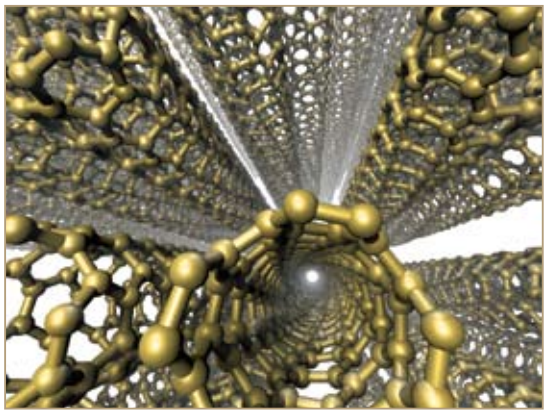
What's new in nano?

By Lynn L. Bergeson

There are many nanotechnology governance activities underway at the federal, state, and international levels of which nano aficionados should be aware. Here is a quick summary of key initiatives.

Federal

***Legislation*:** While not mentioning "nanotechnology," a bill introduced on April 15, 2010, by Senator Lautenberg (D-NJ) contains provisions pertinent to variants of chemicals with "special substantive characteristics." The bill, S. 3209, authorizes the U.S. Environmental Protection Agency (EPA) to evaluate and compel data on new or 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 special substantive characteristics.



Policies: EPA is considering adopting a policy that would require any pesticide registrant that is aware a constituent of a registered pesticide product is at the nanoscale to submit the information to EPA pursuant to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 6(a)(2). EPA is also expected to confirm its view that substitution of a nanoscale active or inert ingredient for a conventionally sized active or inert ingredient in a FIFRA-registered product requires the registrant to submit an application to amend that registration. EPA clarified in November 2008 that it generally considers carbon nanotubes (CNT) to be "new" substances under the Toxic Substances Control Act (TSCA), and, thus, manufacturers (including importers) are required to submit a Pre-Manufacture Notice (PMN) as a prerequisite to commercial activities. CNT manufacturers had until March 2009 to address their TSCA obligations. EPA confirmed in March 2010 that approximately two-thirds of all TSCA inspections since March 2009 have been directed at CNT manufacturers, some of which could be in enforcement jeopardy if any neglected to address their TSCA obligations in view of EPA's CNT policy.

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

Rulemakings: EPA announced in February 2010 that it will propose a categorical Significant New Use Rule (SNUR) for nanoscale chemical substances under TSCA later this year. The SNUR would require manufacturers of nanoscale substances to obtain EPA approval of "new" uses of existing nanoscale substances deemed "significant new uses." EPA is expected to identify existing nanoscale substances that share the same molecular identity as their conventionally sized counterparts listed on the TSCA Inventory as a "category" of chemical substances.

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

EPA also is working on a proposed TSCA Section 8(a) rule to establish reporting requirements for "certain nanoscale materials." The rule is likely to include "existing chemical nanoscale materials."

State

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

International

On March 1, 2010, Health Canada began a public consultation on its adoption of the *Interim Policy Statement on Health Canada's Working Definition for Nanomaterials* (Interim Policy), which is now in effect. For purposes of this initiative, the term "nanoscale" means 1 to 100 nanometers; the term "manufactured" includes engineering processes and control of matter and processes at the nanoscale. According to Health Canada, the key objectives of the Interim Policy are to establish a working means of identifying nanomaterials to assist in collecting information and establishing "internal inventories" regarding products, materials, and substances that are, contain, or make use of nanomaterials and to support regulatory frameworks under the authority of Health Canada.

On Jan. 11, 2010, new European Union (EU) cosmetics legislation entered into force. It requires cosmetic products that contain nanoscale ingredients to be labeled as such. The notification requirements pertinent to products containing nanomaterials apply in January 2013. This is the first EU requirement expressly requiring the labeling of cosmetic products containing nanoscale materials.

Finally, for an excellent summary of current and planned global nanotechnology governance activities, see the March 2010 Organization for Economic Cooperation and Development (OECD) report *Current Development/Activities on the Safety of Manufactured Nanomaterials*, available at the OECD's Web site.

Lots in which to engage and monitor! Stay tuned.

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