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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations because it does not affect the level of protection provided to human health or the environment. As discussed in section I.C. of the preamble to this action, the NPL is a list of national priorities. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is of only limited significance as it does not assign liability to any party. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

K. Congressional Review Act

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Provisions of the Congressional Review Act (CRA) or section 305 of CERCLA may alter the effective date of this regulation. Under 5 U.S.C. 801(b)(1), a rule shall not take effect, or continue in effect, if Congress enacts (and the President signs) a joint resolution of disapproval, described under section 802. Another statutory provision that may affect this rule is CERCLA section 305, which provides for a legislative veto of regulations promulgated under CERCLA. Although *INS* v. *Chadha,* 462 U.S. 919,103 S. Ct. 2764 (1983), and *Bd. of Regents of the University of Washington* v. *EPA,* 86 F.3d 1214,1222 (D.C. Cir. 1996), cast the validity of the legislative veto into question, the EPA has transmitted a copy of this regulation to the Secretary of the Senate and the Clerk of the House of Representatives.

If action by Congress under either the CRA or CERCLA section 305 calls the effective date of this regulation into question, the EPA will publish a document of clarification in the **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Barry N. Breen,

Principal Deputy Assistant Administrator, Office of Land and Emergency Management.

For the reasons set out in the preamble, the Environmental Protection Agency amends title 40, chapter I, part 300, of the Code of Federal Regulations as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.;* 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. Amend table 1 of Appendix B to part 300 by adding the entry for ''WA, Upper Columbia River'', in alphabetical order, to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes [a]
*	*	*	*
WA	Upper Columbia River	Upper Columbia River.	
*	*	*	*

[a] A = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

* * * * *

[FR Doc. 2024–29006 Filed 12–12–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA–HQ–OPPT–2023–0360; FRL–11164–02–OCSPP]

RIN 2070–AL15

Certain Existing Chemicals; Request To Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is finalizing the Health and Safety Reporting Rule under the Toxic Substance Control Act (TSCA) to require manufacturers (including importers) of the sixteen chemical substances identified in this rulemaking to submit copies and lists of certain unpublished health and safety studies to EPA. Health and safety studies sought by this action will inform EPA actions in carrying out its responsibilities pursuant to TSCA, including prioritization, risk evaluation, and risk management.

DATES: This rule is effective on January 13, 2025.

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: Lameka Smith, Data Gathering, Management, and Policy Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1629; email address: *smith.lameka@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 (including import) chemical substances and mixtures. The North American Industrial Classification System (NAICS) codes affected by this rule are those that align with these activities. This typically includes manufacturing and chemical processing sectors, as well as any related industries where these chemicals might be used or introduced into commerce, including those who fall within the following list of NAICS codes:

- Chemical manufacturing (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 is requiring manufacturers of chemical substances listed in this document to submit copies and lists of certain unpublished health and safety studies to EPA. EPA is taking final action on the proposed rule published on March 26, 2024 (89 FR 20918 (FRL–11164–01–OCSPP). This rulemaking is intended to provide EPA with useful information for prioritization, risk evaluations, and risk management activities under TSCA section 6 regarding the chemical substances identified in this final rule. This action lists the chemical substances and their Chemical Abstracts Service Registry Numbers (CASRNs) being added to 40 CFR 716. It also lists specific data reporting requirements.

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

EPA promulgated the Health and Safety Data Reporting Rule that is codified at 40 CFR part 716 under TSCA section 8(d) (15 U.S.C. 2607(d)). EPA is finalizing this rule under its authority in TSCA section 8(d) to require submission of health and safety studies, and lists of studies, regarding certain chemical substances.

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

EPA prepared an economic analysis for the addition of the 16 chemical substances to the TSCA section 8(d) Health and Safety Data Reporting rule (Ref. 1), which is available in the docket and summarized here. EPA estimates that the costs of this action will be approximately $5,884,568 in the first year of reporting and involve 70,630 burden hours (Ref. 1). In addition, EPA has determined that, of the 35 small businesses affected by this action, 2 are estimated to incur a maximum annualized cost impact of more than 1% of revenues. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities (Ref. 1).

II. Background

A. What chemical substances is EPA adding to the final rule?

EPA is amending the list at 40 CFR 716.120 to add 16 chemical substances. The list at 40 CFR 716.120 contains chemical substances for which the health and safety study data reporting is required. Additionally, the chemical specific reporting requirements will be incorporated into 40 CFR 716.21(a)(11). Any special exemptions are required for a specific chemical substance are identified in the table at 40 CFR 716.120 under special exemptions. Special exemptions are reporting requirements that are specific to a chemical substance and include specific language about specific studies and requirements. The chemical substances addressed in this final rule are as follows:

- 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);
- Naphthalene (CASRN 91–20–3);
- Vinyl Chloride (CASRN 75–01–4);
- Styrene (CASRN 100–42–5);
- Tribromomethane (Bromoform) (CASRN 75–25–2);
- Triglycidyl isocyanurate; (CASRN 2451–62–9);
- Hydrogen fluoride (CASRN 7664–39–3);
- N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) (CASRN 793–24–8); and
- 2-anilino-5-[(4-methylpentan-2-yl) amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (CASRN 2754428–18–5).

B. What are the reporting requirements?

Listed in Unit II. are the reporting requirements for the 16 chemical substances identified in Unit II.A. Generally, the reporting described in Unit II.D. is required by March 13, 2025.

The specific types of health and safety studies are listed in Unit II.D. and include the following:

- Manufacturers who, in the 10 years preceding the date a chemical substance is listed, either have proposed to manufacture or have manufactured any of the listed chemical substances must submit to EPA, during the 60-day reporting period specified in 40 CFR 716.65 and according to the reporting schedule set forth at 40 CFR 716.60, a copy of each specified type of health and safety study which is in their possession at the time the chemical substance is listed in part 716.
- Manufacturers who, either at the time of or after the chemical substance is listed in 40 CFR 716, propose to manufacture or are manufacturing the listed chemical substance must submit to EPA during the 60-day reporting

period specified in 40 CFR 716.65 and according to the reporting schedule set forth at 40 CFR 716.60:

•A copy of each specified type of health and safety study which is in their possession at the time the chemical substance is listed;

• A list of the specified types of health and safety studies known to them but not in their possession at the time the chemical substance is listed;

• A list of the specified types of health and safety studies that are ongoing at the time the chemical substance is listed and are being conducted by or for them;

• A list of the specified types of health and safety studies that are initiated after the date the chemical substance is listed and will be conducted by or for them; and

• A copy of each specified type of health and safety study that was previously listed as ongoing or subsequently initiated (*i.e.,* listed in accordance with reporting requirements in Unit II.D., respectively) and is now complete regardless of completion date.

• For this rulemaking, EPA is requiring submission of information only on those studies in which the listed chemical is specifically identified in the studies.

Any person who manufactures (including imports) or who proposes to manufacture the listed chemical substance from January 13, 2025 to March 13, 2025 must:

(1) Inform EPA (by submitting a list) of any studies initiated during the period from January 13, 2025 to March 13, 2025 within 30 days of their initiation, but in no case later than April 14, 2025; and

(2) For those who submitted lists of studies that were ongoing or initiated during the period from January 13, 2025 to March 13, 2025, such persons must submit a copy of each study within 30 days after its completion, regardless of the study's completion date. See 40 CFR 716.60 and 716.65.

C. What are the exemptions under this rule?

Requirements for reporting unpublished health and safety data is provided at 40 CFR part 716, and with explanations of reporting exemptions detailed in 40 CFR 716.20. As explained in the proposed rule (89 FR 20918 March 26, 2024 (FRL–11164–01–OCSPP)), EPA did not include the exemption listed at 40 CFR 716.20(a)(9), which allows for the inclusion of an exemption for persons manufacturing a substance only as an impurity. A person manufacturing or proposing to manufacture a substance listed in this rule must report on the substance where it was only manufactured (or is being proposed for manufacturing) as an impurity. An impurity is defined at 40 CFR 716.3 as a chemical substance that is unintentionally present with another chemical substance. Additionally, pursuant to the procedure at 40 CFR 716.20(b)(5) that requires EPA to identify the chemical grade/purity, EPA is requiring reporting on any chemical grade/purity level of the chemical.

EPA is requiring submissions of health and safety studies from companies manufacturing the identified chemical substances, including when a company is importing the chemical substance as a pure substance, or within a mixture, formulated product, or article that contains the subject chemical substance. This includes instances where the chemical substance is manufactured only as an impurity. EPA considers conditions of use, as discussed in further detail in Unit II. F., associated with circumstances where a chemical substance subject to a risk evaluation even where the chemical substance is an impurity. To such ends, health and safety information associated with the conditions of use, whether as a pure chemical, part of a mixture or article, or as an impurity helps inform such risk evaluation (see *e.g.,* 89 FR 37028, 37033 (''[EPA must include consideration of] known circumstances associated with the chemical (*e.g.,* [. . .] de minimis amounts such as an impurity or within an article, etc.)'')). For this rulemaking, EPA is requiring submission of information only on those studies in which the listed chemical is specifically identified in the studies.

Accordingly, the chemicals included in this final rule are of particular interest to EPA because they are either in the process of prioritization as candidates for high-priority designation or are expected to be candidates in the upcoming years. For those found to be of high-priority designation, EPA is required to initiate a risk evaluation under TSCA section 6(b). 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.

D. What types of studies must be submitted?

Pursuant to 40 CFR 716.10 and 716.50, manufacturers are required to submit the following types of information:

• Lists and copies of unpublished health and safety studies for all substances specified in this rule on health effects, such as toxicity studies (*e.g.,* in vivo, in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetic (absorption, distribution, metabolism, or elimination), including modeling studies, in humans or animals.

• All unpublished studies on environmental effects and physical-chemical properties if performed as described in 40 CFR 716.50.

• All unpublished studies on occupational, general population, consumer, bystander, and environmental exposure, such as: unpublished studies on inhalation and dermal exposure, human biomonitoring, environmental monitoring of indoor and outdoor air, soil, water, and household dust, chamber emission rates from products or polymeric matrices, and unpublished modeling studies that estimate environmental concentrations or human exposures.

• Studies showing any measurable content of the listed substance (single substance or mixture). The composition and purity of test substances must be reported if included as part of the study.

• Surveys, tests, and studies of biological, photochemical, and chemical degradation. Chemical identities are part of the submitted health and safety studies or data and must be submitted to EPA. Information from health and safety studies and/or data relating to chemical substances offered for commercial distribution or subject to reporting under TSCA Section 4 or 5 is not protected from disclosure, with limited exceptions as stated in 15 U.S.C. 2613(2)(B).

The following types of information are not included in this action and need not be submitted to EPA:

• Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule.

• Certain types of studies when the subject of the study is a mixture known to contain a listed substance. These studies include acute oral toxicity; acute dermal toxicity; acute inhalation toxicity; primary eye irritation; primary dermal irritation; dermal sensitization; and physical-chemical properties.

• Analyzed aggregations of monitoring data when either based on monitoring data acquired over five years

prior to the date of this rule, or when the data are not analyzed to determine the exposure or concentration levels of the listed chemical.

E. How to report?

All submitters must report TSCA section 8(d) data electronically using the Chemical Safety and Pesticide Programs (CSPP) Software, which is accessible via EPA's Central Data Exchange (CDX) system available at *https://cdx.epa.gov/* . The CSPP Software provides a TSCA 8(d) Health and Safety Data Reporting application that a registered CDX user will access to submit TSCA section 8(d) records. Information on how to submit TSCA section 8(d) data is available in the docket (EPA–HQ–OPPT–2023–0360) and via EPA's TSCA section 8(d) web page at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/section-8d-health-safety-data-reporting-user-guide-0.* Submitters may also contact EPA's TSCA Hotline at *tsca-hotline@epa.gov* or 202–554–1404. For help with accessing your CDX account, please contact the CDX help desk at *https://cdx.epa.gov/contact* or (888) 890–1995 (for international callers: (970) 494–5500).

1. *Submitting CBI.* Any person submitting copies of records may assert a business confidentiality claim covering all or part of the submitted information in accordance with the procedures described in 40 CFR part 703, and using the CSPP Software. Requirements for asserting and maintaining confidentiality claims are described in 40 CFR 703.5. Such claims must be made concurrent with submission of the information. If no claim accompanies the submission, EPA will not recognize a confidentiality claim, and the information in that submission may be made available to the public without further notice. Confidentiality claims must be substantiated at the time of submission to EPA pursuant to the requirements of 40 CFR 703.5(b). To assert a claim of confidentiality for information contained in a submitted record, the respondent must submit two copies of the document. One copy must be complete, and, on each page containing information claimed as confidential, the respondent must indicate what information, if any, is claimed as confidential by marking the specific information on that page with a label such as ''confidential'', ''proprietary'', or ''CBI.'' The other copy must be a public version of the submission and attachments, with all information that is claimed as confidential removed (40 CFR 703.5(c)). Both the copy containing information claimed as CBI and the ''sanitized'' copy must be submitted electronically. The TSCA section 8(d) Health and Safety Data Reporting application incorporates many of the requirements for asserting CBI claims, including substantiation questions, a required certification statement, and prompts to provide a sanitized copy. Further details regarding the requirements for confidentiality claims can be found in 40 CFR part 703.

2. *Submitting OECD harmonized templates.* Additionally, EPA is requiring all existing information concerning health and environmental effects and that have CBI claims as described in Unit II.E.1. to be submitted in the format of Organization of Economic Cooperation and Development's (OECD) harmonized templates (OHTs), where such templates exist for the type of data pursuant to 40 CFR 703. OECD templates are accessible to the public online at *https://oecd.org/ehs/templates/harmonised-templates.htm.* This can be accomplished by using the freely available IUCLID6 software by exporting the dossier in the OECD Harmonized Template working context. EPA can accept any dossiers generated using any version of IUCLID6 available at *https://www.epa.gov/tsca-cbi/final-rule-requirements-confidential-business-information-claims-under-tsca#Implementation.* EPA believes that some of the data will already be available as an OECD template if the company had already submitted the studies under the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. In addition to the required template format, those subject to this rulemaking must submit any associated full study reports or underlying data as support documents. The full study reports and support documents are necessary for EPA to understand the full context and evaluate the quality of the data, which is necessary for the Agency to review to determine whether such data may be used for any future Agency actions. If an OHT is not available for a particular endpoint for which the manufacturer has relevant information, then the manufacturer must still submit the study under 40 CFR 716.

This rule does not require the submission of OHTs for health and safety studies that do not have CBI claims. As explained in the Response to Comments document (Ref. 2), 40 CFR 703.5(g) already requires that studies containing CBI claims be submitted using OHTs. However, EPA is declining to extend this requirement to those studies without CBI claims. Forgoing an OHT requirement for non-CBI claims alleviates some of the overall submission burden. However, EPA welcomes any OHTs for those non-CBI studies, especially if they have already been prepared pursuant to other authorities (*e.g.,* REACH). EPA also advises manufacturers that it reserves the authority to promulgate OHT requirements for non-CBI health and safety studies in future rulemakings and anticipates doing so.

F. What is the rationale for adding the 16 chemical substances?

EPA's assessment of chemical substances under TSCA section 6 involves a three-stage process: (1) Prioritization; (2) Risk evaluation; and, as applicable, (3) Risk management. Prioritization and risk evaluation are carried out in accordance with procedural regulations at 40 CFR part 702, subparts A and B, respectively.

During prioritization, EPA identifies chemical substances that are candidates for prioritization and then uses reasonably available information to screen each candidate chemical substance against certain criteria and considerations specified in TSCA section 6(b)(1)(A):

- Hazard and exposure potential of the chemical substance;
- Persistence and bioaccumulation of the chemical substance;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of drinking water;
- Conditions of use or significant changes in the conditions of use of the chemical substance. Conditions of use is defined under TSCA section 3(4) to mean ''the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.'';
- Volume or significant changes in the volume of the chemical substance manufactured or processed; and
- Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

EPA identified 15 chemical substances that are the subject of this rule as potential candidates for prioritization based on a screening process that is based on a combination of hazard, exposure (including uses), and persistence and bioaccumulation characteristics. To support the prioritization process as well as to inform its risk evaluation findings on any of these substances that EPA might designate as a high-priority substance, EPA is seeking unpublished health and

safety studies on these chemical substances to ensure that such studies are available to EPA to inform any activities undertaken pursuant to TSCA section 6.

EPA is also including the 6PPD transformation product, 2-anilino-5-[(4-methylpentan-2-yl) amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (CASRN: 2754428–18–5) in response to a citizen's petition filed under TSCA section 21 regarding 6PPD and 6PPD-quinone. Cited in the petition are the potential impacts of 6PPD-quinone to aquatic organisms and on population levels for some fish, such as the coho salmon. The Agency is including this chemical in this request for unpublished health and safety studies to address data needs and to better understand and characterize potential risks associated with this chemical. For details on 6PPD and 6PPD-quinone and EPA's current key actions to address this chemical, please visit, *https://www.epa.gov/chemical-research/6ppd-quinone.*

Information received pursuant to this rulemaking will help inform other EPA activities involving these chemical substances. Additionally, non-CBI collected pursuant to this final rule will be made public via ChemView (*https://chemview.epa.gov/chemview/*), the EPA online system that contains information EPA receives and develops about chemicals regulated under TSCA. ChemView is part of EPA's commitment to strengthen its chemicals management programs by improving access to and the usefulness of chemical information. The goal is for people to easily get information they need to make safe chemical choices and to help businesses, individuals and others make more informed decisions about the chemicals they use.

Benefits of this final rule include addressing market failure stemming from incomplete or imperfect information regarding the hazards associated with the listed chemicals. This final rule addresses market failure by making information about the health and safety effects of the listed chemicals available to EPA. By making this information available, EPA will be able to base decisions on actual data rather than relying on assumptions. Additionally, the information provided by this rule can aid in addressing negative externalities that occur when the costs associated with known hazards are external to manufacturers' decision-making and may result in overuse and/or overproduction of certain harmful products.

III. Summary of Public Comments on the Proposed Rule

EPA received 35 unique public comments during the public comment period for the proposed rule (89 FR 20918, March 26, 2024 (FRL–11164–01–OCSPP)). Comments were submitted by citizens, industry groups and companies, non-governmental organizations, and a state agency. The public comments revealed varied perspectives across different types of commenters.

Industry stakeholders were generally supportive of the need for comprehensive chemical data under TSCA section 6. Some industry commenters, however, expressed concerns about the utility of studies involving low concentrations of chemicals or cases in which the chemical is not the test substance (*e.g.,* included in the study as an impurity of the test substance or test mixture). Many such commenters were not supportive of EPA lifting the impurity exemption and/or requiring the submission of studies with the listed chemical substance at any concentration or purity. Several industry commenters also discussed the proposed OHTs requirement, with different points of view. While some supported the use of templated and standardized submissions, others expressed concerns about the administrative and financial burdens of compliance, particularly with reporting on impurities. Some industry stakeholders suggested extending the reporting deadlines from 90 to 180 days to allow more time for compliance. Finally, many comments from companies or trade groups discussed EPA's draft burden analysis, with many claiming that EPA had underestimated the time and cost related to preparing and submitting OHTs.

Environmental groups and NGOs strongly supported the rule as proposed, including the requirement to submit studies with the chemical substances even when present as impurities. These commenters also highlighted the importance of gathering data on 6PPD and its degradant, 6PPD-quinone, and urged EPA to finalize this rule quickly.

EPA considered all comments and information in the development of this final rule. A comprehensive response to comments document can be found in the docket (Ref. 2).

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. For more information about these references, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA section 8(d): Economic Impact Analysis for the Addition of Sixteen Chemicals to the Health and Reporting Data Rule. December 2024.
2. EPA. Response to Comments. TSCA Section 8(d) Certain Existing Chemicals; Request to Submit Unpublished Health and Safety Data Under TSCA. December 2024.
3. EPA. Supporting Statement under the Paperwork Reduction Act: Section 8 of the Toxic Substances Control Act. EPA ICR No. 2703.01 OMB Control No. 2070–0224. November 2022.

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 14094: Modernizing Regulatory Review

This action is not a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

As required by the PRA, 44 U.S.C. 3501 *et seq.,* the information collection activities associated with TSCA section 8(d) reporting are approved by OMB under OMB Control No. 2070–0224. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2703.01 (Ref. 3). A copy of the approved ICR is in the docket for this rule, and is briefly summarized here.

This action requires the reporting of unpublished health and safety studies to EPA by manufacturers of certain chemical substances that are being added to the Health and Safety Data Reporting Rule in 40 CFR part 716. EPA intends to use the information collected to assist in assessing the chemical substances under TSCA, and to inform any additional work necessary under environmental protection mandates beyond TSCA. Submitters may designate information as confidential, trade secret, or proprietary. EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with TSCA section

14 and EPA's confidentiality regulations, 40 CFR part 2, subpart B.

Respondents/affected entities: Manufacturers (including importers) of the 16 chemical substances identified in the rulemaking, see also Unit I.A. and the ICR.

Respondent's obligation to respond: Mandatory, TSCA section 8(d) (15 U.S.C. 2607(d)), and implementing regulations in 40 CFR part 716.

Estimated number of respondents: 160.

Frequency of response: One-time.

Total estimated burden: 23,962 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,011,604 (per year), with no annualized capital or operation & maintenance costs. (Ref. 1)

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.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are manufacturers of 16 chemicals to be added to the Health and Safety Data Reporting Rule. The Agency has determined that 35 out of 160 of the firms in the affected universe are small entities. Of those small firms, 2 may experience an impact of above 1% and 1 may have impacts above 3%. Details of this analysis are presented in Chapter 6 of the Economic Analysis for this rule (Ref. 1), which can be found in the docket.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million (adjusted annually for inflation) or more (in 1995 dollars) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The costs involved in this action are estimated not to exceed $183 million in 2023$ ($100 million in 1995$ adjusted for inflation using the GDP implicit price deflator) or more in any one year.

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 Orders 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. This rule affects entities who manufacture (including import) chemical substances for commercial purposes. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to regulatory actions considered significant under section 3(f)(1) of Executive Order 12866 and that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of Executive Order 13045.

Since this is not a ''covered regulatory action,'' E.O. 13045 does not apply. However, the Policy on Children's Health does apply. Although this action does not directly concern an environmental health or safety risk to children, the information obtained from the reporting required by this rule will be used to inform the Agency's decision-making process regarding chemical substances to which children may be exposed. This information will also assist the Agency and others in determining whether the chemical substances included in this rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

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

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns. Although this action does not directly impact human health or environmental conditions, EPA identifies and addresses environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023) by requiring reporting of unpublished health and safety data. This regulatory action requires the submission of unpublished health and safety data for 16 chemical substances that will result in more information being available for EPA's use under TSCA section 6, thereby enabling the Agency to better protect human health and the environment, including in low-income and minority communities.

K. 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. This action is not a ''major rule'' under 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

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

Dated: December 10, 2024.

Michal Freedhoff,

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 § 716.21 by adding paragraph (a)(11) to read as follows:

§ 716.21 Chemical specific reporting requirements.

(a) * * *

(11) For 4,4-Methylene bis(2-chloraniline) (101–14–4); 4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol) (140–66–9); Acetaldehyde (75–07–7); Acrylonitrile (107–13–1); Benzenamine (62–53–3); Benzene (71–43–2); Bisphenol A (80–5–7); Ethylbenzene (100–41–4); Naphthalene (91–20–3); Vinyl Chloride (75–01–4); Styrene (100–42–5); Tribomomethane (Bromoform) (75–25–2); Triglycidyl isocyanurate (2451–62–9); Hydrogen fluoride (7664–39–3); N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) (793–24–8); and 2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (2754428–18–5), all unpublished studies on health effects (including toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity); toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies, in humans or animals; environmental effects; environmental fate; physical-chemical properties if performed as described in 40 CFR 716.50; and occupational (both users and non-users), general population, consumer, bystander, and environmental exposure must be submitted. Studies showing any measurable content of the substance in the tested substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study. Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule.

* * * * *

■ 3. In § 716.120, amend the table in paragraph (d) by:

■ a. Designating the table as table 3 to paragraph (d);

■ b. Adding the category sub-heading ''OPPT 2024 Chemicals:'' in alphabetical order immediately preceding the category ''Organohalogen flame retardants:''; and

■ c Adding the entries ''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)''; ''Tribomomethane (Bromoform)''; ''Triglycidyl isocyanurate''; and ''Vinyl Chloride'' after the category sub-heading ''OPPT 2024 Chemicals:''.

The additions read as follows:

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

(d) * * *

TABLE 3 TO PARAGRAPH (d)

Category	CAS No.	Special exemptions	Effective date	Sunset date
*	*	*	*	*
OPPT 2024 Chemicals				
Acetaldehyde	75–07–0	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Acrylonitrile	107–13–1	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 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	March 13, 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	March 13, 2025.
Benzene	71–43–2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Bisphenol A	80–05–7	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Ethylbenzene	100–41–4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Hydrogen fluoride	7664–39–3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 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	March 13, 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	March 13, 2025.
Naphthalene	91–20–3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Styrene	100–42–5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 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	March 13, 2025.
Tribomomethane (Bromoform)	75–25–2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Triglycidyl isocyanurate	2451–62–9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.
Vinyl Chloride	75–01–4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	March 13, 2025.

TABLE 3 TO PARAGRAPH (d)—Continued

Category	CAS No.	Special exemptions	Effective date	Sunset date
*	*	*	*	*	*	*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 162

[CMS–0056–F]

RIN 0938–AU19

Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule adopts updated versions of the retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These updated versions are modifications to the currently adopted standards for the following retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. This final rule also adopts a modification to the standard for the Medicaid pharmacy subrogation transaction.

DATES:

Effective Date: This final rule is effective on February 11, 2025. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register beginning February 11, 2025. The incorporation by reference of certain other publications listed in the rule was approved by the Director as of March 17, 2009.

Compliance Date: Compliance with this final rule is required beginning February 11, 2028.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Severability

A. Purpose

We published a proposed rule titled ''Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard'' (hereafter referred to as the November 2022 proposed rule) that appeared in the November 9, 2022, **Federal Register** (87 FR 67634). In that rule, we proposed to adopt modifications to the retail pharmacy and Medicaid subrogation standards. This final rule adopts modifications to standards for electronic retail pharmacy transactions and the Medicaid pharmacy subrogation transaction adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

1. Need for the Regulatory Action

The modified standards adopted in this rule will benefit the health care industry by offering more robust data exchange and workflow automation, enhanced patient safety, improved coordination of benefits, and expanded financial fields, so that entities may not have to manually enter free text, split claims, or prepare and submit a paper Universal Claim Form. The current retail pharmacy standards adopted in 2009 remain unchanged. In 2018, the National Committee on Vital and Health Statistics (NCVHS) recommended that HHS adopt more recent standards to address evolving industry business needs. Consistent with the NCVHS recommendations and collaborative industry and stakeholder input, we believe the updated retail pharmacy standards we are adopting are sufficiently mature for adoption and that covered entities are ready to implement them.

2. Legal Authority for the Regulatory Action

Through subtitle F of title II of HIPAA, Congress added to title XI of the Social Security Act (the Act) a new Part C, titled ''Administrative Simplification,'' which requires the Secretary of the Department of Health and Human Services (the Secretary) to adopt standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information. More specifically, section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications to them, including additions to the standards, as appropriate, but not more frequently than once every 12 months, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard, thus providing the legal authority for this regulatory action.

B. Summary of the Major Provisions

The provisions in this final rule adopt the following modifications: the NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15) and NCPDP Batch Standard Subrogation Implementation Guide, Version 10 (Version 10). These updated standards will replace the currently adopted NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and the equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), and NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0).

Version 3.0 was adopted to support Federal and State requirements for State Medicaid agencies to seek reimbursement from the health plan responsible for paying the pharmacy claim after the State Medicaid agency has paid the claim on behalf of the Medicaid recipient.

In the November 2022 proposed rule, we proposed to broaden the scope of the subrogation transaction to apply not only to State Medicaid agencies but to