EPA issues significant new use rules for two nanomaterials

EPA earlier this month announced it is promulgating significant new use rules (SNURs) under TSCA for two nanomaterials — siloxane modified silica nanoparticles and siloxane modified alumina nanoparticles — that were subject to premanufacture notices (PMNs). Some stakeholders view the move as a further sign that EPA is willing to use its authority to regulate nanomaterials, although to what extent remains uncertain.

The rules take effect on Jan. 5, 2009 unless the agency receives critical comments before Dec. 5.

The SNURs are the latest action from EPA on the nanotechnology front. The agency recently issued a consent order for carbon nanotubes (see *PTCN*, Oct. 20, Page 1). In addition, EPA provided clarification of TSCA requirements for carbon nanotubes last month (see *PTCN*, Nov. 3, Page 23).

Fewer than 10 SNURs for nanomaterials have been promulgated, according to EPA spokesperson Enesta Jones, but she could not name the materials or when the SNURs had been promulgated because of confidential business information protections.

With the most recent SNURs, anyone who intends to manufacture, import or process either siloxane modified silica nanoparticles or siloxane modified alumina nanoparticles for a significant new use, which includes using either substance without gloves or a respirator and using either substance as a powder, is required to notify EPA at least 90 days before beginning to do so.

"The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs," the agency said in a Nov. 5 Federal Register notice.

According to their PMNs, siloxane modified silica nanoparticles and siloxane modified alumina nanoparticles will be used as additives. Based on data from tests of unidentified analogous material and the substances' physical properties, EPA has determined that there are concerns for lung effects from inhalation and systemic effects from dermal exposure. However, the PMNs indicate worker inhalation exposure to the alumina nanoparticles is expected to be minimal, inhalation exposure to the silica nanoparticles is not expected, and dermal exposure to both materials is also not expected.

"Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance[s] may present an unreasonable risk," the agency said in the FR notice. "EPA has determined, however, that use without impervious gloves or a NIOSH-approved respirator with an [Assigned Protection Factor] of at least 10; the manufacture, process, or use of the substance[s] as a powder; or uses of the substance[s] other than as described in the PMN[s] may cause serious health effects."

EPA would have to be notified at least 90 days before anyone began to manufacture,

process or use the nanomaterials in such ways.

The agency has also determined that the results of a 90-day inhalation toxicity test would help characterize the human health effects of the two nanomaterials, although the test isn't required.

"Manufacture can occur as long as the manufacturer does not engage in the significant new uses," Jones told *Pesticide & Toxic Chemical News* via e-mail.

"[The 90-day inhalation toxicity test] is the test EPA recommends to be conducted to address health concerns cited in the SNUR. In other words, if a manufacturer wants to engage in the new uses or have EPA modify or revoke the SNUR, then conducting these tests could help EPA change its original findings."

The 90-day inhalation study is the same study that is required under the recently issued carbon nanotube consent order. But the study is not designed for determining chronic effects or for nanomaterials, according to John Monica, head of the nanotechnology practice group at the law firm of Porter Wright Morris & Arthur.

Monica told PTCN that EPA can recommend alterations to a study to make it more relevant for a specific material, and in fact did so for the inhalation studies requested in some of the other non-nanomaterial SNURs also announced in the Nov. 5 FR notice.

The SNURs and consent order are a "great opportunity" to get testing done on nanomaterials, but EPA needs to sit a group of experts down to determine how chemical test guidelines need to be modified for nanomaterials, Monica said. "During the request for comments [on the SNURs], someone will raise or should raise the issue."

Monica added he would expect someone to ask EPA to identify the analagous materials and test data it used to determine there are concerns for certain effects.

The SNURs, consent order, and carbon nanotube notice indicate what EPA has maintained all along — that EPA has the authority to regulate nanomaterials under TSCA and is willing to use it, Monica said.

Betsy Mason, an associate in the law firm Goodwin Procter's Environmental and Energy Practices, echoed Monica, telling PTCN that EPA's recent actions show "the agency is willing — perhaps more now than previously — to use the different legal tools available to it under TSCA Section 5 to regulate nanomaterials."

But Mason also noted that it isn't yet clear whether the agency is shifting away from relying on voluntary industry efforts like the Nanoscale Materials Stewardship Program to "bona fide regulation and enforcement" or if it's using the SNURs and consent order as a supplement to encourage more volunteers to participate in such initiatives.
"In either case, I think it's reasonable to expect that EPA will issue more nano-related consent orders and more nano-related SNURs in the future," she said.

U.K. commission urges testing

While EPA is starting to use some of its regulatory powers to address the potential risks of nanomaterials, the United Kingdom's Royal Commission on Environmental Pollution is urging quick action on testing and regulating nanomaterials in a report published Nov. 12.

The commission, which is appointed by the Queen and funded by the government, publishes in-depth reports on critical environmental issues. In its current report, "Novel Materials in the Environment: The Case of Nanotechnology," the commission finds no evidence of harm to human health or the environment from nanomaterials.

"However, it is very early in the development of this technology, and the amount of testing has been relatively limited," the commission said in a statement. "We are aware that laboratory tests on some nanomaterials suggest that they have properties which could cause concern. This strengthens our case for an increase in the amount and type of testing to assess whether these theoretical risks are real, and to monitor their behavior in the environment."

Furthermore, this research has to be done "on a more systematic and strategic" basis, which includes evaluating methods for predicting the fate and effects of nanomaterials, better understanding of the principles that determine nanomaterial toxicity, and enhancing nanomaterial monitoring and surveillance methods, the commission says in its report.

As for the U.K. government, the commission recommends that any revisions to existing regulations should be focused on the properties of nanomaterials, not their size. "Since these properties and functionalities will often differ substantially from those of the bulk material, strict chemical equivalence does not preclude the need for a separate risk assessment," the report says.

Furthermore, the government should prioritize testing, starting with those materials with properties suggesting they pose a risk to human health or the environment. The government should also require companies to report any "reasonable suspicion" that a nanomaterial poses a risk "at the earliest opportunity."

The commission's report is available at www.rcep.org.uk/novelmaterials.htm.

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