ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[OPPTS–400132C; FRL–6389–11]

RIN 2070–AD09

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is lowering the reporting thresholds for certain persistent bioaccumulative toxic (PBT) chemicals that are subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act of 1990 (PPA). EPA is also adding a category of dioxin and dioxin-like compounds to the EPCRA section 313 list of toxic chemicals and establishing a 0.1 gram reporting threshold for the category. In addition, EPA is adding certain other PBT chemicals to the EPCRA section 313 list of toxic chemicals and establishing lower reporting thresholds for these chemicals. EPA is removing the fume or dust qualifier from vanadium and adding all forms of vanadium with the exception of vanadium when contained in alloys. EPA is also adding vanadium compounds to the EPCRA section 313 list of toxic chemicals. However, EPA is not lowering the reporting thresholds for either vanadium or vanadium compounds. EPA is taking these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds and pursuant to its authority to add chemicals and chemical categories that meet the EPCRA section 313(d)(2) toxicity criteria. The additions of these chemicals are based on their carcinogenicity or other chronic human health effects and/or their significant adverse effects on the environment. Today's actions also include modifications to certain reporting exemptions and requirements for those toxic chemicals that are subject to the lower reporting thresholds. This document also announces the effective date of § 372.27 of the Code of Federal Regulations, which contained information collection requirements and which was originally published in the **Federal Register** on November 30, 1994.

DATES: 40 CFR 372.27 became effective on March 17, 1995, when the Office of Management and Budget approved its information collection requirements. This rule shall take effect on December 31, 1999. For purposes of EPCRA section 313(d)(4), the chemical additions shall be considered made as of November 30, 1999, and shall apply for the reporting year beginning January 1, 2000.

FOR FURTHER INFORMATION CONTACT: For technical information on this final rule contact: Daniel R. Bushman, Petitions Coordinator, Environmental Protection Agency, Mail Code 7408, 401 M St., SW., Washington, DC 20460; telephone number 202–260–3882, e-mail address: bushman.daniel@epa.gov. For general information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Hotline, Environmental Protection Agency, Mail Code 5101, 401 M St., SW., Washington, DC 20460, Toll free: 1–800–535–0202, in Virginia and Alaska: 703–412–9877 or Toll free TDD: 1–800–553–7672.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you manufacture, process, or otherwise use aldrin, chlordane, dioxin and certain dioxin-like compounds, heptachlor, hexachlorobenzene, isodrin, mercury, mercury compounds, methoxychlor, octachlorostyrene, pendimethalin, pentachlorobenzene, polychlorinated biphenyls, certain polycyclic aromatic compounds, tetrabromobisphenol A, toxaphene, trifluralin, and vanadium (except alloys) or vanadium compounds. See Table 1 in Unit V.C. for a more detailed listing. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Industry	SIC major group codes 10 (except 1011, 1081, and 1094), 12 (except 1241), or 20 through 39; industry codes 4911 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); 4931 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. section 6921 *et seq.*), or 5169, or 5171, or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis)
Federal Government	Federal facilities

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. 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 in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information or Copies of this Document or Other Support Documents?

1. *Electronically*. You may obtain electronic copies of this document from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–400132. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and any other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the

documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

II. Statutory Authority

EPA is finalizing these actions under sections 313(d)(1) and (2), 313(f)(2), 313(g), 313(h), and 328 of EPCRA, 42 U.S.C. 11023(d)(1)-(2), 11023(f)(2), 11023(g), 11023(h) and 11048; PPA section 6607, 42 U.S.C. 13106.

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using a listed toxic chemical in amounts above reporting threshold levels, to report certain facility specific information about such chemicals, including the annual quantity entering each environmental medium. These reports must be filed by July 1 of each year for the previous calendar year. Such facilities also must report pollution prevention and recycling data for these chemicals, pursuant to section 6607 of PPA.

A. What is the Authority for the Addition of Chemicals?

Section 313 established an initial list of toxic chemicals comprised of more than 300 chemicals and 20 chemical categories. Section 313(d) authorizes EPA to add or delete chemicals from the list, and sets forth criteria for these actions. EPA has added and deleted chemicals from the original statutory list on the basis of the criteria in subparagraph (A), (B) and/or (C) of subsection (d)(2) of EPCRA section 313. Under section 313(e)(1), any person may petition EPA to add chemicals to, or delete chemicals from, the list on the grounds that it does or does not meet the criteria at 313(d)(2)(A) or (B). Pursuant to EPCRA section 313(e)(1), EPA must respond to petitions within 180 days, either by initiating a rulemaking or by publishing an explanation of why the petition is denied. EPCRA section 313(d)(2) states that a chemical may be added to the list if any of the three listing criteria set forth there are met. Therefore, in order to add a chemical, EPA must find that at least one criterion is met, but does not need to examine whether all other criteria are also met. EPA has published a statement elaborating its interpretation of the section 313(d)(2) and (3) criteria for adding and deleting chemicals from the section 313 list (at 59 FR 61432, November 30, 1994) (FRL–4922–2).

B. What is the Authority for the Lowering of Reporting Thresholds?

EPA is finalizing these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds. EPCRA section 313 establishes default reporting thresholds, which are set forth in section 313(f)(1). Section 313(f)(2), however, provides that EPA:

> may establish a threshold amount for a toxic chemical different from the amount established by paragraph (1). Such revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of this section. The amounts established by EPA may, at the Administrator's discretion, be based on classes of chemicals or categories of facilities.

This provision provides EPA with broad, but not unlimited, authority to establish thresholds for particular chemicals, classes of chemicals, or categories of facilities, and commits to EPA's discretion the determination that a different threshold is warranted. Congress also committed the determination of the levels at which to establish any alternate thresholds to EPA's discretion, requiring only that any ''revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements'' of section 313. 42 U.S.C. 11023(f)(2).

For purposes of determining what constitutes a ''substantial majority of total releases,'' EPA interprets the language in section 313(f)(2), ''facilities subject to the requirements of [section 313],'' to refer to those facilities that fall within the category of facilities described by sections 313(a) and (b), i.e., the facilities currently reporting. Subsection (a) lays out the general requirement that ''the owner or operator of facilities subject to the requirements of this section shall'' file a report under EPCRA section 313. Subsection (b) then defines the facilities subject to the requirements of this section:

> [t]he requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20-39, . . . and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) of this section in excess of the quantity of that toxic chemical established under subsection (f) of this section during the calendar year for which a toxic chemical release form is required under this section.

Thus, in revising the reporting thresholds, EPA must ensure that, under the new thresholds, a substantial majority of releases currently being reported will continue to be reported. No further prerequisites for exercising this authority appears in the statute.

C. What is the Authority for Modifications to Other EPCRA Section 313 Reporting Requirements?

Today's actions also include modifications to certain reporting exemptions and requirements for those toxic chemicals that are subject to the lower reporting thresholds. Congress granted EPA rulemaking authority to allow the Agency to fully implement the statute. EPCRA section 328 provides that the ''Administrator may prescribe such regulations as may be necessary to carry out this chapter'' (28 U.S.C. 11048).

III. Background Information

A. What is the General Background for this Action?

Under EPCRA section 313, Congress set the initial parameters of the Toxic Release Inventory, but also gave EPA clear authority to modify reporting in various ways, including authority to change the toxic chemicals subject to reporting, the facilities required to report, and the threshold quantities that trigger reporting. By providing this authority, Congress recognized that the TRI program would need to evolve to meet the needs of a better informed public and to refine existing information. EPA has, therefore, undertaken a number of actions to expand and enhance TRI. These actions include expanding the number of reportable toxic chemicals by adding 286 toxic chemicals and chemical categories to the EPCRA section 313 list in 1994. Further, a new category of facilities was added to EPCRA section 313 on August 3, 1993, through Executive Order 12856, which requires Federal facilities meeting threshold requirements to file annual EPCRA section 313 reports. In addition, in 1997 EPA expanded the number of private sector facilities that are required to report under EPCRA section 313 by adding seven new industrial groups to the list of covered facilities. At the same time, EPA has sought to reduce the burden of EPCRA section 313 reporting by actions such as delisting chemicals it has determined do not meet the statutory listing criteria and establishing

an alternate reporting threshold of 1 million pounds for facilities with 500 pounds or less of production-related releases and other wastes. Facilities meeting the requirements of this alternate threshold may file a certification statement (Form A) instead of reporting on the standard EPCRA section 313 form, the Form R.

In today's actions, EPA is finalizing enhanced reporting requirements that focus on a unique group of toxic chemicals. These toxic chemicals which persist and bioaccumulate in the environment are commonly referred to as persistent bioaccumulative toxic chemicals or PBT chemicals. To date, with the exception of the alternate threshold certification on Form A, EPA has not altered the statutory reporting threshold for any listed chemicals. However, as the TRI program has evolved over time and as communities identify areas of special concern, thresholds and other aspects of the EPCRA section 313 reporting requirements may need to be modified to assure the collection and dissemination of relevant, topical information and data. Towards that end, EPA is increasing the utility of TRI to the public by adding a number of chemicals to the section 313 list of toxic chemicals that persist and bioaccumulate in the environment and by lowering the reporting thresholds for a number of toxic chemicals that have these properties. Toxic chemicals that persist and bioaccumulate are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. EPA believes that the public understands that these PBT chemicals have the potential to cause serious human health and environmental effects resulting from low levels of release and exposure (Refs. 75 and 76). Lowering the reporting thresholds for PBT chemicals will ensure that the public has important information on the quantities of these chemicals released or otherwise managed as waste, that would not be reported under the 10,000 and 25,000 pound/year thresholds that apply to other toxic chemicals.

B. What Outreach Has EPA Conducted?

EPA has engaged in a comprehensive outreach effort. This outreach served to inform interested parties, including industry groups affected by the rule, state regulatory officials, environmental organizations, labor unions, community groups, and the general public of EPA's intention to add certain PBT chemicals to the list of toxic chemicals under EPCRA section 313 and lower the applicable reporting thresholds for a subset of PBT chemicals. For all interested parties, EPA held three public meetings (in Chicago, IL (February 23, 1999); San Francisco, CA (March 5, 1999); and Washington, DC (February 16, 1999)) during the comment period for the proposal. Participants included a range of industry representatives, trade associations (representing both small and large businesses), law firms representing industry groups, environmental groups, the general public, plus other groups and organizations. For state and tribal governments, EPA attended the regularly-held public meetings of the Forum on State and Tribal Toxics Action (FOSTTA) to discuss the PBT proposal. EPA also received substantial public comment on this proposal, to which EPA is responding in this Final Rule and the Response to Comments document (Ref. 69). In response to the strong interest by the public, and to allow more individuals and groups to submit their comments, EPA extended the public comment period to April 7, 1999 (at 64 FR 9957, March 1, 1999) (FRL–6066–1). Additional information regarding EPA's outreach may be found in supporting documents included in the public version of the official record.

IV. Summary of Proposal

A. What Chemicals Did EPA Propose to Add to the EPCRA Section 313 List of Toxic Chemicals?

In an initial screening of PBT chemicals that appear on the list of chemicals of concern in the various chemical initiatives, EPA identified seven chemicals and one category of chemicals that persist and bioaccumulate in the environment but that were not on the list of EPCRA section 313 toxic chemicals. Although identification of these chemicals for initial consideration prior to this rulemaking was based on their status as PBT chemicals, their proposed addition in this rulemaking was based solely on the determination that they meet the EPCRA section 313(d)(2) listing criteria. All of the chemicals proposed for addition were found to be reasonably anticipated to cause serious or irreversible chronic human health effects at relatively low doses or ecotoxicity at relatively low concentrations, and thus are considered to have moderately high to high chronic toxicity or high ecotoxicity. The chemicals and chemicals categories EPA proposed to add to the list of EPCRA section 313 toxic chemicals include: Dioxin and dioxin-like compounds category, benzo(g,h,i)perylene, benzo(j,k)fluorene (fluoranthene), 3-methylcholanthrene, octachlorostyrene, pentachlorobenzene, tetrabromobisphenol A (TBBPA), vanadium (except alloys) and vanadium compounds.

B. What Persistence and Bioaccumulation Issues Did EPA Consider?

As noted above, for purposes of the proposed rule, EPA conducted its first, limited review of chemicals for their persistence and bioaccumulation properties under EPCRA section 313. EPA first established criteria to be used under section 313 for determining if a chemical persists or bioaccumulates in the environment. These criteria were then applied to determine whether the chemicals included in the review have the potential to persist and bioaccumulate in the environment. The initial group of chemicals reviewed were the result of EPA's screening assessment of two lists of persistent and bioaccumulative chemicals: (1) The Great Lakes Binational Level 1 list (Ref. 24); and (2) chemicals that received high scores for persistence and bioaccumulation in the initial version of the Waste Minimization Prioritization Tool (WMPT) developed by EPA's Office of Solid Waste (Ref. 74). Finally, included in this initial review were the chemicals included in the dioxin and dioxin-like compounds category that EPA had proposed for addition to the section 313 list in 1997 (at 62 FR 24887, May 7, 1997) (FRL–5590–1).

1. *Persistence*. A chemical's persistence refers to the length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes. The proposal discussed those aspects of persistence that are important to consider in determining a chemical's persistence in the environment and set forth the criteria that EPA used for determining whether a chemical is persistent for purposes of reporting under EPCRA section 313. Numerous organizations and internationally negotiated agreements have set numerical criteria for environmental persistence, many of which have been developed through consensus processes (Ref. 68). Of those reviewed, the criteria for persistence in water, soil, and sediment tend to cluster around two half-lifes, 1 to 2 months and 6 months while the persistence criterion for air was either a half-life of 2 or 5 days. A half-life of 6 months for water, soil, and sediment and half-lifes of either 2 or 5 days for air were chosen by the international organizations as criteria for chemicals that are being banned or

severely restricted. However, EPCRA section 313 is an information collection and dissemination program. EPA believes that persistence criteria consistent with the criteria applied to chemicals that are of global or regional (e.g., Europe and the Great Lakes) concern and that are targeted for ban, restriction, or phase-out are inappropriate for such a program. Chemicals that meet the persistence criteria used in the international agreements are the extremely persistent chemicals. Applying these strict criteria to EPCRA section 313 would result in a very narrow list of chemicals that would focus on only extremely persistent chemicals. This is inconsistent with one of the fundamental tenets of right-to-know which is to provide the public with information on toxic chemicals that have the potential to cause adverse effects in their community. Further, persistence criteria of half-lifes of 6 months and 5 days have not been used to establish whether a chemical is a PBT chemical but rather whether a chemical should have restrictions on its uses. The Agency stated in the proposal its belief that half-life criteria of 2 months for water, sediment, and soil and 2 days for air will include a better representative sample of chemicals that persist in the environment. Therefore, EPA used a half-life criterion of 2 months for water, sediment, and soil and a half-life of 2 days for air for the purposes of determining under EPCRA section 313 whether a toxic chemical is persistent in the environment. Under these criteria, if a toxic chemical meets any one of the media-specific criteria, it is considered to be persistent.

2. *Bioaccumulation*. Bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. The term refers to both uptake of chemicals from water (bioconcentration) and from ingested food and sediment residues. The discussions and data on bioaccumulation in the proposed rule dealt strictly with aquatic organisms because most of the bioaccumulation data are from aquatic studies. The proposal also discussed, in detail, those aspects of determining bioaccumulation that are important to consider in assessing whether a particular chemical will bioaccumulate in the environment.

A chemical's potential to bioaccumulate can be quantified by measuring or predicting a chemical's bioaccumulation factor (BAF) or a chemical's bioconcentration factor (BCF). Sources of BAF and BCF data for the chemicals included in the proposed rule included a mixture of both predicted and measured BAF and BCF values. The record for the proposed rule includes a document that explains the origin of the BAF or BCF value selected for each PBT chemical (Ref. 71). Most data were retrieved from the U.S. EPA's AQUIRE data base (Ref. 58) and the Japanese Chemicals Inspection and Testing Institute (CITI) data base (Ref. 18a).

As with persistence, a number of organizations and internationally negotiated agreements have set numerical criteria for bioaccumulation, many of which have been developed through a consensus processes. Of those reviewed, the criteria used for bioaccumulation was a BAF/BCF numerical value of either 5,000 or 1,000 or, in some cases, 500. The bioaccumulation criteria chosen by the international organizations as criteria for chemicals that are being banned or severely restricted was 5,000. However, for the same reasons discussed in Unit IV.B.1., EPA stated that the criteria used by the international organizations would not be appropriate for purposes of EPCRA section 313. Therefore, EPA used a BAF/BCF numerical criterion of 1,000 for determining if a chemical is bioaccumulative for purposes of EPCRA section 313.

3. *Persistence and bioaccumulation data*. In the proposal, EPA presented the bioaccumulation and persistence data for the PBT chemicals being considered. More detailed discussions of the sources of these data are provided in the support documents (Refs. 7 and 71). When considering the bioaccumulation and persistence potential of chemical categories, EPA reviewed the individual bioaccumulation and persistence data for the category members and determined in which tier the entire chemical category should be placed. For chemicals that had half-life ranges that bracketed the persistence tiers, EPA considered the types of studies supporting the half-life ranges and determined the most appropriate tier for each chemical.

C. How Did EPA Propose to Address Dioxin and Dioxin-Like Compounds?

In response to a petition from Communities For A Better Environment, EPA issued a proposed rule (at 62 FR 24887) to add a category of dioxin and dioxin-like compounds to the EPCRA section 313 list of toxic chemicals. As part of that action, EPA proposed to move 11 co-planar polychlorinated biphenyls (PCBs) from their listing under Chemicals Abstract Service Registry (CAS) Number 1336–36–3 to the dioxin and dioxin-like compounds category. However, since PCBs persist and bioaccumulate, EPA stated its belief in the proposed rule that PCBs should be subject to lower reporting thresholds. Thus EPA believed there was no need to move the 11 co-planar PCBs to the proposed dioxin and dioxin-like compounds category. Therefore, EPA withdrew its original proposal to modify the listing for PCBs and instead proposed to lower the reporting thresholds for the current PCB listing which covers all PCBs (at 64 FR 710). Because of this change, the proposed dioxin and dioxin-like compounds category included only the 7 polychlorinated dibenzo-*p*-dioxins and the 10 polychlorinated dibenzofurans identified in the proposed rule. In order to focus reporting on those facilities that actually add to the environmental loading of the dioxin and dioxin-like compounds and to reduce reporting burden, EPA proposed to add the activity qualifier ''manufacture only'' to the category. This qualifier would have limited reporting to those dioxin and dioxin-like compounds that are manufactured at the facility, including those coincidentally manufactured.

D. What Proposed Changes to Reporting Requirements for PBT Chemicals Did EPA Consider?

1. *Changes to reporting thresholds*. In evaluating potential lower reporting thresholds for PBT chemicals, EPA considered not only their persistence and bioaccumulation and the purposes of EPCRA section 313, but also the potential burden that might be imposed on the regulated community. Because all PBT chemicals persist and bioaccumulate in the environment, they have the potential to pose greater exposure to humans and the environment over a longer period of time (Refs. 75 and 76). The nature of PBT chemicals indicates that small quantities of such chemicals are of concern, which provides strong support for setting lower reporting thresholds than the current section 313 thresholds of 10,000 and 25,000 pounds. For determining the levels at which reporting thresholds should be set for these chemicals, EPA adopted a two-tiered approach. EPA made a distinction between persistent bioaccumulative toxic chemicals and highly persistent, highly bioaccumulative toxic chemicals by proposing to set lower reporting thresholds based on two levels of persistence and bioaccumulation potential. EPA proposed to set a manufacture, process and otherwise use threshold of 100 pounds for PBT chemicals and a threshold of 10 pounds for that subset of PBT chemicals that are highly persistent and highly

bioaccumulative toxic chemicals. One exception to this is the reporting threshold for the dioxin and dioxin-like compounds category, see the discussion in Unit IV.D.2.

In determining the appropriate reporting thresholds to propose for PBT chemicals, EPA started with the premise that low or very low reporting thresholds may be appropriate for these chemicals based on their persistence and bioaccumulation potentials only. EPA then considered the burden that would be imposed by lower reporting thresholds and the distribution of reporting across covered facilities. Considering the factors described above, in addition to the purposes of EPCRA section 313, EPA proposed to lower the manufacture, process, and otherwise use thresholds to 100 pounds for PBT chemicals and to 10 pounds for that subset of PBT chemicals that are highly persistent and highly bioaccumulative. EPA presented the proposed section 313 reporting thresholds for each of the PBT chemicals considered. For purposes of section 313 reporting, threshold determinations for chemical categories are based on the total of all toxic chemicals in the category (see 40 CFR 372.25(d)).

2. *Special reporting threshold for dioxin and dioxin-like compounds.* The category of dioxin and dioxin-like compounds are highly persistent and highly bioaccumulative toxic chemicals. However, this category of chemicals poses unique problems with regard to setting section 313 reporting thresholds because these chemicals are generally produced in extremely small amounts compared to other section 313 chemicals. In response to EPA's original proposal to add dioxin and dioxin-like compounds, EPA received numerous comments suggesting that the reporting threshold for this category be set at zero. EPA stated its belief that rather than setting a zero reporting threshold it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report. EPA proposed a manufacture threshold of 0.1 gram for the category. EPA expressed its intent to develop reporting guidance for industries that may fall within this reporting category. In addition to the proposed lower reporting threshold for the dioxin and dioxin-like compounds category, EPA requested comment on an alternative way of reporting release and other waste management data for this category. This alternative included reporting release and other waste management data for the dioxin and dioxin-like compounds category in terms of grams of toxicity equivalents (TEQs).

E. What Other Reporting Issues Did EPA Consider for PBT Chemicals?

1. *De minimis exemption.* In 1988, EPA promulgated the *de minimis* exemption because: (1) The Agency believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; (2) the Agency did not believe that these low concentrations would result in quantities that would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509, February 16, 1988); and (3) the exemption was consistent with information collected by the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS). However, given that: (1) Covered facilities currently have several sources of information available to them regarding the concentration of PBT chemicals in mixtures; (2) even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and can reasonably be expected to significantly contribute to exceeding the proposed lower thresholds; and (3) the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA's original rationale for the *de minimis* exemption does not apply to PBT chemicals. EPA therefore proposed to eliminate the *de minimis* exemption for PBT chemicals. EPA did not propose, however, to modify the applicability of the *de minimis* exemption to the supplier notification requirements (40 CFR 372.45(d)(1)) because the Agency believed there was sufficient information available.

2. *Use of the alternative threshold and Form A.* EPA stated its belief that use of the existing alternate threshold and reportable quantity for Form A would be inconsistent with the intent of expanded PBT chemical reporting. The general information provided in the Form A on the quantities of the chemical that the facility manages as waste is insufficient for conducting analyses on PBT chemicals and would be virtually useless for communities interested in assessing risk from releases and other waste management of PBT chemicals. EPA, therefore, proposed excluding all PBT chemicals from the alternate threshold of 1 million pounds.

3. *Proposed changes to the use of range reporting.* EPA stated its belief that use of ranges could misrepresent data accuracy for PBT chemicals because the low or the high end range numbers may not really be that close to the estimated value, even taking into account its inherent error (i.e., errors in measurements and developing estimates). EPA believed this uncertainty would severely limit the applicability of release information where the majority of releases, particularly for PBT chemicals, are expected to be within the amounts eligible for range reporting. Given EPA's belief that the large uncertainty that would be part of these data would severely limit their utility, EPA proposed to eliminate range reporting for PBT chemicals.

4. *Proposed changes to the use of the half-pound rule and whole numbers.* EPA currently allows facilities to report whole numbers and to round releases of 0.5 pound or less to zero. EPA explained its concern that the combination of requiring the reporting of whole numbers and allowing rounding to zero would result in a significant number of facilities reporting their releases of some PBT chemicals as zero. EPA, therefore, proposed that all releases or other waste management quantities greater than 1/10 of a pound of PBT chemicals (except dioxins) be reported, provided that the appropriate activity threshold has been exceeded. For the category of dioxin and dioxin-like compounds, which have a proposed reporting threshold of 0.1 gram, EPA proposed that facilities report all releases and other waste management activities greater than 100 micrograms (ug) (i.e., 0.0001 gram).

5. *Proposed changes to other EPCRA section 313 reporting requirements.* The alkyl lead compounds tetraethyl lead (CAS No. 78–00–2) and tetramethyl lead (CAS No. 75–74–1) are currently reportable under the EPCRA section 313 category listing for lead compounds. However, these two chemicals specifically appear on the Binational Level 1 list of chemicals that have been identified for virtual elimination from the Great Lakes and thus are of special concern. EPA, therefore, proposed that separate reports be filed for these two members of the lead compounds category, which would allow better tracking of these specific lead compounds. In addition, EPA proposed to list ''vanadium'' and ''vanadium compounds'' and delete the EPCRA section 313 listing for ''vanadium (fume or dust).'' Since vanadium without the fume or dust qualifier would be a new section 313 listing, EPA did not propose to include additional reporting on alloys containing vanadium. In the proposal, EPA deferred making a final decision on

vanadium contained in alloys until the Agency could complete a scientific review of issues pertinent to some alloys. EPA proposed to include the qualifier ''except when contained in an alloy'' in the vanadium listing. EPA also requested comment on the adequacy of existing studies for determining the bioaccumulation potential of cobalt and cobalt compounds.

V. Summary of the Final Rule

A. Which Chemicals is EPA Adding to the List of Toxic Chemicals Under EPCRA Section 313?

In this action, EPA is adding seven chemicals and two chemical compound categories to the list of toxic chemicals subject to reporting under EPCRA section 313. These chemicals include: benzo(g,h,i)perylene, benzo(j,k)fluorene (fluoranthene), 3-methylcholanthrene, octochlorostyrene, pentachlorobenzene, TBBPA, vanadium (except when in an alloy), vanadium compounds, and a category consisting of 17 specified dioxin and dioxin-like compounds. EPA has determined that each of these chemicals and chemical compound categories meets the listing criteria under EPCRA section 313(d)(2). Two of these chemicals, 3-methylchloanthrene and benzo(j,k)fluorene (fluoranthene), are being added as members of the polycyclic aromatic compounds (PACs) category. Vanadium, with the qualifier ''fume or dust,'' has been on the list of toxic chemicals since the program's inception in 1987. In today's action, however, the Agency is removing the ''fume or dust'' qualifier from the vanadium listing. However, EPA is not including reporting on vanadium when contained in alloys. EPA is finalizing the proposed qualifier ''except when contained in an alloy'' to the vanadium listing. Therefore all elemental vanadium, unless it is in an alloy, is now reportable under EPCRA section 313. In addition to modifying the qualifier, EPA is also adding a new vanadium compounds category. Thus, all chemical compounds that contain vanadium are reportable under this listing. Further, EPA is finalizing its proposal (62 FR 24887) to add dioxins and 16 dioxin-like compounds. However, the Agency is modifying the qualifier that it originally included with this listing. In the PBT proposed rule, EPA proposed to add the dioxin and dioxin-like compounds category with the qualifier ''manufacturing only.'' However, based on comments the Agency received, EPA is changing this qualifier to include: Manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical.

B. Which Chemicals is EPA Including as PBT Chemicals Under EPCRA Section 313?

EPA has made the final determination that 18 of the chemicals and chemical categories proposed meet the EPCRA section 313 criteria for persistence and bioaccumulation. Thus EPA is lowering the reporting threshold for all of these toxic chemicals. These chemicals and their final thresholds are listed in Table 1 below:

Table 1.—Reporting Thresholds for EPCRA Section 313 Listed PBT Chemicals

Chemical Name or Chemical Category Name	CASRN	Section 313 Reporting Threshold (in pounds unless noted otherwise)
Aldrin	309-00-2	100
Benzo(g,h,i)perylene	191-24-2	10
Chlordane	57-74-9	10
Dioxin and dioxin-like compounds category (manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical)	NA	0.1 grams
Heptachlor	76-44-8	10
Hexachlorobenzene	118-74-1	10
Isodrin	465-73-6	10
Methoxychlor	72-43-5	100
Octachlorostyrene	29082-74-4	10
Pendimethalin	40487-42-1	100
Pentachlorobenzene	608-93-5	10
Polycyclic aromatic compounds category	NA	100
Polychlorinated biphenyl (PCBs)	1336-36-3	10
Tetrabromobisphenol A	79-94-7	100
Toxaphene	8001-35-2	10
Trifluralin	1582-09-8	100
Mercury	7439-97-6	10

Table 1.—Reporting Thresholds for EPCRA Section 313 Listed PBT Chemicals—Continued

Chemical Name or Chemical Category Name	CASRN	Section 313 Reporting Threshold (in pounds unless noted otherwise)
Mercury compounds	NA	10

EPA is deferring its decision for two chemicals and one chemical category. Specifically, EPA is deferring a determination on dicofol while the Agency continues to review the available persistence data. EPA is also deferring its decision on cobalt and cobalt compounds because it needs to further investigate the bioaccumulative potential of these chemicals.

C. What Thresholds Has EPA Established for PBT chemicals?

EPA is finalizing the thresholds it proposed for PBT chemicals in the January 5, 1999 (64 FR 688) **Federal Register**. Specifically, EPA is finalizing two thresholds based on the chemicals' potential to persist and bioaccumulate in the environment. The two levels include setting section 313 manufacture, process, and otherwise use thresholds at 100 pounds for PBT chemicals and at 10 pounds for that subset of PBT chemicals that are highly persistent and highly bioaccumulative. One exception is the dioxin and dioxin-like compounds category. The dioxin and dioxin-like compounds category threshold determination required special consideration because these highly persistent and highly bioaccumulative compounds are manufactured in extremely small amounts compared to other section 313 chemicals. In order to capture release and other waste management data, EPA is setting the threshold for the dioxin and dioxin-like compound category at 0.1 gram.

D. What Exemptions and Other Reporting Issues is EPA Addressing?

EPA is eliminating the *de minimis* exemption for the PBT chemicals included in today's final rule. However, this action will not affect the applicability of the *de minimis* exemption to the supplier notification requirements (40 CFR 372.45(d)(1)). During the inter-agency review process, it was suggested that EPA consider constructing an exemption for facilities in SIC code 5171, i.e., Petroleum Bulk Plants and Terminals. Specifically, it was suggested that EPA exempt the processing of PBT chemicals in petroleum products. Before EPA can consider this exemption, EPA must determine that these facilities process and release and otherwise manage as waste very small aggregate quantities of PBT chemicals. The Agency is soliciting comments and information on this suggestion, particularly any information that could provide a factual basis for such an exemption. Please send your comments to the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section within the next 60 days. EPA will evaluate this suggestion, and provide a response within approximately 180 days.

In today's action, EPA is also excluding all PBT chemicals from eligibility for the alternate threshold of 1 million pounds and eliminating for PBT chemicals range reporting for on-site releases and transfers off-site for further waste management. This will not affect the applicability of the range reporting of the maximum amount on-site as required by EPCRA section 313(g). EPA is addressing the alkyl lead compounds, tetraethyl lead (CAS No. 78–00–2), and tetramethyl lead (CAS No. 75–74–1), in a separate rulemaking for lead and lead compounds (64 FR 42222, August 3, 1999) (FRL–6081–4). Therefore, EPA is not finalizing any action with respect to these two lead compounds in today's action.

EPA proposed to require reporting of all releases and other waste management quantities greater than 1/10 of a pound of PBT chemicals (except dioxin), provided that the accuracy in the underlying data on which the estimate is based supports this level of precision. Also, EPA stated that releases and other waste management quantities would continue to be reported to two significant digits. In addition, EPA stated that for quantities of 10 pounds or greater, only whole numbers would be required to be reported. For the category of dioxin and dioxin-like compounds, which have a proposed reporting threshold of 0.1 gram, EPA proposed that facilities report all releases and other waste management activities greater than 100 µg (i.e., 0.0001 gram). After reviewing all the comments on this issue, EPA is providing additional guidance on the level of precision at which facilities should report their releases and other waste management quantities of PBT chemicals. Facilities should still report releases and other waste management quantities greater than 0.1 pound (except dioxins) provided the accuracy and the underlying data on which the estimate is based supports this level of precision. Rather than reporting in whole numbers and to two significant digits, if a facility's release or other waste management estimates support reporting an amount that is more precise than whole numbers and two significant digits, then the facility should report that more precise amount. The Agency believes that, particularly for PBT chemicals, facilities may be able to calculate their estimates of releases and other waste management quantities to 1/10 of a pound and believes that such guidance is consistent with the reporting requirements of sections 313(g) and (h).

E. What is the Relationship Between This Rule and the Clean Air Act Mercury Information Collection Request?

Throughout calendar year 1999, EPA has been using authority under section 114 of the Clean Air Act to require all coal-fired power plants over 25 mega watts to submit to EPA the results of analyses of the mercury content of their coal. A representative sample of these plants, stratified by type of plant and type of coal burned, have been required to perform stack testing to determine the amount (and species) of mercury emitted. The stack testing will allow EPA to develop a set of emissions factors that can be applied to the mercury in coal analysis to generate mercury emissions estimates for each coal-fired plant. EPA does not intend to continue to require plants to submit either the coal analysis or the stack testing beyond the current requirement. Therefore for the purpose of reporting mercury releases to the TRI, EPA expects coal-fired power plants that do not have monitoring or stack test data for the reporting year to use the emissions factors that EPA will develop and make available to the public in the summer of 2000.

VI. Summary of Public Comments and EPA Responses

A. What Comments Did EPA Receive on its Statutory Authority to Add Chemicals and Lower the Reporting Threshold and What is EPA's Response?

Several commenters assert that EPCRA section 313(f)(2) only grants EPA the authority to raise the statutory thresholds, but not to lower them. They agree that the substantial majority test is met ''as a matter of logical necessity'' when EPA lowers the reporting threshold, and argue that this makes the ''substantial majority'' test essentially meaningless when thresholds are lowered. They argue that this demonstrates that Congress did not intend for EPA to lower reporting thresholds, only to raise them.

These commenters also rely on the language of other provisions of EPCRA section 313 to support their argument that Congress did not grant EPA authority to lower thresholds. They rely on the fact that section 313(f)(2) does not provide that EPA can ''raise or lower'' thresholds, unlike section 313(d), under which EPA can ''add or delete'' chemicals from the list, and section 313(b), under which EPA can ''add or delete'' industry sectors. In addition, the commenters argue that section 313(f)(2) is analogous to section 313(l), where, despite the use of the otherwise neutral term ''modify,'' Congress clearly meant for EPA only to make the reporting requirements less frequent (i.e., less stringent). Based on these provisions, they also argue that, where Congress intended EPA to have the authority to both expand and restrict reporting, the statute explicitly provides the authority, but where Congress only intended to authorize EPA to reduce the reporting burden, it provided a neutral term, and then restricted it. The commenters argue that in section 313(f)(2), Congress qualified EPA's authority with a substantial majority restriction that only makes sense if EPA raises the thresholds.

EPA disagrees with the commenters' interpretations. Section 313(f)(2) clearly authorizes EPA to lower thresholds, as well as to raise them. The plain language of this provision provides that ''the Administrator may establish a threshold different from the amount established by paragraph (1).'' It clearly does not state that the Administrator may only establish a higher threshold than the amount established by paragraph (1), which appears to be the commenters' interpretation. Moreover, in the House debate on the conference report, Representative Edgar, one of EPCRA's sponsors, noted:

> The EPA is authorized to revise these thresholds, but only if such revised thresholds obtain reporting on a substantial majority of total releases, *especially if such revised thresholds raise the statutory levels*,. . . (A Legislative History of the Superfund Amendments and Reauthorization Act of 1986, Committee Print, vol. 6, 5315) (emphasis added).

The clear implication of this statement is that Congress intended EPA to have the authority to lower, as well as to raise, the statutory thresholds.

The commenters' interpretation that EPA lacks the authority to lower the thresholds conflicts with Congressional intent in other ways. During debate on the Conference Report, Representative Edgar noted that ''This act is intended to provide a *comprehensive view of toxic chemical exposure* and, hopefully, provide a basis for more sensible and effective local, State, and national policies.'' *Legislative History* at 5316. See, also, *Legislative History* at 5313 and 5338. And yet without the authority to lower the thresholds, EPA cannot ensure that this objective is achieved. For example, Congress included PCBs on the original list of EPCRA section 313 chemicals, thereby indicating an intent to provide the public with a ''comprehensive view of exposure'' to PCBs; but under the original reporting requirements, EPA only received 6 reports. Under no interpretation can six reports be characterized as obtaining ''a comprehensive view of toxic chemical exposure.'' *Legislative History* at 5315.

EPA also disagrees with the comment that the Agency's interpretation has rendered this provision meaningless. This argument is based on a logical fallacy; a standard need not constrain agency action to the same degree in all circumstances to be meaningful. Congress may impose a standard that constrains actions to varying degrees in different circumstances. In this case, the Congressional debate on this provision indicates that Congress was most concerned with the loss of publicly available information that may result from raising the thresholds. See, e.g., *Legislative History* at 5315-16. It is therefore reasonable to assume that Congress chose to impose a standard that presented a greater constraint on the Agency's ability to raise thresholds, and therefore created a ceiling beyond which the Agency was not authorized to modify thresholds.

Further, notwithstanding the fact that under EPA's interpretation of section 313(f)(2), the Agency can meet the statutory standard without the need for quantitative support when it lowers the threshold, EPA does not believe that Congress has granted it unfettered discretion to establish a different threshold. As discussed at length in Unit VI.E., Congress provided significant guidance in other provisions of the statute and the legislative history, to guide the Agency's exercise of discretion under this provision. Moreover, as noted above, the substantial majority requirement establishes a ceiling beyond which the Agency is not authorized to modify thresholds.

EPA also disagrees with the commenters' interpretation of other provisions of EPCRA section 313. In general, Congress established the basic framework of right-to-know reporting in EPCRA section 313, and selectively granted EPA carefully qualified authority to adjust individual parameters as appropriate. For example, EPA is authorized to modify the chemicals on the EPCRA section 313 list, the SIC codes and facilities covered by section 313, the reporting frequency, and the reporting thresholds, but each grant of authority is constrained to varying degrees by the standards contained in each respective provision. As the commenters have correctly noted, where Congress intended to restrict the Agency's authority to modify the original requirements, it did so explicitly. For example section 313(l) specifically limits EPA's authority to modify the reporting frequency: ''. . .but the Administrator may not modify the frequency to be any more often than annually.'' Similarly Congress included no provision authorizing any amendments to the generally applicable employee threshold. It is therefore reasonable to assume that had Congress intended to only permit EPA to raise the thresholds, they would have included such an explicit restriction in the provision. Moreover, as noted earlier in this unit, the little legislative history that exists on this provision indicates that Congress intended EPA to have the discretion to both raise and lower the reporting thresholds. Further, EPA disagrees with the commenters' interpretation that Congress relied on different statutory construction to indicate its decision not to grant the Agency authority to decrease reporting thresholds, rather than relying on an explicit restriction in the plain language of the statute. EPA is aware of no indication of such Congressional intent in the legislative history, nor have the commenters cited to any. More to the point, the commenters' interpretation is clearly refuted by the inclusion in section 313(l) of an explicit restriction, demonstrating that where Congress

intended to restrict EPA's authority, it did so explicitly.

One commenter argues that EPA lacks authority to lower the thresholds based on a comparison of the language in EPCRA sections 311 and 312 authorizing EPA to revise the section 311 and section 312 thresholds, with the language of section 313(f)(2). The commenter states that Congress could have used this same broad and simple language in section 313, and argues that because it did not, but instead chose to impose the ''substantial majority'' requirement, this demonstrates that Congress did not intend EPA to have the authority to lower the thresholds. Instead, the commenter argues, Congress was concerned with reporting burden when it crafted section 313, and so declined to grant EPA authority to lower the thresholds.

EPA disagrees. There is no significant difference between the language in sections 311, 312, and 313 that supports the commenter's interpretation. Unlike section 313, Congress did not establish thresholds in sections 311 and 312, but granted the Administrator broad discretion to determine whether a threshold was even appropriate; at what level to establish the threshold; and to modify it as appropriate. The language with which Congress conferred this authority provides that ''the Administrator may establish threshold quantities. . . .'' This is almost identical to the language of section 313(f)(2), which simply provides that ''the Administrator may establish a threshold amount for a toxic chemical different from the amount established by paragraph (1).'' The commenter's argument turns wholly on the inclusion of the ''substantial majority'' requirement, and as explained above, EPA does not believe that this standard either precludes EPA from lowering thresholds or demonstrates Congressional intent to do so.

Several commenters challenged EPA's finding that its alternate thresholds would capture a substantial majority of total releases, contending that the Agency had impermissibly relied on an increase in the number of reports submitted. The commenters assert that EPA is required to estimate releases at these facilities and determine, on a percentage basis, whether a ''substantial majority'' of all releases of each chemical, from all facilities subject to EPCRA section 313, will be captured. One commenter noted that, even if lowering the threshold for an EPCRA section 313 chemical results in an increase in the number of reports on the chemical, this does not necessarily mean that the additional reports will capture a substantial majority of the total releases from all facilities subject to EPCRA section 313 reporting. In order for the lower threshold to meet the statutory test, the threshold must result in capturing at least two thirds of all releases of the chemical at covered facilities. The commenter contended that the number of reports is irrelevant to the percentage of releases captured by the reports. If a certain chemical were present at only one facility in the country subject to EPCRA section 313, the submission of one report on the chemical accounting for at least 66% of the releases from that facility would satisfy the ''substantial majority'' test. By contrast, if a lower threshold generated 1,000 new reports on a EPCRA section 313 chemical, the ''substantial majority'' test would not be met if those reports did not account for at least 66% of the total releases from all facilities subject to EPCRA section 313. This may be the case, for example, if a large percentage of releases of the EPCRA section 313 chemical occurred at facilities otherwise subject to EPCRA section 313 that do not meet the threshold for that particular chemical that triggers the obligation to report the releases.

EPA disagrees with the commenter's interpretation. As noted in the proposed rule, EPA interprets the language in 313(f)(2), ''facilities subject to the requirements of [section 313],'' to refer to those facilities that fall within the category of facilities described by sections 313(a) and (b). Subsection (a) lays out the general requirement that ''the owner or operator of facilities subject to the requirements of this section'' file an EPCRA section 313 report. Subsection (b) then further defines the facilities subject to the requirements of this section:

> [t]he requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20-39, . . . and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) of this section in excess of the quantity of that toxic chemical established under subsection (f) of this section during the calendar year for which a toxic chemical release form is required under this section.

Thus, to be subject to the requirements, a facility must meet all three of the requirements laid out in subsection (b). This means that the class of facilities subject to reporting under section 313 will vary according to the individual chemical. Moreover, facilities that have not exceeded a threshold for a particular chemical are not ''subject to the requirements'' of EPCRA section 313 for that chemical.

To determine whether a particular threshold, either higher or lower, for an individual chemical meets the substantial majority test, one would compare the total national aggregate of releases of the chemical by covered facilities at the existing thresholds with the estimated total national aggregate of releases at the proposed alternate threshold, and determine whether a substantial majority of releases reported under the original thresholds would be reported. Logically, the universe of facilities subject to the requirements under a lower threshold will always be either equivalent to, or greater, than the universe of facilities that are subject to the requirements under the existing thresholds. Moreover, because facilities subject to the requirements of section 313 must report ''the annual quantity of the toxic chemical entering each environmental medium,'' EPA can meet the substantial majority standard when lowering the thresholds, without the need for quantitative support; i.e., facilities that report, must report their releases and other waste management quantities. In this instance, the number of reports serves as an adequate surrogate for releases because essentially all releases (and other waste management quantities) will be reported by facilities subject to the requirements of this section.

In other words, facilities ''subject to the requirements of this section'' are those that must file EPCRA section 313 reports. Thus, the baseline against which the ''substantial majority of total releases'' is measured is the category of facilities that currently submit reports. Consequently, if quantitative support for its finding were necessary, EPA would be justified in relying on the number of reports to make its finding.

By contrast, although it is not clear exactly how the commenters interpret the phrase ''facilities subject to the requirements of this section,'' it is clear that they do so without reference to all of the requirements in subsections (a) and (b). And essentially, any interpretation that ignores any portion of subsection (b), results in an interpretation of EPCRA section 313(f)(2) as ''facilities *otherwise* or *potentially* subject to the requirements of this section.'' This is inconsistent with the plain language of section 313(f)(2). The commenters can only support their argument that EPA has not met the ''substantial majority'' test by assuming that all facilities, irrespective of whether they are in a covered SIC code or they exceed the existing thresholds, are subject to EPCRA section

313, and that EPA must ensure that it captures a substantial majority of releases from the universe of those facilities. If this were correct, the addition of certain SIC codes could be a prerequisite to lowering thresholds for certain chemicals. Such a requirement is not currently included in section 313. The commenters have provided no support in either the statute or legislative history for these interpretations. Nor have the commenters provided any support for the interpretation that ''substantial majority'' equates to a particular percentage, such as 66%.

Finally, EPA notes, as it noted in the proposed rule, that, for several reasons, it does not believe that it has the necessary information to develop even reasonably accurate estimates of the potential releases that would be reported at an average facility at each of the identified options for a lowered threshold. Specifically, EPA believes that: (1) Sufficient information is not currently available for these chemicals, and (2) there is insufficient information on the numerous processes employed by all the sectors involved to calculate a comprehensive release estimate for each sector. While there are some data available, comprehensive data are not available for all sectors and chemicals. EPA further notes that none of the commenters provided either any information or methodology to address this issue, notwithstanding EPA's specific request.

Two commenters rely on excerpts from the debate on the Conference Report with respect to section 313(f)(2) to argue that EPA is only authorized to revise the thresholds if EPA presents a convincing analysis that revisions to the threshold will capture a substantial majority of the releases while also ensuring that it is not placing undue burdens on facilities which contribute little to such releases. The commenters argue that EPA has not satisfied the substantial majority requirement, and to do so, must conduct a more thorough assessment of the burden imposed on industry focused on the volume of releases that will be captured, not the number of reports. Another commenter compares the legislative history of sections 311 and 312 with 313, and concludes that Congress clearly intended EPA to factor burden into section 313 threshold questions.

EPA disagrees. Ultimately, EPA must comply with the statutory language, and section 313(f)(2) does not impose any requirement on the Agency to rely on the type of analyses described by the commenter. In addition, the commenters' reliance on the statements made during the Conference Report debate are misplaced. The commenter only quotes part of Representative Edgar's statement; the full quotation indicates only that EPA must present a convincing case, ''based on verifiable, historical data'' that the statutory thresholds warrant revision. As discussed below in Unit VI.E., EPA believes it has presented a convincing case that the thresholds should be lowered for PBT chemicals. The commenter also failed to include the portion of Representative Edgar's statement explaining that a convincing case was particularly necessary if the effect of the modification was to raise the thresholds. See, *Legislative History* at 5315.

Nonetheless, as discussed in greater detail in Unit VI.E., EPA considered the burden that lower thresholds would impose on industry in selecting the PBT thresholds. EPA believes that the levels it has adopted will capture significantly more information about PBT chemicals than current thresholds, but will not be unduly burdensome on industry. In addition, as discussed in the Response to Comments document (Ref. 69), EPA believes that the number of reports filed is a more accurate measure of burden than the volume of releases.

A commenter alleges that EPA's interpretation of section 313(f)(2) contradicts its prior statements regarding threshold changes. The commenterstates that EPA was clear in the original EPCRA section 313 rulemaking that the statute requires a substantial majority finding supported by actual data. For example, in the June 1987 proposed rule, EPA stated: ''The Agency is interested in data that would support the necessary finding that a modified threshold would still generate reporting on a substantial majority of total releases, as the statute requires.'' And in the February 16, 1988 final rule promulgating EPCRA section 313 requirements, EPA stated

> . . .the first few years' data should be evaluated to determine whether modifications of the threshold would meet the statutory test of obtaining reporting on a substantial majority of the releases (i.e., pounds released per year) of each chemical from subject facilities. EPA may consider changing the reporting thresholds based on several years of data collection.

The commenter also notes that in neither the proposed nor final rule establishing EPCRA section 313 requirements did EPA specifically assert that it had the authority to lower thresholds.

EPA disagrees that its statements in this rulemaking contradict its prior statements in the 1988 rulemaking. As a preliminary matter, EPA has never denied that the requirement that a revised threshold obtain reporting on a substantial majority of total releases applies to any action lowering the reporting thresholds. Specifically, EPA's discussion in the 1987 proposed rule was in the context of a response to proposals from the Small Business Administration (SBA) that the Agency raise the thresholds to capture only larger facilities. EPA's statements in the 1988 final rule also need to be evaluated with SBA's proposals in mind. Moreover, while it is true that the discussion to which the commenter cited did not distinguish between lowering and raising the thresholds (it was intended as a response to comments on both sides of the issue), EPA notes that the majority of the comment summary focuses on requests to raise the thresholds. Finally, while it is true that EPA did not specifically assert its authority to lower the thresholds in either rule, neither did EPA deny that EPCRA section 313(f)(2) grants it this authority. However, it is worth noting that in the final rule, EPA responded to comments from environmental and public interest groups requesting that the Agency lower the thresholds, and that EPA never stated or implied that it lacked the authority to lower thresholds.

One commenter states that EPA's authority to lower reporting thresholds is not limitless. The commenter argues that a decision to lower the thresholds must be tied to the overall purpose of the Act, namely, to inform the public of potential health risks posed by the presence of toxic chemicals released to the environment in their communities. A regulatory decision to capture more reports under EPCRA section 313 must be based on the need to inform the public of health risks associated with the releases captured in those reports. Otherwise, the usefulness of the TRI data base begins to diminish. EPA needs to demonstrate that the releases of the PBTs at such small amounts pose a meaningful risk to the public health. Another commenter asserts that EPA is relying on the purposes of EPCRA to support its interpretation of section 313(f), and argues that, although section 313(h) does describe intended uses for TRI data, section 313(h) itself does not describe the purposes or intention of section 313. The commenter instead relies on several provisions of section 313 and argues that the purpose and intention of Congress to make information available to the public was balanced by concerns about the potential burden of the TRI program. The commenter also states that the uses

Congress anticipated for TRI data do not outweigh the balance that Congress intended between generating information and minimizing burden, and do not grant EPA blanket authority to expand the reporting requirements.

EPA agrees with the commenter that its authority to lower reporting thresholds is not limitless, and that its decision to lower the thresholds must be tied to EPCRA's overall purposes. However, EPA believes that Congress granted the Agency broad, but not unfettered, discretion to determine when it is appropriate to lower thresholds, and to determine the specific thresholds that are appropriate. As discussed in greater detail in Unit VI.E., EPA believes that its decision to lower the thresholds, and the thresholds it has chosen, reflect these principles.

However, EPA generally disagrees with the remainder of the commenter's conclusions. As discussed in more detail in Unit VI.F., EPA is not required to base its decisions under EPCRA section 313 on the need to inform the public of health risks associated with reported releases and other waste management quantities. And as discussed elsewhere in this preamble and the Response to Comments document (Ref. 69), EPA believes that the information that will be reported as a result of this rulemaking will provide useful information to the public.

In large measure, the issues raised in the second comment closely relate to the specific thresholds and EPA's rationale for choosing them, and this issue is discussed in more detail in Unit VI.E. However, to the extent it relates to EPA's interpretation of section 313(f)(2), some response is also provided here.

As a preliminary matter, while it is true that EPCRA section 313 does not explicitly identify the purposes of the section, the Conference Report makes clear that subsection (h) of section 313:

> Describes the intended uses of the toxic chemical release forms required to be submitted by this section and expresses the purposes of this section. The information collected under this section is intended to inform the general public and the communities surrounding covered facilities about releases of toxic chemicals, to assist in research, to aid in development of regulations, guidelines, and standards, and for other similar purposes. (Conference Report at 299).

Contrary to the commenter's assertion, the Agency never indicated that it was relying on section 313(h) to expand its authority under section 313(f)(2). Rather, EPA noted that it was relying on the purposes of section 313 as an additional source of Congressional direction to guide the Agency's exercise of discretion under this provision. EPA relied on section 313(h), in part, because the Agency believes that its implementation of EPCRA generally should be guided by EPCRA section 313's purposes. In addition, section 313(h) shares certain elements with the Congressional guidance on section 313(f)(2) in the legislative history. As discussed in greater detail in Unit VI.E., EPA has distilled those common elements, and relied on them to guide its discretion in establishing the specific thresholds under section 313(f)(2).

EPA also disagrees with the commenter's assertion that the purpose of EPCRA is to achieve a balance between the public's right to information about their potential exposures to toxic chemicals and the reporting burden imposed on industry. EPCRA section 313(f)(2) does not require EPA to consider burden in establishing revised thresholds. Although EPA has included the reporting burdens imposed on industry as one consideration in determining the appropriate thresholds, the Agency is also mindful that the authors of EPCRA, while sensitive to the burdens EPCRA section 313 reporting placed on industry, never intended this consideration to outweigh the public's need for access to information concerning release and waste management, and thus their potential exposure to toxic chemicals. See, e.g., *Legislative History* at 5315–16 and 5338–39. And with respect to the assertion that the general purposes of section 313 are to balance the public's right-to-know about toxic chemical releases and other waste management in their communities against the reporting burdens EPCRA section 313 imposes, EPA notes that reporting burden is not included anywhere in section 313(h). Nor does the strong policy directive underlying EPA's overall implementation of EPCRA section 313 support such an interpretation. Representative Edgar, one of the bill's primary architects noted:

> The heart of the Federal Right-to-Know Program is its reporting requirements, which are intended to provide a comprehensive picture of the community's and the Nation's exposure to toxic chemicals. As the Environmental Protection Agency, the States, and localities implement this program, they should be guided by several general principles.
>
> First, Congress recognizes a compelling need for more information about the Nation's exposure to toxic chemicals. Until now, the success of such regulatory programs such as the Clean Air Act, the Resource Conservation and Recovery Act, and the Clean Water Act has been impossible to measure because no broad-based national information has been compiled to indicate increases or decreases in the amounts of toxic pollutants entering our environment. As a result, the reporting provision in this legislation should be construed expansively to require the collection of the most information permitted under the statutory language. Any discretion to limit the amount of information reported should be exercised only for compelling reasons. . . . *Legislative History* at 5313.

Significantly, Representative Edgar did not include reporting burden as one of the general principles that should guide the Agency's implementation of EPCRA section 313. Rather, he stated:

> This is a new Federal initiative, and I recognize the desire of some of my colleagues to move ahead cautiously to ensure that burdens imposed on industry are not excessive. Frankly, my concerns rest with the families that live in the shadows of these chemical and manufacturing plants. I have put myself in their shoes and have fought for a program that looks after their needs. This legislation gets us well on the path to the full disclosure they deserve. *Id* at 5316.

Nonetheless, EPA has considered the legislative history on section 313(f)(2), including the excerpts cited by the commenter, and determined it would be reasonable to include some consideration of the reporting burdens in selecting its revised thresholds. The degree to which EPA included burden in its selection of the thresholds established in this rulemaking is discussed at length in Unit VI.E. and the Response to Comments document (Ref. 69).

EPA agrees that section 313(h) does not grant EPA unfettered discretion to expand EPCRA's reporting requirements; as noted in a previous response, Congress established the basic parameters of the EPCRA section 313 reporting requirements, and selectively granted EPA carefully qualified authority to modify certain of them. In this action, for example, EPA is only affecting the activity thresholds, but Congress established other limitations that govern whether a facility is subject to reporting. For example, facilities with fewer than 10 employees are not subject to reporting under subsection 313(b)(1).

B. What Comments Did EPA Receive on Persistence Criteria, Bioaccumulation Criteria, and Toxicity Criteria, and What Are EPA's Responses?

1. *Comments on EPA's general approach.* Several commenters contend that only chemicals which are globally recognized as persistent bioaccumulative toxic chemicals should form the foundation of the EPCRA section 313 PBT chemical list and criteria. The application of the criteria in this manner is consistent with several existing international agreements and

programs, such as the Great Lakes Binational Strategy, the North American Commission on Environmental Cooperation (NACEC), the United Nations Economic Commission for Europe's (UNECE) agreement to address persistent organic pollutants (POPs), and the United Nations Environmental Programme (UNEP). These programs have prompted widely accepted numerical values for persistence and bioaccumulation and defined parameters for assessing toxicity. These criteria have also been adopted with U.S. support and leadership and the commenters contend that it is not clear why EPA is now taking a vastly different approach to identifying PBT criteria in the proposed rule. The commenters suggest that EPA conform the criteria for PBT chemicals on EPCRA section 313 with the criteria and chemicals that are part of the programs being implemented by the NACEC, UNECE, and UNEP. By doing so, EPA would harmonize the U.S. program with similar international programs that focus on a narrow set of PBT chemicals.

EPA believes that it would be inappropriate to merely adopt the criteria and list of chemicals managed under the international programs cited because the purposes of the TRI program are different than the purposes of the cited international programs. The TRI was established by Congress under EPCRA section 313 in response to public demand for information on toxic chemicals being released in their communities. The TRI program is national in scope, but a significant part of its overriding goal is to provide information on releases to local communities so that they can determine if the releases result in potential risks. The entire concept of TRI, and indeed other, similar Pollutant Release and Transfer Registries (PRTRs) since established in several nations, is founded on the belief that the public has the right to know about chemical use, release, and other waste management in the areas in which they live, as well as the hazards associated with these chemicals. This emphasis is fundamentally different from the global focus of the UNEP negotiation and its concept of residual risk. It is EPA's position that the domestic, community-based purposes of EPCRA section 313 have important implications with regard to the criteria used to identify toxic chemicals as persistent and/or bioaccumulative, as well as the methods and models used to evaluate persistence and/or bioaccumulation.

EPCRA section 313 charges EPA with collecting and disseminating information on releases, among other waste management data, so that communities can estimate local exposure and local risks. One intent of EPCRA section 313 is to provide information to the public so that they can take an active role in determining what risks resulting from toxic chemical releases in their community are acceptable. This basic local empowerment is a cornerstone of the right-to-know program.

EPCRA section 313(h) states that:

> The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available, consistent with section 11044(a) of this title, to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes.

EPCRA section 313 establishes an information collection and dissemination program. EPA interprets EPCRA section 313(g)(2) to require facilities to use readily available information to prepare each chemical-specific EPCRA section 313 report. The statute does not require that the facility conduct additional monitoring or emissions measurements to determine these quantities. A facility must only use readily available data or reasonable estimation methods in preparing the quantitative information it reports.

The purpose of EPCRA section 313 is not to ban the manufacture or use of a chemical, to restrict releases of the chemical, or to dictate how it should be used or released. As a result, the burden and control EPCRA section 313 imposes is significantly less than that imposed by a statute that controls the manufacture, use, and/or release of a chemical. The focus of EPCRA section 313 is not equivalent to the focus of a statute or international agreements in which chemicals are to be banned, phased-out, or restricted.

In contrast, the international agreements cited by the commenters are intended to ban, restrict, or phase-out the manufacture, use and/or release of a limited set of persistent organic pollutants and certain heavy metals that are highly persistent and highly bioaccumulative. Descriptions of the purposes of the Protocol on Persistent Organic Pollutants (POPs); Convention on Long-Range Transboundary Air Pollution (LRTAP), UNECE, UNEP on POPs, North American Commission for Environmental Cooperation's Sound Management of Chemicals (NACEC SMOC), as well as the International Council of Chemical Associations' (ICCA) position on POPs are presented below. The following quotes clearly illustrate that the intent of the international agreements is to narrowly focus on that subset of toxic chemicals which are of regional (e.g., North America and Europe) or global concern.

UNECE LRTAP

> The ultimate objective is to eliminate any discharges, emissions and losses of POPs. The Protocol bans the production and use of some products outright (aldrin, chlordane, chlordecone, dieldrin, endrin, hexabromobiphenyl, mirex and toxaphene). Others are scheduled for elimination at a later stage (DDT, heptachlor, hexachlorobenzene, PCBs). Finally, the Protocol severely restricts the use of DDT, HCH (including lindane) and PCBs. The Protocol includes provisions for dealing with the wastes of products that will be banned. (The 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs); Convention on Long-Range Transboundary Air Pollution, United Nations Economic Commission for Europe (UNECE) at http://www.unece.org/env/lrtap) (Ref. 54)

UNEP

> International action to protect health and the environment through measures which will reduce and/or eliminate emissions and discharges of persistent organic pollutants, including the development of an international legally binding instrument. (Governing Council Decisions 20/24, 1999; United Nations Environmental Programme at http://irptc.unep.ch/pops/newlayout/negotiations.htm) (Ref. 57)

NACEC SMOC

> NACEC SMOC has developed action plans for PCBs, DDT, chlordane, and mercury. The action plans include 1) for PCBs ''work toward the virtual elimination of PCBs in the environment, which the task force is interpreting as no measurable release to the environment'', 2) for DDT ''gradual reduction of DDT use for malaria control'' and ''additional reductions,'' 3) for chlordane ''phase-out of chlordane use'', and 4) for mercury ''reduce sources of anthropogenic mercury pollution.'' The longer-term goal of the plan is to reduce the presence of mercury in the environment to achieve naturally occurring levels.'' (North American Cooperation for the Sound Management of Chemicals (June 1998); North American Commission for Environmental Cooperation at http://www.cec.org/english/profile/coop/Pollute—f.cfm?format=1) (Ref. 40)

ICCA

> *ICCA Position*: ICCA member associations have demonstrated their commitment to sound chemicals management, and to the goal of reducing the potential human health and environmental risks that may be associated with POPs. Many POPs are already subject to considerable voluntary risk management by chemical companies, and the uses of most substances identified as POPs has been discontinued or extremely limited

by chemical companies within the countries represented by ICCA member associations. (International Council of Chemical Associations (ICCA) Briefing Note on Persistent Organic Pollutants (POPs) (April 21, 1998) at http://www.icca-chem.org/issues.htm) (Ref. 26)

In addition, as directed under EPCRA section 313(h), EPA makes the TRI data available to various groups, including international organizations, that, in turn, use the information to decide whether to ban, restrict, or phase-out chemicals.

For the same reasons, EPA also disagrees that only substances globally recognized as POPs should provide the basis of persistence criteria for this rulemaking. POPs are organic chemicals whose characteristics of persistence in the environment, accumulation in biological organisms and toxicity make them priority pollutants that cause significant environmental risks to humans and ecosystems. The substances or substance categories being considered for implementation of global controls through the UNEP negotiations (UNEP/GC.18/32, 1995: aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene, hexachlorobenzene, PCBs, polychlorinated dibenzo-*p*-dioxins and furans) (Refs. 44 and 45) were selected largely because they or their degradation products pose risks that may occur far from their sites of initial entry into the environment. The UNEP action is the global counterpart to similar, regional negotiations, most notably the UNECE Convention on Long-Range Transboundary Air Pollution (LRTAP) (Ref. 54); the North American Free Trade Agreement (NAFTA) CEC Initiative on the Sound Management of Chemicals (Ref. 39); and the bilateral US/Canada agreement to control discharge or release of POPs in the Great Lakes basin (Ref. 23). A central theme of the UNEP action, consistent with its global scope, is the notion of residual risk, meaning specifically that to be subject to the negotiations, it is not sufficient for a substance to pose risks within a nation or regionally, rather it must pose risks to populations and nations distant from release sites.

2. *Comments on EPA's individual criteria.* The same commenters state that EPA should use the international criteria being applied by UNEP, UNECE LRTAP, NACEC SMOC, for persistence, bioaccumulation, and toxicity. Some of these commenters also include the criteria developed by CMA (CMA, PTB Policy Implementation Guidance: Product Risk Management Guidance for PTBs (February 1996)). One commenter includes the criteria developed by the ICCA for POPs. Another commenter states that there is no reason to adopt criteria that are significantly more stringent than those used in other programs. One commenter states that EPA should consider the degree of toxicity and focus on the most toxic chemicals. Some commenters state that EPA should couple the persistence and bioaccumulation criteria to each other. They believe that these criteria should not be considered independently. The numerical criteria presented by some of the commenters are provided below:

Table 2.—Numerical Persistence and Bioaccumulation Criteria Suggested by Commenters

	CMA PTB Policy	NACEC SMOC	UNECE (LRTAP) POPs	UNEP POPs/CEG FRAMEWORK	Environment Canada Toxic Substances Management Policy (June 1995)	ICCA
Persistence	Half-life = 6 months in water or 1 year in soil	Half-life > = 2 days air; 6 months water/soil; or 1 year sediment	Half-life> 2 months water or 6 months soils/sediment; or otherwise sufficiently persistent to be of concern	Half-life > [2 or 6] months soil/sediment; or other evidence that substance is sufficiently persistent to be of concern	Half-life > = 2 days air; 6 months water/soil; 1 year sediment	Half-life = 6 months water, 1 year soil sediments, or 5 days air
Bioaccumulation	BAF/BCF > = 5,000 or estimation techniques	BAF/BCF >= 5,000 or Log K_{ow} > = 5	BAF/BCF > 5,000 or Log K_{ow} > 5 or factors such as high toxicity	BCF/BAF > 5,000 or Log K_{ow}> [4 or 5]; evidence that substance with significantly lower BCF/BAF is of concern, e.g., due to high toxicity/ecotoxicity; or monitoring data in biota indicating sufficient bioaccumulation to be of concern	Half-life > 2 months water or 6 months soils/sediment (or otherwise sufficiently persistent to be of concern)	BCF > 5,000 or log Log K_{ow} > 5 and <7.5, MW<700 and substance is not metabolized

Table 2.—Numerical Persistence and Bioaccumulation Criteria Suggested by Commenters—Continued

	CMA PTB Policy	NACEC SMOC	UNECE (LRTAP) POPs	UNEP POPs/CEG FRAMEWORK	Environment Canada Toxic Substances Management Policy (June 1995)	ICCA
Toxicity	Professional judgment in evaluation of aquatic toxicity, wildlife toxicity, oral/dermal/inhalation toxicity (mammals and birds), reproductive toxicity, neurological toxicity; carcinogenicity, mutagenicity, and/or teratogenicity	Acute and chronic (including toxicity of breakdown products, if appropriate)	Potential to affect human health and/or the environment adversely	Evidence that (chronic) toxicity or ecotoxicity data indicate a potential for damage to human health or the environment caused by the substance resulting or anticipated from long-range transport	CEPA - toxic	Expert judgment that acute aquatic lethality, subchronic and chronic aquatic toxicity, acute wildlife toxicity, oral/dermal/inhalation toxicity in mammals and birds, carcinogenicity, mutagenicity, teratogenicity, reproductive toxicity, neurological toxicity, and immune system effects must be demonstrated or expected to occur at the concentrations observed in the environment

EPA is establishing criteria in this rulemaking for the TRI program for persistence and bioaccumulation. EPCRA section 313(d)(2) already provides toxicity criteria for the TRI program. While EPA chose in this rulemaking to focus on chemicals that are toxic and persistent and bioaccumulative, EPA did not state that the persistence criterion could only be applied in conjunction with the bioaccumulation criterion and vice versa. EPA has not tied the criteria together because there is no scientific rationale to define persistence criteria in terms of both bioaccumulation and persistence and to define bioaccumulation both in terms of persistence and bioaccumulation. As illustrated by the descriptions of persistence and bioaccumulation provided in the proposed rule, persistence and bioaccumulation are separate chemical and/or biological processes. They are not by definition dependent upon the other.

A chemical's persistence refers to the length of time the chemical can exist in the environment before being destroyed. (at 64 FR 698)

and

Bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. (at 64 FR 703)

A chemical is not considered to be persistent if it is only bioaccumulative. For example, a chemical may be extremely persistent and yet not bioaccumulate appreciably. For example, metals cannot be destroyed in the environment and thus are extremely persistent. Some metals bioaccumulate appreciably while others do not. However, the degree to which a metal can bioaccumulate does not affect the metal's persistence in the environment. The connection suggested by the commenters is not scientifically justified. Thus, EPA does not believe that persistence criteria can be applied only in conjunction with the bioaccumulation criteria. EPA reiterates that in this rulemaking the Agency chose to focus on those toxic chemicals that meet both the persistence and bioaccumulation criteria proposed for EPCRA section 313. In the future, the Agency may focus on toxic chemicals that are either persistent or bioaccumulative.

A discussion of the individual criteria is presented in the remainder of this unit.

a. *Persistence*. EPA proposed persistence criteria for the TRI program of half-lifes of 2 months in water, soil, and sediment and 2 days in air. As discussed in Unit VI.B.1., EPA disagrees that it must choose persistence criteria for EPCRA section 313, an information collection and dissemination program, consistent with the international criteria being applied to chemicals that are of global or regional (e.g., Europe and the Great Lakes) concern and that are being targeted for ban, restriction, or phase-out. Chemicals that meet the persistence criteria used in the international agreements are extremely persistent chemicals. Applying these criteria to EPCRA section 313 would result in a very narrow list of chemicals that would focus on only extremely persistent chemicals. This is inconsistent with both the purposes of EPCRA section 313 and with EPA's technical judgment. There is no ''bright line'' that separates what is persistent from what is not persistent. The degree of persistence is a continuum. Chemicals with a half-life of 2 to 6 months are not non-persistent. They are less than chemicals with a half-life of greater than 6 months. The degree of persistence that should be used as criteria is not an absolute scientific determination. Rather it is a combination of science and policy. As discussed in the proposed rule and the remainder of this section, organizations have generally used as persistence criteria half-lifes of 2 months and/or 6 months for water, soil, and sediment.

The determination of which set of numerical criteria to apply will depend on the final intent: for example, providing communities with information on persistent chemicals that can build up in their environment versus banning the manufacture and use and eliminating releases of a chemical that has global impacts. For EPCRA section 313, which provides information on toxic chemicals to communities, researchers, and governments, the criteria should be in keeping with both science and the intent of the statute.

Long-range transport (LRT) and residual risk are relevant domestically, since chemical substances may be transported regionally and transcontinentally, resulting in exposures at sites distant from releases but still within U.S. borders. Nevertheless, as a general rule, the closer the sources and receptor are, the more likely it is that released material will reach that receptor. The 12 UNEP POPs or their degradation products all meet or exceed the half-life criterion of 6 months for soil, water, or sediment, often by large margins (Refs. 44 and 45), and the 6 months criterion thus acts to isolate these substances for international attention aimed at limiting LRT. But a shorter half-life criterion is necessary to protect communities from bioaccumulative toxicants derived from sources closer to home, since, all other things being equal, a pollutant reaches nearby populations in less time than distant ones.

An article by Wania and Mackay (Ref. 81) is often cited in discussions of ''global distillation'' of relatively mobile POPs such as hexachlorobenzene and lindane, which tend to have inverted concentration profiles such that concentrations increase with distance from the source (i.e., from temperate to polar regions) rather than the reverse. What may be less obvious is that the converse is also true; namely, that less volatile substances show no significant latitudinal dependence; that low-mobility POPs such as mirex and the more highly chlorinated PCBs tend to undergo *rapid deposition and retention* close to their sources; and that all but high or relatively high mobility chemicals are expected to show ''normal'' concentration profiles, such that concentrations decline with distance from warmer sources to colder remote regions (Ref. 81). A recent study of organochlorine contaminants in sea otters illustrates this point. Although the levels of total DDTs observed were not considered toxicologically significant, Bacon *et al.* (Ref. 8) found the highest levels in California sea otters (ca. 850 micrograms per kilogram (µg/kg)) but much lower levels in Aleutian otters (40 µg/kg) and southeast Alaska otters (1 µg/kg), and attributed the higher levels in the California otters to extensive DDT use and production in this region from the 1950s to the 1970s. Even UNEP's Criteria Expert Group (CEG), which is charged with developing criteria and procedures for addition of substances beyond the original 12 POPs, has highlighted the importance of ''near-field'' exposures:

> In warmer climates exposures may occur closer to the source; e.g., occupational exposure during use, or local exposure caused by runoff from use or leaking from stockpiles. Food, such as fish, may be a major route of intake also in warmer climates [in contrast to Arctic and sub-Arctic regions] and POPs may accumulate in the food chain and reach high levels in predatory species in these conditions. (UNEP/POPS/INC/CEG/1/2: 1998) (Ref. 56)

An additional factor that argues for adopting the more protective persistence criterion is the need for communities with vulnerable populations to have access to data on release and other waste management quantities. Examples of such populations include toddlers who play in contaminated soil, local farmers who consume their own produce, and subsistence as well as sport fishers, who often consume large quantities of what they catch. The relative importance of any of these pathways depends on the properties of the substance, rates and media of release and other factors, but ingestion of bioaccumulating substances may occur by all of these routes. The Organization for Economic Cooperation and Development (OECD) guidance on the assessment of indirect human exposure to chemical toxicants is consistent with EPA policy, and states that in the case of local, site-specific emissions, one or more of these subgroups may be particularly endangered (Ref. 53).

From a scientific perspective there is no one best persistence criterion. However, it is simply not accurate to state that there is no precedent or basis for using a persistence criterion of 2 months. As outlined in the proposed rule (64 FR 701), similar values have been proposed by several authorities, including the Ontario, Canada Ministry of Environment and Energy (MOEE) for its Candidate Substances List for Bans or Phaseouts (Ref. 36); the Canadian initiative for Accelerated Reduction/Elimination of Toxics (ARET) (Refs. 1 and 2); the International Joint Commission's (IJC) Great Lakes Water Quality Agreement (GLWQA) (Ref. 27); and the UNECE's LRTAP Convention, which did adopt 2 months as the persistence criterion of record for water (Ref. 54). In each of these programs the focus was on persistent, bioaccumulative and toxic substances, and it is noteworthy that all are national or regional, not global, in scope. Thus, a trend exists in which authorities with domestic or regional mandates to take action to reduce risks from indirect exposure to PBT chemicals have recommended half-life criteria substantially lower than 6 months.

EPA's Office of Water maintains a Listing of Fish and Wildlife Advisories (LFWA) for the U.S. and territories, which listed 2,299 advisories in 1997 (Ref. 29). U.S. states and territories and Native American tribes have primary responsibility for issuing advisories for the general population, which include recommendations to limit or avoid consumption of certain fish and wildlife from specific water bodies. The overwhelming majority of the advisories are for well recognized PBT chemicals (chlordane, mercury, PCBs, etc.), but many less familiar substances are also represented. The number and content of advisories in LFWA clearly indicate that toxicologically significant levels of chemical contaminants, specifically PBT chemicals, are often found in fish and wildlife that are caught noncommercially and consumed by the U.S. population. It is generally impossible to determine the exact source(s) of exposure for the species and locations included in any given advisory, but it seems highly unlikely that the majority of listed contaminants in U.S. waters could be derived from non-U.S. (i.e., geographically distant) sources. The LFWA thus lends further support to the contention that concern for exposure to PBT chemicals is not limited to situations where the exposure results primarily from LRT. It should be noted that the fact that no advisories have been issued for a particular chemical does not mean that it does not persist. Not all species of aquatic organisms are tested nor are all water bodies, in addition, each state determines what it will use as the level of concern for issuing an advisory.

A series of Toxic Substances Control Act (TSCA) section 5 Premanufacture Notifications (PMNs) submitted to EPA in 1990 also illustrates that exposure to PBT chemicals is not limited to LRT (Refs. 37 and 38), and also demonstrates: (i) Why EPA believes that the persistence criterion for bioaccumulating substances in soil, water, or sediment should be set substantially lower than 6 months; and (ii) that for purposes of EPCRA section 313, concern for potential exposures to persistent and bioaccumulative toxics

must extend beyond the UNEP's 12 widely acknowledged POPs. The substances in question were alkylated diphenyls for use as solvents, and for which EPA expected discharge to receiving streams and rivers. The submitter supplied data on use and disposal, aquatic toxicity, and biodegradability. The submitted environmental fate data and EPA estimates of biodegradability based on structural analogs suggested that half-lifes in water would be well below 6 months, but not necessarily lower than 2 months. As a result of concerns expressed by EPA, use was limited to sites where resulting water concentrations could be limited to 1 microgram per liter (µg/L) or less; concomitantly, the submitter was also informed of EPA's belief that a potential for *long-term risk* existed, but that EPA could not quantify this risk since assessments typically evaluated releases over only 1 year. In 1998, results of monitoring were announced by the State EPA and revealed that the alkylated biphenyls had been found in fish fillets and sediment samples from the receiving stream.

One commenter contends that the persistence criteria of half-lifes of 2 months for water, soil, and sediment and 2 days for air may not be sufficiently protective (i.e., the criteria may be too high).

EPA disagrees with the comment. EPA believes that it should adopt criteria that focus on toxic chemicals that will build up in the environment, while at the same time not limiting the list of persistent toxic chemicals to only those that are of global concern. As discussed earlier in this section, EPA believes that 2 months is a reasonable half-life criterion given the purposes of EPCRA section 313. EPA believes that application of lower criteria would include so many substances as to be impractical. Further, given the uncertainties that often exist regarding physical properties and environmental behavior of chemicals, caution is especially appropriate for substances with shorter half-lifes, since they are (all other things being equal) less likely to build up in the environment than more persistent substances. EPA believes that the adoption of criteria of half-lifes of 2 months in water, soil, and sediment and a half-life of 2 days in air allows EPA to balance the need to provide communities and other data users with information on toxic chemicals that persist in their environment without being overly inclusive or restrictive.

One commenter contends that a half-life criterion for air of 2 days should be considered sufficient in and of itself for designating substances as persistent.

EPA agrees with the comment. EPA made the following statements in the proposed rule regarding the 2–day air half-life criterion and its use in the determination as to whether a chemical was a PBT under EPCRA section 313:

> For the purposes of determining whether a toxic chemical is persistent in the environment under section 313, EPA used a half-life criterion of 2 months for water/sediment and soil and a half-life of 2 days for air. Given the above discussions, EPA believes that, for purposes of reporting under section 313, these values are appropriate for determining whether a toxic chemical is persistent in the environment and will persist long enough in the environment to bioaccumulate or be transported to remote locations. Under these criteria, if a toxic chemical meets any one of the media specific criteria, then it is considered to be persistent. Thus if a toxic chemical's half-life in water or sediment or soil is equal to or greater than 2 months or greater than 2 days for air then the toxic chemical is considered to be persistent for purposes of section 313. Note that when considering persistence in connection with the potential for a toxic chemical to bioaccumulate, meeting the air half-life criteria alone would not be sufficient, since a chemical's potential to bioaccumulate is usually dependent on it being persistent in either water, sediment, or soil. In determining whether the chemicals in this proposal were persistent, EPA did not rely solely on the persistence in air. (at 64 FR 702)

It is clear from the discussion above that EPA agrees with the commenter that when considering persistence alone an air half-life of 2 days would be considered sufficient to classify a chemical as persistent under EPCRA section 313. However, for the reasons explained above, if a chemical only meets the 2–day air half-life persistence criteria, EPA does not believe that would be sufficient for classifying a chemical as a PBT under EPCRA section 313.

Some commenters contend that EPA's two-tiered approach to the persistence criteria is confusing.

EPA notes that it proposed only one set of persistence criteria for EPCRA section 313, half-lifes of 2 months or greater in water, soil, and sediment and 2 days in air. The Agency did not propose to use half-lifes of 6 months or greater in water, soil, and sediment and 2 days in air as a second set of persistence criteria for EPCRA section 313. However, for purposes of setting reporting thresholds in this rulemaking, the Agency did choose to focus on the subset of PBT chemicals that have half-lifes of 6 months or greater in water, soil, or sediment (and BCF/BAFs greater than 5,000) by proposing a 10 pound reporting threshold.

For the reasons given above, EPA reaffirms its intention to use a half-life of 2 months as the criterion for persistence in water, soil, and sediment and a half-life of 2 days as the criterion for air when characterizing a chemical as persistent for purposes of EPCRA section 313.

b. *Bioaccumulation*. EPA proposed as bioaccumulation criteria for the TRI program bioaccumulation/bioconcentration factors of 1,000. As discussed in Unit VI.B.1., EPA disagrees that it must choose for EPCRA section 313, bioaccumulation criteria consistent with the international criteria. Applying these strict criteria to EPCRA section 313 would result in a very narrow list of chemicals that would focus on only extremely bioaccumulative chemicals. This is inconsistent with the purposes of EPCRA section 313 and with EPA's technical judgment. There is no ''bright line'' that separates what is bioaccumulative from what is not bioaccumulative. The degree of bioaccumulation is a continuum. Chemicals with BCFs or BAFs of 1,000 to 5,000 are not non-bioaccumulative. They are less bioaccumulative than chemicals with BCFs or BAFs greater than 5,000. The degree of bioaccumulation that should be used as a criterion is not an absolute scientific determination. Rather it is a combination of science and policy. As discussed in the proposed rule and below, organizations have generally used as bioaccumulation criteria BAFs/BCFs of 1,000 and 5,000. The determination of which numerical criterion to apply will depend on the final intent: for example, providing communities with information on bioaccumulative chemicals that can accumulate in organisms versus banning the manufacture and use and eliminating releases of a chemical that has global impacts. For EPCRA section 313 which provides information on toxic chemicals to communities, researchers, and governments, the criteria should be in keeping with both the Agency's scientific judgment and the intent of the statute.

From a scientific perspective there is no one bioaccumulation criterion. However, it is simply not accurate to state that there is no precedent or basis for using a bioaccumulation criterion of 1,000. As noted in the proposed rule, for a number of years EPA scientists and programs have used a BCF of 1,000 or more to indicate a high level of concern for bioaccumulation. In addition, this value has been used in some Canadian projects, many dealing with the Great

Lakes basin. Also, Germany proposed a BAF/BCF criterion of 1,000 during negotiation of the LRTAP Protocol. Support for a BAF criterion of 1,000 also comes from the Final Water Quality Guidance for the Great Lakes System (FWQGGLS) (60 FR 15366, March 23, 1995) (FRL–5173–7). In this document, EPA stated that bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem and that chemicals identified as bioaccumulative chemicals of concern (BCCs) (i.e., with BAF values greater than 1,000) would receive increased attention and more stringent controls. The final guidance designated as BCCs those chemicals with human health BAFs greater than 1,000 that were derived from certain field-measured BAFs. One commenter believed that the BAF criteria used in the FWQGGLS did not provide support for the use of a BAF of 1,000 since a more strenuous methodology taking more factors into account was used. However, EPA believes that this does provide support for the criteria established for the purposes of EPCRA section 313 because, although the underlying technical assessments may be more stringent, the bioaccumulation level of concern is still a BAF of 1,000. Also, as noted by some commenters, EPA has proposed to use a BCF/BAF of 1,000 to trigger testing under TSCA section 5(e) (63 FR 53417). Specifically, for chemicals subject to TSCA section 5 that have a BAF of 1,000 or greater and that meet certain toxicity and persistence criteria (similar to the EPCRA section 313 persistence criteria) testing would be ''triggered'' by specific production limits. While the manufacturer of the chemical would be allowed to commercialize the substance, certain controls could be stipulated, including specific limits on exposures, releases, or uses. EPA notes that in the same **Federal Register** document, the Agency has proposed that chemicals that have a bioaccumulation factor of 5,000 and that meet certain toxicity and persistence criteria (e.g., half-life of 6 months or greater in soil) be placed in a ''Ban Pending Testing,'' bin. Chemicals meeting these criteria could be subject to more stringent control up to a ban on commercial production.

Not only is there precedent for the use a BCF/BAF of 1,000, but EPA believes that the purposes of the statute argue for the use of the more expansive criterion. Data on PBT chemicals are the type of information that will be of particular use to specific communities such as those that consist of subsistence fishers. Subsistence fishers (as well as sports fishers) are more highly exposed to PBT chemicals than the general population. Subsistence fishers consume large quantities of what they catch. In addition, children are affected by lower doses of certain PBTs than are adults. Children of both subsistence fishers and sport fishers will consume larger quantities of lake food and seafood than children in other communities. As discussed in Unit VI.B.2., EPA's Office of Water maintains a Listing of Fish and Wildlife Advisories (LFWA) for the U.S. and its territories, which listed 2,299 advisories in 1997 (Ref. 29). The overwhelming majority of the advisories are for well-recognized PBT chemicals (chlordane, mercury, PCBs, etc.), but many less familiar substances are also represented. The number and content of advisories in LFWA clearly indicate that toxicologically significant levels of chemical contaminants, specifically PBTs, are often found in fish and wildlife that are caught noncommercially and consumed by the U.S. population. It should be noted that the fact that no advisories have been issued for a particular chemical does not mean that the chemical does not bioaccumulate. Not all species of aquatic organisms are tested nor are all water bodies. In addition, each state determines what it will use as the level of concern for issuing an advisory. EPA believes that it would be inconsistent with the intent of EPCRA section 313 to limit the information on bioaccumulative toxic chemicals to only information for the most bioaccumulative.

One commenter contends that EPA did not provide scientific justification for its choice of the bioaccumulation criterion of a BCF/BAF of 1,000. The commenter states the EPA's discussion of the origin of the 1,000 BCF/BAF value at a 1976 meeting sponsored by the American Society of Testing and Materials, and its reaffirmation in 1995 in a research article by two of the original authors, the use of the value by scientists in EPA's Office of Research and Development's Duluth Laboratories, by EPA's Office of Pollution Prevention and Toxics in the review of chemicals under TSCA sections 4 and 5, by EPA's Office of Water in the Final Water Quality Guidance for the Great Lakes System, and the use by other authorities, such as the German government, to identify chemicals of high concern for bioaccumulation do not provide a technical basis for choosing a value of 1,000 as a criterion for bioaccumulation. The commenter contends that a criterion of 5,000 is scientifically supportable because chemicals with a BCF/BAF of 5,000 have a high potential to biomagnify.

As discussed above, there is no scientifically ''best'' bioaccumulation criterion. The degree of bioaccumulation is a continuum. A chemical does not bioaccumulate only if it has a BCF that is 5,000 or greater. A chemical that has a BCF of 1,000 will bioaccumulate, specifically the chemical will be present in an organism at a concentration that is 1,000 times greater than its concentration in the surrounding aqueous environment. Rather the choice of a value along the bioaccumulation spectrum is based to a large degree on how the criterion is to be used, e.g., to track chemicals entering a particular environment, or to restrict the use of chemicals, etc. As such the choice of a bioaccumulation criterion is a combination of science and policy.

The commenter did not provide support for the contention that 5,000 was scientifically the ''best'' bioaccumulation criterion. Specifically, the commenter did not indicate why as a scientific matter a BCF of 5,000 was preferable to a BCF of, for example 4,000 or a BCF of 15,500. While the commenter did note that chemicals that have a BCF of 5,000 tend to have a high potential to biomagnify, the commenter did not indicate in what way this factored into his determination that a BCF of 5,000 is the scientifically ''best'' bioaccumulation criterion. In addition, EPA does not agree that a BAF or BCF of 5,000 indicates that a chemical will be more likely to biomagnify since biomagnification is a much more complex process. Biomagnification is not a separate process from bioaccumulation or bioconcentration, but is instead a specific example or subset of both. Biomagnification has been defined as: The result of the processes of bioconcentration and bioaccumulation by which tissue concentrations of bioaccumulated chemicals increase as the chemical passes up through two or more trophic levels (Ref. 43). The difference between bioaccumulation and biomagnification is that for a chemical to biomagnify its level of bioaccumulation must increase as it moves up the food chain. The whole concept of biomagnification can be viewed as controversial (Ref. 9) and biomagnification has been studied for only a few chemicals. Most importantly, biomagnification is not required in order to have a concern for chemicals that bioaccumulate. This is because bioaccumulation in even one species can have a serious impact on that species or any other species that feeds on it. For example, if a chemical only bioaccumulates in fish then the fish will

be exposed to higher concentrations of the chemical as will anything that eats the fish. Therefore, EPA believes that there is no reason to establish biomagnification as a criterion for PBT chemicals since bioaccumulation is of more than sufficient concern in and of itself.

None of the other commenters who believe that the bioaccumulation criterion of 1,000 is too expansive suggested that EPA adopt another value, other than the 5,000 value used in international agreements, addressed in previous responses in this unit. At most, several commenters took issue with the fact that the EPCRA section 313 bioaccumulation criterion (BCF/BAF of 1,000) is 5 fold less than the international bioaccumulation criterion of a BCF/BAF or 5,000. Given that for each of these programs the focus was on PBT chemicals that are of global concern, EPA believes that as a matter of public policy, it is more appropriate for a reporting program to use a more protective criterion than that used in international agreements that seek to ban or severely restrict the use and/or release of chemicals.

One commenter believes that EPA should not adopt a bioaccumulation criterion (BCF/BAF of 1,000) for EPCRA section 313 that is more stringent than the criterion for a Great Lakes BCCs (a human health BAF of 1,000). EPA notes that BCCs will receive stringent controls which is not the case for toxic chemicals identified as bioaccumulative (and persistent) under EPCRA section 313.

Many commenters supported the proposed bioaccumulation criterion of a BCF/BAF or 1,000. However, one of these commenters believes that 1,000 should be the criterion only if the BCF or BAF is a measured value. If the BCF is an estimated value, then the criterion should be 500.

EPA believes that such a two-tiered approach will add confusion. Further, estimated or predicted BCFs are often based on measured data and equations that have been found to correlate well with measured data. In addition, EPA believes that a BCF of 500 is overly expansive. EPA believes that expanding the criteria to include estimated BCFs of 500 would label so many chemicals as bioaccumulative as to be impractical. EPA believes that the adoption of the criterion of BCF/BAF of 1,000 allows EPA to balance the need to provide communities with information on toxic chemicals that bioaccumulate without being overly inclusive or restrictive.

Some commenters contend that EPA's two-tiered approach to the bioaccumulation criteria is confusing. EPA notes that it proposed only one bioaccumulation criterion for EPCRA section 313, a BCF/BAF of 1,000. The Agency did not propose to use a BCF/BAF of greater 5,000 as a second bioaccumulation criterion for EPCRA section 313. However, for purposes of setting reporting thresholds in this rulemaking, the Agency did choose to focus on the subset of PBT chemicals that have a BCF/BAF greater than 5,000 (and half-lifes greater than 6 months) by proposing an even lower reporting threshold.

For the reasons given above, EPA reaffirms its intention to use a BCF/BAF of 1,000 as the criterion for characterizing a chemical as bioaccumulative under EPCRA section 313.

c. *Toxicity*. A number of commenters contend that EPA should set a separate toxicity criteria for PBT chemicals. EPA disagrees. EPCRA section 313 provides toxicity criteria at section 313(d)(2) to be used in adding a chemical to or deleting a chemical from the EPCRA section 313 list of toxic chemicals. These criteria are:

(A) 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.

(B) The chemical is known to cause or can reasonably be anticipated to cause in humans-

(i) cancer or teratogenic effects, or

(ii) serious or irreversible-

(I) reproductive dysfunctions,

(II) neurological disorders,

(III) heritable genetic mutations, or

(IV) other chronic health effects.

(C) The chemical is known to cause or can reasonably be anticipated to cause, because of-

(i) its toxicity,

(ii) its toxicity and persistence in the environment, or

(iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

Given that Congress has provided EPA with specific toxicity criteria, and that listed chemicals are statutorily defined as ''toxic chemicals,'' the Agency does not believe that additional ''toxicity'' criteria would be appropriate. One reason is that the Agency is concerned that this would imply that TRI data on the toxic chemicals that meet the statutory toxicity criteria are of less value than TRI data that meet both the statutory toxicity criteria and some additional toxicity criteria that would be developed by EPA. EPA believes that bifurcating the list with an additional, non-statutory toxicity criteria would be inconsistent with the intent of Congress. In addition, it is worth noting that some of the toxicity criteria presented by the commenters are fundamentally consistent with the toxicity criteria outlined in the statute. However, EPA notes that some of the criteria provided by the commenters are risk criteria rather than hazard criteria. For example, see ICCA Briefing Note on POPs (April 21, 1998) (Ref. 26). As discussed at length in the final rule adding 286 chemicals to the EPCRA section 313 list (59 FR 61432), the EPCRA section 313(d)(2)(B) toxicity criteria (chronic toxicity) are hazard criteria, not risk criteria. The EPCRA section 313(d)(2)(C) criteria are primarily hazard based with only a limited exposure component. To impose additional toxicity criteria for purposes of defining a PBT or a PT or BT chemical based on risk rather than hazard would be inconsistent with EPCRA section 313. See, e.g., *Legislative History* at 5186. Risk assessment may be appropriate for use under statutes that control the manufacture, use and/or release of a chemical. However, EPCRA section 313 is an information collection provision that is fundamentally different from other environmental statutes that control or restrict chemical activities. For these reasons, EPA believes that it is inappropriate to add toxicity criteria, beyond the criteria provided by Congress at EPCRA section 313(d)(2).

3. *Persistence and bioaccumulation consideration under EPCRA section 313(d)(2)(C)(ii) and (iii)*. The criteria that EPA has laid out in this rule for determining if a chemical is a persistent and/or bioaccumulative chemical are not the same criteria EPA uses when conducting assessments for listing chemicals pursuant to EPCRA section 313(d)(2)(C)(ii) and (iii). These sections of EPCRA allow EPA to consider whether a chemical meets the listing criteria based on ''its toxicity and persistence in the environment'' or ''its toxicity and tendency to bioaccumulate in the environment.'' Including consideration of persistence and/or bioaccumulation modifies the way in which EPA assesses a chemical's toxicity for purposes of listing. EPA interprets the results of the toxicity data in light of a chemical's persistence and/or bioaccumulation, and adjusts its concerns for the chemical's toxicity in accordance with the degree to which a chemical persists or bioaccumulates. For example, standard aquatic toxicity tests provide toxicity results in time frames that range from hours to a few weeks. For aquatic toxicity that results

from such short exposure times, a chemical with a persistence half-life of even 2 weeks will result in a greater potential for exposure and therefore increased concern for the concentration at which toxicity is expressed. In this case, EPA would be concerned about the chemical's persistence at levels well below a half-life of 2 months or more. Because EPA's concern under these provisions is with the interrelationship between two chemical properties and how that affects whether the chemical can reasonably be anticipated to cause a significant adverse effect on the environment, EPA believes that it needs to be able to consider a broader range of values. By contrast, the persistence and bioaccumulation criteria established in today's rulemaking serve a different purpose; they are intended to operate independent of a chemical's toxicity, to identify a fixed class of chemicals. EPA has provided this explanation to clarify the different purposes of the persistence and bioaccumulation criteria established in this rule, and the use of persistence and bioaccumulation in assessments pursuant to EPCRA section 313(d)(2)(C)(ii) and (iii).

C. Criteria as they Apply to Metals

Many commenters contend that the persistence criteria proposed by EPA were developed for organic chemicals and cannot be applied to metals, or if applied, are not useful in screening for hazard. The critical parameter in determining risk is bioavailability, not persistence. This has been recognized by international organizations of which EPA is a member, so it is unclear why it is now necessary for EPA to deviate from these policies. Metals are not harmful if they are not in a bioavailable form. Moreover, metals are natural components of the earth's crust and many are accumulated by living organisms because they are essential nutrients. Two of the commenters state that because persistence is defined as ''the failure of a substance to readily biodegrade,'' this concept has no relevance for metals.

EPA disagrees. The scientific literature contains many definitions of persistence which vary in detail, but center on a common theme: persistence is the *ability of a chemical substance to remain in a particular environment in an unchanged form*. This definition makes no mention whatsoever of any specific processes that may impact a substance's environmental fate, such as biodegradation. According to this definition, specific metal compounds may or may not be persistent depending on the form of the metal and environmental conditions, but the elemental metal itself obviously meets the definition, and this was acknowledged in the majority of comments received.

That elemental metals are persistent by definition is widely accepted. While they may take different oxidation states that can be interconverted, the elemental metal itself cannot be destroyed. For example, chromium (VI) may convert to chromium (III). Both are simply different forms of chromium. All elemental metals therefore meet the 2 months half-life criterion automatically. Given this, it is obviously false to assert, as did the majority of commenters on this issue, that EPA's proposed persistence criteria *cannot be applied* to metals. The position of many commenters was that in determining whether a metal or metal compound may actually pose a risk if released to the environment, bioavailability is much more important than the fact that a substance meets the formal ''definition'' of persistence. EPA agrees that bioavailability is important in determining the potential for the metal to be accumulated in organisms, but parent metals do have the potential to become available from metal compounds under common environmental conditions. Availability of the metal ion may be the result of biotic or abiotic processes. There are a number of environmental factors which EPA considers in determining the availability of the metal ion. These include hydrolysis, pH effects on solubility, photolysis, aerobic and anaerobic transformations, and *in vivo* transformations. As outlined in the remainder of this section, it is realistic to expect that, in general, metals when released into the environment can encounter conditions in which they are available at levels sufficient to exert toxicity and bioaccumulate.

EPA also disagrees with the commenters' claims, direct or implied, that metals released to the environment as a result of human activity must be of negligible concern because they:

- Cannot be converted to bioavailable forms; or even if initially bioavailable are rapidly sequestered in such a way that subsequent exposure is impossible; or
- If bioavailable, are naturally wholesome and good because organisms need them to function.

EPA disagrees with this simplistic view. Metals can enter the environment in bioavailable forms or can be converted in the environment into bioavailable forms. As shown below, metals and metal compounds may be available to bioaccumulate under many realistic and common environmental conditions.

The commenters are correct in stating that metals released to the environment from anthropogenic sources are affected by prevailing environmental conditions, meaning broadly the wide variety of physical, chemical and biological processes that act upon them, and these collectively determine the form in which the metal ultimately exists.

According to Klein (Ref. 28), interconversion of inorganic metal compounds can be quite rapid, especially for ionic forms, and as a result the chemical form in which an elemental metal is released may not be the predominant form post-release. Generally, the ionic forms of inorganic metals are the most available. Availability is affected by many factors and its determination is complex. For metals environmental conditions can affect their availability. A detailed scientific discussion of the environmental fate of lead, which is representative of other metals, and that is illustrative of many of the more important environmental variables that affect availability is provided in Refs. 14, 28, 30, 50, 66a, 72, and 84. See also the preamble to EPA's recent proposal to lower the EPCRA section 313 reporting thresholds for lead and lead compounds (64 FR 42222). The same basic chemical properties and environmental variables will affect the degree of availability of a metal in the environment regardless of the specific metal. There is no metal that is unavailable under all conditions.

EPA recognizes that lead and lead compounds are the subject of an EPA proposal under EPCRA section 313 (64 FR 42222). The inclusion of the discussion of the environmental fate of lead and lead compounds does not predetermine EPA's decision on the appropriate thresholds that should be set for lead and lead compounds. That determination will be based on a number of factors, including the bioaccumulation of lead.

Microbial transformations in soil, water, and sediment are often important in determining the overall fate of metals and metal compounds, and therefore the potential for formation of bioavailable forms. Metals known to undergo microbial oxidation/reduction processes include, antimony, arsenic, iron, mercury, selenium, and tellurium (Ref. 11). Arsenic microbiology illustrates the importance of environmental conditions in the interconversion of inorganic forms of arsenic. Microbial populations in activated sludge can oxidize arsenite to arsenate under aerobic conditions, but under anaerobic conditions such as often predominate in sediments, arsenate can be reduced to arsenite and

beyond. Both arsenites and arsenates can be available in the environment (Ref. 11). Microorganisms can reduce mercury in the form of mercuric chloride to elemental mercury, and are also capable of producing elemental mercury from organomercurials such as phenylmercuric acetate and methylmercuric chloride. Although the reduction of Hg^{2+} to elemental mercury can be regarded as decreasing availability, the elemental mercury formed is volatile and more likely to enter the global atmospheric circulation.

Mercury is perhaps better known for its potential to be biomethylated by bacteria in the environment (Ref. 11). Mercury has very high stability constants with organic ligands and can form true organometallic compounds (Ref. 6). As indicated by Stumm and Morgan (Ref. 49), metals and metalloids that form stable alkyl compounds are of special concern because they may be volatile; may accumulate in cells; and are toxic to the central nervous system of higher organisms. Methylmercury is highly bioaccumulative and is by far the best studied example of microbial bioalkylation. However, methylation of arsenic is also fairly well-characterized, involves the replacement of substituent oxygen atoms by methyl groups (e.g., arsenate is biomethylated to form dimethylarsine), and is important in the transfer of arsenic from sediment to the atmosphere (Ref. 11). Lead, germanium, selenium, tellurium, tin, and several other metals can also be biomethylated (Ref. 49).

Many of the commenters noted that certain metals are indeed micronutrients (e.g., cobalt, copper, and iron), and are accumulated precisely because they are required for certain cellular functions. It does not follow, however, that any amount of the same metal is acceptable or desirable. Accumulation of essential elements is usually governed by homeostatic mechanisms that control uptake (Ref. 28), but excessive uptake is possible and can be toxic to an organism. For example, selenium which is a micronutrient can cause selenosis at doses as low as 0.023 milligrams per kilogram per day (mg/kg/day). Clinical signs of selenosis include the characteristic ''garlic odor'' of excess selenium excretion in the breath and urine, thickened and brittle nails, hair and nail loss, lowered hemoglobin levels, mottled teeth, skin lesions, and central nervous system (CNS) abnormalities (peripheral anesthesia, acroparesthesia, and pain in the extremities) (Ref. 61). Similarly, copper, which is an essential nutrient, at high doses can cause vascular injury and hemolytic anemia. It should also be noted that copper exhibits high acute and chronic toxicity to aquatic organisms that results in the death of the organism (61 FR 54381, October 18, 1996) (FRL–5396–9), and inhalation of hexavalent chromium is known to cause cancer in humans (Ref. 60), even though chromium in very small oral doses is a micronutrient (Ref. 25). Moreover, the commenters freely cite Allen (Ref. 4), Chapman (Ref. 18) and other authors to the effect that metals are accumulated ''deliberately'' depending on the physiological needs of the organism, but it is clear that this applies only to metals that are essential nutrients. Metals are generally taken into cells by nutrient metal transport systems, and these are not sufficiently specific to completely exclude nonessential metals, some of which may be toxic and/or bioaccumulative. In this situation nutrient metals can be displaced from their binding sites by undesirable, toxic metals, which then gain access to the cell interior with concomitant exclusion of the essential metal (Ref. 49). Toxic metal ions are then free to react with critical enzymes or otherwise disrupt cellular functions if they reach certain levels. Often this toxicity occurs at relatively low doses. For example, inorganic arsenic is a known human carcinogen and causes chronic toxicity at doses as low as 0.014 mg/kg/day (Ref. 59). Lead has no known biological function in humans but is readily absorbed and has been shown to cause various toxic effects. For example, children can suffer permanent damage from lead poisoning, resulting in lowered intelligence, learning disabilities, hearing loss, reduced attention span, and behavioral abnormalities (Ref. 66).

EPA concludes that under many environmental conditions, metals and metal compounds may be available to express toxicity and to bioaccumulate, and that these effects are not necessarily limited to metals that are not essential nutrients. It is appropriate, therefore, to be concerned about the potential adverse effects, and one step in this direction is to more accurately assess emissions from anthropogenic activities. EPCRA section 313 provides that opportunity. Precedent for this concern exists at the international level in the form of a protocol for heavy metals under the UNECE LRTAP, which is currently being negotiated. The draft protocol expresses concern ''. . .that emissions of certain heavy metals are transported across national boundaries and may cause damage to ecosystems. . .and may have harmful effects on human health. . .,'' and specifically advocates assessing and controlling emissions caused by human activities (Ref. 54).

Several commenters raised the issue of EPA participation in various international organizations, claiming that any attempt to apply EPA's proposed persistence and bioaccumulation criteria and/or assessment approach to metals would violate the policies of these organizations, whose positions EPA has previously endorsed. These claims are false because the commenters either misunderstand or misstate the aforementioned policies. The main focus of the commenter's attention is two documents, the OECD's *Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances* (Ref. 41), and the North American Agreement on Environmental Cooperation (NAAEC)'s *Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative* (Ref. 39). A report from a joint Canada/European Union Technical Workshop on metals (Ref. 17) was also cited by commenters and reached similar conclusions.

The OECD document's pronouncements on metals are contained in paragraphs 22 and 23 of that document. Paragraph 22 reads as follows:

> For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally, the use of bioaccumulation data should be treated with care. Specific guidance will be [but has not yet been] provided on how these data for such materials may be used in meeting the requirements of the classification criteria. (Ref. 41)

By ''degradability as applied to organic compounds'' OECD means molecular degradation, most often by microbial degradation and/or hydrolysis or other abiotic processes, to progressively simpler organic chemical structures, leading eventually to inorganic substances like carbon dioxide and water. But, note, paragraph 22 does not in any way suggest that metals are not persistent. Moreover, it does not suggest that OECD hazard classification criteria cannot be applied, only that ''care'' (i.e., professional judgment) is required in the interpretation of data relative to the classification criteria. In fact, EPA agrees that bioavailability is important in determining the potential for the metal to be accumulated in organisms.

The Agency has analyzed information on the environmental fate of metals, and, as noted above, asserts its professional judgment that the parent metals do have the potential to become available from metal compounds under commonly encountered environmental conditions. Therefore, the Agency's treatment of metals is consistent with the OECD's intent.

The same holds with respect to NAAEC's pronouncements under the SMOC (Ref. 39). The focus of NAAEC/SMOC (Ref. 39) is the development of North American Regional Action Plans (NARAPs) for substances that pose significant risk to human health and the environment in all three member countries (namely, Mexico, Canada, and the United States). To date, NARAPs have been established for DDT/chlordane, PCBs, and mercury (note: a metal). NAAEC/SMOC (Ref. 39) acknowledges the persistence of metals, but highlights the role of expert judgment in assessing potential bioavailability of metals and metal compounds:

> For naturally occurring substances such as metals and minerals, the Task Force understands that the direct application of the persistence and bioaccumulation criteria proves very difficult.....Organometals can behave like other persistent organic pollutants in their metallic form, and as certain compounds, metals tend to be infinitely persistent though not necessarily in a form that is bioavailable, and in some cases, they naturally bioaccumulate for beneficial purposes in organisms (i.e., essential elements). Expert judgment is essential for a meaningful evaluation of these substances.

Further, an earlier section of the document (Ref. 39) states,

> It is understood that expert scientific judgment plays a significant role in acknowledging and addressing the difficulties posed by quantitative criteria for persistence and bioaccumulation, particularly in relation to naturally-occurring substances like metals and minerals where the potential for transformation to complexes or metallic species which are more or less bioavailable, are emerging as important considerations.

It is difficult to read into the preceding any intention to *exclude* metals and metal compounds from consideration, as many commenters imply, and more specifically, to declare that these substances have no potential to pose risk because they are never released in bioavailable forms; cannot be converted to bioavailable forms under any foreseeable circumstances, etc. On the contrary, it is clear from the preceding language as well as the inclusion of mercury among the NARAPs developed to date that any substance judged to be potentially bioavailable and that otherwise meets the SMOC criteria, whether organic or inorganic, should not be excluded as a candidate for action. As outlined above, it is realistic to expect that, in general, released metals can encounter conditions in which they are available at levels sufficient to exert toxicity and bioaccumulate. Therefore, the Agency's treatment of metals is consistent with international policy under NAAEC/SMOC (Ref. 39).

Finally, EPA reminds commenters that a mechanism already exists to address concerns for any metal compound for which the data show that the metal cannot become available. The issue of bioavailability was addressed previously for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (56 FR 23703, May 23, 1991). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes, then the metal will not be available to express its toxicity, and by extension, to bioaccumulate. If the intact metal compound is not toxic and the metal is not available from the metal compound, then such a chemical is a potential candidate for delisting. EPA has received fewer than 10 petitions to delete individual metal compounds because the petitioner contended that the metal portion of the metal compound would not be available under environmental conditions or *in vivo*.

D. Multimedia Modeling

One commenter contends that EPA should clarify how and when multimedia models will be used in the evaluation of PBT chemicals. EPA should not use the EQC model or other multimedia models as the sole determinant of potential risk. If exposure and use information is available, a detailed technical evaluation based on these data is preferred over modeling based on hypothetical exposure and loading scenarios.

The purpose of this rulemaking is to lower reporting thresholds for certain EPCRA section 313 substances that are being designated as persistent and bioaccumulative, and to list several additional substances that meet EPCRA section 313 listing criteria and are also persistent and bioaccumulative. Although neither quantitative risk nor exposure assessments have been performed, nor are they required under EPCRA, designation as a PBT does imply the existence of *potential* risk. However, contrary to the comment, EPA has not proposed that multimedia models be used as the sole factor in determining persistence. As clearly stated in the proposed rule, EPA intends to use such modeling ''as an additional factor, in conjunction with reaction half-lifes for individual media, bioaccumulation/bioconcentration factors, etc., in justifying [the] actions proposed.''

In the proposed rule EPA did explain in a general way (at 64 FR 703) how models would be used in PBT evaluation, and stated that results of multimedia modeling may be used to override compartment (medium)-specific degradation half-lifes, but only if all model inputs are judged sufficiently accurate. This leaves unspecified what specific value(s) might be used for overall environmental persistence *criteria* (expressed either as an overall residence time or overall half-life). To date no international scientific or regulatory authority has proposed any such criterion for POPs/PBT chemicals, and the complex relationship between compartment-specific and overall persistence criteria is in fact a major topic of current research.

One commenter raises concerns regarding the modification EPA made to the EQC III model that deleted advective losses and sediment burial.

EPA modified the model to exclude advective losses and sediment burial because if these processes are included the persistence based on destruction will be underestimated. In multimedia modeling, advection can be viewed as the flow into or out of the evaluative environment or ''box.'' These include processes such as downstream flow in surface waters, dispersion downwind in air, and burial in sediments. The model considers these non-destructive processes to result in loss from the evaluative environment in the same way that destruction does. However, these processes simply result in the transport of a chemical to another part of the environment downwind or downstream from where it is released, or its deposition into sediments, but not the destruction of the chemical.

The persistence of a chemical calculated when the model is run considering advective losses include non-destructive transport processes which remove the chemical from the evaluative environment. For example, the environmental persistence of a chemical released to water which does not significantly partition to sediments, degrade, or volatilize will reflect the rate at which the water to which it is released flows out of the evaluative environment. In this example, the

relative rate of non-destructive transport out of the evaluative environment may be more rapid than the processes which result in the destruction of the chemical. Thus, the persistence calculated by the model will be less than if advective transport from the evaluative environment was not considered.

EPA used the model to evaluate persistence based on destruction in a multimedia environment. This is consistent with EPCRA section 313 persistence criteria in that the criteria are based on destruction, not transport of the chemical. The Level III (non-equilibrium partitioning, steady state mass balance) models are preferred for developing qualitative and quantitative predictions of chemical distribution, pathways, and relative concentrations (Ref. 16). Level III models can also be used to assess persistence (Ref. 33). At steady state (level III) conditions the amount of chemical is unchanging with time and the input and output rates for a compartment are equal. The overall residence time of the chemical is the mass of the chemical in the compartment divided by the input or output rates. This represents the average time the chemical will reside in the compartment. Output may be by reactions that result in the destruction of the chemical or by advective flow (non-destructive) usually in air or water. When the model is modified to eliminate advective flow, the persistence of a chemical based on the rates of reactions that result in the destruction of the chemical can be assessed. Webster et al (Ref. 82) used this approach in evaluating the environmental persistence of chemicals using a multimedia fate model and noted that if advective loss is included, the residence time is reduced and can give a misleading impression of a short persistence. It was also noted that these advective losses ''. . .merely relocate the chemical; they do not destroy it.'' EPA also used a modified version of the EQC level III model as a tool to assist on the characterization of the persistence of the chemicals subject to this rule. In this version of the model only irreversible transformation contributes to net loss of a chemical. In other words, the model was modified to represent a ''closed box'' in which the effect of processes that serve only to move the chemical from within the evaluative environment to outside of it, primarily in air and water (advective losses) were nullified. Sediment processes responsible for transport of the chemical from the evaluative environment such as sediment burial were similarly treated. The intent of this modification was to make sure that only processes responsible for the destruction of the chemical were considered in evaluating its persistence in a multimedia environment. EPA supports the use of level III multimedia models modified, as described, for their ability to simultaneously consider reaction rates and partitioning so as to give a reasonable assessment of the persistence of chemicals in the multimedia environment.

However, EPA notes that its reliance on the multimedia modeling was limited. As discussed in the proposed rule (at 64 FR 703) and in Unit VI.B.2., EPA primarily considered media-specific data and made a case-by-case determination about the persistence of each chemical.

E. Thresholds

The issue most frequently raised by commenters was the Agency's choice of thresholds and the factors that EPA considered in lowering the thresholds. Many commenters contended that EPA should not consider burden in choosing thresholds. They believe that EPA should set a threshold of 10 pounds for PBT chemicals and 1 pound for that subset of PBT chemicals that are both highly persistent and highly bioaccumulative. Some commenters believe that EPA should set a threshold of 1 pound for all chemicals that are PBT chemicals. Numerous commenters believe that the threshold for reporting should be zero. Other commenters believe that burden should have been a greater consideration in EPA's choice of reporting thresholds. Many of these commenters believe that EPA should set thresholds based on some percentage of releases that would be reported.

EPA disagrees with these commenters. As explained in the proposal, the Agency considered a number of factors to determine the appropriate thresholds that should be established for these chemicals. EPA relied on the language of EPCRA sections 313(f)(2) and (h), and the legislative history to elicit the following principles to guide its exercise of discretion in lowering the thresholds, and in selecting the specific thresholds for PBT chemicals: (1) The purposes of EPCRA section 313; (2) the ''verifiable, historical data'' that convinces EPA of the need to lower the thresholds; (3) the chemical properties shared by the members of the class of toxic chemicals for which EPA is lowering the thresholds i.e., the degree of persistence and bioaccumulation; and (4) the reporting burden imposed by revised thresholds to the extent that such consideration would not deny the public significant information from a range of covered industry sectors. Further, EPA believes that in the language of EPCRA section 313, and its legislative history, Congress provided direction on the appropriate weight to allocate to each of these considerations in implementing EPCRA section 313(f)(2). These considerations underlay the entire process by which EPA determined the appropriate thresholds. But, as noted below, the Agency's choice of revised thresholds was governed, and ultimately constrained, by EPCRA section 313's overriding purpose, which is to provide government agencies, researchers, and local communities, with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems.

In general, EPA's implementation of EPCRA section 313 is guided by the statutory purposes described by EPCRA section 313(h), which provides:

> The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available. . .to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes.

In addition to section 313(h), EPA was also guided by several statements on the principles intended to guide EPA's implementation of EPCRA section 313 made by Representative Edgar, one of EPCRA section 313's principal architects, during debate on the Conference Report. See, *Legislative History* at 5313–16. In the course of his statement, Representative Edgar also articulated EPCRA section 313's overriding purpose, which is:

> to provide a *comprehensive view of toxic chemical exposure* and, hopefully, provide a basis for more sensible and effective local, State, and national policies. *Legislative History* at 5316 (emphasis added).

Based on the existing reporting requirements, the Agency believes that there are still significant gaps in the picture the TRI data provides local communities, government agencies, and researchers. One of the most significant of these gaps is a comprehensive picture of the releases and potential exposure of PBT chemicals to humans and the environment. Currently, only a very limited picture of releases and other waste management of PBT chemicals is available from the TRI data, in part, as a result of the current thresholds. For

example, under the current reporting thresholds, in 1997, EPA received only 29 reports on mercury and mercury compounds, and 6 reports on PCBs. This does not present a ''comprehensive view of toxic chemical exposure.'' In addition, information on the releases and other waste management of PBT chemicals is particularly significant because these chemicals both persist and bioaccumulate. Individually, each of these attributes has the potential to pose increased exposures to humans and the environment. Toxic chemicals possessing both attributes have the potential to pose *significant* exposures to humans and ecosystems over a longer period of time; even small amounts of PBT chemicals that enter the environment can accumulate to elevated concentrations in the environment and in organisms, and therefore have a greater potential to result in adverse effects on human health and the environment.

As a first step in addressing the significant gap of information on PBT chemical releases and waste management, EPA considered whether to lower the reporting thresholds for PBT chemicals. EPA then looked to section 313(f)(2) for further guidance on how to proceed. Since lowering the thresholds ensures that ''all facilities subject to the requirements of [section 313]'' will continue to report, the requirement in section 313(f)(2) that a revised threshold obtain a ''substantial majority of total releases of each chemical at all facilities subject to the requirements of this section'' can be met without the need for quantitative support. Consequently, EPA looked to other sources of Congressional direction in the statute and legislative history to guide its exercise of discretion in establishing revised thresholds.

Given that there is no guidance on implementing section 313(f)(2) in the Conference Report, EPA looked to the debate on the Conference Report. In this context, Representative Edgar, stated:

> It is also important to clarify the intent of Congress in establishing thresholds for reporting under this section. . . .These thresholds were designed to obtain reporting on both *a substantial majority of the Nation's toxic chemical releases and to obtain reporting from a large number of firms.* These thresholds reflect Congress' judgement that such thresholds appropriately balance the need for information against the burden on facilities required to provide such information. The EPA is authorized to revise these thresholds, but only if such revised thresholds continue to obtain reporting on a substantial majority of total releases. Any determination by the EPA regarding the ability of revised thresholds to obtain reporting on a substantial majority of releases, especially if such revised thresholds raise the statutory levels, *must be based on verifiable, historical data which presents a convincing case that the statutory levels must be revised. Legislative History* at 5313 (emphasis added).

And during the House debate, Representative Swift noted that any revised threshold ''should be *designed to improve the usefulness of the reports.* It must be structured to obtain reporting on a substantial majority of the *total nationwide releases* of the toxic chemical at *all facilities covered by section 313.*'' *Id.* at 5338 (emphasis added).

In determining how to structure its threshold revisions, and particularly how it would improve the usefulness of the reports, EPA also consulted EPCRA's purposes, laid out in subsection (h). In this context, EPA also considered the statements made by Senator Stafford during debate on the Conference Report:

> This section also requires the Administrator to computerize the data reported on the required forms and to make these data public by various means. Successful implementation of this requirement is vital to the basic purpose of the program. *The data should be managed in the computer in such a way as to allow a wide variety of analyses. For example, it should be possible to retrieve data, not only about individual facilities, but also aggregate data organized by type of chemical, type of effect, geographic location, company name, etc. as well as combinations of these parameters. . . . Legislative History* at 5186 (emphasis added).

Based on this Congressional guidance, EPA reached several conclusions. First, ample ''verifiable, historical data'' exists to support EPA's conclusions that PBT chemicals persist for long periods of time in the environment and bioaccumulate in organisms, including humans; that this persistence and bioaccumulation can result in higher exposures to humans and the environment; and that to ''obtain a substantial majority of the Nation's toxic chemical releases,'' lower thresholds for PBT chemicals are warranted. For example, PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. Multimedia analyses indicate that the majority (80–90%) of human exposure to chlorinated organic compounds, such as PCBs comes from the food pathway, a lesser amount (5–10%) from air, and minute amounts (less than 1%) from water. Most of the data available on human exposure to PCBs in the Great Lakes come from the analyses of contaminant levels in drinking water and sport fish. The consumption of contaminated sport fish and wildlife can significantly increase human exposure to the Great Lakes critical pollutants, such as PCBs. The sport fish are exposed to PCBs by consumption of sediments and through water (Ref. 76). See also Refs. 75 and 77.

Further, EPA strongly believes that increased reporting on PBT chemicals will improve the usefulness of the data on these chemicals. There are currently very few reports for some of the PBT chemicals, such as mercury, mercury compounds and PCBs. The currently available data provide a distorted picture of potential exposures to humans and the environment, because at the current thresholds only a fraction of the releases from facilities otherwise subject to EPCRA section 313 are reported. This limited reporting results in a significant underestimation of the releases from the industry sectors covered by EPCRA section 313. As such, the current data are of limited use for evaluating the potential exposures to humans and the environment of toxic chemicals that persist and bioaccumulate. Expanding the picture of releases, and therefore potential exposures, will increase the utility of all the TRI data on these chemicals. See, e.g., Economic Analysis, Chapter 6.4 (Ref. 67).

On these bases, EPA determined that revising the thresholds would be an important first step in closing the information gap on PBT chemicals. The Agency then began the process of determining the appropriate levels at which to establish the revised thresholds. For a number of technical and policy reasons, EPA chose an approach focused on two classes of PBT chemicals: (1) Toxic chemicals that meet the EPCRA section 313 persistence and bioaccumulation criteria discussed in Unit VI.B., i.e., those toxic chemicals that have half-lifes of 2 months or greater in water/sediment or soil and that have bioaccumulation or bioconcentration factors of 1,000 and (2) the subset of PBT chemicals that are highly persistent and highly bioaccumulative, i.e., those toxic chemicals that have half-lifes of 6 months or greater in water/sediment or soil and that have bioaccumulation or bioconcentration factors of 5,000 or greater.

First, for the most persistent and bioaccumulative toxic chemicals any release will lead to elevated concentrations in the environment and in organisms. EPA believes that such highly persistent and highly bioaccumulative toxic chemicals are of international, as well as national concern, because of the extent of their

persistence and bioaccumulation. As discussed elsewhere in this preamble, these facts have been widely recognized; there are a number of international agreements that ban, restrict, or phase out the manufacture, use and/or release of highly persistent and highly bioaccumulative toxic chemicals.

Similarly, toxic chemicals that are persistent and bioaccumulative are of national, regional, and local concern. As discussed elsewhere in this preamble, toxic chemicals that are persistent and bioaccumulative present a significant concern to many local communities due to the proximity of the communities to industrial sources. All other things being equal, a pollutant reaches nearby populations in less time than distant ones. Thus, toxic chemicals that persist and bioaccumulate can pose significant exposures to communities and ecosystems that immediately surround industrial sources as well as those communities that are subject to regional transport.

Given the international support for the extreme limitations on the use and release of toxic chemicals that are highly persistent and highly bioaccumulative, and the significant exposures that persistent and bioaccumulative toxic chemicals can pose to both local communities and broader regions of the United States and North America, EPA believes that it is appropriate to lower the reporting thresholds for *both* (1) Persistent and bioaccumulative toxic chemicals and (2) for highly persistent and highly bioaccumulative toxic chemicals. In addition, EPA believes this information is important to the public, government agencies, and researchers; for example, the information reported by facilities under the lower thresholds will help these groups assess the loading of the PBT chemicals in both local and regional ecosystems, e.g., a small lake or river or a larger ecosystem such as the Great Lakes or the Chesapeake Bay. See also, Economic Analysis at Chapter 6, pages 32–50 for examples of other uses of TRI data (Ref. 67).

Second, EPA considered how the revised thresholds would provide the information on PBT chemicals needed to assist the public to obtain ''a comprehensive view of toxic chemical exposure,'' as well as to assist government agencies, researchers, and other persons to conduct research and to establish appropriate regulations, guidelines and standards, in accordance with the directives laid out in subsection (h). EPA determined that providing greater information on two identifiable classes of chemicals best achieved these ends. It is consistent with the actions of a significant number of the groups that would use this information; for example, as discussed in Unit VI.B., UNEP is in the process of negotiating an international agreement on the class of persistent organic pollutants with half-lifes of 6 months and BCF/BAF values of 5,000. See also Economic Analysis at Chapter 6, pages 46–48 for examples of how TRI data will be used (Ref. 67). Moreover, EPA determined that data on members within the same class are more easily comparable; the members of the classes EPA established in this rulemaking share a qualitatively comparable level of concern based on their potential for increased exposure. The Agency believed that creating two distinct classes of comparable chemicals would significantly enhance the ability of researchers, government agencies, and other similar persons, to use the reports. Establishing distinct classes of comparable chemicals normalizes the subsequent years' data, providing a baseline against which data users can ascertain trends over time. Consequently researchers can more easily distinguish, and therefore track, the releases and other waste management of highly PBT chemicals, to evaluate the efficacy and progress of the policy strategies intended to address the risks of PBT chemicals, such as the Binational Great Lakes Water Quality Initiative. Finally, administrative convenience argued for establishing a limited number of alternate thresholds. As a practical matter, it would be burdensome for both the Agency and the regulated community to track a variety of individual thresholds for separate chemicals. In addition, because this was only the Agency's initial rulemaking to lower thresholds for certain PBT chemicals, EPA intended that the revised thresholds establish a set of categories that would be generally applicable to future designated PBT chemicals. All of these considerations led the Agency to conclude that it should establish two sets of revised thresholds based on two classes of PBT chemicals.

Thus, having concluded it was appropriate to focus the rulemaking on two classes of chemicals, persistent and bioaccumulative toxic chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative, EPA began the process of determining the specific thresholds that would achieve the purposes of subsections (f)(2) and (h). The intrinsic properties of PBT chemicals argue for very low thresholds. The subset of PBT chemicals that are highly persistent and highly bioaccumulative warrant, in the absence of other considerations, a threshold approaching zero. Any release of these toxic chemicals is of global concern because they can persist for long periods of time, can maintain their identity even after undergoing long range transport, and can bioaccumulate to a significant degree. As discussed above, and at length in Unit VI.B., the potential impacts that can result from any release of toxic chemicals that are highly persistent and highly bioaccumulative have been widely recognized. There are a number of international agreements that ban, restrict, or phase out the manufacture, use and/or release of the most persistent and bioaccumulative toxic chemicals.

However, EPA believes that a zero threshold would be impractical. Attempting to require facilities to determine if they manufacture, process, or otherwise use any amount whatsoever of these chemicals would be extremely burdensome and perhaps technically impossible. Without an actual numerical threshold, many facilities might report some amount of these chemicals in a misguided attempt to assure compliance. This could lead to misleading and inaccurate data on the actual sources of these chemicals. EPA believes that rather than setting a zero reporting threshold it would be better to set a very low threshold that provides facilities with a clear indicator of when they are required to report. In general for purposes of EPCRA section 313, 1 pound is the practical equivalent of zero for these chemicals. EPA explained these considerations in the proposed rule (64 FR 712) and has received no information from commenters that convinces the Agency to pursue a different approach.

EPA then considered the relative degree of persistence and bioaccumulation between the two classes of chemicals. EPA wanted to establish two sets of revised thresholds with the same approximate relationship to each other, as the relative exposure potentials of PBT chemicals to that subset of highly persistent and highly bioaccumulative PBT chemicals. Simply stated, chemicals with half-lifes of 6 months or greater and a BAF/BCF of 5,000 or greater have a higher exposure potential than chemicals with half-lifes of 2 months or greater and a BAF/BCF of 1,000 or greater. However, although, as discussed below, EPA could establish a qualitative relationship, the Agency could not reliably quantify the relative exposure potential across the board for all of the members of both classes. Therefore, in attempting to translate the qualitative exposure potential of PBT

chemicals to that subset of PBT chemicals that are highly persistent and highly bioaccumulative into a qualitative threshold relationship, EPA considered both the attributes of these chemicals and factors specific to thresholds.

The manufacture, process, and otherwise use thresholds are not equivalent to release thresholds although, in many cases, the quantity manufactured or otherwise used will be very similar to the quantity released. Thus, even if EPA were able to quantify the relative exposure potential of PBT chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative, based on their degrees of persistence and bioaccumulation, and their interrelationship, the Agency would not rely solely on this to select a quantitative threshold relationship between these two classes of chemicals because: (1) The manufacturing, processing, and otherwise use thresholds are not equivalent to release thresholds, and (2) the quantity released, not the quantity manufactured, processed or otherwise used, is a critical factor in determining exposure.

Nonetheless, EPA believes that the relative reporting thresholds should be based to some extent upon the qualitative differential between the potential exposures that may result from releases of PBT chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative.

There is not a direct quantifiable relationship between the potential exposures that can result from equivalent releases of a toxic chemical that persists in the environment with a half-life of 6 months and that has a bioaccumulation factor of 5,000 and releases of a toxic chemical that persists in the environment with a half-life of 2 months and that has a bioaccumulation factor of 1,000. The potential exposure to humans and the environment will depend upon a number of factors, including release patterns, environment variables such as soil type, surface water chemistry, the types and distribution of flora and fauna, and fish consumption patterns. However, EPA did consider the relative differences in the potential exposures between these two classes. For example, after 1 year, there will be more than 15 times as much of a highly persistent chemical that remains in the environment than of a persistent chemical, all other things being equal. Similarly, fish will accumulate more than 5 times as much of the highly bioaccumulative chemical than of the bioaccumulative chemical, all other things being equal. While EPA believes that it can qualitatively describe the relative relationship of highly persistent chemicals to persistent chemicals and the relative relationship of highly bioaccumulative chemicals to bioaccumulative chemicals, the Agency cannot at the present time, define the relative relationship of persistence and bioaccumulation between the two classes of chemicals. This is in large part due to the many variables that must be considered in determining the potential exposures both due to the interaction of these chemical attributes and the large number of environmental factors that must be considered when evaluating persistence and bioaccumulation together.

Although EPA could not develop an exact quantitative threshold relationship between the two classes of chemicals, the Agency did consider the factors discussed above and did rely to some extent on the numerical relationships between the highly persistent and persistent chemicals and the highly bioaccumulative and bioaccumulative chemicals. Therefore, given that: (1) Highly bioaccumulative toxic chemicals will accumulate approximately 5 times greater than bioaccumulative toxic chemicals, (2) highly persistent toxic chemicals will remain in the environment after 1 year, at a level about 15 times greater than persistent toxic chemicals, (3) the fact that the EPCRA section 313 reporting thresholds are not release thresholds but that in some instances the quantities manufactured or otherwise used will be very similar to the quantity released, and (4) toxic chemicals that persist in the environment with half-lifes of 2 months and bioaccumulation factors of 1,000 or greater can be of both local and regional concern, EPA believes that the threshold for PBT chemicals should be a factor of 10 greater than the threshold for that subset of PBT chemicals that are highly persistent and highly bioaccumulative. EPA believes that this ratio balances the uncertainties and factors, including numerical factors, that the Agency considered. Therefore, based on the chemicals' intrinsic characteristics, EPA would establish thresholds of 1 pound for that subset of PBT chemicals that are highly persistent and highly bioaccumulative and 10 pounds for PBT chemicals.

However, the legislative history of section 313(f)(2) indicates that in establishing the original thresholds, Congress recognized the burden imposed on the regulated community. Lowering thresholds necessarily will increase that burden. Therefore, EPA determined it would be reasonable to include some consideration of reporting burden in selecting thresholds for PBT chemicals. But EPA accorded less weight to burden than to the other considerations discussed above. First, neither section 313(f)(2), section 313(h), nor any other provision of EPCRA requires EPA to consider burden. Second, EPA was mindful of the fact that in several places in the legislative history Congress made clear it never intended impacts on reporting facilities to outweigh the public's right-to-know about their potential exposures to toxic chemicals. For example, although Representative Edgar recognized that Congress had considered burden in establishing the statutory thresholds, he did not include reporting burden as one of the general principles that should guide the Agency's implementation of EPCRA section 313 as a whole. Rather, he stated:

> This is a new Federal initiative, and I recognize the desire of some of my colleagues to move ahead cautiously to ensure that burdens imposed on industry are not excessive. Frankly, my concern rest with the families that live in the shadows of these chemical and manufacturing plants. I have put myself in their shoes and have fought for a program that looks after their needs. This legislation gets us well on the path to the full disclosure they deserve. *Legislative History* at 5316. See also, *Legislative History* at 5185–86 (Senate debate on the Conference Report).

As noted in Unit VI.A, one of the major pieces of Congressional guidance on the establishment of alternate thresholds was to obtain a comprehensive picture of ''total nationwide releases of the toxic chemical at all facilities covered by section 313.'' This language, plus other Congressional directives on implementing section 313 generally, such as section 313(h), reflect an interest in obtaining information from a broadly representative range of sources. Consequently, EPA determined that the Agency should consider burden only to the extent that it would not deny the public significant information from a range of covered industry sectors.

Therefore, EPA estimated the number of reports that would be submitted by each industry sector for four groups of thresholds, 1 and 10 pounds, 10 and 100 pounds, 100 and 1,000 pounds, and 1,000 pounds for both classes of chemicals. These options were selected for the following reasons. EPA needed a reasonable but finite number of options to evaluate, and the options described above represent a reasonable picture of the entire range of potential revised thresholds. Data limitations on the manufacturing, processing, and otherwise use of PBT chemicals in the numerous industries, processes, and uses covered by EPCRA section 313

constrained EPA's ability to make meaningful and reliable distinctions between threshold options that are less than an order of magnitude apart. For example, while EPA believes it can reliably estimate the difference in the number of reports from a 10 pound reporting threshold and a 100 pound reporting threshold, EPA believes that the data are insufficient to allow it to make a meaningful and reliable distinction in estimates of options that are closer than an order of magnitude such as 35 pounds and 50 pounds. EPA explained its data limitations in the proposal, and commenters provided no information that would allow the Agency to increase the resolution of its analysis. Consequently, for the final rule, EPA analyzed options that were orders of magnitude apart from the two thresholds identified through its technical review: 1 pound for highly persistent and highly bioaccumulative chemicals, and 10 pounds for persistent and bioaccumulative chemicals.

Based on information provided in the economic analysis for this rulemaking, at the technical reporting thresholds EPA would obtain information from a broad range of facilities (Ref. 67a). The analysis showed that at a threshold of 1 pound, the public would obtain information from all industry sectors that are currently subject to EPCRA section 313, and that have been identified as manufacturing, processing, or otherwise using those highly persistent highly bioaccumulative toxic chemicals that are part of this rulemaking (except dioxin and dioxin-like compounds which are discussed below). At a threshold of 10 pounds, the public would obtain information from all industry sectors that are currently subject to EPCRA section 313, and that have been identified as manufacturing, processing, or otherwise using those PBT chemicals that are part of this rulemaking. At the technical reporting thresholds, the estimated costs of the additional reports filed would have totaled $355 million in the first year, and $193 million in subsequent years (Ref. 67). EPA considered these costs, even though it cannot quantify the value of the information obtained or lost at the various thresholds, and cannot quantify the relationship between the reporting costs and the value of the information reported, or lost, at a particular threshold.

At thresholds of 10 pounds for highly persistent and highly bioaccumulative chemicals and 100 pounds for persistent and bioaccumulative chemicals, EPA is still able to obtain a significant amount of information on both classes of PBT chemicals from a wide range of industry sectors and sources. For example, no reporting on TBBPA would be lost from any sources or industry sectors at 100 pounds, and some information on octachlorostyrene would be potentially lost from only one industry sector, pesticide manufacturing facilities. At these thresholds, EPA does, however, lose information significant to local communities; for example, EPA loses considerable reporting on mercury and mercury compounds at 10 pounds, but the loss of information is localized in a limited number of industry sectors, and the public will still obtain some reporting from all of the currently covered industry sectors (Ref. 67a). For this threshold option, EPA estimated the total burden at these thresholds to be $191 million for the first year, and $105 million for subsequent years (Ref. 67).

At thresholds of 100 and 1,000 pounds and higher, EPA's analysis indicated that the public, government agencies, and researchers would lose information on many of the PBT chemicals from certain industry sectors and sources. For example, at a threshold of 100 pounds for toxic chemicals that are highly persistent and highly bioaccumulative, the Agency would not obtain reporting on mercury and mercury compounds generated in boilers in the manufacturing sector or information on octachlorostyrene from the primary metal industries (Ref. 67a). However, at these thresholds, EPA estimated the total first year costs to be $99 million and $55 million in subsequent years (Ref. 67).

These analyses led EPA to several conclusions. First, thresholds of 10 pounds for highly persistent and highly bioaccumulative chemicals and 100 pounds for persistent and bioaccumulative chemicals, achieve a significant reduction in reporting burden. Second, at these thresholds EPA obtains information from a broad distribution of industry sectors. Although EPA also loses information significant to local communities at these thresholds, it maintains the overall distribution of reporting from a broad range of industry sectors nationally. EPA could have attempted to compensate for the community-level loss of information on individual members of the classes of PBT chemicals (i.e., by establishing separate thresholds of 1 pound or 10 pounds for individual chemicals), but only by failing to take reporting burden into account for those individual chemicals. As explained previously, the availability of the data limited EPA's ability to distinguish meaningfully between thresholds separated by less than an order of magnitude. In addition, establishing separate thresholds would sacrifice many of the benefits of receiving information from comparable facilities using comparable chemicals, discussed earlier in this unit. Thus greater information for local communities would be achieved at the expense of the increased utility of the reports for other purposes established under EPCRA section 313(h)--e.g., assisting governmental agencies, researchers, agencies and other persons in the conduct of research and data gathering; and aiding in the development of appropriate regulations, guidelines, and standards. EPA believes that, to be consistent with the overriding policy directive in subsection (h), it must achieve a balance between improving the utility of the reports for all of the groups that rely on TRI data. Finally, as noted earlier in this Unit, administrative convenience argues against the establishment of individual thresholds. Among other issues, it would be burdensome on both EPA and the regulated community to track a variety of separate thresholds. Moreover, EPA intends the revised thresholds established in this rulemaking for the two classes of PBT chemicals to be generally applicable to future members of the two classes; absent a strong technical or policy concern to the contrary, it would ultimately be inconsistent with the purposes of EPCRA section 313 for chemicals that share such common characteristics to have vastly different thresholds.

Therefore, EPA believes its selection of thresholds of 100 pounds for PBT chemicals and 10 pounds for that subset of PBT chemicals that are highly persistent and highly bioaccumulative, balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and potential exposures of PBT chemicals, while factoring in an appropriate degree of the consequent impact on the regulated community.

Dioxin and dioxin-like compounds are highly persistent and highly bioaccumulative toxic chemicals. As discussed above, toxic chemicals that are highly persistent and highly bioaccumulative warrant, in the absence of other considerations, a threshold approaching zero. But, for the reasons discussed previously in this section, EPA does not believe that a zero threshold would be practical. However, because the dioxin and dioxin-like compounds are manufactured in extremely small amounts, EPA needed to select a threshold lower than that for the other highly persistent and highly

bioaccumulative chemicals in order to obtain any reporting.

In choosing reporting thresholds for these chemicals, the Agency considered the extent of the information on dioxin and dioxin-like compounds that would be made available to the public, government agencies and researchers. EPA considered whether this level of information would provide them with ''a comprehensive view of toxic chemical exposure,'' given the attributes of dioxin and dioxin-like compounds, and with ''broad-based national information.'' At a threshold of 0.1 gram, the public would obtain information from all industry sectors that are subject to EPCRA section 313 and that have been identified in the *Inventory of Sources of Dioxin in the United States* (Ref. 3). EPA does not believe that a higher threshold, i.e., 1.0 grams, would provide the public with broad-based national information because there would be no information on the manufacture and release and other waste management of certain sectors. For example, at a higher threshold, EPA anticipates that there would be no reporting from hazardous waste incinerators, pulp mills, non high ferrous foundry industries, and secondary lead smelters (Ref. 67a). At thresholds lower than 0.1 gram, there is greater coverage *within* certain industry sectors, with a concomitant significant increase in burden. EPA believes its selection of a threshold of 0.1 gram for dioxin and dioxin-like compounds balances the purposes of EPCRA section 313 and the Agency's desire to provide a comprehensive picture on releases and exposures of dioxin and dioxin-like compounds while factoring in an appropriate degree of the resultant impact on the regulated community.

F. What Comments Did EPA Receive on Exposure and Risk Considerations and What Are EPA's Responses?

One of the most significant issues raised by commenters relates to the Agency's lack of consideration of quantitative risk in modifying the section 313(f) reporting thresholds. Specifically, a number of commenters believe that EPA should use quantitative risk as a criterion in determining whether to lower the reporting thresholds and in choosing a particular reporting threshold for each PBT chemical. The commenters contend that EPA should conduct risk assessments and make a formal determination that at a particular threshold releases of the PBT chemical pose a risk before lowering the reporting threshold. While the majority of commenters who commented on the issue believe that EPA should make a risk determination before modifying the reporting thresholds, the rationale for their conclusions varied. Some commenters state that a risk determination is required by EPCRA because the intent of EPCRA is to provide information to the public of potential risks posed by the presence of toxic chemicals released to the environment in their communities. Some commenters state that in addition to addressing the substantial majority test, EPCRA section 313(f)(2) requires EPA to use the degree of risk that releases will pose to communities as a determinant in choosing new thresholds. Other commenters state that consideration of risk is a required component of any action under EPCRA section 313. In support of this position, one of the commenters cites two D.C. Circuit Court decisions. Other commenters contend that it would be good public policy to choose a threshold based on risks. Some commenters contend that EPA should lower the reporting thresholds only for those chemicals that present the highest risks to the public. One commenter, however, believes that the Agency should not consider the degree of risk in making a determination to lower the reporting thresholds for PBT chemicals because the consideration of risk in past actions taken by EPA under other environmental statutes have not resulted in a decrease of human health or environmental risks due to PBT chemicals. The commenter states that the increasing number of fish advisories and the lingering and, in some cases, increasing levels of PBT chemicals in the environment and in fish, wildlife, and human tissue demonstrates the magnitude of the failure of the ''risk management strategy.''

EPA disagrees with the commenters' assertion that evidence of risk is required prior to lowering the threshold for any EPCRA section 313 chemical. Section 313(f)(2) addresses revisions to the reporting thresholds. It does not require EPA to establish, prior to the lowering of reporting thresholds, that releases at a particular threshold will result in specific quantitative risks. That section expressly provides that the Administrator may establish a threshold amount for a toxic chemical different from the 25,000 pound threshold for manufacturing and processing activities and the 10,000 pound threshold for otherwise use activities. The only prerequisite for revising the reporting threshold for a toxic chemical is that the revised threshold obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of EPCRA section 313. As discussed in Units II.B. and VI.A., EPA believes that it has satisfied the requirements of EPCRA section 313(f)(2) without the need for quantitative support.

EPA believes that the commenters attribute a purpose to EPCRA that is inconsistent with that clearly intended by Congress. Specifically, Congress stated in EPCRA section 313(h) that:

> The release forms required under this section are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available,. . .to inform persons about releases of toxic chemicals to the environment; to assist government agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. 42 U.S.C. section 11023(h).

Neither EPCRA section 313(h) nor its legislative history directs EPA to limit the collection of information on releases to those releases that, from the Federal government's perspective, pose significant local human and environmental exposure and human health and environmental risks. See, e.g., *Legislative History* at 5186.

Federal and local perspectives on what may be an acceptable risk are likely to be very different. The roles of local government and the Federal government differ significantly in terms of ensuring environmental quality. In passing EPCRA, Congress determined that it is for the public to take the information reported on the use and releases and other waste management of toxic chemicals, and to determine whether these releases result in potential risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations. Congress did not intend the Federal government to consider these specific local factors prior to determining whether certain information should be made public or prior to determining whether a different threshold should be established for one or more toxic chemicals.

The intent of EPCRA section 313 is to move the determination of what risks are acceptable from EPA to the communities in which the releases occur. This basic local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. The burden it imposes is significantly less than the

burden imposed by a statute which controls the manufacture, use, and/or disposal of a chemical. EPCRA section 313 requires that a facility use readily available data, or if such data are not available, reasonable estimates to prepare each chemical-specific report. The statute does not require that the facility conduct monitoring or emissions measurements to determine these quantities. This is in contrast to other environmental statutes that may require a facility to monitor releases, change its manufacturing process, install a specific waste treatment technology, or dispose of wastes in a certain manner. As such, the Agency believes that as a matter of policy the standard that must be met to require information pursuant to EPCRA section 313 is less than that required to regulate a chemical under a statute such as the Clean Air Act. See, e.g., *Legislative History* at 5186.

Further, contrary to assertions by some commenters, EPCRA section 313 does not require the collection of quantitative risk data nor does the statute require that risk data be disseminated to the public. Rather TRI data provide communities with information on releases and other waste management quantities. TRI data cannot, in themselves, provide information on quantitative risks to individual communities. A determination of the potential risk that a chemical release may pose is dependent upon a number of factors, including the toxicity of the chemical, the physical chemical properties of the chemical, the specific media to which the chemical is released, and site-specific information that will determine the estimated exposures. While TRI data are not in themselves measures of risk, they are an important input that local communities can use along with the factors described in this section to determine potential risks to themselves, their children, their communities, and their environment that may result from releases of toxic chemicals.

EPA's decision to lower the reporting threshold for PBT chemicals is rationally related to the EPCRA section 313 goals of informing communities, assisting research and data gathering, and aiding the development of regulations and guidelines. Because PBT chemicals persist in the environment for a significant period of time and bioaccumulate in animal tissues, PBT chemicals have the potential to be pervasive in the environment, in the food chain, and often in humans. In short, for PBT chemicals, releases and other waste management activities for relatively small amounts of PBT chemicals are of concern. Accordingly, pursuant to the intended purposes of EPCRA, even relatively small releases and other waste management activities for PBT chemicals need to be reported in order to inform communities, assist those engaged in research and data gathering, and to aid the development of regulations and guidelines. Lowered reporting thresholds for PBT chemicals are needed to obtain reporting on these relatively small releases and other waste management activities for PBT chemicals. Consequently, EPA believes that including consideration of the quantitative risk in establishing the thresholds would be poor public policy that would be inconsistent with the overall principles of EPCRA.

Finally, the reference by one of the commenters to two D.C. Circuit Court decisions is misplaced. In support of its position that EPA must undertake a risk assessment of any toxic chemical it is considering for lower reporting thresholds, the commenter cites *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1187 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982), and *Milwaukee Metropolitan Sewerage District* v. *EPA*, 40 F.3d 392 (D.C. Cir. 1994). Neither case cited by the commenter addresses EPCRA. Nor do these cases establish a generally applicable principle of law that risk assessments are required prior to any government action. In *Milwaukee Metropolitan Sewerage* the court reviewed standards adopted by EPA in a Clean Water Act regulation. In *American Petroleum Institute* the court reviewed the primary and secondary national ambient air quality standards for ozone promulgated by EPA under the Clean Air Act. Both the Clean Air Act and the Clean Water Act have no bearing on EPCRA section 313. Unlike the statutes at issue in the cases cited by the commenter, consideration of risk is not a requirement of section 313(f)(2) for modifying the reporting thresholds for EPCRA section 313 listed chemicals, and, in fact, the consideration of risk is generally not required for any rulemaking under section 313. *Troy Corporation* v. *EPA*, 120 F.3d 277 (D.C. Cir. 1997).

Some commenters further state that in proposing to change EPCRA section 313 reporting thresholds, EPA has not addressed any of the factors the Agency mentioned when it originally promulgated EPCRA section 313 regulations. In the February 16, 1988 final rule, EPA stated:

> EPA may consider a number of factors for threshold modification including exposure factors such as population density, the distance of population from covered facilities, and the types of releases. Threshold modifications could also take into account the relative potency of the chemical or class of chemicals and effects of concern. (53 FR 4508).

In this statement, the commenters contend that EPA correctly mentions factors that relate to risk (i.e., exposure and relative toxicity). The current proposal to change reporting thresholds under EPCRA section 313 fails to address these factors.

As is clearly evident in the quote from the February 16, 1988 final rule, EPA stated that these were things that it ''may consider'' or that could be taken into account. These statements do not require that the possible factors mentioned above be a basis for any change in the reporting thresholds nor do they preclude the consideration of factors such as the persistence and/or bioaccumulation of toxic chemicals in modifying the reporting thresholds. This statement was not a commitment that EPA would consider risk in any decision to modify reporting thresholds. It merely provided examples of things that the Agency may consider.

As explained in previous responses, EPA does not believe that it would be good public policy to consider factors related to quantitative risk with respect to establishing thresholds for PBT chemicals. Given the degree of persistence and bioaccumulation that these toxic chemicals exhibit, EPA believes that the value of this information to the public outweighs the policy considerations presented in favor of considering risk factors in establishing revised thresholds. Any other decision would be inconsistent with the legislative intent underlying EPCRA section 313.

Finally, EPA notes that this decision is consistent with the approach adopted in modifying the thresholds to establish a 1 million pound manufacture, process, or otherwise use threshold for facilities that have 500 pounds or less of production-related waste (59 FR 61488, November 30, 1994) (FRL–4920–5). Any decision to include risk considerations in establishing modified thresholds under section 313(f)(2) would compel the Agency to re-examine the thresholds established for facilities with less than 500 pounds of production-related waste.

Several commenters contend that a chemical's degree of persistence and bioaccumulation are unrelated to the chemical's exposure potential. They disagree that persistence and bioaccumulation are necessarily indicators of exposure or exposure potential. As an example, the commenter states that many of the compounds EPA is targeting are highly lipophilic, non-water soluble

compounds, and the greatest potential for bioaccumulative effects is through uptake from the water column. EPA should evaluate how these compounds partition in the environment. Those that are not bioavailable have limited exposure potential, and therefore limited risk. Thus, the commenter believes that EPA must consider exposure in conjunction with persistence and bioaccumulation.

EPA disagrees with the commenters. All other things being equal, the chemical with a higher degree of persistence and bioaccumulation will have a greater exposure potential than the chemical with a lower degree of persistence and bioaccumulation. For example, all other things being equal, a chemical that has a half-life in water of 4 months will have a higher exposure potential to aquatic organisms than a chemical with a half-life in water of 1 month. Fifty percent of the first chemical will remain in the water after 4 months while only 12.5% of the second chemical will remain in the water after 4 months. After 4 months, aquatic organisms will be exposed to 4 times more of the first chemical than the second chemical. Clearly the chemical with the greater persistence has the higher exposure potential.

EPA does not believe that the commenter's example supports their contention that persistence and bioaccumulation are unrelated to exposure potential. As EPA understands the commenter's example, chemicals that have the greatest bioaccumulation potential will not be bioavailable in water because they are highly lipophilic and non-water soluble. Thus, because they are not bioavailable in water, they cannot bioaccumulate in aquatic organisms. A well-studied example that clearly contradicts the commenter's claim is the bioaccumulation of polychorinated biphenyls (PCBs) in the Great Lakes. PCBs have BAFs as high as 141,000,000 (Table 1, at 64 FR 707–8) and very, very low water solubility. PCBs have been found throughout the Great Lakes in sediments, water, and aquatic organisms. Multimedia analyses indicate that the majority (80–90%) of human exposure to chlorinated organic compounds, such as PCBs comes from the food pathway, a lesser amount (5–10%) from air, and minute amounts (less than 1%) from water. Most of the data available on human exposure to toxic substances in the Great Lakes come from the analyses of contaminant levels in drinking water and sport fish. The consumption of contaminated sport fish and wildlife can significantly increase human exposure to the Great Lakes critical pollutants. The sport fish are exposed to PCBs by consumption of sediments and in water, from which they bioaccumulate the PCBs (Ref. 62).

Some commenters contend that EPCRA requires that EPA consider the risks that a chemical may pose when making determinations to add a chemical to the EPCRA section 313 list of toxic chemicals. In support of this position, one commenter cites two D.C. Circuit Court decisions.

As discussed in detail in the final rule adding 286 chemicals to EPCRA section 313 (59 FR 61432), EPA disagrees with commenters that the Agency must include a risk assessment component to EPCRA section 313 determinations. While the Agency believes that there are limited circumstances where it may be appropriate to consider risk in making listing determinations, e.g., acute human health effects, EPA does not believe that the intent of EPCRA, the EPCRA section 313 toxicity criteria, or the legislative history support the contention that risk assessment is a required component of all EPCRA section 313 listing determinations.

The EPCRA section 313 toxicity criteria require that exposure and risk factors be considered only when determining if the toxic chemical should be listed on EPCRA section 313 based on its acute human health effects, but even then in only a very limited manner. The statute mandates that EPA consider whether ''a 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.'' EPA has, and will continue to look at exposures reasonably likely to exist beyond facility site boundaries when making a listing determination pursuant to EPCRA section 313(d)(2)(A). However, EPA notes that none of the toxic chemicals added in today's action were added pursuant to paragraph (A) of that section.

The statute is silent on the issue of exposure considerations for the section 313(d)(2)(B) and (C) criteria. The language of section 313 does not prohibit EPA from considering exposure factors when making a finding under either section 313(d)(2)(B) or section 313(d)(2)(C). However, the language of sections 313(d)(2)(B) and (C) does not require the type of exposure assessment and/or risk assessment argued by the commenters. EPA believes that it has the discretion under both section 313(d)(2)(B) and section 313(d)(2)(C) to consider, where appropriate, those exposure factors that may call into question the validity of listing of any specific chemical on EPCRA section 313.

EPA believes that its position regarding the limited use of risk in listing decisions is consistent with the purpose and legislative history of EPCRA section 313, as illustrated in the following passage from the Conference report:

> The Administrator, in determining to list a chemical under any of the above criteria, may, but is not required to, conduct new studies or risk assessments or perform site-specific analyses to establish actual ambient concentrations or to document adverse effects at any particular location. (H. Rep. 99-962, 99th Cong., 2nd Sess., p. 295 (October 3, 1986)). See also *Legislative History* at 5186.

This passage indicates that Congress did not intend to require EPA to conduct new studies, such as exposure studies, or to perform risk assessments. Therefore, Congress did not consider these activities to be mandatory components of all section 313 decisions. EPA believes that this statement combined with the plain language of the statutory criteria clearly indicate that Congress intended that the decision of whether and how to consider exposure under EPCRA section 313(d)(2)(B) and (C) should be left to the Agency's discretion. EPA has carefully considered when and how to use exposure to fully implement the right-to-know provisions of EPCRA. The Agency believes that exposure should be considered only in very limited circumstances when adding a chemical to EPCRA section 313(d)(2)(B) or (C). The Agency's interpretation of the section 313(d)(2) and (d)(3) criteria for modifying the section 313 list of toxic chemicals is discussed in the final rule adding 286 chemicals to EPCRA section 313 (at 59 FR 61440–2). And in fact, EPA's interpretation was upheld by the D.C. Circuit in *Troy* v. *EPA*, 120 F.3d 277. The addition of chemicals pursuant to EPCRA section 313(d)(2)(B) and (C) in today's rulemaking is consistent with this interpretation.

The intent of EPCRA section 313 is to move the determination of which risks are acceptable from EPA to the communities in which the releases occur. This basic, local empowerment is a cornerstone of the right-to-know program. EPCRA section 313 establishes an information collection and dissemination program. It provides the public with information that can be used with other site-specific factors to determine if releases into their communities result in risks that the community determines warrant further action given other factors, such as economic and environmental

conditions, or particularly vulnerable human or ecological populations.

In addition, the reference by one of the commenters to two D.C. Circuit Court decisions is misplaced. In support of its position that EPA must undertake a risk assessment of any toxic chemical it is considering to add to EPCRA section 313, the commenter cites *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1187 (D.C. Cir, 1981), *cert. denied*, 455 U.S. 1034 (1982), and *Milwaukee Metropolitan Sewerage District* v. *EPA*, 40 F.3d 392 (D.C. Cir. 1994). As discussed in a previous response in this unit, neither case cited by the commenter addresses EPCRA. In addition, since both cases were decided prior to *Troy*, by the same court, that decided the specific issue raised by the commenter, nothing in the two earlier cases cited by the commenter can overrule that decision.

G. Which Chemicals is EPA Adding to the List of EPCRA Section 313 Toxic Chemicals?

EPA is adding the following chemicals to the EPCRA section 313 list of toxic chemicals: dioxin and dioxin-like compounds, benzo(g,h,i)perylene, benzo(j,k)fluorene (fluoranthene), 3-methylcholanthrene, octachlorostyrene, pentachlorobenzene, tetrabromobisphenol A, vanadium (except alloys) and vanadium compounds. EPA conducted a hazard assessment on each chemical being added to the EPCRA section 313 list of toxic chemicals today. This assessment was separate and independent from the review conducted to determine each chemical's persistence and bioaccumulation potential, although EPA considered some of the same data in certain of its hazard assessments. EPA finds that each chemical being added today meets the criteria for chronic human toxicity and/or environmental toxicity, as set forth at EPCRA sections 313(d)(2)(B) and (C). A summary discussion of the basis for listing each of these chemicals as well as other related issue are presented in the remainder of this unit. A more extensive discussion of these issues is included in the Response to Comments document (Ref. 69) and supporting documents.

1. *Dioxin and dioxin-like compounds category*. There were a number of comments received on the addition of the dioxin and dioxin-like compounds category and these are addressed in detail in the Response to Comments document (Ref. 69). Most of the comments on the toxicity data that EPA presented in support of the addition of the category concern the dioxin-like compounds since most commenters seemed to agree that 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (dioxin or 2,3,7,8-TCDD) meets the criteria for listing under EPCRA section 313(d)(2)(B). A number of commenters did not believe that there was sufficient information to add any of the dioxin-like compounds while several commenters argue that the data on the octa- and heptachlorodibenzo-*p*-dioxins in particular were not sufficient. Commenters also argue that reliance on established toxicity equivalence factors (TEFs) does not provide sufficient support for determining that the dioxin-like compounds meet the EPCRA section 313(d)(2)(B) criteria.

EPA disagrees with the commenters that contend that there are not sufficient data to add the dioxin-like compounds pursuant to EPCRA section 313(d)(2)(B). 2,3,7,8-TCDD is generally recognized as one of the most studied toxic compounds found in the environment. To require the degree of documentation supporting toxicological classification of 2,3,7,8 -TCDD as a necessary criterion for determining that other dioxin-like compounds exhibit dioxin-like toxicity or for listing under EPCRA section 313 is an arbitrary and unrealistic criteria. As discussed in more detail in the Response to Comments document (Ref. 69), a more scientifically supportable set of criteria for determining if compounds exhibit dioxin-like toxicity was proposed by the World Health Organization European Centre for Environmental Health (WHO-ECEH) and the International Programme on Chemical Safety (IPCS) consultation group. These criteria include: (1) A compound must show a structural relationship to TCDD; (2) a compound must bind to the Ah receptor; (3) a compound must elicit Ah receptor-mediated biochemical and toxic responses; and (4) a compound must be persistent and accumulate in the food chain. Each of the 2,3,7,8 substitute dioxins and furans included in the dioxin TEQ approach meet these criteria (Ref. 3).

The commenters often quoted from the EPA Science Advisory Board (SAB) review of EPA's draft dioxin reassessment, to help support the claim that dioxin-like compounds other than 2,3,7,8-TCDD should not be included in the toxic release inventory. The SAB report is a complex document containing a number of contrasting observations. Care must be taken to accurately capture the SAB's concerns. For example, in their Executive Summary, the SAB concluded that, ''The use of the TEFs as a basis for developing an overall index of public health risk is clearly justified''; they caution, however, ''that practical application depends on the reliability of the TEFs and the availability of representative and reliable data.'' In their summary conclusions, the SAB stated:

> The document (EPA Draft Reassessment) represents a departure from the earlier EPA risk assessment for dioxin, which dealt primarily with 2,3,7,8-TCDD. In addressing a broad range of dioxin-like compounds having the common property of binding to the Ah receptor and producing related responses in cells and whole animals, it creates opportunities for a holistic assessment of the cumulative impacts of these broadly distributed anthropogenic pollutants. Thus, while the environmental concentrations of each compound alone may be too low to produce effects of concern, the combined exposure may be producing effects that warrant concern. The use of the concept of TEFs and the concentrations of the compounds in foods and environmental media to produce an overall index of public health risk is clearly justifiable.

The character and thrust of these statements made by the SAB are significantly different from those selectively chosen by many of the commenters opposing the addition of some or all of the dioxin-like compounds. The apparent contradiction between these broad concluding statements by the SAB and those cited by several commenters is due, in part, to commenters confusing the SAB criticisms of the text of the draft reassessment with statements about the general state of scientific knowledge. The SAB clearly felt that EPA needed to do a more rigorous job of discriminating between the inferences it drew about the toxicity of 2,3,7,8-TCDD, other 2,3,7,8 substitute dioxins and furans, and dioxin-like PCBs. Many of the comments cited were intended to help EPA generate a more rigorous scientific discussion in its final reassessment document rather than to represent substantive conclusions reached by the SAB on the nature of dioxin toxicology. Fully taking these concerns into consideration it was still the SAB's overall judgment, as stated above, that ''the use of the TEFs as a basis for developing an overall index of public health risk is clearly justified.''

Some commenters argue that there are qualitative differences in the toxicity of the different 2,3,7,8-substituted isomers of polychlorinated dioxins (PCDDs) and furans (PCDFs). Specifically, there are structural differences between the more toxic, lower chlorinated isomeric PCDDs and PCDFs and the higher chlorinated cogeners to the extent that the octa- and hepta-PCDDs and PCDFs should not be added to the list of EPCRA section 313

toxic chemicals. These arguments are not valid for several reasons. First, there are data from subchronic studies for both octa- and hepta-PCDDS and PCDFs which demonstrate dioxin-like effects (Refs. 19, 21, 79, and 80). The new WHO TEFs are based on these subchronic studies (Ref. 78). While short-term studies indicate limited dioxin-like effects of these chemicals, these contrasting results are readily explained by the structural differences between the octa- and hepta-PCDDS and PCDFs compared to the lower chlorinated PCDDs and PCDFs. The relative potency of the dioxin-like compounds is related to both their ability to bind to the Ah receptor and their pharmacokinetic properties (Ref. 20). The water solubility of PCDDs and PCDFs decrease with increasing chlorine substitution. Hence the octa- and hepta-PCDDS and PCDFs are significantly less soluble in aqueous solutions compared to the lower chlorinated PCDDs and PCDFs. These solubility problems limit the amount of chemical that can be absorbed in high dose acute toxicity studies. The lack of effect observed in the high dose acute studies is consistent with the limited aqueous solubility of these compounds. However, low dose subchronic studies allow the chemicals to be better absorbed and bioaccumulate to concentrations which produce biochemical and toxic effects (Refs. 19, 21, 79, and 80). Once again this is consistent with the evidence of dioxin-like effects of these chemicals observed in the low-dose subchronic studies. Although not legally required to determine that a chemical meets the listing criteria under EPCRA section 313(d)(2)(B), it should be noted that human exposure to octa- and hepta-PCDDs and PCDFs are subchronic low dose exposures, similar to the experimental studies which demonstrate dioxin-like effects of these chemicals (Refs. 19, 21, 79, and 80).

While there are structural differences between the octa- and hepta- PCDDs and PCDFs compared to the lower chlorinated PCDDs and PCDFs, these differences result in quantitative not qualitative differences in the toxicity of these chemicals. The quantitative differences are demonstrated by the lower potency of the octa- and hepta-congeners compared to TCDD. In addition, the TEFs reflect these quantitative differences by assigning lower TEF values to the octa- and hepta-PCDDS and PCDFs. While there is limited evidence that the shape of the dose-response curve for induction of CYP1A1 activity *in vitro* for octachlorodibenzo-*p*-dioxin (OCDD) is different from TCDD, *in vivo* evidence indicates that the dose response for CYP1A1 induction by octachlorodibenzofuran (OCDF) in three tissues is equivalent to TCDD (Ref. 20). However, it should be noted that these are quantitative not qualitative differences.

Commenters also argue that octa- and hepta-PCDDs and PCDFs should not be listed because ''there is a growing consensus in the scientific community that the potential risks posed by dioxins are largely driven by a limited number of dioxin and dioxin-like compounds (tetra-, penta-, and hexa-PCDDs and PCDFs and certain coplanar PCBs).'' It is important to remember that, as discussed in Unit VI.F., EPCRA section 313 is primarily a hazard-based rather than a risk-based statute. The ''growing consensus'' on dioxin toxicity is probably best captured by the revised TEFs recently established by the WHO (Ref. 78). In this review the scientific evidence for ascribing values of relative toxicity to octa- and hepta-PCDDs and PCDFs was specifically reviewed, as evidenced by the lowering of the TEF for OCDD and OCDF by a factor of 10. In the course of the deliberations by the WHO panel of internationally distinguished scientists, there was the opportunity to remove both octa- and hepta-PCDDs and PCDFs from the TEF listings. However, the WHO panel concluded that the best scientific interpretation of the data available was to leave hepta-PCDDs and PCDFs unchanged and reduce but not eliminate OCDD from TEQ calculations. Even with this reduced toxicity, OCDD and OCDF clearly meet the listing criteria of EPCRA section 313(d)(2)(B).

EPA disagrees with the commenters that contend that TEFs are not adequate support for listing chemicals under EPCRA section 313. The development of TEFs has been a rigorous scientific effort involving a number of international panels of scientific experts and has involved the careful review of all relevant scientific literature. EPA believes that the development and review processes used for the generation of the TEFs was sound and represents a reasoned and reliable judgment on the dioxin toxicity of each of the 17 dioxin and dioxin-like compounds. The Response to Comments document (Ref. 69) includes an extensive discussion of the history of the development of dioxin TEFs which demonstrates why EPA believes that the TEFs are well supported scientifically and consequently have been openly adopted by the international scientific and regulatory community. In addition, as EPA has previously explained (59 FR 61432), the Agency believes that EPCRA section 313 allows a chemical category to be added to the list, where EPA identifies the toxic effects of concern for at least one member of the category and then shows why those effects can reasonably be expected to be caused by all other members of the category. Here, individual toxicity data are not available for all members of the category; however, there is sufficient information to conclude based on generally accepted scientific principles, that all of these chemicals are highly toxic based on structural and physical/chemical property similarities to those members of the category for which data are available.

Thus, EPA reaffirms that there is sufficient evidence for adding dioxin and dioxin-like compounds on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available cancer and other serious chronic health effects data for these compounds. Therefore, EPA is finalizing the listing of dioxin and dioxin-like compounds on the EPCRA section 313 list.

a. *Manufacturing only qualifier for dioxins and dioxin-like compound category*. Comments were mixed with regard to EPA's proposal to add a manufacture only qualifier to the dioxin and dioxin-like compounds category. Some commenters agree with EPA's statements in the proposed rule concerning the burden reduction aspects of the qualifier and the fact that as a result, the dioxin reporting would focus on facilities that manufacture dioxin and dioxin-like compounds rather than those that process or otherwise use raw materials containing dioxin and dioxin-like compounds that have accumulated in those raw materials. Some commenters state that the qualifier would avoid duplicative testing and administrative costs among many processing and using industries which do not necessarily discharge dioxins or furans into the environment. Some commenters state that all releases of dioxin and dioxin-like compounds must be reported, not just those resulting from the manufacture of these chemicals. Other commenters note that a significant gap is created by the manufacture only qualifier because it would exclude the processing and otherwise use of chemicals than contain dioxin and dioxin-like compounds as a result of the processes used to manufacture them. Commenters specifically cite pentachlorophenol as an example of a chemical that is contaminated with dioxin and dioxin-like compounds from its manufacturing process. Commenters state that the processing and use of such chemicals

result in the release of dioxin and dioxin-like compounds that would go unreported under the manufacture only qualifier. One commenter states that if the qualifier is finalized the commenter would like to see language that requires facilities to report if the background levels of dioxin are modified, concentrated, or somehow added to in the manufacturing process. Another commenter states that if the Agency wants to exempt animal sources of dioxin, such as dioxin contained in meat and other animal products, it should craft the rule to do so and not cut out other significant sources of dioxin in the environment by exempting all facilities that process material containing dioxin.

EPA believes that in order to obtain any reporting on dioxin and dioxin-like compounds a very low threshold is required, which is several orders of magnitude lower than the thresholds for other PBT chemicals. At such a low reporting threshold it is estimated that thousands of reports could potentially be filed by facilities, mainly food processing facilities, due to the amount of dioxins in the raw materials they process. The dioxins found in the meat and dairy products that food processors handle have been previously released, circulated in the environment, and bioaccumulated in animals; thus these are not additional loadings to the environment but loadings that have already occurred and cycled through the environment due to the persistence and bioaccumulative properties of these compounds. The unique combination of very low thresholds, the number of food processors that would be required to file, and the fact that they would be filing because of the bioaccumulation of previously released material, led EPA to add the manufacture only qualifier to the dioxins category. The qualifier was added in response to the unique set of conditions that apply to the reporting of dioxin and dioxin-like compounds. The manufacture only qualifier was added to reduce reporting burden on facilities, mainly in the food processing industry, that results from the unique combination of circumstances related to the reporting for these chemicals and to focus on those activities that add to the loading of dioxins in the environment rather than on activities dealing with previously released and bioaccumulated chemicals.

However, EPA acknowledges that the commenters who noted that the processing and otherwise use of chemicals contaminated with dioxin and dioxin-like compounds as a result of their manufacturing process, are correct that these would be newly created and thus any releases of dioxin and dioxin-like compounds that are due to the processing and otherwise use of such chemicals would be new loadings on the environment. In addition, EPA agrees, and has never stated otherwise, that the processing or use of chemicals contaminated with dioxin and dioxin-like compounds could result in the release of these chemicals to the environment. Given the fact that the manufacture of certain chemicals also results in the manufacture of dioxin and dioxin-like compounds that remain with those chemicals as impurities, EPA believes that releases and other waste management quantities for the dioxin and dioxin-like compounds found as impurities with those chemicals should be reported under the dioxin and dioxin-like compounds category. Thus, EPA's original proposal would have created an exemption that was too broad. Consequently, EPA is modifying the qualifier to read as follows:

> Dioxin and dioxin-like compounds (Manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical)

EPA believes that narrowing its proposal in this fashion is consistent with EPA's intention to focus on new loadings to the environment for dioxin and dioxin-like compounds.

One commenter states that the activity qualifier for dioxin and dioxin-like compounds is intended to minimize the burden of reporting on naturally-occurring constituents of raw materials and that this qualifier would be consistent with the PBT criteria set forth by Canada's Department of the Environment in their Toxic Substances Management Policy. The commenter states that the Canadian policy requires a chemical to be ''predominantly anthropogenic'' to be considered a PBT chemical. The commenter states that EPA's assumption that these compounds are ubiquitous in raw materials may be incorrect. The commenter further states that these compounds may be formed in combustion processes due to the ubiquitous presence of *precursor* chemicals in coal, such as natural hydrocarbons and chlorine. The commenter argues that it is not reasonable to expect the hydrocarbon nor the chlorine to be removed from the raw material prior to combustion. Thus, the ''incidental manufacture'' of extremely minute amounts of these chemicals may be unavoidable.

EPA disagrees that the sole basis for its qualifier was to minimize the burden of reporting. The qualifier was added in response to the unique set of conditions that apply to the reporting of dioxin and dioxin-like compounds. As noted above, EPA was, and remains, concerned that, because dioxin is ubiquitous in the environment, the reporting be focused on those facilities that actually add to the environmental loading of these chemicals. EPA did not state that dioxin and dioxin-like compounds would be ubiquitous in all raw material and did not intend to imply that all raw materials contain these compounds. EPA stated that these compounds are ubiquitous in the environment and, thus, facilities that process raw materials containing these compounds might have to report because of the very low reporting threshold necessary to obtain reports from any sources, including those facilities that coincidentally manufacture them. In addition, although the qualifier may be consistent with Canada's Toxic Substances Management Policy, EPA has not proposed any requirement that a chemical must be ''predominantly anthropogenic'' to be considered a PBT chemical under EPCRA section 313. The commenter is correct that dioxin and dioxin-like compounds may be manufactured in combustion processes due to the ''ubiquitous presence of precursor chemicals'' and that such ''incidental manufacture'' may be unavoidable. However, the mere presence of the dioxin precursors will not guarantee dioxin production. There are well documented conditions that favor the formation of dioxins during combustion, and in some cases it may be possible to stringently control fuel composition, flow times, temperature, and other conditions in order to substantially reduce or even eliminate the incidental manufacture of dioxins during combustion processes.

b. *Withdrawal of the proposal to include dioxin-like PCBs in the dioxin category*. Several commenters support EPA's decision to withdraw the proposal to modify the current PCB listing and move the 11 co-planar PCBs to the proposed dioxin and dioxin-like compounds category and retain the co-planar PCBs as part of the current PCB listing. Two commenters support EPA's decision to leave co-planar PCBs out of the dioxin and dioxin-like compounds category since the structure, metabolism, gene regulation, and toxicities of PCBs are substantially different from those of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin. One commenter takes exception to the use of the term ''dioxin-like'' as a way of describing PCBs and other chlorinated

compounds and agrees that the PCBs should be kept out of the ''dioxin-like'' class. Other commenters also argue that PCBs are more appropriately classified as PCBs, not dioxin-like compounds.

One commenter contends that since these chemicals are no longer allowed to be distributed in commerce, maintaining a separate EPCRA section 313 chemical category for these chemicals will streamline data management. This approach will also enable EPCRA section 313 reporting for this category of chemicals to be more consistent with existing data already collected for the purposes of complying with TSCA. Further the commenter asserts that approach is also consistent with EPA's Reinvention Policy and will enable ''one-stop'' reporting.

Another commenter asserts that it is unclear just how many grams of dioxin-like compounds would be excluded from this reporting since there are conflicting Agency proposals at work: the first is a much lower threshold for dioxins. The second includes only dioxins manufactured on site. Since PCBs are not generally manufactured on site, these 11 dioxin-like compounds would not be reported under the proposal if they were included as dioxins. On the other hand, if all dioxins (manufactured, processed, and otherwise used) are included in the EPCRA section 313 threshold determination, these 11 PCBs could make the difference between a facility's reporting or not reporting dioxins. If the dioxin threshold remains as proposed, then the 11 PCBs should remain with the PCB category. Further the commenter argues that if the threshold is expanded to include sources other than those that manufacture dioxin on-site, then the PCBs should be part of the dioxin-like compounds category. If EPA does not modify the dioxin threshold to include all dioxin uses, the 11 dioxin-like PCBs should remain with the PCB category.

While EPA agrees with the commenters that the co-planar PCBs should remain as part of the current PCB listing, the Agency does not agree with all of the reasons the commenters have presented. As EPA stated in the proposed rule:

> . . .EPA has determined that all PCBs persist and bioaccumulate. Since PCBs persist and bioaccumulate, EPA believes that they should be subject to lower reporting thresholds, and thus there is no need to move the 11 co-planar PCBs to the proposed dioxin and dioxin-like compounds category. Therefore, EPA has decided to withdraw its proposal to modify the current listing for PCBs and instead proposes to lower the reporting thresholds for the current PCB listing which covers all PCBs. EPA believes that, since all PCBs persist and bioaccumulate, it is appropriate to lower the reporting threshold for this class of chemicals and that this proposal is less burdensome than requiring separate reporting on the dioxin-like PCBs as part of the proposed dioxin and dioxin-like compounds category (at 64 FR 710).

EPA did not base its decision on a determination that co-planar PCBs were not ''dioxin-like'' and keeping them under the current PCB listing should not be interpreted as such a determination. Also, since EPA is not expanding the qualifier for the dioxin and dioxin-like compounds category to include all processing and otherwise use activities, the amounts of co-planar PCBs that might be reportable under the category would not be expected to contribute significantly to threshold determinations for the category at most facilities.

Four commenters specifically do not support EPA's decision to withdraw the proposal to modify the current PCB listing. Commenters assert that the aggregation of dioxin-like PCBs together with other PCBs will fail to provide reporting of useful information on dioxin-like PCBs. The commenters either contend that the PCBs should be included in the dioxin-like compounds category or the PCBs and all dioxin-like compounds should be reported separately. One commenter argues that the aggregate reporting of dioxin-like PCBs and other PCBs fails to provide any information on the release of dioxin-like PCBs to meet the research, regulatory, or public information goals of EPA's proposal. This commenter raises several points. The commenter contends that specifically, even if some facilities releasing dioxin-like PCBs reported these releases as a portion of their total PCBs production of 10 pounds annually or greater, information on dioxin-like PCBs releases would still be unobtainable. The commenter asserts that aside from the food chain, where some dioxin-like PCBs tend to concentrate disproportionately, available measurements indicate that these dioxin compounds are only a small portion of the mass of all PCB compounds. The commenter further argues that some of these dioxin compounds such as PCB-126 are far more toxic than other dioxin-like and non dioxin-like PCBs. Thus, the commenter asserts that in addition to all of the problems of dioxin-like chemical aggregate reporting, one would not know what, if any, portion of the total PCBs reported were dioxin-like. The commenter contends that the dioxin-like co-planar PCBs also should be reported individually so that a TEQ for all 28 dioxin and dioxin-like compounds can be calculated. Another commenter argues that based on information about current body burdens of co-planar PCBs, they compose as much or an even greater percentage of one's overall exposure than the 17 dioxin and dioxin-like compounds. This commenter cites an EPA document that stated that: ''[e]stimates of exposure to dioxin-like CDDs and CDFs based on dietary intake are in the range of 1-3 pg TEQ/kg/day. Estimates based on the contribution of dioxin-like PCBs to toxicity equivalents raise the total to 3-6 pg TEQ/kg/day.'' Some commenters contend that reporting the co-planar PCBs differently from the 17 dioxin and dioxin-like compounds would make any assessment of the overall release and potential health impact of these types of compounds difficult. One commenter argues that PCBs are currently contaminating sediments and industrial sites nationally and have ruined fish as a natural resource for human consumption across the nation and that the distinction between dioxin-like PCBs and dioxin-like compounds made under this rule is a distinction without a difference. This commenter urges EPA to include all dioxin-like compounds, including PCBs, in the dioxin-like compounds category and to require strict accounting from all sources which release these compounds and which manufacture them, incidentally or by design.

One commenter contends that the failure to report dioxin-like PCBs as a distinct entity separate from other PBT chemicals may hold back information on a significant portion of the total dioxin-like hazard from releases by facilities that report under EPCRA section 313, even if all dioxin and furan releases were reported. The commenter argues that environmental exposure measurements, such as those from fish in San Francisco Bay and from human tissues nationally, indicate that dioxin-like PCBs contribute a very significant portion of the total toxicity hazard from exposure to all dioxin-like chemicals. The commenter also asserts that PCB releases might in some cases represent an inadequately measured yet significant portion of the ongoing dioxin release hazard. If, for example, PCB-126 comprises even 1/10 of the PCBs release measured from San Francisco Bay Area sources, it would contribute substantially to total dioxin-like toxicity emission from some of these facilities. The commenter contends that the failure to provide release information on dioxin-like PCBs under EPA's proposal

may result in failure to inform the public about a significant portion of the total dioxin toxicity that is still released.

EPA agrees that PCBs are toxic chemicals of concern that have caused significant contamination of the environment and that co-planar PCBs may have dioxin-like health effects. However, this does not, in itself, create a requirement that the co-planar PCBs must be moved from their current PCB listing to the dioxin and dioxin-like compounds category. EPA does not believe that the co-planar PCBs must be reported separately from the non co-planar PCBs because they may be more toxic than other PCBs. In general, chemical categories consist of chemicals that vary in their level of toxicity but this variability alone does not mean that release information must be reported separately for each chemical in the category. EPA believes that all PCBs are of concern and that leaving the co-planar PCBs under the current PCB listing will still provide the public with useful and important information. In deciding not to move the co-planar PCBs to the dioxin category, EPA also considered any potential additional burden associated with splitting the reporting for PCBs into two different listings, as well as the fact that facilities are not likely to be able to determine quantities of the specific co-planar PCBs in question. Specifically, EPA considered the lack of readily available estimation techniques for determining quantities of co-planar PCBs, as opposed to other PBT chemicals and the PCB listing as a whole (co-planar PCBs will be included in the estimation of PCBs). EPA determined that since all PCBs are of concern and since the reporting threshold for all of the PCBs under the PCB listing would be lowered substantially, that requiring separate reporting on the co-planar PCBs was not warranted.

One commenter contends that the failure to report dioxin-like PCBs would fail to provide information on that subgroup of dioxin-like compounds for which there is the greatest need for additional information. The commenter argues that EPA's evaluation of the emission of dioxin-like chemicals nationwide shows that there is less information on releases of dioxin-like PCBs than there is for other dioxin compounds. The commenter asserts that similarly, their survey of source information in the San Francisco Bay Area shows that, despite many measurements of dioxin and furan releases, and despite a handful of source measurements confirming PCBs, there are few or no source measurements for dioxin-like PCBs. The commenter argues that the information on releases from facilities is even less available for the dioxin-like PCBs than it is for the other dioxin-like chemicals and that EPA's analysis in the proposed rule fails to consider adequately this extreme need for source release information.

EPA agrees that there is far less information available on co-planar PCBs than for dioxin and other dioxin-like compounds. Much less testing and analysis has been conducted for these chemicals. This would pose an additional problem for reporting on the co-planar PCBs separately from the other PCBs. EPA considered the ability to estimate quantities of specific co-planar PCBs and determined that there is a lack of readily available estimation techniques for co-planar PCBs. In fact, at this time, the Agency would not be able to provide guidance for making a reasonable estimate of quantities of co-planar PCBs that may be manufactured in certain processes. In addition, EPCRA section 313 does not require any additional monitoring beyond that required by other provisions of law so listing the co-planar PCBs separately would not mean that additional source measurements would be developed. Thus, listing under EPCRA section 313 will not require the development of additional monitoring data that could be used to make reasonable estimations of thresholds or releases and other waste management quantities. Given the lack of information available for estimating quantities of co-planar PCBs and the potential additional burden associated with splitting the reporting for PCBs into two different listings, EPA decided to leave the co-planar PCBs under the current PCB listing.

One commenter asserts that the burden on industrial producers of dioxin-like PCBs is not an appropriate reason for excluding dioxin-like PCBs from the dioxin and dioxin-like compounds category because this will not meet EPCRA's right-to-know goal for dioxin-like PCBs. The commenter contends that EPA's cost analysis does not address dioxin-like PCBs specifically and thus, EPA's rationale in Unit VI. of the preamble of the proposed rule (64 FR 688) that ''this proposal is less burdensome than requiring separate reporting on the dioxin-like PCBs'' is not based on any cost analysis in EPA's proposal. The commenter argues further that in any case, aggregate reporting of dioxin-like PCBs with a 10 pound threshold will fail to obtain the required reporting on a substantial majority of dioxin-like PCBs or to provide needed information about dioxin-like PCB releases and therefore, EPA's perceptions regarding reporting burden cannot properly outweigh the public's need for the information which is denied under EPA's new proposal. The commenter refers to the proposal to retain dioxin-like PCBs under the PCB listing as the ''less than 10 pounds exemption.'' The commenter asserts that existing evidence demonstrates that many dioxin producing processes such as waste incinerators, oil-fired boilers, and other processes also produce potentially significant amounts of PCBs which are released to the environment from these facilities. The commenter argues that this evidence suggests that at least some facilities reporting under EPCRA section 313 are likely to be releasing dioxin-like PCBs as a portion of these PCB releases. The commenter contends that the evidence also suggests that most or all releases of dioxin-like PCBs at these facilities may be associated with total annual PCB production of less than 10 pounds per facility and thus, EPA may not meet the requirement that a substantial majority of dioxin-like PCBs be reported under this exemption.

Reporting burden was not the sole or even most important factor in EPA's decision not to move the co-planar PCBs to the dioxin and dioxin-like compounds category. In reaching its final decision, EPA considered the fact that additional information would be collected on all PCBs by lowering the threshold for the PCB listing and that the additional information that would be collected was sufficient for EPCRA section 313 purposes, as well as less burdensome. Even in its proposal EPA did not conclude that reporting burden alone outweighed the public's right-to-know about chemical releases. As stated in other responses to this issue, EPA is also concerned about the ability to estimate quantities of specific co-planar PCBs since there is a lack of readily available estimation techniques for co-planar PCBs. It is correct that EPA did not attempt to quantify the reduction in burden that would result from not including the co-planar PCBs in the dioxin and dioxin-like compounds category. However, EPA believes that it would be inherently less burdensome since facilities would not have to attempt to determine if they can estimate co-planar PCBs separately and filing one form would obviously be easier and less confusing than attempting to track and adjust the amounts that must be applied to two different listings and filing two reports. With regard to the issue of obtaining reporting on a substantial majority of ''dioxin-like PCB'' releases, as stated in EPCRA section 313(f)(2), the

determination of whether a revised threshold meets the ''substantial majority'' standard is measured against the ''total releases of the chemical at all facilities subject to the requirements of this section.'' As EPA stated in the proposed rule:

> For purposes of determining what constitutes a ''substantial majority of total releases'', EPA interprets ''facilities subject to the requirements'' of section 313 as the facilities currently reporting, ... (at 64 FR 689).

Currently, facilities required to report on PCBs must report on all PCBs, not just the co-planar PCBs or any other individual PCBs. The current listing includes all PCBs. Consequently EPA does not believe that the requirements of section 313(f)(2) function as an impediment to its decision to withdraw its proposal to include the co-planar PCBs in the dioxin and dioxin-like compounds category. As discussed in Units II.B. and VI.A., EPA believes that it has satisfied the requirements of EPCRA section 313(f)(2), without the need for quantitative support.

c. *Listing dioxin and dioxin-like compounds as a category versus individual listing of each chemical.* Some commenters contend that reporting dioxin and dioxin-like compounds as one category would not provide useful information and asked that the individual compounds be reported. One commenter recommends that reporting on individual chemical species should be required when the information is available. One commenter who supports the individual reporting of all of the dioxin and dioxin-like compounds, states that the amounts of individual dioxin compounds released from facilities is part of the important public information needed to assist research and policy development. The commenter claims that reporting as a category will not provide the public with the information to assess the relative hazards of releases since one dioxin-like compound can have a relative hazard several orders of magnitude less than 2,3,7,8-tetrachlorodibenzo-*p*-dioxin. This commenter also states that different sources often emit a different mix of dioxin compounds and that this information is widely used to trace dioxin contamination to specific root causes. The commenter states that the relative amounts of the many different dioxin-like chemicals in a sample are compared to create a ''profile'' which might match the profile created by emission from a particular source. The commenter did not support the reporting of the category based on toxic equivalents (TEQs) but thought it important for the users of the data to be able to determine TEQs. Some other commenters make the same general argument that individual isomer reporting is needed to facilitate risk characterization including transport and fate of the different isomers.

Some commenters contend that certain dioxin-like compounds such as octachlorodibenzo-*p*-dioxin and octachlorodibenzofuran should not be reported since they are ubiquitous in the environment and are the least toxic under the toxic equivalent factors (TEFs). One commenter states that EPA should require reporting only for the most toxic congeners: the tetra-, penta-, and hexa-congeners and not the hepta- and octa-congeners which are less toxic and less relevant from a risk standpoint. Other commenters state that only 2,3,7,8-tetrachlorodibenzo-*p*-dioxin should be reported. Some commenters contend that reporting for these compounds should not be required at the same reporting threshold as the other dioxin and dioxin-like compounds. Most commenters who would like to exclude certain dioxin-like compounds did not indicate that they wanted individual reporting of the remaining compounds. Some commenters support the reporting of dioxin and dioxin-like compounds as a category, as EPA proposed. One commenter states that if reporting is not limited to just 2,3,7,8-tetrachlorodibenzo-*p*-dioxin, then the commeter supports EPA's proposal to limit the category to only the 7 dioxins and 10 furans listed in the proposed rule.

After consideration of all of the comments on this issue, EPA has decided that the best way to report on dioxin and dioxin-like compounds is to report them as a category. This is consistent with the way EPA has addressed other groups of chemicals that share the same toxic effect and in this case are also generated as complex mixtures. As discussed in Units VI.G.1.d. and e., reporting as a category and based on TEQs would not provide users of the data with information on which compounds contribute the most to the TEQ total. In addition, requiring facilities to report each compound individually would impose an additional burden on the industries that will be required to report. However, EPA agrees that being able to determine the amounts of the individual dioxin and dioxin-like compounds would make the data more useful. Therefore EPA will add a section to the Form R that will require the reporting facility to provide the distribution of dioxin and each dioxin-like compound for the total quantity that the facility is reporting. If a facility has information on the distribution of the dioxin and dioxin-like compounds, the facility must report either the distribution that best represents the distribution of the total quantity of dioxin and dioxin-like compounds released to all media from the facility; or its one best media-specific distribution. This information is only required if it is available from the data used to calculate thresholds, releases, and other waste management quantities, no additional analysis is required. As with all other reporting under EPCRA section 313, this information will only be required if the facility has information that can be used to make a reasonable estimate of the distribution from the available data. With the distribution of congeners reported on each Form R, the user of the data can determine the grams of dioxin and each individual dioxin-like compound that makes up the total quantity reported on the Form R. Under this reporting mechanism, all of the information that the commenters have stated is important to determining the significance of quantities reported under this category will be provided to the public but the reporting facilities will still only have to file one report. Any of the other possible options, such as reporting in terms of TEQs or reporting each individual compound separately, either do not provide all of the information the commenters would like to have, or impose too great an additional reporting burden without providing the public with significant additional information.

d. *Using mass versus TEQs for reporting releases and other waste management quantities.* Most of the commenters on this issue suggest that EPA should require that release and other waste management data for the dioxin and dioxin-like compounds category be reported in terms of TEQs rather than in terms of absolute grams. The following list is a summary of the various reasons provided by the commenters in support of reporting dioxin and dioxin-like compounds in terms of TEQs: (1) All dioxin data reported under other EPA programs as well as other Federal and state regulatory programs are reported in terms of toxicity equivalents; (2) the public is familiar with dioxin data reported in terms of TEQs and reporting in other units would cause confusion and be misleading; (3) TEQs provide more meaningful information than total weights since they take into account the relative toxicities of the various dioxin-

like compounds; (4) facilities that report under other regulatory programs are likely to rely upon TEQ data that they already have; (5) use of absolute mass may cause misleading comparisons between grams and grams TEQ; (6) releases reported in absolute mass make it difficult to assess the impacts these compounds may have on the environment due to the differences in their toxicities; and (7) reports based on TEQs would provide far more useful information about potential community risks than reports based on the total mass of compounds in the category since more risk information would be provided.

One commenter argues that EPA's justification for adding the category is based on assumptions about the toxicity of the other dioxin-like compounds relative to dioxin itself and that given these assumptions the reporting of TEQs makes sense. The commenter states that under current TEQ schemes, these dioxin-like compounds are all less toxic than dioxin, as much as 1,000 times less, and that facilities should not simply sum emissions on the Form R for compounds with such drastically different toxicities. One commenter suggests that EPA require the reporting of both grams and TEQs and if not both, then just grams. This commenter asserts that if only grams are reported, the data will be somewhat difficult to interpret without any further information, but if only TEQs are required to be reported, then there are uncertainties about what and how much is discharged.

Another commenter states that if EPA is going to require dioxin reporting as a group and not by specific chemicals, TEQ reporting is an unnecessary complication. The commenter states that the TEFs used to formulate the TEQs are constantly reviewed and changed, which would necessitate EPA review and possible reissuance of new TEFs each year. The commenter argues that this would make previous years' TRI data impossible to compare once the changes were made.

While EPA recognizes that TEQs are a common way of expressing quantities of dioxin-like compounds, EPA does not believe that reporting in these units would be the best or most appropriate way to report for the dioxin and dioxin-like compounds category under EPCRA section 313. Although some commenters believe that TEQ reporting should be used since not all of the dioxin-like compounds are as toxic as dioxin itself, EPA has determined that all of the dioxin-like compounds meet the listing criteria of EPCRA section 313. Since all of these compounds meet the listing criteria, the actual mass of each member of the category should be reported. To do otherwise would deny the public information on the actual quantities of toxic chemicals entering the environment. It would also be inconsistent with all other reporting of EPCRA section 313 toxic chemicals since none of them are reported based on relative toxicities. In addition, this would be inconsistent with EPCRA section 313(g)(1)(C)(iv) which requires that ''the annual quantity of the toxic chemical entering each environmental medium'' be reported.

Some of the commenters state that TEQs should be used because they provide more risk information to the public than just reporting mass. While TEQs do provide information on relative toxicity, EPA does not believe that increasing the amount of risk information is a basis for changing the EPCRA section 313 method for reporting from mass-based to relative toxicity-based. As discussed in Unit VI.F., EPCRA section 313 is not a risk-based program, and reporting is not intended to communicate information about relative risks. Rather it provides local communities with data on release and other waste management quantities on listed toxic chemicals, so that they may use the data in conjunction with information on chemical properties (e.g., persistence and bioaccumulation) and site-specific information to determine if releases present a potential risk. It is also not clear, as some commenters state, that the public is more familiar with dioxin data reported in terms of TEQs or that they will understand TEQs any better than grams.

EPA does not believe that the fact that other programs require reporting in TEQs and that facilities will already have TEQ information is a significant reason to require TEQ reporting under EPCRA section 313. Since the first piece of information that is required to determine TEQs is the grams of dioxin and each dioxin-like compound, these facilities should already have the gram-based information they would need. In addition, as stated above, EPCRA section 313 reporting serves the purposes of EPCRA section 313; other programs, e.g., the CWA, are risk-based command and control programs.

Several commenters also disagree with the concerns that EPA raised in the proposed rule, which were:

> . . .there are three significant disadvantages to reporting in TEQs. First, revisions in TEF factors for individual dioxin-like compounds in future years would require changes to the calculations in the reported release and other waste management quantities, thus making year to year comparisons more difficult, unless the particular dioxin-like compounds are identified. Second, some facilities may not be able to report in TEQs, since, although they may be able to estimate a mass quantity for the category as a whole, they may not have enough information to estimate the relative distribution of all category members. Third, TEQ reporting would be different from all other TRI reporting, which is mass-based, and may cause additional confusion. (at 64 FR 712-713)

Some commenters contend that EPA's first concern is not valid since the EPCRA section 313 reporting requirements have been changed several times in the past in spite of difficulties in comparing future reports to past performance. Two commenters state that this same logic could be applied to the use of AP–42 factors which EPA acknowledges have been revised and refined over the years, and that this also diminishes the value of year-to-year reporting comparisons. One commenter suggests that EPA could minimize any confusion that might be caused by a subsequent change in one or more TEFs by each year specifically publishing or cross referencing the TEFs that must be used for that reporting period.

One commenter contends that EPA's second and third concerns appeared weak in light of the much greater risk information provided by a TEQ approach. Some commenters contend that EPA's third concern is not valid since the reporting requirement being proposed for dioxin and dioxin-like compounds is different whether TEQs are used or not. One commenter states that the third concern is clearly dwarfed by the confusion that would ensue if all dioxin-like compounds were reported as equivalent, when the hazards vary by a factor of 500. One commenter states that reporting dioxin on a TEQ basis will cause more rather than less confusion if the public mistakenly compares data in grams with data presented in grams TEQ. Some commenters agreed with the concerns EPA expressed in the preamble. One commenter states that it agreed with these concerns but that the concern about year-to-year comparisons being more difficult also applies to the reporting of a single mass value for the entire category. The commenter contends that since the amounts of the individual dioxin-like compounds would not be known, if TEFs change, one cannot adjust previously reported values to reflect the changes in TEFs. This commenter suggests that in order to make the information reported of greatest use, the mass of dioxin and each of the dioxin-like compounds should be reported once a TEQ threshold is exceeded.

One commenter argues that while TEQs are a valid and scientifically

sound metric for reporting the likely health hazard of a compound, that was not the intended purpose of the EPCRA section 313 reporting requirement. The commenter claims that reporting dioxin and dioxin-like compounds in TEQs will cause confusion, since all other reporting under EPCRA is done in terms of mass and does not take toxicity into account.

EPA believes, as do some of the commenters, that the concerns that were expressed in the proposed rule for reporting dioxin and dioxin-like compounds in terms of TEQs under EPCRA section 313 are valid. EPA disagrees with those commenters who claim that since other changes in reporting have occurred, such as revisions to AP-42 emission factors, there should be no concern for the changes that might occur in TEFs and the resulting TEQs. The fact that certain changes have occurred in reporting requirements or methods of estimation and that those changes may make certain year-to-year comparisons more difficult does not reduce the concern for knowingly selecting reporting units, based on relative toxicity as opposed to emission factors, that have changed in the past and may well change in the future. Also, EPA would be required to choose a particular set of TEFs (i.e., as of 1999) and would need to amend them by rulemaking each time the TEFs were revised. Changes in TEFs and the resulting TEQs would be unlike any of the past changes in EPCRA section 313 reporting since none of these reporting changes were related to the relative toxicity of chemicals that meet the listing criteria of EPCRA section 313. The cross referencing or publishing of the TEFs that must be used for each reporting period would still not allow year-to-year comparisons since without knowing a facility's distribution of each of the category members the TEQ cannot be recalculated. EPA's concerns that some facilities may not be able to report in terms of TEQs are also valid. Although most facilities that will be able to make reasonable estimations for the dioxin and dioxin-like compounds category should be able to report in terms of TEQs, there may be some that can only report in actual mass units and they should not be exempt from reporting. EPA is also still concerned that TEQs would be different than other EPCRA section 313 reporting units, since they are not based on absolute mass, and that this could cause confusion. EPA does not agree with the commenters that state that this does not matter since the reporting for the dioxin and dioxin-like compounds category is going to be different anyway. The only real reporting difference for the dioxin and dioxin-like compounds category is that the reporting units are in grams rather than pounds. To determine the amounts in pounds all that one would have to do is multiply the grams by 0.002204. However, TEQ reporting would be much different since in order to understand the reported value one would need to understand the basis for TEFs, what they are, how they relate to dioxin, and how TEQs are calculated from the individual TEFs. This obviously requires more knowledge on the part of the data user than simply understanding different units of mass and does have the potential to cause some confusion.

One commenter contends that neither total mass nor TEQ reporting provides sufficient information on reduction in potential exposure and risk. The commenter asserts that it is possible that a facility could reduce its dioxin TEQ while releasing a greater mass of dioxin-like compounds, but neither total mass nor TEQ reporting would really provide a good picture of what a facility was doing. The commenter suggests that if EPA wants to provide TEQ information to the public, it should also require facilities to report dioxins by individual chemical, rather than as a group.

Another commenter that favors the reporting of dioxin and dioxin-like compounds as individual chemicals claims that reporting as a category but in TEQs would still fail to reveal the amounts of individual dioxin compounds released. The commenter argues that this alternative would provide no information on individual compounds for use in tracing dioxin source profiles. The commenter contends that reporting in TEQs would provide better information on the relative toxicity hazard based upon today's toxicity information but that information on the relative toxicity of the many dioxin-like chemicals is improving and thus toxicity factors for some of these compounds will change in the future. The commenter claims that in future years the Inventory would have to choose between keeping the old toxicity calculation (and becoming irrelevant in comparison with other research data), or changing the toxicity calculation (and becoming irrelevant for tracking changes in dioxin release rates over time). The commenter contends that the need to aid research and policy development based on current science and the need to track release rates over time are fundamental to the Inventory's purpose and that this alternative must be rejected as just another ill-advised aggregate reporting scheme. The commenter recommends that EPA require the reporting of dioxin and dioxin-like compounds in the way these compounds are measured and analyzed by scientists and government agencies, as individual chemicals, and consider an additional service by EPA to calculate and report dioxin toxicity as TEQ for the year-to-year data using the most recent toxicity information which becomes available.

Several commenters make the point that for dioxin and dioxin-like compounds neither reporting total mass nor reporting in terms of TEQs provides sufficient information on potential exposures and risks, and that neither would allow for the tracing of dioxin source profiles. EPA agrees that neither approach would provide all of the data that the commenters would like to have reported and that being able to determine TEQs would provide additional useful information. A common solution to the TEQ issue that the commenters suggest, was to report dioxin and each individual dioxin-like compound separately rather than as a category. However, EPA believes that this approach would be overly burdensome and unnecessary to get the kind of data that would be the most useful. As discussed in the previous section of this unit, many other commenters requested that dioxin and dioxin-like compounds be reported separately rather than as a category. After consideration of all of the comments on this issue, EPA has determined that the best way to report for the dioxin and dioxin-like compounds category is to report in terms of absolute grams for the entire category. This is consistent with all other reporting under EPCRA section 313 and will provide the most consistent information from year-to-year. However, EPA agrees with most of the commenters that being able to determine TEQs from the reported data and being able to determine which individual chemicals are include in a facilities report would make the data more useful to the public. Therefore, as discussed in the previous section of this unit, EPA will add a section to the Form R that will require the reporting facility to provide the distribution of dioxin and each dioxin-like compound for the total quantity that the facility is reporting. If a facility has information on the distribution of the dioxin and dioxin-like compounds, the facility must report either the distribution that best represents the distribution of the total quantity of dioxin and dioxin-like compounds released to all media from the facility; or its one best media-

specific distribution. This information is only required if it is available from the data used to calculate thresholds, releases, and other waste management quantities, no additional analysis is required. As with all other reporting under EPCRA section 313, this information will only be required if the facility has information that can be used to make a reasonable estimate of the distribution from the available data. With the distribution of the individual members of the category reported on each Form R, the user of the data can determine the grams TEQ that correspond to the absolute grams reported and can adjust the grams TEQ as TEF values change over time. Under this reporting mechanism, all of the information that the commenters state is important to determining the significance of quantities reported for this category will be provided to the public on one Form R. This way all parties can express the data in whichever format they believe is best, and since the first thing that must be determined under any reporting method is the mass of each member of the category, there should be little, if any, additional burden associated with including the distribution.

e. *Using TEQs as the basis for reporting thresholds.* All of the commenters on this issue requested that the reporting threshold for the dioxin and dioxin-like compounds be set in terms of TEQs. Most of the commenters indicate that the reasons they support a TEQ-based threshold were the same as the reasons they support reporting release and other waste management quantities in terms of TEQs (see the first paragraph of the preceding section of this unit). Two commenters argue that since EPA proposed to use TEQs for reporting release and other waste management quantities, that not basing the reporting threshold on TEQs would be inconsistent. The commenters contend that a facility may trigger reporting by having emissions that exceed the threshold (in terms of absolute weight) but have no significant reporting quantity (in terms of TEQ equivalent weight) and, therefore, no significant health risk. The commenters recommend the use of a consistent approach where TEQs are used for both threshold determinations and release and other waste management quantities. The commenters state that such an approach would be consistent with the health risk rationale for EPCRA reporting, yet not rely on site-specific risk approaches that may evolve over time. Another commenter had similar concerns suggesting that it would be extremely burdensome and unnecessarily complex to have thresholds based on absolute grams and release and other waste management quantities reported in TEQs and recommends that EPA should use TEQs for both.

One commenter claims that it may ease the reporting burden somewhat to base the EPCRA section 313 reporting threshold on a TEQ basis rather than attempting to develop mass-based estimates. Another commenter contends that in order to determine the sum of the mass of the 17 dioxin and dioxin-like compounds, one already will have determined the mass of each compound individually and that with data reported by compound, a TEQ can easily be calculated. The commenter also suggests that there are short-term screening bioassays for determining the TEQ of a sample that are less expensive, more sensitive, and can be done more rapidly than traditional analytical chemistry methods. The commenter states that rather than facilities trying to guess what their releases may be, in an attempt to avoid spending money on expensive analytical chemistry methods, if the reporting threshold were based on TEQs, a facility can readily and more inexpensively screen its releases. The commenter argues that having a reporting threshold based on TEQ is more representative of potential health risks and recommends that EPA consider using some amount of TEQs as the reporting threshold. Another commenter suggests that one option would be to report releases of each dioxin-like compound if the total, in TEQ, exceeds some chosen threshold.

One commenter that suggests that TEQs should be used for thresholds, notes that reporting dioxin on a mass basis is quite different from reporting on a TEQ basis. The commenter asserts that since some of the dioxin-like compounds have TEFs of 0.001 then the 0.1 gram threshold could require facilities that produce 0.0001 gram TEQ of dioxin to report. The commenter claims that when compared to the estimate that there are 2,973 grams TEQ of U.S. dioxin emissions such amounts are insignificant and meaningless. The commenter maintains that using TEQs instead of the mass of each compound for determining whether an EPCRA reporting threshold for dioxin and dioxin-like compounds is exceeded would not deprive EPA or the public of information regarding meaningful releases of dioxin. The commenter also recommends that whatever units EPA decides to use should be the same for thresholds and for release and other waste management quantities.

One commenter suggests that EPA should require sources to use toxicity factors in calculating the manufacturing threshold for dioxin and dioxin-like compounds to avoid triggering the threshold based solely on non-detection. The commenter states that the 17 dioxin-like compounds to which the 0.1 gram proposed reporting threshold would apply vary in toxicity by a factor of 1,000 but that EPA does not take this variation in toxicity into consideration for the purpose of determining the manufacturing threshold.

EPA did not propose to use TEQs as the units of measurement for the EPCRA section 313 reporting threshold for dioxin and dioxin-like compounds. EPA has the same concerns for using TEQs for EPCRA section 313 thresholds as it does for reporting releases and other waste management quantities in terms of TEQs, and most of the issues raised here have been addressed in the preceding section of this unit. Most importantly, since EPA has determined that each of the dioxin-like compounds meets the listing criteria of EPCRA section 313, the actual mass of each member of the category should be included in threshold determinations. Also, the fact that the TEFs and thus the TEQs can change over time, is even more important for thresholds since TEF changes would in effect change the threshold, because for example, the same mass quantity that would have exceeded the threshold before the change may not exceed the threshold after the change.

As one of the commenters pointed out, using TEQs as the units for the reporting threshold is much different than using actual mass. The commenter showed how a 0.1 gram threshold for a dioxin-like compound with a TEF of 0.001 would be equivalent to a 0.0001 gram TEQ threshold. The opposite of this is that if the 0.1 gram threshold were in units of TEQ, then for dioxin-like compounds with a 0.001 TEF, it would take 100 grams to reach the reporting threshold. Using TEQs as the units for the reporting threshold would thus be equivalent to establishing separate thresholds for each member of the dioxin and dioxin-like compounds category based on their relative toxicity. EPA does not believe that any of the reporting requirements of EPCRA section 313 should be based on relative toxicities since, as discussed in Unit VI.F., EPCRA section 313 is not a risk-based program and reporting is not intended to communicate information about the Federal government's risk determinations for individual chemicals. Rather it provides local communities with data on release and

other waste management quantities on listed toxic chemicals, so that they may use the data in conjunction with information on chemical properties (e.g. persistence and bioaccumulation) and site-specific information to determine if releases present a potential risk.

Several commenters express concern about consistency between the units of measurement for the threshold for the dioxin and dioxin-like compounds category and the units of measurement used to report releases and other waste management quantities. While EPA is not adopting the use of TEQ as some commenters requested, EPA is being consistent since absolute gram quantities will be used for both thresholds and the reporting of releases and other waste management quantities.

EPA does not agree with those commenters who state that the information collected under a 0.1 gram threshold would, in some cases, represent such a small portion of the estimated national amount of dioxin TEQs that the data would not be useful. On a facility-by-facility basis, the amounts reported may be a small percentage of the national total, but that does not mean that it will not be useful or meaningful to the public. One of the purposes of EPCRA section 313 is to provide information to communities about releases into their community. A small percentage of national releases may pose potential risks to local communities. Further, even information that shows little or no releases helps communities to understand what risks may be or may not be present in their communities and helps government agencies to target resources. In addition, since not all of the sources of dioxin and dioxin-like compounds will be reporting under EPCRA section 313, the amount reported will be a larger portion of the total amount reported under EPCRA section 313 than it will be on a national basis. The issue of how many sources of dioxin and dioxin-like compounds are captured by EPCRA section 313 are addressed in the Response to Comments document (Ref. 69) for this rulemaking.

EPA does not agree that reporting in terms of TEQs would necessarily be less burdensome. As one commenter states, in order to determine the sum of the mass of the 17 dioxin and dioxin-like compounds, one already will have determined the mass of each compounds individually and that with data reported by compound, a TEQ can easily be calculated. Since the TEQs are calculated from the relative amounts of dioxin and each dioxin-like compound that is present, it is an additional step to present the data in terms of TEQs and therefore it should not be less burdensome.

f. *Reporting guidance for dioxin and dioxin-like compounds.* A number of commenters requested that EPA develop reporting guidance for the dioxin and dioxin-like compounds category.

EPA agrees that guidance should be provided to assist facilities in determining threshold and release quantities for the dioxin and dioxin-like compounds category. As EPA stated in the proposed rule:

> EPA intends to develop reporting guidance for industries that may fall within this reporting category. The guidance developed will be consistent with the methods and procedures that EPA has developed for determining if dioxin and dioxin-like compounds are present in various industrial processes, including Method 23 (Ref. 77) developed for electric utilities. In developing the reporting guidance for the dioxin and dioxin-like compounds category EPA will work with interested parties to provide the best possible guidance for reporting facilities (at 64 FR 712).

EPA will provide a guidance document to assist certain facilities in making thresholds and release determinations for the dioxin and dioxin-like compounds category. The guidance document will be consistent with EPA established methods of measuring or estimating quantities of dioxin and dioxin-like compounds, including Method 23.

2. *Benzo(g,h,i)perylene (CAS No. 191-24-2) (Ref. 70).* EPA proposed to add benzo(g,h,i)perylene to EPCRA section 313 pursuant to EPCRA section 313 (d)(2)(C). One commenter states that EPA should not add benzo(g,h,i)perylene to the EPCRA section 313 list of toxic chemicals because there are insufficient data to support the EPCRA section 313(d)(2)(C) determination. The commenter states that EPA used predicted aquatic toxicity values based on quantitative structure activity relationship (QSAR) analysis but did not provide any toxicity data. The commenter contends that EPA did not provide any evidence to support the statement that aquatic QSAR equations show a high correlation between predicted and measured toxicity values, and did not provide any other information to support use of QSAR for this type of chemical.

EPA disagrees with the commenter's statements. EPA provided the following discussion in the proposed rule:

> Three of the chemicals being proposed for listing (benzo(g,h,i)perylene, 3-methylcholanthene, and octachlorostyrene) have been found to meet the EPCRA section 313(d)(2)(C) criteria for ecotoxicity based on predicted aquatic toxicity values generated from quantitative structure activity relationship (QSAR) equations and other predictive techniques. As previously stated (58 FR 63500, December 1, 1993), EPA believes that, where no or insufficient actual measured aquatic toxicity data exist upon which to base a decision, toxicity predictions generated by QSARs and other predictive techniques may constitute sufficient evidence that a chemical meets the section 313 listing criteria. EPA's authority to use such predictive techniques derives from section 313(d)(2) of the statute, which states that EPA shall base its listing determinations on, inter alia, ''generally accepted scientific principles.'' EPA believes that the aquatic QSAR equations that are in widespread use and show a high correlation between predicted and measured aquatic toxicity values can be considered to be ''generally accepted scientific principles'' and can appropriately form the basis of a listing determination (Ref. 70). (at 64 FR 693)

EPA believes that QSAR data is valid predicted aquatic toxicity data and the fact that no actual toxicity studies were provided does not mean that the available data were insufficient to determine that benzo(g,h,i)perylene met the listing criteria of EPCRA section 313(d)(2)(C). In addition, EPA did provide support for the statement that aquatic QSAR equations are in widespread use and show a high correlation between predicted and measured aquatic toxicity values. The docket for the proposed rule contained a document titled ''SAR/QSAR in the Office of Pollution Prevention and Toxics'' In: Environmental Toxicology and Risk Assessment: 2nd Volume, STP 1216. One of the articles in this reference was titled *Validation of Structure Activity Relationships Used By the USEPA's Office of Pollution Prevention and Toxics for the Environmental Hazard Assessment of Industrial Chemical.* This includes the methods of SAR for the class of neutral organic chemicals which, as discussed in the support document, was used for benzo(g,h,i)perylene since it is a neutral organic chemical. Thus, EPA did provide support for its conclusions about QSAR analysis and for the use of QSAR for benzo(g,h,i)perylene.

This commenter also states that EPA uses an estimated Log K_{ow} in its aquatic toxicity prediction and argues that Log K_{ow} is an inaccurate predictor for many chemicals particularly if it is estimated rather than measured. The commenter contends that EPA's basis for the listing of benzo(g,h,i)perylene is a prediction based upon a prediction, with no actual data and that this is not a sufficient basis for listing under EPCRA section 313 and it does not meet the statutory requirements for listing that a chemical is ''known to cause or can reasonably be

anticipated to cause'' a significant adverse effect.

EPA disagrees with the commenter's conclusions. The majority of the SAR calculations in the ECOSAR Class Program are based upon the octanol/water partition coefficient (K_{ow} or Log P) since there is a correlation between Log P and toxicity. Using the measured aquatic toxicity values and estimated Log P values, regression equations can be developed for a class of chemicals. Toxicity values for a chemical within that class may then be calculated by inserting the estimated K_{ow} into the class regression equation and correcting the resultant value for the molecular weight of the compound. The ecological assessment guidelines for predicting the toxicity of chemicals with limited measured aquatic toxicity data have been used for over a decade (Ref. 35). The commenter has not provided the Agency with any concrete information or data indicating that this approach either is not a generally accepted scientific approach or is unreliable, and the Agency finds no reasonable basis to change these techniques at this time. In addition, the commenter did not provide any data to indicate that the predicted Log K_{ow} for benzo(g,h,i)perylene was inaccurate.

This commenter also contends that EPA's failure to consider exposure in this proposed rule is particularly important for benzo(g,h,i)perylene. The commenter argues that given the properties of benzo(g,h,i)perylene, any release into water will result in the vast majority (more than 99%) of the compound being partitioned to sediment or adsorbed onto suspended particulates and organics in the water column and thus the potential for this chemical to be in a toxic form and pose risk in natural systems is low.

EPA disagrees with the commenters' contention that EPA should consider exposure in its determination that benzo(g,h,i)perylene meets the EPCRA section 313(d)(2)(C) listing criteria. As discussed in Unit VI.F., EPA is only required to consider exposure under a limited set of circumstances. In the final chemical expansion rule (59 FR 61432), EPA further explained its policy on the use of exposure considerations under EPCRA section 313(d)(2)(C) and the fact that the Agency does not consider exposure for chemicals that are highly ecotoxic. As EPA explained in the final rule:

> The Agency believes that exposure considerations are not appropriate in making determinations (1) under section 313(d)(2)(B) for chemicals that exhibit moderately high to high human toxicity (These terms, which do not directly correlate to the numerical screening values reflected in the Draft Hazard Assessment Guidelines, are defined in unit II.) based on a hazard assessment, and (2) under section 313(d)(2)(C) for chemicals that are highly ecotoxic or induce well-established adverse environmental effects (at 59 FR 61441).

Although EPA does not believe that it would be appropriate to consider exposure, EPA also disagrees with the commenter's characterization of the fate of benzo(g,h,i) perylene. Environmental fate models show that the chemical will only partition about 60% to the sediment. Also, the Agency cannot rely on the environment to serve as a sink for this chemical. Other environmental conditions such as turbidity, biological activity, or the chemical activity in water could cause redistribution of the chemical into the water column again.

Based upon QSAR equations and other predictive techniques, EPA has concluded that benzo(g,h,i)perylene is toxic. It has the potential to kill fish, daphnia, and algae, among other adverse effects, based on chemical and/or biological interactions. Benzo(g,h,i)perylene can cause these toxic effects at relatively low concentrations. The predicted aquatic toxicity values for benzo(g,h,i)perylene, based upon QSAR analysis using the equation for neutral organics and an estimated Log K_{ow} of 6.7, included calculated values of 0.030 milligrams per liter (mg/L) for the fish 96–hour LC_{50} (i.e., the concentration that is lethal to 50% of test organisms) and 0.0002 mg/L for fish chronic toxicity; 0.012 mg/L for daphnia 48–hour LC_{50} and 0.027 mg/L for the daphnid 16–day chronic LC_{50}; and 0.03 mg/L for the algae 96–hour EC_{50} (i.e., the concentration that is effective in producing a sublethal response in 50% of tests organisms) with an algal chronic toxicity of 0.012 mg/L.

Benzo(g,h,i)perylene can cause its toxic effects at relatively low concentrations, therefore EPA considers it to be highly toxic. Since benzo(g,h,i) perylene is toxic at relatively low concentrations EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish, daphnia, and algae kills, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

EPA reaffirms that there is sufficient evidence for listing benzo(g,h,i)perylene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical. Therefore, EPA is finalizing the addition of benzo(g,h,i)perylene on the EPCRA section 313 list.

3. *Benzo(j,k)fluorene (fluoranthene) (CAS No. 206–44–0) (Ref 70).* EPA proposed to add fluoranthene to EPCRA section 313 pursuant to EPCRA sections 313 (d)(2)(B) and (C). EPA received no comments specific to the carcinogenicity data that EPA presented in the proposed rule in support of the addition of fluoranthene to the EPCRA section 313 list of toxic chemicals. Thus, EPA reaffirms that there is sufficient evidence for adding fluoranthene to this list of EPCRA section 313 toxic chemicals pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

One commenter argues that EPA should refrain from listing fluoranthene pending additional assessment of the data. The commenter contends that EPA's reported toxicity values for fluoranthene span a range of about two orders of magnitude and that for such a wide range, it is necessary to evaluate potential exposure to determine which scenarios, and therefore which types of data, are most relevant to this compound following a release. The commenter argues that fluoranthene is a highly lipophilic compound that will bind primarily to sediment and suspended organics, so it is not clear whether the reported toxicity values on which EPA relies for the listing are applicable to this compound in the environment. EPA assumes the commenter was referring to data used to support EPA's proposal to list fluoranthene pursuant to EPCRA section 313(d)(2)(C).

As discussed in Unit VI.F., EPA does not believe that it is appropriate to consider exposure for chemicals that are highly ecotoxic as the data for fluoranthene clearly shows it is. However, even if EPA were to consider exposure, the commenter provided no data to support the assumption that fluoranthene will bind primarily to sediments and suspended organics, and EPA believes that fluoranthene will partition to water as well as sediment. While the ecotoxicity data for fluoranthene does range over about two orders of magnitude that does not, in itself, form a basis for conducting an exposure assessment. There are data that clearly show that fluoranthene is highly ecotoxic. Thus, an exposure assessment is not required. While it does not impact EPA's assessment, EPA notes that of the ecotoxicity values presented in the proposed rule, 9 were within the same order of magnitude, 4

were one order of magnitude higher, and 2 were two orders of magnitude higher. Thus, 60% are within the same order of magnitude and 87% are within one order of magnitude. EPA does not believe that this represents a very wide distribution as the commenter implies.

Based on the available toxicity data, EPA has concluded that fluoranthene is toxic. It has the potential to kill mysid shrimp, a variety of freshwater benthic species and various saltwater species and it can also cause other adverse effects on fish and mysids, based on chemical and/or biological interactions. Fluoranthene can cause these toxic effects at relatively low concentrations. Ecotoxicity values for fluoranthene include a calculated 96–hour LC_{50} of 0.04 mg/L for mysid shrimp. Using standard acute toxicity tests, fluoranthene has been tested in 12 freshwater species from 11 genera. For freshwater benthic species, the acute 96–hour LC_{50} calculated values are 0.032 mg/L for an amphipod (*Gammarus minus*), 0.070 mg/L for a hydra (*Hydra americana*), 0.17 mg/L for an annelid (*Lumbriculus variegatus*), and 0.17 mg/L for a snail (*Physella virgata*). For saltwater species, the 96–hour LC_{50} values are 0.051 mg/L for a mysid (*Mysidopsis bahia*), 0.066 mg/L for an amphipod (*Ampelisca abdita*), 0.14 mg/L for a grass shrimp (*Palaemonetes pugio*), and 0.50 mg/L for an annelid (*Neanthes arenaceodentata*). Fathead minnows exposed to fluoranthene at a concentration of 0.0217 mg/L for 28 days in a chronic early life-stage test showed a reduction of 67% in survival and a 50.2% reduction in growth relative to the controls. In a 28–day chronic study, mysids exposed to 0.021 mg/L of fluoranthene showed a 26.7% reduction in survival and a 91.7% reduction in reproduction; at 0.043 mg/L all mysids died. In a 31–day study, mysids showed a reduction of 30% in survival, 12% in growth, and 100% in reproduction relative to controls at a concentration of 0.018 mg/L of fluoranthene.

Fluoranthene can cause its toxic effects at these relatively low concentrations, therefore EPA considers it to be highly toxic. Since fluoranthene is toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., kills of mysid shrimp, a variety of freshwater benthic species, and various saltwater species, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for adding fluoranthene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the listing of fluoranthene on the EPCRA section 313 list.

4. *3-Methylcholanthrene (CAS No. 56–49–5) (Ref. 70).* EPA proposed to add 3-methylcholanthrene to EPCRA section 313 pursuant to EPCRA sections 313(d)(2)(B) and (C). EPA received no comments on the carcinogenicity data that EPA presented in the proposed rule in support of the addition of 3-methylcholanthrene to the EPCRA section 313 list of toxic chemicals. Thus, EPA reaffirms that there is sufficient evidence for adding 3-methylcholanthrene to the list of EPCRA section 313 toxic chemicals pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

No comments were received concerning the ecotoxicity data that EPA presented for 3-methylcholanthrene in the proposed rule. Based upon quantitative structure activity relationship (QSAR) equations and other predictive techniques, EPA has concluded that 3-methylcholanthrene is toxic. It has the potential to kill fish and daphnia as well as cause other adverse effects on fish, daphnia, and algae based on chemical and/or biological interactions. 3-Methylcholanthrene can cause these toxic effects at relatively low concentrations. The predicted aquatic toxicity values for 3-methylcholanthrene, based on QSAR analysis using the equation for neutral organics and an estimated Log K_{ow} of 7.05, include a calculated fish 96–hour LC_{50} of 0.009 mg/L and a chronic fish toxicity value of 0.003 mg/L, a daphnia 48–hour LC_{50} of 0.005 mg/L and a 16–day chronic LC_{50} of 0.015 mg/L, and an algae 96–hour EC_{50} of 0.0105 mg/L with a calculated chronic toxicity value of 0.014 mg/L.

3-Methylcholanthrene can cause its toxic effects at these relatively low concentrations; therefore, EPA considers it to be highly toxic. Since 3-methylcholanthrene is toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish and daphnia kills, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for listing 3-methylcholanthrene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the listing of 3-methylcholanthrene on the EPCRA section 313 list.

5. *Octachlorostyrene (CAS No. 29082–74–4) (Ref. 70).* EPA proposed to add octachlorostyrene to EPCRA section 313 pursuant to EPCRA sections 313(d)(2)(B) and (C). One commenter argues that octachlorostyrene (OCS) should not be included in the EPCRA section 313 PBT chemicals list. The commenter contends that OCS was included as a PBT chemical simply because it appears on several lists of persistent and bioaccumulative chemicals and not based on a thorough evaluation of its toxicity. The commenter argues that there is limited toxicity data for OCS and cited two statements that were in EPA's support document for the addition of OCS and the other chemicals being added in this rulemaking. The two statements the commenter cited were:

> The health hazard data which support TRI listing are very limited. Human health data were not located. (Ref. 70 p. 48)

EPA disagrees with the commenters' conclusions. The commenter did not comment on the actual toxicity data that EPA provided as the basis for listing OCS pursuant to EPCRA section 313(d)(2)(B). Rather the commenter takes two statements that were contained in the support document out of context to support their apparent contention that there are insufficient data to list OCS under EPCRA section 313(d)(2)(B). The fact that the commenter has taken these statements out of context is demonstrated by the content of the rest of the paragraph that contained the statements the commenter cited:

> Laboratory studies on rats suggest OCS may have acute and chronic effects on the liver, kidneys, and thyroid. In a long-term study (one year) of rats a LOAEL of 0.31 mg/kg/day was determined based on significant histological effects on these organs. (Ref. 70)

The statements the commenter cited only acknowledged that there was not a vast amount of toxicity data for OCS and specifically, that there were no human studies; they do not support the commenters' conclusion that OCS does not meet listing criteria of EPCRA

section 313(d)(2)(B). In addition, these statements were from the summary section of the discussion on OCS, more detailed discussion of the toxicity data for OCS was contained in the other sections on OCS toxicity but the commenter provided no comments on this information.

EPA reaffirms that there is sufficient evidence for adding OCS to the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(B) based on the available hepatic, nephric, and thyroid toxicity data for this chemical.

The same commenter also claims that the toxicity comparisons to hexachlorobenzene are not supported and that no references or rationale are provided to support basing the aquatic toxicity of OCS on that of hexachlorobenzene. As with the human health data, the commenter argues that there are limited environmental toxicity data for OCS and cited some statements that were in EPA's support document. The statements the commenter cited were:

> So far as is known, after a search of former EEB chemical files, the ecological hazard of OCS has never been formally reviewed under TSCA section 4 or in the OPPT Risk Management (RM) process. OCS was briefly reviewed for aquatic toxicity in August 1986, as part of an OTS (now OPPT) chemical scoring project. Thus, available information on OCS is very limited. (Ref. 70, p. 52)

EPA disagrees with the commenter's conclusions. The commenter has not commented on the actual toxicity data but rather states that the data are limited and that hexachlorobenzene is not an appropriate analogue for predicting the aquatic toxicity data for OCS. The statements the commenter cited only acknowledged that there was not a vast amount of toxicity data for OCS, they do not support the commenter's conclusion that OCS does not meet the listing criteria of EPCRA section 313(d)(2)(C). Contrary to the commenter's statement, EPA did provide a reference to the use of hexachlorobenzene as an appropriate analogue for OCS. As EPA stated in the same section of the support document the commenter cited:

> OCS is one of 7 compounds in this chemical class (chlorinated styrenes) with the generic formula $C_8H_{8-x}Cl_x$, where x equals 8 for OCS. This class is analogous to the chlorinated benzenes; for example hexachlorobenzene (HCB), is considered to be an appropriate analogue chemical for OCS (2). (Ref. 70, page 52).

The reference EPA cited is a previous EPA analysis of this class of chemicals that also used hexachlorobenzene as an appropriate analogue for OCS. EPA believes that since OCS and hexachlorobenzene are both highly chlorinated derivatives of benzene they can reasonably be anticipated to have similar toxicities. However, in addition to aquatic toxicity data on hexachlorobenzene, EPA provided the results of a QSAR analysis of OCS, using a measured Log K_{ow} of 7.7, that gave a predicted 14–day LC_{50} value of 6 µg/L for guppies.

Based upon QSAR equations and analogue data, EPA has concluded that OCS is toxic. It has the potential to kill fish and inhibit photosynthesis in algae, among other adverse effects, based on chemical and/or biological interactions. OCS can cause these toxic effects at relatively low concentrations. The predicted aquatic toxicity value for OCS, based upon QSAR analysis using a measured Log K_{ow} of 7.7, is an estimated 14–day LC_{50} of 6 µg/L for guppies. Based on the chemical analogue hexachlorobenzene, OCS can reasonably be anticipated to inhibit photosynthesis in algae at a concentration of 30 µg/L and have a calculated subchronic EC_{50} value of 16 µg/L for daphnids.

OCS can cause its toxic effects at these relatively low concentrations; therefore, EPA considers it to be highly toxic. Since OCS is toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish kills, and inhibition of photosynthesis in algae and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

EPA reaffirms that there is sufficient evidence for listing OCS on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the addition of OCS on the EPCRA section 313 list.

6. *Pentachlorobenzene (CAS No. 609–93–5) (Ref. 70).* EPA proposed to add pentachlorobenzene to EPCRA section 313 pursuant to EPCRA sections 313(d)(2)(B) and (C). No comments were received concerning the human health toxicity data that EPA presented in the proposed rule. Thus, EPA reaffirms that there is sufficient evidence for adding pentachlorobenzene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available hepatic, nephric, hematological, and developmental toxicity data for this chemical.

No comments were received concerning the ecotoxicity data that EPA presented for pentachlorobenzene in the proposed rule. Based on the available toxicity data, EPA has concluded that pentachlorobenzene is toxic. It has the potential to kill fish and mysid shrimp as well as cause other adverse effects on algae and daphnia, based on chemical and/or biological interactions. Pentachlorobenzene can cause these toxic effects at relatively low concentrations. Aquatic acute toxicity calculated values for pentachlorobenzene include a sheepshead minnow 96–hour LC_{50} of 0.83 mg/L, bluegill sunfish 96–hour LC_{50}s of 0.25 mg/L and 0.3 mg/L, a guppy 96–hour LC_{50} of 0.54 mg/L, and a mysid shrimp 96–hour LC_{50} of 0.16 mg/L. Because pentachlorobenzene can cause these toxic effects at these relatively low concentrations, EPA considers it to be highly toxic. Additional acute toxicity calculated values include algae 96–hour EC_{50}s of 1.98 mg/L and 6.78 mg/L, and daphnia 48–hour EC_{50}s of 1.3 mg/L and 5.28 mg/L. Considering pentachlorobenzene's persistence and bioaccumulation potential pentachlorobenzene is considered highly toxic to aquatic organism at these higher concentrations.

As discussed above, pentachlorobenzene is highly toxic. Because pentachlorobenzene is highly toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish and mysid shrimp kills as well as other adverse effects on algae and daphnia, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for adding pentachlorobenzene on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i), (ii), and (iii) based on the available ecotoxicity information for this chemical.

Therefore, EPA is finalizing the listing of pentachlorobenzene on the EPCRA section 313 list.

7. *Tetrabromobisphenol A (CAS No. 79–94–7) (Ref. 70).* EPA proposed to add TBBPA to EPCRA section 313 pursuant to EPCRA sections 313(d)(2)(B) and (C). One commenter claims that the study cited by EPA in support of its

conclusion that TBBPA meets the EPCRA section 313(d)(2)(B) criteria for listing based on developmental toxicity was not a study on TBBPA. The study in question was submitted to EPA by ICI Americas Inc. with a cover letter identifying Saytex 111, the product tested, as being TBBPA. The product was identified as TBBPA by both name and CAS number.

EPA has determined that the product tested was not TBBPA as claimed by the submitter but has been unable to determine why it was misidentified by the submitter. ICI Americas is now Zeneca at the Delaware location that submitted the study. A Zeneca staff member researched the submission and found that the report was originally from Ethyl Corporation and that no other report on TBBPA was submitted to EPA on that date. Without the misidentified developmental study, no adequate toxicology studies or other data were located by EPA that support the addition of TBBPA pursuant to EPCRA section 313(d)(2)(B). Thus, EPA is not adding TBBPA based on concerns for developmental toxicity or any other human health effects.

The same commenter provides comments on the persistence and bioaccumulation of TBBPA and contends that there are insufficient data to conclude that TBBPA meets the listing criteria of EPCRA section 313(d)(2)(C)(ii) and 313(d)(2)(C)(iii). These two sections deal with EPA's authority to add a chemical based on its ''toxicity and persistence in the environment'' and its ''toxicity and tendency to bioaccumulate in the environment'' respectively. However, the commenter does not contend that TBBPA does not meet the listing criteria of EPCRA section 313(d)(2)(C)(i) which addresses EPA's authority to add a chemical based on its ''toxicity'' without consideration of persistence and bioaccumulation. EPA believes that TBBPA is persistent and bioaccumulative as discussed in Unit VI.H. However, EPA did not propose to add TBBPA to the EPCRA section 313 list of toxic chemicals based on its persistence or bioaccumulation data, and neither of these properties were mentioned in the toxicity discussion of TBBPA in the proposed rule. Rather, EPA based its listing decision on the ecotoxicity data alone which indicated that TBBPA was highly toxic even without consideration of persistence or bioaccumulation.

Based the available toxicity data, EPA has concluded that TBBPA is toxic. It has the potential to kill fish, daphnid, and mysid shrimp, among other adverse effects, based on chemical and/or biological interactions. TBBPA can cause these toxic effects at relatively low concentrations. Aquatic acute toxicity calculated values for TBBPA include a fathead minnow 96–hour LC_{50} of 0.54 mg/L, a rainbow trout 96–hour LC_{50} of 0.40 mg/L, a bluegill sunfish 96–hour LC_{50} of 0.51 mg/L, and a daphnid 48–hour LC_{50} of 0.96 mg/L; mysid shrimp 96–hour LC_{50} values ranged from 0.86 to 1.2 mg/L depending on the age of the shrimp. Aquatic chronic toxicity calculated values from a daphnia 21–day study resulted in a Maximum Acceptable Toxicant Concentration (MATC) that was between 0.30 and 0.98 mg/L (geometric mean 0.54 mg/L) based on a significant reduction in reproduction rates; a fathead minnow 35–day study resulted in a MATC that was calculated to be between 0.16 and 0.31 mg/L (geometric mean 0.22 mg/L) based on adverse effects on embryo and larval survival.

TBBPA can cause its toxic effects at these relatively low concentrations; therefore, EPA considers it to be highly toxic. Since TBBPA is toxic at relatively low concentrations, EPA believes that it causes or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish, daphnid, and mysid shrimp kills, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

EPA reaffirms that there is sufficient evidence for listing TBBPA on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) based on the available ecotoxicity information for this chemical. Therefore, EPA is finalizing the addition of TBBPA on the EPCRA section 313 list.

8. *Vanadium and vanadium compounds.* EPA proposed to add vanadium and vanadium compounds to EPCRA section 313 pursuant to EPCRA sections 313(d)(2)(C). One commenter cited the following statement from the proposed rule, ''However, very few toxicity tests have been conducted with invertebrates.'' The commenter argues that, beyond vanadium pentoxide, the Agency appears to have very little toxicity data on vanadium compounds. The commenter contends that the paucity of toxicity data on many different forms of vanadium compounds in the proposal, as well as in the literature, does not appear to support the Agency's belief that ''the evidence is sufficient to list vanadium and vanadium compounds on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information on vanadium and vanadium compounds'' (at 64 FR 698).

EPA disagrees with the commenters' conclusions. Although there is limited information on vanadium's toxicity on invertebrates, data that were available for invertebrates shows that vanadium is toxic to these species. Furthermore, EPA's assessment of vanadium's toxicity included algae and vertebrates, and showed that the chemical is highly toxic to aquatic organisms. The data on vanadium are not limited to vanadium pentoxide, the ecological data provided in the proposed rule for vanadium evaluates vanadium toxicity based on data for other vanadium compounds including: sodium metavanadate, sodium orthovanadate, vanadyl sulfate, and ammonium vanadate. In assessing the ecological toxicity of vanadium and vanadium compounds, EPA evaluated the parent metal (vanadium) and determined that it is highly toxic to some aquatic species and anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting. Thus, vanadium, the parent metal in vanadium compounds, is the concern, not the other components of each vanadium compound. Many metals are tested in the salt form because these forms are readily soluble in aqueous solutions. The toxicity data for vanadium shows that the metal is highly toxic (aquatic toxicity < 1 mg/L) to the most sensitive species. This evaluation of vanadium's toxicity is acceptable according to traditional guidelines for the assessment of toxic substances as conducted by the Agency for over 2 decades. In addition, when consideration is given to vanadium's persistence it is also considered highly toxic at higher concentrations.

Three commenters contend that since most vanadium compounds are practically insoluble, they consequently have very low bioavailability, and thus it is likely that they could qualify for delisting. The commenters argue that the delisting process is extremely cumbersome, time-consuming and costly. One of these commenters contends that it is inappropriate to list all of vanadium compounds based on aquatic toxicity of the few compounds cited in the proposed rule. The bioavailability of metals such as vanadium was also raised as an issue at the public meetings held for this rulemaking. It was suggested that the parent metal will not be bioavailable from certain metal compounds that may be released into the environment and that therefore the compounds cannot be

properly characterized as a PBT chemicals.

EPA disagrees with these comments. First, it should be noted that EPA has not addressed whether vanadium and vanadium compounds can properly be classified as PBT chemicals in this rulemaking. The sole issue, therefore, is whether vanadium and vanadium compounds meet the EPCRA section 313(d)(2)(C) listing criteria. EPA's analysis of the environmental fate of vanadium and vanadium compounds shows that under many environmental conditions vanadium will be available and thus is able to express its toxicity. The commenters have not provided EPA with any data or acceptable scientific studies indicating that vanadium in any particular compound will not become available in the environment. In fact, at least one commenter appears to indicate that these vanadium compounds may merely have low solubility. In these compounds, the parent metal vanadium can become available. While water soluble vanadium compounds would obviously provide vanadium in an immediately bioavailable form, solubility is not the only factor to consider in determining the bioavailability of vanadium from a vanadium compound. In addition to solubility, processes such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformation (both abiotic and biotic); and bioavailability when the compounds are ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs) need to be considered. In Unit VI.C., EPA discusses in detail the persistence and bioavailability of metals in general.

The issue of bioavailability has been addressed for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories on the EPCRA section 313 toxic chemical list (56 FR 23703). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity. If the intact metal compound is not toxic and the metal is not available from the metal compound then such a chemical is a potential candidate for delisting.

One commenter argued that the lowest toxicity value cited by EPA for a marine algal species was for *Dunaliella marina* with a 9–day LC_{50} of 0.5 mg/L but that EPA omitted a study which tested the same species and reported no significant adverse effects at a concentration of 50 mg/L.

EPA believes that the study that reported the 9–day LC_{50} of 0.5 parts per million (ppm) on *Dunaliella marina,* is accurate and was acceptably conducted within the guidelines for ecological assessments of hazardous chemicals. This study shows the most sensitive species' response to the chemical. There are differences in the two studies that could explain the range of toxicity between the two. They are: (1) Differences in the exposure times, (2) the species used in the experiments, and (3) the form of vanadium that was exposed to the organisms. The exposure time in the study EPA cited reported a 9–day LC_{50} of 0.5 mg/L. However, the study the commenter cites did not report an LC_{50} duration. Also, the species for the study EPA cited reported the test species to be *Dunaliella marina* (*salina*), but the study the commenter cited only reported the genus name for this organism. Furthermore, the study EPA cited reported the form of vanadium as sodium vanadate, but the study the commenter cites only reported using the vanadium compound without reporting the specific salt form. It is clear that any one of the three factors mentioned, or some combination of these factors, likely accounts for the variation in toxicity between the two studies.

One commenter argues that a study, omitted in EPA's review of vanadium toxicity, on nine algal species showed no significant reduction in productivity (as measured by chlorophyll synthesis) at vanadium concentrations in excess of 10 mg/L. The commenter also contends that the authors of the study also demonstrated that phosphate concentrations were critical in the toxicity of vanadium to algae.

The Agency has not neglected to review the study cited by the commenter. However, EPA interprets the study cited by the commenter as describing the competition uptake between vanadium and phosphorus in an algal medium containing two different kinds of phosphorus concentrations (i.e., phosphorus deficient and phosphorus sufficient). Also, this study was performed only on freshwater algae and one form of vanadium (orthovanadate) which only exists in a pH range of 3 to 6. This study did report a moderately high toxicity value for *Scenedesmus acutus* between 5 and 177 M, which continues to support EPA's findings that vanadium is toxic to algae. Furthermore, EPA is aware that there are studies that were not included in the assessment that showed that the chemical was more toxic than the values reported in EPA's assessment. However, each study was carefully reviewed based on EPA's extensive evaluation process which reviews studies for conformance with generally accepted scientific standards and tests. The studies that were reported in EPA's assessment used generally accepted, validated scientific methods for evaluating aquatic toxicity. The toxicity values that were reported in the ecological assessment of vanadium toxicity were from well-conducted studies.

One commenter argues that it appears from a review of the data that the contention that vanadium is highly toxic to algae has no basis. The commenter contends that with the exception of one study on a single species, *Ceratium hirundinella,* none of the studies on freshwater algae showed significant toxicity at concentrations below 10 mg/L. The commenter states that the lowest level of toxicity reported for a marine species (*Dunaliella marina*) was an LC_{50} of 0.5 mg/L, but that there is conflicting evidence that the threshold of toxicity for this species may be higher than 50 mg/L. The commenter concludes that there appears to be little evidence that vanadium is a highly toxic agent to algae. The commenter also argues that evaluating the toxicity of a compound based on the response of individual algal species can be misleading. The commenter contends that algae never exist within either marine or freshwater environments as monocultures, but rather as dynamic mixed populations. The commenter concludes that unless a compound can be shown to have a broad effect over an entire assemblage or over numerous species of either freshwater or marine species, it is not likely to have a significant effect within the natural environment.

EPA's assessment on algae toxicity shows that vanadium is highly toxic based on the most sensitive species' response to the chemical. There is no conflict in the threshold of toxicity of *Dunaliella marina*. As stated above, there are three factors that most probably account for the differences between the study EPA cited and the study the commenter cites. After careful review of the available data, it is EPA's professional judgment that the study EPA cited provides accurate and valid data.

Algae studies have been included in ecological risk assessments for over 2 decades. Several guidelines on different species have been written to show that these genera are important in the environment and show sensitivity in how chemicals affect the biota. EPA

agrees that algae usually do not exist in monocultures in the marine or freshwater environment. However, testing monocultures species is the most accurate method to determine whether a chemical is directly harmful to that species. Therefore, if a compound is highly toxic to a particular species of algae or any species, its effects can be extrapolated to represent other species exposed to that chemical. This evaluation process has been used by the Agency and accepted by OECD for over two decades, and used on thousands of chemicals. Vanadium's toxicity ranges from highly toxic to moderately toxic for algae in EPA's assessment. It is reasonable from the evidence in EPA's assessment of vanadium that the species that is the most sensitive to the chemical can represent the toxicity for all other species based on this narrow range. EPA's final evaluation of any chemical's toxicity is based on the most sensitive species' response.

One commenter contends that the study EPA cited that reported the 144–hour LC_{50} of 0.4 and 0.5 mg/L for vanadyl sulfate ($VOSO_4$) and ammonium metavanadate (NH_4VO_3), respectively, were actually values for $VOSO_4$ and sodium metavanadate ($NaVO_3$) respectively. The commenter contends that the 144–hour LC_{50} for NH_4VO_3 was l.5 mg/L. The commenter also argues that EPA neglected to report from the same study a 144–hour LC_{50} of 1.1 mg/L for vanadate pentoxide (V_2O_5) for this species. The commenter also contends that the findings of 144–hour LC_{50}s of 2.5 to 8.1 mg/L in goldfish (*Carassius auratus*) for the same four vanadium species were also omitted.

The comment concerning the vanadium compounds for the 144–hour LC_{50}s of 0.4 and 0.5 mg/L is correct. EPA inadvertently cited to the incorrect compound in the study. The correct vanadium compounds will be reflected in an update to the support document. However, sodium metavanadate, is still a vanadium compound and the study therefore continues to support EPA's findings that vanadium is highly toxic to fish. The other values of 2.5 and 8.1 mg/L merely provide further support for EPA's finding that the vanadium is moderately toxic to fish. However, considering vanadium's persistence in the environment, EPA believes that it is highly toxic at concentrations between 1 and 10 mg/L. Thus the goldfish values provide further support to EPA's finding that vanadium is highly toxic to some aquatic organisms.

One commenter contends that in assessing the toxicity of vanadium to fish, EPA neglected to review the following studies: (1) Hamilton and Buhl (1997), who reported a 96–hour LC_{50} for the flannelmouth sucker (*Catostomus latipinnis*) of 11.7 mg/L; (2) Taylor et al. (1985), who reported a 96–hour LC_{50} for English sole (*Limanda limanda*) of 26.8 mg/L; (3) Ernst and Garside (1987), who reported a 96–hour LC_{50} for the brook trout (*Salvelinus fontinaliis*) alevins of 24 mg/L and for yearlings of 7–15 mg/L (the authors also reported that the method by which stock solutions are formulated could have a dramatic effect on the toxicity of vanadium through its effects on the polymeric form of the metal in the test study); and (4) Hamilton and Buhl (1990), who reported a 96–hour LC_{50} for chinook salmon (*Oncorhynchus tshawytscha*) fry of 16.5 mg/L.

EPA undertook an exhaustive review of vanadium toxicity. The studies the commenter has listed show that vanadium compounds are moderately toxic to fish, which further support EPA's findings on the toxicity of vanadium. EPA's review of the studies cited in the proposed rule are not contradicted or undermined by the studies provided by the commenter, and continue to support the Agency's conclusion that vanadium and vanadium compounds are highly toxic to some aquatic species.

One commenter states that the background document to support EPA's proposal to list vanadium and vanadium compounds indicates that the proposed listing is based on data for five vanadium compounds: vanadium pentoxide, sodium metavanadate, sodium orthovanadate, vanadyl sulfate, and ammonium vanadate. The commenter contends that EPA may consider listing under EPCRA section 313 for the individual compounds for which the Agency has data, but EPA is not justified in listing a broad ''vanadium and vanadium compounds'' category based on data for only five compounds. The commenter suggests that EPA consider individual listings for these compounds, or a category consisting only of the compounds for which the Agency has data.

EPA disagrees with the commenter's characterization of the Agency's assessment of vanadium and vanadium compounds. In assessing the ecological toxicity of vanadium and vanadium compounds, EPA evaluated the parent metal (vanadium) and determined that it is highly toxic to some aquatic organisms and can reasonably be anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting pursuant to EPCRA section 313(d)(2)(C). Thus, vanadium, the parent metal in vanadium compounds, is the concern, not the other components of each compound. Many metals are tested in the salt form because they are readily soluble in aqueous solutions. The toxicity data for vanadium shows that the metal is highly toxic (aquatic toxicity < 1 mg/L) to the most sensitive species. In addition, because vanadium is persistent, EPA considers any toxicity values between 1 and 10 mg/L as indicating high ecotoxicity. This evaluation of vanadium's toxicity is acceptable according to traditional guidelines for the assessment of toxic substances conducted by the Agency for over two decades.

EPA has also provided sufficient basis for the inclusion of all vanadium compounds in the category. As EPA stated in the 1994 chemical expansion final rule:

> The Agency believes it satisfies the statutory criteria to add a category to the list by identifying the toxic effect of concern for at least one member of the category and then showing why that effect may reasonably be expected to be caused by all other members of the category. (at 59 FR 61442) See also, *Troy, supra* at 277.

EPA developed a hazard assessment for vanadium which reviewed the toxicity data for several vanadium compounds. The assessment indicated that the vanadium from these compounds is highly toxic to aquatic organisms. Since it is the vanadium from these compounds that is highly toxic rather than the intact chemical compound, EPA believes that all chemicals that are a source of vanadium meet the EPCRA section 313(d)(2)(C) listing criteria. Thus, EPA has established the toxic effect of concern, the chemical species that causes the effect, and the basis for why it may reasonably be expected that all members of the vanadium compounds category can cause the effects of concern.

Based on the available toxicity data, EPA has concluded that vanadium and vanadium compounds are toxic. They have the potential to kill fish, algae, and invertebrates as well as causing a range of other adverse effects on fish, algae, and invertebrates, based on chemical and/or biological interactions. Vanadium and vanadium compounds can cause these toxic effects at relatively low concentrations. Toxicity data for vanadium and vanadium compounds include for algae, a 9–day LC_{50} of 0.5 mg/L, a 15–day LC_{50} of 0.5 mg/L, inhibition of growth at 0.1 ppm, adverse effects on cell division at 3 ppb, 20 ppb, and 0.5 ppm; and for fish, a 96–hour LC_{50} of 0.62 ppm, and growth and survival depression of larvae at 0.17 ppm. Because vanadium and vanadium

compounds can cause these toxic effects at these relatively low concentrations, EPA considers these chemicals to be highly toxic. Additional toxicity values include for algae, 9–day LC_{50}s of 2 and 3 ppm, and a 15–day LC_{50} of 2 mg/L; for invertebrates, a 9–day LC_{50} of 10 ppm; and for fish, 96–hour LC_{50}s of 6.4 ppm, 10 ppm, and 7 mg/L, an LC_{50} of 5.6 mg/L, an 11–day LC_{50} of 1.99 mg/L, 14–day LC_{50}s from 1.95 to 4.34 mg/L, and 7–day LC_{50}s from 1.9 to 6.0 ppm. Considering vanadium's persistence, vanadium and vanadium compounds are considered highly toxic to aquatic organism at these higher concentrations.

As discussed above, vanadium and vanadium compounds are highly toxic. Because vanadium and vanadium compounds are toxic at relatively low concentrations, EPA believes that they cause or can reasonably be anticipated to cause a significant adverse effect on the environment. In addition, because of the nature of the potential significant adverse effects, e.g., fish, algae, and invertebrate kills as well as a range of other adverse effects on fish, algae, and invertebrates, and the impacts such effects can have on ecological communities and ecosystems, EPA has determined that they are of sufficient seriousness to warrant reporting.

Thus, EPA reaffirms that there is sufficient evidence for adding vanadium and vanadium compounds on the EPCRA section 313 list of toxic chemicals pursuant to EPCRA section 313(d)(2)(C)(i) and (ii), based on the available ecotoxicity information for vanadium and vanadium compounds.

Therefore, EPA is finalizing the listing of vanadium and vanadium compounds on the EPCRA section 313 list.

a. *Reporting limitation of alloys.* A number of commenters support EPA's proposed determination to defer the reporting of vanadium when contained in alloys (64 FR 717). Many commenters also suggest that the Agency adopt a reporting limitation for the other metals such as chromium, copper, manganese, and nickel which are commonly found in alloys. The commenters assert that alloys have significantly different bioavailability, bioaccumulation, and toxicity characteristics than other forms of metals, and thus should be treated separately. The commenters argue that alloys are inherently more stable than unalloyed materials, do not enter the environment as readily as unalloyed materials and hence do not interact as greatly with organisms, and should be considered safer from an environmental and human health perspective. The commenters suggested that alloys should be treated separately not only for threshold changes, but also for EPCRA section 313 listings in general and recommend excluding alloys from general EPCRA section 313 listings for metals.

One commenter states in regard to the reporting of metals in alloys that it makes little or no sense to require the reporting of such ''useless'' information, since the information does not serve the purpose of informing the community. The commenter contends that not adding vanadium when contained in alloys would help to achieve EPCRA section 313's underlying purpose, i.e., to provide the public with meaningful information, while at the same time reducing the burden on reporting facilities. Another commenter argues that the proposed alloys exemption correctly recognizes that metals in alloys are not generally available for exposure or for toxic effects. The commenter argues that expansion of the exemption would improve the TRI data base by reporting only releases that may pose risks to human health and the environment, thereby providing the public with more meaningful data.

Two commenters state that the definition of vanadium alloys should include ''fused alloy slag'' in the qualifier as well. The commenters contend that the state of the vanadium in a ferroalloy form is one of intimate chemical combination on the atomic level, not a simple mixture of individual components and it is inherently stable and cannot be dissociated by ordinary means. The commenters argue that likewise, the fused alloy slag formed represents an intimate chemical combination of materials as a result of the smelting operation. The commenters assert that these elemental materials may include various components such as gangue or ore, ash of fuel, refractory lining, or other stable oxides with the ultimate characterization resting upon the chemical stability of the resultant fused alloy bearing slag. Thus, the commenters argue, vanadium contained in either alloy or alloy slag form is fused in a stable compound and therefore, no releases of vanadium into the environment would occur from either substance. The commenters state that the true environmental issue to consider in the formulation of an activity qualifier is the leachability of the material in that state, and since in both of the aforementioned cases the vanadium is in a stable compound, leaching would not be expected. The commenters assert that without allowing an exemption for fused alloy slag, large volumes of steelmaking and ferroalloy slag will unnecessarily fall under this reporting requirement. The commenters request that EPA reconsider its position and expand the definition of alloy to include both vanadium alloys and vanadium alloy slags.

EPA agrees with those commenters that support EPA's belief that it would be inappropriate, at this time, to change the status quo regarding reporting vanadium when contained in an alloy. As EPA stated in the proposed rule, the Agency is reviewing the issue of whether there should be any changes to the reporting requirements for metals contained in alloys.

In the proposed rule, EPA did not state, and did not intend to imply, that EPA considers alloys to be ''safe,'' or as some commenters suggested, that EPA had ''correctly'' recognized that metals in alloys are not generally available for exposure or to express their toxic effects. EPA has not completed its review of the alloys issue and has made no conclusions regarding whether there should or should not be any type of limitation or exemption for any metals contained in alloys. EPA's proposal merely recognized that while this issue was under review, it would not be appropriate to add alloy forms of vanadium.

The commenters contend that alloys have significantly different bioavailability, bioaccumulation, toxicity characteristics than other forms of metals and are inherently more stable than unalloyed materials and do not enter the environment as readily as unalloyed materials. EPA believes that the issue with alloys is primarily bioavailability, i.e., do the metals contained in alloys become available. This issue is the focus of EPA's current review. At this point in time, while EPA is in the process of a scientific review of the issues pertinent to alloys, the Agency is not prepared to make a final determination on whether vanadium in vanadium alloys meet the EPCRA section 313(d)(2) toxicity criteria.

The commenters did not provide any data to support their contention. The Agency does not believe that a metal compound in a slag necessarily will be environmentally unavailable; rather, the Agency's experience with a previous EPCRA section 313(d) review of manganese slags, indicates that at least in some cases the metal will be available (60 FR 44000, August 24, 1995) (FRL–4954–6).

Some commenters suggested that EPA create an alloys reporting limitation for all metals contained in alloys. However, as EPA has stated, the review of whether any kind of exemption or reporting limitation should be granted for certain metals in alloys is still under review and until the Agency has thoroughly reviewed the available data, EPA is not

prepared to extend the reporting limitation to any other metals. For example, EPA is not lowering the reporting threshold for cobalt and cobalt compounds, and therefore the Agency is taking no action with respect to a reporting limitation for cobalt when contained in alloys.

One commenter asserts that for reasons of consistency--which helps ensure data quality--with existing EPCRA section 313 metal compound categories, they oppose adding the qualifier ''except when contained in an alloy'' in any new listing for vanadium.

EPA has not completed its review of the alloys issue and has made no conclusions regarding whether there should be any type of general limitation or exemption for any metals contained in alloys. EPA merely recognized that while this issue was under review it would not be appropriate to increase the reporting requirements for those facilities that would otherwise submit reports for vanadium contained in alloys. Therefore, as discussed earlier in this section, EPA has expanded the EPCRA section 313 listing for vanadium by removing the ''fume or dust'' qualifier for vanadium, but has not added the alloy forms of vanadium. Until EPA has the opportunity to fully evaluate the available data, the Agency is not prepared to make a final determination whether vanadium contained in alloys meets the EPCRA section 313(d)(2) listing criteria and should therefore be added. EPA believes that consistency, in this context, does not provide a sufficient basis to require reporting of vanadium contained in alloys.

H. Persistence and Bioaccumulation

The persistence and bioaccumulation data for the PBT chemicals covered by this final rule are listed in Table 3. A discussion of these data follows Table 3.

Table 3.—Persistence and Bioaccumulation Data

Chemical Category/Chemical Name	CASRN	BCF	BAF	Air Half-life	Surface Water Half-life	Soil Half-life
Dioxin/Dioxin-Like Compounds						
*Polychlorinated dibenzo-p-*dioxins						
1,2,3,4,6,7,8-heptachlorodibenzo-*p*-dioxin	35822–46–9	1,466		12.2–4.2 hrs		~20 yrs
1,2,3,4,7,8-hexachlorodibenzo-*p*-dioxin	39227–28–6	5,176		12.4–2.7 hrs		~20 yrs
1,2,3,6,7,8-hexachlorodibenzo-*p*-dioxin	57653–85–7	3,981		12.4–2.7 hrs		~20 yrs
1,2,3,7,8,9-hexachlorodibenzo-*p*-dioxin	19408–74–3	1,426		12.4–2.7 hrs		~20 yrs
1,2,3,4,6,7,8,9-octachlorodibenzo-*p*-dioxin	3268–87–9	2,239		20.4–4.8 hrs		~20 yrs
1,2,3,7,8-pentachlorodibenzo-*p*-dioxin	40321–76–4	10,890		14.8–2.0 hrs		~20 yrs
2,3,7,8-tetrachlorodibenzo-*p*-dioxin	1746–01–6	5,755		9.6–1.2 hrs		20–1.5 yrs
Polychlorinated dibenzofurans						
1,2,3,4,6,7,8-heptachlorodibenzofuran	67562–39–4	3,545		25.0–4.3 hrs		~20 yrs
1,2,3,4,7,8,9-heptachlorodibenzofuran	55673–89–7	3,545		25.0–4.3 hrs		~20 yrs
1,2,3,4,7,8-hexachlorodibenzofuran	70648–26–9	3,586		13.3–3 hrs		~20 yrs
1,2,3,6,7,8-hexachlorodibenzofuran	57117–44–9	3,586		13.3–3 hrs		~20 yrs
1,2,3,7,8,9-hexachlorodibenzofuran	72918–21–9	10,300		13.3–3 hrs		~20 yrs
2,3,4,6,7,8-hexachlorodibenzofuran	60851–34–5	3,586		13.3–3 hrs		~20 yrs
1,2,3,4,6,7,8,9-octachlorodibenzofuran	39001–02–0	1,259		29.4–13.7 hrs		~20 yrs
1,2,3,7,8-pentachlorodibenzofuran	57117–41–6	33,750		11.6–1.2 hrs		~20 yrs
2,3,4,7,8-pentachlorodibenzofuran	57117–31–4	42,500		11.6–1.2 hrs		~20 yrs
2,3,7,8-tetrachlorodibenzofuran	51207–31–9	2,042		11.5–2.1 hrs		~20 yrs
Pesticides						
Aldrin	309–00–2	3,715		10 hrs–1 hr	24 days[1]	9 yrs–291 days
Chlordane	57–74–9	11,050	>6,000,000[2]	5 days–12 hrs	239 days	8-0.4 yrs
Heptachlor	76–44–8	19,953		10.5 hrs–1 hr	129.4–23.1 hrs	4 yrs–8 days
Isodrin	465–73–6	20,180		10 hrs–1 hr		5 yrs–180 days
Methoxychlor	72–43–5	8,128		12 hrs–1 hr	15.2–5 days	136–81 days
Pendimethalin	40487–42–1	1,944		21–2 hrs		1300–54 days
Toxaphene	8001–35–2	34,050		16 days–19 hrs	5 yrs–1 yr	11–1 yrs
Trifluralin	1582–09–8	5,674		3.2–0.42 hrs	36.5–4.5 days[1]	394–99 days
Polycyclic Aromatic Compounds						

Table 3.—Persistence and Bioaccumulation Data—Continued

Chemical Category/Chemical Name	CASRN	BCF	BAF	Air Half-life	Surface Water Half-life	Soil Half-life
Benzo(a)pyrene	50–32–8	912		2.4 hrs	17.3–5.4 yrs	14.6 yrs–151 days
Benzo(b)fluoranthene	205–99–2	5,631		1.4 days–3.4 hrs	≥100 days	14.2 yrs–87 days
Benzo(r,s,t)pentaphene	189–55–9	26,280		13 hrs–1 hr		371–232 days
Benzo(a)anthracene	56–55–3	800		13 hrs–1 hr	3-1.2 yrs	2.0 yrs–240 days
7,12-Dimethylbenz(a)anthracene	57–97–6	5,834		4–0.4 hrs	6 yrs–1 yr	28–20 days
Dibenzo(a,h)anthracene	53–70–3	31,440		13 hrs–1 hr	≥100 days	2 yrs–240 days
3-Methylcholanthrene	56–49–5	17,510		3–0.3 hrs	3.8–1.7 yrs	
7H-Dibenzo(c,g)carbazole	194–59–2	16,900		23–2 hrs		>160 days
Benzo(k)fluoranthene	207–08–9	10,090		12 hrs–1 hr		11 yrs–139 days
Benzo(j)fluoranthene	205–82–3	10,090		12 hrs–1 hr		10.5 yrs
Dibenzo(a,e)pyrene	192–65–4	6,875		13 hrs–1 hr		371–232 days
Dibenzo(a,h)pyrene	189–64–4	26,280		13 hrs–1 hr		371–232 days
Indeno(1,2,3-cd)pyrene	193–39–5	28,620		7.6–0.34 hrs		730–58 days
Dibenz(a,h)acridine	226–36–8	3,500		13 hrs–1 hr		>160 days
Dibenz(a,j)acridine	224–42–0	18,470		23–2 hrs		>160 days
Benzo(g,h,i)perylene	191–24–2	25,420		10.0–0.31 hrs	≥100 days	1.8 yrs–173 days
Dibenzo(a,e)fluoranthene	5385–75–1	26,280		10 hrs–1 hr		371–232 days[3]
5-Methylchrysene	3697–24–3	9,388		5–0.5 hrs	3.8 yrs–79 days[4]	2.7 yrs–255 days[4]
Dibenzo(a,l)pyrene	191–30–0	6,875		13 hrs–1 hr		371–232 days
Benzo(a)phenanthrene	218–01–9	800		13 hrs–1 hr	3.8 yrs–79 days	2.7 yrs–255 days
1-Nitropyrene	5522–43–0	908		4 days–10 hrs	44 yrs–16 yrs	
Benzo(j,k)fluorene (fluoranthene)	206–44–0	5,100		20–2 hrs		13 yrs–110 days
Metals/Metal Compounds Mercury[5] and Mercury compounds	7439–97–6	7,000-36,000		see footnote 5	see footnote 5	see footnote 5
Polychlorinated Biphenyl (PCBs)	1336–36–3		>200,000[2,6]			
2,3,3′,4,4′,5,5′-heptachlorobiphenyl	39635–31–9	4,922		191–19 days	>56 days	>5–3.92 yrs
2,3,3′,4,4′,5-hexachlorobiphenyl	38380–08–4	37,590		127–13 days	>56 days	>5–3.42 yrs
2,3,3′,4,4′,5′-hexachlorobiphenyl	69782–90–7	37,590		114–11 days	>56 days	>5–3.42 yrs

Table 3.—Persistence and Bioaccumulation Data—Continued

Chemical Category/Chemical Name	CASRN	BCF	BAF	Air Half-life	Surface Water Half-life	Soil Half-life
2,3′,4,4′,5,5′-hexachlorobiphenyl	52663–72–6	37,590		114–11 days	>56 days	>5–3.42 yrs
3,3′,4,4′,5,5′-hexachlorobiphenyl	32774–16–6	73,840		88–9 days	>56 days	>5–3.42 yrs
2,3,3′,4,4′-pentachlorobiphenyl	32598–14–4	196,900	>134,000,000[2]	80-8 days	>56 days	7.25–0.91 yrs
2,3,4,4′,5-pentachlorobiphenyl	74472–37–0	196,900		67–7 days	>56 days	7.25–0.91 yrs
2,3′,4,4′,5-pentachlorobiphenyl	31508–00–6	184,300	>141,000,000[2]	80–8 days	>56 days	7.25–0.91 yrs
2′,3,4,4′,5-pentachlorobiphenyl	65510–44–3	196,900		50–5 days	>56 days	7.25–0.91 yrs
3,3′,4,4′,5-pentachlorobiphenyl	57465–28–8	196,900		57–6 days	>56 days	7.25–0.91 yrs
3,3′,4,4′-tetrachlorobiphenyl	32598–13–3	105,900		37–4 days	>98 days	4.83–0.91 yrs
Other Chemicals						
Hexachlorobenzene	118–74–1	29,600-66,000	>2,500,000[2]	1,582–158 days		5.7–2.7 yrs
Octachlorostyrene	29082–74–4	33,113	>117,000,000[2]	10 hrs–1 hr		5.7–2.7 yrs7
Pentachlorobenzene	608–93–5	8,318	>640,000[2]	460–46 days		194 days–>22 yrs
Tetrabromobisphenol A	79–94–7	780; 1,200; 3,200		9 days–1 day	84–48 days	44–179 days

[1]The reported half-life data for water are suspected to include significant removal from the medium by processes other than degradation (e.g., volatilization).
[2]Values are for Piscivorous Fish.
[3]Since data could not be found for this chemical, the data for the dibenzopyrenes (192–65–4; 189–64–0; 191–30–0), which are structural analogues, was used.
[4]Since data could not be found for this chemical, the data for benzo(a)phenanthrene (218–01–9), a structural analogue was used.
[5]The bioaccumulation potential for the parent metals is assumed to be equivalent to the associated metal compounds since in the environment the parent metals may be converted to a metal compound. Since metals are not destroyed in the environment they persist longer than 6 months.
[6]Lowest value reported for a dichlorinated PCB.
[7]Since no data could be found for this chemical, the data for the structural analogues hexachlorobenzene (118–74–1) and pentachlorobenzene (608–93–5) was used.

1. *Persistence*—a. *Dioxin and dioxin-like compounds*. In the proposal, EPA preliminarily determined that dioxin and dioxin-like compounds have persistence half-life values in soil that ranged from 1.5 years to more than 20 with all but one chemical having a soil half-life of more than 20 years. EPA has reviewed information and all comments received on dioxin and dioxin-like compounds' persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that dioxin and dioxin-like compounds persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, dioxin and dioxin-like compounds persist in the environment with a half-life of greater than 6 months making it highly persistent. This, plus other factors, supports EPA's decision to lower the threshold to 0.1 gram.

b. *Aldrin*. In the proposal, EPA preliminarily determined that aldrin has persistence half-life values in soil of 291 days to 9 years and a persistence half-life value in water of 24 days. EPA has reviewed information and all comments received on aldrin's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that aldrin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7).

c. *Chlordane*. In the proposal, EPA preliminarily determined that chlordane has persistence half-life values in soil of 0.4–8 years and a persistence half-life value in water of 239 days. EPA has reviewed information and all comments received on chlordane's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that chlordane persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69)

and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, chlordane persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

d. *Heptachlor*. In the proposal, EPA preliminarily determined that heptachlor has persistence half-life values in soil of 8 days to 4 years and a persistence half-life value in water of 23.1–129.4 hours. EPA has reviewed information and all comments received on heptachlor's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that heptachlor persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, heptachlor persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

e. *Isodrin*. In the proposal, EPA preliminarily determined that isodrin has persistence half-life values in soil of 180 days to 5 years. EPA has reviewed information and all comments received on isodrin's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that isodrin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, isodrin persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

f. *Methoxychlor*. In the proposal, EPA preliminarily determined that methoxychlor has persistence half-life values in soil of 81 to 136 days and a persistence half-life value in water of 5 to 15.2 days. EPA has reviewed information and all comments received on methoxychlor's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that methoxychlor persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7).

g. *Pendimethalin*. In the proposal, EPA preliminarily determined that pendimethalin has a persistence half-life value in soil of 54 to 1,300 days. EPA received several significant comments addressing pendimethalin's persistence potential which are addressed below. EPA has reviewed information and all comments received on pendimethalin's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that pendimethalin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7).

One commenter contends that EPA has miscategorized pendimethalin as a PBT chemical based on limited screening data which conflicts with conclusions reached by EPA in its risk assessment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The commenter believes that the characterization of pendimethalin is inaccurate and will lead to misplaced effort and misplaced focus on listed chemicals, and that there will be no benefit to the public or the environment in lowering the reporting threshold for pendimethalin.

EPA disagrees with the commenter. EPA did not base its determination that pendimethalin meets the EPCRA section 313 persistence criteria, nor that pendimethalin is highly persistent on ''screening'' data. EPA's conclusion that pendimethalin persists with a half-life greater than 6 months is based on a well-conducted study in which pendimethalin degrades in soil with a half-life of 1,322 days. Further, even if these data were discounted, there are numerous data submitted in support of reregistration of pendimethalin under FIFRA that provide strong evidence that pendimethalin meets the EPCRA section 313 persistence criteria, i.e., a half-life greater than 2 months. A more detailed discussion of these data is presented in the following responses. Contrary to the assertion by the commenter, the categorization of pendimethalin as a PBT chemical as described in the proposed rule is not in conflict with the conclusions reached by EPA during the FIFRA assessment. In addition, EPA disagrees that there will be no benefits to the public or the environment from lowering the thresholds for pendimethalin. EPA believes that pendimethalin, like all PBT chemicals, is of special concern because it has the potential to cause adverse effects even when released to the environment in small quantities because it can bioaccumulate in organisms to levels much greater than those present in the environment. EPA believes that lowering the reporting threshold for pendimethalin will provide information to the public that will increase their awareness of low levels of releases to the environment which have the potential to concentrate in organisms and cause adverse effects, which is fully consistent with the purposes of EPCRA section 313.

The commenter states that EPA has ignored bioavailability in designating pendimethalin as a PBT chemical and argues that the true bioaccumulation potential for pendimethalin is greatly overestimated based on the results of the standard laboratory fish bioconcentration study. The commenter asserts that when data on bioavailability, degradation, and depuration are all considered, the ''real world'' bioconcentration potential for pendimethalin is low and, therefore pendimethalin should not be mischaracterized as a PBT chemical.

The bioavailability data the commenter refers to was not specifically identified. Bioavailability of a chemical will vary from environment to environment and soil type to soil type. Caution must be taken, however, not to draw the erroneous conclusion that because a chemical has been shown to have a high affinity to sorb to sediments in aquatic environments that it will not be available for uptake by aquatic organisms. Examples like the PCBs (see Unit VI.F. for a further discussion on this issue) indicate that although some of these compounds have sorption coefficients much greater than pendimethalin, they are still widely found in the tissues of aquatic organisms in contaminated waters. Further, it would be erroneous to state that pendimethalin is not bioavailable because if it were not bioavailable it could not function as an herbicide.

The commenter claims that using EPA's own criteria (half-lifes longer than 2 months in water, sediment, or soil, or a half-life longer than 2 days in air) pendimethalin cannot be classified as persistent. Rather the commenter contends that pendimethalin has ''low'' or ''low to moderate'' persistence.

The commenter is incorrect. The Agency has set persistence criteria of half-lifes for soil, sediment, and water

greater than 2 months and a half-life in air of greater than 2 days. Chemicals meeting these criteria are considered persistent for purposes of EPCRA section 313. There are, in fact, no qualifiers such as ''low,'' ''moderate,'' or ''high'' associated with the persistence criteria. The commenter's characterization of the persistence of pendimethalin as ''low'' or ''low to moderate'' is thus not particularly relevant. It appears, based on the comments, that the commenter defines low to moderate persistence as a half-life of greater than 2 days in air and greater than 2 months in soil, sediment, or water. If this is the case, then the commenter in fact concurs with EPA's assessment of pendimethalin as persistent (half-life greater than 2 months in soil or water and greater than 2 days in air).

If the commenter, instead, meant that pendimethalin has half-lifes of less than 2 months in soil or water, and 2 days in air, EPA notes that the commenter has failed to provide data to support that assertion, and that EPA's review of the data support the Agency's conclusion.

A commenter cites numerous laboratory and field dissipation studies in support of the claim that pendimethalin does not meet the persistence criteria.

EPA disagrees that the degree of persistence of pendimethalin can be characterized by the field dissipation studies cited by the commenter. Field dissipation studies are not equivalent to the studies which measure the half-life for destruction of a chemical in a specific medium (i.e., soil, water, or air). Field dissipation studies are designed to measure the rate or extent of chemical loss from the medium after application of the chemical. The processes by which the chemical is lost may include not only those that result in destruction of the chemical, but those which only transport the chemical from one medium to another such as volatilization. The studies cited by the commenter measure the dissipation of pendimethalin from soil. For a relatively volatile chemical such as pendimethalin, field dissipation studies are of limited use in assessing persistence because an unknown amount of pendimethalin will be transported from soil to air, resulting in a measured loss from that medium, but not destruction. Thus, the field dissipation studies cited by the commenter will underestimate the persistence of pendimethalin in soil.

The commenter cites several laboratory experiments on the degradation of pendimethalin in soil to support the argument that pendimethalin does not meet the persistence criteria. For example, they state that laboratory aerobic soil degradation studies have been conducted in which pendimethalin was applied to soil grab samples and incubated under controlled conditions. Pendimethalin degraded in laboratory soil studies with half-lifes ranging from 31 to 1,322 days. In the *Reregistration Eligibility Decision (RED) for Pendimethalin* (Ref 63) document, EPA explained that 172 days was used instead of 1,322 days because:

> The half-lifes for aerobic soil metabolism ranged from 42-563 days in the literature studies referenced below with a guideline study reporting a half-life of 1,322 days for a total of 27 total observations. Because of the range of half-life values, statistical analyses of the available data were performed. The mean, median, and modal half-lifes are 126, 122, and 122 days, respectively, with a standard deviation of 66 days (n=24). The half-life values of 409, 563, and 1,322 days were not included in the final statistical analyses because they were greater than three standard deviations from the mean. Based on soils and crops that are normally treated with pendimethalin, the reviewer assumed that temperatures would likely range from 20–30 °C and soil moisture contents from 50-75% Field Capacity (FC). The range of observed half-lifes in the above experimental conditions was 72–172 days.

The commenter contends that the 1,322–day half-life value is assumed to be an outlier (Ref. 5), the range was 31 to 172 days. Thus, it is claimed that laboratory studies also indicate that pendimethalin has a low to moderate persistence according to the EPCRA section 313 persistence criteria.

EPA believes that the guideline study that reported a half-life of 1,322 days represents an accurate and representative value for the assessment of the persistence of pendimethalin in the environment. In situations where multiple values for half-lifes are submitted under FIFRA to EPA's Office of Pesticide Program (OPP), statistical analysis may be conducted to determine mean values and standard deviations. The analysis permits the use of a value for exposure assessment modeling that takes into account the variability in data, and allows the exclusion of values more than three standard deviations outside the mean as ''outliers.'' The designation as an outlier does not invalidate the study, and in fact, EPA maintains that even a study designated as an ''outlier,'' if valid, gives useful half-life information.

In their assessment of the persistence of chemicals in soils, OPP focuses on studies using soil types, soil moisture contents, and temperatures consistent with the field application of the chemical in its intended use. In the OPP review of the studies, the reviewer assumed that in the field application of the chemical, temperatures would likely range from 20-30 °C and that soil moisture would range from 50 to 75% field capacity. The consideration of data from studies conducted under these conditions resulted in a half-life range of 72 to 172 days for pendimethalin. It should be noted that even after the elimination of outliers and consideration of studies relevant to normal field application, the entire half-life range is above 2 months, clearly meeting the criteria for persistence in soil, i.e., a half-life of 2 months.

The releases of pendimethalin subject to EPCRA section 313 reporting, in many cases, will not be to agricultural soils under typical application scenarios. EPA, therefore, contends that even though some soil half-life values were not considered by OPP, either because they were derived using studies that did not represent the desired field conditions, or because they were labeled as statistical outliers, the study conditions still represent realistic scenarios for releases reported under EPCRA section 313 and are valid for use in the determination of persistence.

The commenter cites studies conducted using flooded soils to support the argument that pendimethalin does not meet the persistence criteria. The commenter asserts that the studies involved the use of pendimethalin spiked into soil grab samples covered with a shallow layer of water and incubated in the laboratory under controlled conditions. In laboratory flooded soil studies, pendimethalin degradation half-lifes ranged from seven to 104 days with the majority of studies giving half-lifes of less than 2 months. Degradation of pendimethalin was more rapid in flooded soils than in nonflooded soils in most instances. The commenter asserts that these results demonstrate that pendimethalin has a low to moderate persistence in flooded soils according to the EPCRA section 313 persistence criteria.

EPA agrees that the reported degradation half-lifes in laboratory flooded soils studies range from 7 to 104 days. The studies were reviewed for quality and preferred methodologies. Of the studies that are of acceptable quality, EPA chose the highest value (most protective) of the range to determine if the chemical meets the EPCRA section 313 persistence criteria. In this case, the value of 104 days would be used to characterize pendimethalin as persistent in flooded soils. However,

there is not a separate persistence criterion for flooded soils, nor are data on flooded soils preferable to other soil data. EPA notes that other soil studies, as discussed above in this section, indicate a half-life of 1,322 days in soils.

The commenter states that while pendimethalin is stable to hydrolysis, it will degrade in natural water and water/sediment systems under laboratory conditions with degradation half-lifes ranging from 4 to 22 days. Photodegradation is also rapid with half-lifes of approximately 3.5 days. The commenter concludes that these results indicate that pendimethalin has a low persistence in both water and its underlying sediment according to the EPCRA section 313 persistence criteria.

Two of the aerobic aquatic degradation studies cited by the commenter were not provided to the Agency or are not publicly available, (i.e., they are internal American Cyanamid studies). It is unclear from the summary provided whether the cited studies measured destruction of pendimethalin or its loss from the medium by non-destructive water to air transport processes. If the latter is the case, the ''dissipation half-lifes'' cited cannot be used to characterize persistence. EPA agrees that if the half-lifes reported for aerobic aquatic degradation represent half-lifes for destruction of the chemical, they do not meet the criteria for persistence in water. However, as noted, the full studies were not available for review and as such, EPA cannot assume that the studies followed destruction of pendimethalin, or that the studies meet the quality criteria outlined in this rule.

The commenter cites a half-life range of 6 to 22 days derived from an anaerobic aquatic degradation study to support the argument that pendimethalin has a low persistence in both water and its underlying sediment according to the EPCRA section 313 persistence criteria. EPA agrees that the persistence half-life values cited by the commenter do not meet the EPCRA section 313 persistence criteria, but points out that additional data submitted in support of the reregistration of pendimethalin indicated that half-lifes in aquatic environments could be longer. OPP used flooded soil degradation studies to assess the persistence of pendimethalin under anaerobic aquatic conditions. Half-lifes in these studies ranged from 6 to 105 days. In its discussion of the potential impact of pendimethalin on water resources, OPP in the RED notes that pendimethalin has an anaerobic aquatic metabolism half-life of 60 days. EPA believes that after review of the available data on its persistence in water pendimethalin meets the EPCRA section 313 persistence criteria.

EPA agrees that rapid aqueous photodegradation under laboratory studies has been reported for pendimethalin. However, the photolysis screening tests used are designed to allow the determination of rates of photolysis at shallow depths in pure water as a function of lattitude and season. EPA believes that the environmental relevence of these tests should be considered in their use to determine persistence, and that the results are most applicable to shallow, clear waters. EPA believes that the application of the results beyond these environments is tenuous due to the attenuation of light by suspended matter and increasing depth in the aquatic environment. EPA believes that pendimethalin's tendency to sorb to soil and sediments may result, under some circumstances, in its deposition in benthic environments beyond the effects of aqueous photolysis. Therefore, EPA does not believe that the half-life for pendimethalin in water should be based on aqueous photolysis.

The commenter claims pendimethalin will not persist in air according to the EPCRA section 313 persistence criteria for air since it has a half-life of less than 2 days. The commenter discusses the estimation of pendimethalin's atmospheric half-life and a study on its photodegradation in air. The commenter cites the results of a calculation according to the method of Atkinson performed to determine the rate constant for reaction of pendimethalin with OH radicals in the gas phase (Ref 42). A tropospheric half-life of 3.4 hours was calculated using the method. The photolysis of pendimethalin was investigated by Bossan, *et al.*, 1995 (Ref. 15), who reported on the photoreactivity of pendimethalin on airborne fly ash and kaolin using simulated sunlight. Approximately 70% of applied pendimethalin degraded within 30 minutes when adsorbed to fly ash but little degradation was observed after 100 minutes when pendimethalin was bound to kaolin.

EPA agrees that pendimethalin does not meet the persistence half-life criteria for air of greater than 2 days, but because it meets the persistence criteria for soil and water, this does not affect EPA's conclusion. As noted in the proposed final rule (at 64 FR 702), a chemical need only meet one of the media-specific criteria to be considered persistent.

The commenter cites EPA's pendimethalin RED document and cites its conclusion in support of the argument that pendimethalin does not meet the persistence criteria. The commenter describes the RED conclusions as follows:

> Pendimethalin dissipates in the environment by binding to soil, microbially-mediated metabolism and volatilization. It is essentially immobile in soil.
>
> Based on laboratory studies and limited field study information, pendimethalin is slightly to moderately persistent in aerobic soil environments. Persistence decreases with increased temperature, increased moisture and decreased soil organic carbon.

EPA disagrees with the commenters' suggestion that the OPP RED for pendimethalin concludes that it does not meet the EPCRA 313 persistence criteria. As stated in an earlier response, ''moderate'' persistence has no relevance in the context of the proposed rule. A chemical is considered persistent if it has half-lifes of 2 days in air or 2 months in soil, sediment, or water, respectively.

The commenter implies that OPP has concluded that pendimethalin does not meet the persistence criteria by selectively citing the OPP RED while failing to acknowledge other information OPP discussed in the document confirming the persistence of pendimethalin. OPP did not make any formal summary conclusions regarding the overall environmental persistence of pendimethalin. The commenter has selectively cited from the RED by taking a few comments out of context while ignoring additional findings which demonstrate that pendimethalin meets the persistence criteria.

The first statement cited by the commenter addresses dissipation in the environment. Two of the three processes (soil binding and volatilization) responsible for dissipation do not result in the destruction of the chemical and cannot be directly related to persistence. Volatilization results in the relocation of the chemical to the atmosphere. Binding to soil does not destroy pendimethalin and under some soil conditions has been shown to increase persistence. While microbial metabolism of pendimethalin can result in its destruction, it has been shown to be a slow process under many environmental conditions.

The commenter cites OPP's qualitative description of the persistence of pendimethalin in aerobic soil environments as slight to moderate. This does not serve as, nor did OPP intend for this statement to represent, a quantitative description of pendimethalin's persistence in soil. OPP does not attempt to relate this characterization to a numeric range of persistence values in the RED, and the

commenter does not provide a rationale for concluding that OPP's language indicates that pendimethalin does not meet the EPCRA section 313 persistence criteria.

The final sentence of the citation points out factors that decrease persistence, but a more detailed reading of the RED on the subject of pendimethalin persistence in aerobic soils reveals that its persistence increases as temperature and soil moisture decrease, and soil organic carbon increase.

The commenter performed a Level III EQC Multimedia Modeling assessment for pendimethalin assuming ''best case, reasonable case, and worst case'' scenarios. The calculated overall environmental persistence was determined for pendimethalin to be 5 days, 58 days, and 142 days under the ''best, reasonable, and worst case'' scenarios, respectively. The results of the multimedia model indicated that pendimethalin will have a persistence in the environment of less than 2 months, assuming a reasonable case scenario. The commenter claims that multimedia modeling results indicate that pendimethalin will not be persistent according to the EPCRA section 313 persistence criteria.

The commenter notes that the values it calculated using the EQC model are much lower than the 30 days and 487 days calculated for EPA (Ref. 51) assuming best case and worst case scenarios. The commenter alleges that EPA assumed that half-lifes in soil, sediment and water were identical, 54 days and 1,322 days, respectively (Ref. 7). The data presented above, however, indicate that these were erroneous assumptions. The half-lifes for pendimethalin dissipation in water, soil, and sediment are not identical, and the 1,322 day half-life is an outlier.

The commenter concludes that pendimethalin will have a low to moderate persistence whether found in the air, water, soil, or sediment compartments of the environment. The commenter asserts that this is supported by field and laboratory degradation studies, multimedia modeling, and EPA's FIFRA registration environmental assessment of pendimethalin. Therefore, pendimethalin should not be classified as persistent for purposes of inclusion on the EPCRA section 313 list of PBT chemicals.

EPA disagrees that pendimethalin will have low persistence in the environment whether laboratory and field studies or multimedia modeling are considered. Multimedia mass balance models offer the most convenient means to estimate overall environmental persistence from information on sources and loadings, chemical properties and transformation processes, and intermedia partitioning. For the chemicals included in the proposed rule, EPA used a modified version of the EQC model (Ref. 33) to estimate overall environmental persistence. Overall persistence estimated in this way is used as an additional factor, in conjunction with reaction half-lifes for individual media, bioaccumulation/bioconcentration factors, in justifying the determination made by EPA in this rule.

The EQC model is based on the fugacity approach first delineated by Mackay (Ref. 31) and subsequently applied to numerous environmental processes (Ref. 32). It uses an ''evaluative environment'' in which environmental parameters such as bulk compartment dimensions and volumes (e.g., total area, volume of soil and sediment, etc.) are standardized, so that overall persistence for chemicals with different properties and rates of transformation may be compared on an equal basis (Ref. 15). EPA used a version of the EQC level III model (Ref. 33) which was modified to focus on net losses by deleting model terms for advective losses (movement out of the evaluative environment of air and water potentially containing a chemical) and sediment burial (Ref. 82). In this version of the model only irreversible transformation contributes to net loss of a chemical.

The overall persistence obtained from this model is calculated as the total amount in the evaluative environment when steady state is achieved, divided by the total loss rate. The results thus obtained are neither an overall environmental half-life nor a compartment (or transformation)-specific half-life; rather they are equivalent to an environmental residence time. When only irreversible transformation contributes to net loss--i.e., under the conditions of this version of the EQC model--overall environmental persistence times can be converted to half-lifes by multiplying the former by ln 2 (i.e., 0.693). The overall half-life calculated in this way is for dissipation in the environment as a whole and cannot be related directly to any individual compartment.

The commenter selected media-specific environmental half-lifes for use as input to the EQC model. The values were characterized as ''best,'' ''reasonable'' and ''worst'' case. No justification was given for this classification. It appeared that the shortest half-lives were categorized as ''best case.'' Based on the information provided by the commenter, it was not always possible to determine whether the half-lifes for soil or water selected by the commenter for use as input to the EQC model were for destruction of chemical, or its dissipation from the medium. As noted previously, dissipation half-lifes do not necessarily represent destruction of the chemical since non-destructive transport processes such as volatilization can be responsible for loss from the medium. Their use in multimedia modeling could potentially underestimate overall environmental persistence. This is particularly important since the modified EQC model predicted that greater than 90% of the pendimethalin would partition to soil at steady state. If a soil half-life based on loss from soil by nondestructive processes was used rather than one based on the destruction of pendimethalin, its persistence would have been underestimated.

In its modeling of the overall environmental persistence of pendimethalin EPA used the highest, lowest and mean values for the ranges of media-specific half-lifes from valid studies as inputs to the modified EQC model, not the highest and lowest as stated by the commenter. These included a half-life for pendimethalin in soil of 1,322 days. EPA determined that the study was properly conducted and chose the half-life value of 1,322 days for soil because it represented the most environmentally protective half-life derived from a valid study. The calculated overall environmental persistence half-lifes were 1 month, 8 months, and 16 months based on the highest, mean, and lowest half-lifes, respectively. For chemicals in this rulemaking, EPA considered the multi-media modeling EQC results in characterizing persistence in the overall environment. EPA only intended to use multimedia modeling results to override the medium-specific persistence data in limited circumstances, e.g., only if all model inputs are judged to be accurate (and, as noted above, the commenter's inputs cannot be determined to be accurate). But even if EPA were to use the EQC model to assess persistence, pendimethalin would be considered persistent because, with the EPA inputs described above, EQC overall environmental persistence half-lifes were calculated to be greater than 6 months using the mean and maximum air, soil, and water half-lifes calculated.

In response to this comment (even though it was unclear whether the commenter was basing its assertion on degradation data or dissipation data), EPA conducted a new EQC assessment for pendimethalin using the same half-

life inputs selected by the commenter. The calculated overall environmental persistence half-life was greater than 2 months using the longest half-lifes provided by the commenter for air, soil, water, and sediment. These results support EPA's assertion that the persistence of pendimethalin in the environment meets the EPCRA section 313 persistence criteria.

The commenter argues that the scientifically-based risk assessments conducted on pendimethalin as a part of the pesticide registration process should not be ignored, and that EPA should review pesticide PBT chemical classifications with EPA registration information to ensure an accurate analysis has been performed.

The commenter notes that EPA has determined through the review of a complete set of studies that this material used at an approximate rate of 1.0 to 2.0 pounds of active ingredient per acre does not present an unreasonable risk to human health or the environment, that low levels of pendimethalin in manufacturing wastewater releases do not pose an unacceptable risk to the environment, and that reported EPCRA section 313 air releases do not pose a significant risk to human health or the environment.

The commenter concludes that based on the weight of evidence it is clear that releases of pendimethalin from manufacturing do not pose a significant threat to human health and the environment and that pendimethalin should not be branded as having a high potential for harm as indicated by the proposed listing as a PBT chemical and lowering of the reporting threshold.

EPA disagrees that the risk assessments cited by the commenter are relevant to the characterization of pendimethalin as a PBT chemical. The characterization of chemicals as PBT chemicals for the purpose of this rule are based on intrinsic physical-chemical properties. Risk is not an intrinsic property of a substance, but rather the result of the combination of intrinsic hazard (toxicity) a substance possesses and the exposure to a target organism under a defined set of circumstances. It is possible for a substance to present a risk under one set of exposure conditions, but not another. In contrast, a substance characterized as a PBT chemical will remain a PBT chemical, regardless of the exposure to it or its levels in the environment. (See Unit VI.C.)

Toxic chemicals that persist and bioaccumulate are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. Furthermore, these PBT chemicals can have serious human health and environmental effects resulting from low levels of release and exposure.

EPA believes that the substances subject to this rule have been characterized as PBT chemicals using scientifically sound indicators based on the intrinsic properties of the substances. The PBT characterization is independent of the risk the substance may pose under a given set of circumstances. These substances have been characterized as persistent, bioaccumulative and toxic and, therefore, meet the criteria for lowered reporting thresholds.

Further, FIFRA requires the Agency to determine that pesticidal uses of a chemical do not cause ''unreasonable adverse effects on the environment,'' which is defined in FIFRA section 2(bb) as ''any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of pesticides'' (7 U.S.C. section 136(bb)). FIFRA is a regulatory statute, and the impacts of regulation can be immediate and direct (e.g., banning of a chemical), and as such EPA examines not only the hazards presented by the chemical, but also the specific exposure scenarios, and weighs the risks against the benefits of the chemical. The ''unreasonable adverse effects'' determination under FIFRA is specific to the intentional use of the chemical as a pesticide and does not address other uses or releases of the chemical that may result from manufacture, processing, or other use. Furthermore, a determination under FIFRA that the use of a chemical will not result in an ''unreasonable adverse effect'' is not a determination that the chemical is not hazardous or persistent or that the use of the chemical is without risk, but merely that the benefits of agricultural use as a pesticide outweigh its risks as an agricultural pesticide or that the pesticide chemical residues on food or feed meet the standards of section 408 of the Federal Food, Drug, and Cosmetic Act. EPCRA section 313 was not enacted to serve the same purpose as FIFRA. Listing on EPCRA section 313 provides communities with some of the information required to determine what risks may result from the manufacture, processing, and use of a chemical, and to allow local communities to determine for themselves whether such risks are acceptable, information not provided under FIFRA.

h. *Toxaphene*. In the proposal, EPA preliminarily determined that toxaphene has persistence half-life values in soil of 1 to 11 years and a persistence half-life value in water of 1 to 5 years. EPA has reviewed information and all comments received on toxaphene's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that toxaphene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking. (Ref. 7). In addition, toxaphene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

i. *Trifluralin*. In the proposal, EPA preliminarily determined that trifluralin has persistence half-life values in soil of 99 to 394 days and a persistence half-life value in water of 5 to 37 days. EPA has reviewed information and all comments received on trifluralin's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that trifluralin persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7).

j. *Polycyclic aromatic compounds*. In the proposal, EPA preliminarily determined that PACs have persistence half-life values in soil that ranged from 20 days to 13 years. All but a few had half-lifes well in excess of 6 months. These chemicals had persistence half-life values in water that ranged from 79 days to 44 years. EPA received one significant comment addressing the persistence potential of PACs, which is discussed below. EPA has reviewed information and all comments received on PACs' persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that PACs persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7).

One commenter contends that EPA has incorrectly ignored biotreatment

studies in evaluating persistence for PACs. EPA has also ignored a large body of recent research on sequestration and other phenomena that collectively act to reduce the bioavailability of soil contaminants, such as PACs.

Biotreatment studies include activated sludge or other wastewater treatment studies. As EPA stated in the proposed rule (at 64 FR 700), the reason for excluding such studies is that wastewater treatment in general and activated sludge in particular represent conditions that are far removed from ambient (surface) waters, soils, and sediments. Data on environmental fate and persistence of substances in wastewater and activated sludge normally cannot be extrapolated to the other conditions. The commenter seems most concerned about land biotreatment (bioremediation) studies, but in fact goes well beyond the concept of treatability, appearing to infer that EPA has ignored all biodegradation studies of PACs. However, this is incorrect because all mixed-culture biodegradation studies other than activated sludge tests--i.e., field tests as well as lab studies that used authentic soil, water and/or sediment grab samples--were considered in determining persistence for all of the listed substances.

The commenter also discusses recent research indicating that bioavailability of a substance may decline with time of incubation in soil, and suggests that EPA should include ''reasonable bioavailability factors'' in its determination of persistence. As an example of why this is relevant, there has been a concern that Superfund site remediation actions may be mistargeted if they are based on residues released from the soils by vigorous extraction procedures, since chemical substances in soil may become nonbioavailable yet still be extractable for analytical purposes. Additionally, bioremediation may fail to destroy all of a substance that such analysis shows is present, if some portion is sequestered in a non-bioavailable state. Further, the commenter contends that chemicals (including many PACs) are not bioavailable if the bioavailability is considerably less than 100%. The commenter does further specify a numerical bioavailability criteria.

The commenter over-generalizes from the research findings, using selective citation and quotation from the literature to give the impression that all is now known and any substance released to soil is as good as gone toxicologically speaking. Other reports can be quoted to the effect that the many factors determining bioavailability, sequestration, etc. are far from completely resolved, and deserve much further research. Moreover, sequestration does not necessarily imply non-bioavailability. For example, in a study of PAC sequestration and bioremediation, Tang et al. (Ref. 51a) state that:

> The results of the present study suggest that extensive biodegradation by microorganisms does not necessarily remove all of the fraction of an aged compound that is bioavailable since some uptake by worms occurred even after the laboratory-scale bioremediation. . . .it is also possible that a portion of a compound that is sequestered is available to different degrees to dissimilar organisms. . . .It may be that the mass of material that becomes sequestered should be considered as existing in two forms. One form may be unavailable to all organisms because it is physically remote and thus inaccessible. The second form may be differentially available, and its assimilation, toxicity, and/or biodegradation may depend on the properties of the species and its ability to mobilize the molecules from this non-remote location.
>
> [There is] danger if it is assumed that the disappearance of lethality denotes the absence of bioavailability....The point is reinforced by the case of DDT, which is sequestered in soil (13) and whose lethality to insects totally disappears as a result of such sequestration (5), yet a portion of that insecticide was still assimilated by earthworms introduced into soil that was treated in the field with DDT *more than 40 years before the bioassay was performed*. . . .(emphasis added)

And in a similar paper on DDT and dieldrin, Robertson and Alexander (Ref. 43a) state that:

> The significance of soil properties in controlling sequestration is evident in the early observation that the degree of sequestration of lindane after 22 months was greatest in a muck, intermediate in extent in a loam, and least in a sandy loam (11). Thus, *soil properties must be considered in attempting to predict the bioavailability of persistent compounds*. It is also evident from the data presented herein that the bioavailability of a sequestered toxicant varies with the exposed species. Thus, the declines in toxicity of aged DDT and dieldrin to the three test insects were quite different; whereas the lethality of the sequestered compound to one species had almost disappeared, it still was effective against a second. (emphasis added)

The conclusion is manifest: it is that although chemical substances released to soil may become sequestered over time, it cannot be assumed that this process necessarily leads to nonbioavailability even when the time horizon is years. Site- and species-specific factors, as well as substance properties, are important in determining bioavailability. Therefore, it is appropriate to be concerned about the bioavailability in soil and sediment of PACs and other substances that meet the PBT criteria established for this rulemaking.

Further, there is no scientific reason why a chemical can only be considered bioavailable if its bioavailability approaches 100%. The degree of bioavailability will vary depending upon the environmental conditions. In addition, as noted above the degree of bioavailability will also be species dependent. Therefore, EPA believes that the commenter's approach is overly simplistic.

k. *Benzo(g,h,i)perylene*. In the proposal, EPA preliminarily determined that benzo(g,h,i)perylene has persistence half-life values in soil of 173 days to 1.8 years and persistence half-life values in water of greater than 100 days. EPA has reviewed information and all comments received on benzo(g,h,i)perylene's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that benzo(g,h,i)perylene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking. (Ref. 7). In addition, benzo(g,h,i)perylene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

1. *Mercury and mercury compounds*. Because metals may convert to different oxidation states but can never be destroyed, all metals meet the 6 months half-life criterion automatically. EPA received a few significant comments addressing mercury and mercury compounds' persistence. These are discussed below. EPA has reviewed information and all comments received on mercury and mercury compounds' persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that mercury and mercury compounds persist in the environment with half-lives of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and in EPA's support documents for this rulemaking (Ref. 7). In addition, mercury and mercury compounds persist in the environment with a half-life of greater

than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

One commenter asserts that EPA should not classify all forms of mercury as persistent. The commenter agrees that Hg (0) is properly characterized as persistent. However, the commenter contends that EPA is incorrect in characterizing Hg (II) as persistent because it is removed rapidly from the atmosphere via wet and dry deposition.

EPA believes that the commenter confuses residence time with half-life; these terms do not represent equivalent processes. There is a distinction between atmospheric ''half-life,'' which is the amount of time necessary for half of the chemical present to be destroyed in the medium, and atmospheric ''residence time'' which is the length of time a chemical resides in a particular environmental medium. For the purposes of this rule ''half-life'' includes only irreversible chemical transformations resulting in the destruction of chemical whereas ''residence time'' includes factors such as transport of the substance to another medium, for example, wet and dry deposition, sorption, complexation or sequestration; and reversible changes in speciation (i.e., oxidation reduction reactions). EPA agrees that Hg (0) has an average ''residence time'' in the atmosphere of about 1 year and that Hg (II) may be deposited relatively quickly by wet and dry deposition processes, leading to a ''residence time'' of hours to months (Ref. 42a). But the shorter residence times noted for Hg (II) are due to physical transport from the medium, rather than irreversible transformations resulting in the destruction of chemical. Hg (0) released to the atmosphere is rapidly converted to Hg (II) through ozone-mediated oxidation. However, this is not an irreversible reaction, nor does it result in the destruction of the substance since the Hg (II) produced from oxidation of Hg (0) by ozone can be reduced back to Hg (0) by sulfite (Ref. 28a). The persistence of mercury will not be mitigated simply by redox reactions of Hg (0) to and from Hg (II). Whether as Hg (0) or as Hg (II), mercury persists in the environment. Environmental processes may cause it to change oxidation states or to be transported from one environmental medium to another; however, these processes will not destroy it.

EPA agrees that the report cited provides reasonable estimates of the fraction of mercury emissions from each source category that is likely to be in the form of Hg (II) versus the fraction as Hg (0). However, this information is not relevant to the assessment of the persistence of mercury and mercury compounds because persistence considers destruction only.

m. *Polychlorinated biphenyls*. In the proposal, EPA preliminarily determined that polychlorinated biphenyls (PCBs) have persistence half-life values in soil that ranged from 1 to 7 years and persistence half-life values in water that ranged from 56 to 98 days. EPA has reviewed information and all comments received on PCBs' persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that PCBs persist in the environment with half-lifes of 2 months or greater and therefore meet the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical listing can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, all of the PCBs persist in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

n. *Hexachlorobenzene*. In the proposal, EPA preliminarily determined that hexachlorobenzene has persistence half-life values in soil of 3 to 6 years. EPA has reviewed information and all comments received on hexachlorobenzene's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that hexachlorobenzene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and in EPA's support documents for this rulemaking (Ref. 7). In addition, hexachlorobenzene persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

o. *Octachlorostyrene*. In the proposal, EPA preliminarily determined that OCS has persistence half-life values in soil of 3 to 6 years. EPA received one significant comment addressing OCS's persistence potential which is discussed below. EPA has reviewed information and all comments received on OCS's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that OCS persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, OCS persists in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

One commenter believes that OCS should not be considered to be a PBT chemical. The commenter admits that OCS has the potential to bioaccumulate and may theoretically persist in the environment, but cites falling environmental levels of OCS and the lack of evidence of human and environmental toxicity as justification for why OCS should not be considered to be a persistent, bioaccumulative and toxic chemical. The commenters contend that pentachlorobenzene and hexachlorobenzene are not good analogs for OCS.

EPA disagrees. As discussed in Unit VI.G., EPA believes that OCS meets the EPCRA section 313 toxicity criteria. Further, EPA believes that OCS is highly persistent. No measured half-life data for soil or water that met the standards for data acceptability could be located for octachlorostyrene (CAS No. 29082–74–4). Therefore, EPA used half-lifes for the structural analogs pentachlorobenzene (CAS No. 608–93–5) and hexachlorobenzene (CAS No. 118–74–1) for estimating half-lifes for OCS. EPA believes that pentachlorobenzene and hexachlorobenzene are good analogs for OCS because they, like OCS, are highly chlorinated benzene derivatives, which are structurally very similar. By analogy, OCS is expected to have a half-life in soil of greater than 6 months and greater than 2 days in air (Ref. 7). These half-lifes are sufficient to designate OCS as persistent using the criteria described in the proposed rule. EPA believes that its use of analog data is scientifically supportable because like OCS both analogs are highly chlorinated monocyclic aromatics.

EPA believes that the degree of toxicity as well as the degree of persistence and bioaccumulation are inherent to a chemical. The absolute level of a chemical in the environment does not affect its degree of persistence, bioaccumulation, or whether or not it has been shown to cause adverse effects to aquatic organisms. The absolute level in the environment is a factor of both how much is entering the environment and the persistence of the chemical in the environment. The degree to which a chemical is present in aquatic organisms is not only a measure of the BAF, but also inputs into the environment and

persistence. The assertions made by the commenter do not support their contentions concerning the toxicity, persistence, or bioaccumulation of OCS.

p. *Pentachlorobenzene*. In the proposal, EPA preliminarily determined that pentachlorobenzene has persistence half-life values in soil of 194 days to more than 22 years. EPA received no significant comments addressing pentachlorobenzene's persistence potential. EPA has reviewed information and all comments on pentachlorobenzene's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that pentachlorobenzene persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7). In addition, pentachlorobenzene persist in the environment with a half-life of greater than 6 months which supports EPA's decision to lower the threshold to 10 pounds.

q. *Tetrabromobisphenol A*. In the proposal, EPA preliminarily determined that TBBPA has persistence half-life values in soil of 44 to 179 days and persistence half-life values in water of 48 to 84 days. EPA received several significant comments addressing TBBPA's persistence and discusses them below. EPA has reviewed information and all comments received on TBBPA's persistence characteristics. Taking into account this information, as indicated in Table 3, EPA finds that TBBPA persists in the environment with a half-life of 2 months or greater and therefore meets the persistence criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 7).

One commenter states that EPA's determination that TBBPA is persistent in the environment appears to be based upon a model which uses default data, that it is difficult to interpret EPA's methodology for applying its *EQC Model Output for Toxics Release Inventory PBT Rule Chemicals*, and it therefore is not clear how EPA arrived at the conclusion that TBBPA is persistent.

EPA disagrees that it is unclear how the EQC model was used in the assessment of chemical persistence and that EPA used only default data. EPA provided discussion on the conduct of the multimedia modeling in the document titled *EQC Model Output for Toxics Release Inventory PBT Rule Chemicals* (Ref. 33). EPA used chemical-specific input data (i.e., half-lifes in air, soil, water, and sediment and chemical properties) where available in all multimedia modeling runs. No default data were used in lieu of chemical-specific inputs. All chemical-specific inputs for each chemical were listed in this document. Further, EPA explained its use of the modified EQC model not only in the support document identified earlier, but also in the preamble to the proposed rule. In its description of the modeling EPA stated:

> Multimedia mass balance models offer the most convenient means to estimate overall environmental persistence from information on sources and loadings, chemical properties and transformation processes, and intermedia partitioning. For the chemicals included in this proposed rule EPA used the [modified] EQC model. . .to estimate overall environmental persistence. Overall persistence estimated in this way is used as an additional factor, in conjunction with reaction half-lifes for individual media, bioaccumulation/ bioconcentration factors, etc., in justifying actions proposed in this rule.

The EQC model is based on the fugacity approach first delineated by Mackay (Ref. 31) and subsequently applied to numerous environmental processes (Ref. 32). It uses an ''evaluative environment'' in which environmental parameters such as bulk compartment dimensions and volumes (e.g., total area, volume of soil and sediment) are standardized, so that overall persistence for chemicals with different properties and rates of transformation may be compared on an equal basis (Ref. 15). EPA used a version of the EQC level III model (Ref. 33) which was modified to focus on net losses by deleting model terms for advective losses (movement out of the evaluative environment of air and water potentially containing a chemical) and sediment burial (Ref. 82). In this version of the model only irreversible transformation contributes to net loss of a chemical.

The overall persistence obtained from this model is calculated as the total amount in the evaluative environment when steady state is achieved, divided by the total loss rate. The results thus obtained are neither an overall environmental half-life nor a compartment (or transformation)-specific half-life; rather they are equivalent to an environmental residence time. When only irreversible transformation contributes to net loss--i.e., under the conditions of this version of the EQC model--overall environmental persistence times can be converted to half-lifes by multiplying the former by ln 2 (i.e., 0.693). The overall half-life calculated in this way is for dissipation in the environment as a whole and cannot be related directly to any individual compartment.

In the analysis EPA used the highest, lowest and mean values for the ranges of half-lifes for soil, air, and water as inputs to the model. These half-lifes were collected from the literature from scientifically sound studies and were subject to data quality standards. The overall environmental persistence half-life for TBBPA calculated based on the EQC model was greater than 2 months but less than 6 months using the longest half-lifes for air, soil, water, and sediment. These results support EPA's assertion that the persistence of TBBPA in the environment will meet the EPCRA section 313 persistence criteria.

The commenter believes that TBBPA does not meet the persistence criteria for air. To support this contention the commenter refers to a study cited in a World Health Organization (WHO) document (Ref. 83). Specifically the commenter cites photodegradation studies that demonstrated that the half-life of TBBPA absorbed onto silica gel exposed to ultraviolet (UV) radiation was 0.12 day in air. In addition, the commenter contends that studies of the photolysis of TBBPA in the presence of UV light and hydroxyl radicals show that TBBPA was totally degraded within 5 to 6 days with an estimated 33–hour half-life. The commenter did not provide these studies or provide references to the original studies.

Further, the same commenter cites WHO EHC 172 (Ref. 83) for data on photodegradation to support the claim that TBBPA does not meet the persistence criteria for air. A review of the citation provided by the commenter reveals that it is a secondary reference taken from unpublished data from Bayer (Ref. 10). EPA was unable to review the full unpublished study to determine the quality of the data, only the summary found in the WHO document was available. In the WHO summary of the Bayer study TBBPA adsorbed onto silica gel and was exposed to ultraviolet irradiation at the 254 nanometer (nm) wavelength. Eight metabolites were detected and a half-life value of 0.12 days obtained. WHO noted that ''[i]t is difficult to derive environmental conclusions from the results of these experiments.''

EPA believes that the environmental relevance of the test results is doubtful.

While the experiment may demonstrate the potential for TBBPA to undergo photodegradation under laboratory conditions, the experimental conditions, to the extent they could be determined from the short summary provided, were not environmentally relevant.

In order for a molecule to undergo photochemical change it must absorb light. It is well known that only the transitions corresponding to ultraviolet/visible light absorption are inherently energetic enough to lead to chemical reactions. The wavelengths of importance for photochemical transformations is thus ultraviolet/visible light with a wavelength of 110 - 750 nm. When environmental photochemistry at or near the earth's surface is considered, the wavelengths of light of importance are further narrowed because the stratospheric ozone layer effectively prevents UV irradiation of less than 290 nm from reaching the earth's surface. Thus, only the light of the 290-750 nm wavelength absorbed by a molecule can potentially lead to photochemical changes of that molecule in the environment near the earth's surface. EPA believes that because the subject study utilized UV irradiation at the 254 nm wavelength, a wavelength that does not reach the earth's surface due to mitigation by stratospheric ozone, the half-life derived is not relevant and, therefore, cannot be used to determine the persistence of TBBPA in air.

The commenter also refers to studies of the photolysis of TBBPA in the presence of UV light and hydroxyl radicals in which TBBPA was shown to totally degrade within 5 to 6 days with an estimated 33–hour half-life. No additional information or references were provided to enable EPA to evaluate these findings for use in the characterization of the atmospheric half-life TBBPA.

The commenter contends that TBBPA's molecular structure makes it inherently biodegradable. The hydroxyl moiety on the TBBPA molecule can be readily transformed by organisms in the environment. The parent TBBPA molecule is no longer present once this biotransformation takes place. Therefore, based on TBBPA's structure alone, the Agency should consider TBBPA as unlikely to be environmentally persistent.

EPA disagrees with the statement that based on structure alone, the Agency should consider TBBPA as unlikely to be environmentally persistent. While EPA generally believes that measured values from well conducted studies are preferable to structure activity relationships (SAR) as an indicator of persistence, the Agency believes that it is possible to make some general statements about the biodegradability of TBBPA based on its structure.

Current knowledge of structure biodegradability relationships suggests that the presence of multiple bromines on an aromatic molecule adversely effects biodegradation. In fact, when the biodegradability of TBBPA is assessed with EPA structure activity relationship tools for predicting biodegradation from structure (Refs. 46 and 47), the presence of multiple aromatic bromines, a carbon with four single bonds, and the molecular weight of TBBPA are all structural features that reduce biodegradability. Therefore, even if EPA were to base its assessment of the persistence of TBBPA on its molecular structure, the Agency would conclude that it is not readily biodegradable.

The commenter contends that TBBPA will not meet the persistence criteria for water, soil, and sediment because TBBPA will biodegrade in these media. The commenter cites the results of several biodegradation studies as demonstrating that TBBPA is not persistent in these media. The commenter states that even though degradation studies have shown that TBBPA is not ''readily biodegradable'' (i.e., TBBPA is not mineralized to a significant extent by sewage sludge within 28 days) there are studies that indicate it is not persistent. Specifically, in studies submitted to EPA in 1989, TBBPA has been shown to be subject to biodegradation both in soil and sediment under aerobic or anaerobic conditions; TBBPA's estimated half-life derived from these studies is 50 days. In studies submitted by the Brominated Flame Retardants Industry Panel to EPA, TBBPA also was shown to undergo degradation in a sediment/water system with an estimated half-life of 48 to 84 days. (These data were reported under the Agency's TSCA Section 4 test rule.) The commenter argues that these data demonstrate that TBBPA does not meet most widely (and internationally) accepted criteria for persistence in soil or sediments (See Unit VI.B.) Therefore, TBBPA should not be considered to be persistent for purposes of EPCRA Section 313.

The commenter cites additional research conducted on the biodegradation of TBBPA under aerobic and anaerobic conditions in soil (Refs. 47) and asserts that the data indicate that ''TBBPA does not meet the most widely and internationally accepted criteria.'' EPA discusses its assessment of the Springborn soil biodegradation studies elsewhere in the Response to Comments document (Ref. 69). As explained earlier, the international persistence criteria are not relevant to the classification of persistence under the criteria adopted by the Agency, and EPA disagrees that TBBPA should not be considered persistent because it does not meet the ''most widely (and internationally) accepted'' criteria. (See Unit VI.B.)

The commenter makes the argument that TBBPA has been shown to be subject to biodegradation in soil and sediment under aerobic and anaerobic conditions with ''estimated'' half-lifes of 50 days. Although the commenter derived a biodegradation half-life, the method used to do so and the validity of the value could not be determined because no supporting information was provided. EPA questions the validity of the 50–day half-lifes estimated by the commenter on those grounds.

The commenter refers to two soil grab sample studies and a sediment/water microbial system study. These studies investigated the biodegradation of TBBPA in three different soil types in the presence (aerobic) and absence (anaerobic) of oxygen, and the biodegradation of TBBPA in a system containing sediment and river water in the presence of oxygen. In the aerobic soil studies less than 6% ultimate biodegradation (complete biodegradation to CO_2) was observed over the 64–day test period. The major portion of TBBPA remained in the soil. Analysis showed after 64 days 74 to 82% TBBPA remained in a Massachusetts sandy loam soil, 36 to 40% remained in an Arkansas silt loam, and 41 to 43% remained in a California clay loam soil. Over the course of the experiments, TBBPA either remained in soil undegraded, underwent minor structural changes (primary biodegradation), or to a very small extent (<6%), underwent complete biodegradation to CO_2. Individual values for evolved CO_2 in each soil type over time were not reported and biodegradation half-life values were not calculated. If it is assumed in the absence of values for CO_2 evolution at sampling times spaced evenly over the test period reported data, that TBBPA underwent a steady rate of degradation over the duration of the experiments, approximate half-lifes of 44 to 179 days can be estimated (Ref. 7).

Biodegradation half-lifes from the aerobic soil biodegradation experiments can be approximated. The half-life is defined as the amount of time necessary for the destruction of half of the chemical present in the medium. Given that the duration of the soil biodegradation test is 64 days (equivalent to greater than 2 months), a

chemical that undergoes less than 50% biodegradation by the end of the test period would have a half-life of greater than 2 months and meet the EPCRA 313 persistence criteria for soil. In one of the soils in which TBBPA was tested (a Massachusetts sandy loam soil) 74 to 82% of the original TBBPA applied remained in the soil unchanged at the end of the 64–day test period. Thus, in this study, TBBPA was shown to have a half-life in soil of greater than 2 months since less than 50% degradation of TBBPA occurred in 64 days.

The biodegradation of TBBPA in the same three soils as above under anaerobic conditions in a 64–day test has also been studied. The results showed that 44 to 57% of the TBBPA applied to soil remained undegraded in the Massachusetts sandy loam soil after a 64–day test period, 53–65% in an Arkansas silt loam soil, and 90% in a California clay loam soil. Less than 50% destruction of the test chemical occurred over a 64–day (> 2 month) test period in all soils tested. Thus, in this study, TBBPA was shown to have a half-life in soil of greater than 2 months since less than 50% degradation of TBBPA occurred in 64 days.

Aerobic sediment water microbial test systems containing natural sediments and river water were used to measure degradation half-lifes for TBBPA in 56–day experiments. Half-lifes calculated for the biodegradation of TBBPA ranged from 48 to 84 days. Researchers found an apparent correlation between half-lifes and TBBPA concentration, and half-lifes and microbial concentrations. Thus, in this study, TBBPA was shown to have a half-life in sediment water systems of greater than 2 months when either the larger value or the mean of the two values is considered.

Further, the commenter claims that abiotic degradation of TBBPA in water also is expected. The calculated half-life of decomposition of TBBPA by UV radiation in water was 10.2 days in spring, 6.6 in summer, 25.9 in autumn, and 80.7 days in winter. Therefore, TBBPA is not expected to be persistent in water. No other information was provided.

The commenter cites WHO EHC 172 (Ref. 83) for data on photodegradation to support the claim that TBBPA does not meet the persistence criteria for water. In its review of the literature to evaluate the persistence of TBBPA, EPA found no information on its photodegradation in water. A review of the citation provided by the commenter reveals that it is a secondary reference taken from an unpublished study from Bayer (Ref. 10). EPA was unable to review the full unpublished study to determine the quality of the data. Only the summary found in the WHO document was available. The Bayer study on photodegradation in water yielded calculated half-lifes ranging from 6.6 days to 80.7 days with the longest half-life calculated during the winter, when solar irradiation is least intense and the shortest half-life occurring in the summer, when the solar irradiation is most intense. The commenter did not include the fact that the effect of cloud cover lengthened the calculated half-life by a factor of 2. Water depth was also found to influence the direct photodegradation of TBBPA. At the surface of a water body, solar irradiation is fairly uniform; however, as depth increases, both the water itself and materials in it can attenuate the transmission of solar energy through the water column. Irradiance has been shown to decrease by greater than 90% for both ultraviolet and visible light at a depth of 5 meters in a eutrophic lake (Ref. 52). EPA disagrees with the commenter's conclusion that TBBPA photodegradation in water will be sufficiently rapid that it will not meet the persistence criteria. Based on the study cited by the commenter which includes an 80–day (> 2 month) half-life for photodegradation of TBBPA in winter, and the mitigating effects of water depth and cloud cover on rates of photodegradation, EPA believes that a half-life of greater than 2 months in water is supported. EPA, therefore asserts that based on these findings, TBBPA meets the EPCRA section 313 persistence criteria of greater than 2 months in soil and water.

2. *Bioaccumulation*—a. *Dioxin and dioxin-like compounds*. In the proposal, EPA preliminarily determined that dioxin and dioxin-like compounds have BCF values that range from 1,259–42,500 with 6 chemicals over 5,000 and 6 chemicals between 3,500 and 5,000. EPA has reviewed information and all comments received on dioxin and dioxin-like compounds' bioaccumulation characteristics. As indicated in Table 3, EPA finds that dioxin and dioxin-like compounds bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, most of the members of the dioxin and dioxin-like compounds category bioaccumulate in the environment with a value close to, or well above, 5,000, which supports EPA's decision to lower the threshold to 0.1 gram.

b. *Aldrin*. In the proposal, EPA preliminarily determined that aldrin has a BCF value of 3,715. EPA has reviewed information and all comments received on aldrin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that aldrin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71).

c. *Chlordane*. In the proposal, EPA preliminarily determined that chlordane has a BCF value of 11,050. EPA has reviewed information and all comments received on chlordane's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that chlordane bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, chlordane bioaccumulates in the environment with a BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

d. *Heptachlor*. In the proposal, EPA preliminarily determined that heptachlor has a BCF value of 19,953. EPA has reviewed information and all comments received on heptachlor's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that heptachlor bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and in EPA's support documents for this rulemaking (Ref. 71). In addition, heptachlor bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

e. *Isodrin*. In the proposal, EPA preliminarily determined that isodrin has a BCF value of 20,180. EPA has reviewed information and all comments received on isodrin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that isodrin bioaccumulates in the environment with a BAF/BCF value greater than1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, isodrin bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

f. *Methoxychlor*. In the proposal, EPA preliminarily determined that methoxychlor has a BCF value of 8,128. EPA has reviewed information and all comments received on methoxychlor's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that methoxychlor bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71).

g. *Pendimethalin*. In the proposal, EPA preliminarily determined that pendimethalin has a BCF value of 1,944. EPA has reviewed information and all comments received on pendimethalin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that pendimethalin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71).

h. *Toxaphene*. In the proposal, EPA preliminarily determined that toxaphene has a BCF value of 34,050. EPA has reviewed information and all comments received on toxaphene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that toxaphene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, toxaphene bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

i. *Trifluralin*. In the proposal, EPA preliminarily determined that trifluralin has a BCF value of 5,674. EPA has reviewed information and all comments received on trifluralin's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that trifluralin bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71).

j. *Polycyclic aromatic compounds*. In the proposal, EPA preliminarily determined that PACs have BCF values that ranged from 800 to 31,440 with 16 of the 21 members of the category having BCF values greater than 5,000. EPA received several comments concerning the PACs category listing and the bioaccumulation data which are addressed below. EPA has reviewed information and all comments received on PACs' bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that PACs bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71).

Three of the commenters support the retention of a single PACs category while one commenter believes that splitting the category into two categories would be the most appropriate option. Additional specific comments were as follows. One commenter stated that PACs are typically found as mixtures in incoming natural organic raw materials, such as coal and that it would be difficult to separate information into two reporting categories. Another commenter stated that reporting as one category is also more consistent with the Great Lakes Binational Toxics Strategy Level 2 listing for these chemicals. A commenter stated that the alternate proposal to create two PAC categories would be unnecessarily burdensome for the regulated community since reporting facilities would be required to speciate their PAC releases, and, if chemicals from both categories exceeded reporting thresholds, file two Form R reports, instead of one. One commenter stated that use of a single PACs category will simplify the reporting requirements; thus, it will reduce reporting burden. Several commenters stated that according to the proposed rule, 16 of the 21 members of the category had BCF values greater than 5,000 and that one proposal would regard the entire PACs category to be highly persistent and bioaccumulative, regardless of each individual PAC's actual persistence and bioaccumulative properties. Several commenters stated that they believed that splitting the category into two categories would be the most appropriate course. Another commenter stated that no chemical should be added to the highly persistent/bioaccumulative category when it does not fit the criteria and that in order to gain the most accurate information, two separate categories would be the superior solution. The commenter stated that lowering the reporting threshold for the PACs category to 10 pounds is unjustified considering that, according to EPA data, many of the individual PACs within the category do not meet the PBT criteria.

EPA considered splitting the PACs category into two or three categories or listings, but EPA believes, as do most of the commenters, that the most appropriate option is to retain a single PACs category. The PACs category was created because the members of the category are chemically and structurally very similar, share the same toxicological effect (carcinogenicity), and typically are produced, released, and otherwise managed as waste as complex mixtures rather than individual chemicals. As such it would be more difficult to estimate releases if the category were split into two or three categories based on the currently available bioaccumulation data. These reasons support retaining a single PACs category. EPA agrees with those commenters that stated that the retention of a single PACs category would be the simpler and less burdensome option. EPA also

recognizes that, based on currently available information, not all members of the PACs category meet the highly persistence and highly bioaccumulative criteria. Of the 21 chemicals in the PACs category proposed for a lower threshold, 5 have BCF values that nominally do not meet the highly bioaccumulative criteria, while the rest exceed the highly bioaccumulative criteria. Given the structural similarities of the members of this category and the higher bioaccumulation values for 16 of the 21 PACs, the 5 BCF values below 5,000 may underestimate, to some extent, the bioaccumulation potential of these compounds. For purposes of this rulemaking, EPA is classifying the PACs category as persistent and bioaccumulative rather than highly persistent and highly bioaccumulative. Thus, the PACs category will have a reporting threshold of 100 pounds. However, the Agency will continue to assess the bioaccumulation potential of this category and specifically whether the lower bioaccumulation values for 5 members of the category are appropriate.

k. *Benzo(g,h,i)perylene*. In the proposal, EPA preliminarily determined that benzo(g,h,i)perylene has a BCF value of 25,420. EPA has reviewed information and all comments received on benzo(g,h,i)perylene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that benzo(g,h,i)perylene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, benzo(g,h,i)perylene bioaccumulates in the environment with a BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

l. *Mercury and mercury compounds*. In the proposal, EPA preliminarily determined that mercury and mercury compounds have BCF values that ranged from 7,000 to 36,000. EPA has reviewed information and all comments received on mercury and mercury compounds' bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that mercury and mercury compounds bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical category can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, mercury and mercury compounds bioaccumulate in the environment with a value above 5,000, which supports EPA's decision to lower the threshold to 10 pounds.

m. *Polychlorinated biphenyls*. In the proposal, EPA preliminarily determined that PCBs have BCF values that ranged from 4,922 to 196,900. All of the PCBs, except one, had BCF values far exceeding 5,000. The one exception, 2,3,3',4,4',5,5' heptachlorobiphenyl, had a BCF value of 4,922. EPA has reviewed information and all comments received on PCBs' bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that PCBs bioaccumulate in the environment with BAF/BCF values greater than 1,000 and therefore meet the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical listing can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, with one exception, all of the PCBs listed bioaccumulate in the environment with a value far exceeding 5,000, which supports EPA's decision to lower the threshold to 10 pounds.

n. *Hexachlorobenzene*. In the proposal, EPA preliminarily determined that hexachlorobenzene has a BCF value of 29,600 to 66,000. EPA has reviewed information and all comments received on hexachlorobenzene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that hexachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, hexachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

o. *Octochlorostyrene*. In the proposal, EPA preliminarily determined that OCS has a BCF value of 33,113. EPA received one significant comment addressing OCS's bioaccumulation potential which is discussed below. EPA has reviewed this comment and information on OCS's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that OCS bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking. (Ref. 71). In addition, OCS bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

One commenter argued that OCS should not be included in the EPCRA section 313 PBT chemicals list. The commenter contends that OCS was included as a PBT chemical simply because it appears on several lists of persistent and bioaccumulative chemicals and not based on a thorough evaluation of its bioaccumulation. The commenter states that OCS has the potential to bioaccumulate, but nonetheless, OCS levels in fish and aquatic species in the Great Lakes continue to decline. The commenter provides a report on the Great Lakes region and argues that OCS should not be considered a PBT chemical since environmental concentration data show OCS levels in the environment are decreasing at a rate of 8% to 30% per year.

EPA disagrees with the commenter's conclusions. The commenter does not dispute the bioaccumulation values EPA presented in the proposed rule. Rather the commenter agrees that OCS has the potential to bioaccumulate but contends that since environmental concentrations are declining in the Great Lakes region OCS should not be considered a PBT chemical. The fact that OCS levels in the Great Lakes region may be declining is not a basis for concluding that OCS is not a PBT chemical or that it cannot bioaccumulate. There are a number of reasons that could explain a decrease in environmental concentrations of OCS but they do not change the fact that OCS has been shown to be highly bioaccumulative. OCS was included as a PBT chemical because it meets the EPCRA section 313 criterion for bioaccumulation laid out in the proposed rule, not simply because it has appeared on several other lists of PBT chemicals.

p. *Pentachlorobenzene*. In the proposal, EPA preliminarily determined

that pentachlorobenzene has a BCF value of 8,318. EPA has reviewed information and all comments received on pentachlorobenzene's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that pentachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71). In addition, pentachlorobenzene bioaccumulates in the environment with a BAF/BCF value greater than 5,000 which supports EPA's decision to lower the threshold to 10 pounds.

q. *Tetrabromobisphenol A*. In the proposal, EPA preliminarily determined that TBBPA was found to have BCF values of 780; 1,200; and 3,200. EPA received one significant comment addressing TBBPA's bioaccumulation which is discussed below. EPA has reviewed the comments and information on TBBPA's bioaccumulation characteristics. Taking into account this information, as indicated in Table 3, EPA finds that TBBPA bioaccumulates in the environment with a BAF/BCF value greater than 1,000 and therefore meets the bioaccumulation criterion established in this rulemaking. A complete discussion of EPA's findings on this chemical can be found in EPA's Response to Comments document for this rulemaking (Ref. 69) and/or in EPA's support documents for this rulemaking (Ref. 71).

One commenter contends that the available data on TBBPA do not support its classification as a PBT chemical. The commenter argues that the oyster BCF value of 780 does not support the proposed criterion of 1,000. The commenter also notes that EPA fails to consider that TBBPA is not retained in the body once dosing stops in a BCF test and that TBBPA is rapidly eliminated. The commenter states that rapid elimination limits any potential for biomagnification. The commenter notes that only the highest chironomid BCF value (3,200) was cited by EPA and not the fact that this is from a range of 650–3,200.

EPA believes that the available data do support classification of TBBPA as a PBT chemical. Measured BCF values of 780, 1,200, and 3,200 were obtained from TSCA section 4 tests with oysters, fish and chironomids, respectively. The measured BCF values of 1,200 and 3,200 for fish and chironomids respectively, clearly satisfy the EPCRA section 313 bioaccumulatioin criterion of 1,000. EPA is aware that TBBPA will be eliminated from the body eventually once exposure to the chemical is halted; however, continuous or intermittent exposures of TBBPA to organisms may result in significant tissue residues depending on the exposure or release scenarios. The issue of biomagnification of TBBPA is not relevant to determining if TBBPA is a PBT chemical. As discussed in Unit VI.B.3., biomagnification is not required in order to have a concern for chemicals that bioaccumulate. The highest chironomid BCF value was listed because it is considered as a worst case indication of bioaccumulation in sediment-dwelling invertebrates.

I. Exemptions and Other Reporting Requirements

1. *De minimis exemption*. Many of the commenters assert that the initial reasons for adopting the *de minimis* exemption are still valid and that this exemption should be maintained for PBT chemicals. Specifically, several commenters contend that the *de minimis* exemption was initially adopted to alleviate undue burden on reporting facilities and that the elimination of this exemption for PBT chemicals will significantly increase the reporting burden for this rulemaking.

EPA disagrees with the commenters' contention that the initial reasons for adopting the *de minimis* exemption are valid for PBT chemicals. As originally explained in the 1988 final rule implementing the reporting provisions of EPCRA section 313, reiterated in the 1997 final rule adding seven new industry sectors, and discussed in the proposal to this final rule, EPA promulgated the *de minimis* exemption for several reasons, of which burden was only one. In addition to burden reduction, EPA promulgated the *de minimis* exemption because: (1) The Agency believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; (2) the Agency did not believe that these low concentrations would result in quantities that would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509); and (3) the exemption was consistent with information collected under the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS). If EPA had adopted the exemption only to reduce burden, the exemption would have covered all uses of *de minimis* quantities of the toxic chemical in mixtures. The exemption, however, includes only limited uses of the toxic chemical in mixtures (i.e., importing, processing, otherwise use, and manufacturing impurities) that were roughly tailored to whether EPA expected that facilities were reasonably likely to have information that would allow them to determine thresholds and make release calculations.

The purpose of the PBT rulemaking, however, is different from past rulemakings in that it is intended to capture information on significantly smaller quantities of releases and other waste management associated with these chemicals. Most of the PBT chemicals addressed in this rule have been shown to cause adverse effects at concentrations far less than the *de minimis* levels. For example, dioxins have been shown to cause adverse effects at levels in the parts per trillion. In addition, after 10 years of experience with the program, the Agency believes there are many sources of information in addition to material safety data sheets (MSDSs), readily available to reporters to use in making EPCRA section 313 determinations. Some of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745–B–99–003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past 10 years. For example, although the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, only more recently has it been made available on the Internet. (http://energy.er.usgs.gov/products/databases/UScoal/index.htm). Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures. Therefore, given that: (1) Covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures; (2) even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and these small

quantities can reasonably be expected to significantly contribute to the lower thresholds; and (3) the concentration levels originally chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals.

A few commenters assert that reviewing each MSDS, when a facility may have many MSDSs for mixtures used on-site, to see if it includes trace quantities of PBT chemicals will be very time consuming. They contend that they do not have the manpower to track products on an individual basis looking for trace quantities of PBT chemicals and that these activities will be very burdensome.

EPA disagrees that eliminating the *de minimis* exemption for PBT chemicals will greatly increase burden under EPCRA section 313. Covered facilities are not required to report on toxic chemicals in mixtures and trade name products for which they have no concentration information or such information that is not reasonably known. However, if facilities do have information concerning the concentration of PBT chemicals in mixtures, such as on MSDSs, EPA does not believe it is more burdensome for facilities to identify and evaluate process streams containing relatively small quantities of PBT chemicals than for larger quantities of chemicals. Although some burden is associated with the identification and evaluation of process streams, EPA disagrees that the elimination of the *de minimis* exemption would vastly increase the extent of this required effort. Covered facilities will need to identify and evaluate process streams when considering a PBT chemical in concentrations below the *de minimis* level in the same manner they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level. The additional burden can be attributed to resources spent considering and reporting on information they currently are allowed to disregard. Further, as explained above, EPA adopted the *de minimis* exemption for several reasons, of which burden reduction was only one, and EPA does not believe that these original reasons apply to this PBT rulemaking.

Some commenters assert that it is unrealistic for EPA to assume that industry will report only on what they know without making an effort to fill the data gaps and that enforcement actions could arise from reports based on only what is known to a facility.

EPA disagrees, however, because covered facilities are expected to have reasonable knowledge of the toxic chemicals present at their site and need only document their considerations concerning threshold determinations and release and other waste management calculations. As stated in EPCRA section 313(g)(2):

> [i]n order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. *Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.* . . . (emphasis added)

Further, as stated previously, covered facilities are not required to report on toxic chemicals in mixtures and trade name products for which they have no concentration information, or for which such information is not readily available. Therefore, it is unlikely that facilities will have additional enforcement concerns.

Several commenters argue that the need to be consistent with the OSHA HCS that EPA cited in the 1988 final rule continues to be relevant with regards to collecting information on very small quantities.

EPA disagrees that the need to be consistent with OSHA to reduce burden is sufficient to justify retaining the *de minimis* exemption for PBT chemicals. EPA is not required to be consistent with the OSHA HCS. In 1988, EPA chose to be consistent with the OSHA HCS as part of its rationale for the exemption, because the Agency expected facilities to be familiar with these levels and thought that covered facilities might only have access to MSDSs for information on the content and percentage composition of toxic chemicals in mixtures. (See 53 FR 4509) However, EPA has never instructed facilities to stop looking if information concerning a toxic chemical is not on an MSDS. Rather, EPA has consistently instructed facilities to use their best readily available data in determining compliance with EPCRA section 313. As EPA explained earlier, given 10 years of experience with the program, the Agency believes that facilities may have other sources of information, in addition to MSDSs, available to them. Therefore, if a facility has better information regarding the concentration of a toxic chemical in a mixture, for example, that the chemical is above the *de minimis* level, the facility should be using that information to comply with EPCRA section 313. Further, EPA is consistent in some respects because under the OSHA HCS, if an employer has reason to believe that a permissible exposure limit for a component may be exceeded under the mixture's normal circumstances of use, the HCS also requires employers to list chemicals that are below the 1.0% and 0.1% thresholds. Therefore, OSHA adopted exceptions to the 1.0% and 0.1% limits under the HCS. Similarly, PBT chemicals are different from other toxic chemicals in that they may pose a more significant concern to the environment in much smaller quantities than other toxic chemicals. Furthermore, as explained in other responses in this unit, EPA believes the remainder of its rationale for the *de minimis* exemption is not applicable to PBT chemicals. For example, contrary to the commenter's statement, the small concentrations subject to the *de minimis* exemption are not necessarily small quantities and may contribute significantly to exceeding the lowered reporting thresholds.

Some commenters argue that the Agency has not justified why the exemption will result in increased health risk to the public or the environment. One commenter specifically argues that given the extremely low levels of these PBT chemicals in coal, the risk to the general public from these releases, which they believe is the original purpose of the legislation, is not apparent. Another commenter asserts that EPA must demonstrate that the removal of the exemption for specific PBT chemicals will have a public health or environmental benefit. Yet another commenter argues that the concentration of toxic chemicals contained in mixtures is irrelevant to public health concerns when the compounds of concern remain chemically bound within benign compounds.

EPA strongly disagrees with those commenters who indicated that EPA must consider risk to the general public when determining whether to eliminate the *de minimis* exemption. A primary purpose of the TRI program is to provide data on the releases (and other waste management activities) of listed toxic chemicals to communities so that they may use these data in conjunction with toxicity information for the chemical and site-specific information to determine if releases present a potential risk. They can also use TRI data in other ways. For example, an individual can use TRI data as a factor

in choosing a neighborhood in which to live. The purpose of TRI, however, is not to make a national determination of risk, nor did EPA consider risk in its original adoption of the *de minimis* exemption under EPCRA section 313.

Moreover, as previously explained, EPA originally promulgated the *de minimis* exemption based on several considerations that are inapplicable to PBT chemicals. Where, as here, the rationale and factual bases underlying an exemption no longer exist with respect to a particular class, the Agency believes it cannot justify retaining the exemption for that class. Further, the Agency has received no information from any commenters that contradicts the Agency's factual and legal conclusions, or that would otherwise present a basis for retention of the *de minimis* exemption.

EPA also disagrees with the comment that because there are very low levels of PBT chemicals (e.g., mercury) in coal that the risk to the general public is not apparent. EPA believes that the commenter misunderstands the concept of risk. Because a chemical is in a low concentration in coal does not in itself control the level of risk that can result when coal is combusted. For example, mercury compounds are found in very low concentrations in coal. When coal is combusted, mercury compounds are either converted into mercury chloride or reduced to elemental mercury. Some of the mercury/mercury chloride is released to air and some remains in the bottom ash. The concentration of the mercury/mercury chloride in the air wastestream will not be the same as the concentration originally present in the coal. Once the mercury/mercury chloride is released, it will be carried varying distances before it is deposited. Mercury can be transported over large distances, while mercury chloride may be deposited relatively rapidly by wet and dry deposition processes. The amount of mercury in a community or ecosystem will depend upon sources both local and distant. Once mercury has been deposited, it will bioaccumulate in organisms and will also persist in the environment as a sink for exposure and bioaccumulation. The amount of mercury that a human, animal, or plant will be exposed to is related more closely to exposure pathways and the quantity that is present in an ecosystem rather than the concentration in the coal that is combusted. Thus, EPA believes that the commenter is incorrect.

One commenter asserts that the elimination of the *de minimis* thresholds would not yield meaningful additional information. The commenter argues that the proposed rule vastly overstates the significance of TRI data and therefore incorrectly concludes that the *de minimis* thresholds would ''deprive communities of important information on PBT chemicals'' (at 64 FR 714). Instead, the commenter contends, TRI data only provide a snapshot view of releases from the chemical industry and the few other industry sectors subject to TRI reporting and that many potential release sources are not subject to TRI reporting. The commenter argues that these sources overwhelm the limited additional information that will be reported by eliminating the *de minimis* exemption.

EPA disagrees that the proposed rule vastly overstates the significance of the TRI data. The public, all levels of government, and the regulated community have come to rely on TRI data in improving decision-making, measuring pollution prevention, and understanding the environmental and health consequences of toxic chemical releases and other waste management activities. Although the Toxics Release Inventory does not contain a complete inventory of every release, EPA believes it does provide one of the most comprehensive and accessible sources of release and other waste management information available. EPA also disagrees with the commenter's assertion that the data base only contains information from the chemical industry and a few others. In fact, all 20 manufacturing industry groups as well as an additional 7 other industries including metal and coal mining facilities and hazardous waste management facilities are subject to EPCRA section 313. Further, with the addition of these 7 newly covered industries, EPA expects over 27,500 facilities to submit over 110,000 reports on more than 630 toxic chemicals to the TRI for the 1998 reporting year. Currently no other sources of information can provide releases and information on other waste management quantities and qualitative source reduction data with the scope, level of detail, and chemical coverage as data currently included in TRI.

Further, as EPA has previously explained, PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues. Even relatively small releases of such chemicals have the potential to accumulate over time and cause significant adverse impacts on human health and the environment. Therefore, EPA believes it is particularly important to gather and disseminate to the public relevant information on even relatively small amounts of releases and other waste management of PBT chemicals. Under the 10,000 and 25,000 pound/year reporting thresholds, a significant amount of the releases and other waste management activities involving PBT chemicals are not being captured and thus the public does not have the information needed to determine if these chemicals are present in their communities at levels that may pose a significant risk.

Several commenters argue that the *de minimis* exemption already does not apply to the manufacture of a toxic chemical unless the toxic chemical is manufactured as an impurity or is imported. Therefore, any incidental manufacturing of a PBT chemical as a by-product would not be eligible for the *de minimis* exemption and would be subject to reporting. Thus, they argue, the elimination of the exemption will provide little additional information and will not provide added value.

The commenters are correct in stating that there are instances where PBT chemicals are manufactured as by-products and would, therefore, not be affected by the elimination of the *de minimis* exemption. However, as EPA explained in the PBT proposal, there are also many instances where a PBT chemical may exist in a mixture or trade name product at a concentration below the 1% or 0.1% *de minimis* limit but where the processing or otherwise use of the PBT chemical in that mixture would otherwise contribute significantly to or in itself exceed the reporting thresholds (at 64 FR 714). For example, mercury can be found at very low concentrations in steel. A resmelting facility could process and release more than 100 pounds of mercury a year from its resmelting activities. However, although this total quantity is greater than the 10 pound proposed threshold for mercury, if the concentration of mercury in the steel is less than the *de minimis* limit, none of the mercury would be reportable if the *de minimis* level is retained for PBT chemicals. Releases and other waste management associated with these exempt activities would be absent from the TRI data base. Because even minimal releases of PBT chemicals may result in elevated concentrations in the environment or in an organism and can have the potential to cause an adverse effect, EPA believes that all releases of these chemicals are of concern and that such information is significant and of value to the public.

a. *Readily available data.* Some commenters assert that the elimination of the *de minimis* exemption will conflict with the condition that reporters obtain data from readily

available sources. They argue that because concentrations below 1% (and 0.1% for carcinogens) are not required on MSDSs, reporters will no longer be able to use MSDSs to screen for products containing PBT chemicals below these concentrations. They further contend that AP-42 guidance, Air CHIEF CD-ROM, TANKS, CHEMDAT8 and WATER8 would provide additional assistance in estimating the amount of a PBT coincidentally manufactured in wastestreams or released; however, these tools will not help quantify the amount of chemical in materials which are distributed in commerce or used as feedstock. They assert that there are no other consistent sources of information on whether a product contains a PBT chemical below *de minimis* levels. They also assert that the elimination of the *de minimis* exemption will cause additional burden for the regulated community because covered facilities will struggle with how to comply in the absence of information.

The Agency believes that since reporting first began in 1988, new sources of information have become available to covered facilities to use to determine concentrations of toxic chemicals in mixtures. In addition to the data bases and information sources cited by the commenter, EPA believes there are other sources of data that can and should be used in making threshold determinations and release and other waste management calculations for PBT chemicals. Examples of these sources of information include EPA guidance documents (e.g., *EPCRA Section 313 Industry Guidance: Electricity Generating Facilities* (EPA 745–B–99–003)) and trade association guidance documents (e.g., National Council of the Paper Industry for Air and Stream Improvement (NCASI) Technical Bulletins and NCASI's *Handbook of Chemical Specific Information for SARA Title III Section 313 Form R Reporting*). In addition, relevant information has become much more accessible to covered facilities over the past 10 years. For example, the United States Geological Survey's U.S. Coal Quality Database has been in existence since the mid 1970s, but only more recently has it been made available on the Internet. (http://energy.er.usgs.gov/products/databases/UScoal/index.htm) EPA believes that these tools, in addition to the ones cited by the commenter, will help covered facilities quantify the amount of chemical in materials which are distributed in commerce or used as feedstock and will allow covered facilities to make reasonable calculations to comply with EPCRA section 313. Further, the Agency believes that it underestimated how much information covered facilities had available to them in 1988 regarding small concentrations of toxic chemicals in mixtures. Therefore, EPA believes that facilities have sufficient information to make threshold determinations and release and other waste management calculations for PBT chemicals below *de minimis* concentrations. However, as EPA explained above, if a covered facility has no information, including no reasonable estimates or other reasonably known information, on the concentration of the toxic chemical in the mixture, they need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations (at 53 FR 4511). Therefore if the only source of information on a toxic chemical in a mixture is from an MSDS, and the MSDS does not indicate if the chemical is contained in the mixture, the facility is not required to consider the toxic chemical towards threshold determinations or release and other waste management calculations.

Because some facilities covered under EPCRA section 313 have more extensive information available to them than they did in 1988, or EPA underestimated how much information they had available in 1988, and because these facilities are not required to report if they have no information on the concentration of the toxic chemical, the Agency believes that in these cases retention of the *de minimis* exemption would allow facilities to avoid reporting when information is available to them that would otherwise permit them to report.

Some commenters assert that facilities will have to begin monitoring for trace quantities of chemicals in mixtures if the *de minimis* exemption is eliminated for PBT chemicals. One commenter argues that the only way facilities would be able to estimate the levels of dioxin in combustion products and wastewater treatment ''would be to undertake the costly burden of monitoring what comes off at a series of concentrations and temperatures.'' Another commenter asserts that if the *de minimis* level is eliminated, industry would be subject to increased enforcement action because exhaustive testing may be insufficient to detect the chemicals.

EPA disagrees with the commenters because, as stated previously, EPCRA section 313(g)(2) limits monitoring requirements under EPCRA section 313. Under this section, facilities are not required to perform any additional monitoring or analysis of production, process or use other than that already collected under other requirements. However, if a facility is required to monitor toxic chemicals under another statute, this data must be considered in determining thresholds and release and other waste management calculations under EPCRA section 313. EPCRA section 313(g)(2) requires that facilities use readily available data, or in absence of such data, facilities are required to use reasonable estimates. If no monitoring data are available, the facility should use other readily available information in making threshold determinations and release and other waste management calculations. Further, if the facility believes that it has other, more representative data than its monitoring data, the facility should use that information instead.

As to specifically tracking PBT chemicals in wastewater, the commenter does not specify whether the toxic chemicals discussed in the comment are manufactured as by-products, are processed, or otherwise used. As discussed above, the *de minimis* exemption does not apply to toxic chemicals manufactured as by-products. Therefore, if PBT chemicals are coincidentally manufactured during on-site wastewater treatment, covered facilities would be required to consider those PBT toxic chemicals for threshold determinations and release and other waste management calculations even if the *de minimis* exemption were retained for PBT chemicals. Similarly, PBT chemicals manufactured as a result of burning fuel would not be exempt even if the *de minimis* exemption were retained because manufactured by-products are not eligible for this exemption. PBT chemicals in below *de minimis* concentrations in mixtures that are imported, processed, or otherwise used will be affected by the elimination of the *de minimis* exemption. Covered facilities will need to consider these quantities towards threshold determinations and release and other waste management calculations. These calculations would include the amounts contained in combustion by-products and wastewater treatment units. Additional monitoring of these quantities, however, would not be required under EPCRA section 313. Finally, EPA has limited the dioxin listing with the qualifier ''manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created

during the manufacturing of that chemical.'' Therefore, not all processing or otherwise use activities of the dioxin and dioxin-like compounds category must be considered towards a facility's threshold determinations.

Some commenters assert that EPA should maintain the *de minimis* exemption for PBT chemicals present as impurities. They argue that information on PBT chemicals present as impurities is not readily available and that obtaining the relevant data, conducting the initial reviews to determine what information is available, and identifying data gaps would impose a huge burden on industry. They argue that even developing estimates with any accuracy entails a significant amount of time. In the instance of impurities, they assert that the absence of data and the difficulty in developing estimates will result in a heavy burden with little information of value being reported. These commenters believe that the elimination of the *de minimis* level is a requirement to provide new data when utilizing the *de minimis* exemption.

EPA disagrees with these commenters. Although there are burdens associated with obtaining relevant data, determining available information and identifying data gaps, EPA disagrees that the elimination of the *de minimis* exemption for PBT chemicals present as impurities would vastly increase the extent of this required effort. From the comment, it is unclear why requiring facilities to identify and evaluate process streams containing small quantities of PBT chemicals as impurities is more burdensome than for larger quantities of these chemicals manufactured, processed, or otherwise used at a covered facility in excess of the activity thresholds. For example, a facility monitors for chemical A at a concentration of greater than 0.001% and monitors for chemical B at a concentration of greater than 1.5%. The monitoring is done for the same wastestream and the same frequency. There is no differential in effort or burden. Currently, the only difference is that facilities can ignore available data when utilizing the *de minimis* exemption.

One commenter asserts that the *de minimis* exemption should be retained for PBT chemicals present at mining facilities. The commenter argues that the burden upon the mining industry is even greater in the context of the low thresholds proposed for PBT chemicals. Further, the commenter asserts that although EPCRA does not require covered facilities to conduct tests concerning the amount of listed chemicals processed, most reporters rely upon their knowledge of their manufacturing processes and raw materials to produce meaningful data for EPCRA section 313 reporting purposes. The commenter contends that this is not true of the mining industry. Due to the volume of materials moved in the extraction process and the heterogeneous nature of the materials mined, process knowledge often is inadequate to produce a meaningful picture of the minute levels of PBT chemicals that may be present in mining operations. The commenter asserts that inadequate process knowledge combined with the enormous expense of constantly testing the processed materials makes the elimination of the *de minimis* exemption for PBT chemicals unworkable as applied to mining operations.

EPA disagrees with the commenter. As the commenter points out, under EPCRA section 313(g)(2), facilities are not required to perform any additional monitoring or analysis of production, process, or use other than that already collected under other statutory or regulatory requirements. Therefore, there should be no added cost due to testing to comply with EPCRA section 313. However, EPA believes that in many cases mining facilities have the information needed to make reasonable estimates regarding small concentrations of PBT chemicals in the ores mined. In addition, as EPA explained in the 1988 final rule, if a covered facility has no information on the concentration of the toxic chemical in the mixture, including no reasonable estimates, the facility need not consider the chemical in that mixture for threshold determinations and release and other waste management calculations. If a mining facility does have information regarding the concentration of a toxic chemical in a mixture or trade name product, the facility must consider all non-exempted sources of the chemical for threshold determinations. If an activity threshold is exceeded for the chemical, the facility must then calculate release and other waste management quantities. Covered mining facilities will need to identify and evaluate process streams when considering a PBT chemical in concentrations below the *de minimis* level just as they already do for toxic chemicals found in process streams in concentrations above the *de minimis* level. Therefore, given that covered facilities: (1) Are not required to perform additional monitoring; (2) are not required to consider concentrations of toxic chemicals for which they have no information; and (3) need only consider readily available data, EPA disagrees that identifying and evaluating mining activities involving mixtures containing less than 1.0% or 0.1% concentrations of PBT chemicals will be more burdensome than for larger quantities of these chemicals manufactured, processed, or otherwise used at a mining facility in excess of the activity thresholds.

b. *Alternate de minimis level.* Several commenters argue that in lieu of eliminating the *de minimis* exemption for PBT chemicals, it would make more sense to change the level for the *de minimis* exemption for these chemicals. Some commenters argue that a more appropriate approach would be to compare the current thresholds and the current *de minimis* levels and use the same ratio to create a new *de minimis* level for the lowered PBT chemical thresholds. Therefore, they argue, the existing level is 1% for a threshold of 10,000 pounds, so an analogous reduction of the *de minimis* level would be 0.01% for the new proposed threshold of 100 pounds and 0.001% for the new proposed threshold of 10 pounds per year and 1 ppb for dioxins. One commenter argues that the current *de minimis* level of 0.1% for known or suspected carcinogens is not appropriate for dioxins. They suggest that EPA lower the *de minimis* exemption for dioxins proportionally to the lower reporting threshold EPA sets in the final rule. They assert that a reporting threshold for dioxins of 0.002 pound TEQ (not the threshold in the PBT proposal nor the one that EPA is finalizing today), is approximately seven orders of magnitude less than the current 10,000 pound threshold. Therefore, they argue, the 0.1% *de minimis* exemption should be lowered proportionally to 1×10^{-8}%. This translates to a concentration of 100 parts per trillion.

EPA disagrees with these commenters. As explained previously, EPA adopted the *de minimis* exemption for several reasons including the desire to be consistent with information mandated by the OSHA HCS. This OSHA standard requires the listing of hazardous chemicals on MSDSs but allows chemical suppliers to omit from the MSDSs hazardous chemicals that are below certain concentrations: Specifically, levels of 0.1% for OSHA carcinogens and 1.0% for other hazardous chemicals. However, the rationale for the OSHA HCS *de minimis* exemption is not relevant to PBT chemicals and therefore, is insufficient by itself to support an alternative *de minimis* exemption for PBT chemicals.

As explained in the 1983 final rule, OSHA chose the 1.0% concentration limit based on comments that this level seemed to be sufficiently protective of workers and was considered to be reasonable by a number of commenters (48 FR 53280, at 53290, November 25, 1983). OSHA was also persuaded by comments that in some instances the 1.0% cut-off levels may not be protective enough with respect to certain health hazards and adopted the 0.1% level for carcinogens (at 48 FR 53292). Specifically, PBT chemicals are of concern because they persist and bioaccumulate in the environment. Persistence and bioaccumulation were not considered as a part of the OSHA rulemaking. In addition, as explained in other responses in this unit, EPA's original rationale for this exemption is inapplicable to PBT chemials, and the commenters have provided no alternate rationale to support an exemption based on extrapolating new *de minimis* levels from the proposed thresholds. Therefore, given the different intents between the OSHA HCS and EPCRA section 313, EPA does not believe that creating alternative *de minimis* levels for PBT chemicals based on a ratio between the lowered threshold and the OSHA HCS levels is appropriate.

Several commenters support EPA's elimination of the *de minimis* exemption for PBT chemicals. They assert that retention of the *de minimis* exemption would undermine the changes to the reporting threshold and would allow an unnecessary loophole from reporting. They assert that the rule does not require any additional testing for impurities and that the only additional reporting would be for those facilities that use sufficient quantities of mixtures or trade name products containing PBT chemicals as impurities. One commenter asserts that one of the original reasons for the *de minimis* exemption levels, that it was based on OSHA HCS thresholds of 1.0% for hazardous chemicals in mixtures and 0.1% for carcinogens in mixtures, does not apply to raw materials that are not manufactured chemicals, such as crude oil, coal, and mining inputs.

EPA agrees with these commenters and is eliminating the *de minimis* exemption for PBT chemicals addressed in today's rule. As discussed above, the reasons EPA indicated for originally adopting the *de minimis* exemption are not applicable to PBT chemicals. In addition, EPA has received no compelling arguments from commenters to extend the *de minimis* exemption to PBT chemicals. Because the purpose of today's rulemaking is different from past rulemakings in that it is intended to capture information on significantly smaller quantities of releases and other waste management associated with these chemicals, the *de minimis* exemption could significantly limit the amount of reporting on PBT chemicals. Therefore, given that: (1) Covered facilities have several sources of information available to them regarding the concentration of PBT chemicals in mixtures; (2) even minimal releases of persistent bioaccumulative chemicals may result in significant adverse effects and can reasonably be expected to significantly contribute to the proposed lower thresholds; and (3) the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA believes that the reasons for the *de minimis* exemption that the Agency held for previous rulemakings do not apply to PBT chemicals. EPA is therefore eliminating the *de minimis* exemption for PBT chemicals.

c. *Supplier notification*. Several commenters were confused by EPA's failure to modify the *de minimis* exemption for PBT chemicals under the supplier notification requirements. As explained in the PBT proposal, the Agency believes that covered facilities have sufficient information available to them on PBT chemicals. The requirement of additional information under the supplier notification requirements would result in redundancies. Commenters that correctly understood EPA's inaction on this topic support the retention of the *de minimis* exemption for purposes of Subpart C Supplier Notification Requirements under 40 CFR 372.45(d)(1). EPA agrees with these commenters and has therefore taken no action on the supplier notification requirements for PBT chemicals.

2. *Other exemptions.* Although the Agency received several comments regarding the existing exemptions, EPA is not modifying any of these exemptions in this rule. Any changes to these exemptions would require additional rulemaking, and any comments submitted to EPA during this rulemaking will be considered as part of EPA's evaluation of these exemptions.

3. *Use of alternate threshold and Form A.* One issue that commenters raise relates to EPA's proposal to exclude all PBT chemicals from the alternate threshold of 1 million pounds for PBT chemicals. Several commenters argue that EPA should retain the alternate threshold of 1 million pounds for PBT chemicals. EPA disagrees. As stated in detail in the proposal, EPA believes that use of the existing alternate threshold and reportable quantity for Form A would be inconsistent with the intent of expanded PBT chemical reporting. The general information provided on the Form A, on the quantities of the chemical that the facility manages as waste is insufficient for conducting meaningful analyses on PBT chemicals.

A commenter states that because PACs in fuel are destroyed during combustion, EPA should retain the alternate threshold or provide a new alternate threshold. First, the commenter did not provide any information to support the contention that PACs in fuel are destroyed during combustion. And, to the contrary, EPA believes that, even if some or all of the PACs in fuel are destroyed during combustion, additional PACs may be created during the combustion process. Consequently, absent any information to support the basis for such an option, or the need for an alternate threshold, EPA does not believe it would be appropriate at this time to provide a new alternate Form A threshold. Although EPA solicited comments on this issue in the proposal, at this time, the Agency believes that it is appropriate to collect and analyze several years worth of data at the lowered thresholds before EPA considers developing a new alternate threshold and reportable quantity appropriate for PBT chemicals.

In addition, the commenter also appears to be raising a broader issue than just the destruction of PACs during combustion. The commenter implies that when a facility estimates its releases to be zero, the facility should be eligible to use the Form A. However, the commenter appears to misunderstand how to calculate the amounts required to determine eligibility for the Form A. Facilities may use the Form A provided that they do not exceed 500 pounds for the total annual reportable amount for a chemical, and that their amounts manufactured or processed or otherwise used do not exceed 1 million pounds. The annual reportable amount is equal to the combined total quantities released at the facility, treated at the facility, recovered at the facility as a result of recycle operations, combusted for the purpose of energy recovery at the facility, and amounts transferred from the facility to off-site locations for the purpose of recycle, energy recovery, treatment, and/or disposal. The commenter only appears to consider their releases as reportable amounts and does not appear to consider quantities generated from their other waste management activities as reportable amounts. This additional waste management information on PBT chemicals is very important to

communities because it helps them understand the quantities of EPCRA section 313 chemicals that are being transported through their communities, the destination of these EPCRA section 313 chemicals, as well as the reported waste management activity at the receiving facility. In conclusion, EPA has not proposed to disregard this waste management information in calculating the annual reportable amount, therefore the commenter's approach is not consistent with current reporting under Form A or appropriate as an approach for reporting on PBT chemicals.

The commenter also states that the alternate threshold should be retained in order to ensure that only meaningful amounts of substances are reported under EPCRA section 313. EPA disagrees that retention of the alternate threshold would ensure that only meaningful information is reported under EPCRA section 313. The 500 pound waste eligibility could be interpreted by some data users, as a worst case, to mean that greater than 500 pounds of the chemical has been released into the environment (i.e., 500 pounds of production-related waste as release and some quantity of catastrophic release). Other data users may assume that the facility had no catastrophic releases and all of the toxic chemical in waste was managed in a manner other than as a release, e.g., the toxic chemical in waste was recycled. For PBT chemicals where any release is a concern, an uncertainty level of 500 pounds may result in data that is virtually unusable. As a result, EPA does not agree with the commenter that the alternate threshold will ensure that only meaningful amounts of substances will be reported under EPCRA section 313.

In addition, the commenter argues elimination of the alternate threshold for PBT chemicals will cause reporting burdens to increase while failing to provide for the collection of substantial additional release information. EPA's economic analysis used reporting costs for the Form R to estimate the costs to those facilities that would not be able to use the alternate threshold. The economic analysis also evaluated the benefits of the collection of additional release and other waste management of PBT chemicals (Ref. 67). The commenter does not dispute those estimates. As a result, EPA sees no compelling argument to revise its decision to exclude all PBT chemicals from the alternate threshold of 1 million pounds.

A number of commenters argue that EPA should eliminate the alternate threshold of 1 million pounds for all PBT chemicals on the EPCRA section 313 list. One commenter asserts that in light of the relatively small quantities of concern for PBT chemicals, particularly those with no deliberate commercial manufacture, it makes little sense to retain the Form A. The commenter further states that it believes that a modified Form A would be inappropriate due to the concern over releases of these chemicals at low levels. Another commenter adds that the Form A is clearly inappropriate for chemicals that will now have thresholds significantly lower than the 500 pound waste generation level. The commenter further contends that it is not appropriate for EPA to set a new Form A threshold for PBT chemicals, given the need to collect more information on these substances.

EPA agrees with the commenters that all PBT chemicals should be excluded from the alternate threshold of 1 million pounds. As stated in detail in the proposal, EPA believes that use of the existing alternate threshold and reportable quantity for Form A would be inconsistent with the intent of expanded PBT chemical reporting (at 64 FR 715–716). The general information provided in the Form A on the quantities of the chemical that the facility manages as waste is insufficient for conducting meaningful analyses on PBT chemicals.

EPA also agrees that a new alternate threshold for PBT chemicals would be inappropriate due to the concern over releases and other waste management of these chemicals at low levels. As stated in the proposal, even small quantities of persistent bioaccumulative chemicals may cause elevated concentrations in the environment and organisms that may cause significant adverse effects. Given the persistent and bioaccumulative nature of these chemicals and the need for the public to have information about smaller amounts of these PBT chemicals, EPA believes it would be inappropriate at this time to allow an option that would exclude significant information on some releases and other waste management of these chemicals.

In response to EPA's proposal to exclude all PBT chemicals from the alternate threshold of 1 million pounds, one commenter argues that EPA should consider establishing a new alternate reporting threshold for these chemicals. The commenter states that, at a minimum, an alternate reporting threshold of 10 to 100 pounds would be consistent with the throughput-reporting threshold proposed for all PBT chemicals except dioxins. The commenter further states that the SBA's analysis suggests significant reductions in burden associated with alternate reporting thresholds of 50 pounds for PBT chemicals. The commenter states that, based on an SBA study commissioned of petroleum bulk plants, which it estimates will be the largest group of reporters under this proposal, it finds that most of the reports avoided by this alternate threshold would reflect zero releases.

EPA disagrees with the comment suggesting that a new alternate threshold be established for PBT chemicals. As stated in the proposal, even small quantities of persistent bioaccumulative chemicals may cause elevated concentrations in the environment and organisms that may cause significant adverse effects. Given the persistent and bioaccumulative nature of these chemicals and the need for the public to have information about smaller amounts of these PBT chemicals, EPA believes it would be inappropriate at this time to allow an option that would exclude significant information on some releases and other waste management of these chemicals. The general information provided in the Form A on the quantities of the chemical that the facility manages as waste is insufficient for conducting meaningful analyses on PBT chemicals. Therefore, EPA does not agree that a new alternate threshold for PBT chemicals should be established.

The commenter also suggests that reporting burdens will increase while failing to provide for the collection of substantial additional release information. EPA's economic analysis used reporting costs for the Form R to estimate the costs to those facilities that would not be able to use the alternate threshold. The economic analysis also evaluated the benefits of the collection of additional release and other waste management of PBT chemicals (Ref. 67). The commenter does not dispute those estimates. As a result, EPA sees no compelling argument to revise its decision to exclude all PBT chemicals from the alternate threshold of 1 million pounds.

4. *Data precision issues*—a. *Use of significant digits, half pound and whole numbers*. EPA proposed to require reporting of all releases and other waste management quantities of PBT chemicals (except dioxin) that are greater than 1/10 of a pound, provided that the accuracy in the underlying data on which the estimate is based supports this level of precision. EPA further stated that releases and other waste management quantities would continue to be reported to two significant digits. In addition, EPA stated that for quantities of 10 pounds or greater, only

whole numbers would be required to be reported. For the category of dioxin and dioxin-like compounds, which have a proposed reporting threshold of 0.1 gram, EPA proposed that facilities report all releases and other waste management activities greater than 100 µg (i.e., 0.0001 gram).

After reviewing all comments on this issue, EPA is providing the following guidance on the level of precision covered facilities should use to report their releases and other waste management quantities of PBT chemicals. Facilities should continue to report releases and other waste management amounts greater than 1/10 of a pound (except dioxin), at a level of precision supported by the accuracy of the underlying data and the estimation techniques on which the estimate is based.

This approach is consistent with the statutory reporting requirements when estimating reportable amounts. The statute requires facilities to, among other things, report ''[t]he annual quantity of the toxic chemical entering each environmental medium.'' (42 U.S.C. 11023(g)(1)(C)(iv)). To determine this ''annual quantity,'' the statute directs facilities to use readily available data (including monitoring data). When such data are not readily available, the statute directs facilities to use reasonable estimates. (42 U.S.C. 11023(g)(2)). However, while the statute allows for some level of imprecision regarding reportable amounts, it does not create an exemption or exception that would allow facilities to report less precisely than provided for by their data or estimation techniques. Therefore, facilities should report PBT chemicals as precisely as their estimation techniques or readily available data allow. If a facility's release or other management calculations support reporting an amount that is more precise than two significant digits, then the facility should report that more precise amount.

b. *Use of range reporting.* In the preamble to the proposed rule, EPA requested comments on its proposal to eliminate the use of range reporting in Form Rs for PBT chemicals. Commenters disagree with the proposal for a number of reasons outlined below.

Commenters argue that applying different reporting conventions for PBT chemicals would complicate EPCRA section 313 reporting, cause compliance difficulty, and introduce data inconsistencies (i.e., ranges for some chemicals but not for others). Commenters also argue that eliminating the use of range reporting for PBT chemicals has the potential to mislead the public and divert attention from actual risks.

EPA disagrees that the elimination of the use of range reporting for PBT chemicals will cause insurmountable obstacles to EPCRA section 313 reporting and cause compliance difficulties and data inconsistencies. There are already many different industries that report to EPA for 643 chemicals. EPA provides numerous guidance documents and training opportunities to reporting industries. With the finalization of the PBT rule, EPA will provide updated guidance documents, will prepare and provide, in those cases where it is appropriate, chemical-specific guidance documents, and will continue to offer training in order to assist facilities in reporting under EPCRA section 313. EPA also believes that the Agency will be able to adequately explain to the public the different reporting requirements for PBT chemicals so that they are put in context of other TRI data. EPA currently does this for other types of chemicals on the EPCRA section 313 list such as metals and pesticides.

Additionally, EPA believes that the elimination of range reporting is a critical part of this rulemaking, of which the ultimate intent is to provide useful information on PBT chemicals to assist communities in determining if PBT chemicals are present in their communities at levels that may pose an unacceptable risk. This information on PBT chemicals can also be used by government agencies and others to identify problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Consequently, the information collected about these PBT chemicals will inform the public rather than mislead the public and will actually assist the public in determining the risk of PBT chemicals in their communities.

Commenters also argue that reporting numerical values for PBT chemicals assumes a level of accuracy that generally does not exist in the measurement of releases. In addition, commenters state that estimating numerical values would require the use of material balances, which are difficult to apply and essentially inaccurate for chemicals used in low concentrations. Commenters contend that, especially where reports are estimates, ranges may in fact provide more information than point estimates. Commenters argue that, for these reasons, elimination of range reporting will result in inaccurate estimates. Commenters also state that eliminating the use of range reporting for PBT chemicals would give the false impression of precise data, where uncertainty inherently exists.

As stated in the proposal, EPA believes that the use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account its inherent error (i.e., error in measurements and developing estimates) (at 64 FR 716). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500–999. This represents nearly a 100% error. This uncertainty severely limits the applicability of release information where the majority of releases, particularly for PBT chemicals, are expected to be within the amounts eligible for range reporting. The utility of these data would be severely limited given the uncertainty associated with data reported using ranges. Therefore, due to this uncertainty, EPA believes that facilities should report numerical values, not ranges, for PBT chemicals.

In addition, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater and/or more accessible than it was 10 years ago. Because of this improved information availability, EPA believes that many facilities will be able to accurately estimate releases and off-site transfers for further waste management of PBT chemicals in quantities of less than 1,000 pounds without the use of range codes. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting the more specific and useful information from those facilities that can provide it.

Further, the Form R and Instructions and annual TRI data release provide information on the methods used to generate information reported and characterize many of the limitations that may apply to the data. This aids the data user in understanding the overall nature of the information available under EPCRA section 313. Facilities are required, for each release or transfer amount, to indicate on the the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgment. By looking at the

information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in any particular number reported by a facility. Thus, EPA believes that false impressions will not be communicated to the data user about the accuracy of the information filed.

Finally, EPCRA permits facilities to use reasonable estimates in the absence of readily available data to calculate reportable amounts. Compliance with EPCRA section 313 does not require that additional monitoring or sampling be done. Thus, the statute contemplates some level of imprecision in the data that may be filed, yet, by authorizing reporting based on reasonable estimates, affirms the community right-to-know purposes relative to information based on such reasonable estimates. Reporting releases of low volumes of PBT chemicals based on such reasonable estimates is no different than reporting on other toxic chemicals based on the same kind of information. The TRI data that has been reported since 1987 is a blend of estimates based on monitoring data, mass balance calculations, published emissions factors, and engineering calculations or engineering judgment.

The commenters contend that eliminating the use of range reporting for PBT chemicals would be extremely burdensome to facilities. EPA explained in the proposal that the original intent of providing the range reporting option was primarily as a burden reducing measure focused on small businesses. In past expansion activities, EPA has tried to retain burden reducing options wherever feasible. However, EPA does not expect the elimination of range reporting to significantly affect the unit cost of reporting because many facilities that could use range reporting are not choosing to do so. An analysis of the 1997 data reported under EPCRA section 313 reveals that the number of instances in which a range code was used for reporting quantities in sections 5 and 6 of the Form R was 37,168. These 37,168 instances included 7,605,305 pounds of releases and transfers using the median of the range code reported. However, there were 66,842 instances in which range reporting could have been used (i.e., the amounts reported where below 1,000 pounds), but the reporting facility chose instead to report a number rather than a range. These 66,842 instances included 13,662,758 pounds of releases and transfers. Thus, in 64% of the instances where range reporting could have been used facilities reported a number instead. The fact that in a majority of the instances in which range reporting could have been used facilities opted to report specific numbers would appear to indicate that the elimination of range reporting for PBT chemicals is unlikely to impose any significant additional burden on facilities. Therefore, EPA does not expect the elimination of range reporting to have any significant effect on unit reporting costs.

Commenters also argue that the elimination of the use of range reporting for PBT chemicals could result in an increase in the threat to confidential information and a possible increase in trade secret claims. Commenters maintain that Congress considered the need to protect trade secret information in the discussion of reporting chemical use and presence in ranges for EPCRA section 313:

> The conference substitute provides for reporting categories of use and ranges of chemicals present because the exact use of an identified chemical at a facility or the exact amount present may disclose secret processes. In some circumstances, this information may need to be reported in terms of broad 43 categories of use or amount ranges. . . . (H.R. Report No. 99–962, 298)

However, EPA believes that the conference report language cited by the commenter clearly refers only to the use of range reporting for the data element entitled ''maximum amount of the toxic chemical on-site at any time during the calendar year.'' EPA is not precluding range reporting for maximum amounts on-site. Contrary to the notion expressed by the commenter, Congress did not expressly direct EPA to allow range reporting for the reporting of releases and transfers off-site for further waste management. Additionally, in the statute, Congress provided the only means and mechanism for facilities to protect confidential business information (CBI) through the statute's trade secret provisions. If the commenter believes that any report filed might reveal confidential information as to the identity of the chemical, the commenter may choose to file a CBI claim by following the procedures as outlined in 40 CFR part 350. In addition, the statute is clear that trade secret claims may only be made for the identity of the chemical. Therefore, EPA believes that Congress adequately provided procedures for the protection of CBI and that a possible increase in CBI claims does not outweigh the need for increased information on releases and other waste management of PBT chemicals. See, *Legislative History* at 5185.

Commenters also argue that eliminating the use of range reporting for PBT chemicals will not result in the collection of substantial additional release information. EPA disagrees. The issue of range reporting is closely tied to the lowering of the reporting thresholds for PBT chemicals. As EPA noted in the proposal,

> Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment.

EPA also noted in the proposal that,

> Under current reporting thresholds, a significant amount of the releases and other waste management activities involving PBT chemicals are not being captured and thus the public does not have the information needed to determine if PBT chemicals are present in their communities and at levels that may pose a significant risk.

Therefore, by the lowering of reporting thresholds, EPA will receive important information on the quantities of PBT chemicals being released or otherwise managed as waste. Given the lowering of the reporting thresholds, continued use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account any inherent error (i.e., errors in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500–999. This represents a nearly 100% error. This uncertainty severely limits the applicability of release information where the majority of releases, particularly for PBT chemicals, are expected to be within the amounts eligible for range reporting. Given that the large uncertainty would be part of these data and would severely limit their utility, EPA has concluded that facilities must report numerical values, not ranges, for PBT chemicals.

In addition to the above comments, several commenters recommend the use of multiple ranges rather than total elimination of ranges just for PBT chemicals. One commenter generally agrees with EPA's position that reporting ranges ''B'' (11 to 499 pounds) and ''C'' (500 to 999 pounds), as they currently exist, may be too broad to provide meaningful information for PBT chemicals. Because the proposal does not impose any new obligation to measure or test beyond what is currently required, however, the commenter believes it is still

appropriate to retain the ''A'' reporting range of 1 to 10 pounds for PBT chemicals. The commenter contends that the use of a specific number conveys a sense of precision that may not actually exist. The commenter argues that the retention of the ''A'' reporting range in its current form, coupled with the new reporting range of ''greater than zero, but less than 1 pound,'' will provide meaningful and valuable information to the public on PBT chemical transfers or releases.

Another commenter agrees with the purpose underlying the EPA's proposal to prohibit the use of range reporting for PBT chemicals and believes the ranges authorized under the current rules are too broad to be useful for PBT chemicals. However, the commenter believes that EPA should recognize that reporting in ranges is often necessary because uncertainty makes the selection of a single number arbitrary.

Another commenter argues that EPA should retain range reporting for PBT chemicals, even if the ranges are lower than those allowed for non-PBT chemicals. The commenter further contends that they believe that range reporting helps to correct some of the error introduced to EPCRA section 313 reporting through the use of estimates.

EPA disagrees that the Agency should retain the ''A'' reporting range of 1 to 10 pounds for PBT chemicals or that the Agency should retain some form of range reporting for PBT chemicals. As stated in the proposal, EPA believes that the use of ranges could misrepresent data accuracy because the low or the high end range numbers may not really be that close to the estimated value, even taking into account its inherent error (i.e., error in measurements and developing estimates). The user of the data must make a determination on whether to use the low end of the range, the mid-point, or the upper end. For example, a release of 501 pounds could be misinterpreted as 999 pounds if reported as a range of 500–999. This represents a nearly 100% error. Even with a lower range such as 1 to 10 pounds, the uncertainty associated with range reporting could severely limit the applicability of release information for PBT chemicals. Numerical values are particularly important since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues. This means that even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause adverse impacts on the environment and organisms. The utility of these data would be limited given the uncertainty associated with data reported using ranges. Therefore, due to this uncertainty, EPA is requiring that facilities report numerical values, not ranges, for PBT chemicals.

In addition, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater and more accessible than it was 10 years ago. Because of this improved information availability, EPA believes that facilities will be able to accurately estimate releases and off-site transfers for further waste management of PBT chemicals in quantities of less than 1,000 pounds without the use of range codes. Although it may be true that some facilities will be better able to make those estimates than others, EPA does not believe this justifies not collecting the more specific and useful information from those facilities that can provide it. Further, in the Form R, facilities are required, for each release or transfer amount, to indicate the principal method used to determine the amount of release reported. There are codes which allow the facility to indicate whether the estimate is based on monitoring data, mass balance calculations, published emission factors, or other approaches such as engineering calculations or best engineering judgment. By looking at the information provided through the use of these codes, users of the data can gain an understanding of the degree of accuracy or uncertainty in any particular number reported by a facility. Thus, EPA does not believe that false impressions will be communicated to the data user about the accuracy of the information filed.

Finally, as noted earlier EPCRA permits facilities to use reasonable estimates in the absence of readily available data to calculate reportable amounts. EPCRA does not require that additional monitoring or sampling be done in order to report. Thus, the statute contemplates some level of imprecision in the data that may be filed, yet, by authorizing reporting based on reasonable estimates, affirms the community right-to-know purposes relative to information based on such reasonable estimates.

A number of commenters agreed with EPA's proposal that range reporting be eliminated for all PBT chemicals on the EPCRA section 313 list. The commenters agreed with EPA's belief that the use of ranges could misrepresent data accuracy and significantly impact the usefulness of the data.

J. Other Issues

1. *Placing reported data into context.* Several commenters make the same general comment that EPCRA section 313 does not capture all sources of PBT chemical releases and therefore will not provide a complete or accurate picture of the releases of these chemicals. Commenters criticize the proposal for not putting the PBT releases from EPCRA section 313 covered facilities into context, in terms of either risk or the amount of PBT releases expected from non-covered facilities or sources. EPA disagrees with the implication by several commenters that simply because EPCRA section 313 may not capture all the sources of releases of PBT chemicals EPA should not attempt to capture more information from the facilities that do report under EPCRA section 313. This comment has been voiced in every major rulemaking under EPCRA section 313 but, as EPA has stated in the past, this is not an argument that EPA believes should restrict any efforts to collect additional data under EPCRA section 313. The mere fact that for some chemicals significant release sources are not captured does not in any way diminish the importance of the information that can be provided by those facilities that are required to report under EPCRA section 313. There is currently no one single reporting requirement that captures all of the releases of PBT chemicals and makes that information available to the public. For those chemicals that do have large release sources not captured under EPCRA section 313, EPA will use all available data to aid its actions and those of other international and national organizations and the public in efforts to address concerns on PBT chemicals. For example, all data will be considered to aid EPA's PBT strategy or other EPA PBT related programs; EPA will not rely solely on the data collected under EPCRA section 313. In addition, if there are significant sources of PBT chemicals that are not reported under EPCRA section 313, EPA will attempt to let the public know that some sources are not captured. In fact, in the most recent TRI data release documents, EPA has been providing information to the pubic on other sources of releases for certain EPCRA section 313 chemicals. In addition, EPA will continue to improve and augment public information materials so that users of the data will have information available to put in context the releases and other waste management of PBT chemicals by industries reporting under EPCRA section 313 versus those industries that do not report under EPCRA section 313.

In fact, rather than an argument against lowering the reporting thresholds for PBT chemicals, EPA believes that the argument the commenters are making is one that supports expanding the types of facilities that should be required to report under EPCRA section 313 and not an argument that supports denying the public the right-to-know about PBT chemical releases from EPCRA section 313 covered facilities.

Some commenters stated that since EPA did not use exposure or risk considerations, the data on PBT chemical releases will be misleading to the public by indicating risks where none exist. EPCRA section 313 is not a risk-based reporting system, and, as discussed in Unit VI.F., EPA believes that a risk-based approach to EPCRA section 313 reporting is at odds with the overriding policy of EPCRA section 313, which is to get information about the use, disposition, and management of toxic chemicals into the public domain, enabling the users of this information to evaluate the information and draw their own conclusions about risk. The intent of EPCRA section 313 is to move the determination of which risks are acceptable from EPA to the communities in which the releases occur. This basic, local empowerment is a cornerstone of the right-to-know program. In addition, EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data. Consequently, EPA disagrees with the commenters that the information reported on releases and other waste management of PBT chemicals will be misleading to the public.

Another commenter states that the quantities of PBT chemicals reported in the TRI will be far smaller than the quantities of other chemicals which pose far less significant health risks. The commenter is concerned that the small quantities could lead members of the public to overlook the data on PBT chemicals. Therefore, the commenter argues that EPA should present PBT data in a way that draws the public's attention to it. The commenter states that it sees a danger that without sufficient education and guidance, the public may either overestimate or underestimate the health risks from PBT chemicals. The commenter believes that EPA should make a commitment to ensuring that the public is given the necessary education and guidance. EPA understands that the quantities of PBT chemicals may be reported in smaller quantities than other chemicals under EPCRA section 313 and that these quantities have the potential to be overlooked. EPA is also sensitive to the issue that data on PBT chemicals must be presented clearly to assist data users in understanding how the information on PBT chemicals is different from that reported on other chemicals under EPCRA section 313. EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data. Despite the concerns voiced by the commenters, EPA still believes that it is important to collect and disseminate this information so that communities can use the information with other site-specific factors to determine if releases into their communities result in risks that the community determines warrant further action given other factors, such as economic and environmental conditions, or particularly vulnerable human or ecological populations.

Another commenter expresses concern that release numbers for PBT chemical will not be comparable to those for other chemicals with higher reporting thresholds or to releases of the PBT chemical in previous years. The commenter adds that the lower thresholds may mislead the public into thinking that releases are rising or that a new chemical has been introduced at a facility. EPA understands the commenter's concern but does not believe this is a justification for not collecting additional information about PBT chemicals. EPA believes that it will be able to adequately explain to the public the different reporting requirements for PBT chemicals so that they are put in context of other TRI data. EPA will make clear which PBT chemicals were reportable prior to the finalization of this rule and what the reporting threshold was for these chemicals. Finally, EPA will continue to improve its annual public data release as well as its outreach and education efforts to assist users in understanding the data.

2. *Manufacture only qualifier for chemicals other than dioxin.* Many commenters request that EPA add a ''manufacture only'' qualifier to all PBT chemicals, not just the dioxin and dioxin-like compounds category. The commenters assert that the addition of the manufacture only qualifier to all PBT chemicals would greatly reduce the burden of the rule. Some commenters suggest that at a minimum the manufacture only qualifier should apply to polychlorinated biphenyls (PCBs), since EPA's rationale for applying the qualifier to dioxin and dioxin-like compounds is equally applicable to PCBs. One commenter contends that EPA's statement that the manufacture qualifier is appropriate for chemicals that are ''ubiquitous in the environment'' because otherwise many facilities would be required to report simply due to background levels in raw materials applies to PCBs as well. Some commenters suggest that unintentionally manufactured by-products such as hexachlorobenzene and octachlorostyrene should also have the manufacture only qualifier. Some commenters argue that the burden of the rule could be significantly reduced if EPA focused the reporting effort on the manufacturing sector, which should help concentrate EPA's pollution prevention efforts on the sector most likely to be able to make reductions. Some commenters contend that the primary source for PBT chemicals within the EPCRA section 313 reporting sectors is from manufacturing, and these are the sources that should be focused on for tracking PBT chemicals. Some commenters assert that EPA has acknowledged that many chemicals identified as persistent and bioaccumulative are not imported, processed, or otherwise used, but are manufactured as by-products (at 64 FR 715). Some commenters assert that they agree that manufacturing is the primary source for environmental loading of PBT chemicals from EPCRA section 313 facilities, and thus the effort for reporting should be concentrated on the sources where PBT chemicals are generated and data can be gathered. Some commenters argue that concentration on the manufacturing of PBT chemicals provides an efficient focus for meaningful pollution prevention efforts. Some commenters assert that they are concerned that data from importing, processing, or otherwise use of PBT chemicals will be inaccurate and misleading since processors and users may not have the resources to conduct the analyses required to provide accurate estimates. One commenter contends that the fear of enforcement might motivate those importing, processing, or otherwise using PBT chemicals to report ''some amount'' and that such information is likely to be inaccurate, and will not accurately reflect the true level of concern. Some commenters assert that instead of requiring reports from the many sources where effective emissions reductions may not be possible, that the addition of a manufacture only activity qualifier for all PBT chemicals will provide the public with the most accurate information on PBT chemical emissions and the best opportunity to monitor EPCRA section 313-related

environmental loading of these chemicals.

EPA believes that in order to obtain any reporting on dioxin and dioxin-like compounds a very low threshold is required, which is several orders of magnitude lower than the thresholds for other PBT chemicals. At such a low reporting threshold it is estimated that thousands of reports could potentially be filed by facilities, mainly food processing facilities, due to the amount of dioxins in the raw materials they process. The dioxins found in the meat and dairy products that food processors handle have been previously released, circulated in the environment, and bioaccumulated in animals, thus these are not additional loadings to the environment but loadings that have already occurred and cycled through the environment due to the persistence and bioaccumulative properties of these compounds. The unique combination of very low thresholds, the number of food processors that would be required to file, and the fact that they would be filing because of the bioaccumulation of previously released material led EPA to propose to add only dioxin and dioxin-like compounds that are manufactured. EPA is finalizing the addition of dioxin with a revised qualifier in response to the unique set of conditions that apply to the reporting of dioxin and dioxin-like compounds. EPA proposed and is finalizing the addition of dioxin with a qualifier to reduce reporting burden on facilities, mainly in the food processing industry, that results from the unique combination of circumstances related to the reporting for these chemicals and to focus on those activities that add to the loading of dioxins in the environment rather than on activities dealing with previously released and bioaccumulated chemicals.

EPA did not conclude and does not believe that the manufacturing activity is the only important source of PBT chemical releases to the environment and believes that other activities such as processing or use can result in significant releases of PBT chemicals, including chemicals released to the environment for the first time. As discussed in Unit VI.G., EPA has modified the dioxin qualifier to reflect this. The unique combination of circumstances that exists for dioxin and dioxin-like compounds does not exists for any of the other PBT chemicals being added by this rule. EPA did not conclude that the manufacture qualifier is generally appropriate for other chemicals that are being added and that are ''ubiquitous in the environment.'' The full statement in the proposal was ''These dioxin and dioxin-like compounds are ubiquitous in the environment and thus under the very low reporting thresholds necessary to get reports from any sources (see discussion in Unit VII.A.2.), facilities that process raw materials would be required to report simply because the raw material contains background levels of these chemicals'' (at 64 FR 710). Clearly EPA made this statement in the context of the ''very low reporting thresholds necessary to get reports [for the dioxin and dioxin-like compounds category] from any sources.'' This statement is consistent with the unique combination of circumstances that exists for dioxin and dioxin-like compounds and was not intended to apply to all PBT chemicals.

Neither did EPA conclude that the manufacturing activity is the activity for which facilities would be most likely to be able to make reductions or that EPA's pollution prevention efforts should focus solely on the manufacturing of PBT chemicals. Commenters provided no basis for such a conclusion and EPA believes that processors and users of PBT chemicals also have the opportunity to make effective emissions reductions by using less of a PBT chemical, by not using materials that contain PBT chemicals as contaminants, etc. In addition, the purposes of reporting under EPCRA section 313 are not limited to the collection of information from sources where effective reductions in release and other waste management quantities are possible. Data collected under EPCRA section 313 can serve a variety of information purposes that do not depend on how easy it is for the source to achieve reduction in releases and other waste management. The commenter statement that EPA has acknowledged that many chemicals identified as persistent and bioaccumulative are not imported, processed, or otherwise used, but are manufactured as by-products, is incorrect. The actual statement was: ''[m]any of the chemicals identified as persistent and bioaccumulative in today's action are not imported, processed, or otherwise used but are manufactured as by-products'' (at 64 FR 715). As the words ''today's action'' clearly demonstrate, this statement was not a broad statement about all PBT chemicals but simply an acknowledgment that many of the PBT chemicals in the proposed rule were by-products. In addition, this statement was made in the context of the discussion on the *de minimis* exemption about how removing the exemption for PBT chemicals would affect the chemicals in the proposed rule; it was not a statement made in connection with the discussion on the manufacture only qualifier. EPA also did not state that manufacturing is the primary source for environmental loading of PBT chemicals from facilities covered under EPCRA section 313. The discussion on the loading of chemicals in the environment from manufacturing was in relation to the reporting of dioxin which, as discussed above, presents a unique combination of circumstances that EPA considered to determine how to focus its listing decision and does not apply to all PBT chemicals. EPA disagrees with the statements that data from facilities that import, process, or otherwise use PBT chemicals will be inaccurate and misleading or that such facilities will report some quantity out of fear of enforcement and that such information is likely to be inaccurate, and will not accurately reflect the true level of concern. EPA believes that facilities that import, process, or otherwise use PBT chemicals will be just as able to report as facilities that manufacture PBT chemicals. It is no more difficult to do calculations regarding small numbers than it is to do calculations on larger numbers, so if a facility that imports, processes, or otherwise uses PBT chemicals has information that allows them to make a reasonable estimation of quantities then they should be just as able to report as any manufacturing facility would be able to report on small quantities manufactured as by-products. If facilities that import, process, or otherwise use PBT chemicals do not have data available that allows them to make a reasonable estimation of quantities then they are not required to report. As for fear of enforcement, EPA can take enforcement actions both for under reporting and over reporting so facilities should not report an amount of a PBT chemical in order to avoid an enforcement action.

EPA does not believe that the unique combination of circumstances that exists for dioxin and dioxin-like compounds exists for any of the other PBT chemicals being added by this rule nor does EPA believe that reduced burden or any of the other reasons suggested by the commenters provide a sufficient reason to focus on manufacturing activity only for the other PBT chemicals in this rule. Therefore, EPA does not believe that it is appropriate to add a manufacture only qualifier to any of the other PBT chemicals in this rule.

3. *Waste management issues.* Some commenters contend that because activities such as recycling, approved

waste disposal, and treatment are incorporated into reported volumes, the EPCRA section 313 reported releases will be substantial overestimates of the actual quantities released to the ambient environment. They further argue that although this information may be useful to source reduction efforts, merging of reporting requirements under section 313 of EPCRA and section 6607 of PPA has resulted in information which is misleading to the public's desire to know the actual exposures that are occurring. Another commenter asserts that by requiring electricity generating facilities to report transfers off-site for treatment and disposal of PCBs from transformers, EPA has established a disincentive to properly dispose of PCB transformers and remove them from use because most PCB wastes transferred to off-site facilities are destroyed in regulated units which destroy at least 99.9999% of the PCBs. They are concerned that because the casual reader may conclude additional releases of PCBs to the environment have occurred, companies would have a disincentive to voluntarily remove PCBs.

The commenters are incorrect in stating that EPCRA section 313 release quantities include recycling and treatment amounts. Under EPCRA section 313, if a chemical activity threshold is met for the chemical, covered facilities are required to report the quantity of the toxic chemical entering each environmental medium; this includes ''releases.'' The definition of release pursuant to EPCRA section 329(8) means:

> any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles) of any hazardous chemical, extremely hazardous substance, or toxic chemical.

There is no language in this definition, any other provision of EPCRA, or in the regulations promulgated pursuant to EPCRA section 313, that limit this definition to ambient releases to the environment which may result in public exposure. In fact the definition specifically includes disposing of toxic chemicals as well as the abandonment of closed receptacles. In addition, neither the statute nor the regulations limit this definition to on-site releases. Therefore, the statutory definition of release under EPCRA section 313 is significantly broader than the commenter seems to believe.

In addition to release reporting, under section 6607(b)(1) of the PPA, if a covered facility meets the reporting thresholds under EPCRA section 313, the facility is required to report the ''quantity of the chemical entering any wastestream (or otherwise released to the environment). . . .'' This quantity includes amounts of the toxic chemical released, treated, and recycled. However, this quantity does not include:

> [t]he amount of any toxic chemical released into the environment which resulted from a catastrophic event, remedial action, or other one time event, *and is not associated with production processes during the reporting year.* (PPA 6607 (b)(7)) (emphasis added)

Therefore, the quantity of the toxic chemical entering the wastestream as collected under section 6607(b)(1) of the PPA, is the amount of the toxic chemical in production related waste. Covered facilities currently report the amount of the toxic chemical in production related waste as quantities of the toxic chemical released, treated, combusted for energy recovery and recycled. These quantities are collected as separate data elements in section 8 of the Form R. Further, facilities report the ultimate disposition of toxic chemicals in waste such that these quantities (i.e., amounts released, treated, combusted for energy recovery, and recycled) are mutually exclusive. Collectively, then, these quantities are the amount entering the waste stream or the quantity of the toxic chemical in production related waste. For example, a covered facility transfers 1,000,000 pounds of PCBs to an incinerator for treatment. The covered facility knows that 999,999 pounds are destroyed in the incinerator and the remaining 1 pound is disposed in a landfill. The facility reports 999,999 pounds as transferred off-site for treatment and 1 pound as transferred off-site for disposal. These two quantities are reported as separate data elements on the Form R. The quantity reported as disposed off-site is considered released because, as explained previously, disposal is a type of release. The entire quantity (1,000,000 pounds) is the amount of production related waste.

Once collected, EPA presents the TRI data to the public in a number of formats. In its annual data release documents, EPA highlights different aspects of the quantities of toxic chemicals released and otherwise managed as waste. For example, EPA presents total on-site releases and, as subsets, presents the quantities released to air, surface water, underground injection and on-site land releases. (See *1997 Toxics Release Inventory* (EPA 745–R–99–003) Figure 2-3 ''TRI On-site Releases'') EPA also presents the quantity of total releases in the public data release. As discussed earlier, under EPCRA section 313, release quantities are not limited to quantities released to the ambient environment. Therefore, total releases, as presented in the public data release include both on and off-site releases as well as a variety of disposal methods. For example, in Table 2-20A of the 1997 public data release, EPA presents TRI on-site and off-site releases by chemical and type of release (e.g., air emissions, underground injection, etc.) (*1997 Toxics Release Inventory*; EPA 745–R–99–003).

In addition to TRI release data, EPA presents production related waste quantities in the public data release. Because production related waste includes releases, EPA includes release quantities with other waste management quantities. However, in this document, the Agency generally distinguishes quantities of the toxic chemical released from other types of waste management. EPA does not count the quantities of toxic chemicals treated, combusted for energy recovery or recycled as quantities released. (See, for example, 1997 Toxics Release Inventory (EPA 745-R-99-003) Table 2-20A ''TRI On-site and Off-site Releases, by Chemical, 1997'' and Table 2-20B ''TRI Chemicals in Waste, by Chemical, 1997'')

Further, EPA does not believe that the TRI program provides a disincentive for the proper and safe handling of PCBs in transformers managed as waste. As explained earlier, covered facilities are required under EPCRA section 313 and section 6607 of the PPA to report quantities of toxic chemicals released or otherwise managed as waste if they meet a chemical activity threshold. Quantities of toxic chemicals sent off-site for treatment are described as such. These transfers are not included as releases. In addition, EPA disagrees that quantities of PCBs sent off-site for treatment will be misunderstood by the public because these quantities are accurately represented in the TRI data base and in the public data release as a separate type of waste management.

Another commenter asserts that the proposed rule will not encourage waste minimization because facilities will not be able to modify process designs to accomodate such minimization simply on the basis of data generated from guidance documents or reasonable estimates. The commenter asserts that although industry has made substantial minimization gains, the technology is not available to treat or remove chemicals of concern from manufactured products or waste (prior to generation) at such low

concentrations and that any future improvements will be enormously expensive due to the low concentrations that would likely be involved.

EPA disagrees with the commenter. In the preamble to the proposed rule, EPA did not assert that covered facilities will begin performing waste minimization activities as a direct result of this rulemaking. Rather, the Agency stated that the PBT chemical rulemaking will provide data on PBT chemicals to EPA, industry, and the public. For example, several EPA offices have ongoing projects and programs that deal with issues concerning PBT chemicals. EPA has established the PBT planning group which is a coordinating body consisting of representatives from various program offices throughout EPA that are dealing with PBT chemicals. This group has developed a strategy to reduce pollution from PBT chemicals through the application of regulatory and nonregulatory authorities, with a strong emphasis on pollution prevention. The availability of that data, in turn, can allow all parties to identify and track releases of PBT chemicals and monitor the progress of the programs designed to reduce the amount of PBT chemicals entering the environment. The data will also allow EPA and others to design prevention strategies that are focused and effective.

In addition, EPA disagrees with the commenter's last assertion concerning the available technology and its costs. Although there are some processes that might not, at present, be amenable to source reduction in terms of PBT chemicals, some processes may be. For example, it may be possible to stringently control fuel composition, flow times, temperature, and other conditions in order to substantially reduce or even eliminate the incidental manufacture of dioxins during combustion processes. Therefore, EPA continues to believe that in some cases, opportunities for pollution prevention will present themselves resulting from information reported under EPCRA section 313 and section 6607 of the PPA.

4. *Modulated reporting thresholds.* The majority of commenters contend that modulating thresholds for reporting so that lower reporting thresholds are used every other year (with current thresholds used in alternate years) would introduce confusion for the regulated community and data users and would not significantly reduce burden. Further it could discourage facilities from establishing common standard procedures for data collection. Modulation will also result in data gaps, undermining data consistency and tracking. Many commenters believe that annual reporting is a fundamental attribute of TRI.

EPA agrees that modulating the reporting thresholds would introduce confusion for both the regulated community and data users. For data users, EPA believes that modulating the reporting thresholds would limit the usefulness of the TRI data because there would be poor data consistency and poorer data quality. For the regulated community, EPA believes that the burden reduction would not be significant and would possibly be offset by the confusion that would be introduced by different thresholds in alternate years.

VII. What Were the Results of EPA's Economic Analysis?

EPA has prepared an economic analysis of the impact of this action, which is contained in a document entitled *Economic Analysis of the Final Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals under EPCRA Section 313* (Ref. 67). This document is available in the public docket for this rulemaking. The analysis assesses the costs, benefits, and associated impacts of the rule, including potential effects on small entities. The major findings of the analysis are briefly summarized here.

A. What is the Need for the Rule?

Federal regulations exist, in part, to address significant market failures. Markets fail to achieve socially efficient outcomes when differences exist between market values and social values. Two causes of market failure are externalities and information asymmetries. In the case of negative externalities, the actions of one economic entity impose costs on parties that are ''external'' to any market transaction. For example, a facility may release toxic chemicals without accounting for the consequences to other parties, such as the surrounding community, and the prices of that facility's goods or services thus will fail to reflect those costs. The market may also fail to efficiently allocate resources in cases where consumers lack information. For example, where information is insufficient regarding toxic releases, individuals' choices regarding where to live and work may not be the same as if they had more complete information. Since firms ordinarily have little or no incentive to provide information on their releases and other waste management activities involving toxic chemicals, the market fails to allocate society's resources in the most efficient manner.

This rule is intended to address the market failures arising from private choices about PBT chemicals that have societal costs, and the market failures created by the limited information available to the public about the release and other waste management activities involving PBT chemicals. Through the collection and distribution of facility-specific data on toxic chemicals, TRI overcomes firms' lack of incentive to provide certain information, and thereby serves to inform the public of releases and other waste management of PBT chemicals. This information enables individuals to make choices that enhance their overall well-being. Choices made by a more informed public, including consumers, corporate lenders, and communities, may lead firms to internalize into their business decisions at least some of the costs to society relating to their releases and other waste management activities involving PBT chemicals. In addition, by helping to identify areas of concern, set priorities and monitor trends, TRI data can also be used to make more informed decisions regarding the design of more efficient regulations and voluntary programs, which also moves society towards an optimal allocation of resources.

If EPA were not to take this action adding certain PBT chemicals to EPCRA section 313 and lowering reporting thresholds, the market failure (and the associated social costs) resulting from the limited information on the release and other waste management of PBT chemicals would continue. EPA believes that today's action will improve the scope of multi-media data on the release and other waste management of PBT chemicals. This, in turn, will provide information to the public, empower communities to play a meaningful role in environmental decision-making, and improve the quality of environmental decision-making by government officials. In addition, this action will serve to generate information that reporting facilities themselves may find useful in such areas as highlighting opportunities to reduce chemical use or release or other waste management and thereby lower costs of production and/or waste management. EPA believes that these are sound rationales for adding chemicals to the EPCRA section 313 list of toxic chemicals and lowering reporting thresholds for PBT chemicals.

B. What Are the Costs Associated With This Rule?

This action will result in the expenditure of resources that, in the absence of the regulation, could be used

for other purposes. The cost of the rule is the value of these resources in their best alternative use. Most of the costs of the rule result from requirements on industry. Approximately 11,300 facilities are expected to submit approximately 20,000 additional Form R reports annually. The estimated composition of this reporting, by chemical, is shown in Table 4.

Table 4.—Summary of Chemical Reporting as Estimated for Proposed and Final Rules

Chemical or Chemical Category	Estimated Number of Reports (Annual)	
	Proposed Rule	Final Rule
Alkyl lead (tetraethyl lead and tetramethyl lead)	134	N/A
Benzo(g,h,i)perylene	353	909
Dioxin and dioxin-like compounds category	1,863	1,475
Hexachlorobenzene	778	778
Mercury; mercury compounds category	5,230	5,346
Octachlorostyrene	230	230
Pentachlorobenzene	707	707
Pesticides (aldrin, chlordane, heptachlor, isodrin, methoxychlor, pendimethalin, toxaphene, trifluralin)	264	264
Polycyclic aromatic compounds (PACs) category	4,699	7,166
Polychlorinated biphenyls (PCBs)	2,267	2,310
Tetrabromobisphenol A	150	150
Vanadium; vanadium compounds category	654	655
Total	17,329	19,990

Table 5 displays the industry costs for this action based on the estimated number of facilities affected and the estimated number of additional reports. Aggregate industry costs in the first year for the rule are estimated to be $145 million; in subsequent years they are estimated to be $80 million per year. Industry costs are lower after the first year because facilities will be familiar with the reporting requirements, and many will be able to update or modify information from the previous year's report. EPA is expected to expend $2.0 million in the first year, and $1.6 million in subsequent years as a result of the rule.

Table 5.—Summary of Reporting and Associated Costs as Estimated for Proposed and Final Rules

	Proposed Rule	Final Rule
Number of new facilities	2,600	3,114
Total number of facilities	9,515	11,257
Number of Form Rs submitted	17,329	19,990
First year industry costs	$126 million	$145 million
Subsequent year industry costs	$70 million	$80 million
EPA costs	$1.4 million	$1.6 million

The estimated cost of the final rule differs from the estimated cost of the proposed rule as shown in Table 5. There are six major reasons for this change. First, EPA received new data during the comment period on the concentrations of PACs and benzo(g,h,i)perylene in distillate fuel oil. Since approximately 18,000 manufacturing facilities subject to EPCRA 313 reporting use distillate fuel oil, this change had a significant positive effect on the estimated number of reports for PACs and benzo(g,h,i)perylene as shown in Table 4. Second, the methodology for estimating reporting from facilities in SIC 5171 (Bulk Petroleum Stations and Terminals) was revised to account for the mix of products containing PBT chemicals that are processed at these facilities. This revision also had a positive effect on the estimated number of reports. Third, because facility-level dioxin emission factors for coal- and oil-burning manufacturing facilities have not been developed, the estimated number of reporting facilities was reduced. Fourth, the reporting qualifier for dioxin was changed from

''manufacture only'' to ''manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical'' in the final rule. This resulted in additional expected reporting from facilities that process or otherwise use chemicals with dioxin impurities. Fifth, the Agency is not lowering EPCRA section 313 reporting thresholds for alkyl leads as part of this rulemaking. Therefore, no additional EPCRA section 313 reporting on alkyl leads is expected at this time. Sixth, the threshold for the PACs category was changed from 10 pounds in the proposed rule to 100 pounds in the final rule.

C. What Are the Benefits of This Rule?

In enacting EPCRA and PPA, Congress recognized the significant benefits of providing the public with information on toxic chemical releases and other waste management practices. EPCRA section 313 has empowered the Federal government, State governments, industry, environmental groups, and the general public to fully participate in an informed dialogue about the environmental impacts of toxic chemicals in the United States. EPCRA section 313's publicly available data base provides quantitative information on toxic chemical releases and other waste management practices. Since the TRI program's inception in 1987, the public, government, and the regulated community have had the ability to understand the magnitude of chemical releases in the United States, and to assess the need to reduce the uses, releases and other waste management of toxic chemicals. TRI enables all interested parties to establish credible baselines, to set realistic goals for environmental progress over time, and to measure progress in meeting these goals over time. The TRI program is a neutral yardstick by which progress can be measured by all stakeholders.

The information reported under EPCRA section 313 increases knowledge of the amount of toxic chemicals released and waste management practices, and thus aids in the evaluation of the potential pathways of exposure, improves scientific understanding of the health and environmental risks of toxic chemicals; allows the public to make informed decisions on where to work and live; enhances the ability of corporate leaders and purchasers to more accurately gauge a facility's potential environmental liabilities; provides reporting facilities with information that can be used to save money as well as reduce emissions; and assists Federal, State, and local authorities in making better decisions on acceptable levels of toxic chemicals in the environment.

There are two types of benefits associated with EPCRA section 313 reporting, those resulting from the actions required by the rule (such as reporting and recordkeeping), and those derived from follow-on activities that are not required by the rule. Benefits of activities required by the rule include the value of improved knowledge about the release and waste management of toxic chemicals, which leads to improvements in understanding, awareness, and decision-making. It is expected that this rule will generate such benefits by providing readily accessible information that otherwise would not be available to the public. The rule will benefit ongoing research efforts to understand the risks posed by PBT chemicals and to evaluate policy strategies that address the risks.

The second type of benefits derive from changes in behavior that may result from the information reported under EPCRA section 313. These changes in behavior, including reductions in releases of and changes in the waste management practices for toxic chemicals may yield health and environmental benefits. These changes in behavior come at some cost, and the net benefits of the follow-on activities are the difference between the benefits of decreased chemical releases and transfers and the costs of the actions needed to achieve the decreases.

Because the state of knowledge about the economics of information is not highly developed, EPA has not attempted to quantify the benefits of adding chemicals to EPCRA section 313 or changing reporting thresholds. Furthermore, because of the inherent uncertainty in the subsequent chain of events, EPA has also not attempted to predict the changes in behavior that result from the information, or the resultant net benefits (i.e., the difference between benefits and costs). EPA does not believe that there are adequate methodologies to make reasonable monetary estimates of either the benefits of the activities required by the rule, or the follow-on activities. The economic analysis of the rule, however, does provide illustrative examples of how the rule will improve the availability of information on PBT chemicals (Ref. 67).

A number of commenters asserted that information on the magnitude of PBT chemical releases that would be reported as a result of this rule is required for EPA and commenters to evaluate the benefit of EPA's proposed alternatives. EPA disagrees with these commenters for the following reasons.

Existing data do not support estimates of releases to multiple environmental media from the full range of facilities that may be affected by the rule because most of the data required for the analysis would only be available after the rule is in place. For most PBT chemicals and industry sectors, up-to-date multi-media release and other waste management estimates for affected facilities do not exist. Even where release estimates are available for an industry sector, most are derived from national activity levels rather than from facility-level information. To the extent that release estimates are available, they tend to cover only a single medium such as air. EPA does not believe that there is sufficient information to make reasonable predictions of the multi-media releases and other waste management information that will be reported as a result of EPCRA section 313 rulemakings.

Some commenters note that EPA has estimated releases of certain PBT chemicals in recent reports such as the Mercury Study Report to Congress (Ref. 65) and the Inventory of Source of Dioxin in the United States (Ref. 73). In fact, EPA reported the results of these reports in its economic analysis for this proposal. These studies do not provide community- or facility-level release estimates. The estimates in these studies are derived using a ''top-down'' methodology in which emission factors are applied to activity levels for entire industries. While having an estimate of multi-media PBT releases for a specific industry sector is a first step, other information would also be required to estimate the releases that would be reported as a result of each proposed alternative. Assuming that multi-media release estimates were available for an entire industry sector, these releases would still have to be divided among individual facilities according to some currently unknown distribution. In addition, there is the complication that EPCRA section 313 reporting thresholds are based on chemical throughput (manufacture, process, or use) rather than chemical release. The relationship between a chemical throughput that triggers the submission of a report, and the releases reported will vary in some currently unknown manner among industries, as well as among facilities within an industry.

Therefore, EPA does not believe that there is sufficient information to make reliable release estimates for this rule, when considering all the affected chemicals and industries. The

uncertainties in the estimated values that go into such a calculation make predictions of facility level reporting extremely imprecise. Historical attempts to estimate the releases expected to be reported under EPCRA section 313 would have been imprecise to the point of being misleading, particularly in respect to estimates of releases per report or per facility (which some commenters have suggested that EPA should make). Further information on the feasibility of *ex ante* release estimates is available in the Response to Comments document (Ref. 69).

Aside from the general issue of uncertainty in the estimates of aggregate releases, predictions of releases per facility or per report (or dollars of reporting cost per pound of releases reported) are likely to be misleading due to the biases built into the estimates. The predicted number of reports (and thus costs) is generally an overestimate, since EPA's economic analyses use conservative estimates to avoid underestimating true costs. On the other hand, predictions of releases will tend to underestimate emissions, because while there may be information available on releases of some chemicals from some sectors, such estimates will not include other sources where releases are not identified until more detailed data (such as TRI data) are collected. Combining the two sets of estimates compounds the problem. Since estimated pounds of releases are underestimated and reports are overestimated, pounds per report would be biased significantly downward. Likewise, estimates of dollars of reporting cost per pound of releases (which varies as the inverse of pounds per report) would be biased significantly upward.

EPA notes that there were various reports and studies about air emissions of toxic chemicals prior to EPCRA section 313, but the collection of facility-level data provided significant new information on releases as well as other waste management. EPA cannot predict, at this stage, the quantity of releases and other waste management that will be reported as the result of this action any more accurately than it could have predicted when it proposed the original EPCRA section 313 rule.

Aside from the issue of whether EPA can predict releases and other waste management quantities prior to TRI reporting, EPA notes that pounds of releases (even if known) are not a reasonable proxy for the benefits of the information being provided. This is because the benefits of an informational regulation are not a linear function of the magnitude of the information being reported. EPA disagrees with the implicit assumption by commenters that the benefits of information from different facilities is strictly and systematically related to the quantity reported as being released. Calculations such as the commenters have suggested presume that the benefit to the public of knowing about a release of 20,000 pounds is twice as large as the benefit of knowing about a release of 10,000 pounds; and that the benefit of knowing about a 40,000 pound release is twice the benefit of knowing about a 20,000 pound release and four times the benefit of knowing about a 10,000 pound release. EPA does not believe this characterization to be accurate.

One of the central purposes of TRI data is to inform the public about releases and other waste management of EPCRA section 313 listed toxic chemicals in their community so that the public can form its own conclusions about risks. The amount of releases and waste management quantities that a community may find relevant or useful will vary depending on numerous factors specific to that community, such as the toxicity of the various chemicals, potential exposure to these toxic chemicals, and the number of other facilities in the area that release EPCRA section 313 listed toxic chemicals. Section 313(h) of EPCRA states that the data are ''to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes'' (See Unit VI.E. for a more detailed discussion on the purposes of EPCRA section 313). Pounds of releases reported does not measure how the data perform these functions, and thus is not a measure of benefits.

Finally, EPA notes that commenters on this rule did not provide information on approaches or methodologies for estimating releases and/or throughput, or on estimating releases from throughput data, for the spectrum of industries, chemicals, and facilities covered by the rule. Instead, some commenters submitted data from EPA studies (that EPA had already reviewed in the context of this rule and used as references for the economic analysis of the proposed rule) for very narrow slices of the regulated universe (for example, estimated mercury releases from electric utilities or estimated dioxin releases from the vinyl industry). EPA considered these data and determined that they are not sufficient to predict the releases and/or throughput that will be reported as a result of this rule. Other commenters simply stated that EPA should consider releases without referencing any data. None of the commenters suggested new methodologies or approaches, or provided information from any sources that EPA had not already reviewed and considered. As a result, EPA continues to conclude that while there are data available to estimate national releases for some chemicals for some sectors, comprehensive, reliable data for all sectors and chemicals are unavailable, resulting in an incomplete data set. Furthermore, as stated previously, the quantity of releases reported are not a measure of the benefits of the rule. EPA does not believe that inaccurate or incomplete estimates of releases would aid the decision-making process for the rule. Therefore, EPA has not estimated the releases that would be reported as a result of the rule.

D. What are the Potential Impacts on Small Entities?

In accordance with the Regulatory Flexibility Act (RFA) and the Agency's longstanding policy of always considering whether there may be a potential for adverse impacts on small entities, the Agency has evaluated the potential impacts of this rule on small entities. The Agency's analysis of potentially adverse economic impacts is included in the Economic Analysis for this rule (Ref. 67). The following is a brief overview of EPA's findings.

1. *Overall methodology*. This rule may affect both small businesses and small governments. For the purpose of its analysis for the rule, EPA defined a small business using the small business size standards established by the Small Business Administration (SBA) at 13 CFR part 121. EPA defined small governments using the RFA definition of jurisdictions with a population of less than 50,000. No small organizations are expected to be affected by the rule.

Only those small entities that are expected to submit at least one report are considered to be affected for the purpose of the small entity analysis, although EPA recognizes that other small entities will conduct compliance determinations under lower thresholds. The number of affected entities will be smaller than the number of affected facilities, because many entities operate more than one facility. Impacts were calculated for both the first year of reporting and subsequent years. First year costs are typically higher than continuing costs because firms must familiarize themselves with the requirements. Once firms have become familiar with how the reporting

requirements apply to their operations, costs fall. EPA believes that subsequent year impacts present the best measure to judge the impact on small entities because these continuing costs are more representative of the costs firms face to comply with the rule.

EPA analyzed the potential cost impact of the rule on small businesses and governments for the manufacturing sector and in each of the recently added industry sectors separately in order to obtain the most accurate assessment for each. EPA then aggregated the analyses for the purpose of determining whether it could certify that the rule will not, if promulgated, have a ''significant economic impact on a substantial number of small entities.'' RFA section 605(b) provides an exemption from the requirement to prepare a regulatory flexibility analysis for a rule where an agency makes and supports the certification statement quoted above. EPA believes that the statutory test for certifying a rule and the statutory consequences of not certifying a rule all indicate that certification determinations may be based on an aggregated analysis of the rule's impact on all of the small entities subject to it.

2. *Small businesses*. EPA used annual compliance costs as a percentage of annual company sales to assess the potential impacts on small businesses of this rule. EPA believes that this is a good measure of a firm's ability to afford the costs attributable to a regulatory requirement, because comparing compliance costs to revenues provides a reasonable indication of the magnitude of the regulatory burden relative to a commonly available measure of a company's business volume. Where regulatory costs represent a small fraction of a typical firm's revenue (for example, less than 1%, but not greater than 3%), EPA believes that the financial impacts of the regulation may be considered not significant. As discussed above, EPA also believes that it is appropriate to apply this measure to subsequent year impacts.

Based on its estimates of additional reporting as a result of the rule, the Agency estimates that approximately 6,300 businesses will be affected by the rule, and that approximately 4,400 of these businesses are classified as small based on the applicable SBA size standards. For the first reporting year, EPA estimates that approximately 17 small businesses may bear compliance costs between 1% and 3% of revenues, and that no small businesses will bear costs greater than 3%. In subsequent years, EPA estimates that approximately 5 small businesses may bear compliance costs between 1% and 3% of revenues, and that no small businesses will bear costs greater than 3%. As stated above, EPA believes that subsequent-year impacts are the appropriate measure of small business impacts.

3. *Small governments*. To assess the potential impacts on small governments, EPA used annual compliance costs as a percentage of annual government revenues to measure potential impacts. Similar to the methodology for small businesses, this measure was used because EPA believes it provides a reasonable indication of the magnitude of the regulatory burden relative to a government's ability to pay for the costs, and is based on readily available data.

EPA estimates that 39 municipalities operate 49 publicly owned electric utility facilities. Of these facilities, 44 are expected to file additional reports as a result of this action. Of these affected facilities, 15 are operated by 15 small governments (i.e., those with populations under 50,000). It is estimated that none of these small governments will bear annual costs greater than 1% of annual government revenues.

4. *All small entities*. As discussed above, approximately 5 small businesses are expected to bear annual costs between 1% and 3% of annual revenues after the first year of reporting. None of the affected small governments are estimated to bear annual costs greater than 1% of annual revenues. No small organizations are expected to be affected by the rule. Thus, the total number of small entities with impacts above 1% of revenues does not change when the results are aggregated for all small entities (i.e., small businesses, small governments, and small organizations).

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IX. Which Regulatory Assessment Requirements Apply to This Action?

A. What is the Determination under Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this is an economically ''significant regulatory action'' because it is likely to have an annual effect of $100 million or more. This action was submitted to the Office of Management and Budget (OMB) for review, and any substantive comments or changes made during that review have been documented in the public version of the official record.

EPA has prepared an economic analysis of the impact of this action, which is contained in a document entitled *Economic Analysis of the Final Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals under EPCRA Section 313* (Ref. 67). This document is available as a part of the public version of the official record for this action (instructions for accessing this document are contained in Unit I.B.) and is discussed in Unit VII.

B. What is the Determination under the Regulatory Flexibility Act?

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the EPA Administrator hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is presented in the small entity impact analysis prepared as part of the Economic Analysis for this final rule (Ref. 67), which is also discussed in detail in Unit VII. and contained in the public version of the official record for this rule. The following is a brief summary of the Agency's factual basis for this certification.

For the purpose of analyzing potential impacts on small entities, EPA used the RFA definition of small entities in section 601(6) of the RFA. Under this section, small entities include small governments, small non-profit organizations, and small businesses. No small organizations are expected to be affected by this final rule. EPA defined small governments using the RFA definition of jurisdictions with a population of less than 50,000, and defined a small business using the small business size standards established by the Small Business Administration (SBA), which are generally based on the number of employees or annual sales/revenue a business in a particular industrial sector has.

Based on EPA's economic analysis, approximately 11,300 facilities are expected to submit approximately 20,000 additional Form R reports annually. Of these facilities, approximately 3,100 are expected to file TRI reports for the first time as a result of today's action. EPA estimates that the cost for collecting this information averages $5,079 per Form R in the first reporting year, and $3,557 in subsequent years. EPA estimates that there are 15 small governments that may be affected by the rule (i.e., EPA analysis estimates that these entities may have to file one or more reports under the final rule). EPA estimates that none of these small governments will bear annual costs greater than 1% of annual government revenues. EPA estimates that 5 small businesses of the approximately 4,400 small businesses potentially affected by the rule will experience annual compliance costs between 1% and 3% of annual sales after the first year of reporting. Given the relatively small estimated impacts on small entities, EPA believes that the rule will not have a significant economic impact on a substantial number of small entities. This determination is for the entire population of small entities potentially affected by this rule, since the test for certification is whether the rule as a whole has a significant economic impact on a substantial number of small entities.

Notwithstanding the Agency's certification of this rule under section 605(b) of the RFA, EPA remains committed to minimizing real impacts

on small entities where this does not unacceptably compromise the informational benefits of the rule. Although not required, EPA intends to prepare guidance for reporting on dioxin that will assist facilities in determining their compliance needs and in properly completing the form, which will help ensure that small entities receive assistance to ease their burden of compliance. EPA has prepared such documents for current reporters and has received positive feedback on their utility from the targeted facilities. In addition, the Agency is always interested in any comments regarding the economic impacts that this regulatory action would impose on small entities, particularly suggestions for minimizing that impact. Such comments may be submitted to the Agency at any time, to the address listed in Unit I.B.

Information relating to this determination has been provided to the Chief Counsel for Advocacy of the Small Business Administration, and is included in the public version of the official record for this rulemaking.

C. What is the Determination under the Paperwork Reduction Act?

The information collection requirements contained in this final rule have been submitted to OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and in accordance with the procedures at 5 CFR 1320.11. OMB has approved the existing reporting and recordkeeping requirements EPA Toxic Chemical Release Inventory Form R (EPA Form No. 9350-1), supplier notification, and petitions under OMB Control No. 2070–0093 (EPA ICR No. 1363). An Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No. 1363.10) to amend the existing ICR to include the burden associated with the lower reporting thresholds, and a copy may be obtained from Sandy Farmer, Office of Information Collections (OIC); U.S. Environmental Protection Agency (2137), 401 M St., SW., Washington, DC 20460, by calling (202) 260–2740, or electronically by sending an e-mail message to ''farmer.sandy@epa.gov.'' An electronic copy has also been posted with this **Federal Register** document on EPA's Homepage with other information related to this action as described in Unit I.B., and may also be downloaded from the Internet at http://www.epa.gov.icr/.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register**, are maintained in a list at 40 CFR part 9. The information requirements contained in this final rule are not effective until OMB approves them.

EPCRA section 313 requires owners or operators of certain facilities manufacturing, processing, or otherwise using any of over 600 listed toxic chemicals and chemical categories in excess of the applicable threshold quantities, and meeting certain requirements (i.e., at least 10 Full Time Employees or the equivalent), to report environmental on-site releases and transfers off-site for release and treatment. Under section 6607 of the PPA, facilities must also provide information on the quantities of the toxic chemicals in certain waste streams, and the efforts made to manage those waste quantities. The regulations codifying the EPCRA section 313 reporting requirements appear at 40 CFR part 372. Respondents may designate the specific chemical identity of a substance as a trade secret, pursuant to EPCRA section 322 (42 U.S.C. 11042). Regulations codifying the trade secret provisions can be found at 40 CFR part 350. Under the final rule, all facilities reporting under EPCRA section 313 on PBT chemicals would have to use the Form R (EPA Form No. 9350-1), which is currently approved by OMB.

For Form R, EPA estimates the industry reporting burden for collecting this information (including recordkeeping) to average 74 hours per report in the first year, at an estimated cost of $5,079 per Form R. In subsequent years, the burden is estimated to average 52.1 hours per report, at an estimated cost of $3,557 per Form R. These estimates include the time needed to review instructions; search existing data sources; gather and maintain the data needed; complete and review the collection of information; and transmit or otherwise disclose the information. The actual burden on any specific facility may be different from this estimate depending on the complexity of the facility's operations and the profile of the releases at the facility.

This final rule is estimated to result in reports from 11,300 respondents. Of these, 3,100 facilities are estimated to be reporting under EPCRA section 313 for the first time as a result of the rule, while 8,200 are currently reporting facilities that will be submitting additional reports. These facilities will submit an estimated additional 20,000 Form Rs. This rule therefore results in an estimated total burden of 2.1 million hours in the first year, and 1.2 million hours in subsequent years, at a total estimated industry cost of $145 million in the first year and $80 million in subsequent years. The existing ICR will be amended to include an additional annual burden of 1.5 million hours (annual average burden for the first 3 years of ICR approval).

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes, where applicable, the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. EPA's burden estimates for the rule take into account all of the above elements, considering that under section 313, no additional measurement or monitoring may be imposed for purposes of reporting.

D. What are the Determinations under the Unfunded Mandates Reform Act and Executive Orders 12875 and 13084?

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action contains a Federal mandate that may result in expenditures of $100 million or more for the private sector in any 1 year, but that it will not result in such expenditures for State, local, and tribal governments, in the aggregate. Accordingly, EPA has prepared a written statement for this rule pursuant to section 202 of UMRA, and that statement is available in the public version of the official record for this rulemaking (Ref. 71a). The costs associated with this action are estimated in the economic analysis prepared for this rule (Ref. 67), which is also included in the public version of the official record and summarized in Unit VII. The following is a brief summary of the UMRA statement for the rule.

This rule is being promulgated pursuant to sections 313(d)(1) and (2), 313(f)(2), 313(g), 313(h), and 328 of EPCRA, 42 U.S.C. 11023(d)(1)–(2), 11023(f)(2), 11023(g), 11023(h) and

11048; PPA section 6607, 42 U.S.C. 13106. The economic analysis contains an analysis of the benefits and costs of this rule, which estimates that the total industry costs of the rule will be $145 million in the first year and $80 million per year thereafter, and concludes that the benefits will be significant but cannot be assigned a dollar value due to the lack of adequate methodologies. EPA believes that the benefits provided by the information to be reported under this rule will significantly outweigh the costs imposed by today's action. The benefits of the information will in turn have positive effects on health, safety, and the natural environment through the behavioral changes that may result from that information.

EPA has not identified any Federal financial resources that are available to cover the costs of this rule. As set forth in the economic analysis, EPA has estimated the future industry compliance costs (after the first year) of this rule to be $80 million annually. Of those entities affected by today's action, EPA has not identified any disproportionate budgetary impact on any particular region, government, or community, or on any segment of the private sector. Based on the economic analysis, EPA has concluded that it is highly unlikely that this rule will have an appreciable effect on the national economy.

EPA has determined that it is not required to develop a small government agency plan as specified by section 203 of UMRA or to conduct prior consultation with State, local, or tribal governments under section 204 of UMRA, because the rule will not significantly or uniquely affect small governments and does not contain a significant Federal intergovernmental mandate.

Finally, EPA believes this rule complies with section 205(a) of UMRA. The objective of this rule is to expand the public benefits of the TRI program by exercising EPA's discretionary authority to add chemicals to the program and to lower reporting thresholds, thereby increasing the amount of information available to the public regarding the use, management, and disposition of PBT chemicals and enabling a more comprehensive view of PBT chemical exposures. In making additional information available through TRI, the Agency increases the utility of TRI data as an effective tool for empowering local communities, the public sector, industry, other agencies, and State and local governments to better evaluate risks to public health and the environment.

As described in Unit IV.D., EPA considered burden in the threshold selection. Existing burden-reducing measures (e.g., the laboratory exemption and the otherwise use exemptions, which include the routine janitorial or facility grounds maintenance exemption, motor vehicle maintenance exemption, structural component exemption, intake air and water exemption and the personal use exemption) will continue to apply to the facilities that file new reports as a result of this rule. EPA also will be assisting small entities subject to the rule, by such means as providing meetings, training, and compliance guides in the future, which also will ease the burdens of compliance. Many steps have been and will be taken to further reduce the burden associated with this rule, and to EPA's knowledge there is no available alternative to the rule that would obtain the equivalent information in a less burdensome manner. For all of these reasons, EPA believes the rule complies with UMRA section 205(a).

In addition, today's rule does not create an unfunded Federal mandate on State, local or tribal governments, nor does it significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 1(a) of Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), and section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), do not apply to this proposed rule.

E. What are the Determinations under Executive Orders 12898 and 13045?

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency must consider environmental justice related issues with regard to the potential impacts of this action on environmental and health conditions in low-income populations and minority populations. Pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), if an action is economically significant under Executive Order 12866, the Agency must, to the extent permitted by law and consistent with the Agency's mission, identify and assess the environmental health risks and safety risks that may disproportionately affect children.

By lowering the section 313 reporting thresholds for PBT chemicals, EPA will provide communities across the United States (including low-income populations and minority populations) with access to data that may assist them in lowering exposures and consequently reducing chemical risks for themselves and their children. This information can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, the informational benefits of the rule will have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children.

F. What are the Determinations under Executive Orders 13132 and 12612?

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), which will take effect on November 2, 1999. In the interim, the current Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987) still applies. This action is expected to have a limited impact on municipal governments which operate electric utilities. EPA estimates that 39 municipalities operate 49 publicly owned electric utility facilities. Of these facilities, 44 are expected to file additional reports as a result of this action. Therefore EPA concludes that this rule will not have a substantial direct effect on 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 12612.

G. What are the Determinations under the National Technology Transfer and Advancement Act?

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use

available and applicable voluntary consensus standards.

This action does not involve technical standards, nor did EPA consider the use of any voluntary consensus standards. In general, EPCRA does not prescribe technical standards to be used for threshold determinations or completion of EPCRA section 313 reports. EPCRA section 313(g)(2) states that ''In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation.''

H. What are the Determinations under the Congressional Review Act?

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective December 31, 1999.

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements, Superfund.

Dated: October 25, 1999.

Carol M. Browner,

Administrator.

Therefore, 40 CFR part 372 is amended as follows:

PART 372—[AMENDED]

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

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

§ 372.22 [Amended]

2. In § 372.22(c), remove the phrase ''§ 372.25 or § 372.27.'' and add in its place ''§ 372.25, § 372.27, or § 372.28.''.

§ 372.25 [Amended]

3. Section 372.25 is amended as follows:

i. In the introductory text of § 372.25, remove the first clause ''Except as provided in § 372.27,'' and add in its place ''Except as provided in §§ 372.27 and 372.28,''.

ii. In paragraphs (f), (g), and (h), remove the reference ''§ 372.25'' and add in its place ''§ 372.25, § 372.27, or § 372.28''.

4. In § 372.27, add a new paragraph (e) to read as follows:

§ 372.27 Alternate threshold and certification.

* * * * *

(e) The provisions of this section do not apply to any chemicals listed in § 372.28.

5. Add a new § 372.28 to subpart B to read as follows:

§ 372.28 Lower thresholds for chemicals of special concern.

(a) Notwithstanding § 372.25 or § 372.27, for the toxic chemicals set forth in this section, the threshold amounts for manufacturing (including importing), processing, and otherwise using such toxic chemicals are as set forth in this section.

(1) Chemical listing in alphabetic order.

Chemical name	CAS No.	Reporting threshold
Aldrin	00309–00–2	100
Benzo(g,h,i)perylene	00191–24–2	10
Chlordane	00057–74–9	10
Heptachlor	00076–44–8	10
Hexachlorobenzene	00118–74–1	10
Isodrin	00465–73–6	10
Mercury	07439–97–6	10
Methoxychlor	00072–43–5	100
Octachlorostyrene	29082–74–4	10
Pendimethalin	40487–42–1	100
Pentachlorobenzene	00608–93–5	10
Polychlorinated biphenyl (PCBs)	01336–36–3	10
Tetrabromobisphenol A	00079–94–7	100
Toxaphene	08001–35–2	10
Trifluralin	01582–09–8	100

(2) Chemical categories in alphabetic order.

Category name	Reporting threshold
Dioxin and dioxin-like compounds (Manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical) (This category includes only those chemicals listed below).	0.1 grams
67562–39–4 1,2,3,4,6,7,8-Heptachlorodibenzofuran	

Category name		Reporting threshold
55673–89–7	1,2,3,4,7,8,9-Heptachlorodibenzofuran	
70648–26–9	1,2,3,4,7,8-Hexachlorodibenzofuran	
57117–44–9	1,2,3,6,7,8-Hexachlorodibenzofuran	
72918–21–9	1,2,3,7,8,9-Hexachlorodibenzofuran	
60851–34–5	2,3,4,6,7,8-Hexachlorodibenzofuran	
39227–28–6	1,2,3,4,7,8-Hexachlorodibenzo-*p*-dioxin	
57653–85–7	1,2,3,6,7,8-Hexachlorodibenzo-*p*-dioxin	
19408–74–3	1,2,3,7,8,9-Hexachlorodibenzo-*p*-dioxin	
35822–46–9	1,2,3,4,6,7,8-Heptachlorodibenzo-*p*-dioxin	
39001–02–0	1,2,3,4,6,7,8,9-Octachlorodibenzofuran	
03268–87–9	1,2,3,4,6,7,8,9-Octachlorodibenzo-*p*-dioxin	
57117–41–6	1,2,3,7,8-Pentachlorodibenzofuran	
57117–31–4	2,3,4,7,8-Pentachlorodibenzofuran	
40321–76–4	1,2,3,7,8-Pentachlorodibenzo-*p*-dioxin	
51207–31–9	2,3,7,8-Tetrachlorodibenzofuran	
01746–01–6	2,3,7,8 Tetrachlorodibenzo-*p*-dioxin	
Mercury compounds		10
Polycyclic aromatic compounds (PACs) (This category includes only those chemicals listed below).		100
00056–55–3	Benz(a)anthracene	
00205–99–2	Benzo(b)fluoranthene	
00205–82–3	Benzo(j)fluoranthene	
00207–08–9	Benzo(k)fluoranthene	
00206–44–0	Benzo(j,k)fluorene	
00189–55–9	Benzo(r,s,t)pentaphene	
00218–01–9	Benzo(a)phenanthrene	
00050–32–8	Benzo(a)pyrene	
00226–36–8	Dibenz(a,h)acridine	
00224–42–0	Dibenz(a,j)acridine	
00053–70–3	Dibenzo(a,h)anthracene	
00194–59–2	7H-Dibenzo(c,g)carbazole	
05385–75–1	Dibenzo(a,e)fluoranthene	
00192–65–4	Dibenzo(a,e)pyrene	
00189–64–0	Dibenzo(a,h)pyrene	
00191–30–0	Dibenzo(a,l)pyrene	
00057–97–6	7,12-Dimethylbenz(a)anthracene	
00193–39–5	Indeno[1,2,3-cd]pyrene	
00056–49–5	3-Methylcholanthrene	
03697–24–3	5-Methylchrysene	
05522–43–0	1-Nitropyrene	

(b) The threshold determination provisions under § 372.25(c) through (h) and the exemptions under § 372.38(b) through (h) are applicable to the toxic chemicals listed in paragraph (a) of this section.

§ 372.30 [Amended]

6. Section 372.30 is amended as follows:

i. In paragraph (a), remove the phrase ''in § 372.25 at'' and add in its place ''in § 372.25, § 372.27, or § 372.28 at''.

ii. In paragraphs (b)(1), the introductory text of (b)(3), (b)(3)(i), and (b)(3)(iv), remove the reference ''§ 372.25'' and add in its place ''§ 372.25, § 372.27, or § 372.28''.

§ 372.38 [Amended]

7. Section 372.38 is amended as follows:

i. In paragraph (a), add the following sentence at the end of the paragraph to read as follows: ''This exemption does not apply to toxic chemicals listed in § 372.28, except for purposes of § 372.45(d)(1).''.

ii. In paragraphs (b), (c) introductory text, (d) introductory text, and (f), remove the reference ''§ 372.25'' and add in its place ''§ 372.25, § 372.27, or § 372.28''.

iii. In paragraphs (g) and (h), remove the phrase ''§ 372.25 or § 372.27'' and add in its place ''§ 372.25, § 372.27, or § 372.28''.

8. Section 372.65 is amended as follows:

i. In the table in paragraph (a), revise the entry for ''Vanadium'' and alphabetically add four chemicals.

ii. In the table in paragraph (b), revise the CAS no. entry ''7440–62–2'' and add four chemicals in numerical CAS no. sequence.

iii. In the table in paragraph (c), alphabetically add two categories, ''dioxin and dioxin-like compounds'' and ''vanadium'', and alphabetically add two chemicals, ''benzo(j,k)fluorene'' and ''3-methylcholanthrene'', under the polycyclic aromatic compounds (PACs) category.

The revisions and additions read as follows:

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

* * * * *

(a) * * *

Chemical name	CAS No.	Effective date
* * * *	* * *	
Benzo(g,h,i)perylene	00191–24–2	1/00
* * * *	* * *	
Octachlorostyrene	29082–74–4	1/00
* * * *	* * *	
Pentachlorobenzene	00608–93–5	1/00
* * * *	* * *	
Tetrabromobisphenol A	00079–94–7	1/00
* * * *	* * *	
Vanadium (except when contained in an alloy)	7440–62–2	1/00
* * * *	* * *	

(b) * * *

CAS No.	Chemical name	Effective date
* * * * * * *		
7440–62–2	Vanadium (except when contained in an alloy)	1/00
* * * * * * *		
00079–94–7	Tetrabromobisphenol A	1/00
00191–24–2	Benzo(g,h,i)perylene	1/00
00608–93–5	Pentachlorobenzene	1/00
* * * * * * *		
29082–74–4	Octachlorostyrene	1/00
* * * * * * *		

(c) * * *

Category name	Effective date
* * * * * * *	
Dioxin and dioxin-like compounds (Manufacturing; and the processing or otherwise use of dioxin and dioxin-like compounds if the dioxin and dioxin-like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical)	
(This category includes only those chemicals listed below)	1/00
67562–39–4 1,2,3,4,6,7,8-Heptachlorodibenzofuran	
55673–89–7 1,2,3,4,7,8,9-Heptachlorodibenzofuran	
70648–26–9 1,2,3,4,7,8-Hexachlorodibenzofuran	
57117–44–9 1,2,3,6,7,8-Hexachlorodibenzofuran	
72918–21–9 1,2,3,7,8,9-Hexachlorodibenzofuran	
60851–34–5 2,3,4,6,7,8-Hexachlorodibenzofuran	
39227–28–6 1,2,3,4,7,8-Hexachlorodibenzo-*p*-dioxin	
57653–85–7 1,2,3,6,7,8-Hexachlorodibenzo-*p*-dioxin	
19408–74–3 1,2,3,7,8,9-Hexachlorodibenzo-*p*-dioxin	
35822–46–9 1,2,3,4,6,7,8-Heptachlorodibenzo-*p*-dioxin	
39001–02–0 1,2,3,4,6,7,8,9-Octachlorodibenzofuran	
03268–87–9 1,2,3,4,6,7,8,9-Octachlorodibenzo-*p*-dioxin	
57117–41–6 1,2,3,7,8-Pentachlorodibenzofuran	
57117–31–4 2,3,4,7,8-Pentachlorodibenzofuran	
40321–76–4 1,2,3,7,8-Pentachlorodibenzo-*p*-dioxin	
51207–31–9 2,3,7,8-Tetrachlorodibenzofuran	
01746–01–6 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin	

Category name		Effective date
* * * * * * *		
Polycyclic aromatic compounds (PACs): This category includes only those chemicals listed below).		
* * * * * * *		
00206–44–0	Benzo(j,k)fluorene	1/00
* * * * * * *		
00056–49–5	3-Methylcholanthrene	1/00
* * * * * * *		
Vanadium compounds		1/00

9. In § 372.85, revise the introductory text of paragraph (b)(15)(i), add a new paragraph (b)(15)(ii), and revise paragraphs (b)(16)(i)(B) and (b)(16)(ii)(B) to read as follows:

§ 372.85 Toxic chemical release reporting form and instructions.

* * * * *

(b) * * *

(15) * * *

(i) An estimate of total releases in pounds (except for dioxin and dioxin-like compounds, which shall be reported in grams) per year (releases of less than 1,000 pounds per year may be indicated in ranges, except for chemicals set forth in § 372.28) from the facility plus an indication of the basis of estimate for the following:

* * * * *

(ii) Report a distribution of the chemicals included in the dioxin and dioxin-like compounds category. Such distribution shall either represent the distribution of the total quantity of dioxin and dioxin-like compounds released to all media from the facility; or its one best media-specific distribution.

(16) * * *

(i) * * *

(B) An estimate of the amount of the chemical transferred in pounds (except for dioxin and dioxin-like compounds, which shall be reported in grams) per year (transfers of less than 1,000 pounds per year may be indicated as a range, except for chemicals set forth in § 372.28) and an indication of the basis of the estimate.

* * * * *

(ii) * * *

(B) An estimate of the amount of the chemical in waste transferred in pounds (except for dioxin and dioxin-like compounds, which shall be reported in grams) per year (transfers of less than 1,000 pounds may be indicated in ranges, except for chemicals set forth in § 372.28) to each off-site location, and an indication of the basis for the estimate and an indication of the type of treatment or disposal used.

* * * * *

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