

EPA DOES THE NANO "WALTZ" (ISSUES, THEN WITHDRAWS, THEN PROPOSES TSCA RULES FOR NANOSCALE SUBSTANCES)

**Lawrence Culleen
Leigh Logan**

The U.S. Environmental Protection Agency (EPA or Agency) waltzes into the nanotechnology regulatory arena by taking one step forward, one step back, and then a half step forward again. On June 24, 2009, EPA issued direct final significant new use rules (SNURs) pursuant to its authority under Section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 23 chemical substances which previously were the subject of premanufacture notices (PMNs). 74 Fed. Reg. 29,982. Included among these 23 chemical substances were two nanoscale materials described as multi-walled carbon nanotubes (CNTs) and single-walled CNTs. Prior to the SNURs becoming effective, EPA received correspondence stating that the commenter intended to submit adverse and/or critical comments concerning the two SNURs affecting the CNT substances, causing the Agency to have to withdraw the SNURs for those particular CNT materials. 74 Fed. Reg. 42,177. As expected, EPA has recently re-issued the SNURs as proposed rules. In doing so, the Agency continues to show its willingness to use TSCA as a mechanism to stalk nanotechnologies.

Background

EPA has struggled to find effective mechanisms to gather information concerning nanoscale chemical substances and to provide risk-management oversight of the commercialization of new nanoscale substances. During the Bush administration, in an attempt to enhance its understanding of nanoscale materials, EPA launched a voluntary effort, called the Nanoscale Materials Stewardship Program (NMSP), which is comprised of two parts. The Basic Program invited participants (i.e., manufacturers and importers who

develop nanoscale materials) to provide voluntarily existing scientific information on the materials they manufacture, process, import, or use. The In-Depth Program requested participants to develop voluntarily and provide to EPA new information and data about nanoscale materials over a longer period of time. By December 2008, 29 entities had submitted information under the Basic Program, while only five had committed to participate in the In-Depth Program. *See* <http://www.epa.gov/oppt/nano/stewardship.htm>.

In January 2009, EPA issued an Interim Report hailing the NMSP as a success; however, the Agency noted that there are data gaps pertinent to the potential environmental effects and health and safety risks of nanoscale materials that the NMSP has left unfilled. Accordingly, the Agency is now considering the various mechanisms within its TSCA authority to gather testing data and information to fill those gaps (more on this below). The direct final SNURs were intended to be the first of such actions. The proposal of the SNURs should help put EPA back on track, albeit a little delayed.

The CNT-related SNUR actions followed on the heels of EPA's Oct. 31, 2008, announcement stating that CNTs not previously listed on the TSCA Inventory are considered "new" chemicals pursuant to TSCA Section 5. 73 Fed. Reg. 64,946. The October 2008 announcement put manufacturers and importers of nanoscale materials on notice that if an entity intends to manufacture, import, process, or use a CNT, it must first either conclude that the substance appears on the Inventory or submit a PMN to EPA. The Agency had noted that after March 1, 2009, it would focus its monitoring and enforcement efforts to ensure that entities comply with the TSCA new chemicals regulations with respect to CNTs.

Direct-Final SNUR Re-Issued as Proposal

EPA's requirements for issuing expedited SNURs require the Agency to withdraw a direct final SNUR

when adverse comments are received. 74 Fed. Reg. 42,177. The SNURs that have now been reissued as proposed rules are intended to require any manufacturer, importer, and processor of the listed CNT substances to notify EPA 90 days before commencing any “significant new use” of the two substances. 74 Fed. Reg. 57,430. SNUR notifications allow the Agency to assess and evaluate the intended new use of a chemical substance and to determine if EPA will take action to limit or prohibit that activity before it occurs.

For rulemaking purposes, for EPA to determine if a particular use of a chemical substance is a significant new use, TSCA Section 5(a)(2) requires the Agency to consider certain factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

74 Fed. Reg. 29,982. For the CNT chemical substances addressed in the proposed SNURs, EPA stated that it had also considered the toxicity of the chemical substances as well as the likely human exposures and environmental releases associated with the potential new uses.

Withdrawal and Re-Issuance of SNURs Does Not Deter EPA’s Regulatory Efforts

The TSCA Interagency Testing Committee (ITC) has echoed EPA’s interest in being at the leading edge of regulatory activity for nanoscale technologies. As if to

encourage the Agency to bounce back after having to withdraw the direct-final CNT SNURs, in its 64th report, the ITC reiterated EPA’s intention to require the submission of new and existing data on the potential health and environmental effects of nanoscale materials. 74 Fed. Reg. 38,878. The ITC was established by Congress to provide recommendations to the EPA administrator regarding chemical substances and mixtures to which the Agency should give “priority consideration for the promulgation of rules for testing.” These recommendations, provided in the form of a report submitted to the administrator every six months, establish a Priority Testing List consisting of the chemical substances and mixtures that the ITC believes warrant testing and investigation, as well as the reasons for the ITC’s revisions to same. The 64th report covers the ITC’s activities from November 2008 through May 2009, which included a review of nanoscale materials and EPA’s NMSP. While the ITC report made no revisions to the TSCA Section 4(a) Priority Testing List for this reporting period, its report focused on the ITC’s continued effort to review nanoscale materials.

The ITC’s recent report strongly suggests that EPA likely will require the submission of some or possibly many of these categories of studies in the future when exercising its TSCA authority with respect to nanoscale materials. If manufacturers eventually are required to address these data gaps, the data collection and research efforts could be both expensive and time-consuming.