

PRE-PUBLICATION NOTICE

On Monday, May 11, 2020, Alexandra Dapolito Dunn, the EPA Assistant Administrator for Chemical Safety and Pollution Prevention, signed the following document:

Action: Final Rule.

Title: Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under the Toxic Substances Control Act (TSCA) Section 8(a)

FRL #: 10008-14

Docket ID #: EPA-HQ-OPPT-2018-0321

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (<https://www.govinfo.gov/app/collection/fr>) and on Regulations.gov (<https://www.regulations.gov>) in the docket identified above. Notwithstanding the fact that EPA is posting a pre-publication version, the final rule will not be promulgated until published in the *Federal Register*.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

This page is intentionally left blank.

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704 and 712

[EPA-HQ-OPPT-2018-0321; FRL-10008-14]

RIN 2070-AK57

Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements

Under the Toxic Substances Control Act (TSCA) Section 8(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing amendments to the definition of small manufacturer, including a new definition for small government, in accordance with the Toxic Substances Control Act (TSCA). Changes to the small manufacturer definition impact certain reporting and recordkeeping requirements established under TSCA. EPA is also finalizing other minor changes.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0321, 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>.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Tyler Lloyd, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: lloyd.tyler@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 (defined by statute at 15 U.S.C. 2602(9) to include import) chemical substances, including byproduct chemical substances, and are subject to either of the following: (1) Reporting under the TSCA Chemical Data Reporting (CDR) requirements at 40 CFR part 711 or (2) TSCA reporting and recordkeeping requirements at 40 CFR part 704 or other TSCA reporting requirements which reference the small manufacturer standards at 40 CFR part 704.3. Any use of the term

“manufacture” in this document will encompass “import” and the term “manufacturer” will encompass “importer” unless otherwise stated.

The potentially regulated community consists of entities that produce domestically or import into the United States chemical substances listed on the TSCA Inventory. The Agency's previous experience with TSCA section 8(a) data collections has shown that most respondents affected by this collection activity are from the following North American Industrial Classification System (NAICS) code categories:

- Chemical manufacturing or processing (NAICS code 325); and
- Petroleum and coal products manufacturing (NAICS code 324).

The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions at 40 CFR part 711.8. If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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

TSCA section 8(a)(1) authorizes EPA to promulgate rules under which manufacturers and processors of chemical substances must maintain such records and submit such reports as EPA may reasonably require (15 U.S.C. 2607(a)(1)). TSCA section 8(a) generally excludes small manufacturers and processors of chemical substances from the reporting (reporting and recordkeeping) requirements established in TSCA section 8(a). However, EPA is authorized by TSCA section 8(a)(3)(A)(ii) to require TSCA section 8(a) reporting and recordkeeping from small manufacturers and processors with respect to any chemical substance that is the subject of

a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6; that is the subject of an order in effect under TSCA section 4 or 5(e); that is subject to a consent agreement under TSCA section 4; or that is the subject of relief granted pursuant to a civil action under TSCA section 5 or 7.

TSCA section 8(a)(3)(B) requires EPA, after consultation with the Administrator of the Small Business Administration (SBA), to prescribe by rule the standards for determining the manufacturers and processors which qualify as small manufacturers and processors. In 1988, EPA established the general TSCA section 8(a) small manufacturer definition for use in other rules issued under TSCA section 8(a), which are codified at 40 CFR 704.3. TSCA section 8(a)(3)(C) requires EPA, after consultation with the SBA Administrator and no later than 180 days after June 22, 2016, to review the adequacy of those standards and, after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted. Pursuant to TSCA section 8(a)(3)(C), in the **Federal Register** of November 30, 2017, EPA announced that it determined that revision of these standards is warranted (82 FR 56824) (FRL-9968-41).

TSCA section 8(a)(5) requires EPA, to the extent feasible when carrying out TSCA section 8, to not require unnecessary or duplicative reporting and to minimize the cost of compliance for small manufacturers and processors.

C. What action is the Agency taking?

EPA is finalizing an amendment to update the size standards definition for small manufacturers for reporting and recordkeeping requirements under TSCA section 8(a). In addition to updating the definition for small manufacturers, EPA is finalizing a definition for small governments as proposed. EPA is also finalizing as proposed a technical correction to the

small manufacturer reference at 40 CFR 704.104 for Hexafluoropropylene oxide, which only includes a rule-specific small processor definition and not a small manufacturer definition. When reviewing the small manufacturer size standards, EPA found this to be an inadvertent error. As originally promulgated, 40 CFR 704.104 included the small manufacturer standard via the cross reference in 40 CFR 704.104(c)(2) to the exemption provisions in 40 CFR 704.5, which was lost when the exemptions at 40 CFR 704.5 were amended and the necessary corresponding change was not made at 40 CFR 704.104(c)(2) (52 FR 41297, October 27, 1987 (FRL-3280) and 53 FR 51717, December 22, 1988 (FRL-3368-1)). Lastly, EPA is finalizing the proposed update to the current small manufacturer definition in the Preliminary Assessment Information Rule (PAIR) rule at 40 CFR 712.25 to align it with the updated small manufacturer definition at 40 CFR 704.3. Further details of these amendments are in Unit II.

Because the small manufacturer size standard under TSCA section 8(a) impacts the CDR rule more than other TSCA section 8(a) reporting rules at this time, EPA included amendments to the small manufacturer definition and revisions to CDR as one proposed rule (84 FR 17692; April 25, 2019 (FRL-9982-16)). However, as stated in the proposed rule, EPA recognizes that the changes to the small manufacturer definition will also apply to 8(a) rules other than CDR and EPA is now finalizing these amendments as two separate actions.

D. Why is the Agency taking this action?

EPA previously determined that revision of the TSCA section 8(a) size standards for small manufacturers is warranted (82 FR 56824, November 30, 2017 (FRL-9968-41)). TSCA section 8(a)(3)(C), which was amended in 2016, requires EPA, after consultation with the Administrator of the SBA, 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). EPA's determination, supporting documents, and comments received can be found at <http://www.regulations.gov> under docket ID No. EPA-HQ-OPPT-2016-0675. In response to the determination, EPA proposed an update to the small manufacturer definition as part of the proposed rule entitled “TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a),” issued in the **Federal Register** on April 25, 2019 (84 FR 17692 (FRL-9982-16)).

In reviewing the TSCA section 8(a) size standards for small manufacturers, EPA also decided to add a definition for small governments in order to reduce report burden for governments reporting under CDR. Additionally, when reviewing the small manufacturer size standards, EPA found an inadvertent error in the small manufacturer reference at 40 CFR 704.104 for Hexafluoropropylene oxide and is taking the opportunity to correct that error. Lastly, EPA is updating to the current small manufacturer definition in the PAIR rule at 40 CFR 712.25, which has not been updated since it was established in 1982, in order to align it with the definition at 704.3.

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

EPA evaluated the costs and benefits of modifying standards for small manufacturers with regard to CDR and other TSCA section 8(a) reporting. This analysis, which is available in the docket, is discussed in Unit II. and is briefly summarized here (Ref. 1).

The modified standards for small manufacturers affect some TSCA section 8(a) rules, including CDR. These rules use the TSCA section 8(a) small manufacturer definition to identify the entities exempted from reporting or subject to other reduced reporting requirements. The amendments are expected to have the greatest impact on CDR and could affect the need to

submit, or the number of chemicals reported in, a CDR report for a given site. As discussed in the proposed rule, there is no measurable impact to other current TSCA section 8(a) rules either because EPA has not received any chemical reports for the rule for an extended period of time or because the rule uses a different definition that is not being changed by this amendment (see Unit IV.A. of the proposed rule for a more detailed discussion (84 FR 17692; April 25, 2019)). The amendments, discussed in detail in Unit II., result in a cost savings.

1. *Impact of amendments to the small manufacturer definition.* The final amendment is estimated to eliminate CDR reporting entirely for 127 industry sites and reduce reporting by eliminating the need to report at least one chemical for additional 173 industry sites (Ref. 1). The final amendment is an update of the current two-standard definition (see Unit II.A.). For sites that are considered small under the first standard (\$120 million and 100,000 lbs), it is possible to be considered small for chemical substances with production volumes below 100,000 lbs and not small for chemical substances with production volumes above 100,000 lbs, even when the site's total annual sales are less than \$120 million. Such sites will continue to report the chemical substances with production volumes over 100,000 pounds. For sites considered small under the second standard (\$12 million) and sites considered small for all of their chemical substances under the first standard, such sites will be eliminated entirely from reporting. This reduction in reporting is in addition to the sites already not reporting because they meet the current small manufacturer definition.

Under the amended definition, incremental future CDR reporting cycle burden reductions and cost savings are estimated at 92,000 hours and \$7.0 million, respectively, over a four-year CDR reporting cycle (Ref. 1). On an annualized basis, using a 3 percent and 7 percent discount rate over a 10-year period yields net annualized incremental cost savings of \$1.7 million and

\$1.7 million per year, respectively (rounding to two significant figures results in the same number) (Ref. 1).

2. Impact of adding a small government definition. The following government entities reported under CDR during the 2016 reporting period: one site owned by the U.S. federal government, four foreign government-owned sites, seven municipalities, one county-level public utility district, and one tribal entity. In total, for the 2016 CDR reporting period, EPA identified 14 government entities who reported to CDR. Under this final amendment to add a small government definition and based on information from the 2016 CDR submission period, four of these government entities would be exempt from the need to report. The burden and cost savings associated with the exempted entities, in future reporting cycles, are included in the estimates for the final definition with incremental future CDR reporting cycle burden reduction and cost savings estimated at 440 hours and \$34,000 respectively, over a four-year CDR reporting cycle (Ref. 1). On an annualized basis, using a 3 percent and 7 percent discount rate over a 10-year period yields net annualized incremental cost savings of \$8,000 and \$7,900 per year, respectively (Ref. 1).

II. Modifications to Small Manufacturer Definition and Size Standards

EPA is finalizing modifications to the TSCA section 8(a) small manufacturer size standards, following EPA's determination on November 30, 2017 that revision to the current size standards is warranted (82 FR 56824). These final standards apply to TSCA section 8(a) rules unless a different standard is identified in the regulatory text of a particular rule. The current chemical-specific TSCA section 8(a) rules that use the small manufacturer definition listed in 40 CFR 704.3 are: §§ 704.25 (11-Aminoundecanoic acid); 704.33 (P-tert-butylbenzoic acid (P-TBBA), p-tert-butyltoluene (P-TBT) and p-tert-butylbenzaldehyde (P-TBB)); 704.45

(Chlorinated terphenyl); 704.95 (Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis- (EDTMPA) and its salts); and 704.175 (4,4'-methylenebis(2-chloroaniline) (MBOCA)). As proposed on April 25, 2019 (84 FR 17692), EPA is also finalizing a TSCA section 8(a) definition for small government entities, finalizing a technical correction to the small manufacturer reference at 40 CFR 704.104 for hexafluoropropylene oxide, and finalizing an update to the current small manufacturer definition in the PAIR rule at 40 CFR 712.25, in order to align it with the definition at 704.3.

A. Scope and content of the final Small Manufacturer Definition update

For the TSCA section 8(a) small manufacturer definition update, EPA is finalizing an update to the current definition based on inflation. This definition applies to chemical manufacturers (including importers), but not to chemical processors. Because the amended definition predominantly impacts the CDR, in which reporting is required by manufacturers and not processors, EPA believes it is not necessary to develop a definition of “small processor” for purposes of TSCA section 8(a) at this time and that it is best to continue the past practice of developing definitions for small processors on a rule-by-rule basis, as applicable.

All data in this preamble correspond to impacts to the manufacturing portion of the chemical industry, as evaluated for the CDR. The final definition is as follows:

Small manufacturer definition. When EPA proposed the update to the current small manufacturer definition (84 FR 17692; April 25, 2019), EPA inflated the current definition based on 2017\$. EPA is now finalizing the definition based on 2018\$, to ensure that the definition is as up-to-date as possible at the time of finalization. EPA applied the same economic analysis for updating the definition with 2018\$ that is used in the proposal (84 FR 17692; April 25, 2019). EPA is basing the update of the current two-standard definition at 40 CFR 704.3 on inflation by

adjusting the sales standard level for the first part from \$40 million to \$120 million (originally proposed as \$110 million) and for the second part from \$4 million to \$12 million (originally proposed as \$11 million). The impacts of this option are provided in Unit I.E.2. The final definition will read:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$120 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 (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

Under CDR, sites that meet the small manufacturer definition are exempted from reporting either for the full site (based on the second standard) or for particular chemical substances (based on the first standard), unless the chemical substance the site is manufacturing (including importing) is the subject of one of certain TSCA actions: A rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6, or an order in effect under TSCA section 5(e), or relief that has been granted under a civil action under TSCA section 5 or 7. As part of this rule, EPA is finalizing as proposed the amendment to add TSCA section 4 orders to the list of certain TSCA actions. The authority to issue section 4 orders was added to TSCA when the

statute was amended in 2016.

Relative to the 2016 reporting period, EPA estimates that the updated definition will eliminate reporting entirely for 127 industry sites that reported under the 2016 CDR and will reduce reporting by eliminating the need to report at least one chemical for an additional 173 industry sites that reported under the 2016 CDR (Ref. 1). Overall, 1,248 chemical reports from industry sites will no longer be submitted to CDR. In sum, the use of the inflation adjustment definition results in a reduction of two percent of sites, an overall reduction of three percent of chemical reports, and a reduction of 0.09 percent of total volume reported (Ref. 1).

Inflation index. The current small manufacturer definition at 40 CFR 704.3 specifies that EPA will use an inflation index for purposes of determining the need to update the two standards comprising the definition. On April 25, 2019, EPA proposed an amendment to use the Gross Domestic Product (GDP) deflator, or implicit price deflator, instead of the Producer Price Index (PPI) for Chemical and Allied Products, when determining the need to adjust the total annual sales values. As discussed in the proposal, the GDP deflator is less volatile and is broader than the PPI for Chemicals and Allied Products, and therefore EPA believed it would be a better measure for considering future updates to the revenue size standards. After considering comments on this proposed amendment, however, EPA will not be finalizing the change to GDP as an inflation index. While GDP is less volatile, EPA now recognizes that PPI for Chemicals and Allied Products is a better overall accounting of chemical manufacturers that would be subject to reporting under TSCA section 8(a) because it directly reflects the chemical manufacturing sector as opposed to the U.S. economy as a whole. Instead of using the GDP deflator as proposed, EPA will amend the small manufacturer definition at 40 CFR 704.3 to use a five-year average for the PPI for Chemicals and Allied Products when determining if the small

manufacturer definition warrants adjustment. This change will better protect against volatility while continuing to be representative of the chemical manufacturers that fall under the small manufacturer definition. The regulated community had an opportunity to comment on EPA's desire to change to an indicator that was less volatile. Commenters did not comment that changing to a less volatile indicator would be unfavorable but rather commented on which indicator would be best suited for determining if an update was warranted. EPA believes that the change to a 5-year average PPI will be beneficial to the regulated community. In any given year PPI could change drastically. By taking a 5-year average of PPI, EPA could ensure that uncharacteristic market swings do not unduly influence EPA's decision to update the small manufacturer definition. Further discussion of this change can be found in the Response to Public Comment in Unit III.

Small government definition. EPA is also finalizing as proposed a definition for small government. EPA is adding a small government definition to reduce the reporting burden for governments that may lack necessary resources. EPA will use the same definition for small government as the Regulatory Flexibility Act (5 U.S.C. 601(5)): A small governmental jurisdiction is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. State and tribal governments are not considered small governments.

EPA estimates 33 government sites report under CDR in a four-year cycle. Under the added definition of small government, reporting will be eliminated entirely for four government sites with an associated six chemical reports.

Application of standards. The size standards in this final rule will apply to all manufacturers of chemical substances subject to TSCA section 8(a) reporting and recordkeeping

rules, unless a different standard is identified in the regulatory text of a particular TSCA section 8(a) rule. TSCA section 8(a) rules with different definitions than the current small manufacturer definition at 40 CFR 704.3 are: the nanoscale rule at 40 CFR 704.20; certain chemical-specific rules at 40 CFR 704.43 (chlorinated naphthalenes) and 40 CFR 704.102 (hexachloronornbornadiene); and the Preliminary Assessment Information Rule (PAIR) at 40 CFR 712. EPA is finalizing an amendment to the current small manufacturer definition in the PAIR rule at 40 CFR 712.25 to use the updated small manufacturing definition at 704.3. As explained in the proposal (84 FR 17692; April 25, 2019), the other TSCA section 8(a) rules noted previously will retain small manufacturer definitions different than the small manufacturer definition at 40 CFR 704.3. Additionally, because of an inadvertent error, there is currently no applicable definition of “small manufacturer” in 40 CFR 704.104 (hexafluoropropylene oxide); EPA is finalizing a correction to cross reference the small manufacturer definition at 40 CFR 704.3, as discussed in the proposal, to correct this error.

B. Agency Objectives

Compliance with TSCA section 8(a) reporting and recordkeeping requirements involves the expenditure of time, money, and personnel resources. These costs have particular impact on entities that have limited financial and personnel resources, such as smaller manufacturers. These smaller manufacturers tend to have fewer administrative personnel and less capability for data compilation and recordkeeping than larger manufacturers.

The information collection authority of TSCA section 8(a) reflects Congressional recognition of EPA's need for sufficient data from the chemical industry to enable the Agency to effectively carry out its TSCA obligations. EPA has concluded that if a manufacturer produces a subject chemical in substantial quantities, it is inappropriate to exempt that company from TSCA

section 8(a) reporting requirements. Production data is valuable to EPA as an indicator of potential for chemical exposure and high-volume chemical production reflects a greater potential for environmental release. For this reason, EPA is maintaining the annual production or importation volume modifier of 100,000 lb at any individual site owned or controlled by the manufacturer or importer for the first part of the updated small manufacturer definition.

The standards should not prevent TSCA section 8(a) reporting of information that is representative of manufacturers of different sizes. Manufacturers of different sizes have varying amounts of capital available, and therefore may utilize different production processes, techniques, and equipment. Different methods of production may cause the potential for chemical exposure to vary among manufacturers of different sizes. It is important for the Agency to be able to monitor these differences. To ensure that EPA will receive information from a representative portion of manufacturers regulated under TSCA section 8(a), the structure of the definition and levels of the size standards have been designed to allow the Agency to obtain production, use, and exposure data from a variety of manufacturers.

A final objective for the standards is that they be easily applied by both industry and the Agency. The updated small manufacturer definition uses readily available data. These data enable identification of companies which are small manufacturers. The standards can also be easily enforced because the selected criteria for the small manufacturer definition will enable EPA to monitor compliance with the exemption. For further discussion of EPA's methodology and considerations for developing the size standards in this final rule, see Unit IV. of the proposed rule (84 FR 17692; April 25, 2019) and Unit III. of this action.

III. Response to Public Comment

The Agency reviewed and considered all comments received on the proposed rule. EPA

received ten public comments pertinent to the small manufacturer definition update, which included comments from chemical manufacturers, chemical distributors, electric utilities, scrap metal recyclers, petroleum industry representatives, biotechnology companies, and environmental organizations. Copies of all comments are available in the docket for this action (EPA-HQ-OPPT-2018-0321). A discussion of the comments germane to this rulemaking and the Agency's responses follows.

1. *Comment.* Two commenters supported the proposed update to the current two-standard definition at 40 CFR 704.3. (Docket IDs: EPA-HQ-OPPT-2018-0321-0089, EPA-HQ-OPPT-2018-0321-0102.)

Response. EPA acknowledges the comment.

2. *Comment.* Four commenters requested that EPA implement a variable employment-based size standard for CDR and TSCA section 8(a) that uses different industry specific standards defined by NAICS codes, similar to the final rule for Fees for the Administration of the Toxic Substances Control Act (fees rule) (83 FR 52694, October 17, 2018 (FRL-9984-41)), which is based on the SBA definition for small business, as opposed to the current two-standard revenue-based definition. One commenter further stated that EPA should finalize an employment-based size standard for CDR reporting with the addition of a 100,000 lb volume modifier. Commenters stated that using a definition similar to that in the fees rule would provide consistency and “more accurately reflect the business size of companies in the chemical industry.” Another commenter noted that the EPA’s economic analysis for the proposed rule (Ref. 2) shows that the “SBA Only” definition would provide the least regulatory burden. The same commenter requested to know why a “definition that is variable and maintained by another agency would be unwieldy.” (Comment IDs: EPA-HQ-OPPT-2018-0321-0091, EPA-HQ-OPPT-

2018-0321-0096, EPA-HQ-OPPT-2018-0321-0097, EPA-HQ-OPPT-2018-0321-0104.)

Response. Using a variable employment-based size standard similar to the fees rule leads to a reduction of information that would hamper EPA’s ability to carry out the Agency’s obligation under TSCA. As discussed in the proposal, EPA examined the utility of several criteria for “small” including a definition based on SBA’s definition for small businesses. EPA’s decision to finalize the update to the small manufacturer definition as proposed (using 2018\$ rather than 2017\$) is a result of EPA balancing Agency data needs under TSCA section 8(a) for implementing TSCA against the burden imposed on the regulated community. EPA also considered comments on the 2017 determination and the 2019 proposed rule, held multiple meetings with SBA to obtain input, and developed new analyses to understand the impact of the updated definition on the CDR requirements.

The economic analysis for the proposed rule (Ref. 2) evaluated an unmodified SBA-based definition (“SBA Only”) in addition to SBA-based definitions that included production volume modifiers of 100,000 lb, 50,000 lb, and 25,000 lb (SBA+100k, SBA+50k, SBA+25k). The purpose of the production volume modifier was similar to its purpose in the existing definition: to balance the need to minimize the reporting and recordkeeping burden on small manufacturers with EPA’s need for exposure-related information that will be reported under TSCA section 8(a). EPA’s analysis found that using SBA standards in isolation results in a large loss of information, approximately 20% of chemical reports and 24% of sites, in addition to those already not reported to CDR as a result of the current definition (“Baseline”) (See Ref. 2, Table ES-1). While this option provides the least regulatory burden, it also creates the greatest loss of data to the Agency. EPA determined that losing such a large amount of information would hamper EPA’s ability to effectively carry out and implement the requirements of TSCA.

EPA calculated the loss of reports for chemicals on the TSCA Work Plan for Chemical Assessments to be 23% for SBA Only, 7% for SBA+100k, and 3% for the inflation definition. The TSCA Work Plan, originally released in 2012 and updated in 2014, identified a work plan of chemicals for further assessment under TSCA. 2016 amendments to TSCA require that at least 50 percent of all chemical substances undergoing risk evaluation come from the 2014 update to the Work Plan, until the Work Plan chemical list is exhausted. Disproportionate losses of reporting on TSCA Work Plan chemicals constitute a potential loss of information necessary for key Agency decisions. Again, EPA determined that losing an additional 23% or 8% of information on TSCA Work Plan chemicals would hamper EPA's ability to effectively carry out and implement the requirements of TSCA.

Prior to finalizing this final rule, EPA updated its analysis of the reporting impact of the updated small manufacturer definition, as well as the potential reporting impacts of alternative small manufacturer definitions. In the updated analysis, EPA compared the final rule's inflation adjusted small manufacturer definition to the TSCA fees rule's small manufacturer definition with a series of production volume modifiers. The calculated impacts remained largely unchanged from the proposed to final rule. (See the supporting document, Economic Analysis for the Final Rule on the TSCA Section 8(a) Small Manufacturer Definition Update for a more in-depth analysis (Ref. 1)). These impacts of the various alternative small manufacturer definitions were part of the basis for deciding to finalize the updated definition as proposed (updated with 2018\$ rather than 2017\$).

In deciding to finalize the updated definition as proposed (updated with 2018\$ rather than 2017\$), EPA considered the practicality of implementing any potential definition. SBA's variable definition is developed and managed by SBA, and EPA cannot simply cite SBA's

definition. As was done with the TSCA fees rule, EPA would need to finalize an SBA-based definition in part or in whole as part of its own regulations. While EPA adopted parts of the SBA definition for the fees rule, CDR and the fees rule operate differently for small manufacturers. Under the fees rule, small manufacturers pay a reduced fee but are still subject to the same requirements as large manufacturers. Under the CDR rule, however, small manufacturers are completely exempt from reporting. Given the differences in impact that a small manufacturer definition has for the fees rule and CDR, EPA carefully considered the balance between a reduction in burden and the loss of data from small manufacturer reporters when updating the TSCA section 8(a) small manufacturer definition.

As stated, under the fees rule, small manufacturers pay a reduced fee (i.e., a reduction of burden) while for CDR small manufacturers are completely exempt from reporting (i.e., an elimination of burden). While both the fees rule and CDR are implemented under TSCA, they have different purposes. The purpose of the fees rule size standards is for apportionment of fees between small and large entities in the context of the implementation of new provisions for TSCA sections 4, 5, and 6. This purpose does not include any data quality and data availability consequences, which are part of CDR considerations. EPA uses CDR data to support risk screening, risk assessment, chemical prioritization, risk evaluation, and risk management activities, among other activities. This information allows EPA to develop an understanding of the types, amount, end uses, and possible exposure to chemicals in commerce.

Additionally, the SBA definition is used to define the largest size a business can be to participate in government contracting programs and compete for contracts reserved or set aside for small businesses. Applications for these programs are reviewed on a case-by-case basis and a determination is made if a business qualifies. For the CDR rule, however, the small manufacturer

definition is self-implementing. EPA does not make a determination on whether a company is exempted as a small manufacturer or is required to report to CDR, prior to CDR reporting. For CDR, it is up to the manufacturer to determine if the small manufacturer definition applies. A small manufacturer definition differentiated by NAICS codes could be difficult to apply for reporters because CDR imposes site-based reporting requirements and multiple NAICS codes could apply to a given site. To apply a small manufacturer definition differentiated by NAICS codes, the reporter would have to select a single NAICS code. For importers and domestic manufacturing sites with multiple activities to which multiple NAICS codes could apply, this can pose a problem for the reporter and EPA. If the manufacturer chooses an incorrect code that results in no reporting of chemical data, then EPA would not be aware that the company is involved in chemical manufacturing. EPA would have difficulty determining if an appropriate NAICS code was selected for a given site that has multiple applicable NAICS codes, and, consequently, would have difficulty determining if a site is appropriately exempted from reporting due to qualification as a small manufacturer based on the choice of NAICS code. EPA believes the current revenue and production volume approach is more amenable to compliance monitoring and believes that it would be more difficult to determine the appropriate NAICS classification for a company because often multiple NAICS apply to a site.

For these reasons, EPA has decided to finalize the updated small manufacturer definition as proposed (updated with 2018\$ rather than 2017\$), instead of finalizing an employee-based size standard.

3. *Comment.* In addition to broadly updating the small manufacturer definition to an employment-based size standard for all manufacturers subject to reporting under TSCA section 8(a), two commenters specifically asked that EPA use the SBA size standard for the utility

sector. One commenter went on to state that “EPA should incorporate the SBA size standard of 750 employees as the definition of ‘small manufacturer’ for NAICS 221112, fossil fuel electric power generation; or define ‘total sales’ for NAICS 221112 as only including sale of electricity from coal-fired generation.” (Comment IDs: EPA-HQ-OPPT-2018-0321-0105, EPA-HQ-OPPT-2018-0321-0104.)

Response. EPA is finalizing a standardized two-part revenue-based small manufacturer definition that applies to all chemical substance manufacturers. Given the difficulties that EPA has already described in implementing a small manufacturer standard defined by industry sector, EPA does not believe that the Agency should adopt industry-specific standards. If EPA made specific standards for one industry, it would need to consider additional standards for other industries that requested a standard different from those in the general TSCA section 8(a) small manufacturer definition, which would result in a complex and unworkable definition. That being said, EPA did conduct an analysis of the CDR submitters from utilities sites (government and industry) and also considered the public commenters’ recommendation to use the SBA size standard for NAICS code 221112, fossil fuel electric power generation. From this analysis, EPA found that CDR reporters represent a variety of utilities, one of which is electricity generation. NAICS code 221112 does not have high representation in CDR and is not the most often used electricity NAICS.

EPA disagrees with the concept of relying only on sales associated with a subset of the production of the reportable chemical substance. As described in Unit II.B., the purpose of the small manufacturer exemption is to reduce (or eliminate) the burden of compliance for those entities that have limited financial and personnel resources. Reducing the sales of a company to only a subset of its revenue does not identify the companies that have such limited resources.

4. *Comment.* One commenter requested that EPA implement a third standard, in addition to the proposed two-part revenue-based standard, for the small manufacturer definition under TSCA section 8(a). The commenter asked that this third standard be an employee-based size standard combined with a production limit, specifically “a small manufacturer definition of 500 or fewer employees, as defined by the U.S. Small Business Administration Office of Advocacy, if annual production (including import) volume of the particular substance does not exceed 100,000 lbs. at any individual site.” (Comment ID: EPA-HQ-OPPT-2018-0321-0102)

Response. EPA disagrees with the comment. Adding a third standard using a different metric than the first two standards would unduly complicate the definition because companies would not only have to identify their company sales volume, but would also have to determine the number of employees. If EPA added a standard of 500 or fewer employees to the proposed SMD definition, another 34 sites (1%) and 829 reports (2%) would be eliminated. The additional loss of information incurred as a result of adding this third standard would hamper EPA’s ability to effectively carry out and implement the requirements of TSCA. Due to the need to balance the reduction of the reporting and recordkeeping burden on small manufacturers with EPA’s need for exposure-related data, EPA would need to adjust the third standard in such a way that it would not result in additional losses of information. Thus, adding a third standard would introduce additional complexity but without further reducing burden or information received by EPA. See the response to Comment 2 for further discussion.

5. *Comment.* Two commenters recommended that EPA retain the use of the PPI for Chemicals and Allied Products in future updates of the size standard threshold instead of changing to GDP when determining if an update to the TSCA section 8(a) small manufacturer size standards is warranted. (Comment IDs: EPA-HQ-OPPT-2018-0321-0096, EPA-HQ-OPPT-

2018-0321-0102.)

Response. After reviewing the comments received, EPA decided that it will not finalize the change to Gross Domestic Product (GDP) as an inflation index. Instead, EPA will amend the small manufacturer definition at 40 CFR 704.3 to use a five-year average of the PPI for Chemicals and Allied Products when determining if the small manufacturer definition warrants adjustment. EPA proposed the change to GDP because a GDP deflator is less volatile and is broader than the PPI for Chemicals and Allied Products, and therefore EPA believed it to be a better measure when considering an update to the revenue size standards in the proposed definition. While GDP is less volatile, EPA now recognizes that PPI for Chemicals and Allied Products is a better overall accounting of chemical manufacturers that would be subject to reporting under TSCA section 8(a) because it directly reflects the chemical manufacturing sector as opposed to the U.S. economy as a whole. By using a five-year average of PPI for Chemicals and Allied Products, EPA will be able to protect against volatility while continuing to account for the chemical manufacturers that fall under the small manufacturer definition.

6. *Comment.* Three commenters requested that EPA change the production volume modifier. Two commenters requested that EPA remove or raise the 100,000 lb production volume modifier used as part of the first standard for TSCA section 8(a) small manufacturer definition. Another commenter asked that EPA evaluate the impacts of decreasing the 100,000 lb production volume modifier. One commenter asked that EPA show “why 100,000 lbs. is an appropriate modifier and consult with the SBA on this threshold.” Additionally, the commenter asked that the Agency “consider a volume modifier with an employee-based standard.” One commenter stated that, with no change in the existing 100,000 lb modifier, the proposed increases of annual company sales thresholds are unlikely to provide regulatory relief from

reporting for small scrap metal recyclers. The commenter further stated that while the 100,000 lb limit made sense when inorganic chemical substances were exempt from reporting (before 2003), the threshold has not made sense since inorganic chemical manufacturers became subject to reporting under IUR/CDR because inorganic chemicals are denser than organic chemicals and the production volume threshold is quickly reached. To support their public comments, the commenter provided excerpts from industry testimonies made during the 1975 Senate hearings on pending TSCA legislation. (Comment IDs: EPA-HQ-OPPT-2018-0321-0097, EPA-HQ-OPPT-2018-0321-0100, EPA-HQ-OPPT-2018-0321-0111).

Response. EPA disagrees that the production volume modifier should be changed (either raised or lowered) or that industry-specific modifiers should be developed. EPA has updated the revenue thresholds for the small manufacturer definition based on changes to the value of the U.S. dollar as a result of inflation. There is, however, no corresponding basis for adjusting the production volume modifier. In developing the initial small manufacturer standard, EPA included a production volume modifier to ensure that chemical substances manufactured or imported at high volumes were reported to EPA. The commenters have provided no support to indicate that the 100,000 lb threshold requires updating as a result of changes to the chemical manufacturing sector.

Regarding industry-specific modifiers, such as for the scrap metal industry, EPA believes that it would be difficult and resource intensive for EPA to establish, administer, and update industry- or chemical-specific modifiers that align with the 100,000 lb threshold. As stated in EPA's response to Comment 2, EPA does not feel it is appropriate to have small manufacturer standards that are differentiated by industry. Please see EPA's full response to Comment 2 for further discussion.

7. *Comment.* One commenter asked that EPA justify why EPA chose to “to round its inflation adjustment of the threshold by two significant figures – from \$112 million to \$110 million for the first standard and \$11.2 to \$11 million for the second standard.” (Comment ID: EPA-HQ-OPPT-2018-0321-0096.)

Response. EPA used two significant figures instead of three significant figures for the levels of the revenue standards. EPA does not consider the additional precision to be merited based on the type of information being used to make the inflation adjustment. The underlying data used for inflating the revenue standard does not support the use of more than two significant figures. Since proposing the updated small manufacturer definition, however, EPA has decided to use 2018\$ as the basis for inflation rather than 2017\$, to ensure that the definition is as up-to-date as possible at the time of finalization. EPA is basing the update of the current two-standard definition at 40 CFR 704.3 on inflation by adjusting the sales standard level for the first part from \$40 million to \$120 million (originally proposed as \$110 million) and for the second part from \$4 million to \$12 million (originally proposed as \$11 million).

8. *Comment.* EPA received one comment on statutory and executive order reviews. The commenter emphasized that tribal consultation under Order 13175, and EPA’s 1984 Indian Policy, should have been carried out by this rulemaking. (Comment ID: EPA-HQ-OPPT-2018-0321-0092)

Response. EPA disagrees that a tribal consultation was necessary for this rule. EPA stated in Unit VII.G of the proposed rule that this rule would not have tribal implications because it is not expected to have substantial direct effects 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). EPA concluded that the impacts of the rule would not significantly nor uniquely affect the communities of tribal governments. Thus, EPA determined that Executive Order 13175 did not apply to this rule.

Even though EPA determined that Executive Order 13175 did not apply, EPA conducted tribal outreach on the TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a) from May 2019 through August 2019 to provide information to tribes on the proposed rule and to obtain feedback. Two nationwide outreach sessions were also conducted, and tribal comments were accepted through August 30, 2019. In addition, EPA developed supplemental background information to further explain the proposed actions to tribes. EPA previously responded to this comment in the Response to Public Comments for the TSCA Chemical Data Reporting Revisions for Reporting and Recordkeeping Requirements under TSCA Section 8(a) (Ref. 4).

9. *Comment.* One commenter requested that EPA “commit to updating the size standard threshold every time the inflation index has risen by 20% or more from the last adjustment.” The commenter points out that the proposed rule does not obligate EPA to update the small manufacturer definition. The commenter asks that EPA make future updates to the small manufacturer definition automatic. (Comment ID: EPA-HQ-OPPT-2018-0321-0096)

Response. EPA appreciates the comment but does not feel that such a commitment is necessary. While the updated small manufacturer definition at 40 CFR 704.3 does not establish a timeline or obligation for updating the small manufacturer definition in the future, the 2016 Amendments to TSCA require that EPA review the adequacy of the size standards no less than once every 10 years. The requirements under TSCA will lead to routine reevaluation of the small manufacturer definition under section 8(a). Committing to an automatic update, as requested,

would bind EPA to making the adjustment when PPI changed 20% and would disallow any future flexibility. Instead, future updates to the small manufacture definition will follow the requirement at TSCA section 8(a)(3)(C), which require EPA to review the standards every ten years, in addition to changes in PPI. Other factors that EPA may consider include changes in SBA's definition, inflation, and other economic or global factors that may have impacted chemical manufactures. The factors EPA considers are made on a case-by-case basis. As required by TSCA, EPA will consult with SBA when updating the definition.

10. *Comment.* One commenter stated that with respect to the 93 fewer reporting sites, EPA did not show which part of the modified revenue definition applied. The commenter stated that "if all or the majority of the sites are now exempt due to the first standard of \$11 million, the purpose of having a second prong is unclear." (Comment ID: EPA-HQ-OPPT-2018-0321-0097).

Response. As stated in the economic analysis, the structure of the definition was designed for effective targeting of small manufacturers (Ref. 1). Note that the information from baseline conditions for this question is unmeasured (i.e., CDR does not receive reports from these manufacturers). Nonetheless, not all sites that are exempted are expected to meet the conditions of the Second Standard of annual sales less than \$12 million. EPA considered the increment of the changes in the proposed rule via the 93 fewer reporting sites (now calculated to be 127 using an updated analysis); EPA found that although a larger portion of sites incur exemption via the Second Standard compared to the First Standard, there is a non-trivial portion of sites that incur exemption via the First Standard (Refs. 3 and 4).

11. *Comment.* Two commenters specified that EPA needs to better determine the information loss resulting from a revised small manufacturer definition. One commenter stated that the "definition update would result in less data collected by EPA and thus less information

available to the public on the chemical substances in their environment.” Another commenter said that EPA was not required to base the update to the small manufacturer definition on inflation but had the discretion to update the standards to best meet the goals of TSCA.

Additionally, the commenter believes that “EPA has failed to evaluate whether and how the proposed standards will affect its ability to implement the law effectively, contrary to its Section 8 mandate.” Lastly, the commenter pointed out that updating the definition will have minimal economic benefits. (Comment IDs: EPA-HQ-OPPT-2018-0321-0092, EPA-HQ-OPPT-2018-0321-0100)

Response. EPA appreciates the comment but disagrees that EPA has not adequately evaluated the impacts of the updated small manufacturer definition. EPA, however, does agree that EPA was not required to base the update to the small manufacturer definition on inflation, yet EPA believes the decision to do so best meets the goals of TSCA. As shown in the Economic Analysis for the proposed rule (Ref. 2), EPA considered the impact the updated small manufacturer definition would have on the number of companies reporting, number of sites reporting, number of chemical reports received, number of chemicals in chemical reports, total volume of all chemicals in chemical reports, number of full reports, number of chemical reports received covering chemicals that are intended for products used by children, and the number of chemical reports received covering chemicals on the 2014 update to the TSCA Work Plan. EPA selected the last two parameters in particular as important data for effective implementation of TSCA.

Under CDR, manufacturers of chemicals with consumer uses must further identify whether a chemical is present in or on any product intended for use by children. EPA uses this information to inform its analysis of chemicals that are of concern due to their potential impact

on children's health. The loss of such reporting would decrease the amount of information EPA has regarding chemicals used in children's products, which EPA has worked to retain while balancing relief to small manufacturers. Further, the 2014 update to the TSCA Work Plan plays an important role in the new prioritization and risk evaluation processes under TSCA (Ref. 5). TSCA requires that 50 percent of all chemical substances on which risk evaluations are conducted be drawn from the 2014 update to the TSCA Work Plan, meaning that EPA will need to draw at least 50 percent of High-Priority Substance candidates from that list. By operation of this statutory directive, all TSCA Work Plan chemicals will eventually be prioritized (82 FR 33753, July 20, 2017, FRL-9964-24)). Information on manufacture, processing, and use of these chemicals through TSCA section 8(a) reporting will support prioritization and EPA's evaluations of these chemicals. The loss of chemical reports on Work Plan chemicals may affect the timeliness and quality of EPA's risk evaluations.

Lastly, EPA considered several approaches, including approaches by SBA and others, when amending the small manufacturer definition. The discussion is further documented in Appendix B of the Economic Analysis (Ref. 1). EPA considered alternative small business definitions used by U.S. federal government agencies, including other small business definitions used by EPA, with a focus on the purpose of the small business size standards and the approach used to establish them.

12. *Comment.* One commenter asked that the updated small manufacturer definition not apply to mercury reporting under CDR. This request was made because the mercury reporting rule promulgated by EPA on June 27, 2018 includes certain exemptions for persons who already report for mercury and mercury-added products to CDR (83 FR 30054). The commenter points out that EPA included this exemption because comparable data would be provided to EPA under

the CDR rule. The commenter then states that this assumption may no longer be correct if EPA modifies the small manufacturer standards as proposed.

Response. EPA appreciates the comment. The first reporting cycle for the mercury inventory closed on July 1, 2019. The Agency is currently assessing data received in preparation for the statutory deadline for publishing the mercury inventory not later than April 1, 2020. The Agency is amenable to suggestions of ways to improve the reporting requirements related to mercury supply, use, and trade in the United States, and will take all comments under consideration for future program refinement.

IV. References

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

1. EPA (2019). Economic Analysis for the Final Rule on TSCA Section 8(a) Small Manufacturer Definition Update (RIN 2070-AK57). Office of Pollution, Prevention, and Toxics. Washington, DC. April 2020.

2. EPA (2019). Economic Analysis for the Proposed Rule on TSCA Section 8(a) Small Manufacturer Definition Update (RIN 2070-AK33). Office of Pollution, Prevention, and Toxics. Washington, DC. April 2019.

3. EPA (2014). TSCA Work Plan for Chemicals Assessments: 2014 Update.

<http://www.epa.gov/sites/production/files/2014->

02/documents/work_plan_chemicals_web_final.pdf. Retrieved January 30, 2018.

4. EPA (2020). TSCA Chemical Data Reporting Revisions for Reporting and Recordkeeping Requirements under TSCA Section 8(a).

5. EPA (2018). EPAB CDR Database Statistics Report (General Report and Special Reports on Inorganics and Government/Industry). Office of Pollution Prevention and Toxics, Economic and Policy Analysis Branch. September 2018.

6. EPA (2018). Information Collection Request Proposed Addendum to Chemical Data Reporting under the Toxic Substances Control Act (TSCA section 8(a)) (EPA ICR No. 1884.12; OMB Control Number 2070-0162). September 2018.

V. Statutory and Executive Order Reviews

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

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

EPA prepared an economic analysis of the potential costs, cost savings, and benefits associated with this action. A copy of the economic analysis, entitled *Economic Analysis for Final Rule on the TSCA Section 8(a) Small Manufacturer Definition Update* (Ref. 1), is available in the docket and is briefly summarized in Unit I.E.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings on this final rule can be found in the Economic Analysis.

C. Paperwork Reduction Act (PRA)

This final rule does not impose a new or revised information collection activities, but the changes in the definitions impact the burden estimates associated with existing reporting and recordkeeping rules because the respondent universe changes. EPA has therefore submitted an addendum to the existing Information Collection Request (ICR) for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* (Ref. 6). The existing ICR is identified under EPA ICR No. 1884.11 and approved under OMB Control No. 2070-0162. The ICR Addendum is identified under EPA ICR No. 1884.12, a copy of the ICR Addendum in the docket for this rule, and is briefly summarized here.

Respondents/affected entities: Entities potentially affected by this ICR include companies manufacturing (including importing) chemical substances listed on the TSCA Inventory and regulated under TSCA section 8.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 5,660.

Frequency of response: Reporting under CDR occurs every four years. The next CDR collection will occur in 2020.

Total estimated burden: A reduction of 23,014 hours per year from the total burden currently approved. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: A reduction of \$1,760,578 per year, includes \$0 annualized capital or operation and maintenance costs.

For TSCA section 8(a) reporting outside of CDR, including the TSCA section 8(a) Preliminary Assessment Information Rule (PAIR) (OMB control number 2070-0054) or any of the existing chemical specific TSCA section 8(a) rules, EPA did not estimate incremental burden and cost either because EPA has not received any chemical reports under those rules for an extended period of time, or because the rule uses a rule specific definition that is not being changed by this final rule. For these reasons, no change is expected in the impacted universe of respondents, respondent burden or respondent cost for the PAIR or other chemical specific TSCA section 8(a) rules and no ICR addendums in these cases are needed. The technical correction for hexafluoropropylene oxide also did not change the respondent universe, burden or cost that would need to be captured in an ICR addendum.

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

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities subject to the requirements of this action are manufacturers and importers of chemical substances, including byproduct chemical substances, and are subject to either of the following: (1) Reporting under the TSCA Chemical Data Reporting (CDR) requirements at 40 CFR part 711 or (2) TSCA reporting and recordkeeping requirements at 40 CFR part 704 or other TSCA reporting requirements which reference the small manufacturer standards at 40 CFR part 704.3. The Agency has determined that no currently exempt small manufacturers will become newly

subject to any current TSCA section 8(a) rules under the new TSCA section 8(a) small manufacturer definition, because all manufacturers that are currently exempt will remain exempt under the final definition. Moreover, the updated definition allows exemptions for certain current reporters, thereby eliminating their reporting burden. EPA also notes that there are no adverse small entity impacts to small government entities because under the final rule, all entities defined as small for purposes of small government assessment are the same entities that are newly eligible to take the small government exemption and eliminate their CDR reporting burden entirely. A small amount of incremental burden will be incurred for rule familiarization and is less than 1% of revenues for each small parent company. Details of this analysis are presented in the Economic Analyses (Ref. 1).

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and will not significantly or uniquely affect small governments. According to the information derived using the 2016 CDR, there are government entities that report to CDR, including: seven municipalities, one county-level public utility district, and one tribal entity. However, under the changes finalized by this action, four of the municipalities will be exempt, with the remaining entities incurring a minimal average incremental burden and cost per site at about 0.1 hours and \$8 per year, respectively. Consequently, impacts will not exceed \$100 million for all governments.

In sum, the final rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this final rule is not subject to the requirements of sections 202, 203, or 205 of UMRA.

F. Executive Order 13132: Federalism

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

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

This action will not have tribal implications because it is not expected to have substantial direct effects 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). According to the information presented in the economic analysis for the TSCA section 8(a) small manufacturer definition update (Ref. 1), one tribal entity reported during the 2016 CDR collection. Under the final rule, this entity is estimated to incur a minimal average incremental burden and cost per site at about 0.5 hour and \$36 per year, respectively. Consequently, EPA has concluded that the impacts of the final rule will not significantly or uniquely affect the communities of tribal governments. Thus, Executive Order 13175 does not apply to this final rule.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying to those regulatory actions that concern environmental health and safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order

13045 because it does not concern an environmental health risk or safety risk.

I. 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 the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

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

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

This action will not have high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The final rule is directed at manufacturers (including importers) of chemical substances. All consumers of these chemical products and all workers who come into contact with these chemical substances could benefit if data regarding the chemical substances' health and environmental effects were developed. Therefore, it does not appear that the costs and the benefits of the final rule will be disproportionately distributed across different geographic regions or among different categories of individuals.

VI. Congressional Review Act (CRA)

Pursuant to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the

Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 704 and 712

Chemicals, Confidential business information, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 11, 2020.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I, subchapter R, is 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. Amend § 704.3 as follows:

a. Revise the definition of “small manufacturer or importer”.

b. Add, in alphabetical order, the definition for “small government”.

The additions and revisions read as follows:

§ 704.3 Definitions.

* * * * *

Small government means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

* * * * *

Small manufacturer means a manufacturer (including importer) that meets either of the following standards:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$120 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 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its

total annual sales, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity of substances produced or imported by that manufacturer (including 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 five-year average of 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.

* * * * *

3. Amend § 704.104 by revising subparagraph (c)(2) to read as follows:

§ 704.104 Hexafluoropropylene oxide.

* * * * *

(c) * * *

(2) Persons described in §704.5 (a) through (f).

* * * * *

PART 712--[AMENDED]

4. The authority citation for part 712 continues to read as follows:

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

5. Amend § 712.25 by revising paragraph (c) to read as follows:

§ 712.25. Exempt manufacturers and importers.

* * * * *

(c) Persons who qualify as small manufacturers (including importers) in respect to a specific chemical substance listed in § 712.30 are exempt. However, this exemption does not apply with respect to any chemical in § 712.30 designated by an asterisk. A manufacturer is qualified as small and is exempt from submitting a report under this subpart for a chemical substance manufactured at a particular plant site if it meets the definition for small manufacturer in § 704.3.

* * * * *