



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2016-0675; FRL-9968-41]**

**TSCA Reporting and Recordkeeping Requirements; Standards for Small Manufacturers and Processors; Final Determination**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** On December 15, 2016, EPA issued a notice in the **Federal Register** requesting public comment on whether revision to the current size standards for small manufacturers and processors, which are used in connection with reporting regulations under the Toxic Substances Control Act (TSCA) section 8(a), is warranted. This document describes EPA's final determination that revision to the current size standards is warranted.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Lynne Blake-Hedges, Chemistry, Economics, and Sustainable Strategies Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8807; email address: *blake-hedges.lynne@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. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture or process chemical substances or mixtures. 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 applies to them. Potentially affected entities may include:

- Basic Chemical Manufacturers (NAICS code 3251);
- Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filament Manufacturers (NAICS code 3252);
- Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturers (NAICS code 3253);
- Paint, Coating, and Adhesive Manufacturers (NAICS code 3255);
- Other Chemical Product and Preparation Manufacturers (NAICS code 3259); and
- Petroleum Refineries (NAICS code 32411).

*B. How Can I Get Copies of this Document and Other Related Information?*

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0675, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**II. What Action is the Agency Taking?**

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends the Toxic Substance Control Act (TSCA), the nation's primary chemicals management law. A summary of the new law is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>. This particular action involves revised TSCA section 8(a)(3)(C), which requires EPA, after consultation with the Administrator of the Small Business Administration, to review the adequacy of the standards for determining which manufacturers and processors qualify as small manufacturers and processors for purposes of TSCA sections 8(a)(1) and 8(a)(3). (Note that under TSCA section 3(9), manufacture includes import.) TSCA furthermore requires that (after consulting with the Small Business Administration and providing public notice and an opportunity for comment) EPA determine whether revision of the standards is warranted. For the reasons described below, EPA determines that revision of the standards is warranted.

In the 1980s, EPA issued standards that are used in identifying which businesses qualify as small manufacturers and processors for purposes of the reporting and recordkeeping rules issued under TSCA section 8(a). Under TSCA section 8(a)(1), small manufacturers and processors are generally exempt from section 8(a) reporting requirements, except in limited cases set forth in TSCA section 8(a)(3).

In 1982, EPA finalized standards for determining which manufacturers of a reportable chemical substance qualify as small manufacturers for purposes of the section 8(a) Preliminary Assessment Information Reporting (PAIR) rules, codified in 40 CFR Part 712, Subpart B. The small manufacturer standard for PAIR rules is found at 40 CFR 712.25(c).

In 1988, EPA established general small manufacturer standards for use in other rules issued under TSCA section 8(a) (40 CFR 704.3). For example, these are the standards that now

apply to the Chemical Data Reporting (CDR) rule (40 CFR Part 711). The general standards are somewhat different from the earlier standards that are codified for use in the PAIR rules. The general small manufacturer standards are as follows:

*Small manufacturer or importer* means a manufacturer or importer that meets either of the following standards:

1. *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

2. *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

3. *Inflation index.* EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA shall provide **Federal Register** notification when changing the total annual sales values.

Pursuant to authority under section 8(a)(3)(B), certain section 8(a) rules codify slight variations of the general small manufacturer standards at 40 CFR 704.3. (See, e.g., 40 CFR 704.45). Other rules issued under TSCA section 8(a) establish (for use in a particular rule) analogous standards for small processors (See, e.g., 40 CFR 704.33).

As an initial step in evaluating whether a change in these current size standards are warranted, EPA reviewed the change in the Producer Price Index (PPI) for Chemicals and Allied Products between 1988 (the year the general size standards at 40 CFR 704.3 were last revised) and 2015 (the most recent year of PPI data available) (Ref. 1). EPA found that the PPI has changed by 129 percent, far exceeding the 20 percent inflation index specified as a level above which EPA may adjust annual sales levels in the current standard if deemed necessary. This change to the PPI is pertinent for both the \$4 million annual sales standard and the \$40 million threshold used in the combined sales and production standard. Furthermore, among the more than 500 revenue-based size standards set by the Small Business Administration (SBA), the lowest is \$5.5 million, and more than 75% of those standards are in excess of \$7.5 million. Some revenue-based standards are as high as \$38.5 million. Thus, EPA's existing \$4 million annual sales standard is an outlier at the low end of this range. Along the same lines, the sales-only size standard EPA recently adopted for the TSCA section 8(a) nanoscale reporting rule is \$11 million, significantly larger than \$4 million. Because of the magnitude of the increase in the PPI since the last revision of the size standards and because the current annual sales standard is comparatively low given current revenue-based size standards developed by SBA, EPA preliminarily determined that a revision to currently codified size standards is warranted.

On December 15, 2016, EPA published its preliminary determination and requested public comment on the adequacy of the current standards and whether revision of the standards is warranted. In addition, EPA consulted with the SBA and received feedback on the

consultation from SBA on April 5, 2017. SBA's consultation feedback recommended that EPA "apply a comprehensive approach that not only evaluates inflation but also examines other important factors, such as the characteristics of firms and industries associated with manufacturing or importation of chemical substances and percentage of firms impacted by the rules, to determine whether or not a revision to the current size standards is warranted."

EPA reopened the public comment period on May 9, 2017 to give the public an opportunity to review SBA's consultation feedback to inform their comments on EPA's preliminary determination. On May 9, 2017, EPA's preliminary finding and its basis remained the same as in the December 15, 2016 publication in the **Federal Register**.

EPA's decision not to consider a more comprehensive range of factors as recommended in SBA's consultation feedback before taking the current action is appropriate because the current action is limited to determining whether "revision of the standards" is warranted or not. See TSCA section 8(a)(3)(C)(ii). (The set of size standards covered by this determination are those that EPA has issued under TSCA section 8(a)(3)(B), pertinent to information collection under TSCA section 8(a).) EPA found that the PPI index changed by a percentage far exceeding the 20 percent inflation index. EPA had previously specified 20 percent as a level above which EPA may adjust annual sales levels in the current standard if deemed necessary. This change in the PPI index (along with the observation that the current annual sales standard is comparatively low given current revenue-based size standards developed by SBA) is a sufficient basis to determine that *some* revision of the standards is warranted, even if there are other factors that could have supported the same conclusion. EPA notes that the SBA's Office of Advocacy substantively agreed with EPA's preliminary determination (that a revision to the current size standards is warranted) even though it requested EPA to consider additional factors in reaching that conclusion.

EPA received a number of comments on its preliminary determination. Most commenters agreed with EPA's preliminary determination that an update is warranted. SBA submitted comments that argued that EPA should have considered more than the second (i.e., the sales-only) standard when making a final determination, such as whether the standard is structured appropriately. This comment is similar to the SBA's recommendation in its consultation feedback that EPA evaluate a broader set of factors related to firm and industry characteristics and percentage of firms impacted by section 8 rules to determine whether or not a revision to the standards is necessary. However, as previously noted, the change in the PPI index (along with the comparative analysis of the current annual sales standard) is a sufficient basis to determine (even if other factors could have supported the same conclusion) that some revision of the standards for small manufacturers and processors is warranted, for both the sales-only and the sales plus production standards.

Two commenters questioned whether a revision to the standards is warranted. One of these commenters argued that the standards should not be changed, based on the serious nature of unspecified chemicals of concern. The second commenter argued that a revision to the standards that would result in classifying more manufacturers or processors as small is not warranted because states need to have complete information about chemical use, including volume, location, and toxicity, in order to effectively respond to emergencies and to prioritize resources to address concerns among various chemicals.

EPA does not agree that either argument justifies a determination that revision of the standards is not warranted. The first commenter did not explain how chemical risks would be exacerbated by updating the status quo of small manufacturer standards. With regard to the second comment, the outcome of the rulemaking (i.e., whether it would result in exempting more firms from reporting than under the current standards) cannot be known until the

rulemaking is complete. Although revising the size standards for inflation could be presumed to increase the number of exempt firms, the second commenter did not explain how such increase would necessarily translate into a loss of information necessary for states to effectively respond to emergencies and prioritize resources. With respect to the need of states to have complete information about the toxicity of particular chemical substances, EPA notes that the size standards at issue in this action only relate to the collection of information under TSCA section 8(a). The primary information collection under TSCA section 8(a) is the Chemical Data Reporting rule, 40 CFR Part 711, which collects exposure-related data rather than hazard data. In any event, although the exemption of small businesses from reporting necessarily reduces the amount of chemical information EPA collects, Congress nonetheless decided to provide for an exemption and directed EPA to determine the need for revision. As explained above, EPA believes the currently promulgated standards are clearly outdated with respect to the current understanding of what qualifies a business as small. EPA has not yet proposed any revisions to the size standards; any changes would be established through future notice and comment rulemaking. At that time, public comments regarding the merits of any proposed revisions would be sought by EPA and subsequently addressed.

Several commenters also provided their opinions on how the standards should be specifically revised or explained why specific parts of the standards ought to be maintained. For example, SBA commented that, when developing standards, EPA should consider a broad range of factors that may potentially be relevant in the context of TSCA reporting. These factors include barriers to entry, start-up and expansion costs, capital versus labor intensiveness of industries, average firm size (employment and revenue), growth trends, and technological factors. Multiple commenters agreed with SBA's recommendations. Additionally, one commenter argued that the combined sales and production standard should be revised by

lowering its production threshold and not changing its \$40 million sales threshold. However, the scope of this action is limited to a general determination as to whether *some* revision to the TSCA small manufacturer and processor standards is warranted. More particular issues (i.e., relating to how the standards ought to be revised) will be addressed in a subsequent rulemaking and are beyond the scope of this action. Although EPA has no obligation to respond to the suggestions for specific revisions submitted as comments on this action, EPA intends to consider these comments as it develops its rulemaking proposal. Members of the public who wish to maintain previously submitted comments or who wish to submit new comments may do so following the publication of EPA's proposal in the **Federal Register**. EPA will address such comments prior to finalizing any changes to the TSCA size standards.

EPA's preliminary determination that a revision to size standards was warranted did not include the size standard for nanoscale materials found at 40 CFR 704.20. See 81 FR 90842 (determination was only with respect to *currently codified* size standards as of December 15, 2016). EPA promulgated the size standards at 40 CFR 704.20 on January 12, 2017, along with the other provisions of EPA's reporting and recordkeeping rule for nanoscale materials. Concurrent with promulgating the size standards at 40 CFR 704.20, EPA indicated that it would consider the adequacy of the size standards at 40 CFR 704.20 in the course of finalizing this determination under TSCA section 8(a)(3)(C). 82 FR 3650. At this point, EPA has not made a determination as to whether the size standards in the nanotechnology rule warrant revision. EPA will further evaluate the need for any revision as part of the rulemaking to revise the standards identified in this final determination.

Based on EPA's preliminary determination, a review of the comments on the preliminary determination, and the feedback from consultation from SBA, EPA is now making a final

determination under TSCA section 8(a)(3)(C)(ii) that revision to the TSCA section 8(a) size standards for manufacturers and processors is warranted.

### III. References

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

U.S. Bureau of Labor Statistics. "Producer Price Index, Series WPU06, Chemicals and Allied Products, 1933-2015". Retrieved November 14, 2016 from <http://data.bls.gov/cgi-bin/srgatet>.

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

Dated: November 21, 2017.

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[FR Doc. 2017-25822 Filed: 11/29/2017 8:45 am; Publication Date: 11/30/2017]