



Manufacturers, Importers and Processors of Certain Nanoscale Materials Must Report to EPA

Dec 04, 2017

Categories:

[Publications](#)

Authors:

[Chris Kim Kahn](#)

Nanoscale materials are found in a myriad of products including paints, filters, insulation, lubricants, electronics, batteries, glass, tires, and cosmetics. Manufacturers (including importers) and processors of these products should evaluate whether they manufacture or process nanoscale materials and whether they have any obligations under EPA's rule on reporting of nanoscale materials under the Toxic Substances Control Act (TSCA). Current manufacturers and processors of nanoscale materials subject to the rule have until August 14, 2018 to submit reports through EPA's electronic submission portal.

Nanoscale materials subject to this rule must fit the particle size criteria and the unique and novel properties criteria. The particle size criteria is met if the diameter of the particles range from 1-100 nanometers (nm). A single grain of confectioners (10X) sugar has a particle size of 74,000 nm. Size is not the only criteria to be subject to reporting; the particle size must also impart some unique and novel properties on the material from those associated with other forms or sizes of the same chemical substances. For example, nanoscale silver particles impart antibacterial properties that non-nano-sized silver particles do not possess.

Manufacturers and processors of nanoscale materials should begin, if they have not started already, evaluating whether the reporting obligations under this regulation applies to their activities. This evaluation, as well as the collection of any reasonably ascertainable information and the preparation of any reports, can take some time, particularly if reports for numerous chemicals are necessary. If required, the report must include known or reasonably ascertainable information on the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing information concerning environmental and health effects. The reporting obligation under the regulation is ongoing and persons who intend

to manufacture or process nanomaterials in the future must report to EPA at least 135 days before actual manufacture or processing of nanomaterials. There is no requirement that the person making the report conduct any tests. Instead, the rule requires reporting of known or reasonably ascertainable information to EPA through the electronic submission portal.

Although this regulation requires the reporting of information, EPA has not made a determination of any ascertainable risk associated with nanoscale materials. Instead, the information to be gathered under the rule will facilitate EPA's determination of whether further action is needed for any specific nanoscale material. Consequently, a prudent manufacturer or processor of nanoscale materials will closely evaluate the information being provided to EPA to anticipate any need for further action.

Note, the regulation includes various exemptions from reporting. Exempted from the rule are enzymes, lipids, carbohydrates, viruses and microorganisms. Additionally, "articles" are excluded from the rule, which are defined as a manufactured item formed to a specific shape or design which has an end use function dependent in whole or in part to the specific shape. Fluids and powders can never be excluded articles. Also exempted are small manufacturers and processors.

Certain materials are exempt from regulation under TSCA, including nanomaterials that are: Subject to regulation by the U.S. Food and Drug Administration under the Federal Food, Drug and Cosmetic Act (foods and drugs), used in research and development facilities, subject to U.S. Department of Energy regulation (radioactive material), subject to the Federal Insecticide, Fungicide, and Rodenticide Act (pesticides), or were previously reported to EPA under another TSCA regulation.

Manufacturers and processors will want to evaluate and identify whether they produce or manufacture nanomaterials that must be reported by August 14, 2018, consult with customers and suppliers about known or reasonably ascertainable information, and evaluate any need to make a confidential business information (CBI) claim pertaining to the report.

If you have any questions about the new rule or any other environmental regulatory or litigation issues, please contact [Chris Kahn](#) or [Phil Schworer](#), or any other attorney in Frost Brown Todd's [Environmental Practice Group](#).

© 2026 FBT Gibbons LLP. May be considered attorney advertising in some jurisdictions.