

3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (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 Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: June 21, 2021.

Edward Messina,

Acting Director, Office of Pesticide Programs.

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

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1383 to subpart D to read as follows:

§ 180.1383 *Bacillus velezensis* strain RTI301; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Bacillus velezensis* strain RTI301 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2021–13806 Filed 6–28–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA–HQ–OPPT–2020–0474; FRL–10020–38]

RIN 2070–AB11

Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule, issued pursuant to the Toxic Substances Control Act (TSCA) and the TSCA Health and Safety Data Reporting rule, requires manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. The chemical substances subject to this rule are listed in this document and consist of the 20 designated by EPA as High-Priority Substances and the 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA). EPA is taking this action because the TSCA Interagency Testing Committee (ITC)

added these chemical substances to the *Priority Testing List* through its 69th and 74th Reports and EPA will use this information to inform the risk evaluations currently underway for 20 High-Priority Substances and for future prioritization.

DATES: This final rule is effective July 29, 2021. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time July 13, 2021

A request to withdraw a chemical substance from this final rule pursuant to 40 CFR 716.105(c) must be received on or before July 13, 2021. (See Unit IV. of the **SUPPLEMENTARY INFORMATION.**)

Dates for the reporting requirements are enumerated in Unit III.B. of the **SUPPLEMENTARY INFORMATION.**

ADDRESSES:

Comments. Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0474, by using the *Federal eRulemaking Portal* at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

Withdrawal requests. For submission of a withdrawal request, see Unit IV. of this document. Each withdrawal request must be identified by docket ID number EPA–HQ–OPPT–2020–0474.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Diana Fahning, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8621; email address: fahning.diana@epa.gov.

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (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 is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include: Chemical manufacturers (including importers), (NAICS codes 325 and 324110), *e.g.*, persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

A. What action is the Agency taking?

EPA is issuing a final rule pursuant to TSCA section 8(d) to require manufacturers (including importers) of chemical substances listed in this document and on the ITC's TSCA section 4(e) Priority Testing List to submit lists and copies of certain unpublished health and safety studies to EPA. The regulatory text of this document lists the chemical substances and their Chemical Abstracts Service Registry Numbers (CASRN) that are being added to the Health and Safety Data Reporting rule. It also lists the specific data reporting requirements imposed by this final rule.

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

EPA promulgated the Health and Safety Data Reporting rule under TSCA section 8(d) (15 U.S.C. 2607(d)), and it is codified at 40 CFR part 716. EPA is using this TSCA section 8(d) rule in accordance with 40 CFR 716.105 to gather information on chemical substances. These studies are expected to provide EPA with useful information for conducting TSCA activities such as prioritization and risk evaluation.

The Agency adds substances to the rule via rule or notice, in accordance with 40 CFR 716.105(a) or (b), respectively. The rule requires certain past, current, and prospective manufacturers (which under TSCA includes importers) to submit copies and/or lists of unpublished health and safety studies on the listed chemical substances that they manufacture. In some cases, EPA may also require processors to comply with the rule.

The TSCA section 8(d) Health and Safety Data Reporting rule provides for the addition of TSCA section 4(e) Priority Testing List chemical substances to the list of chemical substances subject to the rule (see Table of Chemicals, 40 CFR 716.120) (Ref. 1). Whenever EPA announces the receipt of an ITC Report, EPA may, amend the TSCA section 8(d) Health and Safety Data Reporting rule by adding the recommended (or designated) chemical substances to the TSCA section 4(e) list. In doing so, EPA must provide a 14-day period (measured from the date of publication of the **Federal Register** document announcing the rule) for persons to submit information showing why a chemical substance, mixture, or category of chemical substances should be withdrawn from the amendment. The amendment adding these chemical substances to the Health and Safety Data Reporting rule is effective July 29, 2021. If EPA withdraws a chemical substance from the amendment, a **Federal Register** document announcing this decision is to be published no later than July 29, 2021.

C. Comments Received on the 74th Report of the ITC

EPA received seven public comments on the 74th Report of the ITC. One comment requested additional information be provided for why certain organohalogen flame retardants being added to the Priority Testing List (PTL). Several comments questioned whether requiring 8(d) reporting for a chemical substance for which EPA has issued a Section 4 Test Order would be redundant and/or produce data in time

for use in a risk evaluation under TSCA section 6 on the applicable chemical substance. EPA also received a comment on chemicals substances to remove from the PTL. Additionally, one commenter recommended additional activities for EPA to conduct related to fulfilling data needs (*e.g.*, via the use of Test Orders pursuant to section 4 of TSCA).

EPA has reviewed the comments and continues to believe that it is appropriate to list these chemical substances in this document onto the ITC's TSCA section 4(e) Priority Testing List to prompt EPA to implement their authority pursuant to TSCA section 8(d), to require manufacturers (including importers) to submit lists and copies of certain unpublished health and safety studies to EPA. The 74th ITC Report provided the basis for its inclusion of all chemical substances that were added to the PTL. Regarding possible redundancies of published and previously submitted information under other TSCA programs, under 40 CFR 716.20(a) certain studies are exempt from the copy and list submission requirements of 40 CFR 716.30 and 716.35. Within EPA's current timeline for risk evaluations under TSCA section 6, data received via this 8(d) action would be received in time for use in risk evaluations for chemical substances that have been designated as high-priority substances, and data received on the other chemical substances listed in this document would help inform future prioritization activities, as well as help inform other agency decisions involving such chemical substances. In regard to chemical substances being recommended for deletion from the PTL and for requests for certain activities to be undertaken in regard to certain chemical substances, EPA will consider such recommendations during future ITC discussions and during decision-making related to its various TSCA statutory authorities.

D. Why is this action issued as a Final Rule?

The regulations at 40 CFR 716.105(b) and (c) establish the process for this action to amend the TSCA section 8(d) Health and Safety Data Reporting rule.

III. Final Rule

A. What chemical substances are added?

In this document, EPA is adding chemical substances to the TSCA section 8(d) Health and Safety Data Reporting rule. This addition implements 40 CFR 716.105(b), which generally provides that "chemical substances, mixtures, and categories of

chemical substances that have been added to the TSCA section 4(e) Priority List by the Interagency Testing Committee, established under section 4 of TSCA, will be added to § 716.120 . . .” This addition also addresses the request of the TSCA ITC in its 74th Report (Ref. 2) to add certain chemical substances listed in that report to the TSCA section 8(d) Health and Safety Data Reporting rule. The specific chemical substances being added to the rule are listed in the regulatory text at the end of this document.

B. What are the reporting requirements?

Listed in this unit are the reporting requirements for the chemical substances added by this final rule to the TSCA section 8(d) model Health and Safety Data Reporting rule. The specific types of health and safety studies that must be reported for each of the chemical substances added to the Health and Safety Data Reporting rule as a result of this document can be found in Unit III.C.

1. Persons who, in the 10 years preceding the date a chemical substance is listed, either have proposed to manufacture (including import) or have manufactured (including imported) 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 in part 716.

2. Persons who, at the time the chemical substance is listed in part 716, propose to manufacture (including import) or are manufacturing (including importing) 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:

i. 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.

ii. 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.

iii. 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.

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

v. 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 III.B.2.iii. and iv., respectively) and is now complete—regardless of completion date.

3. Persons who, after the time the chemical substance is listed in part 716, propose to manufacture (including import) the listed chemical substance must submit to EPA during the reporting period specified in 40 CFR 716.65 and according to the reporting schedule set forth at 40 CFR 716.60:

i. A list of the specified types of health and safety studies known to them but not in their possession at the time they propose to manufacture (including import) the listed chemical substance.

ii. A list of the specified types of health and safety studies that are ongoing at the time they propose to manufacture (including import) the listed chemical substance and are being conducted by or for them.

iii. A list of the specified types of health and safety studies that are initiated after the time they propose to manufacture (including import) the listed chemical substance and will be conducted by or for them.

iv. A copy of each specified type of health and safety study which is in their possession at the time they propose to manufacture (including import) the listed chemical substance.

v. 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 III.B.3.iii. and 3.iv., respectively) and is now complete—regardless of the completion date.

The reporting described in Unit III.B. is required by September 27, 2021. Any person who manufactures (including imports) or who proposes to manufacture (including import) the listed chemical substance from July 29, 2021 to September 27, 2021 must inform EPA (by submitting a list) of any studies initiated during the period from July 29, 2021 to September 27, 2021 within 30 days of their initiation, but in no case later than October 27, 2021. In addition, if any such person has submitted lists of studies that were ongoing or initiated during the period from July 29, 2021 to September 27, 2021 to EPA, such person 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.

Detailed guidance for reporting unpublished health and safety data and

explanations of reporting exemptions is provided at 40 CFR part 716.

Persons reporting under this rule may also assert CBI claims for certain information included in their submission. TSCA section imposes the following requirements:

- CBI claims must be asserted must be asserted at the time the information claimed as CBI is submitted to EPA. Information submitted with a confidentiality claim may be made public without further notice.

- Information claimed as CBI must be substantiated at the time of submission, with the exception of those types of information exempt from substantiation under TSCA section 14(c)(2).

- All persons making a CBI claim must provide a standard statement concerning the need for the CBI claim and a certification that the statement of need is true and correct.

- Where a specific chemical identity is claimed as CBI, a structurally descriptive generic name must be provided for disclosure to the public.

The 8(d) reporting application accommodates these requirements, incorporating the required statements and certifications, and will prompt the submitter to provide substantiation prior to making a submission that includes CBI claims.

C. What types of studies must be submitted?

Pursuant to 40 CFR 716.20(b)(5) and 716.50, the types of unpublished health and safety studies that must be reported and the chemical grade/purity requirements that must be met or exceeded in individual studies for the chemical substances added to the Health and Safety Data Reporting rule as a result of this document are as follows:

Under this rule, manufacturers (including importers) of High-Priority Substances are required to submit the following:

- Lists and copies of unpublished health and safety studies for all High-Priority Substances specified in this rule on health effects, such as toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies, in humans or animals.

- All unpublished studies on environmental effects, environmental fate, and physical-chemical properties if performed as described in 40 CFR 716.50 are also required under this rule.

- All unpublished studies on occupational (both users and non-users), general population, consumer, 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 modelling studies that estimate environmental concentrations or human exposures.

- Studies showing any measurable content of the High-Priority 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.

Under this rule, manufacturers (including importers) of organohalogen flame retardants are required to submit the following:

- Lists and copies of unpublished health and safety studies for all organohalogen flame retardants specified in this rule on health effects, such as toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies, in humans or animals.

- All unpublished studies on environmental effects, environmental fate, and physical-chemical properties if performed as described in 40 CFR 716.50 are also required under this rule.

- All unpublished studies on occupational (both users and non-users), general population, consumer, 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 modelling studies that estimate environmental concentrations or human exposures, must be submitted.

- Studies showing any measurable content of the organohalogen flame retardant 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 requirements under 40 CFR 716.35 and the submission of studies requirements under this rule.

D. Rationales and Background for Chemical Additions and Reporting Requirements

1. High-Priority Substances

The 20 High-Priority Substances identified in this rule have been designated High-Priority under TSCA section 6(b) because EPA has found that each of these chemical substances may present an unreasonable risk of injury to health or the environment (Ref. 3). EPA is seeking unpublished health and safety studies to ensure that such studies are available to EPA to inform its risk evaluation findings of whether any of these High-Priority Substances present an unreasonable risk of injury to health or the environment. Further, this information will be considered, as appropriate, when reviewing potential analogue data for read across and/or category development in assessing new chemicals.

2. Organohalogen Flame Retardants

EPA requests this information to help support prioritization and evaluation activities under TSCA (see TSCA section 6(b), and as discussed above). Further, this information will be considered, as appropriate, when reviewing potential analogue data for read across and/or category development in assessing new chemicals. Additionally, CPSC, a representative member of the ITC, needs information on a group of organohalogen flame retardants because the Commission voted to grant a petition to begin rulemaking for this class of chemicals under the Federal Hazardous Substances Act (FHSA), (Ref. 5). Organohalogen flame retardants may be added to consumer products to prevent or slow combustion, but are additive, *i.e.*, not covalently bound to the substrate, which can be textiles, polymers, or foam. Most organohalogen flame retardants are semi-volatile compounds (SVOCs), that can migrate into air, where they bind to airborne particles and surfaces in the home. In addition to direct contact with organohalogen flame retardant-

containing products, a substantial portion of exposure is believed to occur from exposure to household dust, especially in children. Biomonitoring studies and measurements of household dust and indoor air demonstrate that exposure to organohalogen flame retardants is nearly ubiquitous.

Many organohalogen flame retardants have been shown to cause health effects. Health effects associated with organohalogen flame retardants include carcinogenicity (*e.g.*, halogenated alkyl phosphates), developmental effects (*e.g.*, polybrominated diphenyl ethers (PBDEs)), and developmental neurotoxicity (*e.g.*, Decabromodiphenyl ether (decaBDE)).

In 2015, CPSC was petitioned by a number of organizations and individuals, such as consumer groups, medical associations, workers, and firefighter organizations, to ban the use of all additive, non-polymeric organohalogen flame retardants under the authority of the FHSA in the following consumer products: (1) Durable infant or toddler products, children's toys, child care articles, or other children's products (other than car seats, which are under Department of Transportation's jurisdiction); (2) Residential upholstered furniture; (3) Mattresses and mattress pads; and (4) The plastic casings of electronic devices (Ref. 5).

CPSC granted the petition in 2017 and directed staff to complete a scoping and feasibility study in cooperation with the National Academy of Sciences, Engineering, and Medicine (NASEM). The task for this project was to develop a scientifically based scoping plan to identify the potential health hazards associated with additive, nonpolymeric organohalogen flame retardants as a class. The NASEM Committee published the report, "A Class Approach to Hazard Assessment of Organohalogen Flame Retardants" in May 2019 (Ref. 6). A key conclusion of the NASEM Committee is that organohalogen flame retardants cannot be treated as a single class. Rather, the NASEM Committee identified 14 subclasses of organohalogen flame retardants, based on chemical structure, physicochemical properties of the chemicals, and predicted biologic activity. The NASEM Committee identified 161 organohalogen flame retardants and more than 1,000 analog chemicals. CPSC staff is undertaking the risk assessment of 14 classes of organohalogen flame retardants following the recommendations of the NASEM Committee.

Because preliminary searches show that little or no health and safety

information is available for many of the 161 organohalogen flame retardants, including the organohalogen flame retardants being added here to the TSCA section 8(d) Health and Safety Data Reporting rule, the submission of the lists and copies of the unpublished health and safety studies specified in this rule is being required under the TSCA section 8(d) Health and Safety Data Reporting rule for these OFR additions. As indicated above, this information will also inform TSCA activities such as future prioritization efforts and, with potential read-across data, new chemical reviews. Further, EPA will coordinate with ITC members to share information received, as appropriate (e.g., to help inform CPSC's evaluation of specific chemicals).

E. What are the incremental economic implications of this action?

EPA prepared an economic analysis for the addition of the 50 chemical substances to the TSCA section 8(d) Health and Safety Data Reporting rule, entitled, "TSCA Section 8(d): Economic Impact Analysis for Adding 50 Chemicals from the 74th ITC Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting Rule." (Economic Analysis, Ref. 7) a copy of which is included in the docket for this rulemaking. The total one-time cost associated with this final rule is estimated to be approximately \$185,000 based on approximately 1,900 and 420 hours of industry and EPA burden, respectively.

IV. Requesting a Chemical Substance Be Withdrawn From This Final Rule

As specified in 40 CFR 716.105(c), EPA may, in its discretion, remove a chemical substance, mixture, or category of chemical substances from this final rule for good cause prior to the effective date of this final rule. Any person who believes that the reporting required by this final rule is not warranted for a chemical substance listed in this final rule must submit to EPA detailed reasons for that belief. You must submit your request to EPA on or before July 13, 2021 and in accordance with the instructions provided in 40 CFR 716.105(c) and (d). In addition, to ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPPT-2020-0474. If the EPA Administrator withdraws a chemical substance, mixture, or category of chemical substances from the amendment, in accordance with 40 CFR 716.105(c), a **Federal Register** document announcing this decision will be published no later than July 29, 2021.

V. 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. 40 CFR 716.120. Substances and listed mixtures to which this subpart applies. Available online at: https://www.ecfr.gov/cgi-bin/textidx?SID=94b50835053a07b80c3517fff641aeba&mc=true&node=pt40.33.716&rgn=div5#se40.33.716_1120.
2. ITC. Notice; Seventy-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments. **Federal Register** (86 FR 22414, April 28, 2021) (FRL-10020-39). Available online at: <https://www.govinfo.gov/content/pkg/FR-2021-04-28/pdf/2021-08839.pdf>.
3. EPA. High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability. **Federal Register** (84 FR 71924, December 30, 2019) (FRL-10003-15). Available online at: <https://www.govinfo.gov/content/pkg/FR-2019-12-30/pdf/2019-28225.pdf>.
4. EPA. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act; Final Rule. **Federal Register** (82 FR 33753, December 20, 2017) (FRL-9964-24). Available online at: <https://www.federalregister.gov/documents/2017/07/20/2017-14325/procedures-for-prioritization-of-chemicals-for-risk-evaluation-under-the-toxic-substances-control>.
5. CPSC. U.S. Consumer Product Safety Commission Petition: Products Containing Organohalogen Flame Retardants. Docket ID number: CPSC-2015-0022. Available online at: <https://www.regulations.gov/docket?D=CPSC-2015-0022>.
6. CPSC. National Academies of Sciences, Engineering, and Medicine 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25412>. Available online at: <http://nap.edu/25412>.
7. EPA. TSCA Section 8(d): Economic Impact Analysis for Adding 50 Chemicals From the 74th ITC Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting Rule. September 10, 2020.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

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

The Office of Management and Budget (OMB) has exempted actions under TSCA section 8(d) related to the Health and Safety Data Reporting rule from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993). As such, this final rule was not reviewed by OMB under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0004. This action does not impose any burden requiring additional OMB approval. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This action requires the reporting of health and safety data to EPA by manufacturers (including importers) of certain chemical substances requested by the ITC to be added to the Health and Safety Data Reporting Rule in its Seventy-Fourth Report of the ITC (Ref. 2). EPA intends to use information collected under the rule to assist in chemical assessments 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 regulation, 40 CFR part 2, subpart B.

Respondents/affected entities: Manufacturers (including importers) of 50 chemical substances requested by the ITC to be included in the Health and Safety Data Reporting Rule.

Respondents' obligation to respond: Mandatory (15 U.S.C. 2607(d)).

Estimated number of respondents: 23.
Frequency of response: Once.

Total estimated burden: 1,854 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$146,745 (per year), with no annualized capital or operation and maintenance costs.

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b), 5 U.S.C. 601 *et seq.*, I hereby certify that this action will not have a significant economic impact on a substantial number of small entities as defined by the RFA. The small entities subject to the requirements of this action are manufacturers (including importers) of 50 chemicals requested by the ITC to be added to the Health and Safety Data Reporting Rule. EPA estimates that 106 of the 129 firms in the affected universe are small entities. Of those small firms, all would have cost impacts of less than 1% of annual revenue. Details of this analysis are presented in the Economic Analysis of this rule (Ref. 7), which can be found in the docket.

D. 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 does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers (including importers) of 50 chemical substances listed in 40 CFR 716.120(d) of the regulatory text of this document. The total quantified one-time costs of this final rule are approximately \$183,812.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). 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). 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. Thus, E.O. 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 those regulatory actions that concern environmental health or safety risks that the Agency 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 a covered regulatory action because it is not “economically significant” under Executive Order 12866 and it does not concern an environmental health risk or safety risk. Although this action would not establish an environmental standard intended to mitigate health or safety risks, the information that would be submitted to EPA in accordance with this rule would be used to inform the Agency’s decision-making process regarding chemical substances to which children may be disproportionately exposed. This information may also assist the Agency and others in determining whether the chemical substances covered in this proposed rule present potential risks, which would allow 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 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 and has not otherwise been designated by the Administrator of OMB’s Office of Information and Regulatory Affairs as a “significant energy action.”

I. 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.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994). However, the Agency believes that the information collected through this rule will inform the TSCA risk evaluations that are

planned for these chemicals and will thereby enable the Agency to better protect human health and the environment, including in low-income and minority communities.

L. 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” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

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

Dated: June 17, 2021.

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. In § 716.21, add paragraphs (a)(9) and (10) to read as follows:

§ 716.21 Chemical specific reporting requirements.

(a) * * *

(9) For 1,3-Butadiene (106–99–0), Butyl benzyl phthalate (BBP)—1,2-Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester (85–68–7), Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2- dibutyl ester) (84–74–2), o-Dichlorobenzene (95–50–1), p-Dichlorobenzene (106–46–7), trans-1,2-Dichloroethylene (156–60–5), 1,2-Dichloropropane (78–87–5), Dicyclohexyl phthalate (84–61–7), Diethylhexyl phthalate (DEHP)—(1,2-Benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester) (117–81–7), Diisobutyl phthalate (DIBP)—(1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester) (84–69–5), Formaldehyde (50–00–0), 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB) (1222–05–5), Phthalic anhydride (85–44–9), 4,4’-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (79–94–7), and 1,1,2-Trichloroethane (79–00–5), 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 High-Priority 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.

(10) For purposes of this paragraph, the term *organohalogen flame retardant* includes any substances listed in paragraph(d) of this section under the category "Organohalogen flame retardants". For any organohalogen flame retardant, 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 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 organohalogen flame retardant 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 requirements under 40 CFR 716.35 and the submission of studies requirements under this rule.

* * * * *

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

■ a. Adding in alphabetical order the category "High-Priority Substances" and entries "1,3-Butadiene", "Butyl benzyl phthalate (BBP)—1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester", "Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)", "o-Dichlorobenzene", "p-Dichlorobenzene", "1,1-Dichloroethane", "1,2-Dichloroethane", "Trans-1,2-Dichloroethylene", "1,2-Dichloropropane", "Dicyclohexyl phthalate", "Di-ethylhexyl phthalate (DEHP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)", "Di-isobutyl phthalate (DIBP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis(2-methylpropyl) ester)", "Ethylene dibromide", "Formaldehyde", "1,3,4,6,7,8-Hexamethylcyclopenta [g]-2-benzopyran (HHCMB)", "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)", "Phosphoric acid, triphenyl ester (TPP)", "Phthalic anhydride", "1,1,2-Trichloroethane", and "Tris(2-chloroethyl) phosphate (TCEP)"; and

■ b. Adding in alphabetical order the category "Organohalogen flame retardants" and entries "Bis(2-ethylhexyl) tetrabromophthalate", "Bis(hexachlorocyclopentadieno) cyclooctane", "1,2-Bis(2,4,6-tribromophenoxy)ethane", "1,1'-Ethane-1,2-diylbis(pentabromobenzene)", "2-Ethylhexyl-2,3,4,5-tetrabromobenzoate", "2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate", "2,2'-[(1-Methylethylidene)bis[2,6-dibromo-4,1-phenylene]oxymethylene]bis[oxirane]", "Mixture of chlorinated linear alkanes C14-17 with 45-52% chlorine", "N,N-Ethylene-bis(tetrabromophthalimide)", "Pentabromochlorocyclohexane", "(Pentabromophenyl)methyl acrylate", "Pentabromotoluene", "Perbromo-1,4-diphenoxybenzene", "Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester", "Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester", "Propanoic acid, 2-bromo-, methyl ester", "Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)", "Tetrabromobisphenol A bis(2-hydroxyethyl) ether", "Tetrabromobisphenol A diallyl ether", "Tetrabromobisphenol A dimethyl ether", "2,4,6-Tribromoaniline", "1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene", "Tris(2-chloroethyl) phosphite", "Tris(1-chloro-2-propyl)phosphate", "Tris(2-chloro-1-propyl)phosphate", "Tris(2,3-dibromopropyl) phosphate", "1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione", "Tris(1,3-dichloro-2-propyl)phosphate", "Tris(tribromoneopentyl)phosphate", and "2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine".

The additions read as follows:

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

* * * * *
(d) * * *

Category	CAS No.	Special exemptions	Effective date	Sunset date
High-Priority Substances:				
1,3-Butadiene	106-99-0	§ 716.21(a)(9)	7/29/21	9/27/21
Butyl benzyl phthalate (BBP)—1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester	85-68-7	§ 716.21(a)(9)	7/29/21	9/27/21
Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)	84-74-2	§ 716.21(a)(9)	7/29/21	9/27/21
o-Dichlorobenzene	95-50-1	§ 716.21(a)(9)	7/29/21	9/27/21
p-Dichlorobenzene	106-46-7	§ 716.21(a)(9)	7/29/21	9/27/21
1,1-Dichloroethane	75-34-3	§ 716.21(a)(9)	7/29/21	9/27/21
1,2-Dichloroethane	107-06-2	§ 716.21(a)(9)	7/29/21	9/27/21
Trans-1,2-Dichloroethylene	156-60-5	§ 716.21(a)(9)	7/29/21	9/27/21
1,2-Dichloropropane	78-87-5	§ 716.21(a)(9)	7/29/21	9/27/21
Dicyclohexyl phthalate	84-61-7	§ 716.21(a)(9)	7/29/21	9/27/21
Di-ethylhexyl phthalate (DEHP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117-81-7	§ 716.21(a)(9)	7/29/21	9/27/21

Category	CAS No.	Special exemptions	Effective date	Sunset date
Di-isobutyl phthalate (DIBP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis-(2methylpropyl) ester)	84-69-5	§ 716.21(a)(9)	7/29/21	9/27/21
Ethylene dibromide	106-93-4	§ 716.21(a)(9)	7/29/21	9/27/21
Formaldehyde	50-00-0	§ 716.21(a)(9)	7/29/21	9/27/21
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5	§ 716.21(a)(9)	7/29/21	9/27/21
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	79-94-7	§ 716.21(a)(9)	7/29/21	9/27/21
Phosphoric acid, triphenyl ester (TPP)	115-86-6	§ 716.21(a)(9)	7/29/21	9/27/21
Phthalic anhydride	85-44-9	§ 716.21(a)(9)	7/29/21	9/27/21
1,1,2-Trichloroethane	79-00-5	§ 716.21(a)(9)	7/29/21	9/27/21
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	§ 716.21(a)(9)	7/29/21	9/27/21
* * * * *				
Organohalogen flame retardants:				
Bis(2-ethylhexyl) tetrabromophthalate	26040-51-7	§ 716.21(a)(10)	7/29/21	9/27/21
Bis(hexachlorocyclopentadieno)cyclooctane	13560-89-9	§ 716.21(a)(10)	7/29/21	9/27/21
1,2-Bis(2,4,6-tribromophenoxy)ethane	37853-59-1	§ 716.21(a)(10)	7/29/21	9/27/21
1,1'-Ethane-1,2-diylbis(pentabromobenzene)	84852-53-9	§ 716.21(a)(10)	7/29/21	9/27/21
2-Ethylhexyl-2,3,4,5-tetrabromobenzoate	183658-27-7	§ 716.21(a)(10)	7/29/21	9/27/21
2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate	20566-35-2	§ 716.21(a)(10)	7/29/21	9/27/21
2,2'-[(1-Methylethylidene)bis(2,6-dibromo-4,1-phenylene)oxymethylene]bis[oxirane]	3072-84-2	§ 716.21(a)(10)	7/29/21	9/27/21
Mixture of chlorinated linear alkanes C14-17 with 45-52% chlorine ..	85535-85-9	§ 716.21(a)(10)	7/29/21	9/27/21
N,N-Ethylene-bis(tetrabromophthalimide)	32588-76-4	§ 716.21(a)(10)	7/29/21	9/27/21
Pentabromochlorocyclohexane	87-84-3	§ 716.21(a)(10)	7/29/21	9/27/21
(Pentabromophenyl)methyl acrylate	59447-55-1	§ 716.21(a)(10)	7/29/21	9/27/21
Pentabromotoluene	87-83-2	§ 716.21(a)(10)	7/29/21	9/27/21
Perbromo-1,4-diphenoxybenzene	58965-66-5	§ 716.21(a)(10)	7/29/21	9/27/21
Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester	6294-34-4	§ 716.21(a)(10)	7/29/21	9/27/21
Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester	38051-10-4	§ 716.21(a)(10)	7/29/21	9/27/21
Propanoic acid, 2-bromo-, methyl ester	5445-17-0	§ 716.21(a)(10)	7/29/21	9/27/21
Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)	21850-44-2	§ 716.21(a)(10)	7/29/21	9/27/21
Tetrabromobisphenol A bis(2-hydroxyethyl) ether	4162-45-2	§ 716.21(a)(10)	7/29/21	9/27/21
Tetrabromobisphenol A diallyl ether	25327-89-3	§ 716.21(a)(10)	7/29/21	9/27/21
Tetrabromobisphenol A dimethyl ether	37853-61-5	§ 716.21(a)(10)	7/29/21	9/27/21
2,4,6-Tribromoaniline	147-82-0	§ 716.21(a)(10)	7/29/21	9/27/21
1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene	3278-89-5	§ 716.21(a)(10)	7/29/21	9/27/21
Tris(2-chloroethyl)phosphite	140-08-9	§ 716.21(a)(10)	7/29/21	9/27/21
Tris(1-chloro-2-propyl)phosphate	13674-84-5	§ 716.21(a)(10)	7/29/21	9/27/21
Tris(2-chloro-1-propyl)phosphate	6145-73-9	§ 716.21(a)(10)	7/29/21	9/27/21
Tris(2,3-dibromopropyl)phosphate	126-72-7	§ 716.21(a)(10)	7/29/21	9/27/21
1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	52434-90-9	§ 716.21(a)(10)	7/29/21	9/27/21
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8	§ 716.21(a)(10)	7/29/21	9/27/21
Tris(tribromoneopentyl)phosphate	19186-97-1	§ 716.21(a)(10)	7/29/21	9/27/21
2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine	25713-60-4	§ 716.21(a)(10)	7/29/21	9/27/21

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COUNCIL ON ENVIRONMENTAL QUALITY

40 CFR Part 1507

[CEQ-2021-0001]

RIN 0331-AA08

Deadline for Agencies To Propose Updates to National Environmental Policy Act Procedures

AGENCY: Council on Environmental Quality.

ACTION: Interim final rule; request for comments.

SUMMARY: The Council on Environmental Quality (CEQ) is extending the deadline by two years for Federal agencies to develop or revise proposed procedures for implementing the procedural provisions of the National Environmental Policy Act (NEPA).

DATES:

Effective date: This interim rule is effective June 29, 2021.

Comments due date: CEQ must receive comments on this interim rule by July 29, 2021.

ADDRESSES: You may submit comments through any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-456-6546.

■ *Mail:* Council on Environmental Quality, 730 Jackson Place NW, Washington, DC 20503.

Instructions: All submissions must include the agency name, “Council on Environmental Quality,” and docket number, CEQ-2021-0001, for this rulemaking. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. Do not submit electronically any information you consider to be private, Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

■ *Docket:* For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.