

TSCA INTERAGENCY TESTING COMMITTEE REPORT SIGNALS CONTINUED EMPHASIS ON AGENCY REQUESTS FOR AND REVIEW OF DATA ON NANOSCALE MATERIALS

The Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) has submitted its 64th report to the US Environmental Protection Agency (EPA or Agency), and the Report demonstrates the Agency's intention to require the submission of new and existing data on the potential health and environmental effects of nanoscale materials.¹

By the authority provided in TSCA Section 4(a), the ITC was established in order 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."² 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 include a review of nanoscale materials and EPA's Nanoscale Materials Stewardship Program (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 began discussions of nanoscale materials in 2004 when briefings regarding the chemical substances commenced with EPA and other governmental agencies such as the National Institute of Environmental Health Sciences (NIEHS), the National Institute for Occupational Safety and Health (NIOSH), and the National Institute of Standards and Technology. At that time, informal workgroups were created with the intention to better understand the risks and effects of nanoscale materials on health

Brussels

+32 (0)2 290 7800

Denver

+1 303.863.1000

London

+44 (0)20 7786 6100

Los Angeles

+1 213.243.4000

New York

+1 212.715.1000

Northern Virginia

+1 703.720.7000

San Francisco

+1 415.356.3000

Washington, DC

+1 202.942.5000

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¹ Sixty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments; Notice, 74 Fed. Reg. 38878 (August 4, 2009).

² The ITC is comprised of representatives from the Council on Environmental Quality, US Department of Commerce, National Institute of Standards and Technology, National Oceanographic and Atmospheric Administration, US Environmental Protection Agency, National Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, National Science Foundation, Occupational Safety and Health Administration, Agency for Toxic Substances and Disease Registry, Consumer Product Safety Commission, US Department of Agriculture, US Department of Defense, US Department of the Interior, and the US Food and Drug Administration.

and the environment. In 2006, ITC received another briefing by EPA on the Agency's nanotechnology research programs and reviewed EPA's nanotechnology white paper, but while it understood the importance of nanotechnology, the ITC questioned the ability to discuss nanoscale materials in its reports or to add them to its Priority Testing List because many nanotechnology chemicals are lacking Chemical Abstracts Service Registry (CAS) numbers.

Most currently, during the reporting period, the ITC reviewed nanotechnology reports from both EPA and NIOSH. EPA's NMSP interim report³ reiterated the Agency's stance that pursuant to TSCA Section 5, chemical substances that have a different molecular identity from those already listed on the TSCA Inventory are considered to be "new" and require submission of a premanufacture notice (PMN) to EPA 90 days prior to commencing manufacture or import of the new substance. This position also was articulated by EPA during October 2008, when the Agency announced that this is particularly the case for carbon nanotubes (CNTs).⁴ On June 24, 2009, EPA issued direct final significant new use rules (SNURs) pursuant to TSCA Section 5(a)(2) for 23 chemical substances which previously were the subject of PMNs⁵, some of which included single- and multi-walled CNTs. A recent notice indicates that the direct final SNUR will be withdrawn in so far as it relates to two substances that previously had been reported to EPA.⁶

3 Nanoscale Materials Stewardship Program, *Interim Report*, US Environmental Protection Agency, Office of Pollution Prevention and Toxics, available at: www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf (January 2009).

4 *Toxic Substances Control Act Inventory Status of Carbon Nanotubes*; Notice, 73 Fed. Reg. 64946 (October 31, 2008).

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

6 Specifically, on July 22, 2009, EPA received a Notice of Intent to Submit Adverse or Critical Comments to the June 24, 2009 SNURs published in the Federal Register, specifically addressing the single- and multi-walled CNTs. Following the requirements of the expedited SNUR rulemaking process, EPA has now withdrawn the SNURs for these particular chemical substances and will eventually publish a separate notice and comment rulemaking relating to proposed SNURs for these CNTs. See *Certain Chemical Substances; Withdrawal of Significant New Use Rules*, 74 Fed. Reg. 42177 (August 21, 2009).

In its June 2009 Report, the ITC also notes that EPA intends to propose a TSCA Section 8(a) rule to collect data and information on the production, uses, and potential for exposure to existing nanoscale materials. Further, the Agency plans to develop a proposed TSCA Section 4 rule to gather and develop needed data relating to the effects of nanoscale materials on safety, health, and the environment.

These recent actions and proposals by EPA are a part of a continued effort by the Agency to demonstrate its willingness and ability to utilize its regulatory authority under TSCA to better determine and understand the toxicity, exposure, and environmental effects of commonly-used nanoscale materials. These actions also track recent actions by California's Department of Toxic Substances Control (DTSC), which has created a "call-in" program whereby the DTSC is requiring companies and universities that produce CNTs in California to submit any and all information they have pertaining to various questions that address the usage, presence, safety, and hazards of CNTs.

The ITC noted that many government agencies continue to have data gaps pertaining to nanoscale materials. Particularly, the ITC stated that additional data is necessary for occupational exposure to nanoscale materials, including employee exposure risks during manufacturing, processing, and downstream use scenarios. Further, the ITC observed that more data are necessary to assess more fully issues regarding mammalian toxicology (especially human health effects) and to the potential environmental effects of nanoscale materials (including toxicity to wildlife, chemical fate, as well as physical and chemical properties). These data gaps are quite extensive, and 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.

In its Report, the ITC also provided a list of both specific and generic nanoscale materials for which it requires additional data. Included in this list are single- and multi-walled CNTs.⁷

Comments on the ITC's 64th report were to be submitted to EPA on or before September 3, 2009. Based on these and other regulatory actions, research institutions and companies engaged in research, development, and manufacture of CNTs and other nanoscale materials should anticipate increasing regulatory oversight of such materials.

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

Lawrence E. Culleen*

+1 202.942.5477

Lawrence.Culleen@aporter.com

Fern Phillips O'Brian

+1 202.942.5028

Fern.O'Brian@aporter.com

Matthew T. Heartney

+1 213.243.4150

Matthew.Heartney@aporter.com

Karen J. Nardi

+1 415.356.3010

Karen.Nardi@aporter.com

* Senior Legal Assistant Leigh Logan assisted in drafting this advisory.

⁷ Other nanoscale materials addressed include C60 Fullerenes, C90 Fullerenes, Carbon Black (nano form), Titanium Oxide nanowires, Titanium Oxide nanoparticles, Zinc Oxide (nano form), Silver (nano form), Silica [crystalline] (nano form), Quartz (nano form), Cerium Oxide (nano form), Indium Tin Oxide (nano form) (includes various CAS numbers), Dendrimers, Carbon Nanofibers, Quantum Dots with Cd Core, Quantum Dots with Se Core, Nanoceramic Particles, and Nanoclays.