



## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2019-0080; FRL 10018-91]

RIN 2070-AK61

Hexachlorobutadiene (HCBD); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h)

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is finalizing a rule under the Toxic Substances Control Act (TSCA) to address its obligations under TSCA for hexachlorobutadiene (HCBD) (CASRN 87-68-3), which EPA has determined meets the requirements for expedited action under TSCA. This final rule prohibits all manufacturing (including import), processing, and distribution in commerce of HCBD and HCBD-containing products or articles, recognizing that there is unintentional production of HCBD as a byproduct during the production of chlorinated solvents, and that results in distribution in commerce of a very limited subset of that byproduct for burning as a waste fuel. These requirements will impact the amount of HCBD that will be manufactured, processed, distributed in commerce, used or disposed, thus reducing the exposures to humans and the environment from those activities prohibited under this final rule.

**DATES:** This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For purposes of judicial review and 40 CFR 23.5, this rule shall be promulgated at 1 p.m. eastern standard time on [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0080, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center

(EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Victoria Ellenbogen, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, (7404T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-2053; email address: [ellenbogen.victoria@epa.gov](mailto:ellenbogen.victoria@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](mailto: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), process, distribute in commerce, or use hexachlorobutadiene (HCBBD) and HCBBD-containing products or articles. 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:

- Petroleum Lubricating Oil and Grease Manufacturing (NAICS Code 324191);
- Other Basic Inorganic Chemical Manufacturing (NAICS Code 325180);
- All Other Basic Organic Chemical Manufacturing (NAICS Code 325199);
- Plastics Material and Resin Manufacturing (NAICS Code 325211);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS Code 325998);
- All Other Plastics Product Manufacturing (NAICS Code 326199);
- All Other Rubber Product Manufacturing (NAICS Code 326299);
- Cement Manufacturing (NAICS Code 327310);
- Hazardous Waste Treatment and Disposal (NAICS Code 562211);
- Hazardous Waste Collection (562112);
- Solid Waste Combustors and Incinerators (NAICS Code 562213);
- Other Chemical and Allied Products Merchant Wholesalers (NAICS Code 424690);
- Crude Petroleum Extraction (NAICS Code 211120);
- Facilities Support Services (NAICS Code 561210);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS Code 325998).

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

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

Section 6(h) of TSCA, 15 U.S.C. 2601 *et seq.*, directs EPA to issue a final rule under TSCA section 6(a) on certain persistent, bioaccumulative, and toxic (PBT) chemical substances. HCBD (CASRN 87-68-3), which is produced only as a byproduct in the production of chlorinated solvents, is one such chemical substance. More specifically, EPA must take action on

those chemical substances identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1) that, among other factors, EPA has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals: Methods Document. (Ref. 2) TSCA section 6(h) directs EPA to take expedited action on the substance to reduce exposure to the substance, including to exposure to the substance as an impurity or byproduct, to the extent practicable. This final rule is final agency action for purposes of judicial review under TSCA section 19(a).

*C. What action is the Agency taking?*

EPA published a proposed rule on July 29, 2019 to address the five PBT chemicals EPA identified pursuant to TSCA section 6(h) (84 FR 36728; FRL-9995-76). After publication of the proposed rule, EPA determined to address each of the five PBT chemicals in separate final actions. This final rule prohibits the manufacturing (including import), processing, and distribution in commerce of HCBd and HCBd-containing products or articles after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], except for the unintentional production of HCBd as a byproduct during the production of chlorinated solvents and the processing and distribution of the byproduct for burning as a waste fuel. In addition, after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], manufacturers, processors and distributors of HCBd or HCBd-containing products or articles must maintain, for three years from the date the record is generated, ordinary business records related to compliance with the prohibitions and restrictions. This provision is not intended to require subject companies to retain records in addition to those specified herein, except as needed pursuant to normal business operations.

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

EPA is issuing this final rule to fulfill EPA's obligations under TSCA section 6(h) to take timely regulatory action on PBT chemicals, including HCBd, "to address the risks of injury to

health or the environment that the Administrator determines are presented by the chemical substance and to reduce exposure to the substance to the extent practicable.” Consistent with that requirement, the Agency is finalizing this rule to reduce exposures to HCBD that could occur from prohibited activities to the extent practicable.

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

EPA has evaluated the potential costs of these restrictions and prohibitions and the associated reporting and recordkeeping requirements. The “Economic Analysis for Regulation of Hexachlorobutadiene (HCBD) Under TSCA Section 6(h)” (Economic Analysis) (Ref. 3), is available in the docket and is briefly summarized here.

- *Benefits.* EPA was not able to quantify the benefits of reducing the potential for human and environmental exposures to HCBD. As discussed in more detail in Unit II., EPA did not perform a risk evaluation for HCBD, nor did EPA develop quantitative risk estimates. Therefore, the Economic Analysis (Ref. 3) qualitatively discusses the benefits of reducing the potential for exposure under the final rule for HCBD.

- *Costs.* Total quantified annualized social costs for this final rule are approximately \$77,900 (at both 3% and 7% discount rates). Potential unquantified costs are those associated with testing, reformulation, importation of articles, foregone profits, and indirect costs. The limited data available for those costs prevents EPA from constructing a quantitative assessment.

- *Small entity impacts.* This final rule will impact approximately one small entity; which is not expected to incur impacts of 1% or greater of their revenue.

- *Environmental Justice.* This final rule will increase the level of protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population or children.

- *Effects on State, local, and Tribal governments.* This final rule will not have any

significant or unique effects on small governments, or federalism or tribal implications.

#### *F. Children's Environmental Health.*

Executive Order 13045 applies if the regulatory action is economically significant and concerns an environmental health risk or safety risk that may disproportionately affect children. While the action is not subject to Executive Order 13045, the Agency's Policy on Evaluating Health Risks to Children (<https://www.epa.gov/children/epas-policy-evaluating-risk-children>) is to consider the risks to infants and children consistently and explicitly during its decision making process. This final rule will reduce the exposure that could occur from activities now prohibited under this final rule to HCBP for the general population and for potentially exposed or susceptible subpopulations such as children. More information can be found in the Exposure and Use Assessment (Ref. 5).

## II. Background

### *A. History of this Rulemaking*

TSCA section 6(h) requires EPA to take expedited regulatory action under TSCA section 6(a) for certain PBT chemicals identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1). As required by the statute, EPA issued a proposed rule to address five PBT chemicals identified pursuant to TSCA section 6(h) (84 FR 36728, July 29, 2019). The statute required that this be followed by promulgation of a final rule no later than 18 months after the proposal. Although EPA proposed regulatory actions on each chemical substance in one proposal, in response to public comments (EPA-HQ-OPPT-2019-0080-0544), (EPA-HQ-OPPT-2019-0080-0553), (EPA-HQ-OPPT-2019-0080-0556), (EPA-HQ-OPPT-2019-0080-0562) requesting these five actions be separated, EPA is finalizing five separate actions to individually address each of the PBT chemicals. EPA intends for the five separate final rules to publish in the same issue of the *Federal Register*. More discussion on these comments is in the Response to Comments document which is available in the docket (Ref. 4). The details of the proposal for HCBP are described in more detail in Unit II.D.

Under TSCA section 6(h)(1)(A), the chemical substances subject to expedited action are those that:

- EPA has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the 2012 TSCA Work Plan Chemicals: Methods Document or a successor scoring system;
- Are not a metal or a metal compound; and
- Are chemical substances for which EPA has not completed a TSCA Work Plan Problem Formulation, initiated a review under TSCA section 5, or entered into a consent agreement under TSCA section 4, prior to June 22, 2016, the date that TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act(Pub. L. 114-182, 130 Stat. 448).

In addition, in order for a chemical substance to be subject to expedited action, TSCA section 6(h)(1)(B) states that EPA must find that exposure to the chemical substance under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator (such as infants, children, pregnant women, workers, or the elderly), or to the environment on the basis of an exposure and use assessment conducted by the Administrator. TSCA sections 6(h)(2) further provides that the Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to TSCA section 6(h)(1).

Based on the criteria set forth in TSCA section 6(h), EPA proposed to determine that five chemical substances meet the TSCA section 6(h)(1)(A) criteria for expedited action, and HCB<sub>12</sub>D is one of these five chemical substances. In addition, in accordance with the statutory requirements to demonstrate that exposure to the chemical substance is likely under the conditions of use, EPA conducted an Exposure and Use Assessment for HCB<sub>12</sub>D. As described in the proposed rule, EPA conducted a literature review with respect to HCB<sub>12</sub>D to identify, screen, extract, and evaluate the reasonably available information on use and exposures. This information is in the document entitled “Exposure and Use Assessment of Five Persistent,

Bioaccumulative and Toxic Chemicals” (Ref. 5). Based on this review, which was subject to peer review and public comment, EPA proposed to find that exposure to HCBd is likely, based on information detailed in the Exposure and Use Assessment.

*B. Other Provisions of TSCA Section 6*

*1. EPA’s approach for implementing TSCA section 6(h)(4).*

TSCA section 6(h)(4) requires EPA to issue a final TSCA section 6(a) rule to “address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and reduce exposure to the substance to the extent practicable.” EPA reads this text to require action on the chemical, not specific conditions of use.

The approach EPA takes is consistent with the language of TSCA section 6(h)(4) and its distinct differences from other provisions of TSCA section 6 for chemicals that are the subject of required risk evaluations. First, the term “condition of use” is only used in TSCA section 6(h) in the context of the TSCA section 6(h)(1)(B) finding relating to likely exposures under “conditions of use” to “the general population or to a potentially exposed or susceptible subpopulation ... or the environment.” In contrast to the risk evaluation process under TSCA section 6(b), this TSCA section 6(h)(1)(B) threshold criterion is triggered only through an Exposure and Use Assessment regarding the likelihood of exposure and does not require identification of every condition of use. As a result, EPA collected all the information it could on the use of each chemical substance, without regard to whether any chemical activity would be characterized as “known, intended or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of,” and from that information created use profiles and then an Exposure and Use Assessment (Ref. 4) to make the TSCA section 6(h)(1)(B) finding for at least one or more “condition of use” activities where some exposure is likely. EPA did not attempt to precisely classify all activities for each chemical substance as a “condition of use” and thus did not attempt to make a TSCA section 6(h)(1)(B) finding for all chemical activities summarized in the Exposure and Use Assessment (Ref. 4). Second, TSCA section 6 generally requires a risk

evaluation under TSCA section 6(b) for chemicals based on the identified conditions of use. However, pursuant to TSCA section 6(h)(2), for chemical substances that meet the criteria of TSCA section 6(h)(1), a risk evaluation is neither required nor contemplated to be conducted for EPA to meet its obligations under TSCA section 6(h)(4). Rather, as noted in Unit II.B.3., if a previously prepared TSCA risk assessment exists, EPA would have authority to use that risk assessment to “address risks” under TSCA section 6(h)(4), but even that risk assessment would not necessarily be focused on whether an activity is “known, intended or reasonably foreseen,” as those terms were not used in TSCA prior to the 2016 amendments and a preexisting assessment of risks would have had no reason to use such terminology or make such judgments. It is for this reason EPA believes that the TSCA section 6(h)(4) “address risk” standard refers to the risks the Administrator determines “are presented by the chemical substance” and makes no reference to “conditions of use.” Congress did not contemplate or require a risk evaluation identifying the conditions of use as defined under TSCA section 3(4). The kind of analysis required to identify and evaluate the conditions of use for a chemical substance is only contemplated in the context of a TSCA section 6(b) risk evaluation, not in the context of an expedited rulemaking to address PBT chemicals. Similarly, the TSCA amendments require EPA to “reduce *exposure to the substance* to the extent practicable,” without reference to whether the exposure is found “likely” pursuant to TSCA section 6(h)(1)(B).

Taking all of this into account, EPA reads its TSCA section 6(h)(4) obligation to apply to the chemical substance generally, thus requiring EPA to address risks and reduce exposures to the chemical substance without focusing on whether the measure taken is specific to an activity that might be characterized as a “condition of use” as that term is defined in TSCA section 3(4) and interpreted by EPA in the Risk Evaluation Rule , 82 FR 33726 (July 20, 2017). This approach ensures that any activity involving a TSCA section 6(h) PBT chemical, past, present or future, is addressed by the regulatory approach taken. Thus, under this final rule, manufacturing, processing, and distribution in commerce activities that are not specifically excluded are

prohibited. The specified excluded activities are those which EPA determined were not appropriate to regulate under the TSCA section 6(h)(4) standard. Consistently, based on the Exposure and Use Assessment, activities associated with HCBd that are no longer occurring are addressed by this rule and thus the prohibitions adopted in this rule reduce the exposures that will result with resumption of past activities or the initiation of similar or other activities in the future. Therefore, EPA has determined that prohibiting these activities will reduce exposures to the extent practicable. The approach taken for this final rule is limited to implementation of TSCA section 6(h) and is not relevant to any other action under TSCA section 6 or other TSCA statutory actions.

## *2. EPA's interpretation of "practicable."*

The term "practicable" is not defined in TSCA. EPA interprets this requirement as generally directing the Agency to consider such factors as achievability, feasibility, workability, and reasonableness. In addition, EPA's approach to determining whether particular prohibitions or restrictions are practicable is informed in part by certain other provisions in TSCA section 6, such as TSCA section 6(c)(2)(A), which requires the Administrator to consider health effects, exposure, and environmental effects of the chemical substance; benefits of the chemical substance; and the reasonably ascertainable economic consequences of the rule. In addition, pursuant to TSCA section 6(c)(2)(B), in selecting the appropriate TSCA section 6(a) regulatory approach, the Administrator is directed to "factor in, to the extent practicable" those same considerations.

EPA received comments on the proposed rule regarding this interpretation of "practicable." EPA has reviewed these comments and believes the interpretation described previously within this Unit is consistent with the intent of TSCA and has not changed that interpretation. EPA's interpretation of an ambiguous statutory term receives deference. More discussion on these comments is in the Response to Comments document for this rulemaking (Ref. 4).

*3. EPA did not conduct a risk evaluation or assessment.*

As EPA explained in the proposed rule, EPA does not interpret the “address risk” language to require EPA to determine, through a risk assessment or risk evaluation, whether risks are presented. EPA believes this reading gives the Administrator the flexibility Congress intended for issuance of expedited rules for PBTs and is consistent with TSCA section 6(h)(2), which makes clear a risk evaluation is not required to support this rulemaking.

EPA received comments on the proposed rule regarding its interpretation of TSCA section 6(h)(4) and regarding EPA’s lack of risk assessment or risk evaluation of HCBP. A number of commenters asserted that while EPA was not compelled to conduct a risk evaluation, EPA should have conducted a risk evaluation under TSCA section 6(b) regardless. The rationales provided by the commenters for such a risk assessment or risk evaluation included that one was needed for EPA to fully quantify the benefits to support this rulemaking, and that without a risk evaluation, EPA would not be able to determine the benefits, risks, and cost effectiveness of the rule in a meaningful way. As described by the commenters, EPA would therefore not be able to meet the TSCA section 6(c)(2) requirement for a statement of these considerations. Regarding the contradiction between the mandate in TSCA section 6(h) to expeditiously issue a rulemaking and the time needed to conduct a risk evaluation, some commenters stated that EPA would have had enough time to conduct a risk evaluation and issue a proposed rule by the statutory deadline.

EPA disagrees with the commenters’ interpretation of EPA’s obligations with respect to chemicals subject to TSCA section 6(h)(4). TSCA section 6(h)(4) provides that EPA shall: (1) “Address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance” and (2) “reduce exposure to the substance to the extent practicable.” With respect to the first requirement, that standard is distinct from the “unreasonable risk” standard for all other chemicals for which a section 6(a) rule might be issued. EPA does not believe the TSCA section 6(h) contemplates a new evaluation of any kind, given evaluations to determine risks are now addressed through the TSCA section 6(b) risk

evaluation process and TSCA section 6(h)(2) explicitly provides that no risk evaluation is required. Moreover, it would have been impossible to prepare a meaningful evaluation under TSCA and subsequently develop a proposed rule in the time contemplated for issuance of a proposed rule under TSCA section 6(h)(1). Although EPA does not believe the statute contemplates a new evaluation of any kind for these reasons, EPA reviewed the hazard and exposure information on the five PBT chemicals EPA had compiled. However, while this information appropriately addresses the criteria of TSCA section 6(h)(1)(A) and (B), it did not provide a basis for EPA to develop sufficient and scientifically robust and representative risk estimates to evaluate whether or not any of the chemicals present an identifiable risk of injury to health or the environment.

Rather than suggesting a new assessment is required, EPA reads the “address risk” language in TSCA section 6(h)(4) to contemplate reliance on an existing EPA assessment under TSCA, similar to a risk assessment that may be permissibly used under TSCA section 26(l)(4) to regulate the chemical under TSCA section 6(a). This interpretation gives meaning to the “address risk” phrase, without compelling an evaluation contrary to TSCA section 6(h)(2) and would allow use of an existing determination, or development of a new determination based on such an existing risk assessment, in the timeframe contemplated for issuance of a proposed rule under TSCA section 6(h). However, there were no existing EPA assessments of risk for any of the PBT chemicals. Thus, because EPA had no existing EPA risk assessments or determinations of risk, the regulatory measures addressed in this final rule focus on reducing exposures “to the extent practicable.”

In sum, because neither the statute nor the legislative history suggests that a new evaluation is compelled to identify and thereby provide a basis for the Agency to “address risks” and one could not be done prior to preparation and timely issuance of a proposed rule, and no existing TSCA risk assessment exists for any of the chemicals, EPA has made no risk determination finding for any of the PBT chemicals. Instead, EPA implements the requirement

of TSCA section 6(h)(4) by reducing exposures of each PBT chemical “to the extent practicable.”

For similar reasons, EPA does not believe that TSCA section 6(c)(2) requires a quantification of benefits, much less a specific kind of quantification. Under TSCA section 6(c)(2)(A)(iv), EPA must consider and publish a statement, based on reasonably available information, on the reasonably ascertainable economic consequences of the rule, but that provision does not require quantification, particularly if quantification is not possible. EPA has reasonably complied with this requirement by including a quantification of direct costs and a qualitative discussion of benefits in each of the preambles to the final rules. EPA was unable to quantify the indirect costs associated with the rule. Further discussion on these issues raised in the comments is in the Response to Comment document. (Ref. 4)

### *C. HCBd Overview, Health Effects, and Exposure*

HCBd is a halogenated aliphatic hydrocarbon that is produced as a byproduct during the manufacture of chlorinated hydrocarbons, particularly perchloroethylene, trichloroethylene, and carbon tetrachloride (Ref. 6). As described in the proposed rule, the majority of HCBd that is unintentionally produced as a byproduct is destroyed via incineration by the manufacturer, which EPA views as being consistent with the approach taken at the international level under Article 6 of the Stockholm Convention. The remainder of the HCBd byproduct is sent off-site for incineration or for burning as a waste fuel by cement manufacturers in cement kilns (EPA-HQ-OPPT-2016-0738-0012), an identified source category under Annex C of the Stockholm Convention. EPA views this burning of such waste as consistent with the approach taken at the international level under Article 6 of the Stockholm Convention. EPA has not identified any current intentional use of HCBd. The destruction and removal efficiency from incineration of the HCBd byproduct is expected to be significant but not complete, resulting in potential for air releases from incinerator flue gas and land releases from disposal of ash and slag. Minor water releases from equipment cleaning are possible (Ref. 5). According to EPA Toxics Release

Inventory (TRI) data, over 9 million lbs of HCBd byproduct were generated by chemical manufacturers in reporting year 2017, with almost 8.9 million lbs treated for destruction on-site via incineration. TRI reports show other waste management activities of HCBd byproduct including 58,000 lbs being treated for destruction off-site, 33,000 lbs burned for energy recovery off-site, and 2,400 lbs released to air (Ref. 7). Exposure information for HCBd is further detailed in EPA's Exposure and Use Assessment (Ref. 5) and discussed in the Response to Comments (Ref. 4).

As described in EPA's Environmental and Human Health Hazards of Five Persistent, Bioaccumulative, and Toxic Chemicals, HCBd is considered a possible human carcinogen (Ref. 8). Inhalation and oral animal data for HCBd indicate renal, reproductive, and developmental effects in rats (Ref. 8). Health effects included renal adenomas and carcinomas, reduced body weight in adults, and reduced fetal body weight. Women who are occupationally exposed may transfer HCBd to infants via breastmilk (Ref. 5).

HCBd is toxic to aquatic life following acute and chronic exposures at very low concentrations (Ref. 8). Data show acute toxicity in aquatic invertebrates, fish and algae, and chronic toxicity in fish. A single toxicity test was identified for terrestrial organisms, showing reduced chick survival in quail. The Hazard Summary provides more information on these hazardous endpoints (Ref. 8). The studies presented in the document entitled "Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals (Hazard Summary) (Ref. 8) demonstrate these hazardous endpoints. EPA did not perform a systematic review or a weight of the scientific evidence assessment for the hazard characterization of these chemicals. As a result, this hazard characterization is not definitive or comprehensive. Other hazard information on these chemicals may exist in addition to the studies summarized in the Hazard Summary that could alter the hazard characterization.

In the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1), HCBd scored high (3) for hazard (possible human carcinogen); moderate (2) for exposure (based on

TRI data); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall screening score for HCBDB was high (8) (Ref. 1).

In consideration of the production, use, and destruction of HCBDB, the environmental and human health hazards of HCBDB, and the public comments on the proposed rule that are further discussed in Unit III.A., EPA determines that HCBDB meets the TSCA section 6(h)(1)(A) criteria. EPA determines in accordance with TSCA section 6(h)(1)(B) that, based on the Exposure and Use Assessment and the reasonably available information, exposure to HCBDB under the conditions of use is likely to the general population, to a potentially exposed or susceptible subpopulation, or to the environment. EPA's determination is based on the opportunities for exposure throughout the lifecycle of HCBDB, including the potential for exposures, and EPA did not receive any significant comments or information to call the exposure finding into question.

#### *D. EPA's Proposed Rule Under TSCA Section 6(h) for HCBDB*

EPA did not propose to regulate HCBDB under TSCA section 6(h) because of the limited releases and given that the potential for exposure from uses of this chemical is already addressed by actions taken under other statutes and EPA determined further measures would not be practicable. As discussed in the proposed rule, HCBDB is regulated under various statutes implemented by the Federal Government, such as the Clean Air Act (CAA) and Resource Conservation and Recovery Act (RCRA). According to TRI data, most of the HCBDB manufactured in the United States is subsequently destroyed via incineration.

EPA, however, proposed an alternative regulatory action of prohibiting the manufacture of HCBDB, which is further discussed in the proposed rule.

#### *E. Public Comments and Other Public Input*

The proposed rule provided a 60-day public comment period, with a 30-day extension provided. (Ref. 4). The comment period closed on October 28, 2019. EPA received a total of 48 comments, with three commenters sending multiple submissions with attached files, for a total of

58 submissions on the proposal for all the PBT chemicals. This includes the previous request for a comment period extension (EPA-HQ-OPPT-2019-0080-0526). Two commenters submitted confidential business information (CBI) or copyrighted documents with information regarding economic analysis and market trends. Copies of all the non-CBI documents, or redacted versions without CBI, are available in the docket for this action.

In this preamble, EPA has responded to the major comments relevant to the HCBD final rule. Of the comment submissions, 10 directly addressed EPA's proposal regarding HCBD. Additional discussion related to this final action can be found in the Response to Comments document (Ref. 4).

#### *F. Activities Not Directly Regulated by this Final Rule*

EPA is not regulating all activities or exposures to HCBD in this rule, even though the Exposure and Use Assessment (Ref. 5) identified potential for exposures under conditions of use. One such activity is disposal. EPA generally presumes compliance with federal and state laws and regulations, including, for example, RCRA and its implementing regulations and state laws, as well as the CAA, the Clean Water Act, and the Safe Drinking Water Act (SDWA). As described in the proposed rule, regulations promulgated under the authority of the RCRA govern the disposal of hazardous and non-hazardous wastes. HCBD is listed as a hazardous constituent under Appendix VIII of 40 CFR part 261 and Appendix IX of part 264, providing EPA with authority to regulate wastes containing this chemical, and to address releases from RCRA-permitted treatment, storage and disposal facilities. HCBD is listed as a hazardous waste under RCRA in 40 CFR 261.33, Hazard Waste Code U128. In addition, HCBD is a constituent that may also cause a waste to be defined as a characteristic hazardous waste under 40 CFR 261.24. As a hazardous waste, HCBD is subject to regulation under 40 CFR parts 262 through 265, 268, and parts 270 and 271. HCBD is also a hazardous constituent under 40 CFR part 258, Appendix II (Criteria for Municipal Solid Waste Landfills, or MSWLF), which is part of the groundwater assessment program for corrective action at MSWLFs. Industrial waste (non-hazardous) landfills

and construction/demolition waste landfills are primarily regulated under state regulatory programs, and in addition they must meet the criteria set forth in federal regulations which may include requirements for siting, groundwater monitoring and corrective action depending upon what types of wastes are accepted. Disposal by underground injection is regulated under both RCRA and SDWA.

In addition, the CAA requires EPA to regulate hazardous air pollutants (HAP) such as HCBD. CAA section 112 requires that the Agency establish National Emission Standards for Hazardous Air Pollutants (NESHAP) for the control of hazardous air pollutants from both new and existing major sources. The CAA requires the NESHAP to reflect the maximum degree of reduction in emissions of HAP that is achievable, taking into consideration the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements. This level of control is commonly referred to as maximum achievable control technology (MACT). The CAA also establishes a minimum control level for MACT standards known as the MACT “floor.” The MACT floor is the minimum control level allowed for NESHAP and is defined under the CAA section 112(d)(3) (Ref. 9). The chemical manufacturers that produce HCBD are in NAICS group 325 and therefore fall under the NESHAP regulations for miscellaneous organic chemical manufacturing found at 40 CFR part 63 subpart FFFF. These regulations require facilities to treat chemicals in their waste streams at high efficiencies. For example, emissions from process vents must be reduced by greater than or equal to 99% by weight depending on the chemical in the waste stream. According to TRI data, chemical manufacturers that submit reports for HCBD are treating the byproduct via incineration at greater than 99.99% treatment efficiency with some reporting an efficiency greater than 99.9999%. Under the CAA, facilities in certain industries are required to implement a Leak Detection and Repair (LDAR) program to reduce fugitive air emissions. Included in those industries are synthetic organic chemical manufacturers that produce the HCBD byproduct. The LDAR program requires these facilities to monitor components such as pumps, valves, connectors and

compressors for leaks. When leaks are detected, the facility is required to repair or replace the leaking component.

In view of these comprehensive, stringent programs for addressing disposal and air releases, EPA determined that it is not practicable to impose additional requirements under TSCA on the disposal and air releases of the HCBd byproduct.

In addition, EPA proposed not to use its TSCA section 6(a) authorities to directly regulate occupational exposures. As explained in the proposed rule, as a matter of policy, EPA assumes compliance with federal and state requirements, such as worker protection standards, unless case-specific facts indicate otherwise. The Occupational Safety and Health Administration (OSHA) has not established a permissible exposure limit (PEL) for HCBd. However, under section 5(a)(1) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 654(a)(1), each employer has a legal obligation to furnish to each of its employees employment and a place of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm. The OSHA Hazard Communication Standard at 29 CFR 1910.1200 requires chemical manufacturers and importers to classify the hazards of chemicals they produce or import, and all employers to provide information to employees about hazardous chemicals to which they may be exposed under normal conditions of use or in foreseeable emergencies. The OSHA standard at 29 CFR 1910.134(a)(1) requires the use of feasible engineering controls to prevent atmospheric contamination by harmful substances and requires the use of respirators where effective engineering controls are not feasible. The OSHA standard at 29 CFR 1910.134(c) details the required respiratory protection program. The OSHA standard at 29 CFR 1910.132(a) requires the use of personal protective equipment (PPE) by workers when necessary due to a chemical hazard; 29 CFR 1910.133 requires the use of eye and face protection when employees are exposed to hazards including liquid chemicals; and 29 CFR 1910.138 requires the use of PPE to protect employees' hands including from skin absorption of harmful substances. The provisions of 29 CFR 1910.132(d) and (f) address hazard assessment, PPE selection, and

training with respect to PPE required under 29 CFR 1910.133, 1910.135, 1910.136, 1910.138, and 1910.140. EPA assumes that employers will require, and workers will use, appropriate PPE consistent with OSHA standards, taking into account employer-based assessments, in a manner sufficient to prevent occupational exposures that are capable of causing injury.

EPA assumes compliance with other federal requirements, including OSHA standards and regulations. EPA does not read TSCA section 6(h)(4) to direct EPA to adopt potentially redundant or conflicting requirements. Not only would it be difficult to support broadly applicable and safe additional measures for each specific activity without a risk evaluation and in the limited time for issuance of this regulation under TSCA section 6(h), but imposing such measures without sufficient analysis could inadvertently result in conflicting or confusing requirements and make it difficult for employers to understand their obligations. Furthermore, EPA cannot conclude that broadly imposing specific measures is practicable for all of the varied workplaces. Rather, where EPA has identified worker exposures and available substitutes, EPA is finalizing measures to reduce those exposures. As discussed in the proposed rule, EPA assumes that the worker protection methods used by employers, including in response to existing OSHA standards, in addition to the regulatory measures taken for each chemical, meaningfully reduce the potential for occupational exposures. Although some commenters agreed with this approach, others thought that EPA should establish worker protection requirements for those uses that would be allowed to continue under the final rule. Information provided to EPA before and during the public comment period on the proposed rule indicates that employers are using engineering and process controls and providing appropriate personal protective equipment (PPE) to their employees consistent with these requirements, and EPA received no information on HCBD to suggest this is not the case. Further, EPA has not conducted a risk evaluation on HCBD or any of the other PBT chemicals. Without a risk evaluation and given the time allotted for this rulemaking, EPA cannot identify additional engineering or process controls or PPE requirements that would be appropriate to each chemical-specific circumstance. For these

reasons, EPA has determined that it is not practicable to regulate worker exposures in this rule through additional engineering or process controls or PPE requirements.

Finally, EPA received comments regarding the use of PBT chemicals in research and development and laboratory use. Laboratory use is addressed under newly established 40 CFR 751.401(b) as the manufacturing, processing, distribution-in-commerce and use of any chemical substance, or products and articles that contain the chemical substance, for research and development, as defined in new 40 CFR 751.403. *Research and Development* is defined in new 40 CFR 751.403 to mean laboratory and research use only for purposes of scientific experimentation or analysis, or chemical research on, or analysis of, the chemical substance, including methods for disposal, but not for research or analysis for the development of a new product, or refinement of an existing product that contains the chemical substance. This will allow, for example, for samples of environmental media containing PBTs, such as contaminated soil and water, to be collected, packaged and shipped to a laboratory for analysis. Laboratories also must obtain reference standards containing PBTs to calibrate their equipment, otherwise they may not be able to accurately quantify these chemical substances in samples being analyzed. However, research to develop new products that use PBTs subject to 40 CFR part 751, subpart E, or the refinement of existing uses of those chemicals, is not included in this definition, and those activities remain potentially subject to the chemical specific provisions in 40 CFR part 751 subpart E. EPA believes it is not practicable to limit research and development activity as defined, given the critical importance of this activity to the detection, quantification and control of these chemical substances.

More information on the comments received and EPA's responses can be found in the Response to Comments document (Ref. 4).

### III. Provisions of This Final Rule

#### *A. Scope and Applicability*

EPA carefully considered all public comments related to the proposal. This final rule

differs from EPA's proposal by finalizing a prohibition on the manufacturing (including import), processing, and distribution in commerce of HCB<sub>2</sub>D, and HCB<sub>2</sub>D-containing products and articles, except for the unintentional production of HCB<sub>2</sub>D as a byproduct during the production of chlorinated solvents, and the limited processing and distribution of HCB<sub>2</sub>D for burning as a waste fuel. The effective date is 30 days after publication of the final rule.

*1. Regulating HCB<sub>2</sub>D.*

EPA received comments disagreeing with EPA's proposal not to regulate HCB<sub>2</sub>D. One commenter stated that EPA must act under TSCA section 6(h) to include a total phase-out of the chemical (EPA-HQ-OPPT-2019-0080-0575). Another commenter stated that by not prohibiting uses of HCB<sub>2</sub>D, EPA's approach allowed ongoing exposures, including to potentially exposed and susceptible subpopulations, and potential expansion of uses (EPA-HQ-OPPT-2019-0080-0567). Three commenters noted that HCB<sub>2</sub>D was listed in the Stockholm Convention on Persistent Organic Pollutant (POPs) which prohibits the intentional manufacture of HCB<sub>2</sub>D and stated that the manufacture of HCB<sub>2</sub>D should be eliminated (EPA-HQ-OPPT-2019-0080-0570) (EPA-HQ-OPPT-2019-0080-0567) (EPA-HQ-OPPT-2019-0080-0531). EPA received one comment supporting EPA's proposal and finding that no new risk management measures are required to reduce exposure of HCB<sub>2</sub>D to the extent practicable (EPA-HQ-OPPT-2019-0080-0557).

In response to comments, EPA is finalizing a prohibition on the manufacturing, processing, and distribution of HCB<sub>2</sub>D and HCB<sub>2</sub>D-containing products or articles, recognizing that there is unintentional production of HCB<sub>2</sub>D as a byproduct during the production of chlorinated solvents, that results in processing and distribution in commerce of a very limited subset of that byproduct for burning as a waste fuel. However, as explained below, EPA disagrees with commenters that a total ban of HCB<sub>2</sub>D production as a byproduct is practicable. The potential for exposure from incineration and distribution for incineration of the byproduct is substantially addressed by actions taken under other statutes. As discussed in EPA's proposed

rule and in Unit II.F., HCB<sub>2</sub>D is regulated under various statutes implemented by the Federal Government, such as CAA and RCRA. According to TRI data, most of the byproduct HCB<sub>2</sub>D manufactured in the United States is subsequently destroyed via incineration due in large part to the high waste treatment efficiencies achieved by the chemical manufacturers. Chemical manufacturers that submit TRI reports for HCB<sub>2</sub>D byproduct are treating the chemical via incineration at greater than 99.99% treatment efficiency with some reporting an efficiency greater than 99.9999%.

Given the known uses and efficiency of the destruction of HCB<sub>2</sub>D created as a byproduct, EPA is issuing a final rule to prohibit all manufacturing, processing, and distribution in commerce of HCB<sub>2</sub>D and products and articles containing HCB<sub>2</sub>D, while recognizing the continuation of the production of HCB<sub>2</sub>D as a byproduct during the production of chlorinated solvents, and the resulting processing and distribution of HCB<sub>2</sub>D for burning as a waste fuel. This final rule allows the current, highly regulated, unintentional production as a byproduct and incineration and distribution for incineration of such byproduct to continue and ensures that other uses do not commence.

## *2. HCB<sub>2</sub>D uses.*

Multiple commenters submitted comments to EPA discussing HCB<sub>2</sub>D uses. Commenters pointed out that EPA's website had previously identified uses of HCB<sub>2</sub>D as a solvent in rubber manufacturing and in hydraulic, heat transfer, or transformer fluid (EPA-HQ-OPPT-2019-0080-0575) (EPA-HQ-OPPT-2019-0080-0546). Commenters further noted that EPA's Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal for HCB<sub>2</sub>D document identified numerous uses for HCB<sub>2</sub>D beyond its production as a byproduct (Ref. 4) (EPA-HQ-OPPT-2019-0080-0575) (EPA-HQ-OPPT-2019-0080-0546). According to one commenter, EPA had not addressed these activities in its proposed rule, much less established that it would be impracticable to ban these uses to reduce exposure. This commenter stated that EPA should ban these past uses (EPA-HQ-OPPT-2019-0080-0546). Another commenter felt that EPA's proposed

rule neglected to discuss or mention legacy uses and legacy disposals of PBT chemicals, and other commenters stated that HCBd has been listed in Annex A of the Stockholm Convention in order to avoid new possible future uses of HCBd (EPA-HQ-OPPT-2019-0080-0541) (EPA-HQ-OPPT-2019-0080-0531) (EPA-HQ-OPPT-2019-0080-0575).

In addition, multiple commenters expressed concerns about EPA's conclusion that "a prohibition on the manufacture of HCBd would effectively prohibit the manufacture of the three solvents" (trichloroethylene, carbon tetrachloride, and perchloroethylene) and therefore that a ban was impracticable. The commenters made recommendations for alternative regulatory approaches. One commenter stated that EPA had failed to consider banning HCBd, except as a byproduct to the manufacture of other chemicals, to reduce exposure to the extent practicable (EPA-HQ-OPPT-2019-0080-0546). The commenter further stated that EPA could have considered banning all manufacture except as a byproduct of manufacture of perchloroethylene, trichloroethylene, and carbon tetrachloride, to ensure that HCBd is not manufactured for a purpose other than its incidental production as a byproduct (EPA-HQ-OPPT-2019-0080-0546).

EPA appreciates the comments provided regarding HCBd. EPA's Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal for HCBd document was a preliminary summary of available information on uses, past and present, of HCBd (Ref. 4). EPA requested comment on the document but did not receive confirmation of ongoing uses other than those discussed in the proposed rule. EPA has not identified any uses of HCBd. The only activity involving HCBd is burning as a waste fuel as a result of unintentional HCBd production as a byproduct.

However, recognizing commenters' concern about prohibiting HCBd uses that are not currently ongoing to avoid, for example, the return of past uses, EPA is finalizing a change from the proposal and is prohibiting all manufacturing, processing, and distribution in commerce of HCBd and products and articles containing HCBd, but allowing the continuation of the unintentional production of HCBd as a byproduct during the production of chlorinated solvents

and the resulting processing and distribution of HCBD for burning as a waste fuel. This approach ensures that the types of allowable activities involving HCBD are severely limited by precluding the manufacture, processing, or distribution of HCBD for a purpose other than its incidental and unintentional production as a byproduct and allows burning of that byproduct as a waste fuel. Any other activity involving HCBD is prohibited by the final rule, and thus the final requirements are consistent with restrictions on the intentional production and use of HCBD under Annex A of the Stockholm Convention. Moreover, the highly regulated burning of the byproduct as a waste fuel is also consistent with Article 6 of the same Convention. Thus, the final rule requirements reduce the exposures to humans and the environment that could occur with any activity involving HCBD not directly related to its manufacture as a byproduct or burning as a waste fuel.

### *3. Chlorinated Solvents Resulting in HCBD as a Byproduct.*

EPA received comments regarding the chlorinated solvents that unintentionally produce HCBD as a byproduct. One commenter recommended that EPA consider whether viable alternative synthetic routes exist that do not result in such production (EPA-HQ-OPPT-2019-0080-0541). One commenter stated that EPA should solicit information, regarding whether HCBD-free production methods for chlorinated solvents exist from industry before concluding that a ban on HCBD would entail a ban on chlorinated solvents (EPA-HQ-OPPT-2019-0080-0551). Another commenter stated that EPA must act under section 6(h) to include a total phase-out of the chemical and any processes that lead to creation of HCBD as a byproduct (EPA-HQ-OPPT-2019-0080-0575). Others requested EPA require best available techniques and environmental practices to control emissions and releases from sources of HCBD, and suggested EPA develop a plan to eliminate HCBD to the extent practicable through alternative chlorinated solvent manufacturing (EPA-HQ-OPPT-2019-0080-0567).

EPA appreciates the comments regarding alternatives and actions to be taken on chlorinated hydrocarbons, particularly perchloroethylene, trichloroethylene, and carbon

tetrachloride, that unintentionally create HCBD as a byproduct. EPA is not aware of alternative methods for the production of chlorinated solvents that do not unintentionally produce HCBD as a byproduct and did not receive additional information in the comments on the proposal. As discussed in the proposed rule, prohibiting all manufacture of HCBD would effectively preclude the manufacture of trichloroethylene, carbon tetrachloride and perchloroethylene and EPA does not believe precluding manufacture of these solvents to reduce the exposure to the HCBD byproduct is practicable at this time. EPA is not addressing these three solvents during this TSCA section 6(h) rule making, which applies solely to PBT chemicals. Additionally, the solvents are the subject of the risk evaluation process pursuant to TSCA section 6(b). Where unreasonable risks are identified as part of those risk evaluations, EPA is required to take action under TSCA section 6(a) to address unreasonable risk. In addition, these chlorinated solvents are widely used in dry cleaning, metal degreasing, and other industries. To broadly assess the economic impact of a prohibition of the manufacture of these three chemicals, EPA estimated the potential market value loss by multiplying the national production volume of each of these chemicals by an average price per pound. This resulted in an estimated impact \$213 million to \$541 million (average \$368 million) worth of production (see the Economic Analysis for the proposed rule for details on this estimation) (Ref. 10). Therefore, EPA's final rule allows the continuation of the unintentional production of HCBD as a byproduct during the production of chlorinated solvents and processing and distribution of the HCBD byproduct for burning as a waste fuel, and prohibits all other manufacturing, processing, and distribution in commerce of HCBD and products and articles containing HCBD.

#### *4. Recordkeeping.*

In addition, EPA is requiring that all persons who manufacture, process, or distribute in commerce HCBD and HCBD-containing products or articles maintain ordinary business records related to compliance with the prohibitions and restrictions, such as invoices and bills-of-lading. EPA revised this language slightly from the proposal to improve clarity. These records will have

to be maintained for a period of three years from the date the record is generated, beginning on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

*B. TSCA Section 6(c)(2) Considerations*

*1. Health effects, exposure, and environmental effects.*

HCBD is toxic to aquatic invertebrates, fish, and birds. Data indicate the potential for renal, liver, and developmental effects in mammals. HCBD has been identified as a possible human carcinogen. The studies presented in the Hazard Summary (Ref. 8) demonstrate these hazardous endpoints. These hazard statements are not based on a systematic review of the available literature and information may exist that could refine the hazard characterization. Additional information about HCBD health effects, use, and exposure is in Unit II.C. and further detailed in the Hazard Summary (Ref. 8). Information on use and exposures is also in Unit II.C. and is further detailed in EPA's Exposure and Use Assessment (Ref. 5, Ref. 8).

*2. The benefits of the chemical substance or mixture for various uses.*

HCBD is unintentionally manufactured as a waste byproduct by chemical manufacturers. The majority of what is manufactured is destroyed via incineration by the manufacturer. A small percentage of the HCBD is sent off-site for burning as a waste fuel by cement manufacturers.

*3. The reasonably ascertainable economic consequences of the rule.*

*a. Overview of cost methodology.*

EPA has evaluated the potential costs of the final action for HCBD. Costs of the final rule were estimated based on the assumption that under regulatory limitations on HCBD, processors that use HCBD in their products would switch to available alternative chemicals to manufacture the product, or to products that do not contain HCBD. Costs for rule familiarization and recordkeeping were estimated based on burdens estimated for other similar rulemakings. Costs were annualized over a 25-year period. Other potential costs include, but are not limited to, those associated with testing, reformulation, imported articles, and some portion of potential revenue

loss. However, these costs are discussed only qualitatively, due to lack of data availability to estimate quantified costs. More details of this analysis are presented in the Economic Analysis (Ref. 3).

*b. Estimated costs of this final rule.*

Total quantified annualized industry costs for the final rule is \$354. Total annualized Agency costs associated with implementation of the final rule were based on EPA's best judgment and experience with other similar rules. For the final regulatory action, EPA estimates it will require 0.5 FTE at \$77,576 per year (Ref. 3).

Total quantified annualized social costs for the final rule are estimated to be \$77,930 (at both 3% and 7% discount rates annualized over 25 years). As described earlier in Unit III.B.3, potential costs such as testing, reformulation, and imported articles, could not be quantified due to lack of data availability to estimate quantified costs. These costs are discussed qualitatively in the Economic Analysis (Ref. 3).

*c. Benefits.*

As discussed in Unit II., although EPA reviewed hazard and exposure information for the PBT chemicals, this information did not provide a basis for EPA to develop scientifically robust and representative risk estimates to evaluate whether or not any of the chemicals present a risk of injury to health or the environment. Benefits were not quantified due to the lack of risk estimates. A qualitative discussion of the potential benefits associated with the final action for HCBP is provided. HCBP is persistent, bioaccumulative, and a possible human carcinogen. It is not intentionally manufactured in the United States. Since EPA is effectively excluding from prohibition all current activities involving HCBP as a byproduct, no benefits to human health or the environment are expected; the benefit is the prevention of individuals from being occupationally exposed to HCBP via the inhalation and dermal routes in the future. The toxicity of potential substitutes for HCBP has not been assessed at this time.

*d. Cost effectiveness, and effect on national economy, small business, and technological innovation.*

With respect to the cost effectiveness of the final regulatory action and the primary alternative regulatory action, EPA is unable to perform a traditional cost-effectiveness analysis of the actions and alternatives for the PBT chemicals. As discussed in the proposed rule, the cost effectiveness of a policy option would properly be calculated by dividing the annualized costs of the option by a final outcome, such as cancer cases avoided, or to intermediate outputs such as tons of emissions of a pollutant curtailed. Without the supporting analyses for a risk determination, EPA is unable to calculate either a health-based or environment-based denominator. Thus, EPA is unable to perform a quantitative cost-effectiveness analysis of the final and alternative regulatory actions. However, by evaluating the practicability of the final and alternative regulatory actions, EPA believes that it has considered elements related to the cost effectiveness of the actions, including the cost and the effect on exposure to the PBT chemicals of the final and alternative regulatory actions.

EPA considered the anticipated effect of this rule on the national economy and concluded that this rule is highly unlikely to have any measurable effect on the national economy (Ref. 3). EPA analyzed the expected impacts on small business and found that no small entities are expected to experience impacts of more than 1% of revenues (Ref. 3). Finally, EPA has determined that this rule is unlikely to have significant impacts on technological innovation.

#### *4. Consideration of alternatives.*

EPA has not identified any uses of HCBP. Therefore, chemical alternatives were not considered.

#### *C. TSCA Section 26(h) Considerations*

In accordance with TSCA section 26(h) and taking into account the requirements of TSCA section 6(h), EPA has used scientific information, technical procedures, measures, and methodologies that are fit for purpose and consistent with the best available science. For

example, EPA based its determination that human and environmental exposures to the HCBDB byproduct are likely in the Exposure and Use Assessment (Ref. 5) discussed in Unit II.A.2, which underwent a peer review and public comment process, as well as using best available science and methods sufficient to make that determination. The extent to which the various information, procedures, measures, and methodologies, as applicable, used in EPA's decision making have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this final rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, are in the public docket for this action (EPA-HQ-OPPT-2019-0080). In addition, in accordance with TSCA section 26(i), and taking into account the requirements of TSCA section 6(h), EPA has made scientific decisions based on the weight of the scientific evidence.

#### IV. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. All records in docket EPA-HQ-OPPT-2019-0080 are part of the record for this rulemaking. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014.  
*<https://www.epa.gov/assessingand-managing-chemicals-under-tsca/tsca-work-plan-chemical-assessments-2014-update>*. Accessed March 1, 2019.

2. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012.  
*[https://www.epa.gov/sites/production/files/2014-03/documents/work\\_plan\\_methods\\_document\\_web\\_final.pdf](https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf)*. Accessed March 1, 2019.

3. EPA. Economic Analysis for Regulation of Hexachlorobutadiene (HCBd) Under TSCA Section 6(h). December 2020.
4. EPA. Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h). *Response to Public Comments*. December 2020. (Docket EPA-HQ-OPPT-2019-0080).
5. EPA. Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals. December 2020.
6. United Nations Environment Program Stockholm Convention on Persistent Organic Pollutants (2012). Risk profile on hexachlorobutadiene. Report of the Persistent Organic Pollutants Review Committee on the work of its eighth meeting.
7. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Hexachlorobutadiene*. August 2017. (EPA-HQ-OPPT-2016-0738-0004).
8. EPA. Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals. December 2020.
9. EPA. National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing; Final Rule. **Federal Register** (63 FR 63852, Nov. 10, 2003) (FRL-7551-3)
10. EPA. Economic Analysis for Proposed Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA section 6(h). June 2019.
11. Keweenaw Bay Indian Community. Re: Notification of Consultation and Coordination on a Rulemaking Under the Toxic Substances Control Act: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h). September 25, 2018.
12. Harper, Barbara and Ranco, Darren, in collaboration with the Maine Tribes. Wabanaki Traditional Cultural Lifeways Exposure Scenario. July 9, 2009.

## V. Statutory and Executive Order Reviews

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

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

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

EPA prepared an economic analysis of the potential costs and benefits associated with this action. A copy of this economic analysis, *Economic Analysis for Final Regulation of Hexachlorobutadiene (HCBD) Under TSCA Section 6(h)* (Ref. 3) is in the docket and is briefly summarized in Unit III.B.3.

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

This action is considered a regulatory action under Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs of this final rule can be found in the Economic Analysis (Ref. 3), which is briefly summarized in Unit III.B.3.

*C. Paperwork Reduction Act (PRA)*

The information collection activities in this rule have been submitted for approval to the OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2599.02 and OMB Control No. 2070-0213. A copy of the ICR is available in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

*Respondents/affected entities:* Entities potentially affected by paperwork requirements of this final rule include manufacturers (including importers), processors, and distributors of HCBD.

*Respondent's obligation to respond:* Mandatory (40 CFR 751.413).

*Estimated number of respondents:* 9.

*Frequency of response:* On occasion.

*Total estimated burden:* 4.5 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$354 (per year), includes \$0 annualized capital or operation & maintenance costs.

The ICR submitted to OMB for approval under OMB Control No. 2070-0213 addresses the paperwork requirements of this final rule as well as the paperwork requirements of the other final rules addressing PBT chemicals under TSCA section 6(h) promulgated by EPA elsewhere in this issue of the *Federal Register*. For the combined paperwork requirements of all five final rules, EPA estimates a total of 102 respondents, 88 burden hours (per year), and a cost of approximately \$6,920 (per year) that includes no annualized capital or operation and maintenance costs.

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 EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule and the other final rules addressing PBT chemicals under TSCA section 6(h).

#### *D. 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.* One small business, an importer, is

expected to be affected by the rule familiarization and recordkeeping requirements of the final rule. The one small entity assessed is not expected to incur impacts of 1% (or greater) of their revenue. Because this entity's impacts are less than 1%, EPA presumes no significant economic impact on a substantial number of small entities. Details of this analysis are presented in the Economic Analysis (Ref. 3).

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and will not significantly or uniquely affect small governments. The final rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this final rule is not subject to the requirements of sections 202, 203, or 205 of UMRA. The total quantified annualized social costs for this final rule are approximately \$77,900 (at both 3% and 7% discount rate), which does not exceed the inflation-adjusted unfunded mandate threshold of \$160 million.

*F. Executive Order 13132: Federalism*

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

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

This action does not have tribal implications because it is not expected to have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this final rule.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with tribal officials during the development of this action. EPA consulted with representatives of Tribes via teleconference on August 31, 2018, and September 6, 2018, concerning the prospective regulation of the five PBT chemicals under TSCA section 6(h). Tribal members were encouraged to provide additional comments after the teleconferences. EPA received two comments from the Keweenaw Bay Indian Community and Maine Tribes (Refs. 11 and 12).

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not an economically significant regulatory action as defined by Executive Order 12866. While the action is not subject to Executive Order 13045, the Agency considered the risks to infants and children under EPA's Policy on Evaluating Health Risks to Children. EPA did not perform a risk assessment or risk evaluation of HCBD, the available data indicate exposure to HCBD may disproportionately affect children, and effects information indicating developmental effects. This regulation will reduce the exposure to HCBD that could occur from the prohibited activities for the general population and for potentially exposed or susceptible subpopulations such as children. More information can be found in the Exposure and Use Assessment (Ref. 5).

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

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

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

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

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

EPA believes that this action does not have disproportionately high and adverse health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Economic Analysis (Ref. 3), which is in the public docket for this action. EPA believes that the restrictions on HCBP in this final rule will reduce the potential for exposure in the United States, thus benefitting all communities, including environmental justice 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 751

Environmental protection, Chemicals, Export Notification, Hazardous substances, Import certification, Reporting and recordkeeping.

Andrew Wheeler,

*Administrator.*

Therefore, for the reasons stated in the preamble, 40 CFR part 751 is amended as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES  
UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

1. The authority citation for part 751 continues to read as follows:

**Authority:** 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

2. Amend § 751.403 by adding in alphabetical order the term “HCBD” to read as follows:

Subpart E—Persistent, Bioaccumulative, and Toxic Chemicals

§ 751.403 Definitions.

\* \* \* \* \*

*HCBD* means the chemical substance hexachlorobutadiene (CASRN 87-68-3).

\* \* \* \* \*

3. Add § 751.413 to read as follows:

**§ 751.413 HCBD.**

(a) *Prohibition.* After [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], all persons are prohibited from all manufacturing, processing and distribution in commerce of HCBD and HCBD-containing products or articles, except for the following:

(1) Unintentional production of HCBD as a byproduct in the production of chlorinated solvents; and

(2) Processing and distribution in commerce of HCBD for burning as a waste fuel.

(b) *Recordkeeping.* After [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], manufacturers, processors and distributors of HCBD or HCBD-containing products or articles must maintain ordinary business records related to compliance with the prohibitions, restrictions and other provisions of this section, such as invoices and bills-of-lading. These records must be maintained for a period of three years from the date the record is generated.

