# EPA Reporting and Recordkeeping Requirements of Chemical Substances when Manufactured or Processed as Nanoscale Materials (Final Rule)

Establishes reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale.

Updated last **March 14, 2017**
for the 01/12/17 Final Rule.

#### WHAT IT DOES

The Environmental Protection Agency (EPA) has issued a final rule (noticed via 82 FR 3641) that requires electronic reporting and recordkeeping by manufacturers and processors (including importers) of certain nanoscale chemical substances that are intended for commercial use. EPA derives this authority from the Toxic Substances Control Act (TSCA; 15 U.S.C. 2601 et seq.), specifically its authority to report and retain information on toxic substances (15 U.S.C. 2607, 40 CFR 704). The purpose of this new rule is to compile an inventory of chemical substances at the nanoscale level that are produced for commercial uses. The EPA does not presuppose that these substances pose any specific harm to human health or the environment. Instead, tracking these materials will inform the EPA if additional action under TSCA is necessary. The EPA states that the intention of the new ruling is not to define what is a nanomaterial, but rather to use important characteristics of nanomaterials to identify what qualifies a chemical substance or mixture for reporting.

This new rule applies to manufacturers and processors who are actively producing or importing "discrete" nanoscale chemical substances, as well as those who intend to produce or import such materials. A reportable material must first be considered a "chemical substance," as previously defined by TSCA (15 U.S.C. 2602(2)), and also be:

- Solid at standard temperature and pressure (25 degrees Celsius and 1 atmospheric pressure); and
- Manufactured or processed:
  - In a form where any particles are nanoscale size (1 – 100 nanometer (nm). These include nanoparticles that comprise agglomerates as well as aggregates; and
  - To exhibit unique and novel properties because of its size. Nanoscale substances have different chemical, stability, and reactivity characteristics than substances at the bulk scale (sizes greater than 100 nm). Consequently, if the substance fits the specified size range, yet does not have a size-dependent property that differs from that at the bulk scale, then the substance is not classified, according to the new rule, as reportable nanoscale material.

To be defined as a "discrete" form of a *previously*-reportable chemical substance, the substance must differ from the previous substance in one or more of the following ways:

- Any one or combination of:
  - A modification to at least one property of particular interest for health and human safety evaluation including: *zeta* potential, specific surface area, dispersion stability, or surface reactivity;
  - A change in mean particle size greater than 7 times the standard deviation of the measured values (± 7 times the standard deviation); or
  - A change to the manufacturing process that effects one or both of the following:
    - A change in size; or
    - A change in the substance's properties as listed above;
- The new substance has a different shape; or

- The previously-reportable chemical substance is coated with another, different chemical substance or mixture.

Both engineered and naturally occurring discrete nanoscale materials are subject to this rule.

Exemptions

The rule exempts from reporting certain substances and actors.

Excluded substances include:

- By-products (unintended products or side-products that are also nanoscale), which are not intended to be made commercially available;
- Those materials that comprise less than 1% by weight of the article or compound with which the nanoscale substance is incorporated or surface-associated;
- Certain biological materials;
- Inorganic substances that separate completely in water to form ions that are smaller than 1 nm, because they do not exhibit new size-dependent properties; and
- Nanoscale chemical substances to be used as pesticides (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*), or as a food, food additive, drug, cosmetic or device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*)).

Excluded actors include:

- Research and development entities producing small quantities of discrete chemical substances;
- Entities that have previously submitted a notice under TSCA section 5 to EPA for a reportable chemical substance on or after January 1, 2005, except in the event that a new discrete form of the reportable nanoscale chemical substance has been or is intended to be manufactured or produced. The purpose of this specific exemption is to avoid duplicative reporting; and
- "Small" manufacturers or processors, defined as a company with sales of less than $11 million per year.

Reporting Timeline and Methods

Reporting entities should submit information, as required by previous regulation (40 CFR 704.11), using the EPA Central Data Exchange (CDX) portal, which was established originally under TSCA (40 CFR 704.20(e)).

If an entity is already generating a reportable material, then its production must be reported to EPA within one year of the final effective date of the rule. Companies intending to produce new reportable materials are required to file their report at least 135 days before beginning or within 30 days of having begun the manufacture or process.

EPA will make available the non-confidential information reported under the new rule through their database portal, which is located at ChemView; the agency does not intend to use information reported under this rule to publish an official separate database/inventory for nanomaterials. Entities may claim confidentiality through established EPA processes (40 CFR 704.7).

#### RELEVANT SCIENCE

Chemical substances that have structures with at least one dimension that measures approximately 1 – 100 nanometers (nm) are commonly referred to as nanoscale materials or nanomaterials. The nanoscale is thousands of times smaller than the human eye can see. For instance, a human hair is approximately 80,000 – 100,000 nanometers wide. Thus, a nanoscale chemical substance that is 100 nm large is approximately 800 – 1,000 times smaller than the width of a human hair. Nanoparticles can be attracted to other nanoparticles resulting in either agglomerates, which are nanoparticles weakly bound to one another, or aggregates, which are nanoparticles that are strongly bonded together.

Nanoscale chemical substances typically have properties different than the same chemical substances with structures at a larger scale (also known as the bulk scale), such as greater strength, lighter weight, and greater chemical reactivity. Greater strength and lighter weight could, for example, impart characteristics like light weight but high durability for objects like space ships. Greater chemical reactivity can be either a useful feature or might cause harm. For example, nanoscale materials have the potential to enhance the efficiency of a battery, to detect cancer cells, or to detect whether a person's insulin level is at abnormal levels. But other nanomaterials could enter human cells (or coat them) and alter normal functions, thereby causing cellular dysfunction or perhaps permanent damage.

This new rule focuses on important specific characteristics of particular interest in health and safety evaluation. Such properties include:

- Zeta potential (*electrostatic potential*) measures the tendency of a nanomaterial to move through a particular environment. It is a measure of the average friction that is felt by the nanoparticle, which changes depending on the environment. Measuring this property will help scientists discern, for example, whether nanomaterials released into the environment could move into a local water source and potentially pose health risks.
- Specific surface area is defined as the ratio of the total surface of the nanomaterial per mass of sample (m2/g). This property is an important factor because chemical reactions take place at the nanomaterial's surface, so an increase in the amount of surface also increases the number of possible reactions that could occur relative to the same material with less surface (i.e., bulk scale material). Thus, the higher the surface area as well as the greater amount of nanomaterial, the larger the total surface and greater opportunity for chemical reactions to occur. For instance, one gram (1 g) of nanoparticles that have a specific surface area of 350.0 m2/g would yield a total surface area of 350.0 m2. Thus, 15 grams of this material would provide the same surface area as an American football field (5,351.2 m2).
- Surface reactivity, the potential scale of reactions that could occur at the surface of a material, increases as more surface area is available. Because nanomaterials have much more surface than bulk-scale materials, and because materials only react at their surfaces (rather than at their internal structure), nanomaterials tend to have greater surface reactivity than other materials. Reactivity may influence changes in the local environment as well as to the nanomaterial, which may or may not be detrimental. This property can be beneficial, for example, to enhance battery life and power electric vehicles.
- Shape influences functionality and performance.

This rule also requires reporting of materials that have discrete nanoscale coatings, which fall within the description of 1 - 100 nm in any one dimension. For instance, if a product has a core that is of non-reportable material, but the coating qualifies under the ascribed parameters, then the coating must be reported.

#### RELEVANT EXPERTS

Mike Hochella, Ph.D., University Distinguished Professor of the Virginia Tech Department of Geosciences; Director of the Virginia Tech National Center for Earth and Environmental Nanotechnology Infrastructure (NanoEarth); Affiliate Professor of the Center for the Environmental Implications of NanoTechnology (CEINT) Duke University.

#### BACKGROUND

The European Union has already released regulations regarding nanomaterials. The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation spearheads the classification, labelling, and packaging of chemical substances and mixtures, which aims to ensure a high level of protection of human health and the environment potentially posed by nanomaterials. The EPA position contrasts that of the European Commission, which has rejected the idea of a specific mandatory reporting obligation for nanomaterials. Instead, the European Commission recommends such data to be collected under REACH's registration rules. Accordingly, the European Chemicals Agency developed "nano observatory" pages with existing nanomaterial information.

#### ENDORSEMENTS & OPPOSITION

Endorsements:

- Biotechnology Industry Organization (BIO) submitted a public comment that agrees with the exemption of certain biological materials from the EPA new ruling. BIO stated, "We agree with EPA that the properties of all biological materials such as DNA, RNA and proteins are not a function of the size range of such materials *per se* but rather of the precise molecular structure or nucleotide sequence (in the case of DNA and RNA), shape, and other features, which in each instance will determine the reactivity and other properties of the biological material." In addition, BIO acknowledges and agrees with EPA to exclude reporting of enzymes because of their specific lock-and key configuration that makes them biologically active as well as being produced only by biological processes. Indeed, it "would be almost impossible to accurately report these as nanomaterials or even as derived from nanotechnology, given that they exist in nature almost everywhere on earth and thus are naturally occurring and are not derived from processes using nanotechnology tools."

Opposition:

Nanotechnology Industries Association (NIA) submitted a public comment that indicated reporting of nanoscale materials is duplicative, stating "NIA notes that TSCA already provides requirements for nanomaterials (as for any substance) by the premanufacturing notification process (PMN) and Chemical Data Reporting Rule (CDR). This process is working satisfactorily; an additional nano-specific rule such as the one proposed can therefore only be seen as duplicative." Additionally, NIA feels that no harm has been reported from exposure to nanomaterials stating, "Based on scientific findings over last decade(s) no novel nanospecific hazards have been identified (Oomen et al, 2013, Krug 2014). Consequently[,] there is no reason why nanoscale forms of chemical substances should be treated differently from conventional chemical substances. As stated by the European Commission's 2nd Regulatory Review on Nanomaterials Published 3 October 2012 '...nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not...'".

#### STATUS

The EPA final rule was originally scheduled to become effective on May 12, 2017. Since its publication, the new effective date has been shifted to July 11, 2017.

#### RELATED POLICIES

Public Law 114-329, the American Innovation and Competitiveness Act, reauthorized research funding that is provided through the National Nanotechnology Initiative to member agencies. Such agencies include the National Science Foundation, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, National Institute of Standards and Technology, and Environmental Protection Agency (SciPol brief available).

#### POLICY HISTORY

The EPA originally proposed this rule in April 2015.

#### PRIMARY AUTHOR

Nancy Birkner, Ph.D.

#### EDITOR(S)

Aubrey Incorvaia, MPP; Andrew Pericak, MEM

**RECOMMENDED CITATION**

Duke SciPol, “EPA Reporting and Recordkeeping Requirements of Chemical Substances when Manufactured or Processed as Nanoscale Materials (Final Rule)” available at http://scipol.duke.edu/content/epa-reporting-and-recordkeeping-requirements-chemical-substances-when-manufactured-or (03/14/2017).