

Developments on nanomaterial governance in US gather pace

Nanotechnology governance initiatives in the US abound and there is no reason to think the pace will slow. Lynn L. Bergeson **offers a summary of key initiatives.**

Congress is considering legislation to amend the Toxic Substances Control Act (TSCA), the core federal chemical management law (🔗 **CW 15 April 2010**). Under the current interpretation of the US Environmental Protection Agency (EPA), a chemical sharing the same molecular identity as a chemical listed on the TSCA inventory is considered an existing chemical (and thus no premanufacture notice is required), regardless of whether the chemical possesses novel properties that influence its risk profile. Some believe this interpretation has contributed to the current debate questioning TSCA's core adequacy.

While never mentioning "nanotechnology," a bill (S 3209) introduced in the Senate in April contains provisions pertinent to variants of chemicals with "special substance characteristics", language widely believed to be a surrogate for nanoscale chemical substances. The bill authorises the agency 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.

The House of Representatives is also expected soon to introduce TSCA reform legislation. In a discussion draft of House legislation circulated in April, "substance characteristic" is defined "with respect to a particular chemical substance, the physical and chemical characteristics that may vary for such substance," and whose variation may bear on toxicological properties, including chemical structure and composition, size or size distribution, shape, surface structure, reactivity, and other characteristics and properties that may bear on toxicological properties. It is unclear if any House bill will contain similar language. Even if it does, it is unclear whether more mature TSCA reform proposals will reflect this approach essentially to regulate nanoscale substances as new chemicals.

In April, the EPA expressed interest in adopting a policy pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that would require any existing pesticide registrant that is aware a constituent of a registered pesticide product is at the nanoscale to submit notification of that information to the agency under FIFRA section 6(a)(2), which requires pesticide registrants to submit to the EPA "adverse

information the EPA seeks by reinterpreting section 6(2)(2) in the first place. At the time of writing, issuance of the new policy has been delayed, reportedly due to concerns other federal agencies have with the policy.

The EPA is also expected soon to formally 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

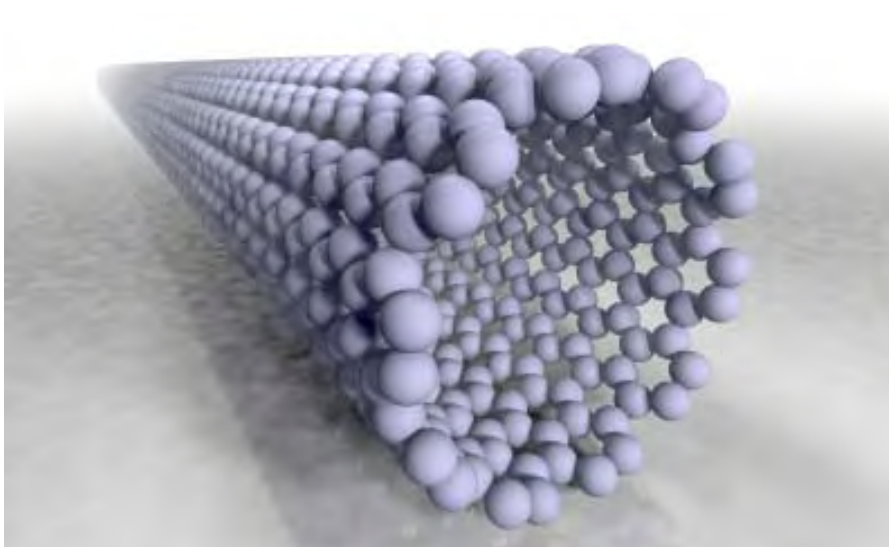


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Facilities manufacturing carbon nanotubes have been a priority for EPA inspections

effects" information about their products. Many have expressed significant concern with the agency's reinterpretation of these provisions to obtain information regarding the presence of nanomaterials in registered pesticide products. The concern is that this approach will stigmatise nanopesticides, brand any information submitted in connection with nanopesticides as "adverse effects" information (thereby inviting product liability and/or personal injury claims) and fail to yield the

registrant to submit an application to amend that registration. The EPA has maintained this position publicly for several years, but has yet to express it in any formal written document.

The agency has also said it intends soon to formally respond to the International Council on Technology Assessment (ICTA), petition filed on 1 May 1 2008, urging it to adopt the view that products containing nanoscale silver should be regulated as pesticides. The ICTA points to "preliminary evidence" that nanosilver can exert effective antibacterial action at a considerably lower concentration than that of silver ions, suggesting that the antibacterial properties and toxicity of nanosilver are not explained purely by its chemical composition and the production of silver ions. The council asked the EPA to take action on an estimated 600 unregistered nanosilver products marketed in the US.

The agency clarified in November 2008 that it generally considers carbon nanotubes (CNTs) to be "new" substances under TSCA

The Senate bill contains language believed to be a surrogate for nanoscale chemical substances

and thus manufacturers (including importers) are required to submit a premanufacture notice as a prerequisite to commercial activities. CNT manufacturers had until March 2009 to address their TSCA obligations. The EPA confirmed in March this year that approximately two thirds of all TSCA inspections since March 2009 have been directed at CNT manufacturers, some of which are expected to be in enforcement jeopardy if any neglected to address their TSCA obligations under the agency's CNT policy.

According to a report released by the federal Government Accountability Office (GAO) last month ([CW 1 July 2010](#)), the agency faces challenges in effectively regulating nanomaterials that may be released in air, water, and waste because it lacks the technology to monitor and characterise these materials, or each controlling federal statute includes volume-based regulatory thresholds that may be too high for effectively regulating the production and disposal of nanomaterials.

In preparing its report, the GAO identified examples of current and potential uses of nanomaterials; determined what is known about the potential human health and environmental risks from nanomaterials; assessed actions the EPA has taken to understand better and regulate the risks posed by nanomaterials as well as its authorities to do so; and identified approaches that other selected national authorities and actions US states have taken to address the potential risks associated with nanomaterials. It also analysed selected laws and regulations, reviewed information on the EPA's Nanoscale Materials Stewardship Program, and consulted with EPA officials and legal experts to obtain their perspectives on the agency's powers to regulate nanomaterials.

The report identifies marketed products that incorporate nanomaterials already available across eight sectors: automotive; defence and aerospace; electronics and computers; energy and environment; food and agriculture; housing and construction; medical and pharmaceutical; and personal care, cosmetics, and other consumer products. Within each sector, it identified a variety of other uses that are currently under development and are expected to be commercialised soon. It also says the extent to which nanomaterials present a risk to human health and the environment "depends on a combination of the toxicity of specific nanomaterials and the route and level of exposure to these materials."

The White House Office of Science and Technology Policy (OSTP) announced in March 2010 that it has created a new inter-

agency group on emerging technologies, including nanotechnology, to provide federal agencies with a forum in which to discuss emerging policy issues. The forum is expected to enhance communication and coordination on nano policy issues.

Earlier this month the OSTP published a Request for Information on the National Nanotechnology Initiative (NNI). According to the OSTP, the purpose of the request is to enhance the value of the NNI by seeking comments from stakeholders by 15 August for

The EPA faces challenges regulating nanomaterials released in air, water, and waste – GAO

the next NNI Strategic Plan, which is due in December. The OSTP is interested in responses that address one or more of its questions, which are broadly categorised under goals and objectives; research priorities; investment; coordination and partnerships; evaluation; and policy, as related to the NNI.

SNUR for nanomaterials

The EPA announced in February that it will propose a categorical TSCA significant new use rule (SNUR) for nanoscale chemical substances this year. The SNUR will require manufacturers of nanoscale substances to obtain EPA approval of new uses of existing nanoscale substances deemed "significant new uses." The agency 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.

The EPA plans to issue a TSCA section 4 test rule this year 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.

It also says it is developing 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".

Last year, the California Department of Toxic Substances Control issued a data call-in requiring the submission of data by January

2010 from CNT manufacturers. This year it is expected to issue call-ins for data on nanometal oxides, including nano titanium dioxide and nano zinc oxide, and nanometals, including nanosilver and nano zerovalent iron.

The draft regulations for safer consumer product alternatives, issued by the department on 23 June, would create a list of chemicals that it deems "toxic" and believes could harm people or the environment. Products containing those chemicals would be prioritised based upon such factors as the volume in commerce, the extent of public exposure, and how the product is eventually disposed. Manufacturers of those products would have to perform an "alternatives assessment" ([see pages 13-14](#)) to determine if a viable safer alternative is available.

Curiously, nanoscale is defined under the proposal as one or more dimensions of the order of 1,000nm or less, rather than the usual 100nm. This definition adds more fodder to the global debate over the nanomaterials definitional void that plagues the nano community. The department intends to complete the formal Administrative Procedures Act (APA) rulemaking process by the end of this calendar year. Further comment will presumably be accepted at that time.

There is a lot in which to engage and monitor. Stakeholders are urged to engage as often as possible to ensure governance initiatives are properly focused.

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