

Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce

What Chemicals are Reportable?

Question 1: My company manufactures a nanoscale material in the form of primary particles less than 100 nanometers in the reactor system but almost immediately due to Van der Waal forces forms aggregates and agglomerates with particle sizes far greater than 100 nanometers(nm). Are these types of nanostructured materials with particle sizes greater than 100 nm considered reportable chemical substances under this rule?

No. The definition of a reportable chemical substance is a combination of particle size and unique and novel properties. For the example given in the question, the form consisting of primary particles at "creation" would not meet the definition of a reportable chemical substance, unless the manufacturer was making a form of carbon black consisting solely of those primary particles that exhibit size dependent properties. Because in the example the particle size of the aggregates and agglomerates is greater than 100 nm, that form of carbon black as manufactured is not a reportable chemical substance.

Question 2: Can you describe what is considered a reportable chemical substance? Is there some way to differentiate between genuinely new nanoscale materials in commerce and traditional products?

Under this rule a reportable chemical substance is 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 manufactured or processed to exhibit unique and novel properties because of its size. 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.

The rule also includes a definition of unique and novel properties. 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 or size. For purposes of this rule, EPA defined unique and novel properties to include an element of intent, meaning that those properties are the reason why the chemical substance is manufactured in that form or size. In order to be reportable it is not sufficient that a chemical substance contains particles in the size range of 1-100 nanometers; it must also have a size-dependent property different from properties at sizes greater than 100 nanometers and those properties are the reason that the chemical substance is manufactured or processed in that form or size.

Intentionally manufacturing or processing nanoscale gold so that it exhibits a red or purple color instead of a yellow color is an example of a unique or novel optical property seen at the nanoscale. Such a change would likely result in changes of other properties, such as specific surface area which can result in different health and safety impacts. Unique and novel properties

which impact performance generally cannot be isolated from concurrent changes in properties that impact biological systems. Some nanostructured materials are stronger or have different magnetic properties compared to other forms or sizes of the same material. Others are better at conducting heat or electricity. They may become more chemically reactive or reflect light better or change color as their size or structure is altered. A property is novel when it is different from the properties associated with other forms or sizes of the same chemical substance. As noted on www.nano.gov, when particle sizes of solid matter in the visible scale are compared to what can be seen in a regular optical microscope, there is little difference in the properties of the particles. But when particles are created with dimensions of about 1–100 nanometers, the materials' properties can change significantly from those at larger scales.

Question 3: What is the difference between enhanced properties and unique and novel properties?

Enhanced properties are generally described as increased reactivity or surface area when particle size decreases. While reactivity and surface area increase, there is often little difference in the intrinsic properties of the particles in ranges above 100 nanometers. When particles are created with dimensions in the 1–100 nanometer range, the materials' properties can change significantly from those at larger scales. Not all enhanced properties are unique or novel. For example, grinding or engineering pigments for better performance which results only in incidental amounts of particles between 1-100 nm would not constitute a nanoscale material with unique or novel properties. Grinding or engineering pigments for better performance which results in almost all particles that are less than 100 nm would constitute a nanoscale material with unique or novel properties.

Question 4: To what objects and collections of objects does the 1-100 nm measurement apply? In other words, does that mean any form with particles 1-100 nm or does that include aggregates and agglomerates greater than 100 nm but based on primary particles less than 100 nm?

Chemical substances required to be reported would include any form with particles 1-100 nm but would not include aggregates or agglomerates greater than 100 nm even if they contain primary particles less than 100 nm.

Question 5: If a reportable chemical substance is reported as a new chemical for one use but later has a different use from the one reported, would this require reporting under this rule?

Because this rule is one-time reporting of nanoscale forms of chemical substances in commerce, new uses of reportable chemical substances do not require additional reporting under this section 8(a) reporting requirement. However, if under the new use the person manufactures or processes a discrete form of the reportable chemical substance then that person would be required to report under this rule. Note that there may be notification requirements unrelated to this section 8(a) reporting rule if a company manufactures or processes the chemical substance for a use that is subject to a significant new use rule (SNUR) for the chemical substance.

Question 6: Is reporting for mixtures’ notifier-specific or substance-specific. For example, if a manufacturer reports and sells to 10 processors, does each processor report?

Reporting for mixtures is not required, but you must report each individual reportable chemical substance in a mixture. Any reportable chemical substance that is incorporated into a mixture or substrate would require reporting for manufacturing or processing of that chemical substance. If a manufacturer sells a mixture containing a reportable chemical substance to multiple processors, then each processor is also required to report.

Question 7: Please clarify the criterion to exclude chemical substances that dissociate completely in water to form ions that are smaller than 1 nm. How fast or what is the rate of dissociation?

The rate of dissociation or how fast that dissociation occurs does not affect which chemicals are excluded. If the chemical substance completely dissociates to form ions smaller than 1 nm it is not a reportable chemical substance.

Question 8: What are the criteria to discern one shape from another shape? How would manufacturers and processors distinguish between the different morphologies identified in the rule as for example a rod from an ellipsoid, needle, wire, and/or fiber as these shapes could be considered on a continuum?

A different morphology would be any change in the shape of particles. Different morphology does not include random shape changes or natural variation in shapes of particles that are not definitive and that occur in a continuum. Some nanoscale materials are engineered to give all the particles a certain morphology or shape. The change in shape needs to be a specifically engineered change in the shape of particles of a nanoscale material, to effect a change and form a unique or novel property for a chemical substance in the particle size range of 1-100 nm.

Question 9: Are mixtures ever reportable under the rule?

Mixtures are not reportable under this rule, however the components of any mixture that contains reportable chemical substances subject to the rule would be reported. If you manufacture (including import) or process chemical substances as part of a mixture, you would evaluate the requirements for each chemical substance in the mixture.

Question 10: Why are coated nanomaterials defined separately from chemical mixtures? What does the rule mean by coating? There are cases where discrete nanomaterials are surface treated (commonly coated with polymeric substances) in a similar fashion as defined for chemical mixtures.

The term coating in the rule describes surface treating or coating of a reportable chemical substance with another chemical substance. The change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all of the other intrinsic characteristics of the reportable chemical substance remain the same. Coating or surface treating a nanoscale material results in a nanoscale material with different properties. The rule does not require that

every chemical substance coated or surface treated with another chemical substance be reported. However, any type of engineering including surface treatment of a chemical substance that results in a reportable chemical substance triggers a reporting requirement.

Comment 11: Is it EPA's intention to require reporting on large molecules within the size range of 1 – 100 nm, which are not normally considered to be nanoscale materials (for example, monomers, polymers, colloids, organic and inorganic pigments and dyes, polymer dispersions, etc.)? Are polymers or metals attached to ligands which are larger than 1 nm in size also considered a nanoscale material for reporting?

In order to be a reportable chemical substance, the chemical must not only be a particle in the size range of 1-100 nanometers. It must also have a unique or novel property, which is any size-dependent property that varies from those associated with other forms or sizes of the same chemical substance, and such property is a reason that the chemical substance is manufactured or processed in that form. While these categories of large molecules are not exempt per se, monomers, polymers, and colloids, organic and inorganic pigments and dyes, and polymer dispersions are not reportable chemical substances unless they are manufactured at the nanoscale to exhibit unique or novel properties that are not exhibited by other forms or sizes of the same chemical substance. Large molecules and chemicals attached to ligands greater than 1 nm that do not meet the definition do not need to be reported unless they meet the definition of a reportable chemical substance.

Who is Required to Report?

Question 12: My company manufactures ink/toner products and is planning to import their products, which include a chemical substance with particle sizes of 1-100 nm, used as a pigment and/or additive in toner and ink cartridges. Is my company required to report even though the chemical substance is incorporated into a formulation that is not manufactured or processed in the United States?

Under TSCA, the definition of manufacture is not limited to domestic manufacture; the definition of manufacture includes import. This includes importing a chemical substance as part of a formulation. The chemicals in the formulation are subject to any manufacturing reporting requirements under TSCA including the reporting and recordkeeping rule for chemical substances that are nanoscale materials. If the chemical substance is imported in a form that meets the definition of a reportable chemical substance, the importer of the toner must report under 40 CFR 704.20.

Question 13: My company is currently processing carbon nanotubes for research and development (R&D). Within the next few years there is a probability that we will be selling products containing the carbon nanotubes. At that point, we would not be exempt from this reporting requirement. Would it be proactive for us to report to the EPA now, even though we are still in the R&D phase, or should we wait until we are processing for production?

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule. The rule will become effective on August 14, 2017. By August 14, 2018 you would need to report any non-exempt processing of a reportable chemical substance that occurred before August 14, 2017. If you begin non-exempt processing of a reportable chemical substance after August 14, 2017 you would need to report at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except if you have not formed an intent to manufacture or process at least 135 days before commencing such manufacture (including import) or processing, in which case the information must be filed within 30 days of the formation of such an intent. You are the best judge on when to report to meet the requirement of reporting 135 days before processing a reportable chemical substance or within 30 of forming an intent to manufacture or process.

You will also need to determine if the carbon nanotubes you are processing meet the definition of a reportable chemical substance. Not all carbon nanotubes contain particles less than 100 nm although most of them would be described as having unique and novel properties.

EPA considers most forms of carbon nanotubes as new chemical substances (See 73 FR 64946) Are you importing the carbon nanotubes or purchasing the carbon nanotubes from a domestic supplier? Can your supplier confirm they are on the TSCA Inventory? If you cannot confirm they are on the TSCA Inventory, then apart from this section 8(a) reporting rule you may also need to submit a pre-manufacture notice (PMN) under TSCA section 5 for the carbon nanotubes if you are the importer of record or your domestic supplier may need to submit a PMN. You can learn whether your nanotubes are on the TSCA Inventory by submitting a *bona fide* request to EPA pursuant to procedures in 40 CFR 720.25.

Question 14: What is required of processors that do not know about the particle size and other characteristics of formulations they process or use?

Reporting of information under the rule is required only to the extent that information is known or reasonably ascertainable. This standard applies both to the extent of an entity's obligation to determine whether it is required to report, and to the extent of information any entity is required to report. If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable to processor to determine whether the supplier is selling them a nanoscale material subject to reporting and if so provide them with what reportable information they have. Their supplier is not required to provide any additional information to the processor but might provide other supporting information, for example, whether their supplier has reported or intends to report the chemical substance under this rule. If the supplier provides information indicating that the substance is not reportable or if the processor lacks any other means of reasonably ascertaining whether the substance is reportable, the processor does not need to perform tests to determine whether the substance is reportable. Information developed in the normal course of business or that the processor chooses to develop

must also be used. The processor may want to document the steps they took to determine if reporting was required.

If the information provided by the supplier indicates that reporting is required, the processor is required to report information that is known or reasonably ascertainable, which may include information obtained from the supplier. This would include situations where the processor may not know the exact chemical identity or some of its physical properties. Companies that purchase formulations but do not change or modify those formulations and only use them are not considered processors and are not required to report under the rule. Importers that purchase formulations are considered to be the same as manufacturers and are required to report under the rule even if they do not change or modify those formulations and only use the formulation.

The obligations imposed by the reasonably ascertainable standard are discussed more fully in the Chemical Data Reporting final rule, 76 FR 50816, 50829 (August 16, 2011).

Question 15: Is a processor of a reportable chemical submitted as a PMN required to report?

Only persons who submitted the section 5 submission after January 1, 2005 are exempt from reporting. Other manufacturers and processors would still be required to report.

Question 16: Where in the supply chain must a nanoscale material be reported: at every point in the supply chain, or only at the point of manufacture? Would this include incorporation into articles and substrates?

Each manufacturer and processor in the supply chain must report reasonably ascertainable information on the reportable chemical substance. Once a chemical substance has been incorporated into an article, no further reporting is required as persons that manufacture or process chemical substances as part of articles are exempt from reporting.

Question 17: The physical properties that define discrete forms of a reportable chemical substance sometime cannot reliably be measured and the rule appears to require companies to conduct tests on these or other physical-chemical properties to determine whether they must report. Many of these tests are not commonly performed.

Testing is not required under a TSCA section 8(a) rule. While manufacturers and processors are not required to test for the properties identified in the definition of discrete forms of a reportable chemical substance, they are still required to determine their compliance obligations under the rule based upon information that is in their possession or which is reasonably ascertainable. If information within a company's possession or that is reasonably ascertainable does not demonstrate that the company is manufacturing or processing a discrete form of a reportable chemical substance, there is no obligation to report. EPA expects that in most cases such information will be in the company's possession or reasonably ascertainable.

Question 18: If a company manufactures or processes a reportable chemical substance solely for export is the company subject to the reporting requirements?

Yes. Persons who manufacture or process reportable chemical substances solely for export are subject to the reporting requirements. TSCA Section 12(b) exemptions for export do not apply to Section 8(a) rules. Note, however, that the processing and use information is restricted to domestic activities, i.e., within the customs territory of the United States.

Question 19: Are importers of a reportable chemical substance required to report under the rule?

Yes. The definition of “manufacture” under Section 3(9) of TSCA includes import.

What Information is to be Reported?

Question 20: Can you clarify whether manufacturers and processors who are only required to report available or reasonably ascertainable information need to develop information to comply with the rule.

Manufacturers and processors are not required to conduct testing or develop information under this rule. However, they are required to report information that is known or reasonably ascertainable.

Question 21: Please provide further clarification on the scope of what would be required under the “known to or reasonably ascertainable by” reporting standard. How would this reporting standard apply to manufacturing, processing and use information?

The term “known to or reasonably ascertainable by” is defined at 40 CFR 704.3. It means “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.” Under the “known to” portion of the standard, a submitter must therefore ascertain what they know about the manufacturing, processing and use of a chemical substance it manufactures (including imports) or processes, without confining its inquiry to what is known to managerial and supervisory employees. A submitter would also be expected to review other information which the manufacturer (including importer) or processor may have in its possession. This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be “known to” the submitter if it is available after a reasonable inquiry within the organization. The standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

Inquiry under the “reasonably ascertainable” portion of standard may also entail inquiries outside the organization to fill gaps in the submitter’s knowledge. Note however, that if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be “reasonably ascertainable” to the submitter. Thus there is not a need to conduct

new customer surveys for purposes of reporting under the rule. As described above, however, existing customer survey data may nevertheless be “known to” the organization.

Question 22: What are some examples of types of information that are considered to be in a person’s possession or control or that a reasonable person similarly situated might be expected to possess, control, or know?

Information could be possessed by employees or other agents of the company reporting under the rule, including persons involved in the research, development, manufacturing, or marketing of a chemical substance. This information includes knowledge gained through discussions, symposia, and technical publications. Other examples include:

- Files maintained by the submitter or employees in the submitter’s company, such as marketing studies, sales reports, or customer surveys;
- Information contained in standard references, such as MSDSs, that contain use information or concentrations of chemical substances in mixtures; and
- Identification numbers from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet.

Question 23: A company manufactures or processes chemical substances but often does not know how these chemical substances are used by downstream customers. Does EPA intend for submitters to send questions to customers requesting information about downstream uses?

It depends on what is meant by sending “questions to customers.” Submitters need not send out a comprehensive set of identical questions to multiple customers in order to fulfill the reporting standard. That is, they need not conduct a new survey of their customers. However, one way of fulfilling the reporting standard might involve limited” inquiries outside the organization (e.g., contacting a major customer or examining that customer’s public website) to fill in gaps in the submitter’s knowledge, where the submitter’s current knowledge is less than what a “reasonable person similarly situated might be expected to possess, control, or know.” See 40 CFR 704.3.

Question 24: All of a company’s products are used to make commercial products through various process steps by different manufacturers. Should the company provide information about consumer uses even if its chemical substance is not the end use product?

Yes. If the chemical substance is used in a consumer product, the company would still report the information if it is known or reasonably ascertainable, even if the company does not manufacture the end use item. The information provided on the reporting form about downstream use is associated with the processing and use of chemical substances and typically relates to processing or use that is outside of the manufacturing, importing, or processing site, unless, of course, the manufacturer, importer, or processor also processes or uses the chemical substance.

Information on subsequent industrial users and processors and on commercial and consumer uses of the chemical substance would be reported on the reporting form to the extent the information is known to or reasonably ascertainable by the manufacturer (includes import) or processor of the subject chemical substance. A company which is a manufacturer or processor must report

information about the distribution and use of the chemical substance that is known to or reasonably ascertainable by the company. To the extent the information is not known or reasonably ascertainable, the company may report NKRA (i.e., “not known or reasonably ascertainable”).

When is Reporting Required?

Question 25: Please clarify how the 135-day reporting requirement for new discrete forms would work. For example, can commercialization begin after notification to EPA or after 135 days after notification to EPA?

The 135-day period is not a formal review-period that prohibits manufacture before the end of the 135-day period. Rather, based on EPA's experience with the PMN reviews in the new chemicals program, EPA believes that in most cases companies have the requisite intent to manufacture or process a reportable chemical substance at least 135 days before manufacturing or processing will begin, and the rule requires reporting based upon this presumed intent. However, if a company does not form the requisite intent 135 days ahead of time, the company must report within 30 days of the formation of such an intent. Moreover, if a company desires to begin manufacture or processing less than 135 days after the submission for this rule is made, the company is free to do so. There is no obligation upon the company to wait 135 days after reporting to manufacture or process.

Question 26: Is there a mechanism or requirement to update any new information if there is a change in manufacture, processing or use after the initial reporting of a reportable chemical substance?

Because this rule only requires one-time reporting, updating with new information is not required unless the change in manufacture or processing creates a new discrete form of a reportable chemical substance.

Question 27: Can EPA clarify if the exemptions for new chemicals reported since January 1, 2005 and the Nanoscale Materials Stewardship Program (NMSP) would exempt information that has changed since the original reporting?

For a reportable chemical substance that was submitted as a new chemical substance under section 5 of TSCA or as part of the NMSP, no updated information would need to be reported unless a manufacturing or processing change resulted in a new discrete form of the reportable chemical substance.

Question 28: What is the criterion for distinguishing new processing methods for a nanoscale material from existing methods? What would constitute a process change that would require filing a new report?

The type of process change is not the criterion; it is the intent of the process change. Any manufacturing or processing change that is intended to change particle size and properties would be a process change that could require new reporting.

General Questions

Question 29: The reporting rule was published in the Federal Register on January 12, 2017. When does this rule become law?

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule 90 days; the rule will become effective on August 14, 2017.

Question 30: Is there a minimum production volume below which no reporting is required, such as 10 or 100 kg?

There is no exemption based on production volume or reporting threshold based on production volume.

Question 31: (a) Is research and development exempt from reporting under the rule? (b) Can you define small quantities? (c) Can companies sell research and development quantities for profit? (d) Is reporting required if the core commercial activity of a company is research and development?

(a) Yes. As described in 40 CFR part 704.5(e), a person who manufactures (including imports), processes, or proposes to manufacture or process a substance subject to reporting under this rule only in small quantities solely for research and development is exempt from the reporting requirements of the rule.

(b) Small quantities solely for research and development (or “small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product”) is defined in 40 CFR part 704.3 to mean quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(c) Yes. The exemption may apply even if a company sells research and development quantities for a profit.

(d) The research and development exemption applies to use for which the specific chemical substance is manufactured. It is irrelevant whether the main commercial activity of the company is research and development or industrial sales or use.

Question 32: Are articles exempt from reporting under this rule?

As described in 40 CFR 704.5(a), a person who imports, processes, or proposes to import or process a reportable chemical substance subject to this rule solely as part of an article is exempt from the reporting requirements of this part with regard to that substance. Manufacturers (including importers) or processors of a reportable chemical substance that is incorporated into an article would be required to report any required information for activities before the chemical

substance is incorporated into the article. An article is defined in 40 CFR 704.3 as manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Question 33: Can imported metal powders ever be considered “articles” regardless of their end use?

No. Powders cannot be considered articles. The definition of article includes the statement that “fluids and particles are not considered articles regardless of shape or design”.

Question 34: Is the purpose of the rule to compile an inventory of nanoscale material chemical substances in commerce?

No. The purpose of the rule is to collect information on the manufacture (including importation); processing; and industrial, commercial, and consumer uses of certain chemical substances that are nanoscale materials. This rule will allow EPA to obtain basic data from those that manufacture or process existing nanomaterials made from substances that are on the TSCA Inventory. EPA will use information gathered through this rule to inform the Agency’s understanding about the manufacture, processing and use of nanoscale substances and to determine if any further action under TSCA, including additional information collection, is needed in specific instances.

Question 35: How do I determine my reporting requirements?

Carefully review the regulations located at 40 CFR 704.20 to determine your reporting requirements. You should consider the following three steps to determine whether you are required to report for each chemical substance that you domestically manufactured (including imported) into the United States since the last principal reporting year:

- o Step I: Is your chemical substance subject to the reporting rule?
- o Step II: Are you a manufacturer (including importer) or processor who is required to report?
- o Step III: What information must you report?

Question 36: Must a submitter conduct new chemical analyses to report information?

No. The regulation does not require submitters to perform new chemical analyses. The information required by the rule is limited to information that is “known to or reasonably ascertainable.” This standard is applicable to all information reported in accordance with 40 CFR 704.20.

Question 37: What should a company do if it determines that it manufactures or processes a chemical substance that is not included on the TSCA Inventory?

In order to manufacture (including import) or process a chemical substance for a non-exempt commercial purpose, it must be: on the TSCA Inventory, a naturally occurring chemical substance as defined by TSCA (see 40 CFR 710.4(b)), or excluded by TSCA Section 3(2)(B)*. You can visit Substance Registry Services to determine whether your chemical substance is on the TSCA Inventory. If your chemical substance is not on the TSCA Inventory, you may need to submit a PMN to the new chemicals program. Please see EPA's PMN Requirement flowchart to determine if a notice must be submitted to the Agency prior to manufacture (including import). You can also phone the TSCA Hotline at (202)-554-1404 for assistance.

For a chemical substance that is not on the TSCA Inventory, a naturally occurring chemical substance as defined by TSCA, or exempted in TSCA Section 3(2)(B)), a person must submit a notice as per 40 CFR 720.22(a)(1) prior to manufacture (including import).

If a person is manufacturing (including importing) a substance which is not on the TSCA Inventory and has not provided the required notice to EPA, each day of such manufacture or importation is a violation of Section 5 of TSCA and could subject the person to enforcement action. If a person finds that it has or may have manufactured or imported a chemical substance in violation of TSCA, contact the Agency at the following address:
<https://www.epa.gov/compliance/epas-edisclosure>.

Significant reductions in penalties may be given to persons who voluntarily disclose such information. Note, however, that continued manufacture, (including importation) or use of such chemical substances remains in violation per Section 15 of TSCA, even after a person has contacted EPA, until the requirements of TSCA Section 5 have been met. These reporting requirements are distinct from the requirements at 40 CFR 704.20.

**Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide; any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.*

Question 38: If a company manufactures a reportable chemical substance for a non-TSCA use, is the company required to report under 40 CFR 704.20?

Substances exempted in TSCA Section 3(2)(B) need not be reported. Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide (but see Question 39 below regarding intermediates in the manufacture of an active ingredient in a pesticide); any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are

defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.

Question 39. A company manufactures Chemical C. Its customers use Chemical C for a variety of uses including as an intermediate in the manufacture of a chemical substance to be used as a pesticide active ingredient. Pesticides are exempt from regulation by TSCA. Does the company need to report industrial processing and use data for this chemical substance?

Yes. The manufacture of a chemical substance that is a pesticide intermediate is manufacture under TSCA.

Question 40: If a company manufactures or processes a reportable chemical substance which may be used for purposes regulated by TSCA and also for uses which are excluded from regulation under TSCA Section 3(2)(B), should the entire quantity that the company manufactures or processes be reported in the submission?

No. Report the manufactured or processed quantity intended for the TSCA use and do not report the quantity that is exempt from TSCA in Section 3(2)(B).

Question 41: Are small manufacturers and processors exempt from reporting requirements of the rule?

Yes. A small manufacturer or processor is defined in the rule as any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than \$11 million.

Question 42: What role does the technical contact play?

The technical contact is the person whom EPA may contact for clarification of the information in a submission. The technical contact should be a person who can answer questions about the reported chemical substance(s). Typically, a person located at the manufacturing or processing site is best able to answer such questions. However, companies may use their discretion in selecting a technical contact or multiple technical contacts. Submitters should consider, in selecting the technical contact, that EPA may have follow-up questions about a submission one or more years after the submission date. The technical contact need not be the person who signs the certification statement.

Confidentiality

Question 43: What are the restrictions on submitting confidential information under the rule?

Information submitted under the rule may be claimed as confidential at the time it is submitted. Submitters must provide upfront substantiation of confidentiality claims for processing and use

information as well as for confidentiality claims for site or chemical identity. See EPA guidance on asserting confidentiality claims at <https://www.epa.gov/tsca-cbi>.

Question 44: What must generally be considered in making a claim of confidentiality under TSCA?

EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR part 2, subpart B and 40 CFR 704.20(h). The Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that for all claims for protection for any confidential information made with this submission the submitter certify they have:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to my competitive position; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 15 U.S.C. 2613(c).