

TSCA Section 8(a) Rule for Chemical Substances Manufactured or Processed as Nanoscale Materials

SEMI Webinar
June 1, 2017

Summary

- Goals.
- Description of Rule.
- Nanoscale Materials Subject to the Rule.
- Selected Changes from Proposed Rule.

Dates

- Final rule issued on January 12, 2017.
- The final effective date of the rule was extended to August 14, 2017 in a notice issued on May 12, 2017.
- Availability of draft guidance for the rule and a request for comment on the guidance were issued on May 16, 2017.

Toxic Substances Control Act (TSCA)

- TSCA provides broad authority to:
 - Gather information on new and existing chemical substances and mixtures.
 - Require testing of chemicals.
 - Screen and control unreasonable risks of new and existing chemicals.
 - Coordinate with other Federal agencies.

Nanomaterials (NMs) under TSCA

- NMs are “chemical substances” as defined by TSCA.
- NMs not on the TSCA Inventory are “new chemicals”.
- TSCA “chemical substance” definition based on molecular identity, not on other properties.
- NMs on the TSCA Inventory are “existing chemicals”.

Goals of Issuing this TSCA Section 8(a) Rule

- Ensure that EPA has basic information on nanoscale materials currently in commerce to:
 - Identify which nanoscale materials are in commerce.
 - Inform EPA efforts to characterize risk.
 - Enhance ability to make appropriate risk management decisions.
- EPA will review data submitted for all nanoscale materials subject to the rule.
- EPA will consider whether further actions or additional data are needed.

TSCA Section 8(a) Final Rule

- Only requires information that is “known to or reasonably ascertainable by” persons subject to the rule.
- Does not require persons subject to the rule to develop data or a minimum data set.
- Submitted data can be claimed confidential.

TSCA Section 8(a) Final Rule

- The rule will require one-time reporting of available information.
- The rule will use electronic reporting.
- General exemptions from section 8(a) reporting include research and development, importing/processing as part of an article, byproducts, and impurities.

Reporting for Existing Nanoscale Materials

- Data reporting for manufacturers and processors of a discrete form of a nanoscale material during the three years prior to the final effective date of the rule.
- Reports must be submitted within one year of the effective date of the rule.

Reporting for New Discrete Forms of Nanoscale Materials

- Data reporting at least 135 days before the intended date of manufacture or processing.
- Except where the person has not formed an intent to manufacture or process a discrete form of a reportable chemical substance 135 days before such manufacturing or processing.
- In that case the information must be filed within 30 days of the formation of such an intent.

Information That Will be Required Where Reasonably Ascertainable

- Specific chemical identity.
- Material characterization.
- Physical-chemical properties.
- Production volume.
- Use.
- Methods of manufacturing and processing.
- Exposure and release information.
- Existing data concerning environmental and health effects.

Reportable Chemical Substances Subject to the Rule

- Solid chemical substances at 25 °C and atmospheric pressure.
- 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 are manufactured or processed to exhibit unique and novel properties because of its size.

Reportable Chemical Substances Subject to the Rule

- Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance, and such properties are a reason that the chemical substance is manufactured or processed in that form.

Reportable Chemical Substances Subject to the Rule

- A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates and agglomerates, measured by weight are in the size range of 1-100 nm.

Chemical Substances Excluded from the Rule

- Chemical substances that dissociate in water to form ions less than 1 nm and biological materials (e.g., DNA, RNA, proteins, enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, and microorganisms).
- Chemical substances formed at the nanoscale as part of a film on a surface.

Chemical Substances Excluded from the Rule

- Chemical substances that have completed a TSCA section 5 review since January 1, 2005.
- R&D activities for persons who manufacture or process a chemical substance only in small quantities for research and development.

Reportable Chemical Substances Subject to the Rule

A discrete form of a chemical substance differs from another form of the same chemical substance in that either:

- (1) The change in the chemical substance is due to all of the following:
 - (i) There is a change in process to affect a change in size and a change in one or more of the properties of the reportable chemical substances identified in (iii);
 - (ii) There is a size variation in the mean particle size that is greater than 7 times the standard deviation of the mean particle size (+/- 7 times the standard deviation); and

Reportable Chemical Substances Subject to the Rule

- (iii) There is a measured change in at least one of the following properties, *zeta* potential, specific surface area, dispersion stability, or surface reactivity, greater than 7 times the standard deviation of the measured value (+/- 7 times the standard deviation).
- (2) Each chemical substance with a different morphology.
- (3) Each chemical substance with a different coating.

Small Business Exemption

- TSCA requires that EPA exempt small businesses from Section 8(a) reporting requirements.
- TSCA allows EPA to define this exemption for Section 8(a) rules after consultation with the Small Business Administration.
- EPA has departed from the standard definition of a small manufacturer or processor in specific Section 8(a) rules when appropriate.

Small Business Exemption

- Current small business exemption generally applicable to TSCA Section 8(a) rules is either:
 - Company sales less than \$40 million per year and not manufactured over 100,000 pounds annually at any individual site owned or controlled by the company; or
 - Company sales less than \$4 million.
- The final rule contains a small business exemption based only on sales. A small manufacturer or processor is defined as any company with sales of less than \$11 million per year.
 - EPA has consulted with the Small Business Administration(SBA).
 - SBA has agreed with this approach.

Comments and Changes from Proposal

Unique and Novel Properties

- Many commenters stated the proposal gave too much discretion to interpret compliance obligations. Commenters suggested clarifying the definition of unique and novel properties, adopting an alternative, or not using it at all.
- EPA has added a definition of unique and novel properties in the definitions section of the regulatory text (See §704.20(a) or Slide 11).

Comments and Changes from Proposal

Trace Amounts

- Commenters suggested alternative definitions of trace amounts stating that the term in the proposed rule is not definitive and gives too much discretion to interpret compliance obligations.
- Commenters suggested including a numerical value to define trace amount.
- See Slide 12

Comments and Changes from Proposal

135 Day Reporting Requirement

- There were numerous comments to not include the 135 day reporting requirement for new discrete forms.
 - A number of commenters thought that EPA was using section 8(a) to require section 5 new chemical review for nanoscale forms of existing chemicals.
 - Commenters also asked EPA to clarify if persons subject to the rule had to wait until the 135 day period was completed before commencing manufacture or processing.
- The 135 day reporting requirement was supported by several commenters.

Comments and Changes from Proposal

135 Day Reporting Requirement

- EPA added language to the 135 day reporting requirement to the final rule:
- “except where the person has not formed an intent to manufacture or process a discrete form of a reportable chemical substance, in which case the information must be filed within 30 days of the formation of such an intent.”

Comments and Changes from Proposal 135 Day Reporting Requirement

- EPA has also clarified that persons reporting do not have to wait 135 days before commencing manufacture or processing.

Comments and Changes from Proposal

Definition of Particle

- Commenters suggested EPA better define particle so it is clear what materials require reporting.
- EPA added a definition of particle and modified the language in the definition of reportable chemical substance for the types of particles measured.
- The language in the reportable chemical substance definition now reads, “where any particles, including aggregates and agglomerates, are in the size range of 1-100 nm”

Comments and Changes from Proposal Reporting Form

- EPA added language to the form instructions that “You may want to consult with your customers or suppliers about the confidentiality of any information you report about them on this form” in response to comments that manufacturers or processors may not accurately identify confidential information obtained from suppliers or customers.

Comments and Changes from Proposal

Confidentiality Claims

- TSCA now requires a supporting statement for all confidentiality claims.
- This is similar to the certification requirements currently in 40 CFR 704.7, which is cross-referenced in the proposed rule.
- In the final rule, EPA revised the wording in the certification to ensure that the certification meets the statutory requirements.