

CLIENT ALERT

EPA Proposes New Regulations for Nanoscale Materials in Commerce

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Manufacturers, importers, and processors of products with nanoscale components, take note: these materials are the subject of an important new rulemaking.

On March 25, 2015, the U.S. Environmental Protection Agency (EPA) proposed new reporting and recordkeeping requirements for substances that are manufactured or processed as nanoscale materials. The proposed rule, which would be promulgated under Section 8(a) of the Toxic Substances Control Act (TSCA), is groundbreaking in several respects:

- This is a rare instance in which EPA proposes to use TSCA Section 8(a) to require reporting by **processors** of covered materials. Typically, only chemical manufacturers and importers are subject to these types of requirements.
- This is the first time that EPA would be using its authority under TSCA to collect existing health and safety data on nanoscale materials already in commerce in the U.S.
- The rule would apply to persons who manufacture or process nanoscale materials, either alone or **as a component of a mixture, composite, or encapsulated material.**

Who would be subject to the rule

Manufacturers and processors of nanoscale materials, as described below, would be required to report certain information to EPA and maintain corresponding records.

What materials would be covered by the rule

Nanoscale materials that would be subject to the regulations are those materials that: (1) are solids at 25°C; (2) have primary particles that are 1-100 nanometers (nm) in size; and (3) exhibit unique and novel characteristics or properties because of their size. Moreover, persons subject to the rule would have to report to EPA on each "discrete form" of a nanoscale material that they manufacture or process. A "discrete form" is defined as a substance that, when compared to another form of the same substance, (a) has a different morphology or different coating; or (b) satisfies all of the following criteria:

- is subjected to a change in process to affect a change either the size or properties of the substance;
- has a difference in mean particle size that is greater than seven times the standard deviation of particle size of the other form of the substance; and
- has a measured change in either zeta potential, specific surface area, dispersion stability, or surface reactivity that is greater than seven times the standard deviation of that property in the other (comparative) form of the substance.

What information would have to be reported to EPA

Persons subject to the rule would have to report the following information for each "discrete form" of a nanoscale material that they manufacture or process: (1) specific chemical identity and molecular structure; (2) material characteristics including particle size, morphology, and surface modifications; (3) physical and chemical properties; (4) maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use, or disposal of the substance; (5) use information describing the category of each use by function; (6) detailed methods of manufacturing or processing; (7) exposure information; (8) release information; (9) risk management practices; (10) existing data concerning environmental and health effects; and (11) production volume information.

Deadlines for Reporting

Any person who has manufactured or processed a covered nanoscale material during the **three years** prior to the effective date of the final rule would have to report to EPA within six months of the effective date.

In addition, any person who proposes to manufacture or process a covered material after the effective date of the rule would have to provide the required information to EPA at least 135 days before commencing manufacture or processing of the material. *In other words, the proposed rule would, in effect, establish a new pre-manufacture / pre-processing notification requirement for nanoscale materials.*

Cautionary Note

Although the proposed rule follows more than four years of OMB delay, it still has the potential to catch many companies by surprise. Unlike most requirements under TSCA Section 8(a), the proposed rule would impose reporting obligations on **processors** of nanoscale materials, including processors of nanoscale materials as a component of a composite or encapsulated material. This aspect of the rule has the potential to sweep in many companies in the manufacturing sector who might not ordinarily think of themselves as being subject to regulation under TSCA.

In addition, the new regulations may place companies that are currently manufacturing or importing nanoscale materials in a precarious position if they have not previously submitted a premanufacture notification (PMN) for those materials and EPA deems the materials to be "new" substances for purposes of TSCA. These companies would be well advised to review EPA's guidance addressing what nanoscale materials are considered to be "new substances" to ensure that they are in compliance with the PMN requirements of TSCA, well before EPA's new proposed reporting regulations take effect.

Next Steps

The proposed rule has a 90-day public comment period, after which EPA will review and consider those comments before issuing any final rule. EPA also anticipates a public meeting during the comment period to obtain additional public input. Companies that currently manufacture or process nanoscale materials – or that may do so in the future – should consider participating in the public comment process. This includes companies that manufacture or process nanoscale materials as part of composites or encapsulated materials.

Related CPSC Activity

Readers should also be aware that the Consumer Product Safety Commission's (CPSC) fiscal year (FY) 2016 [budget request](#) seeks \$7 million in funding to establish a Center for Consumer Product Applications and Safety Implications of Nanotechnology (Consumer Product Nanotechnology Center), which is intended "to help enable safe commercialization of consumer products containing nanomaterials by developing test methods to quantify exposures and assess health risks." The collection of data by EPA in this new proposed rule would be relevant to CPSC as they work to develop new methods of identifying and characterizing nanomaterials in consumer products and understanding human exposure and potential health and safety effects. CPSC has been cooperating for years on interagency efforts on nanotechnology, including with EPA. The 2008 Woodrow Wilson International Center for Scholars report evaluating the CPSC's role in nanotechnology concluded that nanotechnology is found in over 1,800 different consumer products regulated by CPSC, including juvenile products, toys, sports and fitness equipment, home improvement and garden equipment, clothing, appliances, computers, and other electronic devices.

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