health and safety data related to those nanoscale substances. Although this rule was scheduled to be issued in January of this year, it is currently still pending with the White House Office of Management and Budget (OMB).

Further attempts at addressing concerns over the lack of regulation for nanomaterials include a notice by USEPA of its intent to propose a new interpretation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Section 6(a)(2) (reporting adverse affects information) with respect to nanomaterials in pesticides. An “original” interpretation was sent to OMB about a year ago, but was met with strong resistance. Accordingly, USEPA states that it will soon propose a new interpretation, which shall require that registrants and applications report an active or inert ingredient (and any component parts thereof) in a pesticide that is intentionally produced to have at least one dimension measuring between approximately 1 and 100 nanometers. Only existing information known a company

would be reportable.

Finally, USEPA has stated that it will propose a testing rule under Section 4 of TSCA requiring a 90-day in vivo inhalation toxicity testing for certain nanoscale aluminum oxide, nanotubes, and nanoclays. This testing rule was originally slated to be issued at the end of 2010, but is not yet available.

2 Min Read

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