

HETI Horizons

EPA's Information Gathering Rule For Nanomaterials In Commerce

Nanotechnology involves the manipulation of matter on a near-atomic scale to produce new structures, materials and devices. Many, if not most, consumer products utilize nanotechnology. Clothing, sporting goods, skin care, sunscreen, lithium ion batteries, paints and flame retardants all utilize nanomaterials. The continually increasing use of these nanomaterials in the global economy brings continuing challenges to understand, predict and manage potential safety and health risks.

New Reporting and Recordkeeping Requirements



In 40 CFR Part 704.20 *Chemical Substances Manufactured or Processed at the Nanoscale*, the U.S. Environmental Protection Agency (EPA) has established reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale as described in the rule. Specifically, EPA is requiring those companies that manufacture or process, or intend to manufacture or process, these chemical substances to electronically report to EPA certain information – which includes “insofar as known to or reasonably ascertainable by the person making the report, the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing information concerning environmental and health effects”. This rule involves one-time reporting for existing discrete forms of certain nanoscale materials, and a standing one-time reporting requirement for new discrete forms of certain nanoscale materials before those new forms are manufactured or processed.

What Chemicals Are Reportable under the New Rule?

- ◆ EPA defines a reportable chemical substance as a “solid at 25° C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension, and that is intentionally manufactured or processed to exhibit unique and novel properties because of its size”. Items of note in this definition include the size and unique and novel properties of the particles. The rule is designed for nanoscale particles that are purposely generated in the 1-100 nanometer (nm) size range and exhibit different properties than larger sized particles of the same material. [*One nanometer is equal to one billionth of a meter.*] One of the reasons for the explosive growth in the use of engineered nanomaterials (ENMs) in science and industry is the unique properties that they exhibit when they are in size range of less than 100 nm.
- ◆ Nanoparticles of the same material that are engineered to be different shapes, due to the unique characteristics associated with that shape, are both reportable under the rule as new chemicals.
- ◆ Nanoparticles that are coated to another chemical substance are to be reported as a discrete form of the substance.
- ◆ There is no reporting exemption based on production volume or reporting threshold based on production volume.

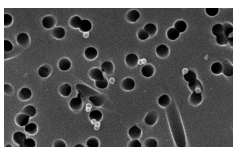
When Are These Chemicals to be Reported?

- ◆ ***The rule became effective on August 14, 2017.***
- ◆ If a company has plans to manufacture a new, discrete form of the chemical substance greater than 135 days in advance, then the company should report this by at least 135 days before manufacturing begins.
- ◆ If a company has plans to manufacture a new, discrete form of the chemical substance less than 135 days in advance, then the company should report this as soon as possible – but no later than 30 days after informing their intent.
- ◆ A company can begin to manufacture or process the new discrete form any time after it has reported under the rule.

What Chemicals Are Not Reportable under the Rule?

- ◆ Nanoparticles in the 1-100 nm size range, that do not exhibit unique and novel properties than similar chemicals at larger sizes, are not required to be reported to the EPA.
- ◆ This rule does not apply to particles or aggregates or agglomerates that exceed 100 nm, even if the individual particles of the aggregates or agglomerates are less than 100 nm.
- ◆ Reporting of mixtures is not required; however new chemicals within the mixture that fit the definition of the rule are reportable.
- ◆ Chemical substances that completely dissociate in water to form ions less than one nanometer are not reportable.
- ◆ Manufacturers and processors are not required to conduct testing or develop information for substances to determine if these substances are reportable. However, they are required to report information that is known or reasonably ascertainable about the products they manufacture, import or export.

Who is Required to Report?



- ◆ Manufacturers of nanoparticles from one nanometer to 100 nm with unique and novel properties.
- ◆ Importers of nanoparticles from one nanometer to 100 nm, including those imported in formulations with unique and novel properties.
- ◆ Exporters of nanoparticles from one nanometer to 100 nm with unique and novel properties.

HETI...Experienced EHS Professionals

HETI provides professional assistance and guidance through the reporting process for companies manufacturing, importing, or exporting chemical substances that are covered by the new rule. We can also assist in developing risk management plans and site-specific SOPs, assessing workplace exposures, and determining exposure control methods for nanotechnology applications.

**To find out more about HETI's nanomaterial support
or other industrial hygiene services, please contact us.**

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