

EPA ISSUES DIRECT FINAL RULE CONCERNING 23 NEW NANOSCALE SUBSTANCES

The US Environmental Protection Agency (EPA or Agency) has taken significant new regulatory action consistent with its continuing oversight efforts regarding the development of new nanoscale materials. On June 24, 2009, the Agency 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).¹ Some of these chemical substances include single- and multi-walled carbon nanotubes (CNTs).

The EPA's SNURs come at the same time that regulators at California's Department of Toxic Substances Control (DTSC) are overseeing a program of data "call-ins" which addresses a number of specific nanoscale materials, including CNTs. While the DTSC's call-in program is proceeding independently of EPA, officials from each of the two agencies are understood to have been in communication with one another.

BACKGROUND

During the Bush Administration, EPA launched a voluntary effort, entitled the Nanoscale Materials Stewardship Program (NMSP), in an attempt to enhance its scientific understanding of the efforts of manufacturers and importers who are developing nanoscale materials. The NMSP had been comprised of a two-part program. The Basic Program invited participants to voluntarily provide existing scientific information on the nanoscale materials they manufacture, process, import, or use. The In-depth Program requested that participants voluntarily develop information and data over a longer time period. As of December 2008, 29 entities had submitted information under the Basic Program, and an additional seven had committed to doing so, while only five organizations had committed to participate in the In-depth Program.² In January 2009, EPA issued an Interim Report hailing the NMSP as a successful program; however, it noted gaps in environmental health and safety data for nanoscale materials that were not filled through the NMSP. Accordingly, the Agency stated that it would consider "how to best use testing and information gathering authorities under [TSCA] to help address those gaps."³ The

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¹ Significant New Use Rules on Certain Chemical Substances, 74 Fed. Reg. 29982 (June 24, 2009) (codified at 40 CFR Part 721).

² Nanoscale Materials Stewardship Program, <http://www.epa.gov/oppt/nano/stewardship.htm>.

³ Nanoscale Materials Stewardship Program, Interim Report, US Environmental Protection Agency, Office of Pollution Prevention and Toxics, January 2009

direct final SNURs are just the beginning of what is likely to be numerous actions taken by the EPA using its authority under TSCA.

The SNURs follow on the heels of the Agency's October 31, 2008 announcement advising that CNTs not previously listed on the TSCA Inventory are to be considered new chemicals pursuant to TSCA section 5.⁴ This action put manufacturers and importers of nanoscale materials on notice that if an entity intends to manufacture or import a CNT, it must submit a PMN to EPA, or, alternatively, conclude that the substance is listed on the inventory. The Agency noted that beginning after March 1, 2009, its monitoring and enforcement efforts would focus on ensuring that companies comply with the TSCA regulations covering CNTs. Clearly, the 23 SNURs reflect EPA's continuing progress in applying its authority to address nanoscale materials through TSCA.

In California, the DTSC issued "call-in" letters in January 2009 to 26 companies and universities that produce or use CNTs within California. Exercising authority granted by legislation enacted in 2006 (Cal. Health & Safety Code §§ 57018-20), the DTSC is requiring recipients of the letters to submit "any or all information, including supporting references," pertaining to six broadly-worded questions.⁵ More recently, the DTSC has announced plans to conduct further call-ins addressing certain reactive nanometal oxides, including aluminum oxide, silicon oxide, titanium oxide, and zinc oxide, as well as nano silver, nano zerovalent iron, and cerium oxide.⁶ Recipients of the January 2009

call-in letters must submit the requested information within one year after the date of the letter (i.e., January 2010).

NEW RULE

The new SNURs affect manufacturers, importers, and processors of any of the 23 listed chemical substances who intend to use the substances for an activity designated as a "significant new use" and requires such entities to report to EPA the intention to do so 90 days prior to commencing the regulated activity. This 90-day period provides the Agency with an opportunity to evaluate and assess the human and ecological risks of the activity, and to determine whether EPA will allow, limit, or prohibit such activity before it actually occurs.

EPA's determination of a significant new use for a chemical is based on a number of 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.⁷

EPA determined that four of the 23 chemical substances likely presented an unreasonable risk to human health or the environment, and therefore are now subject to "risk-based" consent orders pursuant to TSCA section 5(e). While EPA concluded that the other 19 chemical substances did not present such an unreasonable risk, the Agency believes that the PMNs submitted for these chemicals demonstrated the likelihood of increased exposures to the substances if additional uses are undertaken.

The effective date of this new rule is August 24, 2009, and it will be considered to have been promulgated for purposes of

⁴ Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 64946 (Oct. 31, 2008).

⁵ These questions seek information regarding (1) the recipient's "value chain," including any products in which CNTs are used and its "major customers" for such products; (2) the "sampling, detection and measurement methods" used to monitor the presence of CNTs in the "workplace and the environment"; (3) the recipient's "knowledge" of "the current and projected presence of [its CNTs] in the environment"; (4) the recipient's "knowledge" of the "safety" of its CNTs in terms of "occupational safety, public health, and the environment"; (5) the methods used to protect workers and (6) whether the CNTs, if released, "constitute a hazardous waste." See http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/upload/Formal_AB289_Call_In_Letter_CNTs.pdf

⁶ <http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/index.cfm>

⁷ Id.

judicial review on July 8, 2009. While EPA used its authority to issue the regulations as direct final rules, it will accept written comments up to July 24, 2009. If EPA receives any adverse or critical comments, or notices of intent to file same, the Agency will withdraw relevant sections of this rule prior to its effective date, issue a proposed SNUR for the relevant chemical substance, and then provide a 30-day public comment period to respond to the new proposed SNUR.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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