WILMERHALE

EPA to Seek Voluntary Disclosure from Nanomaterials Manufacturers to Assess Environmental Risks and Guide Regulation under TSCA

2005-05-27

The US Environmental Protection Agency (EPA) recently announced a June 23, 2005, public meeting to discuss a pilot program seeking voluntary disclosure of nanomaterials characterization and manufacturing information from industry. The EPA has indicated that it will use that information to inform an initial characterization of risks potentially posed by various nanomaterials in the workplace and other contexts, and, if warranted, as the basis for mandatory reporting, safety testing and/or other direct regulation.

The announcement underscores the key environmental regulatory question facing manufacturers of nanomaterials. That is, whether their particular products are, or will be deemed "new" chemical substances—substances of a "particular molecular identity" that are not already listed on the EPA's inventory of chemicals in commerce (the TSCA Inventory)—and therefore will be subject to pre-manufacture EPA review and approval under the Toxic Substances Control Act (TSCA). The EPA acknowledges the significant regulatory uncertainty surrounding this issue due to the assumed insufficiency of existing chemical naming and identification protocols as applied to nanomaterials. However, the Agency provides no guidance concerning how it will resolve the TSCA Inventory status question in individual cases—or the enforcement consequences of its future status determinations for nanomaterials already in commerce. Rather, the EPA advises that manufacturers (and importers) should resolve the regulatory status of their nanomaterials with the Agency on a case-by-case basis, by submitting a Notice of Bona Fide Intent to Manufacture. For purposes of the pilot program, the EPA is interested only in nanoscale materials already listed on the TSCA inventory (i.e., "existing" chemicals).

The public meeting will be held on June 23, 2005, from 9:00 a.m.-5:00 p.m., at the Washington Plaza, 10 Thomas Circle NW, Washington, DC. The Agency also will accept written comments on the program prior to the meeting date.

Background:Pre-manufacture Review under TSCA

Subject to certain exemptions, TSCA requires chemical manufacturers and importers to submit a pre-manufacture notification (PMN) to the EPA prior to manufacturing a "new" chemical substance.

Preparing a PMN is a time-consuming and costly undertaking, and includes submitting physical data regarding the substance; data on the circumstances of anticipated use, exposure and release; and information on known health effects. After PMN submittal, the EPA has 90 days to complete a screening risk assessment and to either allow the substance to be manufactured and used without conditions, or to limit manufacture or use (usually by negotiated consent order). Manufacturing or importing a substance that has not undergone such review (if not otherwise exempt) is a violation of law.

Contemplated Voluntary Reporting Program

As described, for "new" chemicals, the EPA has broad authority through the PMN (and exemption application) process to collect information and impose use restrictions on a case-by-case basis, as warranted, to assess and assure protection of human health and the environment. However, for "existing" chemicals, the Agency's authority to require testing or impose restrictions is limited by the obligations to first make certain threshold administrative findings of risk, and to complete formal rulemaking procedures. Satisfying these procedural hurdles is time-consuming, resource-intensive and a frequent source of legal challenges. The contemplated voluntary reporting program might allow the Agency to avoid—or at least defer—such rulemaking.

Broad participation in the voluntary program may expedite the EPA's decision-making process regarding any mandatory nanomaterial regulation. But data, information and insight obtained from a well-designed program may also result in more narrowly tailored reporting, or the creation of other rules appropriate to particular circumstances.

New Regulatory Identification and Nomenclature Regime for Nanoscale Materials

More immediately—and equally important—the EPA apparently will use information generated at the public meeting and from the pilot program as the basis for a new chemical substance naming and identification system for nanoscale materials. This system will identify and distinguish not only between macro-scale and nanoscale varieties of "existing" chemicals, but also between existing chemicals and similar (perhaps chemically identical) nanomaterials that the EPA may seek to treat as "new." (The TSCA Inventory identification rules for genetically modified organisms are an example of such an alternative identification methodology.) It is uncertain whether the Agency would act by guidance or rule in establishing any such regime, or whether it would coordinate its efforts with the Chemical Abstracts Service or standards-setting organizations, such as the ASTM International E56 Committee, already working to develop uniform terminology for nanoscale materials.

The EPA Seeks Industry Input by June 23, 2005

Either at the public meeting or in written comments, the EPA seeks industry input on several specific issues, some of which may have implications far beyond any voluntary reporting program, and likely will affect the shape of future nanomaterial regulatory policy. These general nanomaterials policy issues include the following:

- What kinds of information are relevant to the evaluation of potential risks from exposure to

nanoscale materials through their contemplated lifecycle?

- What properties of materials and what methodological approaches are appropriate to characterize and distinguish between various nanoscale materials for regulatory purposes (i.e., TSCA Inventory listings, and potential reporting, use restriction and testing requirements)?
- Is nanoscale material manufacturing process information relevant to identifying particular substances and their properties and characteristics?
- What considerations and approaches are appropriate in developing specialized identifying nomenclature for nanoscale materials for regulatory purposes?
- Should participation in a voluntary pilot program have TSCA Inventory consequences?

The EPA also seeks comment more directly related to the possible voluntary program, on matters such as:

- What should be the purpose and scope of a voluntary reporting program?
- How should the EPA define the nanoscale materials (size, dimensions, shapes, etc.) to be covered by the program?
- Should the program be narrow (looking, for example, only at substances involving environmental release or only those in commercial use) or should it be broad (covering, for example, materials at the R&D stage)?
- How should the program be designed in respect to administration, outcomes, duration, deliverables and next steps?
- Is a voluntary program feasible? Valuable?
- Will companies likely volunteer for such a program? What incentives could the EPA offer to encourage broad participation?
- Comment Period an Opportunity for Industry

The broad agenda of issues proposed for the meeting (and for comment) is an indication of the novelty of the myriad regulatory issues raised by nanoscale materials, and also perhaps of the limits of the EPA's current, defensible information and the potentially related absence of Agency prejudgments. The Agency should be commended for starting the dialog on nanoscale materials by gathering information that may provide a full context for assessing the variety of these materials. In the past, at times, the EPA has acted without such context and, for example, developed a regulatory program for PCBs under TSCA in a manner relatively practicable for one industry (electrical equipment), but largely impracticable or illogical for PCBs' many other applications.

Nanomaterials manufacturers, importers and processors need to be aware of this ongoing dialog and should consider participating in it, both to educate the EPA, and to assure that any regulatory obligations or enforcement policies ultimately arising from the dialog are appropriate, based on sound science and practicable.

For more information on this issue or other nanotechnology and environmental matters, contact either of the authors listed above.