



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 716

[EPA-HQ-OPPT-2023-0360; FRL-11164.1-02-OCSP]

RIN 2070-AL15

### Certain Existing Chemicals; Request to Submit Unpublished Health and Safety Data under the Toxic Substances Control Act (TSCA); Extension of Submission Deadline

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

**ACTION:** Final rule.

**SUMMARY:** In response to requests from stakeholders, the Environmental Protection Agency (EPA or Agency) is amending the deadline for reporting pursuant to the Toxic Substances Control Act (TSCA) Health and Safety Data Reporting rule, which requires manufacturers (including importers) of 16 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. Specifically, EPA is amending the deadline from March 13, 2025, to June 11, 2025, for one of the 16 chemical substances (vinyl chloride) and to September 9, 2025, for the remaining 15 chemical substances. The Health and Safety Data Reporting Rule requires manufacturers (including importers) of certain chemical substances to submit lists and copies of certain unpublished health and safety studies to EPA.

**DATES:** This rule is effective on [INSERT DATE OF PUBLICATION IN THE *Federal Register*].

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0360, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information:* Stephanie Griffin, Data Gathering, Management, and Policy Division (7406M), Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; telephone number: (202) 564-1463; email address: *griffin.stephanie@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 to include import) any of the chemical substances that are listed in 40 CFR 716.120(d) of the regulatory text of this document. The following list of North American Industrial Classification System (NAICS) codes affected by this rule are those that align with these activities:

- Chemical manufacturers (including importers), (NAICS code 325); and
- Petroleum refineries (NAICS code 324110).

This action applies to manufacturers in these NAICS codes who are currently manufacturing (including importing) a listed chemical substance (or will do so during the chemical's reporting period), or who have manufactured (including imported) or proposed to manufacture (including import) a listed chemical substance within the last 10 years.

This action may also affect manufacturers of substances for commercial purposes that coincidentally produce the substance during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts and impurities. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

#### *B. What action is the Agency taking?*

EPA promulgated a final rule in the *Federal Register* of December 13, 2024 (89 FR

100756) (FRL-11164-02-OCSPP)), to require manufacturers (defined by statute to include importers) of 16 specific chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. The 16 chemical substances were added to 40 CFR 716.120 to support ongoing and upcoming activities under TSCA section 6. The Agency is hereby extending the submission deadline established in that final rule from March 13, 2025, to June 11, 2025, for the following chemical substance:

- Vinyl chloride (CASRN 75-01-4).

EPA is extending the deadline established in that final rule from March 13, 2025, to September 9, 2025, for the following chemical substances:

- 4,4-Methylene bis(2-chloraniline) (CASRN 101-14-4);
- 4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol) (CASRN 140-66-9);
- Acetaldehyde (CASRN 75-07-0);
- Acrylonitrile (CASRN 107-13-1);
- Benzenamine (CASRN 62-53-3);
- Benzene (CASRN 71-43-2);
- Bisphenol A (CASRN 80-05-7);
- Ethylbenzene (CASRN 100-41-4);
- Hydrogen fluoride (CASRN 7664-39-3);
- N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) (CASRN 793-24-8);
- 2-anilino-5-[(4-methylpentan-2-yl) amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (CASRN 2754428-18-5);
- Naphthalene (CASRN 91-20-3);
- Styrene (CASRN 100-42-5);
- Tribromomethane (Bromoform) (CASRN 75-25-2); and

- Triglycidyl isocyanurate (CASRN 2451-62-9).

*C. Why is the Agency taking this action?*

The Agency is taking this action to provide additional time for the regulated community to respond to the requirements of the TSCA Health and Safety Data Reporting rule. Through extension requests submitted to the EPA, the Agency has recently become aware that a number of companies are having unanticipated difficulties understanding and complying with the reporting requirements. EPA wants to ensure that companies subject to the rule do not face enforcement consequences due to these unanticipated difficulties, and as discussed further below, believes that additional time is warranted for EPA to provide guidance on particular implementation problems raised in the extension requests that could otherwise frustrate the purpose of the reporting rule.

Additionally, the chemicals included in this final rule are either in the process of prioritization as candidates for high-priority designation or are expected to be candidates in the upcoming years. Collecting health and safety studies on the chemicals included in this final rule will assist EPA in selecting chemicals to designate as high-priority chemicals, as well as in conducting the risk evaluation on such chemicals under TSCA section 6(b). If companies are unable to meet the requirements of the rule and relevant studies are either not provided or provided in an unusable form, EPA may be poorly positioned to conduct prioritization and risk evaluation. Such outcomes complicate EPA's current ability to make use of any information that it would receive via this reporting requirement because the Agency will review information submitted by the deadline and proceed with any TSCA section 6 activities upon processing such information. Incomplete response to this rule could, in turn, result in the Agency in needing to consider new information that could impact activities that had been undertaken, in part, due to the information received by the deadline. Extending the date helps ensure that such late submissions/revisions do not complicate activities undertaken subsequent to the deadline.

Of note, this is the first time where a TSCA section 8(d) reporting rule requires

respondents to prepare Organization of Economic Cooperation and Development (OECD) harmonized templates (OHTs) study submissions containing confidential business information (CBI), where a template is available for the study being provided. EPA explained in the response to comment document for the final rule that it did not anticipate significant amounts of CBI reporting in response to this reporting requirement, and thus did not expect that the requirement to prepare an OHT for a submission containing CBI would interfere with timely submissions of data. However, EPA has recently become aware of unexpected difficulties in complying with the OHT requirement. EPA received an extension request from a respondent company with information demonstrating that the company will need to complete substantially more OHTs than previously estimated based on the personally identifiable information included in such studies (such as a technician's name), which is one of the limited types of information in health and safety studies that may be asserted as CBI. EPA believes the company and others similarly situated to be at risk of non-compliance without additional time. Further, the request leads EPA to believe that a sizeable proportion of submissions may contain CBI, contrary to what EPA had anticipated, as there may be more circumstances where a CBI claim may arise with regard to this data collection. EPA believes it is appropriate to allow additional time for respondents to consider whether an OHT is required and then to prepare any such OHTs.

The timing of these extensions is intended to ensure that the required data submissions will be timely available for use in risk evaluations for chemical substances that have been designated as high-priority substances. Of the 16 chemicals included in this rule, EPA released a draft scope for the TSCA risk evaluation of vinyl chloride for public comment on January 16, 2025 (90 FR 4738; FRL-12439-01-OCSP). Because the draft scope has been available for public comment since January 16, 2025, EPA expects that companies with such health and safety studies are more likely to have prioritized working through those studies to inform relevant comments on the draft scope for risk evaluation under the original reporting deadline and to inform the Agency's subsequent development of a draft risk evaluation. Thus, EPA is extending

the submission deadline for vinyl chloride to June 11, 2025, to allow the Agency to take the submissions into account when preparing a draft TSCA risk evaluation for public comment. For all other chemical substances, the deadline is extended to September 9, 2025.

In letters seeking an extension to the reporting deadline, copies of which are included in the docket, EPA received requests for additional guidance on certain facets of TSCA section 8(d) reporting generally as well as with regard to the OHT requirement. The benefits that EPA and the public would receive via this data collection—in the form of studies that will inform TSCA section 6 activities, among other uses—will be diminished should EPA not receive information as per the requirements of the data collection. Accordingly, EPA believes that additional guidance would be useful to assist companies in complying with this reporting requirement and plans to provide such guidance soon. Further, EPA recognizes the uncertainty and potential legal vulnerability that companies could find themselves in should they not adhere to the reporting requirements despite their attempts to do so. Accordingly, additional time to submit the required information will enable EPA to provide more guidance, as requested, and thereby further ensure that the Agency receives data as per the goals of the rulemaking (e.g., to ensure that the Agency has information needed to conduct prioritization and, as applicable, risk evaluation and risk management activities involving these chemicals).

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

The Health and Safety Data Reporting rule for these 16 chemical substances is promulgated under TSCA section 8(d) (15 U.S.C. 2607(d)), and codified at 40 CFR part 716. In addition, under section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), an agency may issue a final rule without providing notice and an opportunity for public comment if it for good cause finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest.

The Agency finds that notice and public comment is unnecessary because the extension of the reporting period does not alter the substantive existing requirements of the TSCA section

8(d) reporting rule and it is not expected to interfere with the timely implementation of EPA's obligations under TSCA section 6. As such, there is no reason to believe that the public would have an interest in this action and desire to comment upon it. The Agency believes the extension does not represent a significant delay in the processing and availability of information to EPA for TSCA section 6 activities involving these chemical substances. Receiving TSCA section 8(d) submissions pursuant to the deadlines provided in this rule will ensure that such information will be received in time for use in TSCA section 6 activities.

EPA finds that notice and public comment is impracticable because there is insufficient time for notice and comment on an extension to the deadline prior to the original reporting deadline of March 13, 2025. EPA recently became aware of the need for the extension upon receiving numerous stakeholder requests for extensions and further guidance regarding unexpected reporting difficulties, as explained above.

The Agency finds that notice and public comment would be contrary to the public interest because if notice and comment time frames prevented the Agency from extending the reporting deadline, currently March 13, 2025, many TSCA section 8(d) submissions might be provided without sufficient time or guidance to properly prepare them, impairing the ability of the Agency to carry out its prioritization and risk evaluation requirements.

This final rule is effective immediately upon publication. Section 553(d)(1) of the Administrative Procedure Act, 5 U.S.C. 553(d)(3), provides that final rules shall not become effective until 30 days after publication in the *Federal Register*, with an exception "for good cause found and published with the rule." EPA finds that the good cause discussed above for a final rulemaking without notice and comment applies equally to having an immediately effective date for this rule, especially considering the imminent reporting deadline.

## **II. Statutory and Executive Order Reviews**

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

*B. Paperwork Reduction Act (PRA)*

This action does not contain any new information collection burden under the PRA, 44 U.S.C. 3501 et seq. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2070-0224 (EPA ICR No. 2701.01). This action does not create any new reporting or recordkeeping obligations, and does not otherwise change the burden estimates that were approved.

*C. Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 et seq. The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice and comment requirements under the APA because the Agency has invoked the APA “good cause” exemption (see Unit I).

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million (in 1995 dollars and adjusted annually for inflation) or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

*E. Executive Order 13132: Federalism*

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

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

This action does not have Tribal implications as specified in Executive Order 13175 (65

FR 67249, November 9, 2000), because it will not have 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.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not address environmental health or safety risks disproportionately affecting children. Since this action does not concern human health, EPA's 2021 Policy on Children's Health also does not apply.

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

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

*I. National Technology Transfer and Advancement Act (NTTAA)*

This action does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

*J. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). EPA finds that there is good cause to make this rule immediately effective. (See Unit I.)

**List of Subjects in 40 CFR Part 716**

Environmental protection, Chemicals, Hazardous substances, Health and safety,  
Reporting and recordkeeping requirements.

**Nancy Beck,**

*Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 716—HEALTH AND SAFETY DATA REPORTING**

1. The authority citation for part 716 continues to read as follows:

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

2. Amend § 716.120 in table 3 to paragraph (d), under the heading “OPPT 2024 Chemicals”, by:

a. Revising the entries for “Acetaldehyde”, “Acrylonitrile”, “2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone)”, “Benzenamine”, “Benzene”, “Bisphenol A”, “Ethylbenzene”, “Hydrogen fluoride”, “4,4-Methylene bis(2-chloraniline)”, “N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)”, “Naphthalene”, “Styrene”, “4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol)”, “Tribromomethane (Bromoform)”, and “Triglycidyl isocyanurate”; and

b. Removing the entry for “Vinyl Chloride” and adding the entry “Vinyl chloride” in its place.

The revisions and addition read as follows:

**§ 716.120 Substances and listed mixtures to which this subpart applies.**

\* \* \* \* \*

(d) \* \* \*

**Table 3 to Paragraph (d)**

Category	CASRN	Special exemptions	Effective date	Sunset date
* * * * *	* * * * *	* * * * *		
<b>OPPT 2024 Chemicals:</b>				
Acetaldehyde	75-07-0	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Acrylonitrile	107-13-1	§ 716.21(a)(11)	January 13,	September 9,

		applies; § 716.20(a)(9) does not apply	2025	2025
2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone)	2754428-18-5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Benzenamine	62-53-3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Benzene	71-43-2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Bisphenol A	80-05-7	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Ethylbenzene	100-41-4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Hydrogen fluoride	7664-39-3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
4,4-Methylene bis(2-chloraniline)	101-14-4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)	793-24-8	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Naphthalene	91-20-3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025

Styrene	100-42-5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol)	140-66-9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Tribromomethane (Bromoform)	75-25-2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Triglycidyl isocyanurate	2451-62-9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	September 9, 2025
Vinyl chloride	75-01-4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	January 13, 2025	June 11, 2025
* * * * *				