ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[OPPTS–400132; FRL–6032–3]

RIN 2070–AD09

Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Amendments to Proposed Addition of a Dioxin and Dioxin-Like Compounds Category; Toxic Chemical Release Reporting; Community Right-to-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to lower the reporting thresholds for certain persistent bioaccumulative toxic 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 proposing lower reporting thresholds for dioxin and dioxin-like compounds, which were previously proposed for addition to the EPCRA section 313 list of toxic chemicals. EPA is proposing these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds. In addition, EPA is proposing to add certain persistent and bioaccumulative toxic chemicals to the list of chemicals subject to the reporting under EPCRA section 313 and PPA section 6607 and to establish lower reporting thresholds for these chemicals. EPA is proposing to add these chemicals to the EPCRA section 313 list pursuant to its authority to add chemicals and chemical categories that meet the EPCRA section 313(d)(2) toxicity criteria. The proposed additions of these chemicals are based on their carcinogenicity or other chronic human health effects and/or their adverse effects on the environment. As part of today's actions, EPA is amending its proposal published in the **Federal Register** of May 7, 1997, to add a category of dioxin and dioxin-like compounds to the EPCRA section 313 list of toxic chemicals by proposing to exclude the co-planar polychlorinated biphenyls (PCBs) from the category and by proposing to add an activity qualifier to the category. EPA is also proposing to require that separate reports be filed for tetraethyl lead and tetramethyl lead which are listed under the lead compounds category. Today's actions also include proposed modifications to certain reporting exemptions and requirements for those toxic chemicals that would be subject to the lower reporting thresholds.

DATES: Written comments, identified by the docket control number OPPTS–400132, must be received by EPA on or before March 8, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the SUPPLEMENTARY INFORMATION section of this proposal.

FOR FURTHER INFORMATION CONTACT: Daniel R. Bushman, Petitions Coordinator, 202–260–3882, e-mail: bushman.daniel@epamail.epa.gov, for specific information on this proposed rule, or for more information on EPCRA section 313, 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 potentially affected by this action if you manufacture, process, or otherwise use any of the chemicals listed under Table 1 in Unit V.C.1. of this preamble. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Industry	Facilities that: incinerate or otherwise treat, store or dispose of hazardous waste or sewage sludge; operate chlor-alkali processes; manufacture chlorinated organic compounds, pesticides, other organic or inorganic chemicals, tires, inner tubes, other rubber products, plastics and material resins, paints, Portland cement, pulp and paper, asphalt coatings, or electrical components; operate cement kilns; operate metallurgical processes such as steel production, smelting, metal recovery furnaces, blast furnaces, coke ovens, metal casting and stamping; operate petroleum bulk terminals; operate petroleum refineries; operate industrial boilers that burn coal, wood, petroleum products; and electric utilities that combust coal and/or oil for distribution of electricity in commerce
Federal Government	Federal facilities that: burn coal, wood, petroleum products; burn wastes; incinerate or otherwise treat, store or dispose of hazardous waste or sewage sludge.

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 preceding ''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 and various support documents 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 or by phone.* If you have any questions or need additional information about this action, please contact the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section. In addition, the official record for this notice, including the public version, has been established under docket control number OPPTS–400132, (including the references in Unit XI. of this preamble and comments and data submitted electronically as described below). This record includes not only the documents physically contained in the docket, but all of the documents included as references in those documents. A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as Confidential Business Information (CBI), is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC 20460. The TSCA Nonconfidential Information Center telephone number is 202–260–7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. Be sure to identify the appropriate docket number (i.e., ''OPPTS–400132'') in your correspondence.

1. *By mail.* Submit written comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver written comments to: Document Control Office in Rm. G-099, Waterside Mall, 401 M St., SW., Washington, DC, telephone: 202–260–7093.

3. *Electronically.* Submit your comments and/or data electronically by E-mail to: ''oppt.ncic@epamail.epa.gov.'' Please note that you should not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard computer disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPPTS–400132. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI Information that I Want to Submit to the Agency?

You may claim information that you submit in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult with the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

II. Statutory Authority

These actions are proposed under sections 313(d)(1) and (2), 313(f)(2), and 328 of EPCRA, 42 U.S.C. 11023(d)(1)-(2), 11023(f)(2), and 11048.

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using a listed toxic chemical in amounts above reporting threshold levels, to report their environmental releases of each chemical annually. These reports must be filed by July 1 of each year for the previous calendar year. Facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of PPA.

A. Addition of Chemicals

Section 313 established an initial list of toxic chemicals that was 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. Under section 313(e)(1), any person may petition EPA to add chemicals to or delete chemicals from the list. 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 (59 FR 61432, November 30, 1994) (FRL–4922–2).

As discussed in Unit IV. of this preamble, EPA conducted a hazard assessment on each chemical being proposed for addition to the EPCRA section 313 list of toxic chemicals. 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 found that each chemical being proposed for addition meets the criteria for chronic human toxicity and/or environmental toxicity, as set forth at EPCRA section 313(d)(2)(B)–(C).

B. Lowering of Reporting Thresholds

Section 313 contains 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).'' 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 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 has also committed the determination of the levels at which to establish an alternate threshold 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 ''facilities subject to the requirements'' of section 313 as the facilities currently reporting, in part because section 313(b)(1)(A) provides that ''the requirements of [section 313] shall apply'' to facilities that meet all the reporting criteria and hence are required to file reports. 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 guidance for exercising this authority appears in the statute.

While the ''substantial majority'' requirement of section 313(f)(2) applies whether EPA is raising or lowering thresholds, EPA believes that as a practical matter this standard can operate to constrain EPA's action only when the Agency is raising the thresholds and thereby reducing reporting. Under those circumstances the releases reported under the new threshold would be lower than those being reported under the current threshold, and EPA would be required to determine that the reduction in reporting would not be so great as to fail the ''substantial majority'' test. When EPA lowers thresholds, however, the substantial majority test is met as a matter of logical necessity, because the lower thresholds are almost always likely to result in increased, rather than decreased, reporting. The required findings therefore can be made without the need for quantitative support. Thus, EPA has found that the revised reporting thresholds contained in today's proposed action meet the ''substantial majority'' test in section 313(f)(2).

Because Congress provided no prerequisites to the exercise of EPA's authority to lower the thresholds, and little explicit guidance, EPA looked to the purposes of section 313 to help guide the exercise of its discretion. EPCRA section 313(h) indicates that the data collected under EPCRA section 313 are intended

> to inform persons about the 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. (42 U.S.C. 11023(h)).

As EPA has previously articulated in another rulemaking, EPA has identified several purposes of the EPCRA section 313 program, as envisioned by Congress, including: (1) Providing a complete profile of toxic chemical releases and other waste management activities; (2) compiling a broad-based national data base for determining the success of environmental regulations; and (3) ensuring that the public has easy access to these data on releases of toxic chemicals to the environment. See 62 FR 23834, 23836 (May 1, 1997). EPA considered these purposes in exercising its discretion to establish lower reporting thresholds under EPCRA section 313 for persistent, bioaccumulative chemicals.

C. Modifications to Other EPCRA section 313 Reporting Requirements

Congress granted EPA extremely broad 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. Explanation for Lowering Reporting Thresholds

A. General Background

In 1986, Congress passed EPCRA. This new law recognized the unique role that communities can play in assuring environmental protection at the local level. Just prior to the passage of EPCRA, fatal chemical releases from a chemical manufacturing facility in Bhopal, India highlighted the need for developing and sharing both emergency planning information and routine release information with the public. The identification of United States facilities, chemicals, and processes identical to the Bhopal situation brought home the potential for similar accidents in the United States as well as a recognition that routine releases of toxic chemicals associated with routine facility processes could pose significant risks to communities. These routine, annual releases, if assessed at all, were known only to the facilities themselves. Communities however, were unaware of the magnitude and potential consequences of such releases.

Section 313 of EPCRA resulted in the creation of the Toxics Release Inventory (TRI). TRI is a publicly available data base that provides quantitative information on toxic chemical releases and other waste management activities. With the collection of this information for the first time in 1987, came the ability for the public, government, and the regulated community to understand the magnitude of chemical emissions in the United States; to compare chemical releases among facilities and transfers of chemical wastes among States, industries, and facilities; and perhaps most importantly, to assess the need to reduce and where possible, eliminate these releases and other waste management activities. TRI enables all parties interested in environmental progress to establish credible baselines, to set realistic goals, and to measure progress over time, in meeting those goals. The TRI system provides a neutral yardstick by which progress can be measured by all interested parties. TRI is an important tool in empowering the Federal government, State governments, industry, environmental groups, and the general public, to fully participate in an informed dialogue about the environmental and human health impacts of toxic chemical releases and other waste management activities.

Prior to EPCRA, the kind of information contained in the TRI generally was nonexistent or unavailable to the Federal government, State governments, emergency preparedness teams or the general public, and often was not disclosed until after major impacts on human health and the environment were evident. This ''after the fact'' disclosure of information did little to help plan for or prevent such serious health and environmental impacts. While permit data are generally cited as a public source of environmental data, they are often difficult to obtain, are not cross-media, and present only a limited perspective on a facility's overall environmental performance. While other sources of data are sometimes cited as substitutes for TRI data, based on its own research, EPA is unaware of any other publicly available, nationwide data base that provides multi-media, facility-specific release and other waste management information to the public in a readily accessible form. With TRI, and the real gains in understanding it has produced, communities now know which industrial facilities in their area release or otherwise manage as waste listed toxic chemicals.

Under EPCRA section 313, Congress set the initial parameters of TRI, but also gave EPA clear authority to modify TRI in various ways, including 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 TRI 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 that were

determined not to 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 TRI report, the Form R.

In today's actions, EPA is proposing enhanced reporting requirements that focus on a unique group of toxic chemicals. These toxic chemicals which persist and bioaccumulate in the environment are more commonly referred to as persistent bioaccumulative toxics or PBTs. To date, with the exception of facilities subject to the alternate threshold exemption, EPA has not altered the statutory reporting threshold for all 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 proposing to increase the utility of TRI to the public by adding a number of chemicals that are toxic and that persist and bioaccumulate in the environment to the section 313 list 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 it is important that the public understand that these persistent bioaccumulative toxic (PBT) chemicals can have serious human health and environmental effects resulting from low levels of release and exposure. Lowering the reporting thresholds for PBT chemicals would 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 current thresholds.

B. Use of EPCRA Section 313 to Focus on Chemicals that Persist and Biaccumulate

As discussed in Unit VII.A. of this preamble, EPA is proposing to lower the EPCRA section 313 reporting thresholds for certain PBT chemicals. A chemical's persistence refers to the length of time the chemical can exist in the environment before being destroyed by natural processes. Bioaccumulation is a general term that is used to describe the process by which organisms may accumulate certain chemicals in their bodies. The term refers to both uptake of chemicals from water (bioconcentration) and from ingested food and sediment residues. PBT chemicals are therefore toxic chemicals that partition to water, sediment, or soil and are not removed at rates adequate to prevent their bioaccumulation in aquatic or terrestrial species. Chemicals that persist and bioaccumulate have been found in shellfish, birds, human adipose tissue, and other mammals. See Unit V. of this preamble for a more detailed discussion of and definitions for the terms persistence and bioaccumulation.

Review of existing data leads EPA to believe that, as a general matter, the release to the environment of toxic chemicals that persist and bioaccumulate is of greater concern than the release of toxic chemicals that do not persist or bioaccumulate. 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 believes that the availability of information on PBT chemicals is a critical component of a community's right-to-know. Therefore, it is particularly important to gather and disseminate to the public relevant information on the releases and other waste management activities of PBT chemicals.

Thus, for PBT chemicals, releases and other waste management activities that occur at facilities that manufacture, process, or otherwise use such chemicals in relatively small amounts are of concern. 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. By lowering the section 313 reporting thresholds for PBT chemicals EPA would be providing communities across the United States with access to data that may help them in making this determination. This information could 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.

Several EPA offices have ongoing projects and programs that are dealing 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 non-regulatory authorities, with a strong emphasis on pollution prevention. Under this initiative, the reporting of PBT chemicals under EPCRA section 313 will provide data on PBT chemicals to EPA, industry, and the public. The availability of that data 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.

EPA is also participating in several international efforts to reduce or eliminate pollution from PBT chemicals. These efforts include the Commission for Environmental Cooperation (CEC) Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative, the United Nations Environment Programme Persistent Organic Pollutants (POPs) Negotiations, and the Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes Basin.

The program between the United States and Canada focuses on pollution of the Great Lakes by PBT chemicals, which has been a matter of great concern for both countries. EPA has established the Great Lakes National Program Office (GLNPO) to develop and implement programs to reduce pollution of the Great Lakes. GLNPO works in cooperation with counterpart organizations in Canada, most notably Environment Canada, to carry out its mission. The ''Final Water Quality Guidance for the Great Lakes System'' (60 FR 15366, March 23, 1995) (FRL–5173–7) identified ''Pollutants that are bioaccumulative chemicals of concern (BCCs)'' among the ''Pollutants of Initial Focus in the Great Lakes Water Quality Initiative.'' Working with that list, Canada and the United States agreed on an initial list of chemicals identified as ''Substances Targeted by the Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes Basin''

(Ref. 1). A subset of the targeted substances is often referred to as the ''Binational Level 1 List,'' and includes chemicals both countries have committed to ''virtually eliminate'' from the Great Lakes. Virtual elimination is to be attained by programs implemented voluntarily by each country.

EPA discussed the issue of reporting on PBT chemicals under section 313 in its January 12, 1994 chemical expansion proposed rule (59 FR 1788) (FRL–4645–6). In the preamble to the proposed rule, EPA specifically requested comment on whether PBT chemicals should be added to the section 313 list. EPA also asked for comments on what modifications to reporting requirements, such as lowering reporting thresholds or modifying the *de minimis* exemption, would need to be made in order to insure that release and transfer information would be collected for such chemicals. In response to EPA's request for comments on the reporting of PBT chemicals, 39 commenters responded, with 35 of these commenters fully supporting such reporting under section 313. In addition, of the over 620 comments EPA received on its 1997 proposal to add a dioxin and dioxin-like compounds category, over 520 commenters supported lowering the reporting thresholds for the proposed category. Many commenters also suggested that EPA lower the reporting threshold for all toxic chemicals that persist and bioaccumulate. EPA will provide specific responses to these comments as part of any final rule developed to add the dioxin and dioxin-like compounds category to the section 313 list and lower the reporting thresholds.

C. Overview of EPA Process for Developing Its Proposal

This section presents a summary of the processes EPA used to: (1) Develop the persistence and bioaccumulation criteria the Agency is proposing to adopt for purposes of determining whether a chemical is persistent and bioaccumulative under EPCRA section 313; (2) identify the persistent and bioaccumulative chemicals the Agency has chosen to propose for addition in this rulemaking; and (3) determine the appropriate thresholds for the individual toxic chemicals the Agency has identified as persistent and bioaccumulative. A more extensive discussion of EPA's rationales for each of the decisions made during this process is presented throughout the various other sections of this Notice.

As noted in section B. of this unit, much work has already been done, both nationally and internationally, to identify chemicals that could reasonably be anticipated to persist and bioaccumulate. Having determined, for the reasons discussed generally in section B. of this unit, to lower the EPCRA section 313 thresholds for persistent bioaccumulative toxic chemicals, EPA began by reviewing the criteria develop by various organizations.

As discussed in further detail in Unit V.A-B. of this preamble, EPA found that generally the various criteria for both persistence and bioaccumulation clustered around two criteria. For persistence in water, soil, and sediment, the criteria were grouped around half-lives of 1 to 2 months and 6 months, and for persistence in air, either 2 or 5 days. Bioaccumulation criteria were grouped around bioaccumulation factor and/or bioconcentration factor values of 1,000 and 5,000. Bearing in mind that one of Congress's articulated purposes for EPCRA section 313 was to provide local communities with relevant information on the release and other waste management activities of chemicals in their community, that may present a hazard, EPA determined that the criteria that were most consistent with these purposes were, for persistence, half-lives of 2 months for water, sediment, and soil, and 2 days in air, and for bioaccumulation, bioaccumulation/bioconcentration factor values of 1,000 or greater.

EPA developed a preliminary list of chemicals for consideration in this rulemaking by reviewing the chemicals on the Great Lakes Binational Toxics Strategy, Level 1 list and chemicals that had received high scores for persistence and bioaccumulation from EPA's Office of Solid Waste's Waste Minimization Prioritization Tool (WMPT). EPA dropped from further consideration in this rulemaking certain pesticide chemicals included on the Level 1 list, for which assessments were not yet complete. The screening process described here is not part of this rulemaking, but was merely a process designed to identify candidate chemicals for further consideration in this rulemaking. It was not used to select chemicals for addition or to determine for which chemicals a lower threshold would be warranted. The process was intended to allow the Agency to establish internal priorities and to focus its limited resources in this initial rulemaking on those toxic chemicals that would result in significant environmental and public information benefits. The fact that a chemical was not included, either as a result of EPA's screening processes, or as a result of one of the assessments conducted during the rulemaking, does not mean that EPA has finally concluded that the chemical does not persist or bioaccumulate, or that the chemical does not warrant any further consideration under EPCRA section 313.

As an initial step in its rulemaking process, EPA examined the underlying persistence and bioaccumulation data for each of the chemicals that remained after the screening process, and measured the chemicals against EPA's chosen criteria for persistence and bioaccumulation. Only if the chemical met both criteria did EPA determine that in this rulemaking it would be appropriate to lower the EPCRA section 313 ''manufacture,'' ''processing,'' and ''otherwise use'' reporting thresholds. In addition, for the chemicals that were not yet listed under EPCRA section 313, EPA conducted a hazard assessment, and determined, based on the weight of all of the evidence, whether the chemicals met the statutory criteria for listing under EPCRA section 313(d)(2). Note that the EPCRA section 313(d)(2)(C) ecotoxicity criteria include a consideration of data on a chemical's persistence and bioaccumulation (see section 313(d)(2)(C)(ii) and (iii)).

In determining the thresholds for this rulemaking, EPA preliminarily concluded that it would be appropriate to reflect the levels of concern that the various PBT chemicals presented, based on the differing degrees to which the chemicals persist and bioaccumulate. The Agency ultimately chose to adopt a two-tier approach, and to establish two separate thresholds to reflect the chemicals' varying potentials to persist and bioaccumulate, as well as to reflect the Agency's belief that the public has a greater right-to-know about chemicals that can reasonably anticipated to be present in the community at higher levels.

To reach the appropriate levels of concern, the Agency again considered the range of criteria for persistence and bioaccumulation adopted by various organizations, settling again on the criteria of bioaccumulation/bioconcentration factor values of 1,000 and 5,000, and half-lives for soil, sediment, and water of 2 and 6 months. Those chemicals with a bioaccumulation/bioconcentration factor value of 1,000 or greater but less than 5,000, and with a soil, sediment, or water half-life of 2 months or greater but less than 6 months, were considered to be persistent bioaccumulative toxic chemicals, and therefore a low, alternate threshold would be justified. However, those toxic chemicals with a bioaccumulation/bioconcentration factor value of 5,000 or greater, and with

a soil, sediment, or water half-life of 6 months or greater were considered to be highly persistent bioaccumulative toxic chemicals, and EPA determined that an even lower threshold would be appropriate. Because of the unique issues associated with establishing EPCRA section 313 thresholds for the category of dioxin and dioxin-like compounds, EPA is proposing a separate, and even lower, threshold for this chemical category.

Finally, although EPCRA section 313(f)(2) does not compel the Agency to consider the burden to industry resulting from a lower threshold, EPA has determined it would be reasonable, in this rulemaking, to include some consideration of the additional burden involved in lowering the statutory thresholds. While EPA is willing to consider reporting burden in determining appropriate thresholds for the PBT chemicals in the rule, the Agency must be 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 their potential exposure to toxic chemicals. See, e.g., Congressional Record at 5315-16 and 5338-39 (debate on adoption of the Conference Report). In light of the authors' concerns, the Agency has identified two alternate sets of thresholds, which afford a greater or lesser degree of weight to the estimates of industry burden, and is requesting comment on the propriety of the degree to which burden should be taken into account in this rulemaking, and which set of thresholds the Agency should adopt.

IV. Chemicals Proposed for Addition to EPCRA Section 313

A. Statutory Criteria

In an initial review of PBT chemicals that appear on the list of chemicals of concern in the various PBT chemical initiatives, EPA has identified seven chemicals and one category of chemicals that persist and bioaccumulate in the environment that are not currently subject to reporting under section 313. For these chemicals a hazard assessment was conducted to determine if they meet the EPCRA section 313(d)(2) criteria for listing. Although identification of these chemicals for initial consideration has been based on their status as PBT chemicals, their proposed addition is based solely on the determination that they meet the EPCRA section 313(d)(2)(B) or (C) listing criteria. EPCRA section 313(d)(2) sets out criteria for adding chemicals to the list of chemicals subject to reporting under section 313. For a chemical (or category of chemicals) to be added to the EPCRA section 313(c) list of toxic chemicals, the Administrator must determine whether, in her judgment, there is sufficient evidence to establish any one of the following:

(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.

EPA has published additional information on the Agency's interpretation of the section 313(d)(2) and (3) criteria for adding chemical substances from the section 313 list (59 FR 61432). All of the chemicals being proposed for listing in this proposed rule have been determined to cause serious or irreversible chronic 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. EPA believes that chemicals that induce death or serious adverse effects on aquatic organisms at relatively low concentrations (i.e., they have high ecotoxicity), have the potential to cause significant adverse effects on the environment due to the changes that these chemicals may cause in the population of fish and other aquatic organisms. EPA believes that such chemicals can reasonably be anticipated to cause a significant adverse effect on the environment of sufficient seriousness to warrant reporting. Therefore, in accordance with EPA's stated policy on the use of exposure assessments (59 FR 61432), EPA does not believe that an exposure assessment is appropriate for determining whether the chemicals proposed for listing in this rulemaking meet the criteria of EPCRA section 313(d)(2)(B) or (C).

B. Use of Predictive Techniques

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. 2).

C. Technical Review of Chemicals Proposed for EPCRA Section 313 Listing

Summaries of the results of the hazard assessments for the seven chemicals and one chemical category that are being proposed for addition to section 313 are provided below. Additional information and more detailed discussions concerning the toxicity of these chemicals can be found in the support documents in the docket for this rulemaking. Commenters should consult the support documents and review the studies contained and referenced in the docket for further details.

1. *Benzo(g,h,i)perylene (CAS No. 191–24–2) (Ref. 2).* The predicted aquatic toxicity values for benzo(g,h,i)perylene, based on QSAR analysis using the equation for neutral organics and an estimated log K_{ow} of 6.7, include 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 the daphnid 48-hour LC_{50} and 0.027 mg/L for the 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 test organisms) with an algal chronic toxicity of 0.012 mg/L. These predicted aquatic toxicity values indicate that benzo(g,h,i)perylene is toxic at relatively low concentrations and thus is highly toxic to aquatic organisms. EPA believes that the evidence is sufficient to list benzo(g,h,i)perylene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical.

2. *Benzo(j,k)fluorene (fluoranthene) (CAS No. 206–44–0) (Ref. 2).* Benzo(j,k)fluorene or fluoranthene as it is more commonly called, has been tested for complete carcinogenic activity by skin painting in various strains of mice and for tumor-initiating activity using mouse skin initiation-promotion assays and no significant activities were detected in any of these studies. However, using newborn or preweanling mice, there was evidence that the compound was capable of inducing lung and liver tumors. In addition, a reactive metabolite of fluoranthene has been shown to induce mammary tumors in rats.

The potential pulmonary carcinogenicity of fluoranthene was first reported in a 24-week newborn mouse lung adenoma assay. Newborn Swiss-Webster BLU:Ha (ICR) mice were given intraperitoneal injections of 0.7 or 3.5 mg fluoranthene in dimethyl sulfoxide (DMSO) on days 1, 8, and 15 after birth and observed for 24 weeks. Lung tumor incidence was significantly increased in high-dose males (20 out of 27 versus 1 out of 27 in the control) but not in low-dose males or females of both dose groups. The pulmonary carcinogenicity of fluoranthene was confirmed using newborn CD-1 mice. In addition, liver tumors were observed in male mice after 9 months of treatment. In another study using newborn CD-1 mice given 3.5 or 17.3 micromoles fluoranthene for 1 year pulmonary and hepatic carcinogenic activities were also observed. The lung tumor incidence was significantly increased in all dosed groups (in males: 43% at the low-dose and 65% at the high-dose versus 17% in the control group; in females: 35% at the low-dose and 86% at the high-dose versus 12% in the control group) whereas only male mice had higher incidence of liver tumors (64% at the low-dose and 100% at the high-dose versus 17% in the control group).

A genotoxic, ''pseudo-bay'' region diol epoxide metabolite of fluoranthene has been shown to induce mammary tumors in female CD rats. In this study, lightly anesthetized 30-day-old rats were given two injections of 2 or 10 micromoles of anti-2,3-dihydroxy-1,10b-epoxy-10b,1,2,3-tetrahydro-fluoranthene in DMSO directly into mammary tissues beneath the three left thoracic nipples and DMSO under the right nipples. After 41 weeks, 85% of the treated groups developed histologically confirmed mammary tumors, compared to 11% in DMSO control group. The potential mammary carcinogenic activity of fluoranthene itself remains to be studied.

Fluoranthene has been shown to be mutagenic in the Ames test, in a Salmonella forward mutation assay (with potency comparable to that of benzo[a]pyrene), and in a human diploid lymphoblast cell line. A ''pseudo-bay'' region diol epoxide has been detected as a metabolite and found to be highly mutagenic and carcinogenic as well as capable of binding to DNA. Besides genotoxic mechanisms, fluoranthene has also been shown to be a potential immunosuppressive agent as indicated by its ability to suppress B lymphopoiesis and induce apoptosis (programmed cell death) in murine T cell hydridomas.

The International Agency for Research on Cancer concluded that there is inadequate evidence to permit an evaluation of the carcinogenicity of fluoranthene. EPA has listed the compound as a Group D (not classifiable as to carcinogenicity in humans). However, in both cases, recent studies indicating pulmonary and hepatic carcinogenicity as well as mechanistic studies were not fully taken into account at the time of the reviews.

Based on the overall ''weight of evidence'' for carcinogenicity, genotoxicity, metabolism and mechanistic data and consideration of structure-activity relationships, and despite the lack of dermal carcinogenicity, fluoranthene should be classified as a Group ''C'' carcinogen under the ''weight of evidence'' approach of EPA's 1986 Guidelines for Carcinogen Risk Assessment (51 FR 33992, September 24, 1986) because of positive carcinogenicity data in one animal species. Under EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17959, April 23, 1996) fluoranthene would most appropriately fall in the category ''likely'' to produce cancer in humans. EPA believes that the evidence is sufficient for listing fluoranthene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

Section 313 contains a listing for polycyclic aromatic compounds (PACs). All of the members of this category are listed based on concerns for their carcinogenicity. Since part of the basis for listing fluoranthene under section 313 is a concern for carcinogenicity this chemical is being proposed for addition to the section 313 PACs category.

A number of studies have been conducted on the ecotoxicity of fluoranthene. Ecotoxicity values include a calculated 96–hour LC_{50} of 3.9 mg/L for bluegill, a 96–hour LC_{50} of 0.04 mg/L for mysid shrimp, and a 96–hour LC_{50} of 5.0 mg/L for a polychaete. Using standard acute toxicity tests, benzo(j,k)fluorene 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 benzo(j,k)fluorene at a concentration of 0.0217 mg/L for 28 days in 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 benzo(j,k)fluorene 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 benzo(j,k)fluorene. These aquatic toxicity values indicate that benzo(j,k)fluorene is toxic at relatively low concentrations and thus is highly toxic to aquatic organisms. EPA believes that the evidence is sufficient to list benzo(j,k)fluorene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical.

3. *3-Methylcholanthrene (CAS No. 56–49–5) (Ref. 2).* 3-Methylcholanthrene has been clearly shown to be a multi-target potent carcinogen in a variety of studies with a potency that exceeds or is comparable to that of the well known potent carcinogen benzo[a]pyrene. 3-Methylcholanthrene has been found to be a potent carcinogen in rodents by a variety of routes of administration. It

has been shown to induce skin tumors and local sarcomas by topical and subcutaneous routes, respectively, with a potency higher than that of benzo[a]pyrene. 3-Methylcholanthrene has induced lung tumors in mice by intravenous injection and in addition to skin tumors it produced a 100% incidence of leukemia in mice after repeated skin application. Following oral administration, 3-methylcholanthrene induced hepatomas in Wistar rats maintained on a low protein diet and in newborn suckling albino mice, it also induced mammary tumors in young female rats, induced forestomach tumors in rodents, and skin tumors in young rats. Oral administration of 3-methylcholanthrene to hamsters induced intestinal, mammary, and ovarian tumors. 3-Methylcholanthrene has been shown to be positive in a wide variety of gene mutation assays, in cell transformation assays using nine different cell types, and in both *in vitro* and *in vivo* sister chromatid exchange assays. *In vivo* binding of 3-methylcholanthrene to DNA in mouse cells has also been demonstrated.

Considering structure-activity relationships, 3-methylcholanthrene does contain the characteristic ''bay-region'' found in most carcinogenic polycyclic aromatic hydrocarbons. Metabolism and mechanistic data indicate that the bay-region 9,10-dihydrodiol of 3-methylcholanthrene is a proximate carcinogen of this chemical in the newborn mouse model and most likely also in the initiation-promotion model with the bay-region diol epoxide being the ultimate carcinogen. There is also some possibility that 1-hydroxylation of 3-methylcholanthrene may be another additional metabolic activation pathway.

Although not evaluated in EPA's IRIS data base, based on the overall ''weight of evidence'' for carcinogenicity, genotoxicity, metabolism, and mechanistic data and SAR consideration, 3-methylcholanthrene would be classified as a Group B2 carcinogen (i.e., it is a probable human carcinogen) under the ''weight of evidence'' approach of EPA's 1986 Guidelines for Carcinogen Risk Assessment (51 FR 33992, September 24, 1986) (FRL–2984–3), and would fall in the category ''likely'' to produce cancer in humans under EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17959, April 23, 1996) (FRL–5460–3). EPA believes that the evidence is sufficient for listing 3-methylcholanthrene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

Section 313 contains a listing for PACs. All of the members of this category are listed based on concerns for their carcinogenicity. Since part of the basis for listing 3-methylcholanthrene under section 313 is a concern for carcinogenicity this chemical is being proposed for addition to the section 313 PACs category.

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 daphnid 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. These predicted aquatic toxicity values indicate that 3-methylcholanthrene is toxic at relatively low concentrations and thus is highly toxic to aquatic organisms. EPA believes that the evidence is sufficient to list 3-methylcholanthrene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical.

4. *Octachlorostyrene (CAS No. 29082–74–4) (Ref. 2).* A short-term (28–day) study and a subchronic (90–day) feeding study of rats demonstrated that octachlorosytrene can cause adverse liver, thyroid, and kidney effects. In the 28–day study, hepatomegaly and a dose-dependent increase in the prevalence and severity of liver injury (histological changes) were seen in both male and female rats. In male rats only, histological changes in the thyroid (including increased epithelial height, reduced colloid density, and angular collapse of thyroid follicles) were observed; suggesting male rats are more sensitive to the thyroid-toxic effects of octachlorosytrene than females. In the 90–day study, a number of adverse effects not detected in the 28–day study were observed. Increased liver, kidney, and spleen weights were observed in both male and female rats, while only increased liver weights were seen in the 28–day study. Dose-dependent histological effects were seen in the liver, thyroid, and kidney of treated animals in the 90–day study. Kidney lesions, not detected in the 28–day study, became more pronounced with increasing dose in the 90–day study. Kidneys of treated rats showed glomerular adhesions associated with proteinaceous casts in the lower nephron and focal tubular. In addition, changes in hepatic enzyme activities and serum biochemical parameters were noted in both the 28- and 90–day studies. A 1 year oral study of rats (20 per gender and per dose group) exposed the animals to 0, 0.05, 0.5, 5.0, and 50 parts per million (ppm) of octachlorostyrene in the diet. Morphological changes in the liver, kidney, and thyroid were similar to the effects observed in the 28 and 90–day studies. The 1 year study found the histological effects in affected organs to be the most sensitive endpoint. Although the histological changes could be detected at doses as low as 0.05 ppm, at these low doses changes were judged to be minor and probably adaptive. The No Observed Adverse Effect Level (NOAEL) was judged by the study authors to be 0.5 ppm in the diet or 0.031 milligrams per kilogram per day (mg/kg/day). Correspondingly, the Lowest Observed Adverse Effect Level (LOAEL) would be 5.0 ppm in the diet or 0.31 mg/kg/day for significant histological changes in the liver, kidney, and thyroid. Statistically significant increases in organ weights, such as those discussed above, are gross indicators of damage to the organ and significant histological changes in organs indicate serious damage and impaired organ functions. EPA believes that the evidence is sufficient for listing octachlorostyrene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available hepatic, nephric, and thyroid toxicity data for this chemical.

The ecotoxicity data for octachlorostyrene are very limited. However, based on QSAR analysis using a measured log K_{ow} of 7.7, an estimated 14–day LC_{50} value of 6 micrograms per liter (µg/L) for guppies has been calculated for octachlorosytrene. In addition, toxicity data for hexachlorobenzene, a chemical analogue for octachlorostyrene due to its structural similarity, is available. Hexachlorobenzene inhibits photosynthesis in algae at a concentration of 30 µg/L and a subchronic EC_{50} value of 16 µg/L has been calculated for daphnids. These predicted and analogue aquatic toxicity values indicate that octachlorostyrene is toxic at relatively low concentrations and thus is highly toxic to aquatic organisms. EPA believes that the evidence is also sufficient to list octachlorosytrene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical.

5. *Pentachlorobenzene (CAS No. 608–93–5) (Ref. 2).* A subchronic, 90–day,

feeding study on pentachlorobenzene has been conducted that utilized 8 experimental groups (3 male, 5 female) of 10 rats each. A statistically significant increase in kidney weights, decreased heart weights, and an increase in hyaline droplets in proximal kidney tubules was noted in male rats receiving 8.3 mg/kg/day (125 ppm in diet). Female rats receiving the next highest dose, 18 mg/kg/day (250 ppm in diet), and their offspring showed increased liver/body weight ratios. At higher doses, up to 72 mg/kg/day (1,000 ppm in diet), animals of both sexes showed hepatocellular enlargement, increase in adrenal and kidney weights, increased white blood cell (WBC) counts, and lowered red blood cell (RBC) indices. The lowest dose of 8.3 mg/kg/day is considered a LOAEL from this study. The results of this subchronic feeding study were used by EPA to establish an oral reference dose (RfD) for pentachlorobenzene. A second 13-week feeding study in rats and mice used lower feed concentrations of pentachlorobenzene than the above study (i.e., 0, 33, 100, 330, 1,000 or 2,000 ppm) and 10 animals of each sex per group per species. Evidence of kidney, liver, hematological, and thyroid toxicity were observed, supporting the results of first study. In male rats, histological lesions included a spectrum associated with hydrocarbon or hyaline droplet nephrology. Nephropathy was seen in rats of both sexes. Both rats and mice exhibited centrilobular hepatocellular hypertrophy. The data from these subchronic exposure feeding studies indicate that oral exposure to pentachlorobenzene may have serious toxic effects to the kidney and liver as well as serious hematological effects. Statistically significant increases in organ weights, such as those discussed above, are gross indicators of damage to the organ and significant histological changes in organs indicate serious damage and impaired organ functions.

In one study, dose groups of 10 female weanling rats were exposed to 0, 125, 250, 500, or 1,000 ppm of pentachlorobenzene in feed. The dams were treated for 67 days, then mated with untreated males and treated continually through gestation and nursing. Suckling pups of dams receiving 18 mg/kg/day (250 ppm in feed) and higher doses of pentachlorobenzene through gestation and weaning developed tremors. The pups and dams at this dose or higher also exhibited increased liver/body weight ratios. Almost all (28% survival rate from day 4 to weaning) of the pups in the high dose group (1,000 ppm) died before weaning. In another study using a different strain of rats, groups of 20 mated female rats were treated with 0, 50, 100, or 200 mg/kg/day of pentachlorobenzene by gavage at days 6 to 15 of gestation. The authors of the study reported a significant increase in skeletal abnormalities (extra ribs) in pups whose mothers had been treated with all levels of pentachlorobenzene. At 200 mg/kg/day of pentachlorobenzene an increase in sternal defects, a decrease in fetal body weights, and a nonsignificant decrease in the number of fetuses per litter was reported.

EPA believes that the evidence is sufficient for listing 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.

A number of ecotoxicity studies have been conducted on pentachlorobenzene including studies on algae, daphnids, shrimp, and fish. 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. These acute toxicity values indicate that pentachlorobenzene is toxic at relatively low concentrations and thus is highly toxic to aquatic organisms. 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 (discussed in Unit V.C.1. of this preamble) pentachlorobezene is considered highly toxic to aquatic organism even at these higher concentrations. EPA believes that the evidence is sufficient to list pentachlorobenzene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical.

6. *Tetrabromobisphenol A (CAS No. 79–94–7) (Ref. 2).* In a study completed in 1985 and submitted to EPA in 1992, tetrabromobisphenol A was shown to produce developmental effects in rats. The study appears to have followed testing guidelines applicable at the time it was conducted and uses an adequate number of animals (25 per dose group) to allow statistical analysis. In the study, tetrabromobisphenol A was administered to rats by gavage in corn oil from day 6 through 15 of gestation at doses of 0, 2.5, 10, or 25 mg/kg/day. The study found a LOAEL of 10 mg/kg/day for significantly reduced fetal body weights when analyzed on a litter basis. At 25 mg/kg/day, slight maternal toxicity, increased frequency of resorption and delayed ossification and other abnormalities in offspring were observed. Malformations and developmental delays included significant increases in the litter incidences of fetuses with enlarged hearts, rear limb malformations, and ''remarkable'' delays in the ossification of the skull, vertebrae, ribs, and pelvis. Two other studies of rats using fewer animals (five per dose group) did not report evidence of developmental toxicity in offspring although higher doses were used and maternal death was reported. However, it is likely that these other studies lacked the sensitivity necessary to detect the effects reported in the first study. EPA believes that the evidence is sufficient for listing tetrabromobisphenol A on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available developmental toxicity data for this chemical.

A number of ecotoxicity studies have been conducted on tetrabromobisphenol A including studies on algae, daphnids, shrimp, oysters, and fish. Aquatic acute toxicity calculated values for tetrabromobisphenol A 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. These aquatic toxicity values indicate that tetrabromobisphenol A is toxic at relatively low concentrations and thus is highly toxic to aquatic organisms. EPA believes that the evidence is sufficient to list tetrabromobisphenol A on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(C) based on the available ecotoxicity information for this chemical.

7. *Vanadium (CAS No. 7440–62–2) and Vanadium Compounds (Ref. 2).* Vanadium is currently listed under

section 313 with the qualifier (fume or dust). EPA is proposing to remove the fume or dust qualifier for vanadium and to add a vanadium compounds category. Therefore, EPA is presenting the following information as the basis for determining that vanadium other than fume or dust forms and vanadium compounds meet the section 313(d)(2) criteria for listing chemicals.

a. *Algae.* Vanadium has been shown to have toxic effects in algae. One study found that growth of *Chlorella* decreased at vanadium concentrations as low as 100 parts per billion (ppb), and at 50 to 1,000 ppm production was lowered by 25 to 34% compared to the controls. Different results were obtained in a second study where, for *Chlorella*, the maximum stimulatory effects on biomass production and chlorophyll synthesis were found at 500 ppb vanadium in the medium. Inhibitory effects on dry weight and chlorophyll content were found at concentrations of approximately 25 ppm vanadium, and growth was found to cease at 100 ppm vanadium. The toxic threshold for vanadium content in the algae was determined to be 150 to 200 nanograms per gram (ng/g) dry weight. Another study found the growth of the dinoflagellate *Ceratium hirundinella* to be inhibited by 0.1 ppm vanadium. In marine studies, acute toxicity tests on *Dunaliella marina*, *Proocentrum micans*, and *Asterionella japonica* with sodium metavanadate produced 9-day LC_{50} values of 0.5 ppm, 3 ppm, and 2 ppm respectively.

Vanadium appears to influence cell division processes in algae. It has been reported that 3 ppb vanadium as sodium vanadate prevented complete synchronization of *Bumilleriopsis filiformis*. In another study it was found that, in the range of vanadium concentration known to stimulate *Chlorella pyrenoidosa*, toxic effects on cell division were apparent. In continuous light, in the presence of 20 ppb vanadium as NH_4VO_3, mean cell size increased significantly, with maximal increase occurring at 0.5 ppm vanadium. These large cells had giant nuclei with multiple chromosomes. In addition, synchronous growth of the algae with vanadium ceased after three division periods, after which a division occurred, which generally produced larger than normal autospores. It was postulated that during growth, normal duplication of genetic material occurred, producing nuclei with multiple sets of chromosomes. However, subsequent nuclear division was inhibited by vanadium and the subsequent division of autospores did not occur, producing giant cells with large nuclei. In another study it was observed that ultrastructural changes in enlarged cells of *Scenedesumus obliquus* induced by growth at elevated concentrations of vanadium (0.8 to 9 ppm), included thickened cell walls, and larger numbers of vacuoles, starch granules, and lipid droplets.

One study has reported that the 15–day LC_{50} for an estuarine and salt-water green alga (*Dunaliella marina*) is 0.5 mg/L of sodium metavanadate and that the 15–day LC_{50} for a salt-water pennote diatom (*Asterionella japonica*) is 2 mg/L.

b. *Invertebrates.* Vanadium is commonly found in trace amounts in shell fish and crustaceans. The uptake of vanadium in molluscs, crustaceans, and echinoderms indicated that besides the food pathway, direct surface sorption processes are of major importance in the bioaccumulation of the metal. However, very few vanadium toxicity tests have been conducted with invertebrates. Reported toxicity values include 9-day LC_{50} values for *Nereis diversicolor* (worm), *Mytilus galloprovincialis* (mussel), and *Carcinus maenas* (crab) of 10, 35, and 65 ppm vanadium (as $NaVO_3$ in the seawater) respectively. These moderately high values are supported by another report that found that the critical concentration for vanadium in *Mytilus edulis* was between 50 and 100 ppm.

In a study of the toxicity of the heavy metals selenium, zirconium, and vanadium on the freshwater ciliated protozoan *Tetrahymena pyriformis*, the addition of 20 ppm vanadium as vanadyl sulfate significantly lowered the growth and locomotor rate (measured as swimming speed) of the organism. In another study, a median survival time (MST) of 8 hours was reported for *Daphnia magna* in media containing 30 ppm vanadium added as vanadate.

c. *Vertebrates.* Studies with American flagfish (*Jordanella floridae*) indicated a 96–hour LC_{50} of 11.2 ppm vanadium. Growth and survival in a 96–hour test was depressed, particularly in the larvae, at 0.17 ppm vanadium. At a concentration of 0.041 ppm there was stimulation of growth and reproductive performance in female fish. The sublethal threshold for toxicity of vanadium was estimated to be 0.08 ppm.

Studies have reported that vanadium is moderately toxic to juvenile rainbow trout (*Salmo gairdneri*) and whitefish (*Coregonus clupeaformis*) with 96–hour LC_{50} values of 6.4 and 17.4 ppm respectively, with toxicity increasing slightly with decreasing pH. Pronounced histopathological lesions were observed in gills and kidneys of trout exposed to sublethal concentrations of vanadium, with damage increasing with increased exposure to the metal. Vanadium induced premature hatching of eyed eggs at concentrations from 44 to 595 ppm. Curiously, eyed eggs of trout were 200 to 300 times more resistant to vanadium than fingerlings, and the metal did not appear to induce histopathological lesions in the developing embryos. It appeared that juvenile whitefish avoided vanadium concentrations of 500 ppm or higher in the test water.

It has also been reported that vanadium causes dose-related histopathological effects on the lamellae of gills in juvenile rainbow trout, suggesting that the gills are a critical site for the lethal action of vanadium. Of the three toxic materials tested (vanadium, nickel, and phenol), vanadium was that most potent lethal agent with a 96–hour LC_{50} of 10 ppm vanadium.

It has been reported that for vanadium the 7-day LC_{50} values for trout are within a narrow range, from 1.9 to 6.0 ppm vanadium, added as V_2O_2. Toxicity decreased with increasing water hardness, and was greater at pH 7.7, where H_2VO_4 was predicted to be the predominant vanadium ion. A second study reported the effects of vanadium on two life stages of brook trout, *Salvelinus fontinalis*, observing that the alevins of the fish were less sensitive to vanadium that were yearlings, the 96–hour LC_{50} being 24 and 7 mg/L respectively. Another study reported a 96–hour LC_{50} of 0.62 ppm for *Therapon jarbua* with vanadium presented as V_2O_5.

The rainbow trout (*Salmo gairdneri*) is one of the most commonly used fish for toxicity studies; for this species the LC_{50} value for vanadium was reported to be 5.6 mg/L. Increasing the exposure time resulted in progressively lower LC_{50} values, the lowest being 1.99 mg/L for an 11–day exposure period. Similar results have been reported where the LC_{50} values decreased from 4.34 mg/L for 5 days exposure to 1.95 mg/L for 14 days. Neither of these groups was able to define a minimum lethal level for rainbow trout. Other studies indicated that small rainbow trout are more resistant than larger fish to vanadium pentoxide. In general rainbow trout eggs were 10 to 15 times more resistant to pentavalent vanadium than fingerlings.

Some of the aquatic toxicity data discussed above are at relatively low concentrations indicating that vanadium is highly toxic to certain aquatic organisms. In addition, considering

vanadium's persistence and bioaccumulation potential (discussed in Unit V.C.1. of this preamble), EPA also believes that vanadium is highly toxic to aquatic organisms at the higher concentrations. EPA believes 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 for vanadium and vanadium compounds.

It has been suggested that the bioaccumulation data for vanadium are insufficient to support the designation of vanadium as bioaccumulative based on the criteria proposed in this rulemaking. As such, while EPA is proposing to add vanadium compounds and all forms of vanadium to EPCRA section 313, the Agency is not proposing to revise the reporting thresholds for vanadium or vanadium compounds at this time. EPA requests comment on the sufficiency of the bioaccumulation data for vanadium.

EPA requests comment on its proposal to require reporting on the chemicals listed above under EPCRA section 313 and on the data supporting the proposed listings.

V. Persistence and Bioaccumulation: Criteria, Data Evaluation Methods, and Technical Review of Chemicals

This is EPA's first effort under section 313 to review chemicals for their persistence and bioaccumulation properties and it is limited to a relatively small group of chemicals. EPA may review additional chemicals in the future to determine if they should be considered persistent and bioaccumulative under section 313 and, if not already on the section 313 list, whether they should be added. In pursuing this action, EPA first established criteria that should be used under section 313 for determining if a chemical persists or bioaccumulates in the environment. The criteria were then applied to determine whether the chemicals included in this review can reasonably be anticipated to persist and bioaccumulate in the environment. The chemicals initially reviewed were drawn from two lists of persistent and bioaccumulative chemicals, including the Binational Level 1 list (Ref. 1) and 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 were also considered (Ref. 3). The chemicals on these lists were reviewed as part of the screening process which is not part of this rulemaking. Finally, included in this initial review were the chemicals included in the dioxin and dioxin-like compounds category that EPA has proposed for addition to the section 313 list (62 FR 24887, May 7, 1997) (FRL–5590–1). This proposed rule only presents the data for those chemicals for which assessments have been completed under the initial review; it does not eliminate any chemical from possible future designation as persistent or bioaccumulative or from future consideration for lower reporting thresholds for purposes of reporting under section 313. Any future lowering of the reporting thresholds for PBT chemicals will be done through rulemaking.

A. 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 environmental media for which persistence is measured or estimated include air, water, soil, and sediment with water being the medium for which persistence values are most frequently available. It is important to distinguish between persistence in a single medium (air, water, soil, or sediment) and overall environmental persistence. Persistence in an individual medium is controlled by transport of the chemical to other media, as well as transformation to other chemical species. Persistence in the environment as a whole is a distinct concept. It is based on the observations that the environment behaves as a set of interconnected media, and that a chemical substance released to the environment will become distributed in these media in accordance with the chemical's intrinsic (physical/chemical) properties and reactivity. For overall persistence, only irreversible transformation contributes to net loss of a chemical substance. This unit discusses those aspects of persistence that are important to consider in determining a chemical's persistence in the environment and sets forth the criteria that EPA used for determining that a chemical is persistent for purposes of reporting under section 313.

1. *Measurement of persistence in individual media.* A common measure of persistence in individual environmental media is a chemical's half-life, or the amount of time necessary for half of the chemical present to be eliminated from the medium. Thus, after one half-life, one half of the original amount of the chemical remains, after two half-lives one quarter of the original amount remains, after three half-lives one eighth remains, and so on. If other potentially confounding factors are ruled out, measured half-lives will normally reflect the rate(s) of one or more transformation processes. Confounding factors include, for example, transport of the substance to another medium; sorption, complexation or sequestration; and reversible changes in speciation. Transformation may occur by a variety of processes. In air, for chemicals in the gas phase, the most important process contributing to their destruction is oxidation by photochemically generated hydroxyl radicals (Ref. 4). However, photolysis and oxidation by ozone and nitrate radicals are also important transformation processes for some chemicals. In water, soil, and sediment the chief process resulting in net loss for most chemical substances is microbial degradation (i.e., biodegradation), but hydrolysis, direct and indirect photolysis and abiotic oxidation/reduction reactions may also play a role. Whether a given measured half-life reflects only one of these processes or more than one depends on the molecular structure of the chemical in question, and on the experimental design. The experiment may be designed to measure a net (overall) half-life for the medium of interest, or it may be designed to focus on a specific transformation process.

In the environment, degradation half-lives for chemical substances depend not only on chemical properties and structure, but also on characteristics of the surrounding environment. There are many environmental factors that can affect a substance's half-life, including, for example, temperature, pH, sunlight intensity, hydroxyl radical concentration, and the activity of the microbial community. As a result, there is substantial variability in environmental half-lives in both space and time, and this variability is reflected in the available literature data.

Variability in persistence data can be illustrated by means of examples. Webster et al. (Ref. 5) discuss the atmospheric oxidation of 2,2′,4,4′-tetrachlorobiphenyl, which reacts with hydroxyl radicals in a reaction that is dependent upon temperature and hydroxyl radical concentration (Ref. 6). Based on measured radical concentrations (Ref. 7), they estimated that in mid-latitudes in July at 15 °C the half-life is approximately 2 weeks, whereas in January at -5 °C it increases to 6 months at the same location. Even greater differences are expected when comparing polar and tropical latitudes. A second example is the hydrolysis of lindane (Ref. 5). Based on reliable measured data, the half-life for hydrolysis in ocean water at pH 8.1

varies from greater than 100 years at 0 °C to 75 days at 30 °C (Ref. 8). Finally, Vink and Zee (Ref. 9) measured rates of transformation of several pesticides in surface waters of The Netherlands and found large variations in half-lives. Half-lives ranged from 70 to 173 days for aldicarb, 1 to 139 days for simazine, 2 to 347 days for methoxone (MCPA), and 3 to 1,400 days for mecoprop. In this example, further analysis showed that much of the variability could be attributed to environmental factors that either directly or indirectly affect microbial activity.

Variability in rates of biodegradation is especially important because this is the dominant transformation process in soil and water/sediment for the majority of organic chemicals. This variability tends to be less predictable than the variability in abiotic transformation processes such as atmospheric oxidation and hydrolysis. The first two examples above demonstrate the dependence of half-lives for hydroxyl radical oxidation in the atmosphere and hydrolysis in water on measurable environmental parameters (i.e., temperature, hydroxyl radical concentration, and pH). However, even when these variables are controlled, measured rate constants can easily vary by an order of magnitude and this is reflected in literature data (e.g., Refs. 8 and 10).

2. *Data evaluation methods for persistence in each environmental medium.* The ideal situation in which to evaluate persistence would be one in which sufficient data are available for a chemical substance of interest, from studies using environmentally relevant protocols, to fully characterize the distribution of its half-lives. To ''fully characterize'' the distribution means to collect enough data to allow calculation of a mean and standard deviation of half-lives for each substance and environmental medium. Field studies, such as are often conducted to determine pesticide fate in the environment, are generally considered the most informative studies if properly conducted. The problem is that persistence is difficult to study in the field due to the high expense typical of these studies, the unpredictability of weather, and so on. Moreover, it is often difficult or impossible to determine a meaningful half-life for transformation due to an inability to eliminate or adjust for transport of the test substance out of the medium of interest. The ideal situation is rarely if ever achieved, and even with relatively well-tested chemicals it is necessary to use laboratory data and, often, estimates of half-lives.

In both laboratory studies and estimation methods, it is common to focus on specific transformation processes. Thus, for example, a common technique is to study biodegradability by collecting a ''grab sample'' of soil or natural water/sediment, transporting the sample to the laboratory, spiking the sample with the chemical of interest, and measuring the chemical's disappearance over time while running controls to rule out contribution of other fate processes. EPA believes it is appropriate to use grab sample studies in addition to field studies. Where experimental conditions can be optimized to mimic those in the field and the balance and interactions between microbial species in the sample can be preserved, the results of grab sample biodegradation studies are expected to be sufficiently representative of field results to allow general characterization of biodegradative persistence in environments similar to those from which the grab sample was collected.

In view of these limitations on existing persistence data, to determine a chemical's persistence for purposes of section 313 reporting, EPA adopted an approach to data selection and review that emphasizes experimental data but utilizes both laboratory and field data, as well as estimated half-lives in certain situations. Although there are certain limitations to existing persistence data, EPA believes that for the chemicals included in this proposed rule the available data are sufficient to make a reasonable determination regarding their environmental persistence.

a. *Air.* For air, the rate constant for the reaction of hydroxyl radicals in the vapor phase with the chemical of interest, whether experimentally determined or estimated, was usually the only information available. Very few experimental data were available for the chemicals included in this proposed rule, and EPA therefore used the Atmospheric Oxidation Program (AOP) (Ref. 11), which is based on the estimation method of Kwok and Atkinson (Ref. 12), to estimate rate constants for this process. Half-lives for air were then calculated using default hydroxyl radical concentrations based on published monitoring data for relatively pristine (3×10^5 radicals per cubic centimeter (cm^3)) and polluted (3×10^6 radicals/cm^3) air. In many cases the chemical of interest is expected to exist partially or mainly in the particulate phase. Because half-lives for the particulate phase are likely to be higher, where data on particulate phase half-lives were available they were given greater weight in judging overall half-life in air than data on gas-phase hydroxyl radical reaction. Data from studies in which emissions from wood smoke had been exposed to sunlight were available for several PACs and thus they were given greater weight in judging overall half-life in air for these compounds. Photolysis may also be an important transformation process in air, and half-lives for photolysis were used in the evaluation of overall atmospheric half-life if experimental data were available and indicated that the process was significant at light wavelengths in the visible range (greater than 290 nanometers (nm)).

As indicated above, because of insufficient experimental data EPA used the estimation method of Kwok and Atkinson (Ref. 12) to calculate rate constants for hydroxyl radical oxidation in the vapor phase in the atmosphere, and these data provided the basis for air half-lives for most of the chemicals included in this proposed rule. The Atkinson methodology, as embodied in the Atmospheric Oxidation Program (AOP) (Ref. 11), is generally accepted as the method of choice for estimation of atmospheric oxidation potential and is currently in use worldwide.

b. *Water, sediment, and soil.* For the surface water/sediment compartment, biodegradation is the dominant transformation process for most of the chemicals included in this proposed rule. Therefore, biodegradation data from field or grab sample studies were most often used as the basis for overall half-lives for this environmental compartment. Field studies were preferred, but if only grab sample studies were available the half-life for this compartment was expressed as a range of values. Data from longer term laboratory studies were preferred over other data. Although laboratory-determined half-lives for direct or indirect photolysis (when this process was important and data were available) were almost always lower, the data were not used to determine half-lives for the medium unless from aquatic simulation tests. The rationale is that most of the chemicals included in this proposed rule are expected to sorb strongly to particulate and suspended material in water, and be removed from the surface layers where sunlight penetration is most significant. Hydrolysis data were considered in the determination of overall water/sediment half-life for chemicals with hydrolyzable functional groups if data were available.

Evaluation of half-life data for the soil compartment was similar to that for the water/sediment compartment. As with water/sediment, if only grab sample studies were available, the half-life for

the compartment was expressed as a range of values, but here the possibility of photolysis on the soil surface was noted. Field study data were not qualified in this manner because it was assumed that study plots had been exposed to all relevant transformation processes simultaneously. Photolysis was not considered quantitatively when soil half-lives were based on grab sample data because of the inherent limitations of available photolysis data. Most such available data are for photolysis in water, organic solvents, or water/solvent mixtures, but photolysis rates under these conditions are rarely similar to those for the same chemical sorbed to soil.

As noted above only biodegradation data from field or grab sample studies were used in the determination of overall half-lives for water/sediment and soil. No data from microbial pure culture screening (e.g., Ready Biodegradability tests) or biotreatment studies were used in the evaluation because these types of studies cannot be used to derive environmentally relevant biodegradation half-lives since the environment is much more complex than a microbial pure culture. Data (biodegradation or other) on persistence in benthic sediments were generally not available for the chemicals included in this proposed rule. Data were available for some polychlorinated biphenyls (PCBs); however, and such data were considered in the determination of overall water/sediment half-life for PCBs.

3. *Standards for acceptability of persistence data*. The standards listed below were applied in determining the acceptability of data for soil and water/sediment. At a minimum, studies needed to have information on the following parameters:

- Identity of the tested chemical.
- Study type: grab sample (and what medium the sample came from, i.e., water; soil; sediment; some combination thereof) or field test.
- Degradation rate; or data in table or figure for degradation versus time, from which a rate could be calculated; or rate data already expressed as a half-life or rate constant.
- Analytical method used to measure degradation.
- Initial concentration (dosing) of tested chemical.

Although a lack of the types of information listed below was not necessarily grounds for rejection, a study was considered more valuable if information was given on:

- Purity of the tested chemical.
- Temperature of incubation (or field temperature in the case of field studies).
- Location and characteristics (especially, likelihood of prior contamination and thus development of an acclimated microbial population) of field sites or sites from which grab samples were collected, as appropriate.
- Mass balance obtained with respect to starting level of the test chemical.
- Degree of replication of test vessels, field plots, etc.
- Use of appropriate controls, especially sterile controls to account for any abiotic loss of the tested chemical.

For field and grab sample studies it was important, for interpretation of results in relation to the overall transformation half-life, that processes leading to transport of the chemical out of the medium of interest be ruled out. Which processes were of importance was not always easy to ascertain or predict, but usually this could be done to a first approximation. With respect to field tests especially, but also grab sample tests, special attention was given to the possibility of volatilization (e.g., removal of the volatilized chemical could falsely be attributed to transformation) and sorption.

The following factors were generally considered grounds for rejection of biodegradation studies (Ref. 13). They do not necessarily apply to other types of studies.

- Less than 10% of the tested chemical initially present was lost in the study.
- Degradation rate was determined from a curve for which the r^2 value was low (generally, 0.5 or lower).
- There was reason to believe that abiotic reactions may have contributed to the observed rate of degradation, but there was no sterile control (not applicable to field studies).
- Incubation temperature was less than 10 °C, or was otherwise ''extreme'' (not applicable to field studies).
- Grab samples, if applicable, were held in laboratory storage for an excessive period of time prior to test initiation (generally, greater than several days).
- Initial test chemical concentration was high enough to lead to the possibility that toxicity to the microbial population accounted wholly or partially for low observed degradability (if applicable); generally, levels of the tested chemical greater than 500 mg/L for water and greater than 1,000 mg/L for soil were grounds for suspicion.

For many of the chemicals included in this proposed rule, biodegradation was judged to be the critical process controlling overall persistence in soil or water, but data were available for one or the other but not both media. Under these circumstances EPA assumed that half-lives for biodegradation are roughly comparable in the two compartments. This assumption is based on independently derived but consistent results reported by Boethling, et al. (Ref. 13) and Federle, et al. (Ref. 14). In the first study (Ref. 13), measured half-lives from existing literature data were collected for a wide variety of organic chemicals whose biodegradability had been tested using both soil and water/sediment grab samples (but not necessarily in the same study or by the same investigator). Mean ratios of half-life in water to half-life in surface soil were then calculated for the 20 study chemicals. These ratios varied widely but their overall mean was approximately one. Therefore, it is reasonable to assume that biodegradation in aerobic surface waters is about as fast as biodegradation in soil. Federle et al. (Ref. 14) compared biodegradation rates under various conditions in much the same fashion, but they utilized experimental data generated *de novo* in carefully controlled laboratory tests. Scaling factors (ratios of half-lives) for river water versus soil varied widely as observed in the first study (Ref. 13), but the overall mean was again approximately one.

EPA requests comment on its methodology for determining persistence in the absence of chemical-specific data.

4. *Numerical criteria for persistence in each environmental medium*. Numerous organizations and internationally negotiated agreements have set numerical criteria for environmental persistence, many of which have been developed through consensus processes (Ref. 15). A half-life in water of greater than 4 days is used by EPA's Office of Pesticide Programs (OPP) to trigger bioaccumulation testing of pesticides in fish (Ref. 16). Under the Clean Air Act Amendments of 1990 a list of chemicals of priority concern was developed using a half-life in surface waters of greater that 15 days (Ref. 17). A half-life of 30 days for surface waters was used to identify persistent chemicals on the Toxic Substances Control Act Chemical Substances Inventory (Ref. 18). A number of Canadian projects, many dealing with the Great Lakes basin, have developed lists of chemicals for various actions using a half-life in water criterion of greater than 50 or 56 days with some of the projects also using a sediment half-life criterion of 50 or 56 days or in some cases 180 days (Ref. 15). Another Canadian project, the Canadian Toxic Substances Management Policy (TSMP), used less conservative half-life

values of 6 months in water and 2 years in sediment with an air half-life of 5 days (Ref. 19). Under the North American Free Trade Agreement Commission for Environmental Cooperation (NAFTA-CEC), final screening criteria are under review that use half-life persistence criteria of greater than 6 months for water, 6 months for soil, 12 months for sediment, and 2 days for air (Ref. 20 and 21). Half-life criteria established for persistent chemicals under the United Nations Economic Commission for Europe, Convention on Long-Range Transboundary Air Pollution (UNECE-LRTAP) Protocol on POPs are 2 months for water, 6 months for soil, 6 months for sediment, and 2 days for air (Ref. 20 and 22). In negotiation of the LRTAP POPs Protocol, Germany proposed somewhat more conservative half-life values of 2 months for water, soil, and sediment and 2 days for air (Ref. 20 and 22). The Chemical Manufactures Association (CMA) in its policy for identifying PBT chemicals (Ref. 23) and the International Council of Chemical Associations (ICCA) criteria for identifying persistent organic pollutants (POPs) (Ref. 24) have both used half-life criteria of 180 days for surface water, 360 days for soil, and 5 days for air. In addition, in preparations for scheduled negotiations for the United Nations Environment Program (UNEP) Global Negotiations on POPs an analysis was prepared that discusses international criteria for chemical persistence (Ref. 20).

The above criteria for persistence in water, soil, and sediment tend to cluster around two half-lives, 1 to 2 months and 6 months. A persistence half-life criterion of 6 months seems adequate to ensure that chemicals acknowledged by many groups to be the most persistent are captured, for example the chemicals on the Binational Level 1 list or the chemicals under consideration in the UNEP global POPs negotiations (Ref. 20). But it may be inadequate to capture other chemicals that persist long enough to bioaccumulate to toxic levels. Any chemical exhibiting such properties would be missed by a 6–month criterion.

A 2–month half-life criterion for persistence in water would be consistent with many of the criteria discussed above. In addition, 2 months represents the approximate duration of standard aquatic bioconcentration and chronic toxicity tests, and is therefore thought to be adequate for detecting most long-term toxic effects as well as any tendency for a chemical to accumulate in fatty tissue of aquatic organisms. For example, among current, internationally harmonized Office of Prevention, Pesticides and Toxic Substances (OPPTS) test guidelines in the 850 series are methods for fish (Ref. 25) and oyster (Ref. 26) bioconcentration factors (BCF), for which maximum recommended test durations are 28 to 60 and 28 days, respectively. Test guidelines for ecotoxicity include methods for daphnid chronic toxicity (Ref. 27), mysid shrimp chronic toxicity (Ref. 28), fish early-life stage toxicity (Ref. 29), and tadpole sediment subchronic toxicity (Ref. 30), for which the recommended maximum test durations are 21 days, 28 days, up to 60 days post-hatch, and 30 days, respectively. Sixty days is also sufficient to encompass nearly all bioconcentration data in the Japanese Chemicals Inspection and Testing Institute (CITI) data base (Ref. 31), which contains data from carp bioconcentration tests, mostly of 42 or 56 days' duration, for more than 400 chemicals tested under the Chemical Substances Control Law (CSCL) of Japan. Further, most reliable fish bioconcentration data in EPA's AQUIRE data base (Ref. 32) are from 32–day tests or other tests of comparable duration. Based on the available information, EPA believes the use of a 2–month half-life criterion for persistence in water would be an appropriate criterion to use for determining whether a chemical is persistent in water for purposes of section 313.

As with water, the various groups discussed above have set persistence criteria for soil and sediment that range from 2 to 12 months. As discussed under section A.3. of this unit, two separate studies (Refs. 13 and 14) have suggested that biodegradation in aerobic surface water can be assumed to be about as fast as biodegradation in soil. Therefore, it is appropriate to set the half-life criterion for soil at the same value as for water; i.e., 2 months. Similar considerations apply to the selection of a sediment persistence criterion. Very few data on persistence of chemicals in benthic sediments are available. Deeper layers of aquatic sediment are surely anaerobic, and this is especially likely if the levels of organic matter are high. Boethling et al. (Ref. 13) found that anaerobic biodegradation in flooded soil was on average 3 to 4 times slower than aerobic degradation in surface soil. But surficial sediments are likely to be aerobic and for this situation it is logical to use the same half-life as for the overlying water (i.e., 2 months). In actuality, the precise point in depth at which sediments become anaerobic varies from site to site and is not predictable. Therefore, EPA believes that it is appropriate to use the water criterion for both water and sediment.

The persistence criteria for air selected or proposed by the organizations discussed above are either 2 or 5 days (Ref. 33). As part of the analysis of the UNEP Global Negotiations on POPs (Ref. 20) both theoretical and empirical arguments were presented that support a half-life criterion of 2 days for air. The analysis suggested that the air persistence criterion mainly pertains to the ability of a chemical to persist in air for a sufficient amount of time to be transported to remote regions. For long range transport corresponding to transoceanic or transcontinental distances (i.e., 2,500 miles) to occur, a chemical needs to persist in the air between 7 and 10 days. For a 2–day half-life a significant amount (1/16) of a chemical initially released to air will remain after 8 days. The analysis also concluded that for the chemicals on the initial UNEP list of 12 POPs, all exceeded or were close to the 2–day half-life criterion for air.

The 5–day half-life air criterion proposed by some groups would be sufficient for only 2 half-lives at best to occur in a 10–day transit time. This implies that concern for long-range transport in air should only exist if at least ¼ of the original amount of a chemical released remains after long range transport. However, depending on the quantity of the chemical originally released, amounts below ¼ of that originally released may still be of toxicological significance, especially for chemicals that persist and bioaccumulate. Moreover, even greater amounts of a chemical may be deposited closer to the original source and in much less time than it takes for long range transport. Thus, under a 2–day half-life criterion the amount of an airborne chemical that is available to be deposited at shorter distances can be significant. For example, after 4 days the amount of a chemical with a 2–day half-life in air that will remain available for deposition is ¼ of the original amount released and the amount deposited for a 5–day half-life would be even greater. It has been noted (Ref. 34) that not all chemicals that have been identified as of concern for persistence and bioaccumulation are long-range pollutants, with some POPs with certain properties tending to undergo rapid deposition close to their sources rather than more widespread distribution. This is especially relevant to reporting under section 313 which seeks (among other things) to provide information

concerning chemicals present in local communities. These considerations suggest that the 5–day air criterion is not sufficiently inclusive.

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.

EPA solicits comment on the use of the 2 month criterion in this rulemaking.

5. *Persistence in the multimedia environment.* The environment may be viewed as a set of interconnected media: air, water, sediment, and soil. When a chemical substance is introduced into the environment it becomes distributed among the individual media according to its chemical properties and reactivity, and characteristics of the environment. For example, a chemical released to air may degrade quickly by any of several transformation processes, or it may be deposited on soil, vegetation or surface water, depending on its volatility, tendency to sorb to particulate matter in the atmosphere, prevailing rates of precipitation and particle deposition, and so on. Likewise, a chemical released to surface waters or soils may degrade quickly, or it may volatilize or, in the case of soil, migrate through surface layers and eventually reach ground water. All intermediate forms of chemical distribution behavior are also possible.

In a closed system, thermodynamics determine the distribution of a chemical at equilibrium, absent irreversible transformation of the chemical. Under these conditions the chemical's volatility, as reflected by its Henry's Law constant, and its hydrophobicity, as reflected by its n-octanol/water partition coefficient, are the primary determinants of the final distribution. The tendency to move from one medium to another in response to thermodynamic forces is referred to as partitioning. Partitioning may have a marked effect on the overall persistence of a chemical in the multimedia environment. A chemical may have a relatively long half-life in one medium, but, even if released directly to that medium, may rapidly partition to another where its degradation rate is different. For example, if a volatile chemical that is relatively persistent (i.e., has a long half-life) in water and soil but is rapidly oxidized in the atmosphere is released to water or soil, the chemical's persistence in the receiving medium will be relatively unimportant, as it will quickly volatilize, then degrade in air. The overall persistence of the chemical will be much lower than predicted from transformation half-lives for soil and water alone.

The way in which a chemical enters the environment is also an important consideration. Using the example above, a volatile chemical that is emitted to soil or water will have a different and higher overall persistence than if the same substance is emitted directly to air. This is because the process of moving from one environmental medium to another--called intermedia transport--is time dependent. Intermedia transport is complex and a full characterization includes a suite of mass transfer coefficients, rain rates, and rates of aerosol and dry deposition, sediment deposition and resuspension, and soil water and solids runoff (Ref. 35).

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 an approach based on the EQC model (Ref. 35) to estimate overall environmental persistence. Overall persistence estimated in this way is used as an additional factor, in conjunction with reaction half-lives 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. 36) and subsequently applied to numerous environmental processes (Ref. 37). 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. 38). EPA used a version of the EQC level III model (Ref. 35) 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. 5). 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-lives 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. EPA has performed this calculation and the results are discussed in Unit V.C.3. of this preamble.

In this analysis EPA used the highest, lowest, and mean values for the ranges of half-lives identified as described above, as inputs to the model. In addition to reaction half-lives for air, water, and soil, the EQC model requires half-lives for the sediment compartment. Measured values were used where available, but since there were few such data, where biodegradation was the rate-determining process, the half-life in the surface layer of sediments was assumed to be the same as that for aerobic biodegradation in the water column. The rationale is that sediment surface layers are likely to be aerobic, and therefore rates of biodegradation will be similar at the sediment-water interface and in the water column.

It has been proposed that reaction half-lives for input into multimedia mass balance models like the EQC model be expressed as lognormal distributions with defined standard

deviations, the standard deviation being derived by assigning default values if adequate experimental data are unavailable (Ref. 5). Overall environmental persistence can then be expressed as a distribution and a sensitivity analysis can be conducted to identify which reaction half-lives are most critical in determining overall persistence. Another result of the sensitivity analysis may be to show that one or more compartmental half-lives can be assumed to be infinite without having a marked effect on the overall environmental persistence.

While meeting any one of the medium-specific criteria for persistence in water, soil, or sediment is sufficient to classify a toxic chemical as persistent for purposes of section 313, EPA also considers the results of multimedia modeling. If the results of multimedia modeling indicate that a toxic chemical does not meet the persistence criteria then, EPA may exclude that chemical from further consideration as persistent. The use of multimedia modeling results to override the medium-specific persistence data will only be considered if all model inputs are judged to be accurate. For example, if the multimedia modeling results are being driven by a chemical's half-life in air but that half-life is not considered to be very reliable, then EPA does not believe that the multimedia modeling should override the medium-specific criteria. EPA will make a case-by-case determination for any chemical that is not considered persistence on the basis of multimedia modeling.

EPA solicits comments on this overall approach to the use of multimedia modeling as discussed in this proposed rule, and on any actual or proposed modifications to the fate model described above.

B. Bioaccumulation

Bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. The discussions and data on bioaccumulation in this proposed rule deal strictly with aquatic organisms because most of the bioaccumulation data are from aquatic studies. This is not to imply that bioaccumulation cannot occur in non-aqueous environments. The term bioaccumulation refers to uptake of chemicals by organisms both directly from water and through their diet (Ref. 39). EPA has defined bioaccumulation as the net accumulation of a substance by an organism as a result of uptake from all environmental sources (60 FR 15366). The nondietary accumulation of chemicals in aquatic organisms is referred to as bioconcentration, and may be described as the process through which a chemical is distributed between the organism and environment based on the chemical's properties, environmental conditions, and biological factors such as an organism's ability to metabolize the chemical (Ref. 40). EPA has defined bioconcentration as the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces (60 FR 15366). A chemical's potential to bioaccumulate can be quantified by measuring or predicting the chemical's bioaccumulation factor (BAF). EPA has defined the BAF as the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time (60 FR 15366). A chemical's potential to bioaccumulate can also be quantified by measuring or predicting the chemical's bioconcentration factor (BCF). EPA has defined the BCF as the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through water only and the ratio does not change substantially over time (60 FR 15366). This Unit discusses those aspects of determining bioaccumulation that are important to consider in assessing whether a particular chemical will bioaccumulate in the environment.

1. *Use of BAFs versus BCFs.* In general, because BAFs consider the uptake of chemicals from all routes of exposure they are considered better predictors of the accumulation of chemicals within fish than BCFs which only consider uptake of chemicals directly from water. EPA reached this same conclusion with regard to the use of BAFs in setting criteria for the protection of the Great Lakes. Specifically, EPA stated that BAFs were a better predictor of the concentration of a chemical within fish tissues in the Great Lakes System because they include consideration of the uptake of contaminants from all routes of exposure (60 FR 15366). However, considering all routes of exposure greatly complicates the analysis of bioaccumulation and the calculation of BAFs. Biomagnification and trophic transfer via the food chain must be considered in such determinations. Also, the percent lipid content of fish at certain trophic levels must be factored in or normalized for developing BAFs for non-polar chemicals (60 FR 15366). Thus, the BAF value for a chemical may be much higher than its BCF value when these other parameters are considered; the former is much more difficult to calculate and more assumptions must be made.

Measured BAFs are based on field measurements of concentrations of chemicals in various biota and water. Thus, BAFs will vary depending on where in the food chain one samples organisms for analyses. For example, a carp (an omnivore, lower in the food chain) will have a different BAF than a pike (a top predator, high in the food chain and at a high trophic level). BCFs and BAFs are not mutually exclusive of one another but can be related. A predicted BAF can be derived by multiplying a laboratory-derived BCF by a food-chain multiplier (FCM) (defined as the ratio of BAF to an appropriate BCF) or by multiplying an estimated BCF by a FCM value. BAFs predicted by using FCMs include many but not all of the environmental fate processes (for example, metabolism) and interactions that affect bioaccumulative chemicals. When these processes or interactions are significant, predicted BAFs will be larger than field-derived BAFs. Therefore, BAFs measured in the field are preferred. An additional complicating factor in determining BAFs is the interconnectivity of the water column and sediments in aquatic ecosystems. This means that chemical residues in fish can also be predicted via biota-sediment accumulation factors (BSAFs) which use the concentration of the chemical in sediment as a reference point (60 FR 153661).

Although BAFs can be measured or calculated, a BCF value is more commonly measured or predicted because such measurements do not require the consideration of the often complex issues of food and sediment exposure required for BAF determinations. EPA has been using BCF values as an indicator of bioaccumulation potential for industrial chemicals and pesticides for many years (Ref. 41). In addition, well-known and established test guidelines for determining BCF values exist (Refs. 25 and 26). These test guidelines suggest that only a limited number of aquatic species be tested, mainly fathead minnows and/or oysters and occasionally rainbow trout, which helps to reduce variability in test results. BCF values for many organic chemicals have been calculated using these test guidelines, particularly for some chemicals tested under TSCA section 4. In addition, equations for predicting

BCF values have been developed that correlate well with measured values (Refs. 40 and 42). The most recent of these equations was developed by comparing predictions with measured data for 694 chemicals and is believed to provide a significantly better fit to the existing measured data than other methods (Ref. 40). Due to the consideration of additional sources of exposure, BAF values are usually higher than BCF values, thus using a BCF value should not usually over-predict the potential for bioaccumulation in aquatic species.

The number of measured or predicted BAFs available is limited while measured BCFs exist for many chemicals and can be predicted rather easily. While BAFs may be better predictors of the concentration of a chemical in fish, in the absence of appropriately measured or predicted BAFs, a BCF value can be used as an indicator of a chemical's potential to bioaccumulate. For purposes of determining if a chemical is bioaccumulative under section 313 EPA will use BAF values when available and BCF values for toxic chemicals for which appropriately determined BAFs do not exist. EPA requests comment on this approach.

2. *Predicting BAFs and BCFs.* Appropriately measured BAF or BCF values are always the data of first choice, however these values are expensive to measure if done properly and thus are not as readily available as predicted values. In the absence of valid measured data, EPA believes that it is appropriate to use predicted BAF and BCF values since available prediction methods provide values that correlate well with measured data. EPA has published procedures for predicting BAFs (60 FR 15366). However, since BAFs require consideration of complex exposure paths, BCFs are the more commonly predicted indicator of a waterborne chemical's potential to bioconcentrate in aquatic organisms. BCF values are often predicted from a chemical's octanol/water partition coefficient (K_{ow}). A chemical's K_{ow} is a ratio of the chemical's concentration in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase n-octanol-water system. The information is usually reported as the common logarithm (base 10) of K_{ow}, log K_{ow}, rather than as K_{ow} itself. A chemical's log K_{ow} provides an indication of the chemical's ability to bioconcentrate based on the assumption that bioconcentration is a thermodynamically driven partitioning process between water and the lipid phase of the exposed organism, and therefore can be modeled using n-octanol as a surrogate for biological lipids. Thus, the relationship between log K_{ow} and BCF is valid only for chemicals that bioconcentrate in tissues containing lipids (Refs. 40 and 41). BCFs are usually predicted from regression equations of the general form: log BCF = a log K_{ow} + b where a and b empirically determined constants (Ref. 43). The equation, log BCF = 0.79 log K_{ow} -0.4, has been determined to provide a good correlation with measured BCF values (Ref. 42) and has been used by EPA for a number of years. In addition, the bilinear model method developed by Bintein, et al. (Ref. 44) provides a much better correlation with measured BCF values for chemicals with log K_{ow} values greater than 6. Recently a study was conducted that improved the correlation between prediction equations and measured BCF values (Ref. 40). The new equation, developed by comparing predictions with measured data on 694 chemicals, is log BCF = 0.77 log K_{ow} -0.7 + ΣFi, where Fi are correction factors for structural characteristics of the chemical in question (Ref. 40). This new equation is believed to provide an even better fit to the existing measured BCF data base.

EPA request comments on its methodology for predicting BCF values and on the use of predicted BCFs for quantifying the bioaccumulation of chemicals in this rulemaking when measured BCFs are not available.

3. *Standards for acceptability of measured BAF and BCF data.* Measured BAF or BCF values are the preferred source of bioaccumulation data if the values are from appropriately conducted studies. EPA has published procedural and quality assurance requirements for field-measured BAFs for the Final Water Quality Guidance for the Great Lakes System (56 FR 15366). While these requirements are specific to the Guidance for the Great Lakes System, they do provide a basis for some general factors to be considered when reviewing measured BAF data, for example:

- The trophic level of the fish species tested should be determined.
- For organic chemicals, the percent lipid should be either measured or reliably estimated for the tissue used in the determination of the BAF.
- The concentration of the chemical in the water should be measured in a way that can be related to particulate organic carbon (POC) and/or dissolved organic carbon (DOC) and should be relatively constant during the steady-state time period.
- For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the ambient water should be either measured or reliably estimated.
- For inorganic and organic chemicals, BAFs should be used only if they are expressed on a wet weight basis; BAFs reported on a dry weight basis should not be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

EPA also used some general guidelines for selecting measured BCF values for this proposed rule. The goal was to limit the number of individual measured BCF values to be considered to 10 for any given chemical (where applicable), and to select a single recommended BCF from the available measured values for each chemical. The general guidelines used were:

- Data obtained by the kinetic method were preferred to data from the equilibrium method, especially for chemicals with high log K_{ow} values, which are less likely to have reached equilibrium in standard tests.
- For equilibrium-method studies a BCF value in the middle of the range of values with the longest exposure times was selected, especially for substances with high log K_{ow} values (for the same reason as noted above).
- Low exposure concentrations of the chemical were favored in order to minimize the potential for toxic effects and maximize the likelihood that the total concentration of the chemical in water was equivalent to the amount that was bioavailable.
- Data obtained under flow-through conditions were selected whenever possible.
- Data were rejected if significant contamination of the exposure medium by food, excreta, or other adsorbents was suspected, since this may reduce the bioavailability of the test chemical.
- Warm-water fish were preferred to cold-water fish since more data were available for warm-water species. EPA also considered whether the measured BCF values were from studies that were conducted in a manner consistent with the well-known and established test guidelines for determining BCF values (Refs. 25 and 26).

4. *Sources of BAF and BCF data for chemicals included in this proposed rule.* The data used to assess the bioaccumulative properties of the chemicals included in this proposed rule includes a mixture of both predicted and measured BAF and BCF values. Appropriately measured BAF and BCF values were used where available, but in the absence of appropriately measured values, predicted values were used. Measured

BCF values were identified mainly from a review of a data base of BCF values for 694 chemicals compiled by Syracuse Research Corporation (SRC) to support the development of an improved BCF prediction equation (Ref. 45). Other BCF values were predicted using the equation developed by Meylan, et al. (Ref. 40). Additional measured or predicted BCF values were obtained from previous chemical reviews, hazard assessments, TSCA section 4 activities, and other references. In addition, measured BAF values for certain chemicals were obtained from EPA's Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors (Ref. 46). The record for this proposed rule includes a document that explains the origin of the BAF or BCF value selected for the each PBT chemical (Ref. 47).

The measured BCF values contained in the data base developed by SRC were obtained primarily from the U.S. EPA's AQUIRE data base (Ref. 32); a large data base of BCF values collected by the Japanese Chemicals Inspection and Testing Institute (CITI) (Ref. 31); the National Library of Medicine's Hazardous Substances Data Bank (HSDB) (Ref. 48); and sources referenced in the Environmental Fate Data Base (EFDB) (Refs. 49 and 50). Most data were retrieved from AQUIRE (277 chemicals) and CITI (479 chemicals). Only fish BCF data were collected for the data base, which does not contain data for any other species. The record for each chemical contains up to 10 individual BCF measurements, and a single recommended value selected from the listed measurements which was chosen following EPA-approved selection criteria (Ref. 47). If available, data were also collected for each individual BCF value on fish species, concentration of test substance, percent lipid in test organism, test method (equilibrium or kinetic), and fish tissue on which measurements were based (whole body, fillet, or edible tissue). A separate field in each data base record contains the rationale for selection of the recommended BCF value. Printouts of the data base records for each PBT chemical whose BCF data came from this data base are included in the record for this proposed rule (Ref. 47).

5. *Numerical criteria for bioaccumulation.* EPA used a BAF/BCF numerical criterion of 1,000 for determining if a chemical is bioaccumulative for purposes of section 313. The initial basis for the consideration of a BCF value of approximately 1,000 as an indicator of high bioaccumulation potential is linked to information developed at a meeting sponsored by the American Society for Testing and Materials held in 1976 which was published in the open literature two years later (Ref. 51) and which was recently reaffirmed (Ref. 52). Additional support for the use of a numerical cut off of 1,000 for bioaccumulation has developed over a number of years. In chemical reviews conducted under TSCA, EPA uses BCF values of between 100 and 1,000 to indicate a medium concern for the potential bioaccumulation of a chemical and a BCF of 1,000 or more to denote a high concern (Refs. 53 and 54). EPA's Duluth Laboratory (Refs. 55 and 56) studied 83 chemicals, 59 of which had predicted BCF values of less than 188 (log K_{ow} less than 3.5). Of the 59 chemicals, none had predicted BCF values that were high enough to have demonstrable environmental effects. This indicated that bioconcentration testing should not be necessary for chemicals with predicted BCF values of less than 188 (Ref. 54). However, there were some chemicals whose BCF values were between 188 and 1,000 (log K_{ow} 3.5 to 4.35) that were found to bioconcentrate significantly (Ref. 55). Thus EPA established a BCF range of equal to or greater than 100 and less than 1,000 to indicate a medium concern for bioaccumulation and a BCF value of greater than 1,000 for a high concern. In addition, the usefulness of the BCF cut off value of 1,000 for high concern was affirmed in an EPA-sponsored workshop (the Testing Triggers Workshop) which was conducted in 1982 (Ref. 57). Furthermore, a BCF value of 1,000 has been used by many groups over the years to denote chemicals of high concern for bioaccumulation potential, especially with regard to the need to conduct long-term chronic toxicity testing (Refs. 51, 58, 59, 60, 61, 62, and 63).

As with BCF values, EPA believes that it is appropriate, for section 313 purposes, to use a criterion of 1,000 for BAF values. Since BAF values include consideration of additional routes of exposure it is appropriate to use a criterion that is at least equal to that set for BCF values. Support for a BAF criterion of 1,000 also comes from the Final Water Quality Guidance for the Great Lakes System (60 FR 15366). In that 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., those with BAF values greater than 1,000) would receive increased attention and more stringent controls. That final Guidance designated as BCCs those chemicals with human health BAFs greater than 1,000 that were derived from certain field-measured BAFs or certain predicted BAFs. That previous designation of a high level of concern for chemicals with BAF values greater than 1,000 provides further support for the use of a BAF/BCF criterion of 1,000 for determining whether a chemical should be classified as bioaccumulative for purposes of section 313.

As with persistence, a number of organizations and internationally negotiated agreements have set numerical criteria for bioaccumulation, many of which have been developed through consensus processes. Some Canadian projects, many dealing with the Great Lakes basin, have used a BAF/BCF criterion of 5,000 or 1,000 or even 500 (Refs. 19, 64, and 65). Under the NAFTA-CEC, final screening criteria are under review that use a BAF/BCF criterion of 5,000 (Ref. 21) and the UNECE-LRTAP Protocol on POPs also established a BAF/BCF criterion of 5,000 (Ref. 22). In negotiation of the LRTAP Protocol, Germany proposed a BAF/BCF criterion of 1,000 (Ref. 22). The Chemical Manufactures Association (CMA) in its policy for identifying PBT chemicals (Ref. 23) established a BAF/BCF criterion of 5,000.

EPA requests comment on its use of the 1,000 BCF/BAF criterion.

C. Technical Review of Persistence and Bioaccumulation Data and Modeling Results

1. *Persistence and bioaccumulation data.* Table 1 below presents the bioaccumulation and persistence data for the PBT chemicals being considered in this proposed rule. More detailed discussions of the sources of these data are provided in the support documents (Refs. 47 and 66) which commenters should consult for additional information.

EPA's approach to the collection of persistence data was to identify reasonable ranges of half-lives for the principal environmental media (air, water/sediment, soil). By identifying reasonable ranges of half-lives for each chemical EPA was able to consider the available data in determining whether a chemical's half-life in a particular medium was above or below half-life criteria selected for persistence in that medium. For example, if the reasonable range of half-lives for a chemical in soil were from 3 to 5 months then EPA could conclude that the chemical would exceed a 2–month soil half-life criterion. In cases where the range of half-lives for

a chemical bracketed a particular criterion, EPA determined whether the available data supported the higher or lower end of the half-life range. For example, when considering a 6–month half-life criteria, if a chemical's half-lives in water range from 5 to 10 months, but the higher value was based on a better study, then EPA believes that it is reasonable to conclude that the chemical's half-life is greater than 6 months. EPA believes that this approach provided sufficient certainty to determine, for purposes of section 313, whether the persistence of a chemical in the principal environmental media was above or below a particular criterion.

As discussed in Unit VII.A.1.a., EPA used a two-tiered approach in considering the bioaccumulation and persistence potential for the chemicals in this proposal. For persistence the two tiers are for chemicals that persist in the environment in either water, sediment, or soil with a half-life of 2 months or greater but less than 6 months and for chemicals that persist in any of these media with a half-life of 6 months or greater. The two tiers for bioaccumulation are for BAFs and BCFs of equal to or greater than 1,000 but less than 5,000 and equal to or greater than 5,000. There are several chemical categories included in Table 1 for which the persistence and bioaccumulation potential of the members of the category vary. When considering the bioaccumulation and persistence potential of chemical categories EPA reviewed the individual bioaccumulation and persistence data for the category members and determined which tier the entire chemical category should be placed in. Some chemicals had half-life ranges that bracketed the persistence tiers, for example, heptachlor has a soil half-life range of 8 days to 4 years. In cases where the persistence data would determine which, if either tier a chemical should be in, a determination had to be made as to the most appropriate persistence data to use. This was the case for five of the chemicals discussed in the following paragraph. For these chemicals EPA considered the types of studies supporting the half-life ranges and determined the most appropriate tier for each chemical. The support document (Ref. 67) contains a more detailed description of the rationale for EPA's decision. Commenters should consult the docket for additional information.

Table 1.—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
Dicofol	115-32-2	12,303		8 days–19 hrs	8.2 days–13 hrs	348-259 days
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

Table 1.—Persistence and Bioaccumulation Data—Continued

Chemical Category/Chemical Name	CASRN	BCF	BAF	Air Half-life	Surface Water Half-life	Soil Half-life
Polycyclic Aromatic Compounds						
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						
Cobalt[5] and Cobalt Compounds	7440-48-4	1-2,000,000		see footnote 5	see footnote 5	see footnote 5
Mercury[5] and Mercury compounds	7439-97-6	7,000-36,000		see footnote 5	see footnote 5	see footnote 5
Vanadium[5] and Vanadium compounds	7440-62-2	100,000-1,000,000		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
2,3′,4,4′,5,5′-hexachlorobiphenyl	52663-72-6	37,590		114–11 days	>56 days	>5–3.42 yrs

Table 1.—Persistence and Bioaccumulation Data—Continued

Chemical Category/Chemical Name	CASRN	BCF	BAF	Air Half-life	Surface Water Half-life	Soil Half-life
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.

Benzo(j,k)fluorene (fluoranthene) has a soil half-life range of 110 days to 13 years, however the 13–year value is based on the results of a field study and thus fluoranthene was determined to persist in soil for greater than 6 months. As mentioned above, heptachlor has a soil half-life range of 8 days to 4 years, however the 4–year value is based on the results of a field study and thus heptachlor was also determined to persist for greater than 6 months in soil. Tetrabromobisphenol A has a surface water half-life range of 48 to 84 days and a soil half-life range of 44 to 179 days. Based on a review of the grab sample studies, it was determined that tetrabromobisphenol A should have a half-life in water and soil of greater than 2 months but less than 6 months. Trifluralin has a soil half-life range of 99 to 394 days, based on a review of the field studies for trifluralin it was determined that it should have a soil half-life of greater than 2 months but less than 6 months.

For a significant number of substances in several congeneric series (polychlorinated dioxins; furans; PACs), half-lives were derived by extrapolation from data for other substances in the series. This approach is generally considered acceptable if appropriate allowance is made for minor differences in molecular structure. 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-lives for the structural analogs pentachlorobenzene (CAS No. 608–93–5) and hexachlorobenzene (CAS No. 118–74–1) for estimating half-lives for octachlorostyrene.

For the dioxin and dioxin-like compounds category the half-lives in soil for all members is clearly greater than 6 months. For bioaccumulation the members of this category have BCF values that range from a low of 1,259 to a high of 42,500 with 6 chemicals over 5,000 and with 6 chemicals between 3,500 and 5,000. Based on this data EPA believes that, as a category, the dioxin and dioxin-like compounds should be considered to have a BCF value greater than 5,000 since most of the members are close to or well above 5,000. However, as discussed in Unit VII.A.2., a special reporting threshold is required for this category, and therefore the BCF value for the category was not a major factor in selecting the proposed reporting threshold.

For the members of the polycyclic aromatic compounds (PACs) category, all but a few had soil or surface water half-lives well in excess of 6 months. The BCF values for the category ranged from a low of 800 to a high of 31,440 with 15 of the 20 category members having BCF values greater than 5,000. Based on this data EPA believes that, as a category, the polycyclic aromatic compounds should be considered to have a BCF value greater than 5,000. As an alternative, the category could be separated into two categories with appropriate reporting thresholds for each category. However, this would

tend to be more burdensome since some facilities might have to file two reports and because it would require further speciation of the members of the category.

EPA requests comment on this alternative proposal to create two PACs categories.

The section 313 listing for PCBs is not a category listing but its CAS number covers all PCBs making it the equivalent of a category of chemicals. For the PCBs in Table 1 and for additional PCBs listed in the support document (Ref. 66), the soil half-lives are greater than 6 months, the reported BAF values are well above 5,000 (Table 1 and Ref. 47), and, with one exception, the BCF values for those PCBs in Table 1 are above 5,000. For the one exception, 2,3,3′,4,4′,5,5′-heptachlorobiphenyl, the estimated BCF is 4,922 which, considering the data for the other PCBs, EPA believes is sufficiently close to 5,000 for this chemical to be considered to have a BCF of 5,000. Based on the available data EPA believes that all members covered by the section 313 PCBs listing should be considered to have soil half-lives greater than 6 months and BAF/BCF values greater than 5,000.

For metals and metal compounds, although a metal or metal compound can be converted to another metal compound, the metal is not destroyed in the environment. Thus, metals obviously persist for greater than 6 months. As for bioaccumulation potential, the BCF values are reported as ranges of values with extremely high values at the upper end of the range. For purposes of section 313 reporting, EPA considered mercury and mercury compounds to have BCF values greater than 5,000. During the inter-agency review process, some reviewers raised questions about the adequacy of the studies that were used to make the BCF determination for cobalt and cobalt compounds. EPA specifically requests comment on the adequacy of these studies for determining bioaccumulation potential for cobalt and cobalt compounds. At this time cobalt and cobalt compounds do not appear on the proposed regulatory text list of PBT chemicals with lowered reporting thresholds. However, depending on comments received, EPA may add cobalt and cobalt compounds to that list in the final rule. As discussed in Unit IV.C.7. of this preamble, EPA is also requesting comment on the sufficiency of the bioaccumulation data for vanadium and vanadium compounds.

EPA requests comment on its evaluation of persistence and bioaccumulation for each of the chemicals included in this rulemaking.

2. *Epoxidation of certain pesticides.* Epoxidation is one of the major mechanisms of microbial metabolism of the cyclodiene pesticides including aldrin, heptachlor, and isodrin (Ref. 68). Aldrin is epoxidized to dieldrin (Ref. 69); isodrin is epoxidized to endrin; and heptachlor is converted to heptachlor epoxide (Ref. 70). These transformations are common and have been reported to occur in microbes, crustaceans, insects, fish, mammals, and birds (Refs. 71, 72, 73 and 74). Epoxides of heptachlor and aldrin are both insecticidal, and thus their biological activity is prolonged in soil.

The persistence and bioaccumulation data for the epoxides endrin, dieldrin, and heptachlor epoxide are included in the support documents for persistence and bioaccumulation (Refs. 47 and 66). The persistence and bioaccumulation data for endrin include 3 to 7 hours in air, greater than 112 days in surface water, and 333 to 4,300 days in soil with a BCF value of 4,591. The persistence and bioaccumulation data for dieldrin include 3 to 30 days in air, greater than 56 days in surface water, and 175 to 1,080 days in soil with a BCF value of 4,467. The persistence and bioaccumulation data for heptachlor epoxide include 6 to 60 hours in air and 33 to 522 days in soil with a BCF value of 14,454. Thus all of these compounds persist in at least one medium and are highly bioaccumulative. Regarding the toxicity of these epoxides, EPA's Integrated Risk Information System (IRIS) indicates that dieldrin and heptachlor epoxide have been classified by EPA as Group B2 carcinogens (i.e., they are probable human carcinogens) and that endrin caused convulsions and liver toxicity in a 2–year feeding study in dogs (Ref. 75).

The epoxidation of the parent compounds aldrin, heptachlor, and isodrin is important in light of the fact that the epoxides produced are persistent, bioaccumulative, and toxic. Therefore, in the medium that the epoxide is formed the parent compounds are being transformed into another toxic chemical. This means that the half-lives of the parent compounds in the epoxidizing medium may underestimate the concern for the parent compounds since they are converted to another toxic chemical that also persists and bioaccumulates. This could be characterized as extending the persistence of a toxic chemical in that media. Often these compounds are considered together and listed as aldrin/dieldrin, isodrin/endrin, and heptachlor/heptachlor epoxide.

The rates of transformation from the parent chemical to the epoxide have not been well-characterized in all relevant media. However, it is important to consider that transformation of these parent compounds to their epoxides, regardless of the rate, results in the formation of products that are of concern for their persistence, bioaccumulation potential, and toxicity.

3. *Multimedia modeling results.* The results of the modified version of the EQC multimedia modeling runs were presented as ''total persistence half-lives'' (Ref. 76). The EQC model defines ''overall persistence'' or ''residence time'' as the ratio of the amount of chemical present in the evaluative environment at steady state to the total rate of loss. Total persistence is also expressed as the reciprocal of the total removal rate constant. The total persistence half-lives are calculated by multiplying the overall persistence by ln 2.

The use of the medium (i.e., the midpoint of the half-life range) and high half-life values for each medium resulted in overall persistence half-lives of greater than 2 months for all chemicals in Table 1 of this unit except 7,12-dimethylbenz(a)anthracene, heptachlor, methoxychlor, and trifluralin.

7,12-Dimethylbenz(a)anthracene was modeled using half-life ranges of 24 minutes to 4 hours for air, 1 to 6 years for water and sediment, and 20 to 28 days for soil. The results of the modified EQC model suggest that at steady state, sufficient quantities of this chemical will volatilize to the atmosphere and undergo hydroxy radical oxidation, and partition to soils with subsequent biodegradation that the overall environmental persistence will be 1 month.

Half-life ranges used for heptachlor were 1 to 10.5 hours for air, 23 hours to 5 days for water, and 8 days to 4 years for soil and sediment. Half-life ranges used for methoxychlor were 1 to 12 hours for air, 5 to 15.2 days for water and sediment, and 81 to 136 days for soil. Trifluralin was modeled using half-life ranges of 25 minutes to 3.2 hours for air, and 99 to 394 days for water, soil, and sediment. The modified EQC model predicts that at steady state, sufficient quantities of these chemicals will volatilize to the atmosphere and undergo hydroxy radical oxidation that the overall environmental persistence will be 0.03 months for heptachlor, 0.7 months for methoxychlor, and 0.6 months for trifluralin.

It should be noted that all of these compounds are expected to enter the atmosphere associated with particulate

matter or in particulate form. The method used for the estimation of hydroxy radical oxidation half-lives is applicable to chemicals in the vapor phase. Rates of oxidation for chemicals in particulate form or associated with particulate matter may be overestimated, but the extent is unknown and thus there is some question as to the accuracy of the data used in the modeling. Also, since sediment half-lives were not available for these chemicals, the sediment half-lives used in the modeling were that same as the surface water half-lives. Since sediment half-lives are usually longer than surface water half-lives this may result in an underestimation of the ''total persistence half-lives'' generated by the modified EQC model. In fact, when modeled using sediment half-lives four times that of the surface water half-lives, the ''total persistence half-lives' for these chemicals did increase (Ref. 76). For heptachlor there is also the issue of the epoxidation to heptachlor epoxide and how that transformation affects the overall persistence of heptachlor/heptachlor epoxide. Also, since 7,12-dimethylbenz(a)anthracene is a member of the polycyclic aromatic compounds category EPA believes that it would be best not to separate it out from the other 20 carcinogenic members of the category.

As stated in section A.5. of this unit, EPA intends to only use multimedia modeling results to override the medium-specific persistence data if all model inputs are judged to be accurate. Because of the uncertainties associated with the air half-lives for these chemicals and the lack of data on sediment half-lives, which could affect the modified EQC modeling results, EPA does not believe that the modeling results should be used to override the medium-specific persistence data for these chemicals.

EPA requests comments on how the results of the modified EQC multimedia modeling for these chemicals should affect their status as PBT chemicals for purposes of EPCRA section 313.

VI. Modifications to Proposed Dioxin and Dioxin-Like Compounds Category

In response to a petition from Communities For A Better Environment, EPA issued a proposed rule (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 PCBs from their listing under CAS number 1336–36–3 to a dioxin and dioxin-like compounds category. To accomplish this, EPA proposed to add a qualifier to the current PCB listing so that it would read ''polychlorinated biphenyls (PCBs) (excluding those PCBs listed under the dioxin and dioxin-like compounds category)'' and to list each of the 11 PCBs by name and CAS number in the proposed dioxin and dioxin-like compounds category. As discussed in Unit V.C. of this preamble, 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. Because of this change, the proposed dioxin and dioxin-like compounds category would include only the 7 polychlorinated dibenzo-*p*-dioxins and the 10 polychlorinated dibenzofurans identified in the proposed rule.

EPA requests comment on its withdrawal of the proposal to modify the current listing for PCBs by adding the qualifier described above.

In addition to the above modification to the dioxin and dioxin-like compounds category, EPA is proposing to add an activity qualifier to the category that limits reporting to facilities that manufacture these chemicals. 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. of this preamble), facilities that process raw materials would be required to report simply because the raw material contains background levels of these chemicals. In order to focus reporting on those facilities that actually add to the environmental loading of these chemicals, EPA is proposing to add the activity qualifier ''manufacture only'' to the category. This will mean that only those dioxin and dioxin-like compounds that are manufactured at the facility, including those coincidentally manufactured, will be the subject of reporting under section 313. This will not only focus attention on activities that add to the loading of these chemicals in the environment but it also significantly reduces the reporting burden for industry that would result without the activity qualifier.

EPA requests comment on this proposed qualifier for the dioxin and dioxin-like compounds category.

VII. Proposed Changes to Reporting Requirements for PBT Chemicals

A. Changes to Reporting Thresholds

1. *Selection of lower reporting thresholds.* In selecting potential lower reporting thresholds for PBT chemicals, EPA considered not only their persistence and bioaccumulation but also the potential burden that might be imposed on the regulated community. Each of these important considerations is discussed below.

a. *Persistence and bioaccumulation.* Because all PBT chemicals persist and bioaccumulate in the environment, they have the potential to pose human health and environmental risks over a longer period of time. Thus, even small amounts that enter the environment can lead to elevated concentrations in the environment and in organisms which can result in adverse effects on human health and the environment. 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 25,000 and 10,000 pounds. For determining how low reporting thresholds should be set for these chemicals, EPA has adopted a two-tiered approach. This approach recognizes that toxic chemicals that have very high persistence and bioaccumulation potentials (e.g., chemicals with half-lives of 6 months or more and BAF/BCF values of 5,000 or more), like those that have been widely recognized as PBT chemicals, are of greatest concern. EPA believes that for toxic chemicals that are highly persistent and bioaccumulative, any release of the toxic chemical can result in elevated concentrations in the environment and organisms because of their very high persistence and bioaccumulation potentials. As a result, consideration of persistence and bioaccumulation alone would lead EPA to set a reporting threshold for the subset of highly persistent bioaccumulative chemicals that approaches zero in order to provide relevant data to communities. Thus, EPA believes that it is appropriate to set a low threshold for toxic chemicals that persist and bioaccumulate and to set a lower threshold for toxic chemical that are highly persistent and

bioaccumulative. EPA has made this distinction between persistent bioaccumulative chemicals and highly persistent bioaccumulative chemicals by proposing to set lower reporting thresholds based on two levels of persistence and bioaccumulation potential. The two levels are for those PBT chemicals included in this rule that persist in the environment with a half-life of 2 months or greater but less than 6 months and that have BAF or BCF values of 1,000 or greater but less than 5,000 (the 2–month and 1,000 group) and for those chemicals that persist in the environment with a half-life of 6 months or greater and that have BAF or BCF values of 5,000 or greater (the 6–month and 5,000 group). EPA believes that based solely on the degree of persistence and bioaccumulation it would be appropriate to set section 313 manufacture, process, and otherwise use thresholds to 10 pounds for chemicals meeting the 2– to 6–month and 1,000 to 5,000 criteria and to 1 pound for chemicals meeting both the 6–month or greater and 5,000 or greater criteria. One exception to this is the reporting threshold for the dioxin and dioxin-like compounds category. See Unit VII.A.3. below.

EPA believes that it is appropriate to set two thresholds based on the degree of persistence and bioaccumulation of the chemicals because chemicals with a half-life of 6 months or greater and a BAF/BCF of 5,000 or greater have a higher exposure potential than chemicals with a half-life of 2 months or greater and a BAF/BCF of 1,000. EPA believes that communities have a greater right-to-know about chemicals which can reasonably be anticipated to be present in the community at higher levels. This greater exposure potential is illustrated in the examples below.

More of a given quantity of a chemical with a half-life of 6 months will exist in the environment 1 year after release than of a given quantity of a chemical with a half-life of 2 months. Specifically, on January 1, a facility releases 100 pounds of a chemical with a half-life of 6 months. On July 1, 50 pounds will remain in the environment; on December 31, 25 pounds will remain in the environment. On January 1, the same facility releases 100 pounds of a chemical with a half-life of 2 months. On July 1, 12.5 pounds will remain in the environment; on December 31, 1.6 pounds of the chemical will remain in the environment. The chemical with the half-life of 6 months will result in long-term elevated quantities of the chemical in the environment. Further, releases of persistent toxic chemicals that occur more frequently than once a year can rapidly result in large increases in the amounts of the chemicals present at any one time in the environment because the environment does not have sufficient time to remove these chemicals through degradation. This example is somewhat oversimplified because a chemical's biodegradation rate is dependent on so many environmental conditions and may fluctuate during the year depending on changes in environmental conditions. However, all conditions being equal, the chemical with the longer half-life will be present in the environment for a longer period of time.

The increased exposure potential also applies to chemicals with different BCFs. The identical amount of two different chemicals, chemical A with a BCF of 1,000 to fish and chemical B with a fish BCF of 5,000 will result in different exposures to fish that consume other organisms lower in the food chain, that have also been exposed to these chemicals. For example, organisms that consume the fish exposed to chemical B will usually be exposed to greater quantities of the chemical than organisms that consume the fish that was exposed to chemical A, assuming identical feeding rates and other conditions. Due to concerns for its higher accumulation potential, a lower threshold will be set for Chemical B.

b. *Consideration of burden in threshold selection.* As discussed above, 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 this class of chemicals based on their persistence and bioaccumulation potentials only. EPA then considered the burden that would be imposed by four sets of reporting thresholds. The thresholds considered were: (1) the 1 and 10 pound thresholds discussed above; (2) 10 pounds for chemicals in the 6–month and 5,000 group with 100 pounds for chemicals in the 2–month and 1,000 group; (3) 100 pounds for chemicals in the 6–month and 5,000 group with 1,000 pounds for chemicals in the 2–month and 1,000 group; and (4) 1,000 pounds for both groups of chemicals. For each set of thresholds EPA estimated the number of facilities that might be required to report for the various PBT chemicals (see Table 4 in Unit X.E.4. of this preamble). Based on the potential burdens, EPA believes it is appropriate to lower the reporting thresholds to a level that would capture significantly more information about PBT chemicals than current thresholds but that would not be unduly burdensome on industry. Therefore, EPA is proposing to lower the manufacture, process, and otherwise use thresholds to 100 pounds for toxic chemicals meeting the 2– to 6–month and 1,000 to 5,000 criteria and to 10 pounds for toxic chemicals meeting the 6–month or greater and 5,000 or greater criteria.

EPA requests comment on its consideration of industry burden in establishing lower reporting thresholds, including the extent to which burden should be considered in EPA's decision. EPA requests comment on whether the Agency should lower the reporting thresholds to 1 pound for the 6–month and 5,000 group and 10 pounds for the 2–month and 1,000 group rather than the 10 and 100 pound reporting thresholds proposed in this document. EPA requests comment on whether there are any policy reasons for selecting the 1 and 10 pound reporting thresholds rather than the 10 and 100 pound reporting thresholds. Such policy reasons could include the fact that the 10 pound reporting threshold for the chemicals in the 6–month and 5,000 group, i.e., the chemicals that are highly persistent and bioaccumulative, may not capture all releases that are of concern to local communities. Alternatively, EPA also seeks comment on reasons for selecting reporting thresholds of 100 pounds and 1,000 pounds.

For purposes of this rulemaking the Agency has focused on persistence and bioaccumulation as a basis for setting lower reporting thresholds. EPA believes it has discretion to use other factors as part of its basis for modifying the reporting thresholds. For example, EPA could consider biomagnification, relative toxicity, persistence only or bioaccumulation only. EPA requests comment on these factors and on other factors that the Agency could consider in selecting reporting thresholds in the future.

c. *Relationship of TRI reporting thresholds to other statutory thresholds.* For purposes of establishing EPCRA section 313 reporting thresholds, Congress has expressed a clear intent to obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of the section, and to assure that this information is reported to EPA and the states and provided to the user community. In this action, by proposing to lower the reporting thresholds for certain persistent and bioaccumulative chemicals listed on EPCRA section 313, EPA is working to assure that communities are provided with data on these toxic chemicals, which are frequently manufactured, processed, or otherwise used in

quantities well below the existing reporting thresholds of 25,000 pounds and 10,000 pounds and consequently are not reported to EPA and the states. In choosing the proposed EPCRA section 313 thresholds for these PBT chemicals EPA took into consideration a number of factors including small business impacts, overall reporting burden, and report generation in addition to utility of the information. It has been EPA's goal, under the EPCRA section 313 program, to maintain a balance between community right-to-know and overall reporting burden for the affected industry.

EPCRA section 313 provides one of several authorities through which EPA collects data. Each of these authorities has different criteria and different purposes. Many are aimed at supporting environmental decisionmaking and standard setting with community involvement in these processes. The thresholds established under EPCRA section 313 are designed to meet the statutory requirements of the Act as well as the overarching goal of informing the public about chemical releases and other waste management practices in their communities. Other EPA statutes such as the Clean Water Act (CWA), the Clean Air Act (CAA), and Resource Conservation and Recovery Act (RCRA) also have information collection provisions, whose criteria, coverage, scope and purpose may be different from that of EPCRA section 313. The thresholds proposed here, for purposes of EPCRA section 313, should not be construed to limit or expand the data collection goals or authorities of other EPA programs.

For example, the Office of Air and Radiation (OAR) may require any sector to provide data as necessary to support the further implementation of the CAA. Under section 114 (a) of the CAA, the Administrator of EPA has the authority to write letters requesting and requiring the submission of data from CAA covered sources. A CAA data collection, may in part, be focused on the need to address questions about a specific industry sector or a particular type of emission. In such an instance, EPA may decide to base its information request on different facility sizes, thresholds of release, or burden of reporting. EPA has submitted an Information Collection Request to the Office of Management and Budget for an information collection effort under Section 114 of the CAA that would require all coal fired power plants over 25 MW to submit to EPA the results of analyses (coal sampling and for a representative sample of plants stack testing). This would allow a calculation of facility-specific mercury emissions for each coal fired plant. Unlike this proposed rule, the information collection effort under the CAA would require that analysis be performed that power plant operators may not be currently performing and thus would allow emissions estimates that may be more precise than those that would otherwise be provided under this proposed rule.

2. *Special reporting threshold for dioxin and dioxin-like compounds.* Based on the persistence and bioaccumulation data for the category of dioxin and dioxin-like compounds that EPA has proposed for addition to section 313, they would ordinarily be included in the 6–month and 5,000 group. However, this category of chemicals poses unique problems with regard to setting section 313 reporting thresholds. These chemicals are generally produced in extremely small amounts compared to other section 313 chemicals. Thus, in order to capture any release data at all, a much lower reporting threshold than those proposed above is required. EPA has received numerous comments suggesting that the reporting threshold for this category be set at zero. However, EPA does not believe that a zero threshold would be practical. 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 reporting threshold, many facilities might report some amount of these chemicals just to make sure that they are in compliance. This could lead to misleading and inaccurate data on the actual sources of these chemicals as well as imposing increased burden on reporting facilities. 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. EPA believes that a manufacture, process, or otherwise use reporting threshold of 0.1 gram for the category would capture the majority of releases likely to come from section 313 facilities. Since the current section 313 reporting instructions and forms do not require the reporting of amounts less than 1 pound, they would be modified to allow for the reporting of amounts less than 1 pound. 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.

EPA requests comment on whether reporting at this level would provide meaningful information to communities.

In addition to the proposed lower reporting threshold for the dioxin and dioxin-like compounds category, EPA is considering an alternative way of reporting release and other waste management data for this category. The toxicity of dioxin-like compounds is often expressed in terms of toxicity equivalents or TEQs. TEQs are determined by summing the products of multiplying concentrations of individual dioxin-like compounds times the corresponding toxicity equivalence factor (TEF) for that compound. Because of their common mechanism of action, TEFs have been established for dioxin-like compounds. TEFs represent order of magnitude estimates of the relative potency of dioxin-like compounds compared to 2,3,7,8-tetrachloro-p-dioxin (i.e., dioxin), and have been considered by EPA and the international scientific community to be a valid and scientifically sound approach for assessing the likely health hazard of dioxin-like compounds (Ref. 78). TEFs for the dioxin-like compounds included in the proposed dioxin and dioxin-like compounds category range from 0.5 to 0.001. Reporting release and other waste management information as a sum of all of the grams of the individual members of the dioxin and dioxin-like compounds category would not provide any information to determine the TEQs unless the distribution of the dioxin and dioxin-like compounds were otherwise known for any reported quantity. Without the distribution data the public would not be able to determine the relative hazard associated with such release and other waste management information. In addition, Agency reports concerning dioxin and dioxin-like compounds commonly describe dioxin emissions in terms of TEQs. Therefore, as an alternative to reporting release and other waste management data for the dioxin and dioxin-like compounds category as a grams-only sum of all members, EPA is proposing to have this information reported in terms of grams of TEQs. However, 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. However, if these problems can be resolved then reporting in terms of TEQs may provide more useful data to the public. Under this alternative method of reporting release and other waste management information, reporting thresholds would still be based on the total absolute weight of the members of the dioxin and dioxin-like compounds category, not on the equivalent weight of TEQs.

EPA requests comments on this alternative method of reporting release and waste management information for the dioxin and dioxin-like compounds category.

3. *Proposed reporting thresholds by chemical/category.* Table 2 contains the proposed section 313 reporting thresholds for each of the PBT chemicals included in this proposed rule. For purposes of section 313 reporting, threshold determinations for chemical categories must be based on the total of all toxic chemicals in the category (see 40 CFR 372.25(d)). For example, a facility that manufactures three members of a toxic chemical category would count the total amount of all three toxic chemicals manufactured towards the manufacturing threshold for that category. One report is filed for the category and all releases are reported on one Form R (the form for filing reports under EPCRA section 313 and PPA section 6607).

Table 2.—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
Dicofol	115-32-2	10
Dioxin and dioxin-like compounds category (manufacture only)	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	10
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
Mercury compounds	NA	10

B. Proposed Changes to the Use of the de minimis Exemption

As part of the final rule implementing the reporting provisions of EPCRA section 313 (53 FR 4500, February 16, 1988), EPA adopted a limited *de minimis* exemption for listed toxic chemicals in mixtures. The *de minimis* exemption allows facilities to disregard certain concentrations of chemicals in mixtures or other trade name products they import, process, or otherwise use in making threshold calculations and release and other waste management determinations for section 313 reporting. This exemption does not apply to the manufacture of a toxic chemical unless the toxic chemical is manufactured as an impurity or is imported.

EPA adopted this exemption in response to comments requesting some type of concentration limitation for listed toxic chemicals in mixtures or other trade name products as a burden reducing measure. Commenters contended that it would be extremely

burdensome for suppliers, processors, and other users of mixtures or trade name products to have to account for quantities below a *de minimis* level. Most of these commenters requested that EPA adopt a *de minimis* concentration limitation consistent with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) requirement. The HCS provides that a supplier does not have to list a ''hazardous chemical'' component in a mixture if that chemical comprises less than 1.0% of the mixture or 0.1% where the chemical is a carcinogen as defined in 29 CFR 1910.1200(d)(4). OSHA chose the 1% and 0.1% limits because the Agency believed that they generally appeared to be protective of workers and were considered reasonable by a number of commenters.

EPA adopted the *de minimis* exemption primarily as a means of reducing burden associated with the new (at the time) EPCRA section 313 reporting requirements. The Agency chose the HCS levels because: (1) They were consistent with the existing OSHA requirements for developing Material Safety Data Sheet (MSDS) information and with other requirements under EPCRA sections 311 and 312; (2) suppliers of products were familiar with these levels; (3) for the first 2 years of reporting, users of these mixtures are only likely to be able to rely on the product MSDS for information about the content and percentage composition of covered toxic chemicals in these products; and (4) EPA did not expect that the processing and otherwise use of toxic chemicals at less than the *de minimis* concentration in mixtures would, in most instances, contribute significantly to the threshold determinations or releases of listed toxic chemicals from any given facility.

When determining whether the *de minimis* exemption applies to a listed toxic chemical, the facility must consider only the concentration of the toxic chemical in mixtures and trade name products in process streams in which the toxic chemical is involved in a reportable activity. If the toxic chemical in a process stream is manufactured as an impurity, imported, processed, or otherwise used and is below the appropriate *de minimis* concentration level, then the quantity of the toxic chemical in that process stream does not have to be applied to threshold determinations nor included in release or other waste management determinations. If a toxic chemical in a process stream is below the appropriate *de minimis* level, all releases and other waste management activities associated with the toxic chemical in that stream are exempt from EPCRA section 313 reporting. It is possible to meet an activity (e.g., processing) threshold for a toxic chemical on a facility-wide basis, but not be required to calculate releases or other waste management quantities associated with a particular process because that process involves only mixtures or trade name products containing the toxic chemical below the *de minimis* level.

As stated above, the intent of the *de minimis* exemption was primarily burden reduction. The *de minimis* exemption was not intended to be a general small quantity exemption, but rather an exemption based on the limited information likely to be readily available to facilities newly affected by EPCRA section 313. EPA did not expect in 1988 that ''the processing and [otherwise] use of mixtures containing less than the *de minimis* concentration would, in most instances, contribute significantly to the threshold determinations or releases of listed toxic chemicals from any given facility'' (53 FR 4509). However, given 10 years of experience with the program, EPA believes that there are many instances where a PBT chemical may exist in a mixture at a concentration below the 1% (or 0.1% for OSHA carcinogens) *de minimis* but where the manufacture, process, or otherwise use of the PBT chemical in that mixture would otherwise contribute significantly to or exceed the reporting thresholds proposed in this rule.

For example, a raw material is processed that contains less than the *de minimis* level of a PBT chemical. The quantity of raw material processed results in significantly more than the threshold quantity of the PBT chemical being processed. Also, during the processing of the PBT chemical, its concentration in the process stream remains below the *de minimis* level. However, the concentration of the PBT chemical in the wastestream that results from that processing activity is above the *de minimis* concentration level for that PBT chemical and the wastestream containing that PBT chemical is released to the land. In this example, because the concentration of the PBT chemical in the process stream is below the *de minimis* concentration, the *de minimis* exemption can be taken. As a result, (1) The quantities processed do not have to be applied to the processing threshold for that PBT chemical at the facility, and (2) quantities of the PBT chemical that are released or otherwise managed as waste as a result of this specific processing activity are exempt from release and other waste management determinations. The exemption applies even though the PBT chemical is concentrated above the *de minimis* level in the wastestream. This information would not be included in that facility's Form R.

In addition, EPA believes that the information available to the typical EPCRA section 313 reporter is generally greater than it was 10 years ago. Since 1987, the Air Pollution Emission Factors (AP-42) guidance document has been repeatedly updated and expanded. For example several new sections were added in 1996, including a section specific to electroplating. In the early 1990s, the Factor Information Retrieval data base (FIRE) was developed. EPA has developed several additional guidance documents and software programs, including Air CHIEF CD-ROM, TANKS, CHEMDAT8, and WATER8 (this is an analytical model for estimating chemical-specific air emissions from wastewater collection and treatment systems) to aid facilities in estimating releases. Facilities also have access to guidance from trade associations, e.g., National Council of the Paper Industry for Air and Stream Improvement, Inc. (NCASI).

Given that there may be significant releases of PBT chemicals in mixtures when the PBT chemicals exist below the *de minimis* limit and that even minimal releases of persistent bioaccumulative chemicals may result in elevated concentrations in the environment or in an organism that reasonably can be anticipated to result in significant adverse effects, EPA believes that allowing facilities to continue to take the *de minimis* exemption for PBT chemicals would deprive communities of important information on PBT chemicals. While these chemicals may exist in mixtures at below the *de minimis* levels they will concentrate in the environment and in organisms. Further, many of the PBT chemicals addressed in today's action 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 concentration levels in the parts per trillion. Thus, because PBT chemicals can cause adverse effects at concentrations well below *de minimis* levels, EPA believes that the *de minimis* principle may no longer apply. See *Environmental Defense Fund v. EPA*, 82 F.2d 451, 466 (D.C. Cir. 1996); *Alabama Power Co. V. Costle*, 636 F.2d 323, 360 (D.C. Cir 1979). In addition, for the reasons articulated above, EPA is concerned about whether other similar regulatory exemptions continue to be

supportable for PBT chemicals. See e.g., 40 CFR 372.38(c).

Further, EPA believes that lowering the reporting thresholds for these chemicals while leaving the *de minimis* exemption in place may result in very limited reporting and undermine the very purpose of this action. Without a concomitant change in the *de minimis* exemption, lowering the reporting thresholds would not increase reporting for some of the PBT chemicals because much of their releases would be exempt due to their generally low concentrations in mixtures or other trade name products that are processed or otherwise used. The facility may exceed the reporting threshold based on some processes that involve the PBT chemical in a mixture where the PBT chemical is above the *de minimis* level or on activities for which the *de minimis* exemption is not applicable. However, EPA expects there will be significant numbers of activities that occur for which the *de minimis* exemption could otherwise be taken. All releases and other waste management activities associated with these activities would therefore be exempt.

Given that use of the *de minimis* exemption could significantly limit the amount of reporting on PBT chemicals for which lower reporting thresholds are being proposed in today's notice. EPA is proposing to eliminate the *de minimis* exemption for those toxic chemicals.

Therefore, EPA is proposing to modify 40 CFR 372.38(a) to add the following sentence to the end thereof:

> This exemption does not apply to toxic chemicals listed in § 372.28 (i.e., the chemicals for which thresholds have been lowered), except for purposes of § 372.45(d)(1).

EPA is not proposing to extend this modification to 40 CFR 372.45(d)(1) because the Agency believes that there is sufficient information available on PBT chemicals by suppliers. Requirement of additional information in this case would result in redundancies.

In past expansion actions, EPA has tried to retain burden reducing options wherever feasible. However, as the TRI program evolves to meet emerging community needs, EPA will need to reassess these exemptions and modify them as appropriate. EPA notes that the increase in burden resulting from eliminating the *de minimis* exemption for PBT chemicals would be limited to facilities that import, process, otherwise use or manufacture as impurities these chemicals. Many of the chemicals identified as persistent and bioaccumulative in today's action are not imported, processed, or otherwise used but are manufactured as byproducts. In the preamble to the 1988 final rule implementing the reporting provisions of EPCRA section 313 (53 FR 4500, February 16, 1988), EPA explained, that the ''*de minimis* limitation does not apply to the byproducts produced coincidentally as a result of manufacturing, processing, use, waste treatment, or disposal'' (see 53 FR 4501, column 1). EPA further explains on page 4504, column 3, its decision about the application of the *de minimis* exemption to impurities and byproducts:

> EPA has distinguished between toxic chemicals which are impurities that remain with another chemical that is processed, distributed, or used, from toxic chemicals that are byproducts either sent to disposal or processed, distributed, or used in their own right. EPA also considers that it would be reasonable to apply a *de minimis* concentration limitation to toxic chemicals that are impurities in another chemical or mixture. . . .Because the covered toxic chemical as an impurity ends up in a product, most producers of the product will frequently know whether the chemical is present in concentrations that exceed the *de minimis* level, and, thus may be listed on the Material Safety Data Sheet (MSDS) for that product under the OSHA HCS.
>
> This final rule does not adopt a *de minimis* concentration limitation in connection with the production of a byproduct. EPA believes that the facility should be able to quantify the annual aggregate pounds of production of a byproduct which is not an impurity because the substance is separated from the production stream and used, sold, or disposed of, unlike an impurity which remains in the product. (53 FR 4500, February 16, 1988).

Because many of the PBT chemicals being addressed in today's action are manufactured as byproducts and the *de minimis* exemption does not apply to such chemicals, eliminating it would have no effect on the reporting of those chemicals.

For toxic chemicals in mixtures that are imported, processed, or otherwise used, the increase in burden resulting from the elimination of the *de minimis* exemption would be limited because EPCRA does not require additional monitoring or sampling in order to comply with the reporting requirements under EPCRA section 313. EPCRA section 313(g)(2) states:

> 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 in the environment beyond the monitoring and measurement required under other provisions of law or regulation.

Information used should be based on production records, monitoring, or analytical data, guidance documents provided by EPA and trade associations and reasonable judgement on the part of the facility's management. No further monitoring or analysis of production, process, or use is required.

EPA requests comment on its proposed modification of the *de minimis* exemption. EPA also requests comments on whether the Agency should modify the exemptions at 40 CFR 372.38(c) (e.g., the laboratory exemption, and the otherwise use exemptions, including the structural component exemption, the routine janitorial or facility grounds maintenance exemption; the personal use exemption, the motor vehicle maintenance exemption, and the intake air and water exemption) such that they will not apply to PBT chemicals. The legal authority for these exemptions is also the *de minimis* principle, and as noted above, EPA is concerned that this doctrine may not be applicable to PBT chemicals.

C. Proposed Changes to the Use of the Alternate Threshold and Form A

On November 30, 1994, EPA published a final rule (59 FR 61488) that provides that facilities that have 500 pounds or less of production-related waste (the sum of sections 8.1 through 8.7 of Form R) may apply an alternate manufacture, process, and otherwise use reporting threshold of 1 million pounds. Facilities that have less than 500 pounds of production-related waste of a listed toxic chemical and that do not manufacture, process, or otherwise use more than 1 million pounds of that listed toxic chemical may file a Form A certification statement certifying that they do not exceed either of these quantities for the toxic chemical. This certification statement includes facility identification information and chemical identification information. EPA adopted the alternate threshold and the Form A as a means of reducing the burden associated with EPCRA section 313.

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 proposed in this rule. While the Form A does provide some general information on the quantities of the chemical that the facility manages as waste, this information is insufficient for conducting analyses on PBT chemicals

and would be virtually useless for communities interested in assessing risk from releases of PBT chemicals. First, the threshold category for amounts managed as waste does not include quantities released to the environment as a result of remedial actions or catastrophic events not associated with production processes (section 8.8 of Form R). Thus, the waste threshold category will not include all releases. Given that even small quantities of PBT chemicals may result in elevated concentrations in the environment or in an organism, that reasonably can be anticipated to result in significant adverse effects, EPA believes it would be inappropriate to allow an option that would exclude information on some releases. Second, the 500 pound waste threshold category could be interpreted by some 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 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 release, e.g., the toxic chemical in waste was recycled. For chemicals where any release is a concern, an uncertainty level of 500 pounds will result in data that are virtually unusable. As a result, EPA is proposing to exclude all PBT chemicals from the alternate threshold of 1 million pounds. Therefore, EPA proposes to modify 40 CFR 372.27 to add a new paragraph (e) to read as follows:

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

EPA requests comment on this limitation to the use of the Form A certification statement.

D. Proposed Changes to the Use of Range Reporting

For releases and off-site transfers for further waste management of less than 1,000 pounds of the toxic chemical, EPA allows facilities to report the amount either as a whole number or by using range codes. The reporting ranges are: 1–10 pounds; 11–499 pounds; and 500–999 pounds. For larger releases and off-site transfers for further waste management of the toxic chemical, the facility may report only the whole number. While EPA provided range reporting primarily as a burden reducing measure focused on small businesses, the Agency notes a number of drawbacks. 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., 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 to 999. This represents a 100 percent 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 that would be part of these data would severely limit their utility, EPA believes that facilities should report numerical values, not ranges, for PBT chemicals. EPA, therefore, proposes to modify 40 CFR 372.85(b)(16)(i) to read as follows:

An estimate of the total releases in pounds per year (releases of toxic chemicals of less than 1,000 pounds per year may be indicated in ranges, except for toxic chemicals set forth in § 372.28) from the facility plus an indication of the basis of estimate:

EPA also proposes to modify 40 CFR 372.85(b)(16)(ii)(B) to read as follows:

An estimate of the amount of the chemical in waste transferred in pounds per year (transfers of toxic chemicals of less than 1,000 pounds per year may be indicated in ranges, except for toxic 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.

EPA requests comment on its proposal to not allow the use of range reporting in Form Rs for PBT chemicals.

E. Proposed Changes to the Use of the Half-Pound Rule and Whole Numbers

EPA requires that facilities report numerical quantities in sections 5, 6, and 8 of Form R as whole numbers and does not require more than two significant digits (except where the Agency allows range reporting; see Unit VII.D. of this preamble). EPA currently allows facilities to round releases of 0.5 pounds or less to zero (see Toxic Chemical Release Inventory Reporting Forms and Instructions: Revised 1997 Version (EPA 745–K–98–001), p. 27). 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, notably dioxins, as zero. EPA, therefore, is proposing that all releases or other waste management quantities greater than a tenth of a pound of PBT chemicals (except dioxin) be reported, provided that the appropriate activity threshold has been exceeded. Releases and other waste management activities would continue to be reported to two significant digits. For quantities of 10 pounds or greater only whole numbers would be required to be reported. For quantities less than 10 pounds, fractional quantities, e.g., 6.2 pounds, rather than whole numbers would be required, provided the accuracy in the underlying data on which the estimate is based supports this level of precision. For the category of dioxin and dioxin-like compounds, which have a proposed reporting threshold of 0.1 gram, EPA is proposing that facilities report all releases and other waste management activities greater than 100 micrograms (i.e., 0.0001 gram). Remember, EPCRA only requires reporting to be based on the best readily available information or reasonable estimates.

EPA requests comment on the proposed requirement that, other than for the dioxin and dioxin-like compounds category, all non-zero releases of PBT chemicals greater than one tenth of a pound be reported. EPA also requests comment on using fractional quantities for reports under 10 pounds. EPA also requests comment on the proposed requirement that all non-zero releases of dioxin and dioxin-like compounds greater than 100 micrograms be reported.

VIII. Proposed Changes to Other EPCRA Reporting Requirements

A. Individual Reporting of Tetraethyl and Tetramethyl Lead

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. These alkyl lead compounds appear on the Binational Level 1 list of chemicals that have been identified for virtual elimination from the Great Lakes and are thus of special concern. It is not currently possible to individually track these two alkyl lead compounds under section 313 since they are not specifically identified in reports submitted under the lead compounds category. In order to track these alkyl lead compounds, EPA is proposing that separate reports be filed for these two members of the lead compounds category, which will allow identification of facilities that have these specific lead compounds. EPA believes that this method of reporting is consistent with the purpose and legislative history of EPCRA section

313, as illustrated in the following passage from the Conference report:

> In cases where the list of chemicals for which reporting is required refers to compounds of a ''chemical'' which is a group of related chemicals rather than a specific chemical with accompanying Chemical Abstracts Service (CAS) number, the person submitting the form may include aggregate data including all releases of those individual chemicals on one reporting form rather than listing data separately for each individual chemical in the group. Thus, for example, a single form can be submitted for ''polybrominated biphenyls'' as listed in Senate Environment and Public Works Committee Print No. 99-169 without identifying the individual polybrominated biphenyls being released or reporting release data separately for each one. This does not preclude the Administrator from requiring reporting on individual chemicals for which aggregate reporting otherwise would be required. (H. Rep. 99-962, 99th Cong., 2nd Sess., p. 296 (Oct. 3, 1986)).

As the last sentence in this passage clearly indicates, EPA is not precluded from requiring that members of a chemical category be reported separately.

Under this proposal, if any of the current manufacture, process, or otherwise use reporting thresholds for the lead compounds category are met, a facility would file one report for all members of the category excluding the two alkyl lead compounds. If the facility has 1 pound or more of tetraethyl or tetramethyl lead applicable toward the threshold determinations for the lead compounds category then separate reports would be filed for tetraethyl and tetramethyl lead. As an alternative proposal, the amounts of tetraethyl and tetramethyl lead could be combined and included in a single separate report.

EPA requests comment on whether this provision is appropriate, and if so, whether two separate reports should be filed for each of these alkyl lead compounds or whether one report that includes the amounts of both tetraethyl and tetramethyl lead should be required.

For this initial rulemaking on PBT chemicals, EPA reviewed the persistence and bioaccumulation data for tetraethyl lead and tetramethyl lead but not the available data for elemental lead or other lead compounds. EPA is aware of additional available data that may indicate that lead and/or lead compounds meet the bioaccumulation criteria discussed in this proposed rule. EPA intends to review these additional data to determine if lead and/or lead compounds should be considered PBT chemicals and whether it would be appropriate to establish lower reporting thresholds for these chemicals. Any such determination will be made part of an additional rulemaking activity.

B. Reporting Limitation for Cobalt and Vanadium in Alloys

EPA is proposing to list ''vanadium'' and ''vanadium compounds'' and delete the EPCRA section 313 listing for ''vanadium (fume or dust).'' EPA is also requesting comment on the adequacy of existing studies for determining the bioaccumulation potential of cobalt and cobalt compounds. Depending on the comments received, EPA may lower the reporting thresholds for cobalt and cobalt compounds. Both of these metals can be found in various types of alloys and are subject to reporting under section 313 when contained in these alloys. In response to several petitions that EPA has received, the Agency has been reviewing the issue of how metals contained in alloys should be reported under section 313. Because this issue is currently being reviewed, EPA does not believe that, at this time, it would be appropriate to increase reporting for those facilities that must submit reports for these metals when contained in alloys. EPA is therefore proposing to limit the reporting for vanadium and cobalt to exclude alloys that contain these metals from the lower reporting thresholds.

Since vanadium without the fume or dust qualifier would be a new section 313 listing EPA does not believe that, at this time, facilities should be subject to any additional reporting on alloys containing vanadium. EPA is therefore proposing to include the qualifier ''except when contained in an alloy'' in the new listing for vanadium. Including this qualifier will effectively exclude vanadium from reporting when contained in an alloy. EPA requests comment on the proposed qualifier to the vanadium listing.

If EPA lowers reporting thresholds for cobalt and cobalt compounds the situation would be somewhat more complicated since, unlike the proposed revised listing for vanadium, it is already a listed section 313 chemical and thus facilities must currently report on cobalt when contained in alloys. Since EPA has not made any final decisions concerning the reporting of cobalt or other metals in alloys EPA would not be prepared to make any changes, including lowering thresholds, to the current reporting requirements for cobalt when contained in alloys. If the reporting threshold for cobalt and cobalt compounds is lowered after considering comments, EPA would propose to exclude cobalt contained in alloys from the lower reporting thresholds and retain the current reporting thresholds for cobalt when contained in alloys. This would result in no changes to the reporting requirements for cobalt contained in alloys until EPA makes a final determination on whether there should be any changes to the reporting requirements for metals contained in alloys. However, EPA would not simply add the same qualifier to the listing for cobalt that is proposed to be added to vanadium since the alloy forms of cobalt will still be reportable but only under the current reporting thresholds. Therefore, EPA would make this distinction at 40 CFR 372.28, which is the new section of the CFR that will set forth the lower section 313 reporting thresholds being proposed in this action. This section would indicate that only cobalt not contained in an alloy would be subject to the lower reporting thresholds. As with the lower reporting thresholds proposed for other chemicals, EPA would also make this distinction clear in the section 313 Form R and Form A reporting instructions and other documents.

For purposes of section 313 reporting, EPA considers metal compounds that are used to make alloys to exist as the parent metal in the alloys. Under this proposed limitation for alloys, reporting facilities that use vanadium or cobalt to make alloys would still report for these metals since they are being used to manufacture an alloy. However, once incorporated into the alloy vanadium would not be reportable. Similarly, if EPA lowers the reporting threshold for cobalt and cobalt compounds in the final rule, cobalt incorporated in an alloy would not be subject to the lower reporting thresholds. Thus, the limitation on alloys reporting for vanadium and cobalt would apply to vanadium and cobalt compounds once they are incorporated into an alloy. The cutting, grinding, shaving, etc. of an alloy does not negate the reporting limitations for alloys containing vanadium and cobalt.

IX. Request for Comment

EPA recognizes that as the TRI Program has expanded, total reporting burden on the regulated community has increased. EPA is genuinely interested in reducing TRI reporting burden, while assuring that the goals and objectives of EPCRA section 313 continue to be met. During the inter-agency review process, EPA received several suggestions that, if implemented, may alter TRI reporting burden. In many cases, burden might decrease; in others it might increase. EPA welcomes comments on the following suggestions, particularly with respect to the resulting impacts on total burden and the Agency's ability to

continue to meet the goals and objectives of EPCRA section 313.

During the inter-agency review process the issue of using other factors in identifying PBT chemicals and/or in setting alternative reporting thresholds was raised. For example, it was suggested that EPA use throughput data and emissions factors to estimate the releases that would be reported at an ''average'' facility at each of the identified options for a lowered threshold and that EPA then use those estimates to select the lowered threshold that would capture some overall percentage of releases, e.g., 75–80%. EPA has not estimated the total national releases to all media for the toxic chemicals in this proposed rule (and in previously proposed and final rules) because EPA believes that (1) there is insufficient information 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 the sector. While there are data available for some chemicals for some sectors, comprehensive data for all sectors and chemicals are unavailable and consequently, decisions would need to be based on an incomplete data set. It was also suggested that EPA might consider ''throughput'' (i.e., manufacture, processing, and use) in setting reporting thresholds. While data are generally more available on throughput than on releases, EPA also did not attempt to estimate the proportion of throughput covered by alternative reporting thresholds because of its concern that these estimates may not be of sufficient quality and completeness to help inform the selection of appropriate reporting thresholds with sufficient scientific certainty. EPA invites comment on these approaches and requests comment as well on appropriate methodologies for estimating releases and/or throughput, and on estimating releases from throughput data. EPA welcomes suggestions as well on other approaches that may assist the Agency when it is developing options for lowering TRI reporting thresholds, adding new facilities or adding additional chemicals.

In this proposal, EPA is using two criteria—the persistence and bioaccumulative characteristics—to identify those TRI-listed chemicals that would be subject to the lower PBT reporting thresholds. These criteria were also primary factors in developing the proposed thresholds. EPA believes it has discretion to use other factors as part of its basis for setting lower reporting thresholds. During the inter-agency review process the issue of using alternative criteria in identifying PBT chemicals and/or in setting alternative reporting thresholds was raised. These include, among others, degree of toxicity, environmental presence, and biomagnification. For example, it has been suggested that EPA should consider a chemical's potential to biomagnify (i.e., to increase in the tissues of organisms as it moves up the food chain) in determining if reporting thresholds should be lowered for PBT chemicals. EPA requests comment on whether these other factors should be considered in establishing reporting thresholds for PBT chemicals, and on what data might be available to use in considering such factors. For this issue, EPA specifically requests comment on the state of the science related to biomagnification and the current capability to establish appropriate quantitative criteria for biomagnification.

It has also been suggested that EPA should consider lowering the reporting thresholds for toxic chemicals that are either persistent or bioaccumulative. It has been suggested that if a toxic chemical meets either criteria, the toxic chemical is of concern if it can result in elevated concentrations in either the environment or in organisms. For example, metals are persistent and releases of metals will result in elevated concentrations in the environment because they do not degrade. This is independent of whether or not the metal is also bioaccumulative. EPA requests comment on whether it should consider lowering the reporting thresholds for EPCRA section 313 chemicals that are either persistent or bioaccumulative based on the criteria proposed in this rule.

During the inter-agency review process it was also suggested that EPA propose other mechanisms for further minimizing the potential impacts associated with lowering the reporting thresholds for PBT chemicals. For example, it was suggested that EPA develop a modified Form A with thresholds more appropriate for the PBT chemicals. Specifically, it was suggested that EPA develop an alternate threshold and a reportable quantity lower than the current Form A for the PBT chemicals. This could also be done in conjunction with other changes to the Form A that EPA is considering. While not adverse to considering such an approach, EPA believes that, in order to consider such an alternate threshold and reportable quantity for PBT chemicals, it may be appropriate for the Agency to collect and analyze several years worth of data at the lowered thresholds, including data from the recently added industry sectors, before it considers developing an alternate Form A threshold and reportable quantity appropriate for PBT chemicals. EPA requests comment on whether it should consider an alternate threshold and reportable quantity for PBT chemicals, as well as any suggestion on what should be considered if the Agency were to move forward with such a proposal.

There may also be other ways to minimize the burden associated with lowering the threshold. For example, one alternative to eliminating the *de minimis* exemption altogether would be to establish lower *de minimis* thresholds for PBT chemicals. EPA believes that such a modified exemption would need to be structured to ensure reporting on the majority of releases for the PBTs covered by this rule, while still providing burden relief for those facilities which import, process, use or manufacture extremely small concentrations (as impurities) of these chemicals. It has also been suggested by others that EPA might consider an activity qualifier restricting the lower reporting threshold to the manufacture of the PBTs, retaining the higher current thresholds with respect to import, process, or use activities. This would extend the approach EPA is proposing for dioxin to other PBT chemicals. EPA requests comment on these options and other similar approaches that might be adopted to reduce the burden associated with this PBT proposal.

It has also been suggested that EPA modulate the thresholds for reporting, requiring reporting at the lower thresholds every other year and reporting at the current thresholds in the out years. Because this would have the effect of modifying the reporting frequency for many facilities, EPA believes that it must comply with the EPCRA section 313(i) requirements for modifying the EPCRA section 313 reporting frequency. EPA is requesting comment on the utility of a modulated approach and whether that approach would provide for significant burden reduction for affected facilities. Specifically, EPA is interested in the comments on the approach itself as well as comments on whether EPA should modify the reporting frequency pursuant to EPCRA section 313(i) for either a select group of chemicals, such as the PBTs, or for a subset of facilities. In providing comments on this issue, commenters are encouraged to focus on the procedures laid out in section 313(i) of EPCRA. They are as follows:

To modify the reporting frequency, EPA must first notify Congress and then delay initiating the rulemaking for at least 12 months. In addition, EPA must find:

(A) ...that the modification is consistent with the provisions of subsection (h) of [section 313] based on -

(i) experience from previously submitted toxic chemical release forms,

(ii) determinations made under paragraph (3).]

Paragraph (3), in turn, provides that EPA must determine

(A) The extent to which information relating to the proposed modification provided on the toxic chemical release forms has been used by the Administrator or other agencies of the Federal government, States, local governments, health professionals and the public.

(B) The extent to which information is (i) readily available to potential users from other sources, such as State reporting programs, and (ii) provided to the Administrator under another Federal law or through as State program.

(C) The extent to which the modification would impose additional and unreasonable burdens on facilities subject to the reporting requirements under this section.

EPA welcomes comment on the availability of information that would allow the Agency to make the requisite findings under paragraph 3(B), especially how consideration of alternate reporting requirements should pertain to the recently added SIC codes for which reporting has not yet been received, the lack of readily available information on PBT chemicals from existing sources, and what available information may exist to allow EPA to address the requirements of the law. Therefore, EPA would be particularly interested in information relating to the findings required under paragraph 3(B).

X. Economic Analysis

EPA has prepared an economic analysis of the impact of this proposed action, which is contained in a document entitled ''Economic Analysis of the Proposed Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals under EPCRA Section 313'' (Ref. 79). This document is available in the public docket for this rulemaking. The analysis assesses the costs, benefits, and associated impacts of the proposed rule, including potential effects on small entities. The major findings of the analysis are briefly summarized here.

The estimates included in the following discussion reflect the estimated impacts associated with the PBT chemicals identified in the proposed regulatory text. However, as indicated previously, the Agency is also considering and seeking comment on lowering the reporting thresholds for cobalt and cobalt compounds. The estimated effect of lowering the reporting thresholds for cobalt and cobalt compounds would result in an estimated 3,500 reports, at an estimated burden of 370,000 hours (at a cost of $25 million) in the first year and an estimated burden of 208,000 hours (at a cost of $14 million) in each subsequent year. EPA estimates that 2 small businesses may experience impacts between 1% and 3% in subsequent years. Additional information about the potential effects associated with lowering the reporting thresholds for cobalt and cobalt compounds is included in the economic analysis (see Ref. 79).

A. 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 proposed 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 proposed action adding certain PBT chemicals to TRI and lowering reporting thresholds, the market failure (and the associated social costs) resulting from the limited information on the release and disposition of PBT chemicals would continue. EPA believes that today's action will improve the scope of multi-media data on the release and disposition 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 and thereby lower costs of production and/or waste management. EPA believes that these are sound rationales for adding PBT chemicals to the TRI program and lowering reporting thresholds.

B. Regulatory Options

EPA evaluated a number of options in the development of this proposed rule. The options were created by varying the reporting thresholds for the PBT chemicals from their current levels of 25,000 pounds for manufacture and processing, and 10,000 pounds for otherwise use of EPCRA Section 313 chemicals. The options in table 3 summarize the scope of EPA's analysis.

Table 3.—Summary of Options Considered

Regulatory Option	Description of Option
Option 1	Reporting threshold of 1 pound manufactured, processed, or otherwise used for the highly persistent bioaccumulative chemicals. Reporting threshold of 10 pounds manufactured, processed, or otherwise used for the persistent bioaccumulative chemicals. Reporting threshold of 0.1 gram manufactured for the dioxin and dioxin-like compounds category.
Option 2	Reporting threshold of 10 pounds manufactured, processed, or otherwise used for the highly persistent bioaccumulative chemicals. Reporting threshold of 100 pounds manufactured, processed, or otherwise used for the persistent bioaccumulative chemicals. Reporting threshold of 0.1 gram manufactured for the dioxin and dioxin-like compounds category. This is the preferred option presented in the regulatory text.
Option 3	Reporting threshold of 100 pounds manufactured, processed, or otherwise used for the highly persistent bioaccumulative chemicals. Reporting threshold of 1,000 pounds manufactured, processed, or otherwise used for the persistent bioaccumulative chemicals. Reporting threshold of 0.1 gram manufactured for the dioxin and dioxin-like compounds category.
Option 4	Reporting threshold of 1,000 pounds manufactured, processed, or otherwise used for the highly persistent bioaccumulative chemicals and the persistent bioaccumulative chemicals. Reporting threshold of 1.0 gram manufactured for the dioxin and dioxin-like compounds category.

Reporting under all four options is affected by other proposed changes in reporting requirements for PBT chemicals. These proposed changes include the elimination of the *de minimis* exemption for PBT chemicals with lower thresholds and a requirement for all facilities to report on PBT chemicals using the Form R. The effect of the other proposed changes on reporting is described in chapter 2 of the economic analysis (Ref. 79).

Table 4 in section E.4. of this unit displays, for each option, the estimated number of additional reports for PBT chemicals expected under EPCRA section 313.

In proposing this rule, EPA has sought to balance the public's right to know about toxic chemical releases and other waste management practices in their neighborhoods and the benefits provided by this expanded knowledge with the costs the rule will likely impose on industry, including the impact on small entities.

C. Costs

The proposed rule will result in the expenditure of resources that, in the absence of the regulation, could be used for other purposes. The cost of the proposed rule is the value of these resources in their best alternative use. Most of the costs of the proposed rule result from requirements on industry. Table 5 in section E.4. of this unit displays the industry costs for each option based on the estimated number of facilities affected and the estimated number of additional reports. Under the option presented in the regulatory text (Option 2), approximately 9,500 facilities will submit approximately 17,000 additional Form R reports annually. As shown, aggregate industry costs in the first year for the proposed alternative are estimated to be $126 million; in subsequent years they are estimated to be $70 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 $1.8 million in the first year, and $1.4 million in subsequent years as a result of the proposed rule.

D. Benefits

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. TRI 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. TRI's publicly available data base provides quantitative information on toxic chemical releases and other waste management practices. Since TRI'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 and releases 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 system is a neutral yardstick by which progress can be measured by all stakeholders.

The information reported to TRI increases knowledge of the amount of toxic chemicals released to the environment and the potential pathways of exposure, improving 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 TRI 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 decisionmaking. It is expected that this rulemaking will generate such benefits by providing readily accessible information that otherwise would not be available to the public. The proposed 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 to 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 TRI 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 proposed rule, or the follow-on activities. The economic analysis of the proposed rule, however, does provide illustrative examples of how the proposed rule will improve the availability of information on PBT chemicals (Ref. 79).

E. 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 also evaluated the potential impacts of this proposed rule on small entities. The Agency's analysis of potentially adverse economic impacts is included in the Economic Analysis for this proposed rule (Ref. 79). The following is a brief overview of EPA's findings.

1. *Overall methodology*. This proposed rule may affect both small businesses and small governments. For the purpose of its analysis for the proposed rule, EPA defined a small business using the small business size standards established by the Small Business Administration (SBA). (For example, the SBA size standard is 500 employees for approximately 75% of the manufacturing industries, and either 750, 1,000 or 1,500 for the remaining manufacturing industries, which would mean that more than 98.5 percent of the manufacturing firms are classified as small businesses (Ref. 80)). EPA is interested in receiving comments on its use of the SBA size standards for defining small businesses. 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 proposed 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 proposed rule.

EPA analyzed the potential cost impact of the proposed 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 proposed 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 proposed rule, the Agency estimates that approximately 5,300 businesses will be affected by the proposed rule, and that approximately 3,600 of these businesses are classified as small based on the applicable SBA size standards. For the first reporting year, EPA estimates that approximately 16 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 4 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 46 publicly owned electric utility facilities, operated by a total of 37 municipalities, may be affected. Of these, an estimated 17 are operated by 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 4 small businesses are expected to bear costs over 1% of revenues after the first year of reporting. None of the affected small governments are estimated to bear costs greater than 1% of revenues. No small organizations are expected to be affected by the proposed 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).

Table 4.—Summary of Reporting Under Regulatory Options

Chemical or Chemical Category	Estimated Number of Reports (Annual)			
	Option 1	Option 2	Option 3	Option 4
Alkyl lead (tetraethyl lead and tetramethyl lead)	134	134	134	134
Benzo(g,h,i)perylene	798	353	6	0
Dioxin and dioxin-like compounds category	1,863	1,863	1,863	812
Hexachlorobenzene	3,772	778	73	3
Mercury; mercury compounds category	11,378	5,230	2,367	1,454
Octachlorostyrene	303	230	67	65
Pentachlorobenzene	3,314	707	36	11
Pesticides (Aldrin, Chlordane, Dicofol, Heptachlor, Isodrin, Methoxychlor, Pendimethalin, Toxaphene, Trifluralin)	280	264	199	186
Polycyclic aromatic compounds (PAC) category	5,488	4,699	4,046	2,620
Polychlorinated biphenyls (PCBs)	3,605	2,267	1,259	177
Tetrabromobisphenol A	150	150	150	150
Vanadium; vanadium compounds category	654	654	654	654
Total	31,739	17,329	10,854	6,266

Table 5.—Summary of Reporting and Industry Cost of Regulatory Options

Regulatory Options	Annual		Estimated Industry Costs ($ million per year)	
	Number of Reporting Facilities	Number of Reports	First Year	Subsequent Years
1. Reporting threshold of 1 lb for highly PB chemicals, 10 lb for PB chemicals, 0.1 gram for dioxin	18,082	31,739	$232	$127
2. Reporting threshold of 10 lb for highly PB chemicals, 100 lb for PB chemicals, 0.1 gram for dioxin	9,515	17,329	$126	$70
3. Reporting threshold of 100 lb for highly PB chemicals, 1,000 lb for PB chemicals, 0.1 gram for dioxin	6,187	10,854	$78	$44
4. Reporting threshold of 1,000 lb for highly PB chemicals and PB chemicals, 1 gram for dioxin	3,748	6,266	$45	$25

XI. References

1. The Great Lakes Binational Toxics Strategy, Canada — United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes, signed by Carol Browner, Administrator U.S. Environmental Protection Agency and Sergio Marchi, Minister of the Environment Government of Canada. 1997.

2. USEPA, OPPT. *Support Document for the Addition of Certain Chemicals to Section 313 of the Emergency Planning and Community Right-to-Know Act*. U.S. Environmental Protection Agency, Washington DC (1998).

3. USEPA, OSWER. *Waste Minimization Prioritization Tool Beta Test Version 1.0 User's Guide and System Documentation (Draft). Appendix D Draft Prioritized Chemical List*. U.S. Environmental Protection Agency, Washington DC, EPA530-R-97-019, June 1997.

4. Atkinson, R., ''Kinetics and Mechanisms of the Gas-Phase Reactions of the Hydroxyl Radical with Organic Compounds.'' *J. Phys. Chem. Ref. Data* Monograph No. 1 1989.

5. Webster, E., Mackay, D. and F Wania, F, ''Evaluating Environmental Persistence.'' *Environ. Toxicol. Chem.*, in press (1998).

6. Anderson, P.N. and RA Hites, R.A., ''OH Radical Reactions: The Major Removal Pathway for Polychlorinated

Biphenyls in the Atmosphere.'' *Environ. Sci. Technol.* v. 30, (1996), pp. 1756-1763.

7. Altshuller, A.P., ''Ambient Hydroxyl Radical Concentration: Measurements and Model Predictions.'' *J. Air Pollut. Contr. Assoc*. v. 39, (1989), pp. 704-708.

8. Ngabe, B., Bidleman, T.F., and Falconer, R.L., ''Base Hydrolysis of Alpha- and Delta-hexachlorocyclohexane.'' *Environ. Sci. Technol*. v. 27, (1993), pp. 1930-1933.

9. Vink, J.P.M. and Van Der Zee, E.A.T.M., ''Pesticide Biotransformation in Surface Waters: Multivariate Analyses of Environmental Factors at Field Sites.'' *Water Res.* v. 31, (1997), pp. 2858-2868.

10. Saleh, F.Y., Dickson, K.L., and Rodgers Jr., J.H., ''Fate of Lindane in the Aquatic Environment: Rate Constants of Physical and Chemical Processes.'' *Environ. Toxicol. Chem*. v. 1, (1982), pp. 289-297.

11. Meylan, W.M. and Howard, P.H., ''Computer Estimation of the Atmospheric Gas-phase Reaction of Organic Compounds with Hydroxyl Radicals and Ozone.'' *Chemosphere* v. 26, (1993), pp. 2293-2299.

12. Kwok, E.S.C. and Atkinson, R., ''Estimation of Hydroxyl Radical Reaction Rate Constants for Gas-phase Organic Compounds Using a Structure-reactivity Relationship: an Update.'' *Atmos. Environ*. v. 29, (1995), pp. 1685-1695.

13. Boethling, R.S., Howard, P.H., Beauman, J.A., and Larosche, M.E., ''Factors for Intermedia Extrapolation in Biodegradability Assessment.'' *Chemosphere* v. 30, (1995), pp. 741-752.

14. Federle, T.W., Gasior, S.D., and Nuck, B.A., ''Extrapolating Mineralization Rates from the Ready CO2 Screening Test to Activated Sludge, River Water and Soil.'' *Environ. Toxicol. Chem*. v. 16, (1997), pp. 127-134.

15. USEPA, OPPT. *Persistent, Bioaccumulative Substances on the Toxics Release Inventory (TRI): Report on Persistence Screening Criteria*. Boethling, R. S., U.S. Environmental Protection Agency. (September 4, 1997).

16. USEPA, OW. *Bioaccumulation Testing and Interpretation for the Purpose of Sediment Quality Assessment: a White Paper*. First draft, dated July 1996. Report prepared for the USEPA Bioaccumulation Analysis Workgroup. Prepared for the USEPA Office of Water.

17. ICF Incorporated. *Focus Chemicals for the Clean Air Act Amendments Great Waters Study*. Draft report, dated 15 Aug 1991. Prepared for the USEPA Office of Air Quality Planning and Standards.

18. Clements, R.G., Boethling, R.S., Zeeman, M., and Auer, C.M., ''Persistent Bioaccumulative Chemicals: Screening the TSCA Inventory.'' Paper presented at the SETAC Foundation workshop ''Environmental Risk Assessment for Organochlorine Chemicals,'' July 24-29, 1994, Nottawasaga Inn, Alliston, ON, Canada.

19. Environment Canada. *Towards a Toxic Substances Management Policy for Canada: A Discussion Document*. September 1994.

20. Rodan, B. and Eckley, N., *Science-Policy Assessment of POPs Screening Criteria: Report to the U.S. EPA International Toxics Coordinating Committee*. Draft report dated August 21, 1997.

21. NAFTA-CEC. *Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative*. Report to the North American working group on the sound management of chemicals by the task force on criteria. Draft, July 1997.

22. UNECE-LRTAP. *Draft Composite Negotiating Text for a Protocol on Persistent Organic Pollutants*. United Nations Economic Commission for Europe. EB.AIR/WG.5/R.72, March 10, 1997.

23. CMA. PTB Policy Implementation Guidance. Product Risk Management for PTBs. Chemical Manufacturers Association. February 1996.

24. ICCA. Position on Persistent Organic Pollutants (POPs). In letter to M. Mercier from International Council of Chemical Associations, dated February 23, 1996.

25. USEPA. Fish BCF, OPPTS 850.1730. Ecological Effects Test Guidelines (draft), United States Environmental Protection Agency, Washington, DC, EPA report no. 712-C-96-129. April 1996.

26. USEPA. Oyster BCF, OPPTS 850.1710. Ecological Effects Test Guidelines (draft), United States Environmental Protection Agency, Washington, DC, EPA report no. 712-C-96-127. April 1996.

27. USEPA. Daphnid Chronic Toxicity Test, OPPTS 850.1300. Ecological Effects Test Guidelines (draft), United States Environmental Protection Agency, Washington, DC, EPA report no. 712-C-96-120. April 1996.

28. USEPA. Mysid Chronic Toxicity Test, OPPTS 850.1350. Ecological Effects Test Guidelines (draft), United States Environmental Protection Agency, Washington, DC, EPA report no. 712-C-96-166. April 1996.

29. USEPA. Fish Early-Life Stage Toxicity Test, OPPTS 850.1400. Ecological Effects Test Guidelines (draft), United States Environmental Protection Agency, Washington, DC, EPA report no. 712-C-96-121. April 1996.

30. USEPA. Tadpole Sediment Subchronic Toxicity Test, OPPTS 850.1800. Ecological Effects Test Guidelines (draft), United States Environmental Protection Agency, Washington, DC, EPA report no. 712-C-96-132. April 1996.

31. CITI. *Biodegradation and Bioaccumulation: Data of Existing Chemicals Based on the CSCL Japan*. Edited by Chemicals Inspection Testing Institute, Japan Chemical Industry Ecology-Toxicology Information Center, Tokyo, Japan. October 1992. ISBN 4-89074-101-1.

32. USEPA. AQUIRE, the Aquatic Toxicity Information Retrieval Database. September 22, 1995. http://www.epa.gov/medatwrk/databases/aquire.html

33. USEPA, OPPT. *Persistent, Bioaccumulative Substances on the Toxics Release Inventory (TRI): Persistence Screening Criteria for Air, Soil, Sediment*. Boethling, R.S., U.S. Environmental Protection Agency. (January 21, 1998).

34. Wania, F. and Mackay, D., ''Tracking the Distribution of Persistent Organic Pollutants.'' *Environ. Sci. Technol.* v. 30, (1996) pp. 390A-396A.

35. Mackay, D., DiGuardo, A., Paterson, S., and Cowan, C.E., ''Evaluating the Environmental Fate of a Variety of Types of Chemicals Using the EQC Model.'' *Environ. Toxicol. Chem*. v. 15, (1996), pp. 1627-1637.

36. Mackay, D., ''Finding Fugacity Feasible.'' *Environ. Sci. Technol.* v. 13, (1979), pp. 1218-1223.

37. Mackay, D., Multimedia Environmental Models: The Fugacity Approach. Lewis: Chelsea, MI. (1991).

38. Mackay, D., Paterson, S., and Shiu, W.Y., ''Generic Models for Evaluating the Regional Fate of Chemicals.'' *Chemosphere* v. 24, (1992), pp. 695-717.

39. Rand, G.M., *Fundamentals of Aquatic Toxicology*, 2nd. Ed. Taylor Francis, Washington, DC, (1995), 1125 pp.

40. Meylan, W.M., Howard, P.H., and Boethling, R.S., ''Improved Method for Estimating Bioconcentration Factor from Octanol/Water Partition Coefficient.'' *Environ. Toxicol. Chem*., in press.

41. USEPA, OPPT. Memorandum from Jerry Smrchek, Ph.D., Biologist, Existing Chemicals Assessment Branch, Risk Assessment Division to Myra L. Karstadt, Toxic Release Inventory Branch, Environmental Assistance Division. August 25, 1997. Subject: PBT Project: Identification, Support and

Justification of Bioaccumulation Criteria.

42. Veith, G.D., Kosian, P., ''Estimating Bioconcentration Potential from Octanol/Water Partition Coefficients.'' In *Physical Behaviour of PCBs in the Great Lakes*. Mackay, D., et al, eds Ann Arbor Science, Ann Arbor, MI, (1983), pp 269-282.

43. Barron, M.G., ''Bioconcentration.'' *Environmental Science Technology* v. 24, (1990), pp. 1612-1618.

44. Bintein, S., Devillers, J., and Karcher, W. ''Nonlinear Dependence of Fish Bioconcentration on Octanol/Water Partition Coefficient.'' SAR QSAR Environ. Res. v. 1, (1993), pp. 29-39.

45. Syracuse Research Corporation BCF database for 694 chemicals.

46. USEPA, OW. *Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors*. EPA-820-B-95-005, March 1995.

47. USEPA/OPPT. *Technical Support Document for Determination of Bioaccumulation (BAF) and Bioconcentration (BCF) Values for Persistent Bioaccumulative Toxic (PBT) Chemicals and for Identification of PBT Chemicals*. Jerry Smrchek, Ph.D., Biologist, Existing Chemicals Assessment Branch, Risk Assessment Division. September 1998.

48. Hazardous Substances Data Bank (HSDB) (data base). National Institutes of Health, National Library of Medicine, Bethesda, MD, USA. (1995). http://toxnet.nlm.nih.gov

49. Howard, P.H., Sage, G.W., LaMacchia, A., and Colb, A., ''The Development of an Environmental Fate Database.'' *J. Chem. Inf. Comput. Sci.* v. 22, (1982), pp. 38-44.

50. Howard, P.H., et al., ''BIOLOG, BIODEG, and FATE/EXPOS: New Files on Microbial Degradation and Toxicity as Well as Environmental Fate/exposure of Chemicals.'' *Environ. Toxicol. Chem.* v. 5, (1986), pp. :977-988.

51. *Estimating the Hazard of Chemical Substances to Aquatic Life*, Cairns, J., Jr., Dickson, K.L., and Maki, A.W. (eds.). STP 657, American Society for Testing and Materials, Phila., PA, (1978), 278 pp.

52. Cairns, J., Jr. and Dickson, K.L., ''Ecological Hazard/Risk Assessment: Lessons Learned and New Directions.'' *Hydrobiologia* v. 312, (1995), pp. 87-92.

53. USEPA, OTS. *Testing For Environmental Effects Under the Toxic Substances Control Act*. U.S. Environmental Protection Agency, Office of Toxic Substances, Health and Environmental Review Division, Environmental Effects Branch, Washington, DC, (1983), 24 pp.

54. USEPA, OTS. *Technical Support Document for the Environmental Effects Testing Scheme*. U.S. Environmental Protection Agency, Office of Toxic Substances, Health and Environmental Review Division, Environmental Effects Branch, Washington, DC, (1983), 31 pp.

55. Veith, G.D., DeFoe, D.L., and Bergstedt, B.V., ''Measuring and Estimating the Bioconcentration Factor of Chemicals in Fish.'' *J. Fish. Res. Board Canada* v. 36, (1979), pp. 1040-1048.

56. Veith, G.D., Macek, K.J., Petrocelli, S.R., and Carrol, J., ''An Evaluation of Using Partition Coefficients and Water Solubility to Estimate Bioconcentration Factors for Organic Chemicals in Fish'' In *Aquatic Toxicology*, Eaton, J.G., Parrish, P.R., and Hendricks, A.C., (eds.). STP 707, American Society for Testing and Materials, Phila., PA. (1980) pp. 116-129.

57. Life Systems, Inc. Testing Triggers Workshop: Workshop Report, Project 1247, Contract No. 68-01-6554. U.S. Environmental Protection Agency, Office of Toxic Substances, Washington, DC, (1983), 62 pp.

58. Akerman, J.W. and Coppage, D.L., ''Hazard Assessment Philosophy: A Regulatory Viewpoint.'' In *Analyzing the Hazard Evaluation Process*, Dickson, K.L., Maki, A.W., and Cairns, J., Jr., (eds.). Water Quality Section, American Fisheries Society, Washington, DC., (1979), pp. 68-73.

59. American Institute for Biological Sciences (AIBS). ''Criteria and Rationale for Decision Making in Aquatic Hazard Evaluation (Third Draft),'' Aquatic Hazards of Pesticides Task Group of the American Institute of Biological Sciences. In *Estimating the Hazard of Chemical Substances to Aquatic Life*, Cairns, J., Jr., Dickson, K.L., and Maki, A.W. (eds.). STP 657, American Society for Testing and Materials, Phila., PA., (1978), pp. 241-273.

60. American Society for Testing and Materials (ASTM). ''Proposed Working Document for the Development of an ASTM Draft Standard on Standard Practice for a Laboratory Testing Scheme to Evaluate Hazard to Non-Target Aquatic Organisms,'' ASTM Subcommittee E35.21 on Safety to Man and Environment. In *Estimating the Hazard of Chemical Substances to Aquatic Life*, Cairns, J., Jr., Dickson, K.L., and Maki, A.W. (eds.), STP 657, American Society for Testing and Materials, Phila., PA., (1978), pp. 202-237.

61. Kimerle, R.A., Gledhill, W.E., and Levinskas, G.J., ''Environmental Safety Assessment of New Materials,'' In *Estimating the Hazard of Chemical Substances to Aquatic Life*, Cairns, J., Jr., Dickson, K.L., and Maki, A.W. (eds.) . STP 657, American Society for Testing and Materials, Phila., PA., (1978), pp. 132-146.

62. Maki, A.W. and Duthie, J.R., ''Summary of Proposed Procedures for the Evaluation of Aquatic Hazard,'' In *Estimating the Hazard of Chemical Substances to Aquatic Life*, Cairns, J., Jr., Dickson, K.L., and Maki, A.W. (eds.). STP 657, American Society for Testing and Materials, Phila., PA., (1978), pp. 153-163.

63. Stern, A.M. and Walker, C.R., ''Hazard Assessment of Toxic Substances: Environmental Fate Testing of Organic Chemicals and Ecological Effects Testing,'' In *Estimating the Hazard of Chemical Substances to Aquatic Life*, Cairns, J., Jr., Dickson, K.L., and Maki, A.W. (eds.). STP 657, American Society for Testing and Materials, Phila., PA. (1978), pp. 81-131.

64. International Joint Commission. *A Strategy for the Virtual Elimination of Persistent Toxic Substances. Vol. 1*. Report of the Virtual Elimination Task Force to the International Joint Commission: Windsor, Ontario, Canada, 1993.

65. Ontario Ministry of Environment and Energy. *Candidate Substances for Bans, Phase-outs or Reductions - Multimedia Revision*. Ontario, Canada, October 1993.

66. Aronson, D. et.al., *Chemical Fate Half-Lives and Persistence Evaluation for Toxics Release Inventory PBT Rule Chemicals*. prepared by Syracuse Research Corp. for Robert S. Boethling, USEPA Office of Pollution Prevention and Toxics, Washington, DC. Contract Number 68D50012 Task 451(1998).

67. USEPA, OPPT. *Rationale for Classification of Chemicals Crossing Persistence Categories*. prepared by Dave G. Lynch, Economics Exposure and Technology Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 (1998).

68. Menzie, C.M., *Metabolism of Pesticides Update III*. U.S. Fish and Wildlife Service, Special Scientific Report No. 232 (1980).

69. Lichtenstein, E.P. and Schultz, K.R., ''Epoxidation of Aldrin and Heptachlor in Soils as Influenced by Autoclaving, Moisture, and Soil Types.'' *J. Econ. Entomol.* v. 53(2), (1960), pp. 192-197.

70. Miles, J.R., Tu, C.M., and Harris, C.R., ''Metabolism of Heptachlor and its Degradation Products by Soil Microorganisms.'' *J. Econ. Entomol.* v. 62, (1969), pp. 1332-1338.

71. Carlson, G.P., ''Epoxidation of Aldrin to Dieldrin by Lobsters.'' *Bull.*

Environ. Centime. Toxicol. v. 11, (1974), p. 577.

72. Sanborn, J.R., Francis, B.M., Metcalf, R.L., *The Degradation of Selected Pesticides in Soil: a Review of the Published Literature*. U.S. NTIS, PB-272352, (1977), 633 pp.

73. Rosenblatt, D.H. et al.. Appendix K- Aldrin/Dieldrin. Preliminary assessment of ecological hazards and toxicology of environmental pollutants at Rocky Mountain Arsenal. (1975).

74. Tu, C.M., Miles, J.R., and Harris, C.R., ''Soil Microbial Degradation of Aldrin.'' *Life Sci.* v. 7, (1968), pp. 311-323.

75. IRIS, 1998. U.S. Environmental Protection Agency's Integrated Risk Information System file pertaining to endrin, dieldrin, and heptachlor epoxide.

76. Boethling, R.S., *EQC Model Output for Toxics Release Inventory PBT Rule Chemicals*. USEPA Office of Pollution Prevention and Toxics, Washington, DC. Syracuse Research Corp. Contract Number 68D50012 Task 451, (1998).

77. USEPA. Method 23 - Determination of Polychlorinated Dibenzo-p-Dioxins and Polychlorinated Dibenzofurans from Stationary Sources. Standards of Performance for New Stationary Sources. 40 CFR Part 60 Appendix A.

78. Safe, S.; ''Polychlorinated Biphenyls, Dibenzo-*p*-dioxin and Dibenzofurans and Related Compounds: Environmental and Mechanistic Considerations Which Support the Development of Toxic Equivalency Factors.'' *CRC Crit. Rev. Toxicol.* v. 21, (1990), pp. 51-88.

79. USEPA, OPPT. *Economic Analysis of the Proposed Rule to Modify Reporting of Persistent Bioaccumulative Toxic Chemicals under EPCRA Section 313*, (1998).

80. USSBA. *Office of Advocacy - Statistics - Major Industry, Firms, Establishment, Employment, Payroll and Receipts, 1995*. Information from the Small Business Administration on the Internet. http://www.sba.gov/advo/stats/us—ind95.html. Downloaded on December 10, 1998.

XII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), it has been determined that this is an economically ''significant regulatory action'' because it is likely to have an annual effect of $100 million or more. This action therefore 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 record.

B. Regulatory Flexibility Act

For the reasons explained in Unit X of this preamble, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. In brief, the factual basis of this determination is as follows: there are 17 small governments that may be affected by the proposed rule (i.e., will have to file reports under the proposed rule), none of which will bear annual costs greater than 1% of annual government revenues. EPA estimates that 4 of the approximately 3,600 small businesses potentially affected by the proposed rule will experience annual compliance costs above 1% of annual sales after the first year of reporting. Given these relatively small estimated impacts, for purposes of the RFA, EPA believes that the proposed rule will not have a significant economic impact on a substantial number of small entities. EPA's estimates are based on the economic analysis (Ref. 79), and are also discussed in Unit X. of this preamble. This determination is for the entire population of small entities potentially affected by this proposed 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 above. To ensure consideration during the development of the final rule, comments must be received by the data indicated in the ''DATES'' section.

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

C. Paperwork Reduction Act

The information collection requirements contained in this proposed 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. An Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No. 1363) and a copy may be obtained from Sandy Farmer, OPPE Regulatory Information Division; 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. The information requirements contained in this proposal would not become effective until OMB approves them. 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.

Provision of this information is mandatory, upon promulgation of a final rule, pursuant to EPCRA section 313 (42 U.S.C. 11023) and PPA section 6607 (42 U.S.C. 13106). 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 (hereinafter toxic chemicals) in excess of the applicable threshold quantities, and meeting certain requirements (i.e., at least 10 FTEs or the equivalent), to report environmental releases and transfers of and waste management activities for such chemicals annually. Under section 6607 of the PPA, facilities must also provide information on the quantities of the toxic chemicals in 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 proposed rule, all facilities reporting to TRI on PBT chemicals would have to use the EPA Toxic Chemical Release Inventory Form R (EPA Form No. 9350-1). OMB has approved the existing reporting and recordkeeping requirements related to Form R, supplier notification, and petitions under OMB Control No. 2070–0093 (EPA ICR No. 1363).

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 proposed rule is estimated to result in reports from 9,500 respondents. Of these, 2,600 facilities are estimated to be reporting to TRI for the first time as a result of the rule, while 6,900 are currently reporting facilities that will be submitting additional reports. These facilities will submit an estimated additional 17,000 Form Rs. This proposed rule therefore results in an estimated total burden of 1.8 million hours in the first year, and 1 million hours in subsequent years, at a total estimated industry cost of $126 million in the first year and $70 million in subsequent years.

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.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to EPA at the address provided above, with a copy to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Please remember to include the ICR number in any correspondence. The final rule will respond to any comments on the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act and Executive Order 12875

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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 proposed rule pursuant to section 202 of UMRA, and that statement is available in the public docket for this rulemaking. The costs associated with this action are estimated in the economic analysis prepared for this proposed rule (Ref. 79), which is included in the public docket and summarized in Unit X. of this preamble. The following is a brief summary of the UMRA statement for the proposed rule.

This proposed rule is being promulgated pursuant to sections 313(b)(1)(B) and (d) of EPCRA, 42 U.S.C. section 11023(b)(1)(B) and (d), and section 6607 of the Pollution Prevention Act, 42 U.S.C. section 13106. The economic analysis contains an analysis of the benefits and costs of this proposed rule, which estimates that the total industry costs of the proposed rule will be $126 million in the first year and $70 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. This information is also summarized above in Unit X of this preamble. EPA believes that the benefits provided by the information to be reported under this proposed 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 proposed rule. As set forth in the economic analysis, EPA has estimated the future industry compliance costs (after the first year) of this proposed rule to be $70 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 proposed 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 proposed rule will not significantly or uniquely affect small governments and does not contain a significant Federal intergovernmental mandate.

Finally, EPA believes this proposed rule complies with section 205(a) of UMRA. The objective of this proposed 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 listed toxic chemicals. 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, particularly at the local level.

As described in Unit VII.A.1.ii. of this preamble, EPA considered burden in the threshold selection. The rule also contains reporting requirements that will limit burden (e.g., reporting limitations for vanadium in alloys and a ''manufacture only'' activity qualifier for dioxin). In addition, 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 apply to the facilities that file new reports as a result of this proposed rule. EPA also will be assisting small entities subject to the proposed 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 proposed rule, and to EPA's knowledge there is no available alternative to the proposed 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).

E. Executive Orders 12898 and 13045

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' 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 (62 FR 19885, April 23, 1997), entitled ''Protection of Children from Environmental Health Risks and Safety Risks,'' 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 is providing 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 proposed rule will have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children.

List of Subjects in 40 CFR Part 372

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

Dated: December 24, 1998.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR part 372 be amended as follows:

PART 372—[AMENDED]

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

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

§ 372.22 [Amended]

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

§ 372.25 [Amended]

3. In the introductory text of § 372.25, by removing the first clause ''Except as provided in § 372.27,'' and adding in its place ''Except as provided in § 372.27 and § 372.28,''.

4. In § 372.27, by adding 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. By adding 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
Dicofol	00115-32-2	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 (manufacture only): (This category includes only those chemicals listed below). 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	0.1 grams

Category name	Reporting threshold
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). 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	10
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 at § 372.25(c)–(h) and the exemptions at § 372.38(b)–(h) are applicable to the toxic chemicals listed in paragraph (a) of this section.

§ 372.30 [Amended]

6. In § 372.30(a), by removing the phrase ''in § 372.25 at'' and adding in its place ''in § 372.25, § 372.27, or § 372.28 at''.

7. In § 372.38(a), by adding the following sentence at the end of the paragraph to read as follows:

§ 372.38 Exemptions.

(a) * * * This exemption does not apply to toxic chemicals listed in § 372.28, except for purposes of § 372.45(d)(1).

* * * * *

8. In § 372.65,

i. By removing in paragraph (a) the entry ''Vanadium (fume or dust)'' and adding in its place ''Vanadium (except when contained in an alloy)''.

ii. By removing in paragraph (b) for CAS no. 7440–62–2, the entry ''Vanadium (fume or dust)'' and adding in its place ''Vanadium (except when contained in an alloy)''.

iii. By adding chemicals to paragraph (a) alphabetically.

iv. By adding chemicals to paragraph (b) by CAS no. sequence.

v. By adding two categories to paragraph (c) alphabetically.

vi. By adding two chemicals to paragraph (c) under the polycyclic aromatic compounds (PACs) category.

The amendments 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
* * * *	* * *	

(b) * * *

CAS No.	Chemical name	Effective date
* * * * * * *		
00079-94-7	Tetrabromobisphenol A	1/00
* * * * * * *		
00191-24-2	Benzo(g,h,i)perylene	1/00

CAS No.	Chemical name	Effective date
	* * * * * * *	
00608-93-5	Pentachlorobenzene	1/00
	* * * * * * *	
29082-74-4	Octachlorostyrene	1/00
	* * * * * * *	

(c) * * *

Category name	Effective date
* * * * * * *	
Dioxin and Dioxin-Like Compounds (manufacture only): (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	
* * * * * * *	
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
* * * * * * *	

§ 372.85 [Amended]

9. In § 372.85,

i. By removing in paragraphs (b)(15)(i) introductory text and (b)(16)(ii)(B) the phrase ''may be indicated in ranges'' and adding in its place ''may be indicated in ranges, except for chemicals set forth in § 372.28''.

ii. By removing in paragraph (b)(16)(i)(B) the phrase ''may be indicated as a range'' and adding in its place ''may be indicated as a range, except for chemicals set forth in § 372.28''.

[FR Doc. 98–34835 Filed 12–30–98; 4:17 pm]

BILLING CODE 6560–50–F