



WASHINGTON WATCH

EPA Proposes Significant Reporting and Recordkeeping Requirements for Nanoscale Materials

By Lynn L. Bergeson

On April 6, 2015, the United States Environmental Protection Agency (EPA) proposed an important rule under Section 8(a) of the Toxic Substances Control Act (TSCA) concerning reporting and recordkeeping requirements for certain chemical substances when manufactured (including imported) or processed at the nanoscale. As discussed below, EPA proposes to require persons that manufacture or process these chemical substances to report electronically to the EPA certain information, including the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing data concerning environmental and health effects. EPA also proposes to require any persons who intend to manufacture or process chemical substances as discrete nanoscale materials after the effective date of the final rule to notify the EPA of the same information at least 135 days before the intended date of commencement of manufacture or processing. Stakeholders in the nanoscale chemical substance area who will be directly impacted by this rule when issued in final should review the proposal carefully, understand the reporting requirements, and prepare for the implications of EPA's review of the forthcoming required information.

Chemical Substances that Would Be Reportable

The proposed rule states:

This proposed rule would apply to chemical substances that are solids at 25 °C and atmospheric pressure and that are manufactured or processed in a form where the primary particles, aggregates, or agglomerates are in the size range of 1-100 nanometers (nm) and exhibit unique and novel characteristics or properties because of their size. The proposed rule would apply to chemical substances containing primary particles, aggregates, or agglomerates in the size range of 1-100 nm in at least one dimension. This proposed rule would not apply to chemical substances that only have trace amounts of primary particles, aggregates, or agglomerates in the size range of 1-100 nm, such that the chemical substance does not exhibit the unique and novel characteristics or properties because of particle size. EPA is proposing these parameters for purposes of identifying chemical substances that are subject to the rule, not to establish a definition of what is a nanoscale material (EPA, 2015, p. 18334).

Discrete Forms

Under the proposed rule, manufacturers and processors of multiple nanoscale forms of the same chemical substance would in some cases need to report separately for each discrete form of the reportable chemical substance. EPA proposes to distinguish the forms based on a combination of three factors:

1. A change in process to affect a change in size and/or a change in properties of the chemical substances manufactured at the nanoscale;

2. A change in mean particle size of ten percent or greater; and
3. The measured change in at least one of the following properties, zeta potential, specific surface area, dispersion stability, or surface reactivity, is greater than seven times the standard deviation of the measured values.

Chemical Mixtures

The proposed rule would also apply to chemical substances that are manufactured or processed in a nanoscale form “solely as a component of a mixture, encapsulated material, or composite.” (EPA, 2015, p. 18335). Chemical substances at the nanoscale that are manufactured but are then incorporated into mixtures, encapsulated materials, or composites by that manufacturer would not require separate reporting for their incorporation. EPA states that the person reporting the chemical substance would have to report each step of its manufacture, processing, and use to the extent it is known or reasonably ascertainable, however.

Exclusions

EPA notes that a chemical substance, as defined under TSCA Section 3(2), does not include any food, food additive, drug, cosmetic, medical device, pesticide, or other excluded materials. EPA states that such materials are not subject to this rule. EPA proposes to exclude certain biological materials (e.g., DNA, RNA, and proteins). EPA sought comment to identify other specific biological materials that should be excluded from reporting and the reasons for excluding them, including microorganisms and viral-based products, lipids, carbohydrates, enzymes, and peptides. EPA proposes to exclude chemical substances that dissociate completely in water to form ions that are less than one nm. This exclusion would not apply to chemical

substances manufactured at the nanoscale that release ions but do not dissociate in water to form those ions. EPA states that it believes that the chemical substances that would be excluded do not exhibit new properties when their size falls in the range of 1-100 nm and manufacturing or processing such substances at the nanoscale should therefore not be subject to the reporting requirements. EPA sought comment to identify other water soluble compounds that should be excluded from reporting and the reasons for excluding them.

EPA proposes to exclude from the reporting requirements nanoclays, zinc oxide, and chemical substances manufactured at the nanoscale as part of a film on a surface. EPA states that it believes that information collected on these materials “would be of limited value because either they have been well-characterized or they present little exposure potential.” (EPA, 2015, p. 18335). EPA requested comment on these proposed exclusions and whether other chemical substances manufactured at the nanoscale should be excluded. EPA notes that the general exemptions to TSCA Section 8(a) reporting would be applicable. Persons that manufacture or process, or intend to manufacture or process, these chemical substances as part of articles, as impurities, or in small quantities solely for research and development would not be subject to this action.

Importantly and perhaps appropriately, EPA proposes an alternative to the existing exemption for small manufacturers. Under TSCA Section 8(a) rules, a company qualifies as a small manufacturer by meeting either of the following two standards:

1. Sales of the company are less than \$40 million per year and the company does not manufacture more than 100,000 pounds annually of an

individual substance at any individual site owned or controlled by the company; or

2. Sales are less than \$4 million regardless of the quantity manufactured.

The proposed rule would define a small manufacturer or processor as any company with sales of less than \$4 million, as the 100,000-pound threshold in the existing exemption “did not contemplate typical production volumes for chemical substances manufactured at the nanoscale.” (EPA, 2015, p. 18335). EPA requested comment on the proposed small manufacturer or processor exemption.

The proposed rule would not require manufacturers or processors to report certain information already submitted to the EPA. EPA states that a person who submitted a TSCA chemical notice under Section 5 on or after January 1, 2005, would not be required to report regarding the same substance under this proposed TSCA Section 8(a) rule except where the person manufactured or processed a new discrete form of the reportable chemical substance. In addition, any person who has already reported under the Nanoscale Materials Stewardship Program (NMSP) part or all of the information that would be required under the proposed rule would not need to report that information again. EPA states that the purpose of these exemptions is to avoid duplicative reporting and, as an example, new chemical notices that have been reviewed as nanoscale materials would not be subject to reporting the same information under the proposed rule.

Timeline for Reporting

EPA proposes that persons who manufacture or process a discrete form of a reportable chemical substance at any time during the three years prior to

the final effective date of the rule would report to the EPA six months after the final effective date of the rule. EPA also proposes a continuing requirement that persons who intend to manufacture or process a discrete form of a reportable chemical substance on or after the effective date of the rule would report to the EPA at least 135 days before commencement of manufacture or processing.

Reportable Information

EPA proposes one-time reporting of certain information, including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety data. For this proposed rule, EPA modified an information reporting form developed for the NMSP. Any person required to report under the proposed rule would supply the information identified in the form to the extent that it is known to or reasonably ascertainable by them. EPA requested comment on whether any information proposed to be collected is duplicative of information collected under other federal statutes and should thus be excluded.

Development of Additional Data

EPA notes that a TSCA Section 8(a) rule may not require persons to develop test data for submission to the EPA. EPA encourages respondents to provide any relevant data on chemical substances manufactured at the nanoscale that they decide to develop, however. EPA suggests that persons who intend to conduct testing consult with the EPA before selecting a protocol for testing a chemical substance manufactured at the nanoscale. EPA also encourages persons who would be required to submit TSCA Section 8(a)

data under the proposed rule to provide information on the potential benefits regarding the reportable chemical substance.

Discussion

The proposed rule is long overdue, as it has been in the works for years. EPA's perseverance is laudable, as on the whole, the proposal is a thoughtful and useful step in gathering much-needed information on existing chemical substances manufactured at the nanoscale.

EPA needs the information requested to conclude confidently that nanoscale versions of existing chemical substances pose no unreasonable risk, and to reassure the public regarding what the nano community has been stating for years. That said, the proposal will almost certainly elicit a broad array of diverse comments from stakeholders along the value chain. The proposal also breaks new ground in requiring reporting under Section 8(a) for processors (who are typically not subject to reporting under Section 8(a) rules, for example, the Chemical Data Reporting [CDR] rule), perhaps in recognition that different discrete nanoscale forms might be produced via processing. The criteria set forth in the proposal for defining what is subject to reporting, what is exempt, and a requirement for future reporting by entities that intend to manufacture or process a discrete form of a reportable chemical substance at least 135 days before commencement of manufacture or processing will be the subject of much debate

Stakeholders should be familiar with the reporting requirements and prepare for the eventuality of a final rule. Once EPA has the information it seeks under the proposal, there may be other areas of interest EPA may be compelled to pursue. Anticipating these implications is important, both in

terms of being prepared for direct implications (other reporting requirements, potential rulemaking, and related regulatory consequences), but also preparing customers, employees, and other commercial stakeholders for the commercial implications of a final rule. As is always the case, being prepared avoids surprises, facilitates compliance, and enables a thoughtful and timely legal and commercial response to important reporting requirements. Additional information, including a Fact Sheet, is available online at: www.epa.gov/oppt/nano/.

References

Environmental Protection Agency (EPA). (2015). Proposed Rule: Chemical Substances When Manufactured or Processed as Nanoscale Materials, TSCA Reporting and Recordkeeping Requirements. Federal Register, 80(65), Monday, April 6, 2015. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2015-04-06/pdf/2015-07497.pdf>

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