



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 704

[EPA-HQ-OPPT-2010-0572; FRL-9957-81]

RIN 2070-AJ54

Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is establishing reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale as described in this rule. Specifically, EPA is requiring persons that manufacture (defined by statute to include import) 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.

DATES: This final rule is effective [*insert date 120 days after date of publication in the Federal Register*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number

EPA-HQ-OPPT-2010-0572, is available electronically at <http://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; email address: alwood.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Who does this action apply to?

You may be potentially affected by this action if you manufacture or process or intend to manufacture or process nanoscale forms (forms with particle sizes of 1-100 nm) of certain chemical substances as defined in section 3 of TSCA. You are not manufacturing or processing a TSCA chemical substance when you are manufacturing or processing a chemical for use as, e.g., a pesticide (as defined in the Federal Insecticide, Fungicide, and

Rodenticide Act), food, food additive, drug, cosmetic or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act). However, persons that manufacture or process, or intend to manufacture or process these chemical substances as part of articles, as impurities, or in small quantities solely for research and development will not be subject to this action. In addition, the discussion in Unit III. describes in more detail which chemical substances will and will not be subject to reporting under the rule. You may also consult 40 CFR 704.3 and 704.5, as well as the regulatory text in this document, for further information on the applicability of these and other exemptions to this rule.

The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document may apply to them:

- Chemical Manufacturing or Processing (NAICS codes 325).
- Synthetic Dye and Pigment Manufacturing (NAICS code 325130).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- Rolled Steel Shape Manufacturing (NAICS code 331221).
- Semiconductor and Related Device Manufacturing (NAICS code 334413).
- Carbon and Graphite Product Manufacturing (NAICS code 335991).
- Home Furnishing Merchant Wholesalers (NAICS code 423220).
- Roofing, Sliding, and Insulation Material Merchant Wholesalers (NAICS code 423330).
- Metal Service Centers and Other Metal Merchant Wholesalers (NAICS code 423510).

B. What action is the Agency taking?

On April 6, 2015 (80 FR 18330; FRL-9920-90) (Ref. 1), EPA proposed reporting and recordkeeping requirements for persons that manufacture (including import) or process certain chemical substances as described in the proposed rule. EPA received numerous public comments and conducted a public meeting on June 11, 2015 to obtain additional public input. This final rule is based on that proposal and the consideration of the public comments received.

This TSCA section 8(a) rule requires one-time reporting of certain information, including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety information; as well as keeping records of this information for 3 years. EPA is finalizing the proposed requirements with changes to the definition of a reportable chemical substance, including a definition of unique and novel properties and a numerical value to replace the proposed term of trace amounts. There are also additional exemptions to reporting for certain biological materials, while zinc oxide and nanoclays are no longer exempt from reporting. The definition of a small manufacturer or processor exempt from reporting requirements has been changed. These changes, the reasons for the changes, and other clarifications are discussed in more detail in Unit III. EPA has also prepared a detailed response to public comments document (Ref. 2) that is available in the docket. EPA's responses to some of those comments are summarized in Unit III.

C. Why is the Agency taking this action?

These reporting and recordkeeping requirements will assist EPA in its continuing evaluation of chemical substances manufactured at the nanoscale, informed by available scientific, technical and economic evidence. As with current new chemical reviews of

chemical substances manufactured at the nanoscale, each nanoscale material derived from substances on the TSCA inventory would be evaluated on a case-by-case basis without a presumption of either harm or safety. Any evaluation will be based on the specific nanoscale material's own properties and those of any structural analogs.

As indicated in the proposed rule, the requirements of the rule are not based on an assumption that nanoscale materials as a class, or specific uses of nanoscale materials, necessarily give rise to or are likely to cause harm to people or the environment. Rather, any information gathered under this rule will facilitate EPA's determination of whether further action, including additional information collection, is needed for that specific nanoscale material. Consistent with the President's memorandums for Executive Agencies regarding Principles for Regulation and Oversight of Emerging Technologies and U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials (Ref. 3), this rule will facilitate assessment of risks and risk management, examination of the benefits and costs of further measures, and making future decisions based on available scientific evidence.

In addition, EPA will not publish an inventory of chemical substances manufactured at the nanoscale based on the information that will be collected pursuant to the rule. EPA will make non-confidential information reported under the rule available in ChemView (see <http://www.epa.gov/chemview/>).

D. What is the Agency's authority for taking this action?

As described in more detail in Unit II.A. of the proposed rule, the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA), 15 U.S.C. 2601 *et seq.*, provides EPA with authority to require reporting,

recordkeeping and testing, and impose restrictions relating to chemical substances and/or mixtures. The Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

EPA is issuing this rule under TSCA section 8(a), 15 U.S.C. 2607(a), in compliance with the requirements of section 8(a)(5). Under TSCA section 8(a)(5)(A) EPA is to the extent feasible: (A) not require reporting which is unnecessary or duplicative; (B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and (C) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of TSCA. As noted in the response to comments several elements of this rule address duplicative reporting such as the exemption for chemical substances that are nanoscale materials that have already been reported under section 5 of TSCA and for the exemption for information already submitted under the Nanoscale Materials Stewardship Program. The response also explains why this rule does not duplicate chemical data reporting (CDR) under 40 CFR part 711. EPA's economic analysis demonstrated that this rule would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is summarized in Unit V.C. of this rule and is presented in the small entity impact analysis that EPA prepared for this action as part of the Agency's economic analysis in the public docket for this rule. This rule focuses on manufacturers and processors of chemical substances as nanoscale materials with unique and novel properties which are the persons likely to have relevant information on nanoscale materials in commerce.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of this reporting and recordkeeping requirement for manufacturers and processors. This analysis (Ref. 4), which is available in the docket, is briefly summarized here.

Industry is conservatively estimated to incur a burden of approximately 360,000 hours in the first year and 40,100 hours in subsequent years, with costs of approximately \$27.79 million and \$3.09 million, respectively (see Chapter 3 in Ref. 4), while the Agency is expected to use approximately 16,300 hours in the first year and 1,800 hours in subsequent years, with costs of approximately \$1.34 million and \$0.15 million respectively (see Chapter 4 in Ref. 4). Discounted over a 10-year period at three and seven percent, total annualized social costs are estimated to be approximately \$5.71 million and \$6.26 million, respectively. (Ref. 4).

II. Overview of the Final Rule

EPA is describing in this unit the reporting and recordkeeping requirements for manufacturers and processors of certain chemical substances pursuant to TSCA section 8(a). A processor is someone who prepares a chemical substance or mixture after its manufacture for distribution in commerce. Processor activities include a variety of activities. Some examples of processing of a chemical substance are developing or modifying formulations for additional processing or use in commercial applications, incorporating a chemical substance into articles, and using the chemical substance to form other chemical substances.

A. What chemical substances are reportable under this rule?

1. Reportable chemical substances. This rule applies to chemical substances, as defined in section 3 of TSCA, that are solids at 25 °C and standard atmospheric pressure; that are manufactured or processed in a form where any particles, including aggregates and

agglomerates, are in the size range of 1-100 nanometers (nm) in at least one dimension; and that are manufactured or processed to exhibit one or more unique and novel properties. This rule does not apply to chemical substances manufactured or processed in forms that contain less than 1% by weight of any particles, including aggregates and agglomerates, in the size range of 1-100 nm. These parameters are for purposes of identifying chemical substances that are subject to the rule and do not establish a definition of nanoscale material.

EPA added a definition of unique and novel properties in the definitions section of the regulatory text (See 704.20(a)). 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. A reportable chemical substance is not just a substance containing particles in the size range of 1-100 nm; it must also demonstrate a size-dependent property different from properties at sizes greater than 100 nm and is a reason the chemical is manufactured or processed in that form or size. Chemical substances manufactured or processed at the nanoscale that contain incidental amounts of particles in the size range of 1-100 nm are not reportable chemical substances. EPA used “trace amounts” in the proposed rule to define this concept. However, based on the public comments to better define trace amounts including several comments to establish a numerical value, EPA is now using a numerical value of less than 1% of particles from 1-100 nm by weight to define those chemical substances that are not reportable.

i. Discrete forms. Manufacturers and processors of multiple nanoscale forms of the same chemical substance will, in some cases, need to report separately for each discrete form of the reportable chemical substance. Reporting of these discrete forms are not the same as

new chemical reporting under TSCA section 5. The rule distinguishes between discrete forms in three different ways. The first is based on a combination of three factors: 1) a change in process to effect a change in size, a change in properties of the chemical substances manufactured at the nanoscale, or both; 2) a change in mean particle size greater than 7 times the standard deviation of the measured values (± 7 times the standard deviation); and 3) the change in at least one of the following properties, zeta potential, specific surface area, dispersion stability, or surface reactivity, is greater than 7 times the standard deviation of the measured values (± 7 times the standard deviation).

For example, if the specific surface area of one discrete form was measured to be 50 m^2/g with a standard deviation of $\pm 5 \text{ m}^2/\text{g}$, then a change resulting in a new average specific surface area of 85 m^2/g would result in a discrete form of a reportable chemical substance, if factors 1 and 2 were also met. While testing is not required, if performing the test EPA recommends using the same test medium and method when measuring the change in these properties, as even minor changes in the medium and methods can result in large differences in the measured results. EPA's intent for these reporting requirements is to focus reporting on chemical substances on the TSCA inventory that are intentionally manufactured at the nanoscale.

It is the combination of the above three factors, rather than simply size, which distinguishes between different forms of a chemical substance manufactured at the nanoscale, so that unintended variation in size range between production batches does not trigger separate reporting for each batch. The rule does not rely solely on process changes because there may be process changes that are not intended to change the material produced, but rather are intended to improve the efficiency of the process or to use a less expensive

reactant. EPA is focusing on the properties of *zeta* potential, specific surface area, dispersion stability, and surface reactivity because these properties are of particular interest in health and safety evaluation. Other properties of chemical substances manufactured at the nanoscale (e.g., the wavelength at which light is emitted) may be important for how that form of the chemical substance functions but are less likely to be relevant to hazard, fate, exposure, or risk. The combination of the above three factors provides a clear and transparent way to distinguish among discrete forms of chemical substances manufactured at the nanoscale for purposes of TSCA section 8(a) reporting.

For the purposes of this rule, specific surface area is the ratio of the surface area of the nanoscale material to its mass (m^2/kg), or the area of the surface of the nanoscale material divided by volume (m^2/m^3). This is an important factor because chemical reactions take place at the surface of the material. Thus, the higher the surface area, the greater the chemical reactivity, which is an important consideration for human health toxicity and environmental toxicity assessments.

Zeta potential is the electrostatic potential near the particle surface. It can be measured using various methods. See the International Organization for Standardization (ISO) ISO/TR 13014:2012 “Guidance on Physicochemical Characterization for Manufactured Nano-objects Submitted for Toxicological Testing” (Ref. 5) and the description of zeta potential by Colloidal Dynamics (Ref. 6) for examples. It is typically measured by electrophoresis. This is also an important factor as it measures chemical reactivity at the particle surface.

Dispersion stability is the ability of a dispersion to resist changes in properties over time and can be defined in terms of the change in one or more physical properties over a

given time period. See ISO/TR 13097:2013 “Guidelines for characterization of dispersion stability” (Ref. 7) as an example. Changes in dispersion stability affect physical properties that in turn can affect the environmental fate and hazard properties of a chemical substance.

Surface reactivity is the degree to which the nanoscale material will react with biological systems. The surface reactivity of the form of a chemical substance is dependent upon factors such as redox potential, which is a measure of the tendency of a chemical species to lose or acquire electrons, and photocatalytic activity, including the potential to generate free radicals. Reactive oxygen species and free radicals are important in considering toxicity for these materials.

The second way of distinguishing a discrete nanoscale form of a particular chemical substance is by morphology or shape. Examples include spheres, rods, ellipsoids, cylinders, needles, wires, fibers, cages, hollow shells, trees, flowers, rings, tori, cones, and sheets. The third way is that forms of a reportable chemical substance that are coated with different chemical substances would be considered discrete forms for each chemical coating.

ii. Chemical mixtures. Chemical substances that are manufactured or processed in a nanoscale form for the purposes of being sold to others for use as a component of a mixture, encapsulated material, or composite are subject to reporting. Chemical substances at the nanoscale that are manufactured but are then incorporated into mixtures, encapsulated materials or composites by that manufacturer do not require separate reporting for their incorporation. However, the person reporting as to the chemical substance must report the information required as to each step of its manufacture, processing and use to the extent it is known or reasonably ascertainable.

2. Substances excluded from reporting. EPA is excluding from the requirements of

this rule certain biological materials including DNA, RNA, proteins, enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, and microorganisms.

EPA is excluding chemical substances which dissociate completely in water to form ions with a size of less than 1 nm. This exclusion does not apply to chemical substances manufactured at the nanoscale that release ions but do not dissociate in water to form those ions. Chemical substances that dissociate completely in water to form ions with a size of less than 1 nm do not exhibit new size-dependent properties because the same properties would manifest in the dissociated form regardless of whether the substance is at the nanoscale before dissociation. Manufacturing or processing such substances are therefore not subject to the reporting requirements of the rule.

EPA is excluding chemical substances formed at the nanoscale as part of a film on a surface. See the explanation in Unit III. for the changes from the proposed rule and the detailed response to comments in the docket for EPA's explanation and reasoning.

3. General exemptions to TSCA Section 8(a) reporting. The general exemptions to TSCA section 8(a) reporting at 40 CFR 704.5 are applicable to this rule. These include, among other exemptions, the exemption for research and development (R&D) under which a person who manufactures or processes a chemical substance only in small quantities for research and development is exempt from the reporting requirements of this rule. Examples of R&D activity are the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance. It can include production of a chemical substance for use by others in their R&D activities. R&D activity generally includes specific monitored tests undertaken as part of a planned program of activity.

There is also an exemption from reporting for TSCA section 8(a) rules for small

manufacturers and processors. For purposes of this rule EPA is defining and exempting any small manufacturer or processor as a company that has sales of less than \$11 million per year.

4. Other exceptions to reporting. The rule does not require manufacturers or processors to report certain information that has already been submitted to EPA. A person who submitted a notice under TSCA section 5 to EPA for a reportable chemical substance on or after January 1, 2005 is not required to report regarding the same substance under this rule, except where the person manufactured or processed a new discrete form of the reportable chemical substance. In addition, any person who has already reported part of or all of the information that is required under this rule for EPA's Nanoscale Materials Stewardship Program (NMSP) would not need to report that information again under this rule. If, however, information required by this rule was not reported under the NMSP (including information for each discrete form of a reportable chemical substance), then reporting of that information would be required under this rule. The purpose of these exemptions is to avoid duplicative reporting. For example, new chemical notices under TSCA section 5 that have been reviewed by EPA as nanoscale materials are not subject to reporting for the discrete form of a reportable chemical substance that was submitted and reviewed.

B. When will reporting be required?

Persons who manufacture or process a discrete form of a reportable chemical substance at any time during the three years prior to the final effective date of this rule must report to EPA one year after the final effective date of the rule. There is also a standing one-time reporting requirement for persons who intend to manufacture or process a discrete form of a reportable chemical substance on or after the effective date of the rule. These persons

must report to EPA at least 135 days before manufacture or processing of that discrete form 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 which case the information must be filed within 30 days of the formation of such an intent. For example, if a person forms the intent on July 1 to manufacture a reportable chemical substance and intends to commence manufacture of the substance in less than 135 days, that person must report the required information as to the chemical substance no more than 30 days after forming the intent, which would be July 31.

C. What information must be reported?

This rule requires one-time reporting of certain information, including specific chemical identity, actual or anticipated production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety information.

EPA developed a form (Ref. 8) for reporting information including specific chemical identity, material characterization, physical chemical properties, production volume, use, methods of manufacturing and processing, exposure and release information, and existing information concerning environmental and health effects. Any person required to report under this rule must supply the information identified in the form to the extent it is known to or reasonably ascertainable by them. EPA intends to issue guidance for the final rule within six months of issuing the rule including guidance on the reasonably ascertainable standard, consolidating submissions and generic chemical names.

D. How will information be submitted to EPA?

The rule requires electronic reporting similar to the requirements established in 2013

for submitting other information under TSCA (see 704.20(e)). Submitters will use EPA's CDX, the Agency's electronic reporting portal, for all reporting under this rule. In 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a) and 8(d). (Ref. 9) The final rule follows two previous rules requiring similar electronic reporting of information submitted to EPA for TSCA Chemical Data Reporting and for Pre-Manufacture Notices. EPA expects that electronic reporting will save time, improve data quality and increase efficiencies for both the submitters and the Agency.

EPA developed the Chemical Information Submission System (CISS) for use in submitting data for TSCA sections 4, 8(a), and 8(d) electronically to the Agency. The web reporting tool is available for use with Windows, iOS, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. CISS, a web-based reporting tool, provides user-friendly navigation, works with CDX to secure online communication, creates a completed document in Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML.

EPA is requiring submitters to follow the same submission procedures used for other TSCA submissions, *i.e.*, to register with EPA's CDX (if not already registered) and use CISS to prepare a data file for submission. Registration enables CDX to authenticate identity and verify authorization. To submit electronically to EPA via CDX, individuals must first register with that system at http://cdx.epa.gov/epa_home.asp. To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") agrees to

the Terms and Conditions, provides information about the submitter and organization, selects a user name and password, and follows the procedures outlined in the guidance document for CDX available at http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.

Users who have previously registered with CDX for other TSCA submissions, Chemical Data Reporting, or the Toxics Release Inventory TRI-ME web reporting flow, can add the “Submission for Chemical Safety and Pesticide Program (CSPP)” CDX flow to their current registration, and use the CISS web-based reporting tool.

All submitters must use CISS to prepare their submissions. CISS guides users through the process of creating an electronic submission. Once a user completes the relevant data fields, attaches appropriate PDF files, or other file types, such as XML files, and completes metadata information, CISS validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions on submitting and instructions for uploading PDF attachments or other file types, such as XML, and completing metadata information are available through CISS reporting guidance.

CISS allows the user to choose “Print,” “Save,” or “Transmit through CDX.” When “Transmit through CDX” is selected, the user is asked to provide the user name and password that was created during the CDX registration process. CISS then encrypts the file and submits it via CDX. The user will log in to the application and check the status of their submissions. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as “Completed.” The CDX inbox is currently used to notify the users of any correspondence related to user registration. Information on accessing the CDX user inbox is provided in the guidance document for CDX at

http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf. To access CISS go to <https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go <http://www.epa.gov/oppt/chemtest/ereporting/index.html>. Procedures for reporting chemical substances under this rule are similar.

Any person submitting a reporting form could claim any of the information on the form as CBI. Any information which is claimed as confidential will be disclosed by EPA only to the extent and by the means of the procedures set forth in 40 CFR part 2.

D. Confidentiality and the Recent Revisions to TSCA.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law on June 22, 2016, and became immediately effective. This final rule contains one minor change to reflect the new statutory requirements for asserting confidentiality claims. Section 14(c)(1)(B) of the law now requires a supporting statement for confidentiality claims. This statement is similar to the certification currently required in 40 CFR 704.7, which is cross-referenced in the proposed rule. In this final rule, EPA is substituting the wording of the section 14(c)(1)(B) statement for the wording of the certification in §704.7(d) so as to eliminate any possibility of doubt that the certification meets the statutory requirements. While this change was not discussed in the proposed rule, EPA finds there is good cause to make this change without notice and comment. Notice and comment are unnecessary because the new statement is required by statute, and the new language is sufficiently similar to that in the §704.7(d) certification that EPA anticipates no significant effect of the change on companies reporting under the rule or on the public in general.

The law also requires that a generic chemical identity be provided when companies

claim a specific chemical identity as confidential. No conforming change is necessary for this rule, because companies reporting under this rule will be claiming chemical identities as confidential only when there is already a generic identity on the confidential portion of the TSCA Chemical Substances Inventory. CISS will automatically populate the submission with the generic chemical name associated with the Inventory listing. This process provides the greatest degree of structural specificity that is practicable to afford at the current time. EPA will develop guidance regarding generic names as required by TSCA, and will determine appropriate procedures regarding their use and submission.

III. Summary of Response to Comments Including Changes and Clarifications from the Proposed Rule

This unit summarizes EPA's responses to comments for several general areas of comments from multiple stakeholders, and where responses are particularly relevant to the requirements of the final rule. EPA also discusses any changes to and clarifications from the proposed rule. A separate document that summarizes the comments relevant to the proposal and EPA's responses to those comments has been prepared and is available in the docket for this rulemaking (Ref. 2).

Comment 1: Several commenters stated that TSCA applies to chemical substances, not different physical forms or different particle sizes of chemical substances, and that discrete forms or discrete physical forms are not "chemical substances" subject to reporting under section 8(a) of TSCA.

Response: TSCA section 8(a) authorizes EPA to promulgate rules for submission of such reports as the Agency "may reasonably require." EPA believes that the information from this reporting will help EPA to determine whether chemical substances manufactured

and processed at the nanoscale may exhibit behavior relevant to health and safety that is different from that of non-nanoscale forms of chemical substances. EPA thus has the authority to require reporting pertaining to different forms of chemical substances.

Comment 2: Several commenters stated that the proposed information requests are outside those allowed by section 8(a) of TSCA. Commenters specifically identified material characterization including particle size and morphology, methods of manufacture, weight percent of impurities, environmental release information, general population, consumer exposure, risk management practices, and engineering controls. One commenter wanted EPA to explain more clearly the basis of authority for requesting information that does not fall within the scope of the clear statutory authority of TSCA section 8(a).

Response: Section 8(a) gives EPA broad authority to collect information that the Administrator may reasonably require. Section 8(a)(1) authorizes EPA to require reporting of such information with respect to chemical substances as the Administrator may reasonably require. Although it contains limitations with respect to requirements to report with mixtures and to chemical substances manufactured in small quantities for experimentation, those limitations are not relevant to the requirements imposed by this rulemaking. Section 8(a)(2) is best interpreted as listing examples of the kinds of information EPA can require reporting on under section 8(a)(1), not as limiting EPA's authority. If Congress had intended to impose limitations on the kinds of information EPA can collect under section 8(a)(1), it would have added them to the limitations it included in section 8(a)(1). EPA has always interpreted section 8(a) in this fashion, see 58 FR 63134 (November 30, 1993) – an interpretation that is supported by the legislative history of section 8(a), H.R. Conf. Rep. 94-1679, at 80 (1976); S. Rep. No. 94-698, at 22 (1976), H.R. Rep. No. 94-1341, at 42 (1976).

Further, the information required under the rule is consistent with the examples of information discussed in section 8(a)(2). For example, requiring weight percent of impurities is analogous to byproducts, material characterization including particle size and morphology is analogous to molecular structure of chemical substances manufactured and processed at the nanoscale, environmental release falls under methods of disposal, while methods of manufacture, risk management practices, engineering controls, general population and consumer exposure fall under estimates of individuals who would be exposed.

Comment 3: Several commenters noted that processors do not know about the particle size and other characteristics of formulations they process or use and should not be required to report.

Response: Reporting of information under TSCA section 8(a) is required only to the extent the information is known or reasonably ascertainable, and includes information that the Administrator may reasonably require. 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 the 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. 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.

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.

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).

Comment 4: Several commenters also asked EPA if manufacturers and processors are only required to report available or reasonably ascertainable information, does this mean they need to develop information to comply with the rule. Other commenters asked EPA to clarify if manufacturers and processors need to develop information to comply with the rule.

Response: Manufacturers and processors are not required to conduct testing or develop new information under this rule. However, they are required to report information

that is known or reasonably ascertainable.

Comment 5: Many commenters stated the proposal gives 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. One commenter noted that if the requirement that reportable chemicals exhibit unique and novel attributes due to particle size is removed from the definition, the rule would not differentiate genuinely new nanoscale materials from traditional legacy products in commerce. Several commenters stated there should be some differentiation between genuinely new nanoscale materials in commerce and traditional products. Two commenters supported the proposed definition while one commenter supported a definition of 1-100 nm and unique or novel characteristics.

Response: Based on these comments, EPA agrees that what is a reportable chemical substance should be better defined and clarified. EPA is finalizing the rule with further explanation of “unique and novel properties” as described in the National Nanotechnology Initiative’s definition. 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. See <http://www.nano.gov>. 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 also noted on <http://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 nm, the materials’ properties can change significantly from those at larger scales. See also comment 11 and the response for further

clarification on what is considered a reportable chemical substance.

For purposes of this rule, EPA is defining 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. The rule includes a definition of unique and novel properties in the definitions section of the regulatory text (See §704.20(a)). 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. In order to be reportable it's not sufficient that a chemical substance contains particles in the size range of 1-100 nm; it must also have a size-dependent property different from properties at sizes greater than 100 nm and those properties are a 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 would create 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. For example, see the discussion in Unit II.B. of the proposed rule of the range of biological impacts of nanoscale materials. EPA is exempting certain biological materials, in part, because they do not exhibit different size-dependent properties in the size range of 1-100 nm.

Other chemical substances, including as an example some chemicals that commenters proposed that EPA exempt from reporting, such as pigments, polymers, and polymer

dispersions, could be manufactured in nanoscale forms that both exhibit unique and novel properties and in forms that do not. In the concept paper for the NMSP (Ref. 10), EPA stated that many polymers or oligomers, particularly linear or planar polymers, should not be reported even though they have dimensions in the nanoscale. Those polymers did not demonstrate size-dependent properties. The paper did note that when conditions of polymerization or post-reaction processing create free particles that fit the general description of “engineered nanoscale material” those chemical substances should be reported under the NMSP. Please also refer to the comment and response to comment 12 in the response to comments document regarding the difference between enhanced and novel properties.

Comment 6: Several 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. The commenters suggested including a numerical value to define trace amount. Most commenters did not suggest a specific value, although one commenter noted the original definition of the Agency’s draft proposed rule submitted to OMB would have required reporting for those substances containing $\geq 10\%$ particles in the range of 1-100 nm while another commenter suggested using a numerical value of less than 10% of particles as trace amount that would not be considered to be a reportable chemical substance. Commenters asked EPA to clarify if particle size was to be determined by weight, volume, or count. One commenter stated that EPA should not use weight based criteria to determine particle size as that measurement is sometimes skewed by the inclusion of very large particles. Several other commenters suggested using weight based criteria to identify particle size but did not give any reasons why.

Response: Chemical substances manufactured or processed at the nanoscale that

contain incidental amounts of particles in the size range of 1-100 nm are not reportable chemical substances. EPA used trace amounts in the proposed rule to define this concept. However, based on the public comments to more clearly define trace amounts including several comments to establish a numerical cutoff, EPA is instead using a numerical value of less than 1% of particles from 1-100 nm by weight to more clearly define those chemical substances that would not be reportable. EPA has chosen this number because it is the percentage cut-off used in OSHA's hazard communication standard for all chemicals substances that are not OSHA carcinogens (for which there is a 0.1% cut-off) (Ref. 11). This 1% cut-off is a level that industry has used to identify chemicals in safety data sheets (and previously in material safety data sheets.) Industry is already using this cut-off to identify at least some nanoscale chemical substances, e.g., carbon nanotubes in mixtures. EPA is using the weight based method for measuring particles even though that measurement is sometimes altered by the presence of very large particles because it is the most widely used method, and more data will therefore be available. The final rule does not require reporting for any chemical substance where less than 1% percent of the particle size distribution by weight is less than 100 nm.

Changes to the Definition of a Reportable Chemical Substance in the Final Rule.

EPA has added a definition of unique and novel properties in the definitions section of the regulatory text (See 704.20(a)). Unique and novel properties means any size-dependent property that vary from other properties associated with other forms or sizes of the same chemical substance, and such properties are the reason that the chemical substance is manufactured or processed in that form or size. A reportable chemical substance is not just a substance containing particles in the size range of 1-100 nm; it must also have a size-

dependent property different from properties at sizes greater than 100 nm. The final rule no longer states that a reportable chemical substance does not include a chemical substance that only has trace amounts of primary particles, aggregates, or agglomerates in the size range of 1–100 nm, such that the chemical substance does not exhibit the unique and novel characteristics or properties because of particle size. The final rule now states that 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.

Comment 7: A variety of commenters stated that EPA should add additional exemptions for biological materials such as enzymes, lipids, carbohydrates, peptides, polypeptides, nucleotides, liposomes, antibodies, viruses, virus-like particles, viral based products, organelles, and microorganisms. The commenters stated that the additional biological materials should be exempted for the same reason EPA proposed to exempt DNA, RNA, and proteins, that the additional biological materials did not exhibit properties as a function of their size range.

Response: Because they meet the same criteria that EPA identified in the proposed rule, EPA is adding an exemption for enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, and microorganisms in the final rule. The properties of all the exempted biological materials, which can be in the nanoscale, are not a function of the size range per se but rather of the precise nucleotide sequence (in the case of DNA and RNA), shape, and complex biological structures (living cells).

Comment 8: Several commenters identified additional possible exemptions for organic and inorganic pigments and dyes; polymers including polymer dispersions; and

chemical substances used in adhesives, coatings and sealants and chemical substances when they are embedded in a polymer matrix or incorporated into a formulated product such as adhesives, cement, ink, coatings, glass, paint, plastic and rubber because they are well understood or characterized and present low risk and low potential for exposure.

Commenters suggested that EPA include an exemption for polymers and polymer dispersions to be consistent with the polymer exemption under section 5 of TSCA. Commenters also noted TSCA section 5 regulations such as SNURs which exempted requirements for carbon nanotubes, silica, and pigments when incorporated into polymer matrices.

Response: A reportable chemical substance is not just a substance containing particles in the size range of 1-100 nm; it must also have a size-dependent property different from properties at sizes greater than 100 nm. The chemical substances or activities identified by commenters could be manufactured in nanoscale forms that both exhibit unique and novel properties and in forms that do not. If a chemical substance does not exhibit unique and novel properties, then no reporting would be required. EPA lacks information demonstrating minimal risk and exposure for nanoscale forms of the chemical substances or activities that commenters proposed for exemption. The polymer exemption under TSCA section 5 is not based on any consideration of the potential for impacts from polymers with size dependent properties and does not include all polymers. Most of the activities described by commenters for exemption would only require reporting for a reportable chemical substance before it is incorporated into a formulated product or polymer matrix. Reporting would not be required by persons who use the formulated product or polymer matrix. EPA is not including an exemption for these chemical substances and activities because doing so would exempt some of the nanoscale materials in commerce for which EPA is collecting information on health

and safety effects which would allow EPA to better assess and manage risks of nanoscale materials.

Comment 9: Several commenters proposed limited or no reporting for nanoscale materials such as carbon black, silica, titanium dioxide, nanosilver, and nanocellulose, based on the proposed exemption for nanoclays and zinc oxide. The commenters asked EPA to better define the criteria it used to exempt nanoclays and zinc oxide as well-characterized so that the criteria could be applied to these chemical substances. One commenter noted that available information for commercial forms of nanocellulose demonstrate low hazard and risk. Several commenters also described the hazards and exposures of these chemical substances as well-characterized. Several commenters stated that EPA should not exempt zinc oxide and nanoclays as EPA had not identified and made available the data that demonstrated why they are well-characterized.

Response: EPA has decided to not exempt nanoclays and zinc oxide from reporting. When considering the comments to exempt other chemical substances based on its proposed exemption for zinc oxide and nanoclays, EPA realized that it had given too much weight to the available information on zinc oxide and nanoclays. While there is some available information on these chemical substances, EPA does not consider the available information sufficient to extrapolate to all other forms of these chemical substances to exclude information collection under TSCA. Further, this limited information is not a sufficient basis to create a broader exemption by analogy for other chemical substances. Thus, even for chemical substances manufactured as nanoscale materials that could be described as a group as well-characterized or demonstrating low hazard based on data not relating to nanoscale forms in particular, EPA lacks information on how much and what type of specific nanoscale

materials are in commerce and what kind of information is available to assess the properties that can impact health and safety and thus potential risks of those nanoscale materials. The chemical substances that commenters and EPA stated were well characterized could be manufactured in nanoscale forms that both exhibit unique and novel properties and in forms that do not. EPA is not exempting from reporting any of the chemical substances proposed by commenters, including zinc oxide and nanoclays because doing so would exempt some of the nanoscale materials in commerce for which EPA is collecting information on health and safety effects which would allow EPA to better assess and manage risks of nanoscale materials. The type of information described by the commenter regarding nanocellulose is the type of information on health and safety effects which would allow EPA to better assess and manage risks of nanoscale materials.

Changes to Chemical Substances That Are Exempt from the Final Rule: EPA added exemptions for enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, microorganisms in the final rule. EPA did not add any other exemptions to the final rule. EPA did not include the proposed exemptions for nanoclays and zinc oxide in the final rule.

Comment 10: Several commenters stated that EPA cannot require information that violates the language under TSCA section 8(a) prohibiting “any reporting which is unnecessary or duplicative.” Commenters stated that requiring reporting of some of the information already reported to the NMSP would be duplicative, especially the large amount of health and safety information submitted for broad classes of chemical substances such as silica and carbon black. Commenters also asked EPA to explain why the proposed reporting requirements do not duplicate reporting required under CDR.

Response: The reporting required by this rule does not duplicate reporting EPA

would receive under other TSCA regulations. Chemical data reporting (CDR) under 40 CFR part 711 does not require manufacturers to distinguish reporting for different forms of chemical substances including nanoscale materials. This rule also exempts reporting for chemical substances that are nanoscale materials that have already been reported under section 5 of TSCA since 2005 except for new discrete forms. As noted in the interim report on the NMSP (Ref. 12), EPA received limited reporting on nanoscale materials in commerce. The reporting for nanoscale materials such as silica and carbon black gave an overview of the entire industry but not information on individual nanoscale materials. A company reporting a silica or carbon black-based nanoscale material does not have to resubmit the information submitted under the NMSP. However, any reporting of silica or carbon black nanoscale materials would need to include any health and safety information that company possesses for the specific nanoscale material it is reporting. As already noted, CDR reporting does not distinguish between different nanoscale forms of chemical substances. Several commenters stated that EPA needs more information on nanoscale materials in commerce. In the full response to comments document, EPA addresses more specific comments about information required by the rule.

Comment 11: There were numerous comments to not include the 135 day reporting requirement for new discrete forms. This requirement was characterized by several commenters as de facto new chemical reporting. 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 because it provides the Agency with more time to identify potential concerns and initiate appropriate action to address them.

Response: EPA did not intend to create de facto new chemical reporting for new discrete forms of nanoscale materials, because 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 Premanufacture Notice (PMN) program, EPA believes that in most cases companies have the requisite intent to manufacture or process 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. EPA is revising the language in 704.20(f)(2) to clarify that the rule does not prevent manufacturing before the 135-day period has passed. If the company changes its schedule or does not form the intent until a later time, it may wish to document supporting facts.

Further, the comments made EPA realize that the regulatory text as written in the proposal created a result unintended by the Agency (and not commented upon): because (1) the default period of 135 days is greater than the advance of periods required for various section 5 submissions, and (2) the reporting exemption for section 5 submissions in 704.20(c)(2) of the proposal would apply only where the company had already filed a section 5 submission, a company proposing to manufacture a discrete form of a reportable substance for which a section 5 submission had not been filed might conceivably be required to first file a section 8(a) report, followed by a section 5 submission. In such cases EPA only needs the section 5 submission and exercise whatever section 5 authority might be necessary in a

specific case, rather than imposing an additional burden of requiring a duplicative section 8(a) submission. Therefore EPA is adding a new subcategory of non-reportable chemical substances to 704.20(c)(1), for chemical substances that are not on the TSCA Inventory at the time reporting would otherwise be required, to clarify the Agency's original intent in the NPRM. If a reportable chemical substance is not on the TSCA Inventory a manufacturer only needs to submit a new chemical notification under section 5 of TSCA.

Changes to the 135-day Reporting Requirement for Discrete Forms of a Reportable Chemical Substance: EPA has added language to 40 CFR part 704.20(f)(2): "except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent." The language makes clear what companies must do if they do form an intent to manufacture or process a discrete form of a reportable chemical substance less than 135 days ahead of manufacture or processing.

Changes to Chemical Substances That Are Not Reportable: EPA has added language to 704.20(c)(1), exempting chemical substances that are not on the TSCA Inventory from reporting.

Comment 12: There is not standardized testing for the physical properties in the proposed rule identified for manufacturers and processors to determine if they qualify for the rule. EPA should identify test methods to be used to comply with the rule. Many processors will not know to test for these properties. EPA cannot require this testing until validated protocols are developed.

Response: Testing or developing new information is not required by the rule. Only known or reasonably ascertainable information needs to be reported. Companies are only

required to report on known or reasonably ascertainable information. See the response to comment 3 for guidance as to situations in which a company does not know about the physical properties identified in the regulation. In the proposed rule, EPA supplied examples of testing guidelines that could be used for these types of properties should the company desire to do such testing.

Comment 13: Several commenters supported the \$4 million dollar small business exemption. One commenter wanted an even smaller dollar amount so that more small businesses would be required to report. Other commenters supported just using the dollar amount but stated it should be increased to \$9.5 million dollars to account for inflation since 1988 when the current small business amount of \$4 million was established.

Response: Based on these comments and updated economic information, EPA is changing the definition of small business in the final rule to include any company with sales of \$11 million dollars or less. In suggesting EPA change the value to \$9.5 million, the commenter assumed the original \$4 million was promulgated in 1988. However, the \$4 million was initially promulgated in 1984 (49 FR 45425) with a base year of 1983. Therefore, it is appropriate to inflate the \$4 million from \$1983 to \$2015. When accounting for inflation since 1983, EPA calculated the figure to be \$11 million dollars.

In proposing this definition, EPA provided notice and comment on the criteria for small manufacturers and processors subject to this rule, and consulted with the Small Business Administration (SBA) in accordance with TSCA section 8(a)(3)(B). EPA's change to this definition is consistent with both public comments and the feedback we received from SBA.

EPA recognizes that recent amendments to TSCA include a new and separate obligation

under amended TSCA section 8(a)(3)(C), which requires EPA, after consultation with the SBA, to review the adequacy of the standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of TSCA sections 8(a)(1) and 8(a)(3). TSCA furthermore requires that (after consulting with the SBA and providing public notice and an opportunity for comment) EPA make a determination as to whether revision of the standards is warranted. In the **Federal Register** of December 15, 2016 (81 FR 90840) (FRL-9956-03), EPA sought public comment on whether a revision of the current size standard definitions is warranted at this time; announced EPA's initiation of the required consultation with the SBA, and provided its preliminary determination that revision to the currently codified size standards for TSCA section 8(a) is indeed warranted. As part of this effort, EPA will review the adequacy of the standards for small manufacturers and processors in existing TSCA section 8(a) rules, including this one. Any changes resulting from the assessment will undergo consultation with SBA and will be proposed for notice and comment as required by TSCA section 8(a)(3)(C).

Changes to the Definition of a Small Manufacturer or Processor Exempt from the Reporting Requirements of the Rule: The final rule retains a small business exemption based only on sales, but a small manufacturer or processor will be defined as any company with sales of less than \$11 million per year.

Comment 14: Several commenters asked EPA to clarify the objects and collections of objects to which the 1-100 nm measurement applies. 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?

Response: 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. EPA has modified the description of particles that would be subject to reporting in the definition of reportable chemical substance to better reflect this understanding. 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”

Comment 15: Several commenters suggested that EPA should better define particle. One commenter stated “The word ‘particle’ is not a term with specific meaning. It is critical that EPA is clear about the definition of ‘particle’ so that companies understand what materials require reporting. For example, does the term ‘particle’ include solid objects that contain internal crystalline domains at the nanoscale? Does it include dispersions, suspensions, or aerosols? A definition of ‘particle’ would provide an important starting point for determining whether a material is subject to reporting. It should take into account the ability of a ‘particle’ to move freely in its environment.”

Response: EPA will use the definition of particle from ISO, which is a “minute piece of matter with defined physical boundaries.” The notes to the ISO definition should be used as guidance in applying this definition. Note 1: A physical boundary can also be described as an interface. Note 2: A particle can move as a unit. EPA is using this definition because there is international agreement on the definition; the definition addresses the commenter’s questions about the ability of a particle to move in the environment and whether “particle” includes dispersions, suspensions, or aerosols.

Changes to the Final Rule to Clarify the Types of Particles to be Measured: EPA has added a definition of particle and modified the language in the definition of reportable

chemical substance for the types of particles that will be measured.

Comment 16: Several commenters stated that the shape criteria for identifying reportable chemical substances are too vague and unworkable. The commenters asked what the criteria are to discern one shape from another. For example one commenter stated “For morphology, how would manufacturers and processors distinguish between the different morphologies identified in the proposed regulatory text: what definitions would distinguish for example a rod from an ellipsoid, needle, wire, and/or fiber as these shapes could be considered on a continuum? Another commenter stated “It is unclear how different the shapes of two forms would have to be in order to trigger the discrete forms requirement.”

Response: As noted in the proposed rule the different morphology could 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, as commenters have noted, 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 and novel property for a chemical substance in the particle size range of 1-100 nm.

Comment 17: Several commenters objected to imposing the same reporting requirements on both processors and manufacturers stating that some processors will not be aware of information known to manufacturers such as for example chemical identity, physical-chemical properties, byproducts, impurities, health effects data, and general population exposure. In addition, the commenters speculated that processors may report uses and processes already reported by the manufacturer. The commenters felt the reporting

requirements place impractical or burdensome obligations on processors without collecting information that would serve the intended purposes of the rule when manufacturers were in the best position to report information required by the rule. Commenters suggested limiting reporting to only manufacturers or limiting the information to be reported by processors.

Response: Processors are only required to submit information that is known or reasonably ascertainable. In addition, processors may have access to pertinent information that manufacturers do not have access to. Processors can often describe in greater detail how the nanoscale material is processed and used and any characteristics that change because of processing. Details on the processing and use of nanoscale forms of chemical substances with unique or novel properties will give EPA a better understanding regarding how to assess those chemical substances and whether any further actions are warranted under TSCA.

Comment 18: Several commenters stated that EPA should exempt naturally occurring or mined nanoscale materials. One commenter noted that CDR regulations exempt naturally occurring chemical substances as described at 40 CFR § 710.4(b). Several commenters also stated naturally occurring nanoscale materials should be exempt from reporting as they do not meet the criteria of the definition of “manufactured or processed.” Another commenter suggested limiting reporting to engineered nanomaterials as they are “generated for a specific function” or “deliberately manipulated.”

Response: EPA did not exempt naturally occurring materials or limit reporting to chemical substances engineered at the nanoscale because some of these chemical substances meet the criteria of a reportable chemical substance and some of them do not. These chemical substances must be reported only if they meet the definition of containing particles in the size range of 1-100 nanometers and a size-dependent property different from properties at sizes

greater than 100 nanometers. EPA expects that reportable chemical substances would usually be the result of processing of naturally occurring or mined materials by manufacturers and processors

Comment 19: A commenter stated that EPA should add an explicit exemption for nanoscale substances that are unintentionally generated during manufacturing and processing. Another commenter asked EPA to clarify if it matters if a nanoscale substance is intentionally added versus accidentally formed.

Response: If a nanoscale chemical substance is unintentionally generated or added and not intended to be part of the commercially manufactured or processed chemical substance, it may be considered a byproduct or impurity and would be exempt under 40 CFR 704.5(b) or (c). If a nanoscale chemical substance is unintentionally formed but is considered to be part of the function of the commercial product, it would be a reportable chemical substance. A chemical substance which is intentionally produced but is in total or in part unintentionally produced at the nanoscale is not an impurity or a byproduct. There are examples where a chemical substance is intentionally produced, but unintentionally produced at the nanoscale, and the manufacturer knows that it contributes to the function of their product. In those cases, where a company knows about its functionality, the chemical substance is still subject to TSCA reporting requirements. See, for example, EPA's PMN regulations at 40 CFR 720.30(h)(2), which exempts from reporting a byproduct not used for commercial purposes, but retains the reporting requirement if the byproduct is used for commercial purposes. The rule does not require a company to determine the functionality of every impurity or byproduct. A company is required to report that chemical substance when it knows the chemical substance has commercial functionality.

Other Changes to the Final Rule: EPA made other changes to the rule. See the Response to Comments Document (Ref. 2) for further details. EPA has modified the definition of zeta potential to address public comments that zeta potential was not accurately defined in the proposed rule. Because “chemical substances manufactured at the nanoscale as part of a film on a surface” did not adequately describe the films on a surface exemption that was proposed, EPA changed the wording of the exemption to state “chemical substances formed at the nanoscale as part of a film on a surface.”

Changes to the Reporting Form: EPA made the following changes to the reporting form. See the Response to Comments Document (Ref. 2) for further explanation. EPA removed the requirement for an overview of the life cycle in Section C of the reporting form, as that information duplicates information already identified in other parts of the form. Because not all enhanced properties are unique or novel properties, EPA replaced the word enhanced with novel in section C.5. of the 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. In order to help facilitate continued work on sharing available information and to inform future alignment on activities pertaining to nanoscale materials, EPA included the option on the reporting form to share information with Environment and Climate Change Canada and Health Canada per one commenter’s request to provide the option of sharing CBI.

IV. References

The following is a listing of the documents that are specifically referenced in this

document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; Proposed Rule. **Federal Register** April 6, 2015 (80 FR 18330) (FRL-9920-90).
2. 2016. EPA. Response to Comments to the Proposed Rule, Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; RIN 2070-AJ54. Docket # EPA-HQ-OPPT-2010-0572.
3. 2011. Executive Office of the President. Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials. <https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>, and Principles for Regulation and Oversight of Emerging Technologies at <https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf>
4. 2016. EPA. Economic Analysis for the TSCA Section 8(a) Reporting Requirements for Certain Nanoscale Materials (RIN 2070-AJ54). December 2016.
5. 2012. International Organization for Standardization (ISO). Nanotechnologies—Guidance on Physicochemical Characterization for Manufactured Nano-objects Submitted for Toxicological Testing. ISO/TR (Technical Report) ISO/TR 13014:2012.

6. 1999. Colloidal Dynamics. The Zeta Potential. <http://www.colloidal-dynamics.com/docs/CDEITut1.pdf>.
7. 2013. ISO/TR. Guidelines for Characterization of Dispersion Stability. ISO/TR 13097:2013.
8. 2016. EPA. Information Submission Form. TSCA section 8(a) Information Reporting for Nanoscale Materials. EPA Form No. 7710-[tbd]; EPA ICR No. 2517.02; OMB Control No. 2070-NEW.
9. 2013. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule. **Federal Register** (78 FR 72818, December 4, 2013) (FRL 9394-6).
10. 2007. EPA. Nanoscale Materials Stewardship Program – Concept Paper.
11. OSHA. OSHA Hazard Communication Standard; 29 CFR part 1910.1200, https://www.osha.gov/pls/oshaweb/owadispl.show_document?p_table=standards&p_id=1009
- 9.
12. 2009. EPA. Interim Report on the Nanoscale Materials Stewardship Program.
13. 2015. EPA. Chemical-Specific Rules, Toxic Substances Control Act Section 8(a). OMB control No. 2070-0067 (EPA ICR No. 1198.10).
14. 2015. EPA. Addendum to an Existing EPA ICR Entitled: Chemical-Specific Rules, Toxic Substances Control Act Section 8(a). EPA ICR No. 2157.02; OMB Control No. 2070-[new].

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563:

Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket. EPA prepared an economic analysis for this action (Ref. 4), which is available in the docket and discussed in Unit I.E.

B. Paperwork Reduction Act (PRA)

The information collection activities in 40 CFR part 704 related to TSCA section 8(a) reporting rules are approved by OMB under the PRA and assigned OMB control No. 2070-0067 (EPA ICR No. 1198) (Ref. 13). Because this rule revises those information collection activities and the related collection instrument, additional approval by OMB is required. As such, EPA has prepared an addendum to the currently approved ICR; the addendum is identified under EPA ICR No. 2517.02 (OMB Control No. 2070-[new]) (Ref. 14). The ICR document provides the estimated burden and costs for the information collection activities contained in this final rule. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

Respondents/affected entities: Chemical manufacturers (including importers) and processors.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 2,681.

Frequency of response: Variable.

Total estimated burden: 146,855 hours (average per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated burden cost: \$11.33 million (per year), includes \$0 annualized capital or operation and maintenance costs.

Change in approved burden: The total burden in OMB's inventory for the existing, approved ICR (275 hours), will be increased by 146,855 hours, for a new total burden of 147,130 hours. If an entity were to submit a report to the Agency, the annual burden is estimated to average 164 hours per response. Burden is defined in 5 CFR 1320.3(b). As presented in the economic analyses and the ICR addenda, EPA estimates that the TSCA section 8(a) rule will create a total incremental industry burden of 440,566 hours over three years.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small businesses, small governmental jurisdictions and small non-profits. A small business exemption exists under TSCA section 8(a) reporting rules, at 40 CFR 704.5(f). For this action, EPA is modifying the exemption. EPA analyzed potential small business impacts from this rule using both the

SBA employee size standards and the TSCA sales-based definition of small business. The Agency has determined that up to 411 small businesses may be impacted and evaluated the number that may incur costs at below 1% and 3%, and above 3% of sales. EPA estimates that all 411 small businesses identified will incur costs below 1% of sales, which EPA has determined is not a significant adverse economic impact on a substantial number of small entities. Details of this analysis are presented in the small entity impact analysis that EPA prepared for this action as part of the Agency's economic analysis that is in the public docket for this rule (Ref. 4).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. Based on EPA's experience with proposing and finalizing rules under TSCA section 8(a), State, local and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local or Tribal government will be impacted by this rulemaking. In addition, this action will not result in annual expenditures of \$100 million or more for the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175

(65 FR 67249, November 9, 2000), because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk. Nevertheless, the information obtained by the reporting required by this rule will be used to inform the Agency’s decision-making process regarding chemical substances to which children may be disproportionately exposed. This information will also assist the Agency and others in determining whether the chemical substances addressed in this rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low -Income Populations

This action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment. The information collected under this rule will, however, assist EPA and others in determining the potential hazards and risks associated with various chemicals manufactured processed, and used at the nanoscale. Although not directly impacting environmental justice-related concerns, this information will enable the Agency to better assess and protect human health and the environment, including in low-income and minority communities.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 704

Environmental protection, Chemicals, Hazardous materials, Recordkeeping, and Reporting Requirements.

Dated: December 29, 2016.

Louise P. Wise,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 704—REPORTING AND RECORDKEEPING REQUIREMENTS

1. The authority citation for part 704 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

2. Add § 704.20 to Subpart B, to read as follows:

§704.20 Chemical substances manufactured or processed at the nanoscale.

(a) Definitions. For purposes of this section the terms below are defined as follows:

An *agglomerate* is a collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components.

An *aggregate* is a particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

CISS tool means the Chemical Information Submission System, EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

Discrete form of a reportable chemical substance differs from another form of the same reportable chemical substance in one or more of the following 3 characteristics: (i) The change in the reportable chemical substance is due to all of the following:

(A) There is a change in process to effect a change in size, a change in one or more of the properties of the reportable chemical substances identified in paragraph (i)(C) of this definition, or both;

(B) 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

(C) There is a change in at least one of the following properties: zeta potential, specific surface area, dispersion stability, or surface reactivity, that is greater than 7 times the standard deviation of the measured value (+/- 7 times the standard deviation).

(ii) The reportable chemical substance has a different morphology. Examples of morphologies include but are not limited to sphere, rod, ellipsoid, cylinder, needle, wire, fiber, cage, hollow shell, tree, flower, ring, torus, cone, and sheet.

(iii) A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture.

Nanoscale Materials Stewardship Program was a program conducted by EPA from January 2008 to December 2009 under which some nanoscale material manufacturers and processors voluntarily provided EPA available information on engineered nanoscale materials that were manufactured, processed or used.

Particle is a minute piece of matter with defined physical boundaries.

Primary particles are particles or droplets that form during manufacture of a *chemical* substance before aggregation or agglomeration occurs.

Reportable chemical substance is a chemical substance as defined in section 3 of TSCA that is 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.

Small manufacturer or processor means any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than \$11 million. The definition of *small manufacturer* in section 704.3 of this title does not apply to reporting under this section (40 CFR 704.20).

Specific surface area means the ratio of the area of the surface of the reportable chemical substance to its mass or volume. Specific surface area by mass is the ratio of the area of the surface of a nanoscale material divided by the mass (m^2/kg) and the specific surface area by volume is the area of the surface of the reportable chemical substance divided by its volume m^2/m^3 .

Surface reactivity means the reactivity at the surface of a reportable chemical substance. It is dependent upon factors such as redox potential, which is a measure of the tendency of a substance to lose or acquire electrons, photocatalytic activity, including the potential to generate free radicals.

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.

Zeta potential is the electrostatic potential near the particle surface.

(b) Persons who must report. (1) Persons who can reasonably ascertain that they are manufacturers and processors of a discrete form of a reportable chemical substance during

the three years prior to the final effective date of the rule must report except as provided in paragraph (c) of this section.

(2) Persons who can reasonably ascertain that they propose to manufacture or process a discrete form of a reportable chemical substance after the final effective date of the rule which was not reported under paragraph (b)(1) of this section must report except as provided in paragraph (c) of this section.

(c) When reporting is not required. (1) The following chemical substances are not subject to reporting under this section:

- (i) Chemical substances formed at the nanoscale as part of a film on a surface
- (ii) DNA
- (iii) RNA
- (iv) Proteins
- (v) Enzymes
- (vi) Lipids
- (vii) Carbohydrates
- (viii) Peptides
- (ix) Liposomes
- (x) Antibodies
- (xi) Viruses
- (xii) Microorganisms
- (xiii) Chemical substances which dissociate completely in water to form ions that are smaller than 1 nanometer.

(xiv) Chemical substances that are not on the TSCA Chemical Substance Inventory at the time reporting would otherwise be required under this section.

(2) Persons who submitted a notice under 40 CFR parts 720, 721, or 723 for a reportable chemical substance on or after January 1, 2005 are not required to submit a report for the reportable chemical substance submitted except where the person manufactures or processes a discrete form of the reportable chemical substance.

(3) Section 704.5 (a) through (e) apply to reporting under this section. Small manufacturers and processors as defined in paragraph (a) of this section are exempt from reporting under this section.

(4) Persons who submitted some or all of the required information for a reportable chemical substance as part of the Nanoscale Materials Stewardship Program are not required to report the information previously submitted except where the person manufactures or processes a discrete form of the reportable chemical substance.

(d) What information to report. The following information must be reported for each discrete form of a reportable chemical substance to the extent that it is known to or reasonably ascertainable by the person reporting:

(1) The common or trade name, the specific chemical identity including the correct Chemical Abstracts (CA) Index Name and available Chemical Abstracts Service (CAS) Registry Number, and the molecular structure of each chemical substance or mixture. Information must be reported as specified in § 720.45.

(2) Material characteristics including particle size, morphology, and surface modifications.

(3) Physical/chemical properties.

(4) The maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use, or disposal of each chemical substance.

(5)(i) Persons described in paragraph (b)(1) of this section must report the annual production volume for the previous three years before the effective date of the final rule and an estimate of the maximum production volume for any consecutive 12-month period during the next two years of production after the final effective date of this rule.

(ii) Persons described in paragraph (b)(2) of this section must report the estimated maximum 12 month production volume and the estimated maximum production volume for any consecutive 12 month period during the first three years of production.

(iii) Estimates for paragraphs (d)(5)(i) and (ii) of this section must be on 100% chemical basis of the discrete form of the solid nanoscale material.

(6) Use information describing the category of each use by function and application, estimates of the amount manufactured or processed for each category of use, and estimates of the percentage in the formulation for each use.

(7) Detailed information on methods of manufacturing or processing.

(8) Exposure information with estimates of the number of individuals exposed in their places of employment, descriptions and duration of the occupational tasks that cause such exposure, descriptions and estimates of any general population or consumer exposures.

(9) Release information with estimates of the amounts released, descriptions and duration of the activities that cause such releases, and whether releases are directly to the environment or to control technology.

(10) Risk management practices describing protective equipment for individuals, engineering controls, control technologies used, any hazard warning statement, label, safety

data sheet, customer training, or other information which is provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the substance.

(11) Existing information concerning the environmental and health effects.

(e) *How to report.* You must use CDX and the CISS tool to complete and submit the information required under this part to EPA electronically.

(1) *Reporting form.* You must complete EPA Form No. 7710-xx, TSCA §8(a) Reporting for Nanoscale Materials: Information Submission Form.

(2) *Electronic submission.* You must submit the required information to EPA electronically via CDX and using the CISS tool.

(i) To access the CDX portal, go to <https://cdx.epa.gov>.

(ii) The CISS tool is accessible in CDX.

(f) *When to report.* (1) Persons specified in paragraph (b)(1) of this section must report the information specified in paragraph (d) of this section within one year after the final effective date of the rule.

(2) Persons specified in paragraph (b)(2) of this section must report the information specified in paragraph (d) of this section at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent.

(g) *Recordkeeping.* Any person subject to the reporting requirements of this section is

subject to the recordkeeping requirements in §704.11(a) and (b).

(h) Confidential business information. (1) Persons submitting a notice under this rule are subject to the requirements for confidential business information claims in §704.7 (a) through (c).

(2) In submitting a claim of confidentiality, a person attests to the truth of the following four statements concerning all information which is claimed confidential:

(i) My company has taken measures to protect the confidentiality of the information,

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law.

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

[FR Doc. 2017-00052 Filed: 1/11/2017 8:45 am; Publication Date: 1/12/2017]