

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 372**

[OPPTS-400140; FRL-6081-4]

RIN 2070-AD38

Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: EPA is proposing to lower the reporting thresholds for lead and lead compounds which 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 believes that lead and lead compounds are persistent, bioaccumulative toxic (PBT) chemicals that warrant lower reporting thresholds than those currently established under EPCRA section 313. Today's proposed action also includes a limitation on the reporting of lead when contained in certain alloys and proposed modifications to certain reporting exemptions and requirements for lead and lead compounds.

DATES: Written comments, identified by the docket control number OPPTS-400140, must be received by EPA on or before September 17, 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 document.

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 Notice Apply to Me?**

You may be potentially affected by this notice if you manufacture, process, or otherwise use lead or lead compounds. Potentially affected

categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Industry	Facilities that: process copper ores, lead and zinc ores; operate pulp mills, petroleum refineries, primary copper smelters, primary and secondary nonferrous metal smelters, gray/ductile iron foundries, steel foundries, blast furnaces, steel mills, petroleum bulk stations and terminals, industrial boilers that burn coal, wood, petroleum products, and electric utilities that combust coal and/or oil for distribution of electricity in commerce; facilities that manufacture, process, or use inorganic pigments, small arms ammunition, asphalt paving mixtures and blocks, storage batteries, motor vehicles and motor vehicle equipment; manufacture electronic components and accessories.
Federal Government	Federal facilities that: manufacture, process, or use lead or lead compounds; burn coal or petroleum products.

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 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/homepage/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-400140. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center 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 control number (i.e., "OPPTS-400140") 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 your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G-099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is: 202-260-7093.

3. *Electronically.* Submit your comments 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-400140. Electronic

comments on this proposal 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. What is EPA's Statutory Authority for Taking These Actions?

These actions are proposed under sections 313(f)(2) and 328 of EPCRA, 42 U.S.C. 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. What is EPA's Statutory Authority to Lower EPCRA 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)).

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 lead and lead compounds, which the Agency has determined are persistent, bioaccumulative chemicals.

B. What is EPA's Statutory Authority for Making 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. How Did EPA Develop this Proposal and What is the Scope of the Comments Being Solicited?

A. Why Was Lead Not Addressed in the Recently Proposed PBT Rule?

In EPA's recent proposed rule to lower the EPCRA section 313 reporting thresholds for certain PBT chemicals (64 FR 688, January 5, 1999) (FRL-6032-3), EPA reviewed the bioaccumulation data for two lead compounds: tetramethyl and tetraethyl lead. However, the analysis was limited to the data for the intact compounds and did not address the potential availability of lead from these compounds or other lead compounds or the potential for lead to bioaccumulate. In the January 5, 1999 proposed rule for PBT chemicals, EPA made the following statements about lead and 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. (See 64 FR 717, column 1).

Since development of the January 5, 1999 proposed rule, EPA has received numerous comments requesting that the Agency include lead and lead compounds as PBT chemicals under EPCRA section 313 and set lower reporting thresholds (see the docket

support for the proposed rule (docket control number OPPTS-400132)). Many of these comments were received well into the comment period on the January 5, 1999 proposed rule. Rather than delay movement on the January 5, 1999 proposed rule until EPA was ready to proceed with lead and lead compounds, the Agency elected to address lower reporting thresholds for lead and lead compounds as a separate proposal. EPA believes that such an approach will allow both the Agency and those commenters especially interested in lead and lead compounds to focus on the issues specifically related to these substances. Accordingly, today's proposed rule is the result of EPA's review of the available information on lead and lead compounds, and is the Agency's response to the requests for lower reporting thresholds for lead and lead compounds based on their persistence and bioaccumulation.

B. What is the Scope of Comments Being Solicited on this Proposed Rule?

EPA recognizes that this proposal for lead and lead compounds may raise similar issues to those raised in the January 5, 1999 proposed rule. For the purposes of this proposal, however, EPA is only soliciting comments on how these proposed actions would affect EPCRA section 313 reporting on lead and lead compounds, the impacts these proposed changes would have on the burden of section 313 reporting for lead and lead compounds, and the benefits such reporting would provide the public. Comments of a more generic nature were solicited in the January 5, 1999 proposed rule, and should have been submitted during the comment period for that proposal, which closed April 7, 1999. EPA will respond to timely comments on these generic issues in the final PBT chemicals rule. The Agency will limit its consideration of and responses to comments submitted in the comment period for this proposal to those that relate to section 313 reporting of lead and lead compounds. To the extent that comments were submitted on the January 5, 1999 proposed rule that a commenter believes are relevant to this proposal, the commenter must resubmit or reference those comments for inclusion in the docket for this proposal, along with an explanation of why the comments are relevant to lead and lead compounds.

C. What are the Issues on Which EPA is Interested in Receiving Comment?

The Agency is particularly interested in receiving comments on the general policy issues, as they apply to lead and

lead compounds, that were discussed and raised for comment in Unit IX. of the preamble to the PBT proposed rule (see 64 FR 688, at 717). It is important for EPA to clarify that this proposal does not introduce any new issues beyond those associated with lead and lead compounds (e.g., persistence data for lead, bioaccumulation data for lead, estimated number of reports). The Agency is therefore only seeking comments on the generic issues that relate specifically to the proposal to lower the reporting threshold for lead and lead compounds. The changes that EPA is proposing to make to the reporting requirements for lead and lead compounds are discussed in detail in Unit VI. of this preamble, including the applicability to lead and lead compounds of the general amendments to EPCRA section 313 reporting requirements for PBT chemicals presented in the proposed PBT rule.

Accordingly, comments on the following issues, which were previously identified and for which comment was sought in Unit IX. of the preamble to the proposed PBT rule (see 64 FR 688, at 717), are only requested on this proposal insofar as the comments relate particularly to lead and lead compounds: (1) Whether EPA should attempt to estimate the releases that would be reported at an "average" facility at each of the identified options for a lowered threshold, the appropriate methodology for estimating releases from all affected industry sectors, and whether EPA should then use those estimates to select the lowered threshold that would capture some overall percentage of releases, e.g., 75 - 80%; (2) whether EPA should consider lowering the reporting thresholds for lead and lead compounds based on either persistence or bioaccumulation (rather than both); (3) whether EPA should consider other mechanisms for further minimizing the potential impacts associated with lowering the reporting thresholds for lead and lead compounds (i.e., it was suggested that EPA develop a modified Form A with thresholds more appropriate for lead and lead compounds, retain *de minimis* thresholds for lead and lead compounds (perhaps at a lower level), retain whole number reporting, the half-pound rule, and range reporting for lead and lead compounds, establish an activity qualifier restricting the lower reporting threshold to the manufacture of lead and lead compounds, retaining the higher current thresholds with respect to import, process or use activities, and that EPA modulate the frequency of reporting).

D. What Other Comments Should the Public Submit?

EPA believes that the additional information provided by lowering the TRI reporting thresholds for PBT chemicals, including lead and lead compounds, will be valuable to communities and will significantly enhance their knowledge about toxic chemical releases and other waste management activities that may be of concern to them. At the same time, EPA recognizes that today's proposal, along with its earlier proposal to lower reporting thresholds for various other PBT chemicals (64 FR 688), will increase the burden imposed by the TRI program on facilities that must provide information. EPA is mindful of the importance of minimizing reporting burden, while continuing to provide communities with high quality right-to-know information. EPA is genuinely interested in reducing TRI reporting burden, while assuring that the goals and objectives of EPCRA section 313 continue to be met.

EPA has already initiated a number of burden reducing activities in the TRI program. For example, EPA is currently reviewing the original list of EPCRA section 313 chemicals in response to suggestions that EPA evaluate those chemicals against the EPCRA section 313(d) criteria. EPA is also developing reporting guidance, including guidance specifically for small businesses, which will simplify and ease reporting burdens. These efforts include the development of intelligent reporting software with built-in error checking routines and calculation methodologies; the development of a single facility identification program for facilities that report to EPA; and the development of guidance to facilitate more consistent use of chemical nomenclature, reporting units, and time frames across different programs.

As a means of identifying other potential areas for reducing TRI reporting burden, EPA initiated an intensive stakeholder process to comprehensively evaluate current TRI reporting. An important part of this stakeholder process was a review conducted by the Toxics Data Reporting (TDR) Committee of the National Advisory Council on Environmental Policy and Technology (NACEPT). EPA asked the TDR Committee to develop recommendations to improve the right-to-know information available to communities and to help streamline reporting to ease the paperwork burden for facilities affected by the requirements. Specifically, the Committee was asked to examine the

format of and nomenclature in the Form R, seek opportunities for burden reduction, and evaluate EPA's presentation of the data in public information documents. The TDR Committee met eight times between September 1997 and October 1998, and issued its final report in May 1999. The TDR Committee report is available on the Internet at www.epa.gov/opptintr/tri, and a copy of the report is also available in the public version of the official record for this proposed rule.

In their final report to the Agency, after noting that the TDR Committee did not reach final consensus on most issues, the TDR Committee presented the various suggestions raised during the discussions as "ideas" without any indication of the level of support for them. These ideas fall under the broad categories of burden reduction, the public data release (PDR), and the Form R. Some of the burden reduction ideas presented by the TDR Committee include the creation of an intelligent software program for reporters, the integration of reporting across programs, the provision of industry specific guidance, the expansion of the EPCRA section 313 exemptions, and options for increasing eligibility for the alternate threshold as certified by Form A. With regard to the Form R, most of the Committee's suggestions involved the addition of data elements intended to further clarify the information currently collected, particularly on the waste management data. The Committee also offered ideas for improving the PDR, including adding information to the PDR that would provide additional context for the TRI data.

The TDR Committee report also mentions a more general approach for burden reduction that involves establishing, either through regulation or guidance, limitations on the level of effort and data accuracy required for TRI reports. For example, this approach might include greater use of default parameters and standardized estimation methods based on best engineering practices, and/or a percentage rule in which a facility would be required to collect information and report only some fixed percentage of releases (e.g., 90%). This latter approach could allow facilities to focus their reporting efforts on larger sources of releases and ignore some smaller sources, as long as they reported at least the specified percentage of total releases. The absolute quantity not reported would vary from toxic chemical to toxic chemical and from facility to facility. EPA requests comments on the substance of this approach, including mechanisms that would allow

implementation consistent with EPCRA section 313. In particular, EPA is interested in comments regarding the potential impacts of this approach on the facility reporting burden and on the integrity of the TRI data and community right-to-know.

In addition to the TDR Committee report, EPA has received other suggestions for burden reduction in the TRI program. Although EPA has already requested comment on the suggestion that EPA effectively modify the frequency of reporting for PBT chemicals (see 64 FR 688, at 718), and lead and lead compounds (see Unit III.C. of this preamble), it has been suggested that EPA consider changing the frequency of reporting under EPCRA section 313 in general, i.e., require biennial reporting. EPA is requesting comment on the utility of biennial reporting and whether that approach would provide for significant burden reduction for affected facilities. EPA welcomes comment on the availability of information that would allow the Agency to make the requisite findings under EPCRA section 313(i)(3)(B), especially how consideration of alternate reporting requirements should pertain to the facilities in the recently added industry sectors for which first reports have just recently been received, the lack of readily available information on EPCRA section 313 chemicals from existing sources, and what available information may exist to allow EPA to address the requirements of the law.

EPA places great importance on reducing burden on the public and is currently considering the various suggestions it has received, including the ideas in the TDR Committee report, and others received from industry and other agencies. EPA welcomes additional suggestions, and specifically requests comment on the ideas presented in the TDR Committee report, particularly those that relate to burden reduction.

IV. Explanation for Lowering Reporting Thresholds

A. What is the General Background for this Rulemaking?

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 multi-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 (59 FR 61432, November 30, 1994) (FRL-4922-2). Further, a new category of facilities was added to EPCRA section 313 on August 3, 1993, through Executive Order 12856 (58 FR 41981, August 6, 1993), 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 (62 FR 23834, May 1, 1997) (FRL-5578-3). 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 action, EPA is proposing enhanced reporting requirements for lead and lead compounds. Lead and lead compounds are toxic chemicals that persist and bioaccumulate in the environment. 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 lowering the reporting thresholds for lead and lead compounds. Lead and lead compounds, being PBT chemicals, 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 PBT chemicals can have serious human health and environmental effects resulting from low levels of release and exposure. Lowering the reporting thresholds for lead and lead compounds would ensure that the public has important information on the quantities of these PBT chemicals released or otherwise managed as waste, that would not be reported under the current thresholds.

B. Why Should EPCRA Section 313 be Used to Focus on Chemicals that Persist and Bioaccumulate?

As discussed in Unit VI.A. of this preamble, EPA is proposing to lower the EPCRA section 313 reporting thresholds for lead and lead compounds because these substances persist and bioaccumulate in the environment. 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, such as lead and lead compounds, 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 and the data for lead and lead compounds.

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, and specifically lead and lead compounds, 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 even in relatively small amounts are of concern. Under current reporting thresholds, a significant amount of the releases and other waste management activities involving lead and lead compounds are not being captured. The public, therefore, does not have the information needed to determine if lead and lead compounds are present in their communities at levels that may pose a significant risk. By lowering the section 313 reporting thresholds for lead and lead compounds, 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, such as lead and lead compounds. 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 at lower thresholds under EPCRA section 313 would 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 would 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. However, the Canada-United States Strategy for Virtual Elimination of Persistent Toxic Substances in the Great Lakes Basin contains commitments that apply nationwide, including those for alkyl lead. 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, through meeting a series of interim reduction goals, some of which are national in scope. Virtual elimination is to be attained by programs implemented voluntarily by each country. The Binational Level 1 List includes alkyl lead, and the associated commitment reads: "US Challenge: Confirm by 1998, that there is no longer use of alkyl lead in automotive gasoline. Support and encourage stakeholder efforts to reduce alkyl lead releases from other sources."

The information that would be reported under this proposed rule regarding alkyl lead would directly contribute to the Agency's ability to "support and encourage stakeholder efforts to reduce releases" as agreed to in the Binational Strategy.

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 ensure 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. EPA has recently addressed the issue of lower reporting thresholds for certain other PBT chemicals in a proposed rule that was published on January 5, 1999 (64 FR 688) (FRL-6032-3).

V. Review of Persistence, Environmental Fate, and Bioaccumulation Data for Lead and Lead Compounds

A. What are Persistence and Environmental Fate and What Data are Available for Lead and Lead Compounds?

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; however, water is 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.

Although metals and metal compounds, including lead and lead compounds, may be converted from the metal to a metal compound or from one metal compound to another in the environment, the metal cannot be destroyed. Thus, metals are obviously persistent in the environment in some form. The form of the metal that exists in the environment depends on its environmental fate. Environmental fate refers to the ultimate result of physical, chemical, and biological processes acting upon a metal or metal compound once released into the environment. The environmental fate determines whether the metal or the metal from a metal compound will be available for exposure to organisms once released into the environment. The environmental fate of a metal or metal compound varies depending on the environmental conditions and the physical/chemical properties of the metal in question.

The information summarized below for the environmental fate of lead in each environmental medium represents the key elements influencing the transport, transformation, and bioavailability of lead in air, soil, water and sediments. Commenters should consult the support documents and review the studies contained and referenced therein for further information. The information summarized below as well as a more extensive review of the existing data on the environmental fate of lead is contained in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) and in the references contained therein.

Most lead released to air eventually settles back to ground level by dry deposition or washout by rain. Thus, airborne lead is either returned to soil surfaces by deposition or to surface water by deposition or surface runoff. However, while airborne, some lead compounds (e.g., lead halides) can

undergo reactions to produce lead sulfates and carbonates.

After deposition in the soil environment, lead may bind strongly by mechanisms such as the formation of insoluble complexes with organic material, clay minerals, phosphate, and iron-manganese oxides common in many soils. These mechanisms can lower the levels of soluble lead in soils. However, some of the lead in the soil environment (0.2 to 1%) may be water soluble. The extent of sorption appears to increase with increasing pH. Under acidic conditions, levels of lead in soil water can increase significantly. The solubility of lead increases linearly in the pH range of 6 to 3. At a pH of 5 to 9, heavy metals such as lead may bind to the surface of clay minerals. Cation exchange capacity (CEC, related to soil clay content) and pH also influence the capacity of soil to immobilize lead. Generally, as the CEC and pH increase, the capacity of a soil to sorb lead increases. Conversely, soils with lower CEC and pH tend to have a lower capacity to sorb lead. Using organic chelation as a model, the total capacity of soil to immobilize lead can be predicted by the linear relationship developed by Zimdahl and Skogerboe (Ref. 3). Using this equation to predict saturation capacity from CEC and pH, it can be shown that a pH drop from 5.5 to 4.0 would reduce estimated soil absorption capacity 1.5 times, thereby increasing the concentration of available lead in soil water.

A number of field studies demonstrate the effect of environmental conditions on the mobility of lead in soils. In all of these studies, variables including pH, soil organic matter content and the chemical species of lead present, had a significant influence on soil lead mobility. Data indicate that when the pH and soil organic matter content are low and conditions favor the formation of soluble forms of lead, the mobility of lead increases. Therefore, decreasing pH can lead to increasing concentrations of lead in soil water. Other studies demonstrate that when pH and soil organic matter are high, lead mobility in soils is decreased. Limited data indicate that organolead compounds may be converted into water-soluble lead compounds in some soil. Degradation products of tetramethyl and tetraethyl lead, the trialkyl lead oxides, are expected to be significantly more mobile in soils than the parent tetraalkyl lead compounds would be.

The levels of soluble lead in surface waters depend on the pH of the water and the dissolved salt content. Equilibrium calculations show that at a pH greater than 5.4, the total solubility

of lead is approximately 30 micrograms per liter ($\mu\text{g/L}$) in hard water and approximately 500 $\mu\text{g/L}$ in soft water. In soft water, sulfate ions limit the lead concentration in solution through the formation of lead sulfate. The lead carbonates limit lead in solution at a pH greater than 5.4 (Ref. 4). Concentrations as high as 330 $\mu\text{g/L}$ could be stable in water at a pH near 6.5 and an alkalinity of about 25 milligrams (mg) bicarbonate ion per liter. Water having these properties is common, for example, in runoff areas of New York State and New England. In other waters, where alkalinity and pH are higher, the relative concentrations of soluble lead may be lower.

Lead also forms complexes with organic matter in water. The organic matter includes humic and fulvic acids that are the primary complexing agents in soils and widely distributed in surface waters. The presence of fulvic acid in water has been shown to increase the rate of solution of lead sulfide 10 to 60 times (Refs. 5 and 6). At pH levels near neutral (i.e., about 7.0), soluble lead-fulvic acid complexes are present in solution. As pH levels increase, the complexes are partially decomposed, and lead hydroxide and carbonate are precipitated, and may either remain suspended or fall to the sediment. Other studies have shown that humic acid in freshwater and marine sediments, and in the aqueous phases, are capable of complexing various amounts of metals. In some circumstances, this process could potentially reduce the levels of soluble lead present.

At neutral pH, lead generally moves from the dissolved to the particulate form with ultimate deposition in sediments. There is evidence that in anaerobic sediments, lead can undergo biological or chemical methylation. This process could result in the remobilization and reintroduction of transformed lead into the water column where it could be available for uptake by biota, and volatilization to the atmosphere. However, tetramethyl lead may be degraded in aerobic water before reaching the atmosphere.

In conclusion, EPA believes that processes commonly observed in the environment can result in the release of bioavailable (ionic) lead where it can be bioaccumulated by organisms. These processes may occur in soil and aquatic environments with low pH and low levels of clay and organic matter. Under these conditions, the solubility of lead is enhanced and if there are no sorbing surfaces and colloids, lead ion can remain in solution for a sufficient period to be taken up by biota. Lead

sorption to soil organic matter has been shown to be pH dependent. Decreasing pH can lead to increasing concentrations of lead in soil water; while increasing pH can lead to decreasing concentrations of lead in soil water.

The Agency's analysis of the environmental fate of lead and lead compounds, therefore, shows that under many environmental conditions lead is available to express its toxicity and to bioaccumulate. The bioavailability of metals such as lead has been raised as an issue at recent public meetings on EPA's January 5, 1999 proposed rule on PBT chemicals (64 FR 688). It has been suggested that metals will not be bioavailable from certain metal compounds that may be released into the environment and that therefore they should not be considered PBT chemicals. The issue of the bioavailability of metals from metal compounds is broader than just its implications for whether a chemical is a PBT. The issue of bioavailability has been addressed for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (May 23, 1991, 56 FR 23703). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity. If the intact metal compound is not toxic and the metal is not available from the metal compound then such a chemical is a potential candidate for delisting. EPA developed this petition process specifically to address such circumstances.

EPA requests comment on its discussion of the scientific information concerning the fate, transport, and the availability of lead in the environment, and on how this information should be considered in classifying lead as a PBT chemical.

B. What is Bioaccumulation and What Aquatic Bioaccumulation Data are Available for Lead and Lead Compounds?

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 unit (i.e., Unit V.B.) deal strictly with aquatic organisms. This is not to imply that bioaccumulation cannot occur in non-aqueous environments and in fact Unit V.C. of this preamble discusses the bioaccumulation of lead in humans,

including bioaccumulation from non-aqueous media. The term bioaccumulation refers to uptake of chemicals by organisms both directly from water and through their diet (Ref. 7). 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. 8). 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).

A review of the ecotoxicological literature indicates that bioconcentration values of lead and lead compounds (lead salts) in aquatic plants and animals are often above a bioconcentration/bioaccumulation factor of 1,000. Lead is bioaccumulated by aquatic organisms such as plants, bacteria, invertebrates, and fish. The principal form that is believed to be accumulated is divalent lead (i.e., lead in its plus 2 oxidation state (Pb^{+2})). It has been shown that fish held in water at a pH of 6.0 accumulate three times as

much lead as fish held in water at a pH of 7.5 (Ref. 9), thus as pH decreases the availability of divalent lead increases. Older organisms usually have the highest body burdens, and lead accumulates in bony tissues to the greatest extent.

Table 1 below summarizes some of the data reviewed concerning the extent (magnitude) of lead bioaccumulation found to occur in many aquatic plants and animals and the lead bioconcentration factors (BCF) determined or measured from laboratory studies conducted for certain durations using BCF test methods. Only some of the laboratory calculated values or monitored field values near or above a bioaccumulation factor of 1,000 are included in Table 1; additional data can be found in the bioaccumulation support document (Ref. 10). Concentrations of lead monitored in various organisms listed in Table 1 were determined by comparing concentrations in the environment (water) with concentrations measured in the organisms.

Table 1.—Bioaccumulation/Bioconcentration Data for Lead and Lead Compounds in Aquatic Organisms.

Test Species	Chemical Tested/ Monitored (con- centration)	BCF Value ¹	Field Concentration Factor ²	Reference
Freshwater Species				
Snail (<i>Lymnaea palustris</i>)	Lead nitrate (12 µg/L)	1,700; 3,100 (soft tissue); 2,500 (whole animal)	NA	Ref. 11
Phytoplankton, 13 species (<i>Melosira italica</i> and <i>Asterionella formosa</i> were dominants)	Lead (0.4-2.5 µg/dm ³)	NA	10,000x or greater ⁽³⁾	Ref. 12
Green alga (<i>Selenastrum capricornutum</i>)	Lead nitrate (5 µg/L)	10,000 ⁽³⁾	NA	Ref. 13
Green alga (<i>Selenastrum capricornutum</i>)	Lead nitrate (50 µg/L)	2,900 ⁽³⁾	NA	Ref. 13
Green alga (<i>Cladophora sp.</i>)	Lead	NA	390x ⁽³⁾ ; 690x ⁽³⁾ ; and 1,695x ⁽³⁾	Ref. 14
Pondweed (<i>Pontamogeton sp.</i>)	Lead	NA	525x ⁽³⁾ and 1,695x ⁽³⁾	Ref. 15
Rainbow trout (<i>Salmo gairdneri</i>)	Lead (3.5 µg/L; 24 µg/L)	726 (whole fish); 12,540 and 17,300 (intestinal lipids)	NA	Ref. 16
Marine Species				
Blue mussel (<i>Mytilus edulis</i>)	Lead nitrate; Lead (10 µg/L); Lead (500 µg/L)	2,570 and 2,800 (soft parts); 2,427 ⁽³⁾ (kidney) and 306 ⁽³⁾ (soft parts); 4,985 ⁽³⁾ (soft parts)	NA	Refs. 17 and 18
Eastern oyster (<i>Crassostrea virginica</i>)	Lead (1, 3.3 µg/L)	1,320 ⁽³⁾ and 691 ⁽³⁾ (soft parts)	NA	Ref. 19
Brown alga (<i>Fucus vesiculosus</i>)	Lead (1-7.5 µg/L)	NA	570x-3,600x ⁽³⁾	Ref. 20
Algae (<i>Ulva sp.</i>)	Lead (1-7.5 µg/L)	NA	1,140x-7,350x ⁽³⁾	Ref. 20
Algae (<i>Enteromorpha linza</i>)	Lead (1-7.5 µg/L)	NA	1,020x-6,750x ⁽³⁾	Ref. 20
Algae (<i>Blidingia minima</i>)	Lead (1-7.5 µg/L)	NA	900x-12,300x ⁽³⁾	Ref. 20
American Lobster (<i>Homarus americanus</i>)	Lead (50 µg/L)	2,760 (antennal gland)	NA	Ref. 21

¹BCF values are calculated from laboratory studies.

²Field concentrations are estimated from water:organism sample comparisons.

³Value was converted from a dry weight value to a wet weight value using appropriate conversion factors.

Additional information concerning lead's bioaccumulation potential is summarized in the bioaccumulation support document for this proposed rule (Ref. 10). In general, bioconcentration values for four freshwater invertebrate species ranged from 499 to 1,700 (Ref 22). BCFs for two species of freshwater fish were much lower, 42 and 45. However, certain fish tissues have much higher BCF values, e.g., the BCF value for the intestinal lipids in rainbow trout were as high as 17,300. Freshwater phytoplankton and both marine and freshwater algae accumulate or concentrate lead to very high levels

(e.g., greater than 10,000x). BCF values for marine bivalve organisms were as high as 4,985 for blue mussels. Eastern oysters also have BCF values greater than 1,000. These data indicate that many of the BCF values and measured environmental concentration factors for lead are above 1,000 with several species having BCF or observed concentration factors above 5,000. The references cited for blue mussels include a range of values, the upper end of which is very close to 5,000 (i.e., 4,985). There are also a few fish tissues that have BCFs greater than 10,000,

though most of the available fish data are below 5,000.

EPA requests comment on its discussion of the scientific information concerning the bioaccumulation of lead in aquatic organisms, and on how this information should be evaluated in assessing the bioaccumulative potential of lead and lead compounds.

C. What Data are Available on the Human Bioaccumulation of Lead and Lead Compounds?

There is a great deal of information available on the bioaccumulation of lead in humans and the effects that such

accumulation can have. Much of this information is summarized and cited in the following documents, *The Agency for Toxic Substances and Disease Registry Toxicological Profile on Lead* (Ref. 23), *EPA's Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil* (Ref. 24), and *EPA's Air Quality Criteria for Lead* (Ref. 25). EPA's Office of International Affairs has also established an Internet site that provides information on lead including lists of various EPA documents on lead that are available as well as links to other EPA programs and agencies that have information on lead and its hazards (Ref. 26). This unit provides a summary of some of the information from these sources that relates to the ability of lead to accumulate in humans.

The bioaccumulation and persistence of lead in humans is well documented. Although lead has no known biological function in humans, it is readily absorbed through the gut and can be absorbed by inhalation and, to some extent by dermal contact. Absorption of lead can occur as a result of exposure to air-borne forms of lead, as well as ingestion or contact with contaminated soil and dust. Children and developing fetuses are known to absorb lead more readily than adults and to excrete it at a lower total rate. These findings are especially significant since young children are most susceptible to the adverse effects associated with lead exposure. Lead absorption varies from very low levels (e.g., 5%) up to essentially 100%. Lead absorption appears to be linked to particle size, the chemical composition, and other factors (Refs. 27 and 28). Long-lasting impacts on intelligence, motor control, hearing, and neurobehavioral development of children have been documented at levels of lead that are not associated with clinical intoxication and were once thought to be safe. An analysis of human blood-lead level data collected from most recent National Health and Nutrition Examination Surveys (see Ref. 24), showed that approximately 4.4% of the nation's children aged 1-5 years have blood-lead concentrations at or above 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$), which is the current action level established by the Centers for Disease Control. While this is a significant improvement over the 88% of children who had blood lead levels above this threshold in 1976, before the phase-out of lead in gasoline, it is still cause for concern because it leaves nearly 900,000 children aged 1-5 with unacceptably high blood-lead levels.

Once lead is absorbed in the body, it is primarily distributed to the blood,

soft tissues (kidney, bone marrow, liver, and brain) and to the mineralizing tissue (bones and teeth). In one study it was shown that in adults, following a single dose of lead, one-half of the lead absorbed from the original exposure remained in the blood for approximately 25 days after exposure, in soft tissues for about 40 days, and in bone for more than 25 years (Ref. 29). Once in the bone, lead can re-enter the blood and soft tissues. Under certain circumstances, such as pregnancy and lactation, lead can more readily re-enter blood and soft tissues. Thus, accumulation of lead in bone can serve to maintain elevated blood lead levels years after exposure. The total amount of lead in long-term bone retention can approach 200 mg for adult males 60-70 years old (and even higher with occupational exposure). For adults, up to 94% of the total amount of lead in the body is contained in the bones and teeth but for children only about 73% is stored in their bones. While the increase in bone lead level across childhood is modest, the total accumulation rate is actually 80-fold when the 40-fold increase in skeletal mass that children undergo is taken into account. While lead absorption rates are influenced by several parameters, including route of exposure, chemical speciation, the physical/chemical characteristics of the lead and the exposure medium, as well as the age and physiological states of the exposed individual, there is substantial documentation that a significant amount of lead can be absorbed and accumulated in humans.

EPA requests comments on its discussion of the scientific information concerning the bioaccumulation of lead in humans and on how this information should be considered in classifying lead and lead compounds as "highly bioaccumulative."

D. What are EPA's Conclusions from the Review of the Available Data on Lead and Lead Compounds?

EPA's review of the available information on lead and lead compounds has led EPA to conclude that lead and lead compounds are highly persistent and highly bioaccumulative. The persistence of lead in the environment is not in question since, as a metal, lead cannot be destroyed in the environment. With respect to whether lead or lead compounds released to the environment will result in lead that is bioavailable, the data indicate that under many environmental conditions lead does become available. The conclusion that lead is bioavailable in the environment

is confirmed by the data on the bioaccumulation of lead in aquatic organisms and in humans as a result of environmental exposures. As for lead's bioaccumulation potential, lead has been shown to bioaccumulate in laboratory studies and has been found to bioaccumulate in organisms observed in the environment. These data indicate that many of the BCF values and measured environmental concentration factors for lead are above 1,000 with several species having BCF or observed concentration factors above 5,000. The references cited for blue mussels include a range of values, the upper end of which is very close to 5,000 (i.e., 4,985). There are also a few fish tissues that have BCFs greater than 10,000, though most of the available fish data are below 5,000.

A high concern for the bioaccumulation potential for chemicals with BCF values above 1,000 is consistent with the discussion of BCF values in the recent proposed rule on PBT chemicals (January 5, 1999, 64 FR 688). In addition, there is considerable information on the accumulation of lead in humans, including children who are the most susceptible to the toxic effects of lead. The data on lead's persistence and availability in the environment, the observed high bioaccumulation values in aquatic organisms, and lead's ability to accumulate in humans, are the basis for EPA's conclusion that lead and lead compounds are highly persistent and highly bioaccumulative.

E. Are There Particular Issues on Which EPA is Interested in Receiving Comment?

The Agency recognizes that there are several complex technical issues surrounding the availability and bioaccumulation of lead and lead compounds. For example, during the inter-agency review process it was suggested that the bioavailability of lead in the environment could be constrained by many abiotic factors such that lead is not available in certain environments. These abiotic factors include: Soils have a high capacity to immobilize lead and therefore limit its availability; high pH levels may reduce lead bioavailability; organic matter can decrease lead bioavailability; inorganic constituents can reduce lead availability in aqueous environments; and, increasing water hardness can also reduce lead availability. The Agency specifically requests comments on these issues.

VI. What Changes are EPA Proposing to Make to the Reporting Requirements for Lead and Lead Compounds?

A. What Changes are EPA Proposing for the Reporting Thresholds for Lead and Lead Compounds?

EPA is proposing to lower the reporting thresholds for lead and lead compounds.

1. *What was considered in the selection of lower reporting thresholds?* In selecting potential lower reporting thresholds for lead and lead compounds, EPA considered not only their persistence and bioaccumulation but also the potential burden that might be imposed on the regulated community by lower reporting thresholds. Each of these important considerations is discussed below.

a. *How was persistence and bioaccumulation considered in threshold selection?* Because lead and lead compounds 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 lead and lead compounds 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 PBT chemicals, including lead and lead compounds, EPA has adopted a two-tiered approach. Under this approach, EPA identifies PBT chemicals that should have a lower reporting threshold as those chemicals with half-lives of at least 2 months and BAF/BCF values of at least 1,000. This approach also 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 and should have an even lower reporting threshold. 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 the most relevant data to communities. However, 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 chemicals that are highly persistent and bioaccumulative.

Because lead cannot be destroyed in the environment and because lead is available in the environment, EPA believes that lead and lead compounds are highly persistent. The bioaccumulation data for lead and lead compounds includes many BCF or concentration values well above 5,000, and there is additional data that show that lead bioaccumulates in humans. Given this data, EPA considers lead and lead compounds to be highly bioaccumulative. Thus, 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 of 1 pound for lead and lead compounds. This approach is consistent with the general approach that EPA has taken for setting reporting thresholds for PBT chemicals that are highly persistent and highly bioaccumulative as discussed in the recent proposed rule on PBT chemicals (64 FR 688).

As EPA stated in the January 5, 1999 proposed rule, 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 (64 FR 688). This is particularly the case for lead which, as a metal, cannot be destroyed in the environment. Releases of lead and lead compounds from facilities subject to section 313 reporting requirements, therefore, can increase the potential exposure to lead within communities relative to a chemical that can be destroyed.

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 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 exposed to chemical A, assuming identical feeding rates and other conditions. Due to concerns for its higher accumulation potential, a lower

threshold would be set for Chemical B than for Chemical A.

b. *Was burden considered in threshold selection and what is the proposed threshold for lead and lead compounds?* As discussed above, in determining the appropriate reporting thresholds to propose for lead and lead compounds, EPA started with the premise that very low reporting thresholds may be appropriate for lead and lead compounds based solely on their persistence and bioaccumulation potential. EPA then considered the burden that would be imposed by four sets of reporting thresholds. The thresholds considered were: (1) The 1 pound threshold discussed above; (2) 10 pounds; (3) 100 pounds; and (4) 1,000 pounds. For each threshold, EPA estimated the number of additional reports that facilities might be required to file and the costs associated with the filing of those additional reports (see Tables 3 and 4 in Unit VII.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 lead and lead compounds 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 10 pounds for lead and lead compounds. This consideration of burden is consistent with the approach EPA used in the January 5, 1999 proposed rule (64 FR 688), in which the preferred thresholds were set an order of magnitude higher than EPA would have proposed based solely on the degree of persistence and bioaccumulation.

EPA requests comment on its consideration of industry burden in establishing lower reporting thresholds for lead and lead compounds, including comments on the extent to which burden should be considered in EPA's decision. EPA requests comment on whether the Agency should lower the reporting threshold to 1 pound for lead and lead compounds rather than the 10 pound reporting threshold proposed in this document. EPA requests comment on whether there are any policy reasons for selecting the 1 pound reporting threshold rather than the 10 pound reporting threshold. Such policy reasons could include the fact that the 10 pound reporting threshold for lead and lead compounds, which 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.

c. *What is the relationship of the EPCRA section 313 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 lead and lead compounds, 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 lead and lead compounds, 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.

B. *What is the de minimis Exemption and What Changes is EPA Proposing to Make to the Use of the de minimis Exemption for Lead and Lead Compounds?*

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 (48 FR 53280, November 25, 1983).

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 were 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, including lead or a lead compound, may exist in a mixture at a concentration below the 1% (or 0.1% for OSHA carcinogens) *de minimis* level, but where the manufacture, process, or otherwise use

of the PBT chemical in that mixture would otherwise contribute significantly to, or exceed, the lower reporting threshold proposed in this document.

For example, a raw material is processed that contains less than the *de minimis* level of lead. The quantity of raw material processed results in significantly more than the threshold quantity of lead being processed. Also, during the processing of lead, its concentration in the process stream remains below the *de minimis* level. However, the concentration of lead in the wastestream that results from that processing activity is above the *de minimis* concentration level for lead and the wastestream containing lead is released to the land. In this example, because the concentration of lead 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 lead at the facility, and (2) quantities of lead 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 lead 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, to aid facilities in estimating releases. Facilities also have access to guidance from trade associations.

EPA believes that there may be significant releases of lead and lead compounds in mixtures when these 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. Therefore, EPA believes that allowing facilities to continue to take the *de minimis* exemption for lead and lead compounds, would deprive

communities of important information. While these chemicals may exist in mixtures below the *de minimis* levels they will concentrate in the environment and in organisms. Further, lead and lead compounds have been shown to cause adverse effects at concentrations far less than the *de minimis* levels. For example, EPA has stated that it appears that some of the health effects of lead, particularly changes in the levels of certain blood enzymes and in aspects of children's neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold (Ref. 30). Thus, because lead and lead compounds 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.3d 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 lead and lead compounds. See e.g., 40 CFR 372.38(c).

Further, EPA believes that lowering the reporting thresholds for lead and lead compounds, while leaving the *de minimis* exemption in place may result in very limited reporting and undermining the very purpose of this action. Without a concomitant change in the *de minimis* exemption, lowering the reporting thresholds would not increase reporting for lead and lead compounds from some industry sectors due to the low concentrations in mixtures or other trade name products that are processed or otherwise used. A facility may exceed the reporting threshold based on some processes that involve lead or lead compounds in a mixture where the lead or lead compound 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 lead and lead compounds under the lower reporting threshold being proposed in today's action, EPA is proposing to eliminate the *de minimis* exemption for lead and lead compounds.

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).

As indicated in the proposed regulatory text, EPA is proposing to list lead and lead compounds in § 372.28.

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 lead and lead compounds. 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 lead and lead compounds would be limited to facilities that import, process, otherwise use or manufacture as impurities lead and lead compounds. Many facilities may engage in activities that result in the manufacturing of lead and lead compounds as byproducts. In the preamble to the 1988 final rule implementing the reporting provisions of EPCRA section 313 (53 FR 4500), 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).

Because many facilities may engage in activities that manufacture lead or lead compounds as byproducts and since the *de minimis* exemption does not apply to such activities, eliminating it would have no effect on the reporting of lead and lead compounds from those facilities.

For lead and lead compounds 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 for lead and lead compounds. EPA also requests comments on whether the Agency should modify the exemptions at 40 CFR 372.38(c) (e.g., 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 lead or lead compounds. 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, such as lead and lead compounds.

C. What is the Alternative Threshold and Form A, and is EPA Proposing Any 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 reporting for PBT chemicals such as proposed for lead and lead compounds in this proposed 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, such as lead and lead compounds and would be virtually useless for communities interested in assessing risk from releases of lead and lead compounds. 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 lead or lead compounds 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 lead and lead compounds 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 lead or lead compounds in waste was managed in a manner other than as release, e.g., the lead and lead compounds in waste were recycled. For

those chemicals, such as lead and lead compounds, 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 lead and lead compounds 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. As indicated above, EPA is proposing to list lead and lead compounds in § 372.28.

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

D. What is Range Reporting and What Changes is EPA Proposing to Make 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% error. This uncertainty severely limits the utility of release information where the majority of a facility's releases are 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 lead and lead compounds. 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 discontinue the use of range reporting in Form Rs for lead and lead compounds.

E. What is the Half-Pound Rule and Whole Numbers and What Change is EPA Proposing to Make 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 VI.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 lead and lead compounds as zero. EPA, therefore, is proposing that all releases or other waste management quantities greater than a tenth of a pound of lead or lead compounds 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. 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 all non-zero releases of lead and lead compounds greater than one tenth of a pound be reported. EPA also requests comment on using fractional quantities for reports under 10 pounds.

F. What Limitation is EPA Proposing for the Reporting of Lead in Certain Alloys?

Lead can be found in various types of alloys and is 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, specifically stainless steel, brass, and bronze alloys, should be reported under section 313. Because this issue is currently being reviewed and no final decisions concerning the reporting of lead or other metals in alloys have been made, EPA does not believe that, at this time, it would be appropriate to increase reporting for those facilities that must submit reports for lead when contained in these alloys. Thus, EPA is not proposing to make any changes, including lowering thresholds, to the current reporting requirements for lead when contained in stainless steel, brass, and bronze alloys. EPA is therefore proposing to exclude lead contained in stainless steel, brass, and bronze alloys from the lower reporting threshold and retain the current reporting thresholds for lead when contained in stainless steel, brass, and bronze alloys. This would result in no changes to the reporting requirements for lead contained in stainless steel, brass, and bronze alloys until EPA makes a final determination on whether there should be any changes to the reporting requirements for lead and other metals contained in stainless steel, brass, and bronze alloys. Lead contained in stainless steel, brass, and bronze alloys would still be reportable, but only under the current reporting thresholds. 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 threshold being proposed in this action. This section would indicate that only lead not contained in a stainless steel, brass, or bronze alloy would be subject to the lower reporting threshold. EPA would also make this distinction clear in the section 313 Form R and Form A reporting instructions and other documents.

Under this proposed limitation for lead in stainless steel, brass, and bronze alloys, reporting facilities that use lead to make stainless steel, brass, and bronze alloys would report for lead under the lower reporting threshold since lead is being used to manufacture an alloy. However, once incorporated into the stainless steel, brass, and bronze alloy, lead would not be subject to the lower reporting threshold. 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. Thus, the limitation on stainless steel, brass, and bronze alloy reporting for lead would apply to lead compounds once they are

incorporated into an alloy. The cutting, grinding, shaving, etc. of a stainless steel, brass, or bronze alloy does not negate the reporting limitations for stainless steel, brass, and bronze alloys containing lead.

VII. What are the results of EPA's 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 Lead and Lead Compounds under EPCRA Section 313* (Ref. 31). 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.

A. What is the Need for the Rule?

This proposed rule is intended to address the market failures arising from private choices about lead and lead compounds 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 lead and lead compounds. 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 lead and lead compounds. 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 lead and lead compounds. 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.

Certain facilities currently report TRI data on lead and lead compounds under the existing 10,000 and 25,000 pound reporting thresholds. In 1996, EPA received TRI data on the release and other waste management of over a billion pounds of lead and lead compounds from approximately 1,600 facilities. The industry groups reporting the largest amounts of release or other

waste management of lead and lead compounds in 1996 were: Electronic and Other Electrical Equipment and Components (SIC 36); Primary Metal Industries (SIC 33); Rubber and Miscellaneous Plastics Products (SIC 30); Stone, Clay, Glass, and Concrete Products (SIC 32); and Fabricated Metal Products (SIC 34) (Ref. 31). EPA believes that there are additional facilities in these and other industry groups that do not currently report lead and lead compounds to TRI because they do not exceed current reporting thresholds for lead and lead compounds, and/or because the lead-containing materials they handle are currently covered by the *de minimis* exemption. EPA is not able to quantify the total multi-media releases or other waste management from these additional facilities without TRI reporting. Since even small releases of lead and lead compounds are of concern, EPA believes that there is a need for reporting from these additional facilities.

If EPA were not to take this proposed action to lower the reporting thresholds, the market failure (and the associated social costs) resulting from the limited information on the release and disposition of lead and lead compounds would continue. EPA believes that today's action will improve the scope of multi-media data on releases and other waste management of lead and lead compounds. 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 lowering reporting thresholds for lead and lead compounds.

B. What Regulatory Options Were Considered?

EPA evaluated four regulatory options for lower reporting thresholds in the development of this proposed rule. The options were created by varying the reporting thresholds for lead and lead compounds 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 2 below summarize the scope of EPA's analysis.

Table 2.—Summary of Options Considered

Regulatory Option	Description of Reporting Threshold for Lead and Lead Compounds
Option 1	1 pound manufactured, processed, or otherwise used
Option 2	10 pounds manufactured, processed, or otherwise used
Option 3	100 pounds manufactured, processed, or otherwise used
Option 4	1,000 pounds manufactured, processed, or otherwise used

Reporting under all four options is affected by other proposed changes in reporting requirements for lead and lead compounds. These proposed changes include the elimination of the *de minimis* exemption for lead and lead compounds, and a requirement for all facilities to report on lead and lead compounds using the Form R. The effect of these other proposed changes on reporting is addressed in the economic analysis of the proposed rule (Ref. 31).

Table 3 following section E.4. of this unit displays, for each option, the estimated number of additional reports for lead and lead compounds expected from various industry groups under EPCRA section 313. This table is not exhaustive. While EPA believes that it has addressed the industry groups most likely to submit additional reports in economic analysis of the proposed rule (Ref. 31), other industry groups may also file additional reports on lead and lead compounds. EPA requests that commenters provide any available information on other categories of facilities that may be affected by this proposal, as well as any data on the number of facilities in the category that would be affected, and the quantity of lead and lead compounds manufactured, processed, or otherwise used by facilities in the category.

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. What are the Potential Costs of this Proposal?

The proposed rule would 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 would result from requirements on industry. Table 4 following section E.4. of this unit displays the industry costs for each option based on the estimated number of facilities affected by this proposal. Under the option presented in the regulatory text (Option 2), approximately 15,000 facilities would submit additional Form R reports annually. As shown, aggregate industry costs in the first year for the proposed alternative are estimated to be \$116 million; in subsequent years they are estimated to be \$60 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.

Some of the facilities potentially affected by this proposed rule may also be affected by the proposed PBT rule (64 FR 688). If these rules are finalized as proposed, certain facilities may file additional reports on lead or lead compounds, as well as on one or more of the PBT chemicals from the earlier proposal. The ultimate outcome of these separate proposals is, however, uncertain at present. Therefore, certain facility-specific reporting costs have been included in the economic analysis for this proposal and in the economic analysis of the PBT proposal even though these costs would be incurred only once per facility. Upon finalization, the aggregate cost of the two proposals may be less than the sum of the industry costs shown in the economic analyses of these proposals due to this potential double-counting of reporting costs. Under the preferred options presented in the regulatory text of this and the previous proposal, the potential double-counting of industry costs amounts to approximately \$4 million in the first year of reporting. EPA plans to estimate the cost of the final rules for these proposals using the regulatory framework that exists at the time of finalization as a baseline. Further information on the extent of potential double-counting of costs in the analyses of the two proposals is presented in the economic analysis of this proposal (Ref. 31).

EPA is expected to expend \$1.6 million in the first year, and \$1.2 million in subsequent years for programmatic, compliance assistance, and enforcement activities as a result of the proposed rule.

D. What are the Potential Benefits of this Proposal?

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 participate in a fully 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 decision-making. 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 lead and lead compounds 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 of the economics of information is not highly developed, EPA has not attempted to quantify the benefits of changing reporting thresholds for lead and lead compounds. 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 of follow-on activities). 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, provides illustrative examples of how the proposed rule will improve the availability of information on the release and other waste management of lead and lead compounds (Ref. 31).

E. What are the Potential Impacts on Small Entities of this Proposal?

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. 31). The following is a brief overview of EPA's findings.

1. *What was the overall methodology for assessing potential small entity impacts?* 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% of all manufacturing firms are classified as small businesses (Ref. 32). 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.

Potential small entity impacts were calculated for both the first year of reporting and subsequent years under Option 2 (the option presented in the proposed regulatory text). 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. 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 are the best measure of 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. *What are the potential impacts on small businesses?* EPA used annual compliance costs as a percentage of

annual company sales to assess the potential impacts on small businesses of this proposed 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%, or not greater than 3%), EPA believes that the financial impacts of the regulation may be considered not significant.

Based on its estimates for Option 2 of the proposed rule, the Agency estimates that approximately 8,100 businesses will be affected by the proposed rule, and that approximately 5,600 of these

businesses are classified as small based on the applicable SBA size standards. EPA estimates that no small businesses will bear costs greater than 1% of revenues in the first or subsequent reporting years.

3. *What are the potential impacts on 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 36 publicly owned electric utility facilities, operated by a total of 34 municipalities, may be affected under Option 2 of the proposed

rule. Of these, an estimated 18 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 in the first or subsequent reporting years.

4. *What are the potential impacts for all small entities?* As discussed above, no small businesses are expected to bear annual costs over 1% of annual revenues. None of the affected small governments are estimated to bear annual costs greater than 1% of annual revenues. No small organizations are expected to be affected by the 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 3.—Summary of Reporting Under Regulatory Options

SIC Code - Industry Group	Estimated Number of Additional Reports (Annual)			
	Option 1	Option 2	Option 3	Option 4
12 - Coal mining	321	321	321	321
29 - Petroleum refining and related industries	1,033	117	91	90
3241 - Cement, hydraulic	123	123	123	123
33 - Primary metal industries	1,130	1,130	1,109	842
367 - Electronic components and accessories	4,033	4,033	3,109	405
371 - Motor vehicles and motor vehicle equipment	2,862	2,862	1,485	201
4911/4931/4939 - Electric services	414	378	319	248
4953 - Refuse systems (RCRA subtitle C only)	80	74	64	36
5171 - Petroleum bulk stations and terminals	2,459	980	621	55
7389 - Solvent recovery services	26	24	22	14
20-39 - Other manufacturing; industrial combustion	10,142	5,001	1,498	570
Total	22,623	15,043	8,762	2,905

Table 4.—Summary of Reporting and Industry Cost of Regulatory Options

Regulatory Options for Lead and Lead Compounds	Annual Number of Reports	Estimated Industry Costs (\$ million per year)	
		First Year	Subsequent Years
Option 1—Reporting threshold of 1 lb	22,623	\$174	\$91
Option 2—Reporting threshold of 10 lb	15,043	\$116	\$60
Option 3—Reporting threshold of 100 lb	8,762	\$67	\$35
Option 4—Reporting threshold of 1,000 lb	2,905	\$22	\$12

VIII. What are the References Cited in this Proposed Rule?

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. Syracuse Research Corporation. The Environmental Fate of Lead and Lead Compounds. Prepared for David G. Lynch, U.S. Environmental Protection Agency, under contract number SRC 68-D5-0012, March 1999.
3. Zimdahl, R.L., Skogerboe, R.K. 1977. Behavior of Lead in Soil. *Environ. Sci Technol.* 11:1202-1207.
4. USEPA/ORD. Air Quality Criteria for Lead. Research Triangle Park, NC. EPA, Office of Research and Development, Office of Health and Environmental Assessment. 1986. EPA600/8-83-028bF
5. Bondarenko, G.P. 1968. An experimental study of the solubility of galena in the presence of fulvic acids. *Geochem. Int.* 5: 525-531.
6. Lovering, T.G. ed. 1976. Lead in the Environment. Washington, DC: US Department of the Interior, Geological Survey; Geological Survey professional paper no. 957. S/N 024-001-02911-1
7. Rand, G.M., Fundamentals of Aquatic Toxicology, 2nd. Ed. Taylor Francis, Washington, DC, (1995), 1125 pp.
8. Meylan, W.M., Howard, P.H., and Boethling, R.S. 1999. "Improved Method for Estimating Bioconcentration Factor from Octanol/Water Partition Coefficient." *Environ. Toxicol. Chem.* 18:664-672.
9. Merlini, M. and A. Pozzi. 1977. Lead and freshwater fishes. Part 1. Lead accumulation and water pH. *Environ. Pollut.* 12:167-172.
10. USEPA/OPPT. Bioaccumulation/Bioconcentration Assessment For Lead and Lead Compounds. Jerry Smrcek, Ph.D., Biologist, Existing Chemicals Assessment Branch, Risk Assessment Division, March 31, 1999.
11. Borgmann, U., Kramer, O. and C. Loveridge. 1978. Rates of mortality, growth, and biomass production of *Lymnaea palustris* during chronic exposure to lead. *J. Fish. Res. Board Canada.* 35:1109-1115.
12. Denny, P. and R.P. Welsh. 1979. Lead accumulation in plankton blooms from Ullswater, the English Lake District. *Environ. Pollut.* 18:1-9.
13. Vighi, M. 1981. Lead uptake and release in a experimental trophic chain. *Ecotoxicol. Environ. Safety.* 5:177-193.
14. Eisler, R. 1988. Lead hazards to fish, wildlife, and invertebrates: a synoptic review. Biological Report 85(1.14), Contaminant Hazard Reviews Report No. 14, U.S. Fish and Wildlife Service, U.S. Department of the Interior, Laurel, MD, 134 pp.
15. USEPA. Jenkins, D.W. 1980. Biological monitoring of trace metals. Vol. 2. Toxic trace metals in plants and animals of the world. Part II. EPA 600/3-80-091, U.S. Environmental Protection Agency, Washington, DC, pp. 619-778.
16. Wong, P.T.S., Chau, Y.K., Kramer, O. and G.A. Bengert. 1981. Accumulation and depuration of tetramethyllead by rainbow trout. *Water Res.* 15:621-625.
17. Schulz-Baldes, M. 1972. Toxicity and accumulation of lead in the common mussel *Mytilus edulis* in laboratory experiment. *Mar. Biol.* 16:226-229.
18. Schulz-Baldes, M. 1974. Lead uptake from sea water and food, and lead loss in the common mussel, *Mytilus edulis*. *Mar. Biol.* 25:177-193.
19. Zaroogian, G.E., Morrison, G. and J.F. Heltsh. 1979. *Crassostrea virginica* as an indicator of lead pollution. *Mar. Biol.* 52:189-196.
20. Seeliger, U. and P. Edwards. 1977. Correlation coefficients and concentration factors of copper and lead in seawater and benthic algae. *Mar. Pollut. Bull.* 8:16-19.
21. Gould, E. and R.A. Greig. 1983. Short-term low-salinity response in lead-exposed lobsters, *Homarus americanus* (Milne Edwards). *J. Exp. Mar. Biol. Ecol.* 69:283-295.
22. USEPA. Ambient Water Quality Criteria for Lead. 1984. EPA 440/5-84-027, Office of Water, U.S. Environmental Protection Agency, Washington, DC, 1985, 81 pp.
23. ATSDR. Draft Toxicological Profile for Lead. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. August 1997.
24. USEPA/OPPT. Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil - Volume 1. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington DC, EPA 747-R-97-006, June 1998.
25. USEPA/ECAO. Air Quality Criteria for Lead - Volume 1 of IV. U.S. Environmental Protection Agency, Environmental Criteria and Assessment Office, Research Triangle Park, NC, EPA-600/8-83/028aF, June 1986.
26. USEPA/OIA. Technical Information Package for Lead. Internet site: <http://www.epa.gov/oiamount/tips/lead2.htm>. Maintained by the U.S. Environmental Protection Agency, Office of International Affairs. Downloaded March 1999.
27. Davis A., Ruby M., and Bergstrom P. Factors controlling lead bioavailability in the Butte mining district, Montana, USA *Environmental Geochemistry and Health* 1994; 16(3/4):147-157
28. Davis A., Drexler J., Ruby M., and Nicholson A. Micromineralogy of Mine Wastes in Relation to Lead Bioavailability, Butte, *Montana Environ Sci Technology* 1993 Mar 16; 27(7):1415-1425
29. Rabinowitz, M.B., et. al., Kinetic Analysis of Lead Metabolism in Healthy Humans. *Journal of Clinical Investigation.* 1976. 58:260-270.
30. IRIS 1999. U.S. Environmental Protection Agency's Integrated Risk Information System Profile pertaining to lead and lead compounds.
31. USEPA, OPPT. Economic Analysis of the Proposed Rule to Modify the Reporting Requirements for Lead and Lead Compounds under EPCRA Section 313, (1999).
32. 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.
33. USEPA, OPPT. Unfunded Mandates Reform Act (UMRA) Statement for the Proposed Rule to Modify the Reporting Requirements for Lead and Lead Compounds under EPCRA Section 313, April 1999.

IX. Regulatory Assessment Requirements

A. What is the Determination Under Executive Order 12866?

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

In addition, EPA has prepared an economic analysis of the impact of this action, which is contained in a document entitled *Economic Analysis of the Proposed Rule to Modify Reporting of Lead and Lead Compounds under EPCRA Section 313* (Ref. 31). This

document is available as part of the public record for this action, and is briefly summarized in Unit VII. of this preamble.

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

For the reasons explained in Unit VII. 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: none of the approximately 5,600 small businesses potentially affected by the proposed rule will experience annual compliance costs above 1% of annual sales. In addition, EPA estimates that there are 18 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. 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. 31), and are also discussed in Unit VII. 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 proposed 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. The Agency is always interested in any comments regarding the economic impacts that this regulatory action would impose on small entities, particularly suggestions for minimizing that impact. Such comments may be submitted to the Agency at any time, to the address listed in Unit I.C. of this preamble. To ensure consideration during the development of the final rule, comments must be received by the date 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. What is the Determination Under the 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 amended Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No. 1363) and a copy may be obtained from Sandy Farmer, OP 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." The information requirements contained in this proposal are not 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 lead and lead compounds 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 additional reports from approximately 15,000 respondents. Of these, approximately 5,100 facilities are estimated to be reporting to TRI for the first time as a result of the rule, while approximately 9,900 are currently reporting facilities that will be submitting additional reports. These 15,000 facilities will submit an estimated additional 15,000 Form Rs. This proposed rule therefore results in an estimated total burden of 1.7 million hours in the first year, and 0.9 million hours in subsequent years, at a total estimated industry cost of \$116 million in the first year and \$60 million in subsequent years.

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

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

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 as required by section 202 of UMRA, and that statement is available in the public docket for this rulemaking (Ref. 33). The costs associated with this action are estimated in the economic analysis prepared for this proposed rule (Ref. 31), which is included in the public docket and summarized in Unit VII. 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(f)(2) of EPCRA, 42 U.S.C. section 11023(f)(2), and section 6607 of the Pollution Prevention Act, 42 U.S.C. section 13106. The economic analysis estimates that the total industry costs of the proposed rule will be \$116 million in the first year and \$60 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 VII. of this preamble. EPA believes that the benefits provided by the information to be reported under this proposed rule will 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 \$60 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 the proposed rule will not significantly or uniquely affect small governments and does not contain a significant Federal intergovernmental mandate, so no action is needed under section 203 or 204 of UMRA.

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 VI. of this preamble, EPA considered burden in the threshold selection. The proposed rule also contains reporting requirements that will limit burden (e.g., reporting limitations for lead and lead compounds in certain alloys). 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).

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

E. What are the Determinations Under Executive Orders 12898 and 13045

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has considered 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. Since this is an economically significant action (i.e., it is expected to have an annual adverse impact of \$100 million or more), additional OMB review is required under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). The Agency has, to the extent permitted by law and consistent with the agency's mission, identified and assessed the environmental health risks and safety risks that may disproportionately affect children.

By lowering the section 313 reporting thresholds for lead and lead compounds, 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, Chemicals, Community right-to-know, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements, Superfund.

Dated: July 23, 1999.

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.	Report- ing threshold
Lead (this lower threshold does not apply to lead when contained in a stain- less steel, brass or bronze alloy)	7439-92- 1	10

(2) Chemical categories in alphabetic order:

Category name	Reporting threshold
Lead Compounds	10

(b) The threshold determination provisions at § 372.25(c) through (h) and the exemptions at § 372.38(b) through (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).

* * * * *

§ 372.85 [Amended]

8. Amend § 372.85 as follows:

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”.

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