Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Draft guidance; request for comment.

SUMMARY: With this document, EPA is announcing the availability of and requesting public comment on the draft guidance document, entitled: “Guidance on EPA’s Section 8(a) Information Gathering Rule on Nanomaterials in Commerce”. This guidance provides answers to questions the Agency has received from manufacturers (includes importers) and processors of certain chemical substances when they are manufactured or processed at the nanoscale as described in a final rule that appeared in the Federal Register of January 12, 2017. That 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.

DATES: Comments must be received on or before [insert date 30 days after date of publication in the Federal Register].

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 online
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. 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 TSCA section 3. You may also want to consult 40
CFR 704.3 and 704.5, and the January 2017 final rule, for further information on the applicability of the reporting requirements as well as exemptions to the 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).

II. Background

The nanoscale reporting rule that appeared in the Federal Register of January 12, 2017 (82 FR 3641; FRL-9957-81), requires persons that manufacture (defined by statute to include import) or process, or intend to manufacture or process those chemical substances subject to the rule to report to EPA the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing information concerning environmental and health effects.
III. What Action is the Agency Taking?

EPA is announcing the availability of and requesting public comment on the draft guidance document, entitled: “Guidance on EPA’s Section 8(a) Information Gathering Rule on Nanomaterials in Commerce”. This draft guidance provides answers to questions the Agency has received from manufacturers (includes importers) and processors regarding the rule.

This draft guidance is being made available on the Agency’s website at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under#guidance, and is also available in the docket (docket ID number EPA-HQ-OPPT-2010-0572). Please go to http://www.regulations.gov to access the docket and follow the online instructions to submit comments.

EPA is accepting comments regarding the guidance, but is not accepting comments regarding the rule itself, which has already been finalized.

IV. What is the Agency's Authority for Taking this Action?

The final rule was issued under the authority in section 8(a) of the Toxic Substances Control Act as amended by the Frank R. Launtenberg Chemical Safety for the 21st Century Act (TSCA), 15 U.S.C. 2601 et seq., which provides EPA with authority to require reporting, recordkeeping and testing, and impose restrictions relating to chemical substances and/or mixtures.

V. 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.


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[FR Doc. 2017-09998 Filed: 5/12/2017 4:15 pm; Publication Date: 5/16/2017]