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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–TRI–2017–0434; FRL–5927–02–OCSPP]

RIN 2070–AK26

Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In response to a petition filed under the Emergency Planning and Community Right-to-Know Act (EPCRA), the Environmental Protection Agency (EPA) is adding 12 chemicals to the list of toxic chemicals subject to the reporting requirements under EPCRA and the Pollution Prevention Act (PPA). EPA has determined that each of the 12 chemicals meets the EPCRA criteria. In addition, based on the available bioaccumulation and persistence data, EPA has determined that one chemical should be classified as a persistent, bioaccumulative, and toxic (PBT) chemical and designated as a chemical of special concern with a 100-pound reporting threshold.

DATES:

Effective date: November 30, 2022.

Applicability date: This final rule will apply for the reporting year beginning January 1, 2023 (reports are due July 1, 2024).

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–TRI–2017–0434, is available online at *https://www.regulations.gov* or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC). All documents in the docket are listed on *https://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Daniel R. Bushman, Toxics Release Inventory Program Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0743; email: *bushman.daniel@epa.gov.*

For general information contact: The Emergency Planning and Community Right-to-Know Hotline; telephone numbers: toll free at (800) 424–9346 (select menu option 3) or (703) 348–5070 in the Washington, DC Area and International, *https://www.epa.gov/home/epa-hotlines,* or go to the website: *https://www.epa.gov/aboutepa/epa-hotlines#epcraic.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you own or operate a facility that manufactures, processes, or otherwise uses any of the 12 chemicals included in this final rule. 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 facilities may include:

- Facilities included in the following NAICS manufacturing codes (corresponding to Standard Industrial Classification (SIC) codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 113310, 211130*, 212324*, 212325*, 212393*, 212399*, 488390*, 511110, 511120, 511130, 511140*, 511191, 511199, 512230*, 512250*, 519130*, 541713*, 541715* or 811490*.

*Exceptions and/or limitations exist for these NAICS codes.

- Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 212111, 212112, 212113 (corresponds to SIC code 12, Coal Mining (except 1241)); or 212221, 212222, 212230, 212299 (corresponds to SIC code 10, Metal Mining (except 1011, 1081, and 1094)); or 221111, 221112, 221113, 221118, 221121, 221122, 221330 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (corresponds to SIC codes 4911, 4931, and 4939, Electric Utilities); or 424690, 425110, 425120 (limited to facilities previously classified in SIC code 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 424710 (corresponds to SIC code 5171, Petroleum Bulk Terminals and Plants); or 562112 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC code 7389, Business Services, NEC)); or 562211, 562212, 562213, 562219, 562920 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 *et seq.*) (corresponds to SIC code 4953, Refuse Systems).
- Federal facilities.
- Facilities that the EPA Administrator has specifically required to report to TRI pursuant to a determination under EPCRA section 313(b)(2).

To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372, subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

In response to a petition submitted by the Toxics Use Reduction Institute (TURI) that requested the addition of 25 chemicals to the EPCRA section 313 toxic chemicals list (Ref. 1), EPA is adding 12 chemicals to the EPCRA section 313 toxic chemical list. EPA has determined that each of the 12 chemicals meets the EPCRA section 313(d)(2)(B) and/or (C) criteria for listing. EPA is also classifying one chemical as a PBT chemical and adding it to the list of chemicals of special concern with a 100-pound reporting threshold.

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

This action is issued under EPCRA sections 313(d), 313(e)(1) and 328, 42 U.S.C. 11023(d), 11023(e)(1) and 11048. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986.

Section 313 of EPCRA, 42 U.S.C. 11023 (also known as the Toxics Release Inventory (TRI)), requires owners/operators of certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their facilities' environmental releases and other waste management information on such chemicals annually. These facility

owners/operators must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA, 42 U.S.C. 13106.

Under EPCRA section 313(c), Congress established an initial list of toxic chemicals subject to EPCRA toxic chemical reporting requirements that was comprised of 308 individually listed chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that EPA may add a chemical to the list if any of the listing criteria in EPCRA section 313(d)(2) are met. Therefore, to add a chemical, EPA must determine that at least one criterion is met, but need not determine whether any other criterion is met. Conversely, to remove a chemical from the list, EPCRA section 313(d)(3) dictates that EPA must determine that none of the criteria in EPCRA section 313(d)(2) are met. The listing criteria in EPCRA section 313(d)(2)(A)–(C) are as follows:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
- The chemical is known to cause or can reasonably be anticipated to cause in humans: cancer or teratogenic effects, or serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects.
- The chemical is known to cause or can be reasonably anticipated to cause, because of its toxicity (EPCRA section 313(d)(2)(C)(i)), its toxicity and persistence in the environment (EPCRA section 313(d)(2)(C)(ii)), or its toxicity and tendency to bioaccumulate in the environment (EPCRA section 313(d)(2)(C)(iii)), a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA often refers to the EPCRA section 313(d)(2)(A) criterion as the ''acute human health effects criterion;'' the EPCRA section 313(d)(2)(B) criterion as the ''chronic human health effects criterion;'' and the EPCRA section 313(d)(2)(C) criterion as the ''environmental effects criterion.''

Under EPCRA section 313(e)(1), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA issued a statement of policy in the **Federal Register** of February 4, 1987 (52 FR 3479) providing guidance regarding the recommended content of and format for petitions. On May 23, 1991 (56 FR 23703), EPA issued guidance regarding the recommended content of petitions to delete individual members of the metal compounds categories reportable under EPCRA section 313. EPA published in the **Federal Register** of November 30, 1994 (59 FR 61432) (FRL–4922–2) (Ref. 2) a statement clarifying its interpretation of the EPCRA section 313(d)(2) and (d)(3) criteria for modifying the EPCRA section 313 list of toxic chemicals.

D. Why is the Agency's taking this action?

EPA is taking this action in response to a petition submitted under EPCRA section 313(e)(1). EPA is required to respond to petitions by ether initiating a rulemaking to grant the petition or publishing an explanation of why the petition is denied. In this case EPA is partially granting the petition to add 25 chemicals to the EPCRA section 313 toxic chemicals list.

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

EPA prepared an addendum to its economic analysis for this action entitled, ''Economic Analysis Addendum for the Final Rule to Add Twelve Chemicals Identified in a Petition from the Toxics Use Reduction Institute to the EPCRA Section 313 List of Toxic Chemicals'' which presents an updated analysis of the costs of the addition of the twelve chemicals (Ref. 3). EPA estimates that this action would result in an additional 1,342 reports being filed annually. EPA estimates that the costs of this action will be approximately $6,660,633 in the first year of reporting and approximately $3,172,080 in the subsequent years. In addition, EPA has determined that of the 1,283 small businesses affected by this action, none are estimated to incur annualized cost impacts of more than 1%. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities.

II. Summary of Proposed Rule

A. Who submitted the petition and what was requested?

On May 6, 2014, EPA received a petition from the TURI requesting the addition of 25 chemicals to the EPCRA section 313 toxic chemicals list (Ref. 1). The petitioner believed that each of these 25 chemicals meets the EPCRA section 313(d)(2) listing criteria and that the 25 chemicals should be added to the EPCRA section 313 toxic chemical list so that releases can be monitored and reported. The 25 chemicals, listed by name and Chemical Abstracts Service Registry Number (CASRN), are shown here (note that some chemical names are different than those used in the petition because they are listed here using the EPA Registry Name):

- Azodicarbonamide; 123–77–3;
- 1-Bromopropane; 106–94–5;
- 4-Chlorobenzotrichloride; 5216–25–1;
- Cyclododecane; 294–62–2;
- Dibutyltin dichloride; 683–18–1;
- 1,3-Dichloro-2-propanol; 96–23–1;
- Dimethylacetamide; 127–19–5;
- 2,3-Dinitrotoluene; 602–01–7;
- 2,5-Dinitrotoluene; 619–15–8;
- Formamide; 75–12–7;
- 1,2,5,6,9,10-Hexabromocyclododecane; 3194–55–6;
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran; 1222–05–5;
- Hexahydrophthalic anhydride; 85–42–7;
- N-Hydroxyethylethylenediamine; 111–41–1;
- N-Methylformamide; 123–39–7;
- Methylhexahydrophthalic anhydride; 25550–51–0;
- Nitrilotriacetic acid trisodium salt; 5064–31–3;
- Nonylphenol; 25154–52–3;
- Octabromodiphenyl ether; 32536–52–0;
- p-(1,1,3,3-Tetramethylbutyl)phenol; 140–66–9;
- 1,2,3-Trichlorobenzene; 87–61–6;
- Triglycidyl isocyanurate; 2451–62–9;
- Tris(2-chloroethyl) phosphate; 115–96–8;
- Tris(1,3-dichloro-2-propyl) phosphate; 13674–87–8; and
- Tris(dimethylphenol) phosphate; 25155–23–1.

B. How did EPA respond to the petition?

On October 18, 2021, EPA proposed to add 12 of the 25 chemicals included in the TURI petition to the EPCRA section 313 toxic chemicals list (Ref. 4). In separate, unrelated actions, three of the 25 chemicals (1-bromopropane (80 FR 72906, November 23, 2015 (FRL–9937–12–OEI)), nonylphenol (79 FR 58686, September 30, 2014 (FRL–9915–59–OEI)) and 1,2,5,6,9,10-hexabromocyclododecane (81 FR 85440, November 28, 2016 (FRL–9953–28)) have already been added to the EPCRA section 313 chemical list. Of the remaining 10 chemicals, EPA determined that the available data for nine chemicals was not sufficient for EPA to find that the chemicals meet the EPCRA section 313 listing criteria for human health or ecological effects (Refs.

5 and 6). Therefore, EPA did not propose to add the nine chemicals listed here:

- Azodicarbonamide; 123–77–3;
- 4-Chlorobenzotrichloride; 5216–25–1;
- Cyclododecane; 294–62–2;
- Dimethylacetamide; 127–19–5;
- 2,3-Dinitrotoluene; 602–01–7;
- 2,5-Dinitrotoluene; 619–15–8;
- Hexahydrophthalic anhydride; 85–42–7;
- Methylhexahydrophthalic anhydride; 25550–51–0; and
- N-Methylformamide; 123–39–7.

In addition, EPA did not propose to add octabromodiphenyl ether (OctaBDE) (32536–52–0) to the EPCRA section 313 toxic chemical list. EPA issued a significant new use rule (SNUR) that requires notification to EPA 90 days prior to the intended manufacture or import for any use of OctaBDE ether after January 1, 2005 (71 FR 34015, June 13, 2006 (FRL–7743–2); 40 CFR 721.10000). The lack of significant new use notices (SNUNs) under this SNUR indicates that there has been no non-exempt manufacture or import for any use of OctaBDE in the United States since January 1, 2005. In addition, there have been no submissions for OctaBDE under the Chemical Data Reporting (CDR) Rule (*https://www.epa.gov/chemical-data-reporting*) since 2006. In a 2008 evaluation, the United Nations noted that, as of 2005, the manufacture and import of OctaBDE had been phased out by industry and estimated that most of the remaining processing of OctaBDE in the United States was likely negligible and only occurring where remaining stockpiles were being used up or in waste processing facilities (*http://chm.pops.int/portals/0/repository/poprc4/unep-pops-poprc.4-6.english.pdf*). Given that the phase out occurred more than ten years ago, it is even more likely today that there is a negligible amount of OctaBDE remaining that is processed or otherwise used by facilities in the United States. Therefore, EPA did not propose to add OctaBDE to the EPCRA section 313 list since EPA expects that no TRI reports would be filed for this chemical. Section 313(d)(2) of EPCRA provides EPA the discretion to add chemicals to the TRI list when there is sufficient evidence to establish any of the listing criteria. EPA can add a chemical that meets one criterion regardless of its production volume. However, consistent with the Agency's previously articulated position on the use of manufacturing volume thresholds (*e.g.,* 58 FR 63500, December 1, 1993) and as in past chemical reviews (*e.g.,* 59 FR 61432, November 30, 1994) (Ref. 2), EPA adopted a production volume screen for the development of this rule to screen out those chemicals for which no reports are expected to be submitted. If chemicals that did not meet the production volume screen were listed, there would be an economic burden for firms that would have to determine that they did not exceed the reporting threshold. Since the production volume screen indicates that no reports would be filed for such chemicals, there would be no information provided to the public. EPA's position is that it is appropriate at this time to focus on chemicals for which reports are likely to be filed.

In addition to proposing to add HHCB to the EPCRA section 313 toxic chemical list, EPA proposed to add HHCB to the list of chemicals of special concern. There are several chemicals and chemical categories on the EPCRA section 313 chemical list that have been classified as chemicals of special concern because they are PBT chemicals (see 40 CFR 372.28(a)(2)). In a final rule published in the **Federal Register** of October 29, 1999 (64 FR 58666) (FRL–6389–11) (Ref. 7), EPA established the PBT classification criteria for chemicals on the EPCRA section 313 chemical list. For purposes of EPCRA section 313 reporting, EPA established persistence half-life criteria for PBT chemicals of 2 months in water, sediment and soil and 2 days in air, and established bioaccumulation criteria for PBT chemicals as a bioconcentration factor (BCF) or bioaccumulation factor (BAF) of 1,000 or higher. Most chemicals meeting the PBT criteria are assigned 100-pound reporting thresholds. EPA set lower reporting thresholds (10 pounds) for those PBT chemicals with persistence half-lives of 6 months or more in water, sediment, or soil and with BCF or BAF values of 5,000 or higher since these chemicals are considered highly PBT chemicals. The data presented in the hazard assessment for the proposed rule support classifying HHCB as a PBT chemical and designating it as a chemical of special concern with a 100-pound reporting threshold.

III. Summary of Comments Received and EPA Responses

EPA received 31 comments on the proposed rule. Twenty-one of the comments came from private citizens or anonymous commenters. Five comments were received from trade associations including, the American Chemistry Council (ACC) (Ref. 8), Alkylphenols & Ethoxylates Research Council (APERC) (Ref. 9), Fragrance Creators Association and American Cleaning Institute (Ref. 10), Fragrance Science & Advocacy Council (Ref. 11), and Household & Commercial Products Association (Ref. 12). Three comments were received from environmental/public interest groups including, CleanEarth4Kids.org (Ref. 13), Earthjustice (on behalf of Sierra Club, Toxic-Free Future, and Defend Our Health) (Ref. 14), and Silent Spring Institute (Ref. 15). Lastly, two comments were received from government organizations including, the Small Business Administration (Ref. 16) and TURI (Ref. 17). This unit provides summaries of some of the more significant comments and EPA's responses. A complete set of comments and EPA's detailed responses can be found in the Response to Comments (RTC) document that is available in the docket for this rulemaking (Ref. 18).

A. Comments Supporting EPA's Proposed Listing of 12 Chemicals

The 21 private citizens or anonymous commenters and the three commenters from environmental/public interest groups, CleanEarth4Kids.org (Ref. 13), Earthjustice (on behalf of Sierra Club, Toxic-Free Future, and Defend Our Health) (Ref. 14), and Silent Spring Institute (Ref. 15) all supported EPA's proposed addition of the 12 chemicals to the TRI list. Though, as discussed Unit III.E., certain commenters believe that EPA should have proposed the listing of some of the other chemicals included in the TURI petition.

B. Comments on Risk Evaluations Under TSCA Section 6

Comment: ACC (Ref. 8) and the Fragrance Creators Association and American Cleaning Institute (Ref. 10) commented that EPA should complete the risk evaluation being conducted for HHCB under TSCA section 6 before finalizing the proposed addition of HHCB to the TRI chemical list. ACC also stated that, as a matter of policy, EPA should defer from consideration the addition of any chemical to the TRI list that is undergoing a TSCA risk evaluation until that risk evaluation is completed.

EPA Response: TSCA section 6 (*i.e.,* the existing chemicals program) and EPCRA section 313 are two separate EPA programs operating under two separate statutory authorities with different purposes and criteria. EPA does not agree that it should wait until the TSCA section 6 risk evaluation has been completed for HHCB (or any other chemical) before adding HHCB (or any other chemical) to the TRI chemical list. The addition of chemicals to the TRI list is primarily based on an assessment of hazard (*i.e.,* not a risk assessment). The

TSCA section 6 risk evaluations go far beyond what is needed to list a chemical under EPCRA section 313(d)(2) and are for the purpose of determining if there is an unreasonable risk that needs to be mitigated. Moreover, under TSCA, EPA may take actions that could severely limit or even ban the use of a chemical because of unreasonable risk. In contrast, a decision to add a substance to TRI pursuant to EPCRA section 313 does not impose any restrictions on the use or manufacturing of that substance; it establishes requirements for the reporting of releases and other waste management information. In addition, information obtained through TRI can be very helpful to the risk evaluation process, as TRI data can provide information concerning releases and waste management activities.

C. Comments on p-(1,1,3,3-tetramethylbutyl)phenol (CASRN 140–66–9).

Comment: APERC (Ref. 9) commented that they support the addition of p-(1,1,3,3-tetramethylbutyl)phenol (TMBP) to the TRI list for the purpose of providing exposure data that could support future prioritization and risk evaluations of TMBP under TSCA. While supporting the addition of TMBP to the TRI list, APERC did object to some of the hazard characterizations that EPA presented in support of the listing of TMBP. APERC also stated that EPA proposed to list TMBP on the TRI based on it ecotoxicity and ''tendency to bioaccumulate.''

EPA Response: EPA has addressed in detail APERC's comments regarding bioaccumulation potential, toxicity data, and monitoring data in the RTC document (Ref. 18). However, EPA would like to clarify that TMBP meets the listing criteria based on ecological toxicity alone. As EPA stated in the proposed rule ''EPA believes that the evidence is sufficient to list p-(1,1,3,3-Tetramethylbutyl)phenol (TMBP) on the EPCRA section 313 toxic chemicals list pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical alone and also based on its toxicity and tendency to bioaccumulate'' (see 86 FR 57619) (Ref. 4). EPA clearly stated that TMBP meets the EPCRA section 313(d)(2)(C) criteria based on the ecotoxicity data alone (*i.e.,* ''. . . based on the available ecotoxicity information for this chemical alone . . .'') which is covered under section 313(d)(2)(C)(i). In addition, EPA stated that TMBP also meets the 313(d)(2)(C) criteria ''. . . based on ecotoxicity and bioaccumulation potential'' which is covered under section 313(d)(2)(C)(iii). EPA summarized the toxicity data as follows ''In summary, the available data demonstrate that TMBP can cause acute and chronic toxicity to aquatic organisms at low concentrations indicating that TMBP is highly toxic to aquatic organisms'' (see 86 FR 57619) (Ref. 4).

D. Comments on Data Supporting the Addition of HHCB and Its Addition to the List of Chemicals of Special Concern

Comment: The Fragrance Creators Association and American Cleaning Institute (Ref. 10), and the Fragrance Science & Advocacy Council (Ref. 11) provided comments on the toxicity, persistence, and bioaccumulation data for HHCB. The commenters contend that the data do not support classifying HHCB as a PBT chemical under the criteria established for EPCRA section 313. Both commenters provided or cited to additional information, some of it previously submitted for the TSCA risk evaluation process, that they said EPA should consider before finalizing the listing of HHCB.

EPA Response: As discussed in the RTC document (Ref. 18), EPA has reviewed the suggested information. Short summaries of some of their specific comments and EPA's responses are provided here, complete detailed comments and EPA responses can be found in the RTC document (Ref. 18).

E. Comments on HHCB Not Meeting the Persistence Criteria Established for EPCRA Section 313 for PBT Classification

Comment: The Fragrance Creators Association and American Cleaning Institute (Ref. 10) stated that in EPA's 2014 TSCA risk assessment (Ref. 19), EPA cited half-lives of HHCB in water for days to weeks which is below the TRI 2-month half-life criteria. The commenter noted that EPA cited half-lives for HHCB in sludge of 10–69 hours and that since the majority of release of HHCB are to wastewater treatment plants (WWTPs), removal during treatment and degradation in sludge is important. The commenter state that EPA cited a single study on the fate of HHCB in sediments that resulted in a half-life of 79 days (Ref. 20), which they contend may be artificially high due to the high concentration of the test material (Ref. 21). The commenter also cited sampling data that they said show low concentrations of HHCB in the environment (Ref. 22). The commenter stated that several studies found half-lives of HHCB in soils amended with biosolids (*i.e.,* sewage sludge) that ranged from 105 days to 144 days. The commenter stated that for at least one of the studies (Ref. 23), the soil was frozen for three months of the study and the concentrations of HHCB were stable (after one month, the concentrations of HHCB in the four soils were 30 to 90 percent of the initial concentration, and after 90 days, concentrations ranged from 8 to 60 percent of the initial concentration).

EPA Response: EPA's determination that HHCB meets the persistence portion of the PBT criteria and is thus a chemical of special concern was not based on half-lives of HHCB in water. The determination was based on the half-lives for HHCB in soil and sediment which are above the 60-day criteria. The International Flavors and Fragrances (IFF) has submitted a study from 1998 with CBI indicating that HHCB has a half-life of less than 1 year, but this study does not provide sufficient clarity to negate the 60-day window. Similarly, there is not sufficient evidence to support that the half-life of HHCB in river sediments is affected by concentration. Some researchers have published data depicting that the half-life may be impacted by sediment dwelling organisms (Refs. 24 and 25) as well sediment conditions (Ref. 26). However, more information is needed to understand how concentration might impact the half-life of HHCB in sediments. Regarding the data on environmental concentrations and treatment, these are not factors considered under the PBT criteria established for the TRI program (Refs. 7 and 27)). According to the commenter's reference 7 (Ref. 21) the European Union (EU) used a half-life of 79 days for sediment:

> Final conclusion for HHCB's fate in sediment: A limited documented study is present showing a DT50 of 79-days in a lab study at 22 °C but this is considered too high due to too high concentrations used (10 mg/kg soil). In addition, aquatic and soil studies indicate DT50s between 4 and 35-days and therefore this DT50 of 79-days is considered too conservative. In view of the too high concentration which will have limited the biodegradation and too high temperature which will have enhanced the biodegradation, the result of 79-days will be used for the risk assessment, without temperature correction: In conclusion:—The DT50 of 79 days at 12 °C will be used for the risk assessment. (Ref. 21)

EPA's 2014 risk assessment (Ref. 19) concluded the following regarding HHCB persistence in soil and sediment:

> Observed soil and sediment half-lives consistently exceeded 60 days (Table 2–6). Field measurements on biosolids-amended soil indicated that HHCB disappeared almost completely from soil within one year. The half-life based on unfrozen conditions in

biosolids-amended soil studies was around 140 to 144 days (DiFrancesco et al., 2004). The residues in soil after one year ranged from below 10 to 14 percent of the initial concentrations. In the EU RAR (EC, 2008), a half-life of 105 days in the biosolids-amended soil was deemed most relevant for modeling the fate of HHCB in soil using the European Union System for the Evaluation of Substances (EUSES) model, while 79 days was noted for the sediment (Envirogen, 1998; as cited in EC, 2008). EPA/OPPT agrees that these values are reasonable for modeling and assessment purposes. (Ref. 19, page 29)

EPA cited the same data in its assessment for listing under EPCRA section 313. These data exceed the persistence criteria of half-lives in soil or sediment of 60 days or longer under the PBT criteria established for the TRI program. Regarding biodegradation in sludge, in a wastewater environment, HHCB is expected to partition strongly to solid phases based on its high measured log K_{OW} (octanol-water partition coefficient) of 5.9 (see Rimkus, 1999 for a summary of values for musks (Ref. 28)) and the soil/sediment organic carbon partition coefficient (log Koc = 3.6–3.9; Ref. 29) which is supported by the estimated log K_{OC} of 4.1–4.3 (KOCWIN™ program v2.00; in EPI Suite™ v4.11, (Ref. 30)). In addition, Schaefer & Koper (2009) (Ref. 31) extrapolated an average Log Kow of 7.1 conferring more evidence for partitioning to solid phases. Values for both K_d (sorption coefficient) and K_{OC} (organic carbon-normalized sorption coefficient) are generally in the range of 3 to 4 on a logarithmic scale. This means that HHCB will be substantially removed by sorption to sludge in WWTPs; will have low mobility in soil; and will bind strongly to benthic and suspended sediment. In addition to this knowledge, the Office of Water has documented the presence of HHCB in sludge via the National Sewage Sludge Survey in 2005, 2007, 2009, and 2011 (Ref. 32).

The half-life of HHCB in activated sludge at concentrations of 5, 17.4, 25, 25 micrograms per liter (µg/L) has been reported as 69, 10–15, 21, 33 hours, respectively (Refs. 33, 34 and 35—33). HHCB disappearance with subsequent appearance of more polar entities was observed (Ref. 35). The geometric mean from these studies for activated sludge half-disappearance time was 22.5 hours. This corresponds to ''moderate-to-slow'' biodegradation in activated sludge; see guidance in the Estimation Programs Interface (EPI) Suite v4.11 (Ref. 30). Overall complete biodegradation rates have been reported as 15.39% ± 8.29% and a steady state average biodegradation of 12.74% ± 8.29% (Ref. 31); these rates also confer ''moderate-to-slow'' biodegradation rates.

Chen et al. (2014) (Ref. 36) evaluated the dissipation rate of HHCB among other personal care products in soils amended with biosolids (concentration = 2950 micrograms per kilogram (µg/kg)) after a single application and a repeated annual application at three different sites. The dissipation half-life was found to be 900 days for the single treatment and 83 days for an annual treatment. Yager et al. (2014) (Ref. 37) reported that HHCB had migrated down in soil profile and was still detectable 468 days after being amended with biosolids. Poulsen and Bester (2010) (Ref. 38) reported a shorter half-life ($t_{1/2}$ = 20 days) when HHCB was present at lower concentrations (1000 µg/kg) but in a high temperature compost environment with regular turning. As the commentor also notes: ''[. . . several studies found half-lives of HHCB in soils amended with biosolids (sewage sludge) ranging from 105 days to 144 days . . .].''

These results indicate that the half-life of HHCB in soil amended with biosolids or sludge is substantial and demonstrate the substance is persistent under these conditions.

The Fragrance Science & Advocacy Council (Ref. 11) also questioned the persistence data for HHCB and provided studies and references for EPA to consider.

Regarding the range of values identified for persistence in soils, EPA utilizes conservative values to account for a range of possible soil types and land management practices. As the commentor notes: FSAC has calculated half-lives from this study ranging 35–116 days depending on treatment and soil type, further supporting the USGS study.

Because the upper range of these half-lives exceeds the 60-day window, HHCB would still be considered persistent in this compartment. The commentors also note that the concentrations cited by EPA are too high and unrealistic pointing to a technical report submitted to EPA as CBI. Though the concentrations in the technical report are lower than those cited by EPA, the conclusions of that study do not negate that HHCB can persist in soils and biosolids amended soils for >60 days. The major conclusion of the report indicates that ''. . . HHCB has a half-life in soils and sediments significantly less than one year.'' This conclusion was determined by evaluating HHCB concentration in amended soils in microcosms after 365 days and does not provide any precision on the half-life of HHCB in a variety of soil conditions. Thus, the study does not refute the concentrations cited by EPA.

Regarding the review of studies presented in commenter's Appendix 2 of their comments, these studies are currently subject to OPPT's Systematic Review Protocol. The studies and their assigned Health and Environmental Research Online Identification numbers (HEROIDs) included: Litz et al. 2007: 100883141 (Ref. 39), DiFrancesco et al. 2004: 76939752 (Ref. 23), Yager et al. 2014: 23460273 (Ref. 37), Chen et al. 2014a: 54285094 (Ref. 40), Chen et al. 2014b: 54284935 (Ref. 36), and Yang & Metcalfe 2006: 54278926 (Ref. 41). Worth noting is that many of the values reported in these studies are considered high quality according to the commenter and these values also exceed the 60-day half-life criteria. EPA also notes that the DiFrancesco et al. study (Ref. 23) was cited in EPA's ecological hazard assessment for HHCB (Ref. 42).

EPA has concluded that none of the data provide by the commenters change EPA's determination that HHCB meets the persistence criteria established for evaluations under EPCRA section 313 (Refs. 7 and 27).

F. Comments on HHCB Not Meeting the Bioaccumulation Criteria Established for EPCRA Section 313 for PBT Classification

Comment: The Fragrance Creators Association and American Cleaning Institute (Ref. 10) stated that the proposed rule did not provide the complete story regarding the potential for HHCB to bioaccumulation. The commenters noted that in EPA's 2014 risk assessment (Ref. 19), EPA reported BCF and BAF data for several aquatic species that varied but were generally lower than the 1,000 bioaccumulation criteria. The commenters noted that EPA's assessment suggests that HHCB does not biomagnify. The commenters also stated that EPA's assessment notes that metabolism may account for the observation that measured BCFs and BAFs are lower than would be estimated based on the log K_{OW} of HHCB. The commenters cited data indicating that HHCB is metabolized and excreted without significant bioaccumulation. The commenters stated that as a result of this metabolism BCFs estimated using the EPA EPISuite model may not be accurate. The commenters cited EPA's 2014 risk assessment as evidence that EPA relied more on the available BAF values:

> HHCB is considered to be of low to moderate concern for bioaccumulation. BCF values of 1,584 for bluegills and 2,692 for Lumbriculus indicate moderate bioaccumulation potential. However, BAF

values are available for several aquatic organisms are in the range of 20 to 620, indicating low bioaccumulation. These studies, together with results of aquatic food-chain modeling (Arnot- Gobas model) and monitoring data for biota, suggest that HHCB is not subject to biomagnification.

EPA Response: The commenters provided no information or evidence that the BCF values greater than 1,000 reported in EPA's HHCB assessment (Ref. 42) are invalid. These reported values suggest significant bioaccumulation potential for at least some species and come from solid peer-reviewed studies (BCF: 2692, Artola-Garciano et al., 2003 (Ref. 43) and BCF: 1584, Balk & Ford, 1999b (Ref. 26)). Note: Both of these studies are cited in the OPPT 2014 risk assessment for HHCB (Ref. 19). HHCB meets the bioaccumulation criteria established for the TRI program (Refs. 7 and 27). In addition to studies reported in the 2014 Risk Evaluation (Ref. 19), numerous articles have been published by the science community demonstrating a substantially wider range of bioaccumulation values. Yao et al. 2018 (Ref. 44) reported bioaccumulation factors ranging from 52.5 to 46,773.5 for fish species exposed to 0–133 nanograms per liter (ng/L) of HHCB. Similarly, Reiner and Kannan (2011) (Ref. 45) reported BAF values for fish livers ranging from 261 to 2,897 when exposed to two different concentrations of HHCB in water and sediment. The upper range of these bioaccumulation factors further support that HHCB meets the bioaccumulation criteria.

As EPA has previously stated, in the October 29, 1999 **Federal Register** *Notice* biomagnification is not required to have a concern for biomagnification. (64 FR 58682–58683, October 29, 1999) (Ref. 7)

Comment: The Fragrance Science & Advocacy Council (Ref. 11) also questioned the bioaccumulation and biomagnification data for HHCB and provided studies and references for EPA to consider. The commenter contends that HHCB has low to moderate bioaccumulation potential, and low biomagnification potential. The commenter provided a report that they said they had submitted to EPA on behalf of the IFF as a member of the International Fragrance Association, entitled, ''Report on Bioaccumulation and Tropic Magnification Potential in the Aquatic Environment of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB).'' The commenter stated that the report contains information on the bioaccumulation and biomagnification potential of HHCB.

EPA Response: EPA has received the report submitted by IFF and assigned it the HEROID 10365931 (Ref. 46). The report included bioaccumulation values above the 1,000 criteria. For example, there is a BCF value of ~1,550 for Rainbow Trout in Appendix III. In addition to the IFF report provided by the commenter, IFF has submitted another study (Accumulation and Elimination of 14C–HHCB by Blue Gill Sunfish in a Dynamic Flow-Through System, OECD 305E, 1996 (Ref. 47)) indicating a BCF of 1,635 for whole fish exposed to 1 µg/L and a BCF of 1,613 for whole fish exposed to 10 µg/L (mean: 1,624 ± 16). Because the studies cited in the two reports provide bioaccumulation values >1,000, they further support EPA's conclusion that HHCB meets the bioaccumulation criteria established for the TRI program (Refs. 7 and 27)).

The biomagnification information/comments do not impact the conclusion regarding PBT status since the BCFs exceed the bioaccumulation criteria for TRI and as noted above, biomagnification is not part of the PBT criteria established for evaluations under EPCRA section 313 (Refs. 7 and 27).

G. Comments on HHCB Not Being Particularly Toxic

Comment: The Fragrance Creators Association and American Cleaning Institute (Ref. 10) stated that HHCB is not particularly toxic and ''does not exhibit any specific toxic mode of action that contributes to excess ecotoxicity.'' The commenters also stated that ''Moreover, HHCB is typically not found in the aquatic environment above the detection limit (0.04 µg/L), and when it is detected, it is generally less than 1 ug/L,[11] well below the EPA chronic concentration of concern (COC) of 9.7 ug/L established in the 2014 risk assessment.''

EPA Response: EPA does not limit its ecological toxicity criterion to a specific mode of action. For TRI listing purposes, chemicals with acute aquatic toxicity values at or below 1 milligram per liter (mg/L) are considered highly toxic. As discussed in EPA hazard assessment for HHCB, there are numerous acute aquatic toxicity values below 1 mg/L, which show that HHCB is highly toxic to aquatic organisms (Ref. 42). There are also chronic aquatic toxicity values below 0.1 mg/L which EPA also considers highly toxic (Ref. 42). In addition, the studies submitted to EPA following the 2014 risk assessment support this determination. There are no separate toxicity criteria for PBT chemicals. Regarding the presence of HHCB in aquatic environments, EPA does not consider potential exposures or environmental concentrations for chemicals that are highly toxic to aquatic organisms when determining if they meet the EPCRA section 313(d)(2)(C) listing criteria. EPA has explained in detail how it evaluates chemicals under the EPCRA section 313(d)(2) criteria (see 59 FR 61432, November 30, 1994 (FRL–4922–2) (Ref. 2)).

H. Comments on Chemicals EPA Declined To List

Comment: The commenters CleanEarth4Kids.org (Ref. 13), Earthjustice (on behalf of Sierra Club, Toxic-Free Future, and Defend Our Health) (Ref. 14), Silent Spring Institute (Ref. 15), and TURI (Ref. 17) contend that up to eight of the chemicals that EPA determined do not meet the EPCRA section 313(d)(2) listing criteria actually have data that support their listing. The chemicals in question include azodicarbonamide (123–77–3), 4-chlorobenzotrichloride (5216–25–1), dimethylacetamide (127–19–5), 2,3-dinitrotoluene (602–01–7), 2,5-dinitrotoluene (619–15–8), hexahydrophthalic anhydride (85–42–7), methylhexahydrophthalic anhydride (25550–51–0), and N-methylformamide (123–39–7).

EPA Response: EPA has addressed the specific comments on the toxicity of these chemicals in the RTC document (Ref. 18), some of the more general comments are summarized and responded to here.

I. Comments on Chemicals Found on Lists Prepared by the European Union (EU)

Comment: CleanEarth4Kids.org (Ref. 13) cited information on seven of the chemicals that included the listing of the chemicals on various lists prepared by the EU and/or classifications on such lists.

EPA Response: The commenter did not provide specific studies for EPA to consider but rather cited most of the same organizational determinations cited in the TURI petition as evidence that these chemicals met the EPCRA section 313(d)(2) listing criteria which EPA has already considered.

The fact that an organization has placed a chemical on a list (such as the European Commission: Candidate List of Substances of Very High Concern for Authorization) or made some determination as to its toxicity under their regulations or criteria does not necessarily mean that the chemical meets the EPCRA section 313(d)(2) listing criteria. Classifications such as

''Presumed Human Reproductive Toxicant'' are made under the criteria of another regulatory program and do not necessarily mean that there are data sufficient to establish that a chemical meets the EPRCA section 313(d)(2) criteria. As discussed in the RTC document, to the extent possible, EPA has reviewed the available data for such classifications and did not find sufficient information to support listing any additional chemicals. Some of these lists cite concerns for skin, eye and respiratory dangers which may indicate a concern for acute human health effects. For a chemical to be listed under EPCRA section 313(d)(2)(A) based on its acute human health effects, EPA would need to determine that the chemical ''can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.''

K. Comments on Misinterpreted or Inadequate Data

Comment: Earthjustice (Ref. 14) stated that EPA misinterpreted or ignored relevant health effects information, unlawfully concluded that there is inadequate evidence to support listing a chemical because of a lack of chronic animal toxicity studies and did not follow Congress's direction that EPA must also base its listing decisions on ''appropriately designed and conducted epidemiological or other population studies,'' ''laboratory tests'' and other analyses based on ''generally accepted scientific principles.'' The commenter stated that EPA cannot lawfully determine that inadequate evidence exists to support listing without rationally analyzing all of these sources for chemicals under review, including available case studies and analogue data, and utilizing read-across methodologies. The commenter stated that EPA failed to provide an adequate explanation of its proposed decision to deny part of the TURI Petition, as EPCRA requires. The commenter stated that the proposed rule includes only the conclusory assertion that ''EPA has determined that the available data for nine chemicals'' addressed in the TURI Petition ''are not sufficient for EPA to find that the chemicals meet the EPCRA section 313 listing criteria for human health or ecological effects.'' The commenter stated that the references cited in support of EPA's conclusions are technical summaries of the human and ecological toxicity studies reviewed by EPA staff, but that neither the memos nor the proposed rule explain why the evidence for each chemical is inadequate to establish that the chemical ''is known to cause or can reasonably be anticipated to cause'' chronic adverse health effects in humans or significant adverse effects on the environment.

EPA Response: EPA disagrees with the commenters assertions that EPA did not conduct an appropriate review of the toxicity for those chemicals that EPA did not propose to list or explain why the data were insufficient to support any of the EPCRA section 313(d)(2) criteria. Section 313(d)(2) of EPCRA provides that a chemical may be added [to the TRI] if the Administrator determines, in his judgment, that there is sufficient evidence to establish that the chemical is know to cause or can reasonably be anticipated to cause significant adverse acute human health effects or reasonably anticipated to cause adverse effects such as cancer, reproductive effects, neurological disorders, mutagenic effects, and other chronic illnesses EPA included memos (Refs. 5 and 6) in the docket for this rulemaking that addressed these chemicals and provided a summary of the available relevant toxicity data and a conclusion that such data were not sufficient to support listing the chemical under any of the EPCRA section 313(d)(2) criteria. In responding to the TURI petition, EPA conducted a thorough literature search for data relevant to the chemicals named in the petition and the criteria described in EPCRA section 313(d)(2).

In preparing its hazard assessment, EPA conducts a broad review of available data and determines which studies should be included in the assessment. For example, when reviewing the available toxicity data, EPA does not include in its hazard assessment studies that do not provide sufficient information to determine whether a chemical causes a toxic effect that meets the EPCRA section 313(d)(2) criteria. For example, occupational studies and case reports often do not provide sufficient data to determine the doses causing adverse effects, or whether other factors contributed to the observed effects. If available, epidemiological or other population studies can be considered, but often they may not contain sufficient information to determine whether a chemical meets the listing criteria.

In addition, for EPA to be able to rely on a given study, EPA must be able to determine whether the toxic effects observed in are acute or chronic health effects, as this distinction has a significant impact on the information required to support the addition of a chemical to the TRI. The EPCRA section 313(d)(2)(A) listing criteria for acute human health effects contains a requirement that potential exposures must be considered.

In order to list under the acute human health effects criteria, EPA must determine that the effects are significant adverse acute human health effects, the concentration levels that would be of concern, and releases are reasonably likely to exist beyond facility site boundaries that would result in concentration levels of concern. If it is unclear from the available data whether the observed effects are acute or chronic (*e.g.,* epidemiological or occupational studies that lack sufficient details), then EPA may not be able to use the data to support listing.

EPCRA section 313(d) provides that the Administrator may add a chemical to the subsection (c) list at any time if the Administrator determines, in their judgment, that there is sufficient evidence to establish the criteria in EPCRA section 313(d)(2)(A), (B), or (C). The statute thus gives the Administrator discretion to determine what constitutes sufficient evidence to demonstrate these criteria have been met. It further states that such determinations shall be based on ''generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies available to the Administrator'' (emphasis added). The use of the word ''or'' in section 313(d)(2) establishes that a determination could be made on just one of the identified types of data/information. Moreover, the fact that a study on a particular chemical exists, does not mean that it contains information relevant to a listing determination. To list a chemical under the criteria of EPCRA section 313(d)(2)(A) or (B) for human health effects the statutory language requires that EPA be able to support a conclusion that ''The chemical is known to cause or can reasonably be anticipated to cause in humans'' significant adverse acute human health effects or at least one of the listed chronic human health effects. The Agency must determine which studies and data are relevant and evaluate their scientific merits. If EPA determines that a given study does not include sufficient information, for example on whether the effects considered are chronic or acute, the doses causing the effects, the severity of the effects or whether other chemicals were also present, it may determine that further evaluation of the study is not warranted.

EPCRA section 313(e), in turn, governs the scope of the Agency's

obligation to respond to petitions to add or delete a chemical from the TRI. Specifically, it provides that the Administrator shall take one of the following actions in response to a petition to add or delete a chemical from the list: (A) Initiate a rulemaking to add or delete the chemical to the list, in accordance with subsection (d)(2) or (d)(3); or (B) Publish an explanation of why the petition is denied.

EPA stated in the proposed rule that the available data for the chemicals not being listed was not sufficient for EPA to find that the chemicals met the EPCRA section 313 listing criteria for human health or ecological effects. It further stated that it was therefore not proposing to add those chemicals to the TRI. EPA also added two memos (Refs. 5 and 6) to the docket providing additional information regarding its review of the chemicals identified in the TURI petition that EPA was not proposing to add to the TRI. Those memos supported EPA's decision not to propose adding 9 of the chemicals to the TRI. Further support and rationale for EPA's decision is provided the RTC document (Ref. 18).

It is important to note that the petitioner requested the addition of 6 chemicals based on the EPCRA section 313(d)(2)(C) criteria. However, the explicit language of EPCRA section 313(e)(1) only allows any person to ''petition the Administrator to add or delete a chemical from [the TRI] on the basis of the criteria in subparagraph (A) or (B) of subsection (d)(2).'' In other words, it allows any person to request that a chemical be added or deleted from the TRI list only on the basis of the human health criteria in EPCRA section 313(d)(2)(A) and (B). EPCRA does not provide an avenue for petitions to add chemicals to TRI based on the criteria in subsection (d)(2)(C). The petitioners' request to add certain chemicals to the TRI list based on them meeting the criteria in paragraph (d)(2)(C) was an impermissible request. Nevertheless, to thoroughly assess the overall merits of listing these chemicals, EPA conducted an analysis of the available toxicity data and proposed to add four of the chemicals to the TRI. EPA determined that it was not appropriate to propose adding the other two of these chemicals cyclododecane and 2,3-dinitrotoluene to the TRI.

EPA has reviewed the information provided by the commenters with regard to the five specific chemicals for which commenters assert EPA ignored evidence regarding chronic human health effects that would justify their addition to TRI and with regard to the three chemicals for which commenters assert EPA ignored evidence of mutagenic effects. As discussed in detail in the RTC document (Ref. 18), EPA concludes that based on currently available data none of the eight chemicals addressed by the commenter meet the EPCRA section 313(d)(2) listing criteria.

L. Comments on Other Factors To Consider for Listing Decisions

In addition to Earthjustice (Ref. 14), TURI (Ref. 17) suggested that other factors or criteria may be useful and appropriate to consider for listing decisions. The commenter suggested that while toxicity data are lacking for certain chemicals, substantial information can be gained by considering analogs and that using read-across data may be an appropriate approach in these cases. The commenter stated that in addition, it essential to take account of information available from case reports, epidemiological studies, and mechanistic data, even when chronic animal studies are unavailable.

EPA Response: EPA agrees that using analogs and read-across data can be useful but in order to do that information about what structural features are important to the toxicity need to be understood. Just because two chemicals have similar structures does not always mean they will have similar toxic endpoints at similar doses. EPA also agrees that case reports, epidemiological studies, and mechanistic data can provide useful information about potential toxicity, however, under the EPCRA section 313(d)(2)(B) listing criteria that data must be sufficient to conclude that ''The chemical is known to cause or can reasonably be anticipated to cause in humans'' chronic human health effects. In addition, as EPA has previously explained and cited in the proposed rule (Ref. 2), in making determinations under EPCRA section 313(d)(2) EPA considers the severity of the effects and the dose/concentration at which the effects occur. Case reports, epidemiological studies, and mechanistic data don't always provide sufficient information to reach a conclusion about a chemical's acute or chronic human health effects.

M. Comments on EPA's Economic Analysis

The commenters Household & Commercial Products Association (Ref. 12); Fragrance Creators Association and American Cleaning Institute (Ref. 10); and U.S. Small Business Administration Office of Advocacy (Ref. 16) provided comments on EPA's economic analysis for the proposed rule. The commenters suggested that EPA's economic analysis for the proposed rule underestimated the impacts that would result from lowering the reporting threshold for HHCB. These commenters requested that EPA revise its economic analysis based on more recent data including the 2020 Chemical Data Reporting (CDR) rule (Ref. 48), the Final Lists of Manufacturers Subject to Fees for the 20 High Priority Substances Undergoing TSCA Risk Evaluations (Ref. 49) and the Site Emission Survey of Fragrance Formulation Compounders and Product Manufacturers Using HHCB Information to Support the TSCA Risk Evaluation (Ref. 50).

EPA Response: When developing the economic analysis for this final rule (Ref. 3), EPA reviewed currently available data on HHCB manufacture and import, including the sources identified by the commenters, to determine if and how to update the economic analysis to provide the best estimates of reporters and reporting burden for HHCB. Specifically, EPA reviewed the 2020 CDR data (Ref. 48), the Final Lists of Manufacturers Subject to Fees for the 20 High Priority Substances Undergoing TSCA Risk Evaluations (Ref. 49) and the Site Emission Survey of Fragrance Formulation Compounders and Product Manufacturers Using HHCB Information to Support the TSCA Risk Evaluation (Ref. 50). In addition, EPA updated wage rates to 2021 dollars to better estimate costs of reporting.

With respect to the CDR data, EPA did not find that the data were significantly different from the previous 2016 CDR data to warrant any update as the impact on the estimates made by EPA would be inconsequential. Overall production of HHCB remained the same and most of the importers (no companies reported domestic production of HHCB under either the 2016 or 2020 CDR reporting) remained the same. In fact, fewer importers reported to CDR in 2020 than did in 2016. Similarly, numbers of downstream processers and users, which form the basis for EPA's estimates of numbers of reporters and reports for the final rule, were largely the same although the identity of some importers differed.

EPA also reviewed information from the final list of HHCB manufacturers (including importers) responsible for payment of fees under TSCA and included additional HHCB facilities in its estimates of facilities that would report under this final rule as a result. This resulted in six additional reporters because the companies had either been

previously identified by the economic analysis for the proposed rule (Ref. 51) or are operating in NAICS codes that are not subject to TRI reporting.

Finally, EPA also reviewed the Site Emission Survey of Fragrance Formulation Compounders and Product Manufacturers Using HHCB Information to Support the TSCA Risk Evaluation prepared for the Fragrance Creators' Association. As the commenter notes, one of the respondents to the survey indicated that downstream processors and users was in excess of 500. EPA did not find that the results of the survey itself were useful in estimating exact numbers of downstream users and formulators. Many respondents failed to provide an estimate of downstream users and processors, and it is not possible to determine if the respondents also reported under CDR, which is the main data source for the economic analysis. However, EPA did interpret the data as indicative of more potential reporters of HHCB than estimated in the economic analysis for the proposed rule and made adjustments in the economic analysis for the final rule to increase the estimated number of reporters of HHCB from 237 facilities to 1,072 (Ref. 3).

IV. Summary of the Final Rule

EPA is finalizing the addition of 12 chemicals to the EPCRA section 313 list of toxic chemicals. Based on EPA's review of the available toxicity data, EPA has determined that the 12 chemicals can reasonably be anticipated to cause either adverse chronic human health effects at moderately low to low doses and/or environmental effects at low concentrations. EPA has determined that the data show that these 12 chemicals have moderately high to high human health toxicity and/or are highly toxic to aquatic organisms. Therefore, EPA has determined that the evidence is sufficient for listing the 12 chemicals on the EPCRA section 313 toxic chemicals list pursuant to EPCRA section 313(d)(2)(B) and/or (C). The 12 chemicals EPA is adding to the EPCRA section 313 chemical list are listed here by name and CASRN.

- Dibutyltin dichloride; 683–18–1;
- 1,3-Dichloro-2-propanol; 96–23–1;
- Formamide; 75–12–7;
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran; 1222–05–5;
- N-Hydroxyethylethylenediamine; 111–41–1;
- Nitrilotriacetic acid trisodium salt; 5064–31–3;
- p-(1,1,3,3-Tetramethylbutyl)phenol; 140–66–9;
- 1,2,3-Trichlorobenzene; 87–61–6;
- Triglycidyl isocyanurate; 2451–62–9;
- Tris(2-chloroethyl) phosphate; 115–96–8;
- Tris(1,3-dichloro-2-propyl) phosphate; 13674–87–8; and
- Tris(dimethylphenol) phosphate; 25155–23–1.

In addition, EPA has determined that the available bioaccumulation and persistence data for HHCB support a classification of HHCB as a PBT chemical. Therefore, consistent with EPA's established policy for PBT chemicals (see Ref. 7), EPA is establishing a 100-pound reporting threshold for HHCB and including it under 40 CFR 372.28 Lower thresholds for chemicals of special concern.

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, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Petition from the Massachusetts Toxics Use Reduction Institute (TURI), University of Massachusetts Lowell, 600 Suffolk St., Suite 501, Lowell, MA 01854, May 6, 2014.
2. UESPA. Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know. **Federal Register**. 59 FR 61432, November 30, 1994 (FRL–4922–2).
3. USEPA. 2022. Economic Analysis Addendum for the Final Rule to Add Twelve Chemicals Identified in a Petition from the Toxics Use Reduction Institute to the EPCRA Section 313 List of Toxic Chemicals. August 19.
4. USEPA. Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting. **Federal Register**. 86 FR 57614, October 18, 2021 (FRL–5927–03–OCSPP).
5. USEPA, OPPT. Memorandum from Jocelyn Hospital, Toxicologist, Regulatory Development Branch to David Turk, Chief, Regulatory Development Branch. Subject: Review of Toxics Use Reduction Institute (TURI) Petition Chemicals. December 8, 2016.
6. USEPA, OPPT. Memorandum from Kara Koehrn and Thomas Forbes, Regulatory Development Branch, to David Turk, Chief, Regulatory Development Branch. Subject: Review of Toxics Use Reduction Institute (TURI) Petition Chemicals. February 16, 2017.
7. UESPA. Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting. **Federal Register**. 64 FR 58666, October 29, 1999 (FRL–6389–11).
8. American Chemistry Council. Comments on Proposed Rule: Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting (Docket ID EPA–HQ–TRI–2017–0434). December 17, 2021.
9. Alkylphenols & Ethoxylates Research Council. Comments on US EPA Proposed Rule for Addition of Certain Chemicals To Community Right-to-Know Toxic Chemical Release Reporting List under Section 313 of the Emergency Planning and Community Right-to-Know Act Submitted to Docket ID No. EP–HQ–TRI–2017–0434. December 17, 2021.
10. Fragrance Creators Association and the American Cleaning Institute. Comments on the Proposed Addition of HHCB to the Toxics Release Inventory, EPA–HQ–TRI–2017–0434. December 17, 2021.
11. Fragrance Science & Advocacy Council. Comments on the classification of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB) as a persistent, bioaccumulative, and toxic (PBT) chemical and as a chemical of special concern. December 17, 2021.
12. Household & Commercial Products Association. Comments on the Designation of HHCB as a Chemical of Special Concern as part of Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting (EPA–HQ–TRI–2017–0434). December 17, 2021.
13. CleanEarth4Kids.org. Comments on EPA Toxics Release Inventory Program. December 16, 2021.
14. Earthjustice on behalf of the Sierra Club, Toxic-Free Future, and Defend Our Health. Comments on Proposed Rule, Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting, 86, Fed. Reg 57,614 (Oct 18, 2021), EPA–HQ–TRI–2017–0434. December 17, 2021.
15. Silent Spring Institute. Comments on the Community Right-to-Know Toxic Chemical Release Reporting: Addition of Certain Chemicals as Proposed by the EPA on October 18th, 2021. December 15, 2021.
16. U.S. Small Business Administration, Office of Advocacy. Comments on Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting (Docket ID No. EPA–HQ–TRI–2017–0434). December 17, 2021.
17. Massachusetts Toxics Use Reduction Institute. Comments in response to EPA's proposed rule to add 12 of the 25 chemicals that TURI earlier petitioned the EPA to add to EPCRA section 313. University of Massachusetts Lowell. The Offices at Boott Mills West 126 John Street, Suite 14, Lowell, MA 01852. December 17, 2021.
18. USEPA, OPPT. 2022. Response to Comments Received on the October 18, 2021, Proposed Rule (86 FR 57614): Addition of Certain Chemicals;

Community Right-to-Know Toxic Chemical Release Reporting (*i.e.,* EPA's Response to the Toxics Use Reduction Institute (TURI) Petition). November 2022.
19. USEPA. TSCA Work Plan Chemical Risk Assessment, HHCB, 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-g-2-Benzopyran, CASRN: 1222–05–5. 2014.
20. Envirogen. 1998. Fate of HHCB in Soil Microcosms. Envirogen, Inc. Princeton Research Centre, report submitted to International Flavors and Fragrances, Lawrenceville, NJ (as cited in Ref. 25).
21. European Chemical Agency. 2022. Biodegradation in water and sediment: simulation tests. Registration Dossier for 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran EC number: 214–946–9, CAS number: 1222–05–5. Available at: *https://echa.europa.eu/registration-dossier/-/registered-dossier/14504/5/3/3.*
22. Integral Consulting Inc. Analysis of Monitoring Data for HHCB in Sediment of the United States from 2006 to 2019. December 6, 2021. Available at: *https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0430-0047*.
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VI. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-*

regulations/laws-and-executive-orders#influence.

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

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

B. Paperwork Reduction Act (PRA)

This action does not contain any new information collection requirements that require additional approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2070–0212 and 2050–0078.

Currently, the facilities subject to the reporting requirements under EPCRA section 313 and PPA section 6607 may use either EPA Toxic Chemicals Release Inventory Form R (EPA Form 9350–1), or EPA Toxic Chemicals Release Inventory Form A (EPA Form 9350–2), as appropriate under 40 CFR part 372. OMB has approved the reporting and recordkeeping requirements related to Forms A and R, supplier notification, and petitions under OMB Control No. 2070–0212 (EPA Information Collection Request (ICR) No. 2613), which includes an estimated burden of 35.7 hours for submitters of Form R and 21.9 hours for submitters of Form A, and those related to trade secret designations under OMB Control No. 2050–0078 (EPA ICR No. 1428), which includes an estimated average burden of 9.7 hours per response. EPA estimates that this action would result in an additional 1,342 reports being filed annually, and that the costs of this action will be approximately $6,660,633 in the first year of reporting and approximately $3,172,080 in the subsequent years. See Unit I.E. and Ref. 3.

Under the PRA, 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 are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are small businesses (*i.e.,* manufacturing facilities); no small governments or small organizations are expected to be affected by this action. The Agency has determined that of the 1,322 entities estimated to be impacted by this action, 1,283 are small entities. All 1,283 small entities affected by this action are estimated to incur annualized cost impacts of less than 1%. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities. A more detailed analysis of the impacts on small entities is located in EPA's economic analysis (Ref. 3).

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. This action is not subject to the requirements of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. EPA did not identify any small governments that would be impacted by this action. EPA's economic analysis indicates that the total cost of this action is estimated to be $6,660,633 in the first year of reporting (Ref. 3).

E. Executive Order 13132: Federalism

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

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

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

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866 and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

I. National Technology Transfer and Advancement Act (NTTAA)

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

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color) and low-income populations.

Though this action does not address human health or environmental conditions, it does increase access to information available to the public (including to minority and low-income populations) and improves transparency of how certain facilities are managing EPCRA section 313 toxic chemicals. Reporting forms submitted pursuant to TRI reporting requirements provide information on releases and other waste management activities conducted by the reporting facilities. By requiring

reporting on these additional chemicals, this action will be providing communities across the U.S. (including minority and low-income populations) with access to data which they may use to assess potential exposure to these additional chemicals and seek to lower exposures and consequently reductions in potential chemical risks. This information can also be used by government agencies and others to identify potential risks, set priorities, and take appropriate steps to reduce potential risks to human health and the environment. Therefore, EPA believes that this action will have not have a disproportionately high and adverse human health or environmental effect on minority populations, low-income populations, and indigenous peoples. To the contrary, EPA believes that this action will provide utility in the assessment of potential impacts on minority populations (people of color) and low-income populations.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: November 22, 2022.

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 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW—[AMENDED]

■ 1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

■ 2. In § 372.28, amend the table in paragraph (a)(1) by revising the column headings and adding, in alphabetical oder, the chemical ''1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran'' to read as follows:

§ 372.28 Lower thresholds for chemicals of special concern.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Chemical name	CAS No.	Reporting threshold (in pounds)
* * * * * * *		
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran	1222–05–5	100
* * * * * * *		

* * * * *

■ 3. Amend § 372.65 by:

■ a. In paragraph (a), in table 1, adding in alphabetical order entries for ''Dibutyltin dichloride,'' ''1,3-Dichloro-2-propanol,'' ''Formamide,'' ''1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran,'' ''N-Hydroxyethylethylenediamine,'' ''Nitrilotriacetic acid trisodium salt,'' ''p-(1,1,3,3-Tetramethylbutyl)phenol,'' ''1,2,3-Trichlorobenzene,'' ''Triglycidyl isocyanurate,'' ''Tris(2-chloroethyl) phosphate,'' ''Tris(1,3-dichloro-2-propyl) phosphate,'' and ''Tris(dimethylphenol) phosphate''; and

■ b. In paragraph (b), in table 2, adding in numerical order entries for ''75–12–7,'' ''87–61–6,'' ''96–23–1,'' ''111–41–1,'' ''115–96–8,'' ''140–66–9,'' ''683–18–1,'' ''1222–05–5,'' ''2451–62–9,'' ''5064–31–3,'' ''13674–87–8,'' and ''25155–23–1''.

The additions read as follows:

§ 372.65 Chemicals and chemical categories to which this part applies.

* * * * *

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Chemical name	CAS No.	Effective date
* * * * * * *		
Dibutyltin dichloride	683–18–1	1/1/23
* * * * * * *		
1,3-Dichloro-2-propanol	96–23–1	1/1/23
* * * * * * *		
Formamide	75–12–7	1/1/23
* * * * * * *		
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran	1222–05–5	1/1/23
* * * * * * *		
N-Hydroxyethylethylenediamine	111–41–1	1/1/23
* * * * * * *		
Nitrilotriacetic acid trisodium salt	5064–31–3	1/1/23

TABLE 1 TO PARAGRAPH (a)—Continued

Chemical name	CAS No.	Effective date
* * * * * * *		
p-(1,1,3,3-Tetramethylbutyl)phenol	140–66–9	1/1/23
* * * * * * *		
1,2,3-Trichlorobenzene	87–61–6	1/1/23
* * * * * * *		
Triglycidyl isocyanurate	2451–62–9	1/1/23
* * * * * * *		
Tris(2-chloroethyl) phosphate	115–96–8	1/1/23
* * * * * * *		
Tris(1,3-dichloro-2-propyl) phosphate	13674–87–8	1/1/23
* * * * * * *		
Tris(dimethylphenol) phosphate	25155–23–1	1/1/23
* * * * * * *		

(b) * * *

TABLE 2 TO PARAGRAPH (b)

CAS No.	Chemical name	Effective date
* * * * * * *		
75–12–7	Formamide	1/1/23
* * * * * * *		
87–61–6	1,2,3-Trichlorobenzene	1/1/23
* * * * * * *		
96–23–1	1,3-Dichloro-2-propanol	1/1/23
* * * * * * *		
111–41–1	N-Hydroxyethylethylenediamine	1/1/23
* * * * * * *		
115–96–8	Tris(2-chloroethyl) phosphate	1/1/23
* * * * * * *		
140–66–9	p-(1,1,3,3-Tetramethylbutyl)phenol	1/1/23
* * * * * * *		
683–18–1	Dibutyltin dichloride	1/1/23
* * * * * * *		
1222–05–5	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran	1/1/23
* * * * * * *		
2451–62–9	Triglycidyl isocyanurate	1/1/23
* * * * * * *		
5064–31–3	Nitrilotriacetic acid trisodium salt	1/1/23
* * * * * * *		
13674–87–8	Tris(1,3-dichloro-2-propyl) phosphate	1/1/23
* * * * * * *		
25155–23–1	Tris(dimethylphenol) phosphate	1/1/23
* * * * * * *		

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BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R3–ES–2021–0140; FF09E21000 FXES1111090FEDR 234]

RIN 1018–BG14

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Northern Long-Eared Bat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), reclassify the northern long-eared bat (*Myotis septentrionalis*), a bat species found in all or portions of 37 U.S. States, the District of Columbia, and much of Canada, as an endangered species under the Endangered Species Act of 1973, as amended (Act). Our review of the best available scientific and commercial information indicates that the northern long-eared bat meets the Act's definition of an endangered species. Because we are reclassifying the northern long-eared bat from a threatened to an endangered species, we are amending this species' listing on the List of Endangered and Threatened Wildlife to reflect its endangered species status and removing its species-specific rule issued under section 4(d) of the Act.

DATES: This rule is effective January 30, 2023.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov.* Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *https://www.regulations.gov* at Docket No. FWS–R3–ES–2021–0140.

FOR FURTHER INFORMATION CONTACT: Shauna Marquardt, Field Supervisor, U.S. Fish and Wildlife Service, Minnesota Wisconsin Ecological Services Field Office, 4101 American Boulevard East, Bloomington, MN 55425; telephone 952–252–0092. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered within the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species promptly and designate the species' critical habitat to the maximum extent prudent and determinable. In 2015, we listed the northern long-eared bat as a threatened species under the Act, but we have since determined that the northern long-eared bat meets the Act's definition of an endangered species; therefore, we are reclassifying the species as an endangered species. We published a not-prudent determination for critical habitat for the northern long-eared bat on April 27, 2016 (81 FR 24707). Listing a species as an endangered or threatened species can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. This rule reclassifies the northern long-eared bat (*Myotis septentrionalis*) from a threatened species to an endangered species under the Endangered Species Act (Act). It also removes the northern long-eared bat's species-specific rule issued under section 4(d) of the Act, because such rules apply only to species listed as threatened species under the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the foremost stressor impacting the northern long-eared bat is white nose syndrome (WNS; Factor C).

Previous Federal Actions

Please refer to the proposed rule to reclassify the northern long-eared bat as an endangered species (87 FR 16442; March 23, 2022) for a detailed description of previous Federal actions concerning this species.

Peer Review

A species status assessment (SSA) team prepared an SSA report for the northern long-eared bat. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we solicited independent scientific review of the information contained in the SSA report. As discussed in the proposed rule, we sent the SSA report to five independent peer reviewers and received three responses. The peer reviews can be found at *https://regulations.gov* Docket No. FWS–R3–ES–2021–0140. In preparing the proposed rule, we incorporated the results of these reviews, as appropriate, into the SSA report, which was the foundation for the proposed rule and this final rule.

Summary of Changes From the Proposed Rule

To comply with the January 4, 2012, Office of Management and Budget (OMB) memo title, *Clarifying Regulatory Requirements: Executive Summaries* and the Department of the Interior's Departmental Handbook on Preparing **Federal Register** Documents, we added an executive summary to this rule.

During the public comment period, we received comments from several public commenters and one State commenter expressing concerns that the Service was not able to identify actions that would not likely result in a violation of section 9 of the Act (16 U.S.C. 1531 *et seq.*). After evaluating all the information we received during the public comment period and other available information, we created a list of actions that are not likely to result in a violation of section 9 of the Act, if these activities are carried out in accordance with existing regulations and permit requirements. The provided list is not comprehensive and does not absolve any individual or organization from legal liability if a northern long-eared bat is taken. Although we have determined take is unlikely, any take resulting from the actions listed below