

## **Tiny Particles Get Big Attention**

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**By Lynn L. Bergeson**

Regulatory developments are picking up steam. Here's a summary of key initiatives.

### **Federal Measures**

Nanoscale materials may figure in Toxic Substances Control Act (TSCA) reform. While not mentioning "nanotechnology," a bill introduced on April 15, by Sen. Frank Lautenberg (D-NJ) addresses chemicals with "special substantive characteristics." The bill (<http://lautenberg.senate.gov/assets/SCA2010.pdf>) authorizes the U.S. Environmental Protection Agency (EPA) to evaluate and compel data on new/special uses of existing chemicals "separate from any use of the chemical substance that does not exhibit such special substance characteristics" or on new chemical substances exhibiting such characteristics.

The 21st Century Nanotechnology Research and Development Act is up for reauthorization. The House passed legislation in early 2009, but the Senate didn't take it up last year. Several measures have been introduced to promote nanotechnology safety and/or education.

EPA may adopt a policy under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requiring any pesticide registrant aware that a constituent of a registered pesticide product is at the nanoscale to submit information pursuant to FIFRA Section 6(a)(2). EPA also is expected to confirm that substitution of a nanoscale active or inert ingredient for a conventionally-sized active or inert ingredient in a FIFRA-registered product requires an application amending that registration.

EPA clarified in November 2008 that carbon nanotubes (CNT) are generally considered "new" substances and thus manufacturers (including importers) must submit a Premanufacture Notice (PMN) prior to commercial activities. CNT manufacturers had until March 2009 to address TSCA obligations. EPA confirmed this March that approximately two-thirds of all TSCA inspections since March 2009 have been directed at CNT manufacturers; some may face enforcement actions if they neglected TSCA obligations are neglected.

The White House Office of Science and Technology Policy in March 2010 created a new interagency group on emerging technologies, including nanotechnology, to provide a forum to discuss emerging policy issues.

EPA also has been busy with rulemaking. EPA announced in February that it will propose a categorical Significant New Use Rule (SNUR) for nanoscale chemical substances under TSCA Section 5. The SNUR would require nanoscale substances' manufacturers to obtain approval of "significant new uses" of existing nanoscale substances. EPA is expected to identify existing nanoscale substances that share the same molecular identity as their conventionally-sized counterparts on the TSCA Inventory as a "category" of chemical substances.

EPA is working on a TSCA Section 4 test rule where chemical manufacturers must develop data to determine health effects of certain multi-wall CNTs and nanosized clays and alumina. EPA intends to propose the rule in 2010.

EPA also is developing a proposed TSCA Section 8(a) rule to establish reporting requirements for "certain nanoscale materials." It's likely to include "existing chemical nanoscale materials."

### **State Measures**

The California Department of Toxic Substances Control (DTSC) in early 2009 issued a data call-in (DCI) requiring submission of data and information by last January from CNT manufacturers. In 2010, DTSC is expected to issue DCIs for data on nanometal oxides, including titanium dioxide and zinc oxide, and nanometals, including silver and zerovalent iron.

### **International Measures**

Health Canada began a public consultation on March 1 to adopt the Interim Policy Statement on the now in effect Health Canada's Working Definition for Nanomaterials (Interim Policy). For this initiative, "nanoscale" means one to 100 nanometers; "manufactured" includes engineering processes and control of matter and processes at the nanoscale. For more information see [www.hc-sc.gc.ca/sr-sr/consult/\\_2010/nanomater/index-eng.php](http://www.hc-sc.gc.ca/sr-sr/consult/_2010/nanomater/index-eng.php). The policy seeks to establish ways to identify nanomaterials to assist in collecting information and establishing "internal inventories" for products, materials, and substances that are, contain, or make use of nanomaterials, and to support Health Canada's regulatory frameworks.

New European Union (EU) cosmetics legislation established on January 11 for the first time requires cosmetic products that contain nanoscale ingredients to be labeled as such starting in January 2013.

Finally, for an excellent summary of current and planned global nanotechnology governance activities, see the Organization for Economic Cooperation and Development report "Current Development/Activities on the Safety of Manufactured Nanomaterials" ([www.oecd.org/dataoecd/49/49/44947758.pdf](http://www.oecd.org/dataoecd/49/49/44947758.pdf)).

As you can see, there's a lot going on in nanoscale material governance. Interested stakeholders should monitor these developments carefully and engage often.

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*Lynn is managing director of Bergeson & Campbell, P.C., a Washington, D.C.-based law firm that concentrates on chemical industry issues. The views expressed herein are solely those of the author. This column is not intended to provide, nor should be construed as, legal advice. You can e-mail her at [lbergeson@lawbc.com](mailto:lbergeson@lawbc.com).*