

CLIENT ALERT

EPA Issues New Reporting Rule for Nanoscale Materials

January 12, 2017

Impacts manufacturers, importers and processors of products with nanoscale components.

On January 11, 2017, the U.S. Environmental Protection Agency (EPA) published a final rule establishing new reporting and recordkeeping requirements for substances that are manufactured or processed as nanoscale materials. The rule, which will take effect on May 12, 2017, is unique in several respects:

- This is the first instance of EPA exercising its authority under Section 8(a) of the new Toxic Substances Control Act (TSCA) to require reporting by **processors** of covered materials.
- This is the first time that EPA is using its authority under TSCA to require submission of health and safety data on nanoscale materials **already in commerce** in the US.
- The rule applies to persons who manufacture or process nanoscale materials, either alone or **as a component of a formulated product or polymer matrix**.

Who is subject to the rule

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

What materials are covered by the rule

Materials will be subject to the rule if they satisfy all of the following criteria: (i) they are solids at 25°C; (ii) they have particles (including aggregates and agglomerates) that are 1-100 nanometers (nm) in size, in at least one dimension; and (iii) they exhibit novel properties because of their size **and** those properties are the reason why the substance is manufactured or processed in that form or size.

Importantly, separate reporting is required for each “discrete form” of a nanoscale material that an entity manufactures or processes. For purposes of the new rule, a “discrete form” is defined as a substance that, when compared to another form of the same substance, (a) has a different morphology or shape; or (b) has a different coating; or (c) satisfies **all** of the following criteria:

- i. Is subjected to a change in process to affect a change in either the size or properties of the substance.
- ii. 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.

- iii. 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 materials are excluded from reporting

The following categories of materials are excluded from reporting under the new rule:

- Materials manufactured or processed in a form in which particles that are 1-100 nm in size comprise less than one percent (by weight) of the substance.
- Certain biological materials such as DNA, RNA proteins and microbes.
- Substances that completely dissociate in water to form ions smaller than one nm.
- Substances formed at the nanoscale in situ, as part of a film on a surface.
- Substances that are not on the Inventory (these substances are subject to the premanufacture notification (PMN) requirements of TSCA Section 5).

The rule also includes exemptions for certain R&D activities as well as for small manufactures and processors (which are newly defined to mean businesses with combined sales of less than \$11 million per year).

What information must be reported to EPA

Persons subject to the rule are required to report the following information for each “discrete form” of a nanoscale material that they manufacture or process, to the extent such information is known to or reasonably ascertainable by the reporting entity:

- a. Specific chemical identity and molecular structure.
- b. Material characteristics including particle size, morphology, and surface modifications.
- c. Physical and chemical properties.
- d. Maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use, or disposal of the substance.
- e. Use information describing the category of each use by function.
- f. Detailed methods of manufacturing or processing.
- g. Exposure and release information.
- h. Risk management practices.
- i. Existing data concerning environmental and health effects.
- j. Production volume information.

Reporting must be done electronically, through EPA’s “CDX” web portal.

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 must report to EPA within one year of the effective date.

In addition, any person who proposes to manufacture or process a covered material after the effective date of the rule must provide the required information to EPA at least 135 days before commencing manufacture or processing of a discrete form of the reportable substance or within 30 days of forming the intent to manufacture or process a covered material, whichever is later.

Cautionary Note

Unlike most requirements under TSCA Section 8(a), the new rule imposes reporting obligations on *processors* of nanoscale materials – including processors of nanoscale materials as a component of formulations or polymer matrices. This aspect of the rule has the potential to sweep in companies in the manufacturing sector that might not ordinarily consider themselves as being subject to regulation under TSCA.

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