

ARTICLE

EPA Issues Final Guidance on Nanotechnology Reporting Rule on Same Date the Rule Takes Effect

April 2018

On August 14, 2017, the U.S. Environmental Protection Agency (EPA) issued final and improved guidance to assist companies report under the TSCA section 8(a) Nanotechnology Reporting and Recordkeeping Requirements Rule.^[1] The rule became effective on the same day.

Solid nanomaterials and their aggregates and agglomerates between 1-100 nm are potentially subject to these reports. Any products intentionally and primarily composed of aggregates and/or agglomerates > 100 nm are not reportable. The rule, which includes required recordkeeping as well, applies to nanomaterials that are listed on the TSCA Chemical Substances Inventory (TSCA Inventory) that meet the criteria for a Reportable Chemical Substance or RCS.

This rule does not just affect manufacturers and importers. If your company puts a nanomaterial into a formulation (such as a polymeric coating) or an article (such as a piece of equipment or a component of a device), these activities may result in a new EPA reporting obligation. These kind of activities are considered processing, and the companies conducting processing activities with a RCS have to file these reports even if their supplier submitted a premanufacture notification (PMN) or filed one of these section 8(a) reports on their own. Unless they have filed PMNs for a new imported ingredient, most processors have not had to take on this kind of ongoing need for a detailed EPA submission as a condition for commercializing an ingredient. This new obligation is not one that processors can pass along to their suppliers since currently, there is no capability for suppliers to report on behalf of their customers.

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While the final rule and its associated guidance are available, there are many complexities associated with determining whether a given material is subject to TSCA section 8(a) reporting and recordkeeping. Answering the threshold question of whether there is a need to report is still not straightforward. Although specific to nanomaterials, this rule establishes an unprecedented TSCA reporting obligation on an entire class of existing chemicals. The reporting rule applies not only to nanomaterials that qualify as reportable chemicals but also to their discrete nanomaterial forms as defined by a complex number of factors in the rule. These discrete forms will need to be separately reported to EPA.

In the past, most TSCA section 8(a) rules were either limited to manufacturer reporting or due only once. Now, there are two different reporting periods to keep in mind. Companies that manufactured, imported, or processed a reportable chemical in the three years prior to August 14, 2017 will need to file a one-time TSCA Section 8(a) report by August 14, 2018. Companies that intend to manufacture or process a nanomaterial that is listed on the TSCA Inventory for the first time after August 14, 2017 need to file *before* they commercialize for a non-exempt purpose if the reporting criteria are met. These reports are due 135 days before manufacturing or processing is initiated, or if manufacture or processing is scheduled sooner, within 30 days of forming the intent to commercialize. In all cases, companies should document their decisions on whether or not to report and keep these records for at least 5 years.

The failure to report can cause a company to accrue between \$17,000 - \$37,000 per chemical in civil penalties. Again, keep in mind that this reporting requirement does not apply to new chemicals that are not already on the TSCA Inventory for which a PMN is still required. This report is not a substitute for filing a PMN for a new chemical substance.

Among other things addressed by EPA's guidance is the difference between enhanced properties that do not trigger reporting and what entails unique and novel properties that need to be reported. EPA has addressed what it views as the difference between a coating and a surface treatment, as well as what would be considered natural shape variations in a particle that are not subject to reporting. The agency provides more detailed information in the guidance on what kind of searching EPA expects companies to do to meet the "known to or reasonably ascertainable" standard for information collection.

In addition, EPA's guidance alleviates the need to report longstanding chemicals in commerce such as carbon black, silica, many (but not all) polymer resins, and titanium dioxide based on the interpretation it offers on the kinds of particles subject to reporting and its discussion of unique and novel properties. Size alone will not trigger reporting. Many chemical substances 1 – 100 nm in size may be left out as a result, with fewer reports than may have been anticipated. On the other hand, we think it is beneficial that EPA is decisively signaling an intent to return to a science-based approach to nanotechnology by seeking to exclusively identify only those substances that are truly "nano" based on both size *and* performance, as rooted in the U.S. definition of nanotechnology from the National Nanotechnology Initiative:

Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and

manipulating matter at this length scale. (Please see <https://www.nano.gov/nanotech-101/what>).

Nevertheless, changes in coatings may draw otherwise exempt substances back into the reporting framework of the rule, and are predicted to be the source of numerous reports.

For companies affected by the three-year look back reports that are due in August 2018, the good news is that after your Inventory Reset reports are filed in the next six-months, you will have another six months to meet the look back reporting deadline. The bad news is that if you wait that long, you may be too late getting started. These reports are going to be much more extensive to prepare than Reset reports in terms of the information that is needed and the time it will take to collect and prepare it. Because answering the threshold question of whether there is a need to report is still not straightforward, getting through the process outlined above to select the nanomaterials you will report will take longer than you think. How will you go about obtaining the three years of data you need on the products your company has manufactured, imported or processed? How will you identify the subset of products that contain nanomaterials? Who will you need to work with in your organization to establish whether the unique and novel property and other technical criteria of the rule are met? Who is tasked to determine whether you have discrete forms of a RCS?

To determine if your business is affected by the “on-going” reporting aspect of this rule, companies should read the rule and guidance and ask the following questions:

- Do we intend to manufacture, import or process a chemical substance alone or as part of a mixture that is –
 - A solid at 25 °C and standard atmospheric pressure?
 - Manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nanometers in at least one dimension?
- Will we manufacture, import or process this nanomaterial to exhibit one or more unique and novel properties attributable to its size?
- Do any exemptions apply?
- Do I need to worry about distinguishing and reporting discrete forms based on the minimum standards for differentiating a nanomaterial based on size or properties, or when there is a change in shape or coating? Bear in mind that process changes down the road may result in the need to evaluate whether to report a new discrete form.

Even with the benefit of EPA guidance, some issues are still unresolved. It is still not clear which methods are the most appropriate for determining nanomaterial physicochemical characteristics that would lead to reporting. Postings at <http://www.nanomanufacturingassociation.com> include questions submitted by the Nanomanufacturing Association to EPA which are still outstanding, many of which are still relevant.

When reporting confidential business information (CBI), make sure you understand which claims will require substantiation. Suppliers are not required by this rule to provide sensitive information to a customer but EPA is encouraging customer notification. If you do not have information asked for on the reporting form, EPA advises

responding “NKRA” – for “not known or reasonably ascertainable” and documenting your attempt to obtain the information. When reporting confidential business information (CBI), make sure you understand which claims will require substantiation.

EPA states in the preamble to the final rule that “if a company desires to begin manufacturing or processing . . . after the submission for this rule is made, the company is free to do so.” 82 Fed. Reg. 3641 at 3649. There is similar assurance provided in the guidance document in the agency’s response to Question 28.

Unfortunately, this intent does not carry through in the language of the rule itself in 40 C.F.R. § 704.20(f)(2). If asked, it is likely that EPA would find it possible to make a technical correction to the rule so that it aligns better with the agency’s intent. Keep in mind that if EPA identifies hazard or exposure concerns based on the information it gathers through this rule, the agency may seek to regulate these products.

For ready reference, our summary of the compliance obligations for TSCA nanomaterial reporting is below. For questions or assistance, do not hesitate to contact one of us: **Martha Marrapese**: 202.719.7156 or mmarrapese@wiley.law; **Phil Sayre, Ph.D.**: 301.367.3348 or psayre@wiley.law; **Saskia Mooney**: 202.719.4107 or smooney@wiley.law.

Summary of the Final Rule for Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements

1. Effective Date: August 14, 2017

2. Statutory and regulatory authority: Section 8(a) of TSCA, 40 C.F.R. § 704.20.

3. Electronic CDX reporting link: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under#info%20rule>.

4. Who must report:

- **Effective one year from August 14, 2017:** Companies that manufactured, imported, or processed reportable nanomaterials in the three years prior to the effective date.
- **Effective now:** Companies who will manufacture, import, or process discrete forms of existing reportable nanomaterials for the first time must file 135 days prior or within 30 days of forming this intent if manufacturing or processing will begin sooner.
- Small businesses with annual sales (including parent) of < \$11 million are exempt.

5. What chemicals are the subject of these reports:

- A “reportable chemical substance” is a “solid at 25°C and atmospheric pressure that is manufactured or processed in a form where the primary particles, aggregates, or agglomerates are in the size range of 1-100 nm and exhibit unique and novel characteristics or properties because of their size”.

- A discrete form is different due to:
 - A change in process that leads to both a change in size and one or more of the following properties: zeta potential, specific surface area, dispersion stability, or surface reactivity. The changes in size and property have to be greater than 7 times the standard deviation of the measured value for the already identified reported form.
 - A change in morphology (shape).
 - Use of a different coating on the same reportable chemical substance.

6. What substances are excluded from reporting:

- If the reportable chemical form is < 1% by weight of the substance.
- Chemicals after they are incorporated into an article that is then distributed in US commerce, such as prior to the import of an article into the US or after the article leaves a domestic manufacturing facility.
- Research and Development chemicals.
- Chemical substances manufactured at the nanoscale as part of a film on a surface.
- DNA, RNA, proteins.
- Chemical substances which disassociate completely in water to form ions smaller than 1 nm. There is no limit on the time needed for the substance to disassociate.
- Chemical substances for which EPA has received a premanufacture notification (PMN), significant new use notification (SNUN), or low volume/low exposure submission (LVE/LoREX) on or after January 1, 2005.
- Information submitted to the Nanoscale Materials Stewardship Program does not need to be re-submitted if it is for the same discrete form.
- There is no exemption or reporting threshold based on production volume.

7. What information needs to be reported: No new testing is required in order to comply with this reporting rule. The following information needs to be submitted:

- Common name, trade name, specific chemical identity by Chemical Abstracts Index Name, Chemical Abstracts Service (CAS) Registry Number, and molecular structure.
- Particle size, morphology, surface modifications, and related phys/chem properties.
- Maximum weight percentage of impurities and byproducts.
- Annual production volume for prior three years and estimated maximum 12-month production volume during the next two years.
- If a discrete form is first manufactured or processed after the rule's effective date, the maximum 12-month production volume in the first three years of production.
- Use information by category, function, and application; estimates of the amount manufactured and processed for each category of use; and an estimate of the percentage in the formulation for each use.

- Detailed methods of manufacturing or processing.
- Estimates of the number of individuals exposed in their places of employment, descriptions and duration of occupational tasks, and descriptions and estimates of any general population or consumer exposures.
- Estimates of the amounts released, a description and the duration of the activities that cause the releases to occur, and whether the releases are directly to the environment or to control technology.
- Risk management practices including engineering controls, hazard warnings, labels and safety data sheets, and the like provided to persons who are reasonably likely to be exposed.
- Existing data concerning environmental and health effects.

8. When commercialization may begin: RCSs subject to the 3-year lookback reports may remain in commerce. For first time commercialization, EPA's guidance emphasizes that there is no obligation to wait to commercialize after filing the required information.

[1] Environmental Protection Agency, Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, Final Rule, 82 Fed. Reg. 3641 (Jan. 12, 2017); stayed until August 14, 2017 pending issuance of final guidance at 82 Fed. Reg. 22452 (May 16, 2017).