

Experts review legal, regulatory issues surrounding nanotechnology

Pesticide and Toxic Chemical News
Monday July 28 2008

Legal and other experts last week provided an update on regulatory and litigation developments surrounding nanomaterials under FIFRA and TSCA during a seminar hosted by the Environmental Law Institute.

Roger Martella, a former general counsel for EPA, and currently a partner in the law firm of Sidley & Austin, outlined the regulation of nanomaterials under TSCA, because, in his view, "nanotechnology begins with TSCA."

He said EPA has concluded that TSCA does apply to nanomaterials. The more controversial issue is whether a nanomaterial is a new or existing chemical. The answer triggers different provisions of the law.

If a nanomaterial is a new chemical, it triggers Section 5 under TSCA, which requires pre-manufacturing notices and gives EPA a 90-day period to analyze the new chemical before it goes into production. If EPA has concerns about the health risks or other risks of the new chemical, it can impose limitations on the manufacturing, processing, use and distribution of the new chemical.

If a nanomaterial is deemed an existing chemical, there are more limits on the authority of EPA to regulate it.

According to Martella, the determination of whether a nanomaterial is a new or existing chemical depends on whether the chemical is listed in the TSCA inventory under Section 8, which lists all the chemicals currently regulated under TSCA. If it is not on that list, it is a new chemical. If it is on the list, it is an existing chemical. Basically, from EPA's perspective, the size of the chemical is irrelevant.

In evaluating any chemical, EPA looks at its molecular identity — the type and number of atoms, the chemical bonds, etc. If the molecular identity is the same for a chemical, whether in nano or macro form, it is considered the same chemical. The fact that a nanomaterial may have different properties when put into an application is irrelevant in EPA's determination.

While EPA does concede that you can have a new, engineered nanomaterial, such as a nanotube, which does not have a macro equivalent, such new materials would be deemed new chemicals subject to regulation under Section 5 of TSCA.

Environmental and consumer advocates, such as Environmental Defense Fund, have argued that the issue is not as simple as molecular identity. Rather, they contend EPA

should be looking at the effects of these chemicals and that they behave differently at a nanoscale. They assert that all nanomaterials are new chemicals, subject to regulation under Section 5 of TSCA.

Nanomaterials as Pesticides

George Kimbrell, a staff attorney representing the International Center for Technology Assessment (ICTA) contends that nanomaterials can also be pesticides, subject to regulation under FIFRA. As an example of a nanomaterial that constitutes a pesticide, Kimbrell focused his discussion on nanosilver.

Concerns about nanosilver in the environment were first raised by public utilities. In February 2006, public utilities and one of their umbrella organizations, the National Association of Clean Water Agencies, wrote letters to EPA expressing concern about a washing machine, manufactured by Samsung, which releases silver ions with each cycle. Their concern centered on how to remove nanosilver from their wastewater systems. They expressed serious concern about nanosilver's impacts on microorganisms and ecosystems, and proposed EPA regulation of this nanomaterial.

In September 2007, EPA issued its "Guidance on Ion Generation Machines," which allowed washing machines with silver ions to stay on the market, as long as they register the silver as a pesticide. The guidance disavowed any type of action to regulate nanotechnology or nanomaterials. According to Kimbrell, the guidance didn't provide "any ability for the public to comment on the rest of the nanosilver universe or potential for broader regulation of nanosilver."

In 2006 EPA also said it would not regulate nanomaterials as pesticides unless companies were claiming on the product labels that the nanomaterials had germ-killing or anti-microbial properties. Kimbrell claims this provided "quite a big loophole under FIFRA" because at this point, "with even the specter of regulation, companies dropped their germ-killing or anti-microbial claims on their labels and even eliminated reference to the presence of nanomaterials in their products as a way to evade review under FIFRA. Last May, ICTA filed a legal petition against EPA calling on it to regulate nanosilver as a pesticide (see PTCN, May 5, Page 1). In its research, ICTA found more than 270 consumer products available in the United States with nanosilver.

ICTA's petition states that nanosilver is a pesticide under FIFRA because it is an antimicrobial agent and it is intended to kill pests. Kimbrell contends that FIFRA has a very broad definition of what can constitute a pesticide — namely "it is essentially, with enumerated exceptions, anything that is intended to kill pests, including microorganisms."

ICTA argues that because these consumer products are being infused with nanomaterials to serve as a germ killer, they are pesticides, subject to regulation under FIFRA.

In support of its claims, ICTA references a \$212,000 fine levied by EPA against a California company for claiming the nanosilver in some of its computer peripherals protected against germs.

— *Shawna Bligh*

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Report outlines nano regulatory blueprint for next administration

Former EPA official J. Clarence Davies released a report last week entitled "Nanotechnology Oversight: An Agenda for the Next Administration." Oversight is essential, according to Davies, in order to "ensure that the benefits of nanotechnology are maximized and the risks are identified and controlled."

The report has more than 35 recommendations for the next White House administration, which Davies divides into short and long-term agendas.

Among the recommendations, Davies' report encourages the next administration to "maximize the use of existing laws," such as TSCA and the Federal Food Drug and Cosmetic Act (FFDCA). Defining all nanomaterials as new substances under both statutes would, according to the report, enable EPA and the Food and Drug Administration to "consider the novel qualities and effects of nanomaterials." Short-term recommendations include:

- Increasing funding of environment, health and safety (EHS) research, requiring a peer reviewed EHS research plan, strengthening of the National Nanotechnology Initiative (NNI), separation of the NNI's promotional and oversight functions and establishment of a Nanotechnology Effects Institute;
- Regulatory coordination among all federal agencies;
- Increasing budgets and staffing for regulatory agencies;
- Increasing federal agency actions to promote the collection of information on nanotechnology within EPA, FDA and the Occupational Safety and Health Administration (OSHA) and encouraging regulatory rulemaking targeted at nanomaterials;
- Promoting voluntary efforts to analyze nanotechnology risks; and
- Public involvement, including dissemination of nanotechnology information, and promoting stakeholder dialogue.

The report's long-term agenda suggests amendments to both TSCA and the FFDCA to improve their ability to adequately address nanomaterials in cosmetics, food packaging and dietary supplements, as well as utilization of OSHA to regulate worker exposure to nanoparticles.

The report also recommends improvement to the government's forecasting abilities and the creation of a commission to study the oversight of new or emerging technologies. The report says "nanotechnology comes in a treasure chest of riches and a Pandora's box of evils" and concludes that the "challenge of the new century and to the new administration is to use the treasure while keeping shut the lid on the Pandora's box."

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