is not required for an exemption from the requirement of a tolerance. Contact: RD.

6. *PP* IN–10781. (EPA–HQ–OPP–2015–0018). Technology Sciences Group, Inc., 1150 18th Street NW., Suite 1000, Washington, DC 20036, on behalf of BYK Additives, Inc., 1600 W. Hill Street, Louisville, KY 40210, requests to establish an exemption from the requirement of a tolerance for residues for quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, bis(hydrogenated tallow alkyl)dimethylammonium salts with sepiolite (CAS Reg. No. 1574487–61–8), when used as an inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.920. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

7. *PP* IN–10784. (EPA–HQ–OPP–2015–0064). Momentive Performance Materials, 260 Hudson River Rd., Waterford, NY 12188, on behalf of the Dow Chemical Company, 2301 N. Brazosport Blvd., Freeport, TX 77541, requests to establish an exemption from the requirement of a tolerance for residues of acrylic acid, butyl acrylate, styrene copolymer (CAS Reg. No. 25586–20–3) with a minimum number average molecular weight (in amu) of 5,200, when used as an inert ingredient in pesticide formulations under 40 CFR 180.960. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

Amended Tolerance Exemption

1. *PP* 2E8080. (EPA–HQ–OPP–2013–0098). Toxcel, LLC, 7140 Heritage Village Plaza, Gainesville, VA 20156 on behalf of Penn A Kem, LLC, 3324 Chelsea Avenue, Memphis, TN 38108, requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.1263 for residues of tetrahydrofurfuryl alcohol (THFA), (CAS Reg. No. 97–99–4), when used as a pesticide inert ingredient (solvent/co-solvent), to include allowance of one herbicide application prior to the preboot stage to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice; extended use on canola to the early bolting stage; extended use on soybeans up to the bloom growth stage; and allowance of use in herbicides with two applications to field corn and pop corn up to 36 inches tall (V8 stage). The petitioner believes no analytical method is needed because it is not required for the amendment of an exemption from the requirement of a tolerance. Contact: RD.

2. *PP* 4F8336. (EPA–HQ–OPP–2008–0762). BASF Corporation, 26 Davis Dr., Research Triangle Park, NC 27709, requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.1128 for residues of the biofungicide, *Bacillus amyloliquefaciens* MBI 600 (antecedent *Bacillus subtilis* MBI 600), in or on all food commodities, including residues resulting from post-harvest uses, when applied or used in accordance with good agricultural practices. The petitioner believes no analytical method is needed because Bacillus amyloliquefaciens MBI 600 (antecedent *Bacillus subtilis* MBI 600) has an exemption from the requirement of a tolerance without numerical limitations. Contact: BPPD.

Amended Tolerance

PP 4E8328. (EPA–HQ–OPP–2014–0878). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to amend the existing tolerance in 40 CFR part 180.411 for residues of the herbicide fluazifop-p-butyl in or on rhubarb, from 0.5 parts per million (ppm) to 0.4 ppm. Analytical methodology has been developed and validated for enforcement purposes. This method has been submitted to the Agency and is in PAM Vol. II, Method II. Contact: RD.

Authority: 21 U.S.C. 346a.

Dated: March 30, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–07828 Filed 4–3–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 704

[EPA–HQ–OPPT–2010–0572; FRL–9920–90]

RIN 2070–AJ54

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale as described in this rule. Specifically, EPA proposes to require 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 the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing data concerning environmental and health effects. This proposal involves one-time reporting for existing nanoscale materials and one-time reporting for new discrete nanoscale materials before they are manufactured or processed. This information would facilitate EPA's evaluation of the materials and a determination of whether further action, including additional information collection, is needed. Consistent with the President's memorandum for Executive Agencies regarding Principles for Regulation and Oversight of Emerging Technologies, this proposed rule would 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.

DATES: Comments must be received on or before July 6, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2010–0572, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is 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. Does this action apply to me?

You may be potentially affected by this action if you manufacture or process or intend to manufacture or process nanoscale forms of certain chemical substances. 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 would not be subject to this action. In addition, the discussion in Unit III.A. describes in more detail which chemical substances would and would not be subject to reporting under the proposed rule. You may also consult 40 CFR 704.3 and 704.5, as well as the proposed regulatory text in this document, for further information on the applicability of these and other exemptions to this proposed 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).
- Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology) (NAICS code 541712).

B. What is the agency's authority for taking this action?

The Toxic Substances Control 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. EPA is proposing this rule under section 8(a) of TSCA, 15 U.S.C. 2607(a). See also Unit II.A.

C. What action is the agency taking?

EPA is proposing reporting and recordkeeping requirements for persons that manufacture (including import) or process certain chemical substances as described in Unit III.A. Persons who currently manufacture or process these chemical substances as discrete nanoscale materials would be required to notify EPA of certain information described in Unit III.C., including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety data. EPA is also proposing that any persons who intend to begin to manufacture or process chemical substances as discrete nanoscale materials after the effective date of this rule notify EPA of the same information at least 135 days before the intended date of commencement of manufacture or processing. The TSCA section 8(a) rule proposed here involves one-time reporting for existing discrete nanoscale forms of certain chemical substances and one-time reporting for new discrete nanoscale forms of certain chemical substances before they are manufactured or processed. A chemical substance as defined under TSCA section 3(2) does not include any food, food additive, drug, cosmetic, medical device, pesticide or other excluded materials. Such materials are not be subject to this rule.

Included in this proposal are electronic reporting requirements similar to those established in 2013 for other kinds of information: EPA is proposing to require submitters to use EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, for all reporting under this rule. In the **Federal Register** of December 4, 2013 (78 FR 72818) (FRL 9394–6), 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). In proposing to require similar electronic reporting under this rule, EPA intends to save time, improve data quality and increase efficiencies for both the submitters and the Agency (Ref. 1).

This proposed rule and the discussion of the potential risks do not conclude and are not intended to conclude 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, EPA would use information gathered through this reporting rule to determine if any further action under TSCA, including additional information collection, is needed. EPA intends to make conclusions on the basis of specific scientific evidence. As with current new chemical review of nanomaterials, each chemical substance manufactured at the nanoscale will be evaluated on a case-by-case basis and not with the presumption of either harm or safety, but rather its evaluation will be based on the specific nanoscale chemical substance's own properties. If adequate data are not available for the properties of the nanoscale chemical substance, EPA will use data on structural analogues. Being nanoscale is not itself an indication of, or criterion for, hazard or exposure potential. Any potential future restrictions on chemical substances manufactured at the nanoscale would be tailored to protect against the specific harms identified for individual substances or categories. EPA would focus any toxicity concerns or data requirements based on available exposure or hazard data for specific nanoscale chemical substances. If the information provided indicates low risk, EPA would not need to consider further review or regulation of that nanoscale chemical substance unless subsequent information raises risk concerns. For example during review of new chemical substances that are nanoscale materials, EPA typically does not request inhalation toxicity data for chemical substances that are manufactured in forms or handled by processes where no inhalation exposure occurs.

EPA is not proposing to publish an inventory of chemical substances manufactured at the nanoscale based on the information that would be collected pursuant to these proposed TSCA section 8(a) reporting requirements. EPA will make non-confidential information reported under the proposed rule available in ChemView (see *http://www.epa.gov/chemview/*).

D. Why is the agency taking this action?

These reporting and recordkeeping requirements would assist EPA in its continuing evaluation of chemical substances manufactured at the nanoscale, informed by available scientific, technical and economic evidence. This proposed rule is not intended to indicate restrictions or conclusions about the risks of chemical substances manufactured at the nanoscale in general. Rather, the requirements would facilitate EPA's

evaluation of the materials and its determination of whether any further action under TSCA, including additional information collection, is needed.

Consistent with the June 9, 2011 memorandum on the Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials, this proposal is not making any finding about the potential risks of nanoscale materials in general or any specific nanoscale materials (Ref. 2). These generally applicable principles are relevant to promoting a balanced, science-based approach to regulating chemical substances manufactured at the nanoscale and other applications of nanotechnology in a manner that protects human health, safety, and the environment without prejudging new technologies or creating unnecessary barriers to trade or hampering innovation. These principles build on the foundation provided by current regulatory statutes and do not supersede existing legal authorities. In this proposal, EPA's approach seeks to support the policy principle to ''[s]eek and develop adequate information with respect to the potential effects of nanomaterials on human health and the environment and take into account new knowledge when it becomes available'' (Ref. 2). As with current new chemical reviews of chemical substances manufactured at the nanoscale, each nanoscale material would be evaluated on a case-by-case basis and not with the 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.

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

EPA has evaluated the potential costs of establishing the proposed reporting and recordkeeping requirements for potential manufacturers and processors. This analysis (Ref. 3), which is available in the docket, is briefly summarized here.

Under the proposed rule, industry is conservatively estimated to incur a burden of approximately 206,098 hours in the first year and 22,755 hours in subsequent years, with costs of approximately $13.9 million and $1.5 million, respectively (see Chapter 3 in Ref. 3), while the Agency is expected to use approximately 6,539 hours in the first year and 723 hours in subsequent years, with costs of approximately $0.51 million and $0.06 million respectively (see Chapter 4 in Ref. 3). Discounted over a 10-year period at three and seven percent, total annualized costs are estimated to be approximately $2.80 million and $3.08 million, respectively. (Ref. 3.)

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. Overview of Applicable Authority

1. TSCA section 8(a) reporting. Section 8(a) of TSCA authorizes EPA to promulgate rules which require each person (other than a small manufacturer or processor) who manufactures, processes, or proposes to manufacture or process a chemical substance, to maintain such records and submit such reports as the EPA Administrator may reasonably require. TSCA section 8(a) gives EPA authority to determine the format of reporting under this section.

Small manufacturers and processors, as defined by EPA, are exempt from TSCA section 8(a) reporting requirements, unless the manufacture or processing is subject to a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6, or an order under section 5(e). Under TSCA section 8(a)(3)(B), after consultation with the Administrator of the Small Business Administration (SBA), EPA may prescribe standards for determining which manufacturers and processors qualify as small for purposes of reporting under a TSCA section 8(a) rule.

General provisions for TSCA section 8(a) rules appear in 40 CFR part 704 Subpart A. These provisions describe definitions, exemptions (including for articles and research and development), confidential business information claims, and recordkeeping that apply to TSCA section 8(a) rules. For example in 40 CFR 704.3 the definition of *known to or reasonably ascertainable by* is defined to mean all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

In addition, the definitions in TSCA section 3 apply to this rulemaking.

2. Electronic reporting under the Government Paperwork Elimination Act (GPEA). 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's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 4), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to *http://www.epa.gov/cromerr.*

B. Why is EPA interested in nanoscale materials?

There is a growing body of scientific evidence showing the differences that exist between chemical substances and chemical substances manufactured in nanoscale forms (Ref. 5). Chemical substances manufactured at the nanoscale may have different or enhanced properties—for example, electrical, chemical, magnetic, mechanical, thermal, or optical properties—or features, such as improved hardness or strength, that are highly desirable for applications in commercial, medical, military, and environmental sectors (Ref. 6). These properties are a direct consequence of decreasing size, where surface area per unit of volume increases exponentially and quantum effects may appear in the low tens of nanometers and below. Small size itself can also be a desirable property of nanoscale materials. The small size can be exploited for miniaturization of applications/processes and/or stabilization or delivery of payloads to diverse environments or incorporation into diverse products.

Nanoscale materials have a range of potentially beneficial public and commercial applications, including medicine and public health, clean energy, pollution reduction and

environmental cleanup, and improved products such as stronger, lighter, and more durable or conductive materials. These benefits arise from the distinctive properties of nanoscale materials, in that they are potentially more interactive or durable than other chemical substances. Altering the size of a material from conventional particle size can enhance or produce unique properties that are desirable for a variety of commercial applications. However, these unique and enhanced properties can raise new questions, such as whether the material in the smaller form may present increased hazards to humans and the environment.

Government, academic, and private sector scientists in multiple countries are performing research into the environmental and human health effects of diverse nanoscale materials, resulting in a substantial and rapidly growing body of scientific evidence. This research also indicates that, in biological systems or in the environment, not all materials in the nanoscale size range behave differently from larger sized materials of the same substance (Ref. 7). Recently, a governmental organization and an independent scientific committee have reviewed and summarized this evidence and offered views about the implications of this evidence for environmental and human health and safety.

In 2009, the National Institute of Occupational Safety and Health (NIOSH) issued a report (Ref. 8) that summarized the available scientific information about nanoscale materials and identified the following potential health and safety properties:

- ''Nanomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles (nanoparticles). They may also come into contact with the skin or be ingested.''
- ''Based on results from human and animal studies, airborne nanoparticles can be inhaled and deposited in the respiratory tract; and based on animal studies, nanoparticles can enter the blood stream, and translocate to other organs.''
- ''Experimental studies in rats have shown that equivalent mass doses of insoluble incidental nanoparticles are more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors. Results from in vitro cell culture studies with similar materials are generally supportive of the biological responses observed in animals.''
- ''Experimental studies in animals, cell cultures, and cell-free systems have shown that changes in the chemical composition, crystal structure, and size of particles can influence their oxidant generation properties and cytotoxicity.''
- ''Studies in workers exposed to aerosols of some manufactured or incidental microscopic (fine) and nanoscale (ultrafine) particles have reported adverse lung effects including lung function decrements and obstructive and fibrotic lung diseases. The implications of these studies to engineered nanoparticles, which may have different particle properties, are uncertain.''
- ''Some nanomaterials may initiate catalytic reactions depending on their composition and structure that would not otherwise be anticipated based on their chemical composition.''

Earlier the same year, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), an independent scientific committee advising the European Commission's Health and Consumer Directorate, issued a report (Ref. 9) that identified properties similar to those identified in the NIOSH report:

- ''Some specific hazards, discussed in the context of risk for human health, have been identified. These include the possibility of some nanoparticles to induce protein fibrillation, the possible pathological effects caused by specific types of carbon nanotubes, the induction of genotoxicity, and size effects in terms of biodistribution.''
- ''For some nanomaterials, toxic effects on environmental organisms have been demonstrated, as well as the potential to transfer across environmental species, indicating a potential for bioaccumulation in species at the end of that part of the food chain.''

In another survey of scientific research on nanoscale materials (Ref. 10), the authors reported:

> Many studies have examined the pro-inflammatory effects of manufactured nanoparticles, on the basis that their ability to cause inflammation is a major predictor of potential hazard in such particles. The first important finding was that nanoparticles have a more pronounced effect on inflammation, cell damage and cell stimulation than an equal mass of particles of the same material of greater size. This appears to hold true for materials as varied as carbon black, titanium dioxide, various metals and polystyrene. Surface area is the metric driving the pro-inflammatory effects and this is evident both *in vitro* and *in vivo,* particles of various sizes producing inflammatory effects that are directly related to the surface area dose.

A report in the scientific literature has indicated that nanoscale polystyrene beads may cross the placental barrier (in an ex-vivo human placental perfusion model (Ref. 11). Another study found that nanoparticles could translocate to diverse organs following oral exposure in rodents. Once in these diverse sites and organs, the large surface area of nanoscale materials may facilitate increased reactivity and/or an inflammatory response, resulting in toxic effects (Ref. 12).

Two literature surveys describe a broad range of effects in non-mammalian species following exposure to nanoscale materials (Ref. 13 and 14). These include, for example, increased ventilation rates, mucus production, and pathologies, and related alteration of enzyme activities and indicators of oxidative stress in rainbow trout, *Oncorhyncus mykiss* (Ref. 15) and ingestion and accumulation of nanoscale material in the digestive tract, as well as mortality, increased heart rates, and reduced fecundity in *Daphnia magna* (Ref. 16, 17, and 18). Translocation of nanoscale materials from gill and gut surface to blood and other organs in exposed Medaka, *Oryzius latipes,* has also been reported (Ref. 19) and carbon nanotubes, although unable to cross the egg surface, have been shown to delay hatching in zebra fish, *Danio rerio* (Ref. 20).

Published reports of human and ecological exposure to nanomaterials are also limited. For example, in its ''Current Intelligence Bulletin 65: Occupational Exposure to Carbon Nanotubes and Nanofibers'' (Ref. 21), NIOSH summarized and evaluated the available published information on worker exposures to carbon nanotubes (CNT) and nanofibers (CNF). NIOSH determined that, although the potential for worker exposure to CNT and CNF can occur throughout the life cycle of CNT- and CNF-product use (processing, use, disposal, recycling), the extent to which workers are exposed has not been completely characterized. ''Comprehensive workplace exposure evaluations are needed to characterize and quantify worker exposure to CNT and CNF at various job tasks and operations, and to determine what control measures are the most effective in reducing worker exposures.'' ''Data are particularly needed on workplace exposures to CNT and CNF, as well as information on whether in-place exposure control measures (*e.g.,* engineering controls) and work practices are effective in reducing worker exposures.''

There are many scientific questions about the impacts of chemical

substances manufactured at the nanoscale on human health and the environment. Part of EPA's mission under TSCA is to understand potential risks in order to protect human health and the environment. As stated in EPA's White Paper on Nanotechnology (Ref. 22):

> Some of the same special properties that make nanoscale materials useful are also properties that may cause some nanoscale materials to pose risks to humans and the environment, under specific conditions.

EPA needs a sound scientific basis for assessing and managing potential impacts resulting from the introduction of chemical substances manufactured at the nanoscale into commerce.

As described in the 2008 TSCA Inventory Status of Nanoscale Substances—General Approach, many nanoscale materials are considered chemical substances as defined under TSCA section 3(2) (Ref. 23). Nanoscale forms of chemical substances that are not on the TSCA Inventory in any form are considered new chemical substances that require reporting under TSCA section 5. EPA has assessed over 170 of these nanoscale materials as new chemical substances and taken action to control exposures to prevent any potential unreasonable risks to human health or the environment pending development of information which will allow EPA to more fully assess those risks. Nanoscale materials based on chemical substances already on the TSCA Inventory are considered existing chemical substances. These nanoscale materials do not require reporting as new chemical substances because they are nanoscale forms of chemical substances already in commerce.

EPA developed a voluntary Nanoscale Materials Stewardship Program (NMSP or ''the program'') to complement and support its regulatory activities on chemical substances manufactured at the nanoscale. EPA conducted the program from January 2008 to December 2009. Thirty one companies or associations submitted information to EPA for 132 chemical substances manufactured at the nanoscale with available information on how those nanoscale materials were manufactured, processed or used. For more details on the NMSP, see the program's interim report, a copy of which is in the docket (Ref. 24). EPA solicited existing data and information, on a voluntary basis, from manufacturers, processors, and users of chemical substances manufactured at the nanoscale to expeditiously develop knowledge about commercially available nanoscale materials. In addition, the program was designed to identify and encourage use of risk management practices in developing and commercializing chemical substances manufactured at the nanoscale. EPA also participated in a series of National Nanotechnology Initiative public workshops, including co-Chairing a public Risk Management Methods workshop. This workshop was also useful in further identifying additional considerations in risk management practices towards developing and commercializing chemical substances manufactured at the nanoscale of interest to EPA. In the NMSP interim report, which was based on the information EPA received prior to January 2009, EPA identified data needs for existing nanoscale material production, uses, and exposures. For example, in the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009.

To address some of the data needs identified in the NMSP interim report, EPA is proposing reporting requirements under TSCA section 8(a) for persons who are manufacturing, or processing chemical substances manufactured at the nanoscale or intend to manufacture or process these nanoscale materials for commercial purposes. This information would facilitate EPA's evaluation of the materials and determination if any further action under TSCA, including additional information collection, is needed. By gathering data regarding the characteristics, uses, and exposure pertaining to chemical substances manufactured at the nanoscale, EPA will create a more robust database that will expand the Agency's understanding of commercially available nanoscale substances including available environmental health and safety data and risk management practices.

III. Summary of Proposed TSCA Section 8(a) Rule

EPA is proposing reporting and recordkeeping requirements for manufacturers and processors of certain chemical substances pursuant to TSCA section 8(a).

A. What chemical substances would be reportable under this rule?

1. Reportable chemical substances. This proposed rule would apply to chemical substances that are solids at 25 °C and atmospheric pressure and that are manufactured or processed in a form where the primary particles, aggregates, or agglomerates are in the size range of 1–100 nanometers (nm) and exhibit unique and novel characteristics or properties because of their size. The proposed rule would apply to chemical substances containing primary particles, aggregates, or agglomerates in the size range of 1–100 nm in at least one dimension. This proposed rule would not apply to chemical substances that only have 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. EPA is proposing these parameters for purposes of identifying chemical substances that are subject to the rule, not to establish a definition of what is a nanoscale material.

i. Discrete forms. Manufacturers and processors of multiple nanoscale forms of the same chemical substance would, in some cases, need to report separately for each discrete form of the reportable chemical substance. EPA is proposing to distinguish based on a combination of three factors: (1) a change in process to affect a change in size and/or a change in properties of the chemical substances manufactured at the nanoscale; (2) a change in mean particle size of 10% or greater; and (3) the measured 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 +/− 5 m^2/g, then a change resulting in a new average specific area of 85 m^2/g would be reportable if factors 1 and 2 were also met. EPA recommends using the same 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 proposing these reporting requirements is to focus reporting on intentionally manufactured chemical substances at the nanoscale.

EPA is proposing the combination of these three factors rather than simply size to distinguish between different chemical substances manufactured at the nanoscale so that unintended variation in size range between production batches would not trigger TSCA section 8(a) reporting. Also, EPA is proposing not to rely solely on process changes because there may be process changes that are not intended to change the material produced but rather intended to improve the efficiency of the process or to use a cheaper reactant. EPA is focusing on the properties of *zeta*

potential, specific surface area, dispersion stability, or surface reactivity because these properties are of particular interest in a health and safety context, whereas other unique 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 important in a health and safety context. EPA believes that the combination of these three factors will provide a clear and transparent way for the regulated community to distinguish among different chemical substances manufactured at the nanoscale for purposes of TSCA section 8(a) reporting.

For the purposes of this proposed rule, specific surface area is the ratio of the surface area of the nanoscale material to its mass or the area of the surface of the nanoscale material divided by volume. 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. Specific surface area is the ratio of the area of the surface of a nanoscale material divided by the mass (m^2/kg) or the area of the surface of the nanoscale material divided by volume (m^2/m^3).

Zeta potential is the electrokinetic potential in colloidal systems. It is measured as the net number of positive and negative charges per unit particle surface area in Coulomb/m^2 (Ref. 25) and is typically measured by electrophoresis.

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. 26) as an example.

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 an entity to lose or acquire electrons, and photocatalytic activity, including the potential to generate free radicals. Reactive oxygen species (ROS) and free radicals are important in considering toxicity for these materials.

A nanoscale form of a particular chemical substance with a different morphology or shape would also qualify as a discrete form. Examples include spheres, rods, ellipsoids, cylinders, needles, wires, fibers, cages, hollow shells, trees, flowers, rings, tori, cones, and sheets. Nanoscale forms of a particular 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 solely as a component of a mixture, encapsulated material, or composite would also have to be reported. Chemical substances at the nanoscale that are manufactured but are then incorporated into mixtures, encapsulated materials or composites by that manufacturer would not require separate reporting for their incorporation. However, the person reporting the chemical substance would have to report each step of its manufacture, processing and use to the extent it is known or reasonably ascertainable.

2. Substances excluded from reporting. EPA is proposing to exclude from the requirements of this rule certain biological materials (*e.g.,* DNA, RNA, and proteins). EPA is seeking comment to identify other specific biological materials that should be excluded from reporting and the reasons for excluding them, including microorganisms and viral based products (or other combinations of RNA, DNA and protein), lipids, carbohydrates, enzymes, and peptides. However, the properties of biological materials such as DNA, RNA and proteins are not a function of the size range per se but rather the precise nucleotide sequence (in the case of DNA and RNA), shape, and other features.

EPA is proposing to exclude chemical substances which dissociate completely in water to form ions that are less than 1 nanometer. This exclusion would not apply to chemical substances manufactured at the nanoscale materials that release ions but do not dissociate in water to form those ions. EPA believes that the chemical substances that would be excluded do not exhibit new properties when their size falls in the range of 1–100 nanometers and manufacture or processing such substances at the nanoscale should therefore not be subject to the reporting requirements of the proposed rule. EPA is seeking comment to identify other water soluble compounds that should be excluded from reporting and the reasons for excluding them.

EPA is proposing to exclude from the requirements of this rule nanoclays, zinc oxide and chemical substances manufactured at the nanoscale as part of a film on a surface. The Agency believes that information collected on these materials would be of limited value because either they have been well-characterized or they present little exposure potential. EPA requests comment on these proposed exclusions and whether other chemical substances manufactured at the nanoscale should be excluded. EPA requests that commenters explain why they believe the chemical substances manufactured at the nanoscale should be excluded.

3. General exemptions to TSCA Section 8(a) reporting. The general exemptions to TSCA section 8(a) reporting at 40 CFR 704.5 would be applicable to this proposed rule. This includes, among other exemptions, the exemption for research and development under which a person who manufactures or processes, a chemical substance only in small quantities for research and development would be exempt from the reporting requirements of this proposed rule. Examples of research and development (R&D) activity are the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article. 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.

EPA is proposing an alternate exemption for the existing small manufacturer exemption. Under other TSCA section 8(a) rules, a company qualifies as a small manufacturer in 40 CFR 704.3 by meeting either of the following two standards. The first is that sales of the company are less than $40 million per year and the company does not manufacture more than 100,000 pounds annually of an individual substance at any individual site owned or controlled by the company. The second is that sales are less than $4 million regardless of the quantity manufactured.

EPA is proposing a different exemption for purposes of this rule by eliminating the first standard and defining a small manufacturer or processor as any company with sales of less than $4 million. The 100,000-pound threshold in the existing exemption did not contemplate typical production volumes for chemical substances manufactured at the nanoscale. EPA has reviewed over 200 chemical substances manufactured at the nanoscale in the NMSP and the new chemicals program under TSCA. At least 170 of those

chemical substances manufactured at the nanoscale had reported or estimated production volumes less than 22,000 pounds. Based on this experience, exempting manufacturers or processors from reporting annual production volumes of up to 100,000 pounds would exclude a large proportion of companies that characteristically manufacture chemical substances manufactured at the nanoscale in small amounts but would not otherwise be considered small. Given that chemical substances manufactured at the nanoscale tend to be produced in small volumes, EPA does not believe production volume should be a relevant consideration in determining whether a nanotechnology company is a small manufacturer or processor. EPA requests comment on the proposed small manufacturer or processor exemption that would apply for this proposed rule.

4. Proposed exceptions to reporting. The proposed rule would not require manufacturers or processors to report certain information that has already been submitted to EPA. A person who submitted a TSCA chemical notice under section 5 to EPA on or after January 1, 2005 would not be required to report regarding the same substance under this proposed TSCA section 8(a) 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 would be required under this proposed TSCA section 8(a) rule under the NMSP would not need to report that information again under this proposed TSCA section 8(a) rule. If, however, information required by this proposed rule was not reported under section 5 or the NMSP (including information for each discrete form of a reportable chemical substance), then reporting of that information would be required under this proposed TSCA section 8(a) rule. The purpose of these exemptions is to avoid duplicative reporting. For example new chemical notices that have been reviewed as nanoscale materials would not be subject to reporting the same information under this rule.

B. When would reporting be required?

EPA proposes that 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 the rule would report to EPA six months after the final effective date of the rule. EPA also proposes a continuing requirement that persons who intend to manufacture or process a discrete form of a reportable chemical substance on or after the effective date of the rule would report to EPA at least 135 days before commencement of manufacture or processing.

The 135-day period is based on EPA's experience with PMN submissions. TSCA section 8(a) applies to a person ''who manufactures or processes or proposes to manufacture or process a chemical substance''. A company proposes to manufacture or process a chemical substance by forming the intent to do so. Based on EPA's experience, persons form the intent to manufacture or process chemical substances at least 135 days ahead of time. This belief is based on EPA's experience with Premanufacture Notice (PMN) submissions and subsequent notices of commencement (NOCs). Pursuant to section 5(a)(1) of TSCA and 40 CFR 720.22, PMNs are submitted by a person who intends to manufacture a chemical substance, at least 90 days before commencing manufacture. Under 40 CFR 720.102, a company that has submitted a PMN for which the statutory 90-day review period has expired and which has commenced manufacture of that substance must submit an NOC to EPA within 30 days following commencement. For fiscal years 2009–2011, EPA received 1,723 PMNs. Based on EPA's review of NOC receipt date information, EPA determined that NOCs were received within 45 days of completion of the 90-day PMN review for only 16% of these submitted PMNs. Thus, for 84% of the submitted PMNs, the intent to manufacture was formed at least 135 days (*i.e.,* the 90-day PMN review period plus 45 days) before commercialization. Because a company must by necessity form the intent to manufacture a chemical substance some period of time before the PMN is submitted to EPA, the intent to manufacture or process would be made at least 135 days in advance as a general matter.

C. What information would be reported?

This TSCA section 8(a) rule proposes 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 data.

EPA developed an information reporting form for the NMSP (Ref. 27) which has been slightly modified for purposes of this proposed rule. The same information that was requested in the NMSP would be required by this proposed rule, including information on specific chemical identity, material characterization, physical chemical properties, production volume, use, methods of manufacturing and processing, exposure and release information, and existing data concerning the environmental and health effects. The information would be reported on a form similar to that used in the NMSP (Ref. 27). Any person required to report under this proposed rule would supply the information identified in the form to the extent it is known to or reasonably ascertainable by them. A draft of the proposed reporting form (EPA Form No. 7710–[tbd]) is available in the docket for public review (Ref. 28).

EPA is requesting comment on whether any information proposed to be collected requested in this proposed rule is duplicative of information collected under other federal statutes and, thus should be excluded. Please identify the statute and the information that you believe is duplicative.

D. How would information be submitted to EPA?

EPA is proposing electronic reporting similar to the requirements established in 2013 for submitting other information under TSCA (see proposed 704.20(e)). EPA is proposing to require submitters to use EPA's CDX, the Agency's electronic reporting portal, for all reporting under this rule. In 2013 (Ref. 1), 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). 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 Notifications. In proposing to require similar electronic reporting under this rule, EPA intends to 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 tool is available for use with Windows, Macs, 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 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 proposing to require submitters to follow the same submission procedures used for other TSCA submissions, *i.e.,* to register with EPA's CDX 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 Toxic Release Inventory TRI–ME web reporting flow, would be able to 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 would be required to use CISS to prepare their submissions. CISS guides users through a ''hands-on'' 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, the web-based tool 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 voluntary submissions, such as under MOUs, are available, and instructions for uploading PDF attachments or other file types, such as XML, and completing metadata information would be available through CISS reporting guidance.

CISS, a web-based reporting tool, also allows the user to choose ''Print,'' ''Save,'' or ''Transmit through CDX.'' When ''Transmission 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 login 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 proposed rule would be similar. EPA will put a version of the reporting tool in the docket for commenters, and is interested in feedback on the extent of and burden associated with training for using CDX.

EPA believes that electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization, and more easily save a copy for their records or future use. The resource and time requirements to review and process data by the Agency will also be reduced and document storage and retrieval will require fewer resources. EPA expects to benefit from receiving electronic submissions and communicating back electronically with submitters.

Any person submitting a reporting form could claim any part or all of 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.

IV. Development of Additional Data in Connection With the TSCA Section 8(a) Rule

A TSCA section 8(a) rule may require persons subject to the rule to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them, but may not require persons to develop test data for submission to the Agency. However, in view of the lack of information regarding chemical substances manufactured at the nanoscale, EPA would encourage respondents to this proposed rule to provide the Agency with any relevant data on chemical substances manufactured at the nanoscale they decide to develop.

Persons choosing to develop test data should provide data that conform to the Good Laboratory Practice Standards, which are codified at 40 CFR part 792. There are also standard test methods available for properties and information identified in the proposed rule from a number of sources. Some of these sources include but are not limited to ASTM International, the International Organization for Standardization, the National Institute of Standards and Technology, and the Organization for Economic Cooperation and Development. EPA encourages persons who intend to conduct testing to consult with the Agency before selecting a protocol for testing a chemical substance manufactured at the nanoscale. EPA would also encourage persons that would be required to submit TSCA section 8(a) data under this proposed rule to provide information on the potential benefits regarding the reportable chemical substance.

V. Request for Comments

EPA is seeking public comment on all aspects of this proposed rule. In addition to specific requests for comment included throughout this document, EPA is interested in comments pertaining to the specific issues discussed in this unit. EPA also anticipates conducting a public meeting during the comment period to further discuss these and any other issues concerning the proposed rule.

1. *Identifying the chemical substances that would be subject to reporting.* EPA has developed the proposed approach based on the approximate size range of 1–100 nm as used by the NNI for defining nanotechnology (Ref. 6), experience in conducting assessments of new chemicals manufactured at the nanoscale by EPA under TSCA, and data submitted to EPA under the NMSP. EPA is soliciting comment on each aspect of the proposed approach to identifying the chemical substances that would be subject to the reporting requirements of the rule. The Agency is seeking comment on these approaches and alternative approaches for reporting requirements. For example the proposed rule would apply to reportable chemical substances that contain primary particles, aggregates, or agglomerates in the size range of 1–100 nm in at least one dimension. EPA is seeking comments on that aspect of reportable chemical substances. EPA is asking commenters if the current proposal sufficiently encompasses these types of reportable chemical substances.

2. *Distinguishing between nanoscale forms of a reportable chemical substance.* EPA considered several different approaches to distinguish between nanoscale forms of a reportable chemical substance including a percentage or numerical change in measured properties. The agency is also seeking comment on an approach based solely on the behavior of the reportable chemical substance. For example, if a manufacturer or processor knows about

or engineers a reportable chemical substance with multiple nanoscale forms with different performance characteristics then each nanoscale form would be reported. If multiple nanoscale forms of a reportable chemical substance do not perform differently then only a single report of the entire range would be reported. EPA is seeking comment on these and other alternative approaches. EPA is especially interested in comments on whether these approaches would require reporting of sufficiently distinct nanoscale forms of a chemical substance so that reporting would be focused on those nanoscale forms with potential for significantly different physical or chemical characteristics or properties. EPA also seeks comment on each aspect of its proposed reporting such as size increments, the number of standard deviations, morphology, the specific physical-chemical properties identified, exclusions to reporting, and whether companies have the analytical tools to make such distinctions.

3. *Reporting discrete forms at least 135 days before commencement of manufacture or processing.* As discussed in Unit III.B., EPA proposed the 135-day period based on EPA's experience with PMN submissions, and the determination that the intent to manufacture was formed at least 135 days before commercialization (*i.e.,* the 90-day PMN review period plus 45 days). EPA is specifically seeking comment on whether this time-period should be 135 days as proposed, 90 days to be similar to the PMN review period, or some other time period. It would be most helpful if commenters explain why the time period they suggest is appropriate.

4. *Considerations for the Agency's economic analysis.* EPA has evaluated the potential costs for manufacturers and processors of reportable chemical substances for this proposed rule (Ref. 3). EPA is specifically seeking additional information and data that EPA could consider in developing the final economic analysis. In particular, data that could facilitate the Agency's further evaluation of the potentially affected industry and firms, including data related to potential impacts for those small businesses that would be subject to reporting. EPA is especially interested in available data or other measures of the number of and potential growth in the number of commercial nanoscale materials or firms that might manufacture or process such materials.

5. *Electronic reporting.* In proposing to require electronic reporting under this rule that is similar to those established in 2013 for other TSCA reporting, EPA intends to save time, improve data quality and increase efficiencies for both the submitters and the Agency. EPA is specifically interested in comments related to the adoption of the existing mechanisms and related procedures for use in transmitting the reports proposed in this rule, including comments related to the extent to which potentially reporting entities are already familiar with those mechanisms given their existing use for other TSCA reporting. EPA is also interested in feedback on how electronic reporting mechanisms affect reporting entities in terms of reporting time, added efficiencies, and potential burden associated with training to use the electronic systems (*i.e.,* CDX and CISS).

6. *Consideration of potential future rulemaking regarding periodic reporting.* EPA is also seeking comment on the possibility of a future rule that would require periodic reporting of chemical substances manufactured at the nanoscale, similar to reporting that occurs under the Chemical Data Reporting (CDR) rule at 40 CFR part 711. Such a rule could require manufacturers and processors of chemical substances manufactured at the nanoscale to report the type of information collected under the CDR rule to EPA at the same reporting interval as currently required by CDR reporting (every four years). That reporting could occur at lower thresholds for criteria such as production volume. The CDR is a program designed to collect screening-level, exposure-related information on chemical substances and to make that information available for use by EPA and to the public consistent with confidentiality under TSCA Section 14 and EPA regulations in 40 CFR part 2. The CDR rule data are used by EPA to support risk screening, assessment, priority setting and management activities and constitute the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA. For further information see *http://www.epa.gov/oppt/cdr*.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these references and other information considered by EPA. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

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VII. Statutory and Executive Order Reviews

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

The Office of Management and Budget (OMB) has designated this proposed rule as a ''significant regulatory action'' under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, EPA submitted this proposed rulemaking to OMB for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB comments have been documented in the public docket for this rulemaking as required by section 6(a)(3)(E) of Executive Order 12866.

B. Paperwork Reduction Act (PRA)

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request subject to the PRA, 44 U.S.C. 3501 *et seq.,* unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and included on any related collection instrument (*e.g.,* on the form or survey).

The information collection requirements in 40 CFR part 704 related to TSCA section 8(a) reporting rules have already been approved by OMB under the PRA. That information collection request (ICR) has been assigned EPA ICR No. 1198.10 and OMB Control No. 2070–0067. Because this proposed rule would involve revised information collection activities that require additional OMB approval, EPA has prepared an addendum to the currently approved ICR. The addendum, identified under EPA ICR No. 2517.01 and OMB Control No. 2070–NEW (Ref. 29), is available in the docket and is briefly summarized here.

If an entity were to submit a report to the Agency, the annual burden is estimated to average 137 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 proposed TSCA section 8(a) rule would create an industry burden of approximately 206,098 hours in the first year and 22,755 hours in subsequent years.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a docket for this proposed rule, which includes this ICR, under docket ID number EPA–HQ–OPPT–2010–0572. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** for where to submit comments to EPA. Send comments to OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

Since OMB is required to make a decision concerning the ICR between 30 and 60 days after April 6, 2015, a comment to OMB is best assured of having its full effect if OMB receives it by May 6, 2015. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* I hereby certify that this action would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is summarized here, and is presented in a small entity impact analysis that EPA prepared for this proposed action that is part of the Agency's economic analysis in the public docket for this proposed rule (Ref. 3).

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) a small business, as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-

profit enterprise which is independently owned and operated and is not dominant in its field. Since the regulated community is not expected to include small governmental jurisdictions or small not-for-profit organizations, the analysis focuses on small businesses.

A small business exemption exists under TSCA section 8(a) reporting rules, at 40 CFR 704.5(f). For this action, EPA is proposing to modify the exemption. EPA analyzed potential small business impacts from this proposed rule using both the SBA employee size standards and the TSCA sales-based definition of small business. EPA estimates that up to 174 small businesses may be impacted by the proposed TSCA section 8(a) reporting rule and evaluated the number that may incur costs at below 1%, between 1% and 3%, and above 3% of sales. EPA estimates that all 174 small businesses identified would incur costs below 1% of sales.

EPA continues to be interested in the potential impacts of this proposed rule on small entities that are not exempt from reporting and welcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

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 would be impacted by this rulemaking. In addition, this action will not result in annual expenditures of $100 million or more for the private sector. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments, and that the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531–1538, do not apply to this action.

E. Executive Order 13132: Federalism

This action does 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action does not have tribal implications 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, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000).

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. Nevertheless, the information obtained by the reporting required by this proposed 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 proposed 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)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

This action does not affect the level of protection provided to human health or the environment. However, the Agency believes that the information collected under this proposed rule, if finalized, will 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 protect human health and the environment, including in low-income and minority communities.

List of Subjects in 40 CFR Part 704

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

Dated: March 20, 2015.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is proposed to be amended as follows:

PART 704 [AMENDED]

■ 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.

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

A *discrete form of a reportable chemical substance* differs from another

form of the same reportable chemical substance in that either:

(1) The change in the reportable chemical substance is due to all of the following:

(i) There is a change in process to affect a change in size and/or a change in one or more of the properties of the reportable chemical substances identified in (iii);

(ii) There is a size variation in the mean particle size that is greater than 7 times the standard deviation of the mean particle size (+/− 7 times the standard deviation); and

(iii) There is a measured 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 value (+/− 7 times the standard deviation);

(2) 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; or

(3) 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.

The *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.

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

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

A *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 $ 4 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.

Zeta Potential is the electrokinetic potential in colloidal systems. It is measured as the net number of positive and negative charges per unit particle surface area in Coulomb/m^2.

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.

(b) Persons who must report.

(1) 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 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) 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) Zinc oxide

(ii) Nanoclays

(iii) Chemical substances manufactured at the nanoscale as part of a film on a surface

(iv) DNA

(v) RNA

(vi) Proteins

(vii) Chemical substances which dissociate completely in water to form ions that are smaller than 1 nanometer.

(2) Persons who submitted a TSCA chemical notice under 40 CFR part 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 manufactured or processed 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 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 handing, transport, use, or disposal of the substance.

(11) Existing data 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: Data 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 six months 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 the chemical substance.

(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. Persons submitting a notice under this rule are subject to the requirements for confidential business information claims in § 704.7.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 12

[PS Docket No. 14–193; PS Docket No. 13–75; FCC 14–186]

911 Governance and Accountability; Improving 911 Reliability

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment and reply comment deadlines.

SUMMARY: In this document, the Public Safety and Homeland Security Bureau (Bureau) extends the deadline for filing comments and reply comments on its 911 Governance and Accountability Notice of Proposed Rulemaking (911 Governance NPRM), which sought comment on mechanisms to ensure, in cooperation with state and local partners, that the nation's 911 governance structure keeps pace with evolving technology so that all entities providing 911 service capabilities remain accountable for reliable 911 call completion and accurate situational awareness.

DATES: The comment period for the proposed rule published January 22, 2015 (80 FR 3191) is reopened. Comments were due on or before March 23, 2015, and reply comments are due on or before April 21, 2015.

ADDRESSES: You may submit comments to the 911 Governance NPRM, identified by PS Docket Nos. 14–193 and 13–75, by any of the following methods:

- *Electronic Filers:* Federal Communication Commission's Electronic Comments Filing System (ECFS): *http://fjallfoss.fcc.gov/ecfs2/*. Follow the instructions for submitting comments.
- *Paper Filers:* All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8 a.m. to 7 p.m. Eastern Time (ET). All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.
- *People With Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, or audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), (202) 418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: Eric Schmidt, Attorney Advisor, Public Safety and Homeland Security Bureau, (202) 418–1214, *eric.schmidt@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Bureau's Order in PS Docket Nos. 14–193 and 13–75, DA 15–299, adopted and released on March 6, 2015, and pertaining to the proposed rule published January 22, 2015 (80 FR 3191). The complete text of this document is available for public inspection and copying from 8 a.m. to 4:30 p.m. ET Monday through Thursday or from 8 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text is also available on the Commission's Web site at *http://transition.fcc.gov/Daily_Releases/Daily_Business/2015/db0306/DA-15-299A1.pdf,* or by using the search function on the ECFS Web page at *http://www.fcc.gov/cgb/ecfs/*.

Summary

The Bureau released an Order on March 6, 2015, which extends the comment and reply comment filing deadlines for the 911 Governance NPRM, 80 FR 3191, January 22, 2015. The Order responded to a joint petition by the Association for Telecommunications Industry Solutions (ATIS); the Association of Public Safety Communications Officials International (APCO); the Industry Council for Emergency Response Technologies (iCERT); the National Association of State 911 Administrators (NASNA); the National Emergency Number Association (NENA); and the United States Telecom Association (USTA) seeking an extension of the comment period. Pursuant to sections 4(i) of the Communications Act of 1934, as amended, and pursuant to the authority delegated in 47 CFR 0.191, 0.392, and 1.46, the Bureau extended the deadline for filing comments until March 23, 2015, and extends the deadline for reply comments until April 21, 2015.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

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