

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[OPPTS-400140D; FRL-6722-4]

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: Final rule.

SUMMARY: EPA is lowering 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).

The reporting thresholds are being lowered to 100 pounds. The lower reporting thresholds apply to lead and all lead compounds except for lead contained in stainless steel, brass, and bronze alloys. EPA is taking these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds. Today's actions also include modifications to certain reporting exemptions and requirements for lead and lead compounds.

DATES: This rule shall take effect on February 16, 2001; with the first reports at the lower thresholds due on or before July 1, 2002, for the 2001 calendar year.

FOR FURTHER INFORMATION CONTACT: For technical information on this final rule contact: Daniel R. Bushman, Petitions Coordinator, Environmental Protection Agency, Mail Code 2844, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number 202-260-

3882, e-mail address: bushman.daniel@epa.gov. For general information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Hotline, Environmental Protection Agency, Mail Code 5101, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Toll free: 1-800-535-0202, in Virginia and Alaska: 703-412-9877 or Toll free TDD: 1-800-553-7672. Information concerning this action is also available on EPA's Web site at <http://www.epa.gov/tri>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

You may be potentially affected by this action 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 | SIC major group codes 10 (except 1011, 1081, and 1094), 12 (except 1241); or 20 through 39; or industry codes 4911 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4931 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. section 6921 <i>et seq.</i>); or 5169; or 5171; or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis) |
| Federal Government | Federal facilities |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372 subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding of **FOR FURTHER INFORMATION CONTACT** section.

B. How can I get additional information or copies of this document or other support documents?

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

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-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 noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260-7099.

II. What is EPA's Statutory Authority for Taking These Actions?

EPA is finalizing these actions under sections 313(f)(2), 313(g), 313(h), and 328 of EPCRA, 42 U.S.C. 11023(f)(2), 11023(g), 11023(h), and 11048; and section 6607 of PPA, 42 U.S.C. 13106. Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using a listed toxic chemical in amounts above reporting threshold levels, to report certain facility specific information about such chemicals, including the annual releases and other quantities entering each environmental medium. These reports must be filed by July 1 of each year for the previous calendar year. Such facilities also must report recycling and other waste management data and source reduction activities for such chemicals, pursuant to section 6607 of PPA.

A. What is EPA's Statutory Authority To Lower EPCRA Reporting Thresholds?

EPA is finalizing these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds. EPCRA section 313

establishes default reporting thresholds, which are set forth in section 313(f)(1). Section 313(f)(2), however, provides that EPA:

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

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

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

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

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

B. What is EPA's Statutory Authority for Making Modifications to Other EPCRA section 313 Reporting Requirements?

Today's actions also include modifications to certain reporting

exemptions and requirements for lead and lead compounds. Congress granted EPA rulemaking authority to allow the Agency to fully implement the statute. EPCRA section 328 provides that the "Administrator may prescribe such regulations as may be necessary to carry out this chapter" (28 U.S.C. 11048).

III. Background Information

A. What is the General Background for this Action?

Under EPCRA section 313, Congress set the initial parameters of the Toxics Release Inventory (TRI), but also gave EPA clear authority to modify reporting in various ways, including authority to change the toxic chemicals subject to reporting, the facilities required to report, and the threshold quantities that trigger reporting. By providing this authority, Congress recognized that the TRI program would need to evolve to meet the needs of a better informed public and to refine existing information. EPA has, therefore, undertaken a number of actions to expand and enhance TRI. These actions include expanding the number of reportable toxic chemicals by adding 286 toxic chemicals and chemical categories to the EPCRA section 313 list in 1994. Further, a new category of facilities was added to EPCRA section 313 on August 3, 1993, through Executive Order 12856, which requires Federal facilities meeting threshold requirements to file annual EPCRA section 313 reports. In addition, in 1997 EPA expanded the number of private sector facilities that are required to report under EPCRA section 313 by adding seven new industrial groups to the list of covered facilities. At the same time, EPA has sought to reduce the burden of EPCRA section 313 reporting by actions such as delisting chemicals it has determined do not meet the statutory listing criteria and establishing an alternate reporting threshold of 1 million pounds for facilities with 500 pounds or less of production-related releases and other wastes. Facilities meeting the requirements of this alternate threshold may file a certification statement (Form A) instead of reporting on the standard EPCRA section 313 form, the Form R.

On October 29, 1999 (64 FR 58666), EPA finalized enhanced reporting requirements that focused on a unique group of toxic chemicals that persist and bioaccumulate in the environment. These chemicals are commonly referred to as persistent bioaccumulative toxic chemicals or PBT chemicals. Until that action, with the exception of the alternate threshold certification on Form

A, EPA had not altered the statutory reporting threshold for any listed chemicals. However, as the TRI program has evolved over time and as communities identify areas of special concern, thresholds and other aspects of the EPCRA section 313 reporting requirements may need to be modified to assure the collection and dissemination of relevant, topical information and data. Toxic chemicals that persist and bioaccumulate are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. The October 29, 1999, PBT chemical final rule set forth criteria to be used by the EPCRA section 313 program for evaluating whether a listed toxic chemical persists or bioaccumulates in the environment. EPA has evaluated lead and lead compounds using these criteria, and has concluded that lead and lead compounds are PBT chemicals. Thus, as with the PBT chemical final rule, today's action further increases the utility of TRI to the public by lowering the reporting thresholds for lead and lead compounds. Lowering the reporting thresholds for lead and lead compounds will ensure that the public has important information on the quantities of these chemicals released or otherwise managed as waste, that would not be reported under the 10,000 and 25,000 pound/year thresholds that apply to most other listed toxic chemicals.

B. What Outreach Has EPA Conducted?

EPA has engaged in a comprehensive outreach effort relating to this action. This outreach served to inform interested parties, including industries and small businesses affected by the rule, state regulatory officials, environmental organizations, labor unions, community groups, and the general public of EPA's intention to lower the applicable EPCRA section 313 reporting thresholds for lead and lead compounds. EPA held three public meetings (in Los Angeles, CA (November 30, 1999); Chicago, IL (December 2, 1999); and Washington, DC (December 14, 1999)) during the comment period for the proposal. Participants included a range of industry representatives, trade associations (representing both small and large businesses), law firms representing industry groups, environmental groups, the general public, plus other groups and organizations. For state and tribal governments, EPA attended the regularly-held public meetings of the Forum on State and Tribal Toxics

Action (FOSTTA) to discuss the proposed rule. EPA also received substantial public comment on the proposed rule, to which EPA is responding in this Final Rule and the Response to Comments document (Ref. 1). In response to the strong interest in the proposed rule, and to allow more individuals and groups to submit their comments, EPA extended the public comment period. The comment period was first extended from September 17 to November 1, 1999 (at 64 FR 51091, September 21, 1999) (FRL-6382-9) and then again from November 1 to December 16, 1999 (at 64 FR 58370, October 29, 1999) (FRL-6391-8) to allow commenters time to supplement or revise their comments in light of the decisions made in the final PBT chemical rulemaking (64 FR 58666). Additional information regarding EPA's outreach may be found in supporting documents included in the public version of the official record.

IV. Summary of Proposal

A. What Persistence and Environmental Fate Data were Presented 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 it is released into the environment. The environmental fate determines the extent to which 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 in the proposed rule for the environmental fate of lead in each environmental medium represented the key elements influencing the transport, transformation, and bioavailability of lead in air, soil, water and sediments. This information, as well as a more extensive review of the existing data on the environmental fate of lead are contained in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) and in the references contained therein. Based on this information, EPA concluded that processes commonly observed in the environment can result in the release of available (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 showed that under many environmental conditions lead is available to express its toxicity and to bioaccumulate. In the EPCRA section 313 program, the issue of the environmental availability of metals from metal compounds is broader than just its implications for whether a chemical is a PBT. The issue of both the environmental availability and 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 from the EPCRA section 313 list of toxic chemicals. EPA developed this petition policy specifically to address such circumstances.

B. What Aquatic Bioaccumulation Data was Presented 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 term bioaccumulation refers to uptake of chemicals by organisms both directly from water and through their diet (Ref. 3). 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. 4). 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 certain lead compounds (lead salts) in aquatic plants and animals are often

above a bioconcentration/bioaccumulation factor of 1,000 and in some species at or greater than 5,000. Lead is bioaccumulated by aquatic organisms such as plants, bacteria, invertebrates, and fish. The principle 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. 5), 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.

The bioaccumulation 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, can be found in the bioaccumulation support document (Ref. 6). Concentrations of lead monitored in various organisms were determined by comparing concentrations in the environment (water) with concentrations measured in the organisms. In general, bioconcentration values for four freshwater invertebrate species ranged from 499 to 1,700 (Ref. 7). 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 had 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 at or above 5,000. The references cited for blue mussels include a range of values, the upper end of which is essentially 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.

C. What Human Bioaccumulation Data was Presented for 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 (Refs. 8, 9, 10,

and 11). The bioaccumulation 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. 12 and 13). 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 the most recent publicly available National Health and Nutrition Examination Surveys (see Ref. 9), 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 (mg/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 still cause for concern because it indicates that nearly 900,000 children aged 1-5 have 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. 14). 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 may appear modest, the total accumulation rate is actually 80-fold. The increase is 80-fold because children undergo a 40-fold increase in skeletal mass. 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. Such absorbed and accumulated lead can cause significant deleterious health effects, particularly in children.

D. What Proposed Conclusions did EPA Reach from Its Proposal Review of the Available Data on Lead and Lead Compounds?

EPA's review of the available information on lead and lead compounds led EPA to conclude that lead and lead compounds are highly persistent and at the least, 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 available, the data indicate that under many environmental conditions lead does become available. The conclusion that lead is available 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, has been found to bioaccumulate in organisms observed in the environment, and has been found to bioaccumulate in humans. EPA noted in its proposal that 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 at or above 5,000. The references cited for blue mussels include a range of values, the upper end of which is essentially 5,000 (i.e., 4,985). In addition, EPA explained that "[t]he bioaccumulation and persistence of lead in humans is well documented" and requested comment on how such

data should be regarded in classifying lead and lead compounds as highly bioaccumulative.

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 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, provided the basis for EPA preliminarily concluding that lead and lead compounds are highly persistent and highly bioaccumulative.

E. What Changes to the Reporting Thresholds did EPA Propose for Lead and Lead Compounds?

In evaluating potential lower reporting thresholds for lead and lead compounds, EPA considered not only their persistence and bioaccumulation properties and the purposes of EPCRA section 313, but also the potential burden that might be imposed on the regulated community. Because PBT chemicals, including lead and lead compounds, persist and bioaccumulate in the environment, they have the potential to pose greater exposure to humans and the environment over a longer period of time. The nature of PBT chemicals, including 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 10,000 and 25,000 pounds. For determining how low reporting thresholds should be set for PBT chemicals, including lead and lead compounds, EPA adopted a two-tiered approach. Thus, EPA made a distinction between persistent bioaccumulative toxic chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative by setting lower reporting thresholds based on two levels of concern. As explained in the final PBT rule and in the proposed lead rule, this approach identifies as PBT chemicals those that are persistent (i.e., with half-lives of at least 2 months) and those that are bioaccumulative (i.e., based on aquatic studies showing BAF/BCF values of at least 1,000 and/or human data showing evidence of bioaccumulation). Further, as also explained in the PBT rule and the proposed lead rule, highly PBT

chemicals are identified as those that are highly persistent (i.e., with half-lives of 6 months or greater) and those that are highly bioaccumulative (e.g., BAF/BCF values of 5,000 or greater). EPA preliminarily concluded that lead and lead compounds to be highly persistent and highly bioaccumulative toxic chemicals.

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

F. What Other Reporting Issues Did EPA Consider for Lead and Lead Compounds?

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

high for PBT chemicals, EPA's original rationale for the *de minimis* exemption does not apply to PBT chemicals. EPA therefore proposed to eliminate the *de minimis* exemption for lead and lead compounds based on their status as PBT chemicals. EPA did not propose, however, to modify the applicability of the *de minimis* exemption to the supplier notification requirements (40 CFR 372.45(d)(1)) because the Agency believed there was sufficient information available.

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

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

4. *Proposed changes to the use of the half-pound rule and whole numbers.* EPA currently allows facilities to report whole numbers and to round releases of 0.5 pound or less to zero when reporting on EPCRA section 313 listed chemicals not designated as PBT chemicals in the October 29, 1999 final rule. EPA explained its concern that the combination of requiring the reporting of whole numbers and allowing rounding to zero would result in a significant number of facilities reporting their releases of lead and lead compounds as zero. EPA, therefore, proposed that all releases or other waste management quantities greater than $\frac{1}{10}$

of a pound of lead and lead compounds be reported, provided that the appropriate activity threshold has been exceeded.

5. *Proposed exemption for the reporting of lead in certain alloys.* In the proposal, EPA proposed to defer making a final decision on lower reporting thresholds for lead contained in stainless steel, brass, and bronze alloys until the Agency could complete an ongoing scientific review of issues pertinent to the reporting of these types of 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 these three types of alloys. EPA, therefore, proposed to include a qualifier to the listing for lead in 40 CFR 372.28. This qualifier would read "this lower threshold does not apply to lead when contained in a stainless steel, brass, or bronze alloy."

V. Summary of the Final Rule

A. What Threshold Has EPA Established for Lead and Lead Compounds?

EPA is finalizing manufacture, process, and otherwise use thresholds of 100 pounds for lead and lead compounds, with the first reports at this lower threshold due on or before July 1, 2002, for the 2001 calendar year. This lower reporting threshold does not apply to lead contained in stainless steel, brass, and bronze alloys nor do any of the other changes discussed below in Unit V.B. However, lead contained in stainless steel, brass, and bronze alloys remains reportable under the 25,000 pound manufacture and process reporting threshold and the 10,000 pound otherwise use reporting threshold.

B. What Exemptions and Other Reporting Issues is EPA Addressing for Lead and Lead Compounds?

EPA is eliminating the *de minimis* exemption for lead and lead compounds. However, this action will not affect the applicability of the *de minimis* exemption to the supplier notification requirements (40 CFR 372.45(d)(1)). In today's action, EPA is also excluding lead and lead compounds from eligibility for the alternate threshold of 1 million pounds and eliminating range reporting for on-site releases and transfers off-site for further waste management for lead and lead compounds. This will not affect the applicability of the range reporting of the maximum amount on-site as

required by EPCRA section 313(g). EPA proposed to require reporting of all releases and other waste management quantities greater than $\frac{1}{10}$ of a pound of lead and lead compounds. Also, EPA proposed that releases and other waste management quantities would continue to be reported to two significant digits. In addition, EPA proposed that for quantities of 10 pounds or greater, only whole numbers would be required to be reported. After reviewing all the comments on this issue, EPA is providing additional guidance on the level of precision at which facilities should report their releases and other waste management quantities of lead and lead compounds. Facilities should still report releases and other waste management quantities greater than 0.1 pound provided the accuracy and the underlying data on which the estimate is based supports this level of precision. Rather than reporting in whole numbers and to two significant digits, if a facility's release or other waste management estimates support reporting an amount that is more precise than whole numbers and two significant digits, then the facility should report that more precise amount. The Agency believes that, particularly for PBT chemicals such as lead and lead compounds, facilities may be able to calculate their estimates of releases and other waste management quantities to $\frac{1}{10}$ of a pound and believes that such guidance is consistent with the reporting requirements of sections 313(g) and (h).

VI. Summary of Public Comments and EPA Responses

A. How is EPA Responding to Comments Relating to Generic Issues?

EPA received numerous comments relating to the generic issues raised and resolved in the first rulemaking on PBT chemicals, published on October 29, 1999 (64 FR 58666); for example, whether the Agency should select lower thresholds based on a risk assessment. Some commenters merely reiterate comments raised in the previous rulemaking. Other commenters rephrase, in terms of lead and lead compounds, comments that have been previously submitted on these generic issues, without presenting additional information or concerns specific to lead and lead compounds.

In its proposal to lower the thresholds for lead and lead compounds, EPA explicitly limited its request for comments to issues specific to lead and lead compounds, such as whether lead and lead compounds meet the EPCRA section 313 persistence and

bioaccumulation criteria articulated in the PBT rule and proposed lead rule, and whether lead and lead compounds present such unique technical or policy issues that they merit different treatment than that established for either the class of PBT chemicals or the subset of highly persistent and highly bioaccumulative toxic chemicals (see 64 FR 42224 and 58666). Notwithstanding that EPA extended the comment period on this rulemaking to allow for an additional 48 days following publication of the final PBT chemical rule, commenters failed to present issues or information that persuades the Agency to revisit the decisions made with respect to generic issues in the PBT chemical rule, or that provides any basis for treating lead and lead compounds separately from how the Agency generally approaches PBT chemicals within the EPCRA section 313 program.

To the extent that commenters provide comments on the generic issues that were specific to lead and lead compounds, these comments are addressed in this preamble and in the Response to Comments (RTC) document for this final rule (Ref. 1). For responses to those comments on the generic issues that were not specific to lead and lead compounds the reader is referred to the PBT chemical final rule (64 FR 58666) and the associated Response to Comments document (Ref. 15). The remainder of this Unit contains responses to major comments on the issues of the EPCRA section 313 reporting thresholds for lead and lead compounds, the technical information regarding the persistence and bioaccumulation potential of lead and lead compounds, and the alloys reporting limitation for lead. Responses to major comments on EPA's economics analysis (Ref. 16) and regulatory assessment determinations are contained in Units VII and IX respectively. Additional responses to comments not addressed in this preamble are contained in the RTC document for this final rule (Ref. 1).

B. What Comments did EPA Receive on its Statutory Authority to Lower Reporting Thresholds for Lead and Lead Compounds?

Several commenters allege that under EPA's interpretation of EPCRA section 313(f)(2), Congress did not provide an "intelligible principle" for determining whether or how much to lower a statutory threshold, thereby rendering this provision unconstitutional as an improperly broad delegation of legislative power. The commenters raise several points in support of this contention; several commenters cite

EPA's statement in the proposal that "Congress provided no prerequisites to the exercise of EPA's authority to lower [EPCRA section 313] thresholds" to demonstrate that EPA does not have the authority to lower the thresholds without violating the non-delegation doctrine. Other commenters support this allegation merely by reference to the fact that EPCRA section 313(f)(2) does not prohibit the Agency from establishing a threshold of "0." Another commenter contends that the unconstitutional delegation of authority is even more striking than it was in section 109(b)(1) of the Clean Air Act, which at least provided the Agency with the direction to set standards "requisite to protect the public health" and "with an adequate margin of safety." EPCRA, the commenter states, sets forth no standard for establishing reduced reporting thresholds. To support their assertions, several of these commenters specifically cite the decision in *American Trucking Association v. EPA*, 175 F.3d 1027 (D.C. Circuit, 1999) *cert. granted sub nom. Browner v. American Trucking Association*, 120 S.Ct 2003 (US May 22, 2000)(No. 99-1247).

EPA disagrees. As a preliminary matter, EPA disagrees with the interpretation of the non-delegation doctrine articulated in *American Trucking*, and has appealed that decision to the Supreme Court. Nonetheless, EPA believes that Congress has provided an "intelligible principle" sufficient for the delegation of authority contained in EPCRA section 313(f)(2).

The commenters appear to have fundamentally misunderstood EPA's explanation of its rationale for selecting the specific thresholds adopted in the final PBT chemical rule, and the implications these actions had for the selection of the thresholds for lead and lead compounds. As part of the discussion in the final PBT chemical rule, EPA noted that for several reasons, it was establishing "two sets of revised thresholds based on two classes of PBT chemicals," and stated its intention that "the revised thresholds establish a set of categories that would be generally applicable to future designated PBT chemicals." (64 FR 58689). Thus, the selection of the specific threshold for lead and lead compounds is governed by the analyses laid out in EPA's preamble to the final PBT chemical rule and in the proposed lead rule. See also EPA's rationale for the specific threshold chosen for lead and lead compounds, *infra* at Unit VI.E. Under this construct, taking into account the aquatic and human data available.

In the preamble to the final PBT chemical rule, and the associated

Response to Comments Document (Ref. 15), EPA described at length the process by which it distilled Congressional guidance from various sources, such as the language and legislative history of EPCRA sections 313(f)(2) and (h), to guide its exercise of discretion in lowering the thresholds. See (e.g., (64 FR 58687-692). Specifically, EPA explained:

EPA relied on the language of EPCRA sections 313(f)(2) and (h), and the legislative history, to elicit the following principles to guide its exercise of discretion in lowering the thresholds, and in selecting the specific thresholds: (1) The purposes of EPCRA section 313; (2) the "verifiable, historical data" that convinces EPA of the need to lower the thresholds; (3) the chemical properties shared by the members of the class of toxic chemicals for which EPA is lowering the thresholds (i.e., the degree of persistence and bioaccumulation); and (4) the reporting burden imposed by revised thresholds to the extent that such consideration would not deny the public significant information from a range of covered industry sectors. Further, EPA believes that in the language of EPCRA § 313, and its legislative history, Congress provided direction on the appropriate weight to allocate to each of these considerations in implementing EPCRA section 313(f)(2). These considerations underlay the entire process by which EPA determined the appropriate thresholds. But the Agency's choice of revised thresholds was governed, and ultimately constrained, by EPCRA section 313's overriding purpose, which is to provide government agencies, researchers, and local communities, with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems. *Id.* at 58687.

EPA also disagrees with the analyses on which the commenters rely to support their assertions that Congress provided no intelligible principle to guide EPA's delegated authority under EPCRA section 313(f)(2). Whether the legislative guidance offered sufficiently constrains the discretion delegated to the Agency under EPCRA section 313(f)(2) must be evaluated against the actual "power to roam" that this provision confers on EPA. *Michigan v. EPA*, 213 F.3d 663, 680-81 (D.C. Cir. 2000). As discussed in Unit II.A., as EPA interprets the requirements in section 313(f)(2), the standard operates as an effective constraint when the Agency increases the thresholds, but as a practical matter, cannot provide the same level of constraint when the Agency decreases the thresholds.

However, as previously explained, EPA relied on this standard to elicit factors to guide its exercise of discretion. See, 64 FR 58687-692.

But the mere fact that Congress provided neither explicit prerequisites in section 313(f)(2) to the Agency's determination that a lower threshold is warranted, nor a standard whose plain language effectively constrains EPA's discretion in selecting the appropriate lower threshold, does not necessarily render this provision unconstitutional. The issue is whether Congress granted the Agency too much discretion to *modify* the statutory thresholds—not merely whether Congress provided a standard to significantly constrain the Agency's discretion in lowering the thresholds. See *Michigan v. EPA*, 213 F.3d at 680; *International Union v. OSHA*, 37 F.3d 665 (D.C. Cir. 1994). Examination of the former issue demonstrates that in section 313(f)(2), EPA's "power to roam" is relatively narrow.

In section 313(f), Congress established thresholds as a baseline, and delegated authority to EPA to modify them provided that the "revised thresholds shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of this subsection." As previously explained, EPA interprets this to require that any revised threshold obtain reporting on a substantial majority of the total releases reported by facilities reporting under the existing, baseline thresholds. See, Unit II.A. *supra*, and 64 FR 58673-676. This standard effectively constrains EPA's ability to increase the thresholds, and thereby deprive government agencies, researchers, and local communities of information that would provide them with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems, contrary to EPCRA section 313's overriding purpose. The discretion exercised in this rule is EPA's discretion to establish thresholds between 0 and 10,000 pounds or 25,000 pounds; this can hardly be characterized as an "immense power to roam."

Moreover, the impact of any revised threshold is distinctly limited, which courts have recognized as a relevant factor in evaluating the degree of authority that Congress delegates to an Agency. See, e.g., *Michigan*, 2000 WL 180,650 ("a mass of cases in courts had upheld delegations of effectively standardless discretion, and distinguished them precisely on the ground of the narrower scope within which the agencies could deploy that discretion"); *American Trucking*, 175

F.3d at 1037 (“The standards in question affect the whole economy, requiring a more precise delegation than would otherwise be the case” (citations omitted)). Here, that means within the context of all of the other prerequisites Congress established for TRI reporting, and of the other relevant statutory provisions constraining the Agency’s ability to modify those requirements. Irrespective of the modified threshold, a facility must still employ more than ten full-time employees; its primary SIC code must fall within one of the listed SIC codes; and it must be manufacturing, processing, or otherwise using one (or more) of the currently listed chemicals. 42 U.S.C. § 11023 (b). And far from granting EPA unfettered discretion to expand these requirements, Congress selectively granted EPA carefully qualified authority to adjust individual parameters. For example, section 313(l) explicitly limits the Agency’s authority to modify the reporting frequency, “. . . but the Administrator may not modify the frequency to be any more often than annually.” Similarly, Congress included no authority to amend the generally applicable employee threshold; thus facilities with fewer than ten employees are not subject to reporting under subsection 313(b)(1). In section 313(g)(2), Congress also specifically restricted the Agency’s ability to require industry to collect data to report under TRI: “Nothing in [EPCRA section 313] requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment” Accordingly, the scope within which EPA may deploy its discretion under EPCRA section 313(f)(2) is fairly narrow, and its impact limited.

In light of the above, EPA does not believe that the mere fact that the Agency is authorized to potentially select a threshold of “0,” necessarily renders section 313(f)(2) unconstitutional. The issue underlying the non-delegation doctrine, as the DC Circuit has explained is “to make sure that the regulatory principles as applied have their origin in a judgement of the legislature,” not whether Congress authorized the Agency to establish extremely low thresholds. *International Union v. OSHA*, 37 F.3d at 669 (citations omitted). Nor does the fact that Congress did not require the Agency to make specific findings to determine it was appropriate to increase or decrease section 313 reporting thresholds, necessarily demonstrate that Congress failed to provide the Agency

with adequate guidance in delegating its authority under section 313(f)(2).

One commenter further alleged that the Agency has failed to identify an intelligible principle “to channel its application of these factors,” quoting, *American Trucking Association v. EPA*. Another commenter asserts that EPA’s reliance on the general purposes of EPCRA is insufficient, stating that “general purposes or factors cannot substitute for the constitutionally required “intelligible principle” by which to identify a stopping point” when setting levels or thresholds.

As noted above, the Supreme Court has granted EPA’s request to review *American Trucking*. Nonetheless, EPA disagrees that EPCRA section 313(f)(2) falls afoul of the non-delegation doctrine, even as interpreted and applied in that case. As summarized above, in the preamble to the final PBT chemical rule, EPA identified and explained its application of the “intelligible principle” that Congress provided along with the delegation of authority in EPCRA section 313(f)(2). See, 64 FR 58687–692.

EPA also disagrees that its reliance on EPCRA section 313’s general purposes to discern EPCRA section 313’s overriding purpose, and thereby its intelligible principle, is insufficient. The DC Circuit upheld a broad delegation of legislative authority to OSHA based on the Agency’s demonstration of legislative guidance found in the Act’s “overriding purposes.” There, the Court noted

Were the six itemized criteria the full statement of OSHA’s interpretation of its statutory mandate, we might have to vacate the rule, because the agency might still have too much freedom to “roam between the rigor of section 6(b)(5) standards and the laxity of unidentified alternatives. *International Union I*, 938 F.2d at 1317. **But OSHA has gone on to infer from various sections—that the Act’s “overriding purpose” is “to provide a high degree of employee protection.”** 58 FR 16, 614/3–15/1. Thus the Agency reads the Act to require it, once it has identified a “significant” safety risk to enact a safety standard that provides “a high degree of worker protection.” *Id.* at 16, 615/1. It is not permitted to “do nothing at all”, as we had earlier suggested. *Id.* (quoting *International Union I*, 938 F.2d at 1317). **Rather, OSHA reads the Act to permit it to deviate only modestly from the stringency required by section 6(b)(5) for health standards. Accordingly, as construed by OSHA, the Act guides its choice of safety standards enough to satisfy the demands of the nondelegation doctrine.** (citations omitted). *International Union v. OSHA*, 37 F.3d at 669 (emphasis added).

The Court also explained that the underlying purpose of non-delegation doctrine is “to make sure that the

regulatory principles as applied have their origin in a judgement of the legislature.” *Id.* (citations omitted). EPA believes that its application of EPCRA section 313(f)(2) in this rule, as well as in the PBT rule, similarly satisfy the demands of the nondelegation doctrine.

C. What Science Issues Were Raised by Commenters on the Persistence and Bioaccumulation Criteria?

Several commenters contend that the criteria articulated in the PBT chemical rule to characterize the persistence and bioaccumulation of toxic chemicals should not be applied to metals because the development of the persistence and bioaccumulation criteria (as discussed in the PBT chemical rulemaking, see 64 FR 688–729) was based largely on data pertaining to organic substances. Thus they contend it is inappropriate to use these criteria to determine whether inorganic substances, including inorganic metal compounds, should be classified as PBT chemicals.

The Agency disagrees with the commenters’ statement that the PBT rule framework developed by EPA to assess the persistence and bioaccumulation of EPCRA section 313 listed toxic chemicals was designed only for organic substances and is being incorrectly applied to metals. The development of EPA’s framework to assess persistence and bioaccumulation is described in detail in the PBT chemical rulemaking (see 64 FR 688–729) and in the proposed lead rule. This framework was not developed to assess only whether organic chemicals are persistent and/or bioaccumulative, but to assess whether *any* chemical substance is persistent and/or bioaccumulative, including metals and metal compounds. EPA notes that the public had the opportunity to comment on the applicability of the PBT rule criteria to metals in the PBT chemical rulemaking. Furthermore, in the PBT chemical rulemaking, the Agency applied these criteria to mercury and mercury compounds—a metal and metal compounds category. EPA also provided notice in the proposed PBT chemical rulemaking that it was continuing to evaluate the bioaccumulation data for lead and lead compounds, and for cobalt and cobalt compounds—also metals (64 FR 717). EPA made clear the PBT rule criteria were developed to apply to metals and metal compounds, as well as organic compounds and, in fact, has applied the criteria to metals and metal compounds in a previous notice and comment rulemaking. With respect to the half-life and BCF/BAF criteria, scientifically these criteria are quite applicable to metals. Finally in the

lead proposed rule, EPA identified an additional factor for use in determining whether a chemical is, at the least, bioaccumulative. EPA explained that there is clear and convincing evidence that lead is bioaccumulative in humans. However, EPA requested comment on how such human data should be considered in determining whether a chemical should be classified in that subset of PBT chemicals that are highly bioaccumulative. Commenters argue that the human data should not be used to classify lead as bioaccumulative because the quantities of lead that might be reported, they believe, would not reduce human exposures to lead that are of concern. As explained elsewhere, EPA does not believe that human data showing the bioaccumulation nature of lead in humans should be ignored in any assessment of lead's bioaccumulation potential simply on the theory that the level of lead to which humans are exposed and the levels observed in humans may not correlate to the additional information on lead release collected under this rule.

Persistence, bioaccumulation, and toxicity are three distinct, independent characteristics. Although in the PBT chemical rulemaking the experimental evidence used to derive the environmental half-life, BAF and BCF criteria were obtained largely from studies that involved organic substances, this does not preclude the application of these criteria to inorganic substances such as metals and metal compounds (including lead and lead compounds). The basis for the concern and reason for lowering thresholds is based on the ability of the chemical, whether it is an organic chemical or a metal compound, to persist and bioaccumulate. The Agency believes that these criteria should and must be applicable to *all* chemical substances, including metals and metal compounds. EPA provided a detailed response to the issue of metals as PBT chemicals in the PBT chemical rulemaking. Persistence and bioaccumulation are not dependent upon whether a substance contains carbon (i.e., is organic). Substances that are inorganic can persist and bioaccumulate. The underlying molecular properties that determine whether a substance can persist and bioaccumulate are fundamentally the same for organic chemicals as they are for inorganic chemicals, including metals and metal compounds. These properties, as with most chemical and biological properties of a substance, are more dependent on the electronic and steric characteristics of the atoms comprising a substance, the specific

arrangement of the atoms within the substance's molecular structure and, with regard to bioaccumulation, the pharmacokinetics of the substance within the exposed organism and the sensitivity of the organism to the substance.

In addition, it is scientifically valid to establish generic criteria that are applicable to all substances provided that the endpoint or purpose for which the criteria are being established provides a common thread that is not dependent upon the unique elements comprising any given substance. For example, it would be legitimate to establish a category based on a type of arsenic toxicity and include within that category any substance that contains arsenic and exhibits that toxicity regardless of whether individual substances are organic or inorganic. In fact, it is common practice for scientific organizations and regulatory agencies to use generic criteria of this type. One example is the criteria established by the National Toxicology Program (NTP) for characterizing chemical carcinogens. The NTP is required by law to establish a list of all substances which either are known to cause cancer in humans, or may reasonably be anticipated to cause cancer in humans. A criterion used by the NTP to characterize chemicals as known or possible human carcinogens include, among others, tumor incidences in humans or experimental animals. While the vast majority of substances reviewed and tested by the NTP for carcinogenicity are organic substances, and the criterion established by NTP was based largely from toxicological observations pertaining to organic substances, the criterion used by the NTP is the same for inorganic substances as it is for organic substances. The NTP does not use different criteria when evaluating inorganic substances. This is because the ability of a substance to cause cancer is not dependent upon whether the substance is organic. In fact, NTP's current list of substances that are known to be human carcinogens contains both inorganic (including metallic) and organic substances. The carcinogenicity of all of these substances were characterized by the same generic criterion. A detailed discussion of the criteria used by the NTP is available (Ref. 17).

1. *What comments did EPA receive on the persistence of metals and metal compounds?* EPA defines a chemical's persistence as the length of time the chemical can exist in the environment before being destroyed by natural processes. Numerous commenters suggested that EPA adopt a different

definition of persistence for metals and metal compounds. They assert that the definition of persistence as applied to metals and metal compounds should include the transformation of individual metal compounds in the environment. As discussed in detail in the following response to comments on this issue, EPA believes that these factors are irrelevant to the persistence of metals and metal compounds in the environment. The factors that the commenters contend should be considered are those which address the conversion of one metal compound to another, which is irrelevant in determining whether metal compounds are persistent. While these are factors which control the transformation of one metal compound to another compound of the same metal, they are not factors which result in the destruction of the metal. There are no environmental factors which can or will result in the destruction of the metal.

Some commenters disagree with EPA's definition of persistence. They contend that the definition of persistence should be based on the availability of the metal in various environments and the length of time the metal is retained in an organism. One of these commenters stated that "persistence is the length of time an element or compound is available to and/or is retained in an organism or an ecological community, and that the mobility of metals [such as lead] deposited in soils or aquatic sediments becomes an important question when discussing persistence, since they are not persistent in biota unless they reach those environmental compartments and are cleared more slowly than they accumulate."

EPA disagrees with the commenter's definition of persistence. In the PBT chemical rulemaking (64 FR 58666), EPA adopted a policy for use in classifying a toxic chemical as persistent under EPCRA section 313. In the proposed rule to lower the reporting thresholds of lead and lead compounds (64 FR 42222), EPA used this same policy to determine whether lead and lead compounds are persistent. Most of these comments address the issue of persistence generically rather than specifically to lead and lead compounds. EPA responded to these generic issues in the PBT chemical rulemaking (64 FR 58676) and in sections 2a-f of the associated Response to Comments document (Ref. 15). EPA is discussing these issues here as background for the individual issues specific to lead and lead compounds in order to assist in understanding EPA's responses. Persistence is the length of

time a chemical can exist in the environment before being destroyed by natural processes (64 FR 698 and 64 FR 42227). The environmental media for which persistence is measured or estimated include air, water, soil, and sediment. 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. Persistence in the environment as a whole, however, is a distinct concept. It is based on 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 properties and reactivity. For overall persistence, only irreversible transformation contributes to net loss of a chemical substance. With regard to metals, although metals and metal compounds, such as 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 itself cannot be destroyed. A metal by its very nature cannot be destroyed and, therefore, is persistent in the environment as the metal or a metal compound.

The primary purpose of the persistence criterion is to establish how long a chemical substance will remain in the environment. The greater the length of time a substance persists in the environment, the greater is the potential for all forms of life to be exposed to the substance. Persistence is not limited to the duration of time a chemical is present in an organism and EPA does not believe it would be appropriate to incorporate this concept into its definition of persistence. It should be noted that, unlike the commenter's definition of persistence, EPA's definition of persistence does not specifically address the longevity of a substance in an organism. Persistence of a substance in the environment as a whole, or even in a particular environmental medium, is fundamentally unrelated to the substance's biological persistence (i.e., length of time a chemical exists in an organism before being destroyed or excreted). Although there are a few factors (physicochemical factors; e.g., water solubility, reactivity) that have a similar influence on environmental persistence as they do on the biological persistence of a substance, there are a number of other factors that influence biological persistence but not environmental persistence. These other

factors are organism specific, and are related to the anatomical and physiological characteristics of the organism. The Agency believes its environmental persistence criterion should not be extended to include biological persistence because the factors that influence the two persistence types are largely unrelated. Biological persistence in a given organism does not provide any information as to how long a substance will remain in the environment, and therefore is not relevant to the definition of persistence for EPCRA section 313.

One commenter claims that there is a serious flaw in the Agency's reasoning in characterizing all elements, including metals, as being persistent. Specifically, this commenter claims that this reasoning implies that because elements are non-destructible, then any compounds that contain a particular element is also non-destructible. The commenter acknowledges that EPA makes the statement in the proposed lead rule that "specific metal compounds may or may not be persistent, depending on the form of the metal and environmental conditions, but the elemental metal itself obviously meets the definition of persistence." The commenter claims that this statement begs the questions as to why EPA is not evaluating specific metal compounds when the Agency acknowledges that metal compounds differ in their "persistence" and also differ substantially with respect to toxicity and bioaccumulative potential. The commenter states that the above quoted statement could just as easily read ". . . specific carbon compounds may or may not be persistent, depending on the form of carbon and environmental conditions, but the elemental carbon itself obviously meets the definition of persistence." The commenter asserts that, according to EPA, this would mean that all organic compounds are persistent because they contain carbon and carbon is persistent. The commenter states that the Agency does not adopt such reasoning regarding elemental carbon because it would render the PBT chemical assessment methodology useless as an assessment tool. The commenter recommends that the Agency not apply the persistence assessment methodology to metals for the same reasons.

Another commenter believes that EPA's criteria for persistence as it applies to characterizing the persistence of metals is unfair. Specifically, this commenter interprets EPA's persistence assessment methodology as saying ". . . since any metal is persistent in the environment by definition, every

compound of that metal is evaluated and regulated by EPA like the parent metal, even if there are no data on that compound's persistence, even if the persistence in the environmental medium of its concern is very short, and even if that compound's bioavailability is insignificant."

The Agency believes that both of these commenters have misinterpreted the PBT assessment methodology EPA applied to lead and lead compounds.

With respect to the commenter who questioned why EPA is not evaluating the persistence of compounds individually, EPA disagrees that it is either scientifically required, or necessary for purposes of EPCRA section 313, to evaluate the persistence of each lead compound individually. Lead compounds are listed under EPCRA section 313 as a category; this means that all of the individual chemical compounds share common chemical characteristics, such that it is scientifically reasonable to conclude that lead compounds exhibit common toxicological properties/exhibit similar toxicity. For lead compounds, as for all metal compounds listed in an EPCRA section 313 metals category, the relevant common chemical property is the metal, because the toxic constituent is the metal itself, and this is what defines the category. Thus, in evaluating the persistence of lead compounds as an EPCRA section 313 chemical category, the relevant issue for purposes of EPCRA section 313 is the persistence of lead rather than the persistence of the other chemical constituents of the compounds in the category.

Similarly, EPA believes that this commenter's analogy to carbon and organic compounds is misguided. Organic compounds differ significantly from metal compounds in that the presence of carbon in a compound is not a controlling feature in the way that a metal contained in a metal compound is controlling. For example inorganic arsenic compounds are classified as known human carcinogens (Ref. 18). The toxicity is specific to the fact that the compounds contain arsenic and not to the other parts of the arsenic compounds. This is not the case with all groups of carbon compounds. For example, classes of organic chemicals that contain oxygen such as ketones, alcohols, ethers, and carboxylic acids exhibit significantly different physical and chemical properties and toxic effects. This is due to the differing arrangement of the carbon and oxygen within the compound. Even chemicals within the same class of organic chemicals, e.g., ketones, may not exhibit the same toxicity or similar physical

chemical properties. Further, while one arsenic compound will be converted in the environment or *in vivo*, it will not be converted into a substance that does not contain arsenic. In the environment or *in vivo* degradation of one member of a group of organic chemicals, e.g., ketones, carboxylic acids, will not consistently be converted into another chemical of the same class. They will often be converted into a different class of organic chemical.

Thus, while the Agency agrees that elemental carbon is persistent, the Agency would not conclude that all organic substances are persistent simply because they contain carbon. This is because the toxic effects of organic compounds are attributable to the structure of the compounds and *not* the carbon contained in the compounds. Thus EPA would not list a chemical category consisting of carbon and all carbon containing compounds, nor would it make a determination using the PBT assessment methodology that such compounds are PBT chemicals because they contain carbon. The same is true for any other element that is not toxic.

This approach is consistent with the Agency's approach to listing chemical categories, where, in the absence of data on a particular member of the category, EPA adds a chemical category, such as a metal compound category, based on their common chemical characteristics, and without demonstrating separately that each individual member of the category meets the section 313(d)(2) criteria. The D.C. Circuit specifically upheld this approach with respect to listing categories, finding that EPA's action was reasonable (*Troy v. Browner*, 120 F.3d 277, 288-89 (D.C. Cir. 1997)).

In addition, the commenters imply that in using the PBT rule assessment methodology EPA would conclude that all metals and their compounds are persistent and bioaccumulative, and therefore the Agency would require that all metals and their compounds that are listed on the EPCRA section 313 list of toxic chemicals have reduced reporting thresholds. The Agency would like to emphasize that while all metals persist, many metals and their compounds would not be characterized by EPA as bioaccumulative and toxic. For a listed toxic chemical to be considered a PBT chemical, the toxic chemical must be sufficiently persistent and sufficiently bioaccumulative.

Several commenters disagree with the Agency's rationale for characterizing all metals as being persistent, and believe that the issue of persistence has little or no relevance to metals.

The Agency disagrees with the commenters' statement that the issue of

persistence has little or no relevance to metals. EPA believes that persistence is relevant to the hazard potential of metals such as lead for the same reason persistence is relevant to the hazard potential of organic chemicals: for a chemical that persists in the environment, there is a greater potential for exposure and, therefore, a greater potential for the chemical to cause toxicity in an exposed organism or individual. However, in this rulemaking the Agency did not rely on the property of persistence by itself in lowering reporting thresholds for lead and lead compounds, nor does persistence alone necessarily mean that a substance is or can be a hazard to human health and the environment. As stated above, to be classified as a PBT chemical, a chemical must: (1) Be an EPCRA section 313 listed toxic chemical; (2) be sufficiently persistent; and (3) be sufficiently bioaccumulative. In this rulemaking EPA is addressing lead and lead compounds which are EPCRA section 313 listed toxic chemicals and is also considering the bioaccumulation potential of these chemicals.

One of the commenters believes that metals do not necessarily persist, and that the definition of persistence in relation to metals should be qualified to mean how long a metal can remain in a particular form or species (e.g., oxidation state). This commenter also recommends that the Agency should examine data pertaining to certain properties of metals to assess persistence in accordance with this definition, and to allow for the identification of those metals and metal species which are the most/least resistant to change and which are the most or least bioavailable. The properties raised by the commenters include: transformation/dissolution, oxidation, corrosion, sulfide binding, and first hydrolysis constant.

EPA agrees with the commenter's statement that metals, including lead, can exist as different species and compounds. These different species pertain to the oxidation states or, more specifically, the number of electrons missing from the outer orbital of the metal atom. Lead, for example, can exist in a neutral species, Pb^0 (no electrons are missing from the outer electron orbital of the lead nucleus), or as lead compounds in one of two oxidation states: Pb^{+2} or Pb^{+4} (2 and 4 electrons are missing from the outer electron orbital, respectively). As stated in the proposed rule, these species can convert from one to another under certain, commonly encountered environmental conditions. See also Unit VI.C.5. of this preamble. While there may be a

conversion from one lead compound to another lead compound or to metallic lead, or from metallic lead to a lead compound (either in the Pb^{+2} or Pb^{+4} oxidation states), there is no possible conversion either in the environment or *in vivo* that will convert (or degrade) metallic lead or any lead compound into a substance that does not contain lead. Any conversion will always result in the presence of lead or a compound that contains lead. Conversion of a metal atom from one oxidation state to another does not change the number of protons in the nucleus of the atom and, therefore, does not change the metal into another metal or element. In the case of lead, each species of lead (Pb^0 , Pb^{+2} , and Pb^{+4}) **is still lead** because each contain the same number of protons (82) within their nuclei (See Refs. 19 and 20).

EPA disagrees with the commenter's assertion that the Agency consider transformation/dissolution, oxidation, corrosion, sulfide binding, and first hydrolysis constant in determining whether metal compounds are persistent. These are factors which address the conversion of one metal compound to another, which is irrelevant in determining whether metal compounds are persistent. While these are factors which control the transformation of one metal compound to another compound of the same metal, they are not factors which result in the destruction of the metal. There are no environmental factors which can or will result in the destruction of the metal. Therefore, EPA believes that the commenter's definition of persistence is not an appropriate alternative to EPA's definition.

One commenter who agrees with EPA's definition of persistence and, in particular the Agency's characterization of lead as being persistent states that the persistency of lead poses a significant threat to human health and the environment because this property allows lead to remain in the environment without being broken down by natural processes. This commenter disagrees with other commenters who claim that metals are not persistent or that persistence of toxic metals should not be of concern. This commenter believes that persistence enables a substance like lead to travel through ecosystems and through different media and, as such, threatens human health and the environment far beyond the geographic vicinity of the source from which it has been released.

The Agency agrees with the commenter's statement that lead is persistent. The Agency also agrees that

the persistence property of a substance contributes to the ability of the substance to be distributed through ecosystems and through different media to areas beyond the geographic vicinity from where the substance entered the environment. The property of persistence, however, pertains to longevity of a substance, and does not bestow an ability for the substance to partition throughout environmental media. However, the opportunity for exposure to a substance that is capable of partitioning throughout environmental media may be greater if the substance is also persistent, since the substance will remain in the environment for a longer period than a substance that is not persistent.

2. *What comments did EPA receive on the availability and bioavailability of metal compounds?* Commenters suggest that EPA consider environmental availability (which they term "bioavailability") in lieu of bioaccumulation. Many of these commenters assert that unless a metal compound is readily available in the environment, it will not be bioavailable or bioaccumulate. Some attempt to take a risk-based approach to metals and metal compounds in the environment by arguing that when environmental availability is considered, metals and metal compounds will not be present at levels high enough to cause adverse effects.

As discussed in detail below, the level of environmental availability or bioavailability is not a surrogate for bioaccumulation. Even metal compounds that have limited availability or bioavailability can bioaccumulate. The extent of environmental availability or bioavailability will not affect whether bioaccumulation will occur. For example, lead from a sparingly soluble compound and lead from a readily soluble compound will both bioaccumulate. This is in contrast to the commenters' implication that only the lead from the readily soluble lead compound will bioaccumulate. Further as discussed below, the presence of a soluble metal compound is not the only factor, or in many cases the determining factor, that controls the potential for the metal compound to bioaccumulate. A metal compound may undergo various transformations in the environment resulting in a different metal compound which has a much higher availability and/or bioavailability. While metals and metal compounds need to be environmentally available and/or bioavailable as a prerequisite to bioaccumulation, there is not a quantitative relationship between

environmental availability and/or bioavailability and the degree of bioaccumulation. Therefore, EPA believes that availability and bioavailability are not appropriate substitutes for bioaccumulation.

Further, requiring a particular level of environmental availability would effectively be establishing a risk-based approach to lowering thresholds which EPA believes is inappropriate for the following reasons. The availability of lead in the environment will vary depending upon environmental conditions. Choosing one level of environmental availability and applying that individually to each metal compound is neither practical nor scientifically supportable because: (1) As discussed above environmental availability is not necessarily reflective of bioavailability; and (2) the environmental availability of a metal compound depends upon local environmental conditions. There is no "best" or adequately representative set of national environmental conditions. Further, the TRI program is primarily a hazard based program. Risks that may be acceptable at the national level may not be acceptable at a regional or local level.

EPA considers availability in the environment and bioavailability for metal and metal compounds for purposes of bioaccumulation only to determine whether it is impossible for the metal and metal compounds to bioaccumulate, i.e., a compound that is both environmentally and biologically inert cannot bioaccumulate. EPA believes that there are data that indicate that lead and lead compounds are available in the environment, are bioavailable, and bioaccumulate, e.g., data in humans and fish advisories. However, several commenters contended at public meetings on EPA's PBT chemical rulemaking that metals and metal compounds, such as lead and lead compounds, are not available in the environment and thus, cannot bioaccumulate. To address these comments, EPA chose to conduct an environmental fate assessment to describe the environmental availability of lead and lead compounds. Qualitative environmental fate assessments are generally part of a hazard assessment for a chemical. The qualitative environmental fate assessment for lead and lead compounds, however, was not developed, nor was it intended, to be part of an exposure assessment or risk assessment.

Several commenters claim that EPA should consider bioavailability in its assessment of metals and metal compounds, such as lead and lead

compounds. These commenters contend that not all metal compounds and lead compounds in particular are bioavailable. According to the commenters, unless a compound is in a form that is bioavailable, it will present little risk to human health and the environment. One commenter made the following statement:

Because of metals' natural persistence, the weight of scientific opinion holds that bioavailability is a more appropriate criterion for assessing the environmental and health hazards associated with metals. While toxicity is obviously a relevant measure for assessing the hazard posed by a substance, the substance must be available for uptake [bioavailable] before it can exhibit an adverse effect. Bioavailability varies significantly among different species of metals, including lead compounds, and also is influenced by environmental media. Bioavailability can only occur if soluble metal compounds are released. Thus, the rate at which metals transform to soluble/bioavailable species is critical for hazard identification. Simply stated, the natural persistence of metals with toxic properties poses no special hazard if those metals generally are present in environmental media in forms that cannot be taken up by plants and animals.

Other commenters expressed similar views. These commenters believe that the availability of lead from lead compounds differs among lead compounds, and that lead is unavailable from certain lead compounds. Therefore, in the opinion of the commenters, lead compounds from which lead is not available and/or bioavailable cannot be PBT chemicals, and should not be included in this rulemaking.

The Agency disagrees with the commenters' assertions that: (1) EPA did not consider bioavailability of lead in its assessment of lead and lead compounds as bioaccumulative substances; and (2) that bioavailability is only possible for released soluble metal compounds.

The basis for the Agency's disagreement with these comments concerns the commenters' use of the terms "availability" and "bioavailability", which differs significantly from EPA's definition of these terms. The commenters are using the term bioavailability interchangeably with availability, when in fact these two terms have totally different meanings and cannot be used interchangeably. In addition, the commenters have incorrectly concluded that: (1) If lead is not available in the environment, it is not bioavailable and will not bioaccumulate or cause toxicity; (2) lead is only bioavailable when in its ionic oxidation state; and (3) only those lead compounds that are water soluble as released are bioavailable. To respond to

these comments, the Agency needs to first clarify the distinction between "availability" of a metal, and "bioavailability" of a metal or metal compound, and the factors that influence availability and bioavailability of a metal or metal compound.

Availability of a metal is the extent to which a metal, in either its neutral (MG^0) or ionic (MG^{+x}) oxidation state, can reach a state of atomic disaggregation. Inorganic metal compounds that are water soluble will completely dissociate in aqueous media, liberating the metal in its ionic oxidation state. In aqueous solution the metal atoms of the molecules of these substances are completely disaggregated from the rest of their molecular constituents. In this disaggregated state the metal is completely available. Water solubility is not a prerequisite, however, for a metal to become available from a metal compound. In the environment a metal can become available from organometallic substances or inorganic metal compounds that are poorly soluble in water, by undergoing environmental transformations that cause the metal atoms to disaggregate and become available. Environmental transformations that cause metals to become available are summarized below, and discussed in greater detail in Unit V.A. of the proposed lead rule (64 FR 42227-42228), and in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2).

The extent to which a metal can become available from a metal compound in environmental media is dependent upon: (1) The physicochemical properties of the metal and the metal compound; (2) the structural characteristics of the metal compound; and (3) environmental factors, including, but not limited to: presence of aerobic or anaerobic bacteria, pH, moisture content, and organic matter content of soil or sediments. Some or all of these environmental factors can vary between specific terrestrial or aquatic environments. For different compounds that contain the same metal, the relative availability of the metal from each compound can vary within the same terrestrial or aquatic environment. It is also true that the availability of a metal from the same metal compound can vary between specific terrestrial or aquatic environments. Some metal compounds are more susceptible to environmental transformations and subsequent release of the metal than are other metal compounds.

Bioavailability is the extent to which a substance is absorbed by an organism, and distributed to an area(s) within the

organism. This is important because the substance can then exert a toxic effect or accumulate. As with availability, the physicochemical and structural characteristics of a substance play an important role in determining whether the substance is bioavailable and the extent to which it is bioavailable. Unlike availability, however, whether a substance is bioavailable and the extent to which it is bioavailable in a given organism also depends upon the anatomy and physiology of the organism, the route of exposure, and the pharmacokinetics of the substance in the organism (i.e., the extent to which the substance is or can be absorbed by the organism from the exposure site, its distribution and metabolism within the organism, and its excretion from the organism). It is important to stress that bioavailability does not by itself mean that a substance is a hazard to human health or the environment. A substance that has 100% bioavailability does not pose a hazard to human health or the environment if it is not intrinsically toxic. Conversely, for substances that are intrinsically toxic it is not necessary for the substance to be 100% bioavailable to cause toxicity. Depending upon the extent of exposure, toxic potency, and the nature of the toxic effect, even substances that have low bioavailability can still pose a hazard to human health or the environment. Similarly, a substance does not have to have 100% bioavailability in order for it to bioaccumulate. For some compounds, even very limited bioavailability (that is a very small percentage is bioavailable) can result in concern if it is bioaccumulated. Lead and lead compounds are one example. Polychlorinated biphenyls (PCBs) are another (64 FR 706).

Absorption of a substance is a critical component of its bioavailability. Absorption is the movement of a chemical substance from its site of exposure on a terrestrial or aquatic life form into its systemic circulation (bloodstream) or, in the case of unicellular organisms such as algae, inside the cell comprising the organism. In any case, absorption of a substance from any exposure site involves its passage across the biological membranes that compose the exposure site. Chemicals can cross a cell membrane by several mechanisms. These are: (1) Passive permeation (diffusion) through the membrane; (2) passive transport through membrane channels or pores; (3) active transport; facilitated transport; or (4) phagocytosis (also pinocytosis and endocytosis) (Ref. 21). Whether a

substance can or will be absorbed, and the degree to which it can be absorbed depends largely upon the physicochemical properties of the substance, the anatomical makeup of the exposed organism and the site of exposure (Ref. 21). Substances released to the environment that are not absorbable by terrestrial or aquatic species may be transformed in the environment to metabolites that are absorbable and, hence, bioavailable.

An important point to stress regarding the bioavailability of metals is that availability of a metal is **not** a prerequisite for its bioavailability. Metals can be bioavailable in either their neutral (MG^0) or ionic (MG^{+x}) oxidation states; or as part of an intact inorganic or organic compound. When in ionic oxidation states many metals are generally absorbed by active transport processes. Here, cellular membrane-bound proteins carry the metal across the cell membrane and into the cell. While it would seem that most metal ions are sufficiently small and water soluble to simply pass through membrane channels, their hydrated ionic radii are usually too large to permit their passage by this mechanism. Metals in their neutral or ionic oxidation states may be taken up by organisms by phagocytic processes as well. Organometallic substances are substances in which the metal is bonded to carbon-containing substituents. These substances can be absorbed intact by passive diffusion. The absorption of poorly water soluble inorganic metallic substances can occur via phagocytosis, or by other mechanisms. In terrestrial or aquatic life forms that have digestive systems that secrete strong acids, a poorly water soluble inorganic metallic substance or a metal in its neutral oxidation state can react (following oral exposure to the substance) with the acid to form a water soluble salt of the metal. Under these circumstances the metal is made available within the digestive system, and is absorbed in its ionic oxidation state. See Refs. 21, 22, 23, and 24.

The distribution, metabolism, and rate of excretion of a metal or metal compound depends upon the nature of the metal or metal compound, and the anatomy, physiology and genetic makeup of the organism. Metals absorbed in their neutral or ionic oxidation state be excreted unchanged or react with endogenous substances to form a metal compound *in vivo*. Organometallic substances are typically more lipid soluble than is the metal in its neutral or ionic oxidation state, and can be distributed more readily to areas of the organism that otherwise may be

poorly accessible by the metal in its neutral or ionic oxidation state. Organometallic substances may also undergo metabolic transformations *in vivo* in which the metal is liberated from its organic constituents. The same is true for inorganic metallic substances absorbed intact. See Refs. 24, 25, and 26.

Generally the ionic oxidation states of metals are the most available and, for many life forms, the most bioavailable. For aquatic species the bioavailability of a metal is expected to be greater from those metal compounds in which the metal is readily available in aquatic environments than from metal compounds or complexes in which the metal is not readily available in aquatic environments. This is because the metal is in a completely disaggregated state and dissolved in the aqueous media of the aquatic environment, which favors uptake of the metal by aquatic organisms since they are typically immersed in the aqueous media. However, aquatic species can also absorb intact metal compounds (e.g., organometallic substances). Thus, metals may be bioavailable from metal compounds or metal complexes even where the metal is not available in aquatic environments. Many aquatic organisms such as mussels, clams, and oysters, for example, consume as food organic materials suspended in aqueous media. These molluscs use short, hairlike locomotory organelles (cilia) to take in suspended organic materials from the water. Water currents sweep the suspended organic materials into the open shells, where they become fastened to a film of mucus. The cilia sweep the mucus to the mouth of the mussel. Soft, fingerlike organs push the mucus and organic materials into the mouth of the mussel, where it is taken in and digested. As stated by EPA in the proposed rule regarding lead and lead compounds, and by many commenters, lead dissolved in aqueous media may be removed from solution through sorption to suspended organic matter. Although no longer available, the lead in these suspended complexes may still be *bioavailable* in aquatic life forms that consume solid organic materials as food. Another example is that fish can absorb organometallic substances (intact) via passive diffusion through their gill membranes. See Refs. 24, 27, and 28.

The availability of a metal from the *same* metal compound may vary in different terrestrial or aquatic locations. Differences in environmental conditions lead to differences in the environmental fate of the compound in different environments. In an aquatic environment that contains metal ions of the same metal, the bioavailability of the

metal in different aquatic species may vary even though the availability of the metal to each species is the same (i.e., the concentration of the metal in its ionic oxidation state is the same throughout the aquatic environment). These differences in bioavailability in different aquatic species are due to the differences in anatomy, physiology, and pharmacokinetic differences among the species. For different compounds that contain the same metal, the bioavailability of the metal ion in a given organism within a particular terrestrial or aquatic location may vary among different compounds. For a given organism, differences in bioavailability of a metal among compounds that contain the metal may be ascribed to differences in the physicochemical properties of the metal compounds and pharmacokinetic differences.

As mentioned above, metals or metal compounds released to the environment from anthropogenic sources are affected by prevailing environmental conditions, meaning broadly the wide variety of physical, chemical and biological processes that act upon them. These processes collectively determine the metal compounds in which the metal can exist in the environment. Lead can enter the environment as available or bioavailable compounds, or as compounds that are not available or bioavailable. However, lead that enters the environment as compounds that are not available or bioavailable can be converted in the environment to compounds that are available or bioavailable. As mentioned above, the ionic oxidation states of metals are generally the most available and, for many organisms, the most bioavailable. Hence, environmental factors that affect the availability of a metal may indirectly affect the bioavailability of metal. It is therefore important to consider those factors that influence the availability of a metal in the environment, when assessing physical or biological properties of the metal. However, as also discussed above, availability of a metal is not a prerequisite for its bioavailability. Interconversion of inorganic metal compounds can be quite rapid and as a result the metal compound in which the metal is released may not be the predominant metal compound post-release. Availability of a metal from an organometallic compound or insoluble inorganic compound is affected by many factors and its determination is complex, but many of the more important variables are discussed below for lead. A detailed discussion of the environmental fate of lead, that is

illustrative of many of the more important environmental variables that affect availability and bioavailability of metals in general is provided in Unit V.A. of the proposed rule (64 FR 42227-42228), in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2), and below.

In some instances, 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. 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.) Cation exchange capacity (CEC, related to soil clay content) and pH also influence the capacity of soil to immobilize lead. Using organic chelation as a model, the total capacity of soil to immobilize lead can be predicted by a linear relationship equation. Using this model to predict saturation capacity from CEC and pH it can be shown that a decrease in pH from 5.5 to 4.0 will reduce estimated soil capacity 1.5 times, thereby increasing the concentration of available lead in soil water (Ref. 2).

A number of field studies demonstrate the enhanced mobility of lead in soils under a range of environmental conditions. In all of these studies variables including pH, soil organic matter content and the chemical species of lead present played a significant role in increasing soil lead mobility. Limited data also indicate that organo lead compounds may be converted into water-soluble lead compounds in soil. Degradation products of tetramethyl and tetraethyl lead, the trialkyl lead oxides, are expected to be significantly more mobile in soils than the parent compounds (Ref. 2).

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. 29). 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 in runoff areas of New York state and New England.

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. 30 and 31). 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.

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.

It can be concluded that many processes commonly observed in the environment result in the release of lead ion, which is available and bioavailable lead. These processes may occur in soil and aquatic environments with low pH and low levels of organic matter. Under these conditions, the solubility of lead is enhanced and in the absence of 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. A decrease in soil pH can cause sorbed lead to desorb, and increase lead availability in soil water.

A few commenters contend that bioavailability is only possible for released soluble metal compounds. This position is incorrect: EPA has concluded that metal compounds, including lead compounds, that are released as metal compounds that are not soluble or bioavailable may be converted in the environment into metal compounds that are available or bioavailable. Furthermore, as discussed above, a metal compound may not be soluble, but may, nonetheless, be bioavailable.

Several commenters contend that EPA should consider each member of a metal compounds category (such as lead compounds) individually because the availability will vary from metal compound to metal compound within a

category and some metal compounds will not be available at all.

EPA disagrees. As discussed above in Unit VI.C.1. with respect to evaluating persistence for metal compound categories, the Agency believes that it is reasonable to evaluate metal compound categories, such as lead compounds, as a category rather than individually. Moreover, in the case of lead compounds, the bioavailability of a lead compound is not necessarily dependant upon the availability of lead from the compound. That is, the parent lead compound may be bioavailable as is or, if not itself bioavailable, could be converted in the environment into a compound that is bioavailable or from which lead is bioavailable. As EPA has discussed elsewhere in this preamble, the environmental fate assessment indicates that there are many conditions under which lead from lead compounds can become available in the environment. Further, most lead compounds provide bioavailable lead when ingested. In addition, regardless of the relative environmental availability of lead from one lead compound to another, the lead compounds all add to the environmental loading of lead. Thus, even if under the same environmental conditions the lead from compound A is 10 times less available than the lead from compound B, compound A would introduce the same amount of available lead if its releases are 10 times greater. If lead compounds are evaluated individually based on relative environmental availability then the additive effect of the loading of lead from these compounds would be ignored.

Two commenters criticize EPA for not using the latest tools for assessing the availability of metals, including those tools in which the Agency was or is involved with developing. These commenters mention several Agency efforts that pertain to availability and the assessment of metals. These include the Environmental Sediment Guidelines and the Biotic Ligand Model development for the Water Quality Criteria.

The environmental processes that determine the complexation, speciation, and ultimately the availability of lead in the environment have been considered and addressed elsewhere in this preamble. In conducting its assessment of the availability of lead in the environment, EPA reviewed the available documentation on both the simultaneously extracted metals/acid volatile sulfide (SEM/AVS) methodology and the Biotic Ligand Model (BLM). EPA believes that the SEM/AVS methodology as applied to

the Environmental Sediment Guidelines, and the BLM as applied to water quality criteria show great promise for use in conducting *site-specific* assessments of those metals for which it has been validated. However, to date neither the SEM/AVS methodology nor the BLM have been validated for lead, nor have the substantive technical comments provided by the EPA Science Advisory Board been incorporated into these approaches. In addition, EPA does not believe that a means currently exists to incorporate these methodologies into the technical analysis supporting a *nationally* applied regulation such as this rulemaking. While at this stage of their development these methods may be useful in site-specific assessments, they cannot be applied to support national Agency programs such as the TRI Program because of the variability in environmental conditions throughout the United States. On the other hand, the PBT methodology, as used by EPA in the characterization of lead as a PBT chemical, can be used to provide technical support to national regulatory programs such as the TRI Program because this methodology incorporates the environmental processes that determine the complexation, speciation, and the availability of lead in the environment, but does not require site-specific input. EPA believes that the PBT model is an appropriate methodology for assessing the persistence of metals, including lead.

3. *What comments did EPA receive on the bioaccumulation of metals and metal compounds?* Numerous commenters suggest that for metals and metal compounds bioaccumulation is not a relevant endpoint of concern. They contend that for metals and metal compounds: (1) Bioaccumulation is mitigated by environmental factors; (2) that metals and metals compounds are often essential nutrients and thus organisms have developed mechanisms to control their accumulation; (3) that BCF values for metals are dependent upon the concentration of the metal; and (4) that metals do not bioaccumulate at the concentration levels associated with toxicity. As discussed in detail in the following comment responses, EPA does not believe that any of the issues raised by the commenters call into question EPA's scientific and policy reasons for considering bioaccumulation for lead and lead compounds. Not all metals are essential nutrients and even those that are can be accumulated to unsafe levels. In particular, lead is not an essential nutrient. While some metal BCF values

vary with metal concentration this does not change the fact that the metals do bioaccumulate. In addition, bioaccumulation does not need to occur at concentrations that cause toxicity to be of concern, and in fact testing of bioaccumulation should not be conducted at concentrations that are detrimental to the test organism. Moreover, where there is extensive human data showing significant bioaccumulation of a listed toxic chemical, such as here, the bioaccumulation of the metal is obviously of concern. Therefore, EPA believes that bioaccumulation potential is a relevant endpoint of concern for metals, especially for lead and lead compounds.

Several commenters contend that the extent to which a metal bioaccumulates in aquatic organisms is dependent upon the metal's concentration in the aqueous habitat of the organism. Specifically, this commenter states that the BAF or BCF of a substance is inversely related to its concentration in the surrounding aqueous medium: that is, BAFs and BCFs become larger as the external concentration of the substance decreases. Thus, according to the commenter, because a metal's BCF or BAF value in a given aquatic organism will vary depending upon concentration, a single BAF or BCF value cannot be used to define whether a metal bioaccumulates. In effect the commenter is disagreeing with EPA's definition of BCF and BAF since the definitions do not require that all concentrations of the chemical result in the same BCF or BAF.

The Agency is in general agreement with the commenters' position that for a substance that bioaccumulates in aquatic species the degree to which it does so (i.e., the BAF and BCF of the substance) is related in part to the external concentration of the substance. The Agency also believes, however, that external concentration is not the only factor that influences bioaccumulation. As discussed previously, the propensity of a substance to bioaccumulate in a species depends largely upon the pharmacokinetics of the substance in that species. For further discussion on pharmacokinetics and bioavailability and bioconcentration see Unit VI.C.2.

In addition, the Agency believes that when analyzing test data, the conclusion that bioaccumulation decreases as external concentration of a substance increases may be erroneous. It is quite possible that as the concentration of the test substance is increased, biochemical changes that are precursor events to toxicity are initiated. While the increased concentration may not be sufficient to cause death to the

organism, the initiation of the precursor events may cause a stasis in cell growth or function, and interfere with the organism's ability to absorb the metal. In a species where this is the case, it would therefore incorrectly appear that the bioaccumulation of the metal decreases as external concentrations increase. Thus, the Agency is in general agreement with the commenter's position that, for a substance that bioaccumulates in aquatic species, the degree to which it does so is related to the external concentration of the substance. The Agency, however, does not agree that the relationship for metal is always truly inversely related: i.e., that as external concentration increases bioaccumulation decreases. This is not a general phenomenon for all metals and metal compounds in all organisms as suggested by the commenter.

When discussing BCF and BAF values, distinction needs to be made between BAF or BCF values that are measured in a laboratory from those that are measured in an actual environmental setting. The Agency's definition of BCF and BAF (64 FR 42229) pertain to determinations of BAF and BCF under controlled experimental conditions where exposure of the aquatic species to the chemical is kept relatively constant (i.e., external concentration of the substance remains relatively constant). Thus, assays performed in laboratories to determine BAFs and BCFs are conducted under controlled conditions, and any sources of variability in conditions are minimized or eliminated. In a laboratory assay the test concentration is usually set at some percentage below the acute LC₅₀ (the concentration lethal to 50% of the test organisms following acute exposure); often 1/10 of the LC₅₀ of the metal is used. While there is no reason BCF tests cannot be conducted at other concentrations of the test chemical, it would serve no scientific purpose to use concentrations at which the test organism becomes stressed or dies before the test assay is completed or before the organism has the opportunity to bioaccumulate the test chemical. In an actual environmental setting, however, conditions can be variable. No commenter to this rule provided scientific data showing that these BCF values would not be found in the environment. Consequently, EPA believes that appropriately conducted bioaccumulation tests conducted at even at one concentration of lead are valid indicators of the potential for lead to bioaccumulate.

Two commenters claim that EPA dismisses the notion that bioavailable metals are often intentionally

bioaccumulated as beneficial nutrients or are otherwise safely metabolized by plants and animals through biological mechanisms. One of the commenters states that while metals can bioaccumulate, the manner and rate at which they do so varies based upon the nutritional needs of the organism, external concentration of the metal, and speciation of the metal. The commenter also states that the bioaccumulation of metals is fundamentally different than the process by which organic compounds bioaccumulate.

EPA acknowledges that some metals are nutrients in some organisms, including humans, or are otherwise necessary for the subsistence of organisms. Thus, some metals need to be bioaccumulated by the organism. Clearly, such metals need to be bioavailable in the organisms that require these metals. As discussed in greater detail elsewhere in this document and as alluded to by one of the commenters, in many organisms the absorption or uptake of metals across cell membranes involves active (i.e., energy-requiring) processes, whereas absorption or uptake of organic substances is usually the result of passive diffusion across cell membranes. Active transport processes give the organism some ability to regulate the uptake of metals. It is also important to note that active transport across cell membranes is not the only means by which a metal can be absorbed. Organometallic substances, for example, are often absorbed by passive diffusion. Metals and metal containing substances may also be taken up by organisms through phagocytic processes. In addition, as one of the commenters states, metal speciation and concentration are factors that can influence uptake of metals into an organism.

While active transport processes are involved with the uptake of metals needed by the organisms, these processes do not always discriminate those metals that are needed by the organism from those metals that are harmful to the organism. Thus, organisms also have the ability to take up or absorb metals that are not nutrients and that are not necessary for subsistence. Thus, the processes that organisms use to absorb or take up needed metals do not necessarily prohibit or protect them from taking up toxic metals. In addition, even needed metals can be toxic to the organism if over exposure occurs. It is well established that metals that are not needed by an organism can be taken up by the organism, and bioaccumulated by the organism. lead and mercury, for

example, are not known to be essential metals in any species. Yet the uptake and bioaccumulation of these metals by organisms, including humans, is well established. EPA has therefore determined, insofar as commenters are suggesting that EPA consider the nutrient value of metals in this rulemaking, that such comments are irrelevant because lead has no known nutritive value to any species. The results of the studies investigating the bioconcentration of lead and lead compounds in aquatic organisms summarized in Table 1 (64 FR 42230) of the proposed lead rule and the table in Reference 10 of the proposed rule show that lead is taken up and bioaccumulated by many different aquatic organisms. Also, as discussed in Unit VI.D.3., EPA's fish advisory data base demonstrates that many species of fish and shellfish from various aquatic environments in different regions of the country contain lead (see <http://fish.rti.org>) indicating that fish and shellfish bioaccumulate lead under realistic environmental conditions.

Two commenters stated that bioaccumulation of metals does not necessarily indicate the presence of, or a potential for adverse effects. At the outset, EPA stresses that lead and lead compounds are EPCRA section 313 listed toxic chemicals. Therefore, as stated in the proposed rule and elsewhere in this preamble, the toxicity of lead and lead compounds is not at issue in this rulemaking. These commenters state that bioaccumulation of a substance is not an indicator of hazard, and should not be used as a hazard assessment criterion.

The Agency agrees that the ability of a substance to bioaccumulate does not by itself necessarily indicate the presence of, or potential for adverse effects. The Agency believes, however, that the concept of bioaccumulation is relevant to the hazard characterization of metals for the same reasons that it is relevant to the hazard characterization of organic substances: that low-level or sub-toxic exposures to a toxic substance that bioaccumulates could eventually lead to exposures of concern in the organism that bioaccumulates it or increased exposure potential for predator species. The Agency would also like to emphasize that while bioaccumulation of lead in a given aquatic organism may not necessarily be toxic to the organism, the accumulated lead may serve as a source of lead exposure and toxicity to predator species, including humans.

Thus, the high bioaccumulation potential of lead, an EPCRA section 313 listed toxic chemical, within an

organism is anticipated to contribute a greater total body burden relative to a chemical with lower bioaccumulation potential, thereby increasing any toxicity to the organism. High bioaccumulation also increases lead exposure to other organisms that are predators of the organism that has accumulated the lead.

4. *What comments did EPA receive on the relationship of its persistence and bioaccumulation criteria to international criteria?* Two commenters claim that numerous international organizations such as the Organization for Economic Cooperation and Development (OECD) have approached the classification of PBT chemicals in a manner that calls into question EPA's use of persistence and bioaccumulation criteria for accurately identifying the human and environmental health hazards of metals. One of the commenters claims that the OECD Advisory Group on Harmonization of Classification and Labeling (which includes EPA participants) has made the following conclusion: "...For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather, the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species." The commenter recommends that EPA reconsider its characterization of lead as a PBT chemical because, in the opinion of the commenter, there is a lack of scientific support for assessing a metal's PBT characteristics to determine its potential hazard to human health and the environment.

The Agency believes the commenter has misunderstood OECD's position on the applicability of general PBT criteria to metals. The quote is taken from the OECD document entitled *Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances*. (Ref. 32) The pronouncements on metals are contained in paragraphs 22 and 23 of that document. Paragraph 22 reads as follows:

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

By "degradability as applied to organic compounds" OECD means molecular degradation, most often by microbial degradation and/or hydrolysis or other abiotic processes, to progressively simpler organic chemical structures, leading eventually to inorganic substances like carbon dioxide and water. It is important to note that paragraph 22 does not in any way suggest that metals are not persistent. Moreover, it does not suggest that OECD hazard classification criteria cannot be applied to metals, only that "care" (e.g., professional judgment) is required in the interpretation of data relative to the classification criteria. In fact, EPA agrees that in order for a metal to bioaccumulate in an organism it must either be environmentally available or bioavailable. In response to the allegations that lead is not environmentally available, as part of the proposed rule, the Agency analyzed information on the environmental fate of lead, and, as noted above, determined that lead has the potential to become available from lead compounds under commonly encountered environmental conditions. In addition, as explained in Unit VI.D.3, EPA determined that lead and lead compounds are bioavailable. Therefore, the Agency's assessment of lead as a PBT chemical is consistent with the OECD's intent.

EPA does not interpret the above quote to indicate that OECD's position is that its or any PBT chemical criteria are not applicable to lead. As the commenter correctly states, EPA is a member of the OECD Advisory Group on Harmonization of Classification and Labeling. OECD does not recommend that metals and metal compounds be *excluded* from consideration as PBT chemicals, as the commenter implies. More specifically, OECD has not concluded that metals and metal compounds have no potential to bioaccumulate because they are never released as bioavailable compounds; or cannot be converted to bioavailable compounds under any foreseeable circumstances. On the contrary, EPA believes that the preceding language indicates that OECD's position is that any substance judged to be potentially bioavailable, whether organic or inorganic, should not be excluded as a candidate from some form of regulatory action. As discussed in Units VI.C.2. and VI.D.1., it is realistic to expect that, in general, released metals such as lead can encounter conditions in which they are (or can become) available at levels sufficient to bioaccumulate. Therefore, the Agency's use of the PBT criteria in its assessment of lead is consistent with

OECD's position on the general applicability of PBT criteria to metals.

5. *What comments did EPA receive on its metals policy?* Some commenters contend that EPA should not consider all members of the lead compounds category to be PBT chemicals because availability and bioavailability of the lead portion will vary among the compounds. These commenters further state that the toxicity can only be evaluated on a compound-by-compound basis and is dependent on bioavailability.

Members within the lead compounds category listed on the EPCRA section 313 list of toxic chemicals have a common moiety that bestows toxicity, i.e., lead. Consequently, it is reasonable to anticipate that once released into the environment: (1) The metal moiety in each member of the category will become available as a result of abiotic and/or biotic processes or (2) each member of the category will either be bioavailable or will convert into a compound that is bioavailable. For example, different inorganic lead compounds that are released into acidic surface waters will result in the formation of similar soluble inorganic lead compounds. Variation in the level of availability or bioavailability does not negate the consistency of effect across the members of the category.

EPA would like to remind the commenters that a mechanism already exists under EPCRA section 313 to address concerns for any metal compound for which the data show that the metal can never become available. Thus, the issue of availability, which is broader than the issue of a compound's potential to bioaccumulate, was addressed previously for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (May 23, 1991, 56 FR 23703). If a petitioner has information demonstrating that a particular lead compound does not cause toxicity as the intact lead compound, and will not cause lead to be available in the environment to express its toxicity, they can submit a petition pursuant to EPCRA section 313(e)(1) to delete that specific lead compound from the EPCRA section 313 list of toxic chemicals. Under the metals policy EPA considers whether the metal from a metal compound can ever become bioavailable under abiotic or biotic conditions. An assessment of the availability and bioavailability of a lead compound would include processes such as: hydrolysis at various pHs; solubilization in the environment at

various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformations (both abiotic and biotic); bioavailability when the compound is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the material is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the compound will lodge in the lungs and be converted a soluble compound by the lung's defense mechanism).

If the commenters have information demonstrating that a particular lead compound does not cause toxicity as the intact lead compound, and will not cause lead to be available in the environment to express the toxicity of the metal, the commenters can submit a petition pursuant to EPCRA section 313(e)(1) to delete that specific lead compound from the EPCRA section 313 list of toxic chemicals. EPA would address such a petition in accordance with the Agency's longstanding stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703).

6. *What comments did EPA receive that pertain to natural vs. industrially produced lead and lead compounds?* Some commenters contend that natural forms of lead, as opposed to industrially produced lead compounds, should not be classified as PBT chemicals. Other commenters state that because lead occurs naturally, industrial activities involving lead do not change the total amount of lead in the earth; these activities only affect the form and location of the lead in the environment. These commenters believe that the forms of lead that are produced by industrial activity tend to be more hazardous and should be regulated more strictly than the natural forms, such as trace amounts of lead in natural minerals.

EPA disagrees that natural lead compounds should be treated differently than industrially produced lead compounds. While the comment was made specifically for lead it is general to all metals and metal compounds. Both naturally occurring and industrially produced lead and lead compounds, meet the persistence and bioaccumulation criteria. EPA's analysis of the environmental fate of lead demonstrates that it is reasonable to anticipate that under environmental conditions lead can become available from lead compounds, and that whether lead or lead compounds are obtained naturally or produced industrially does

not change the potential for availability of lead. Whether a chemical comes directly from the ground or from a manufacturing plant will not affect whether the chemical is toxic, persistent, and bioaccumulative. These are the result of the inherent properties of the chemical, not from their origin (all other things being equal).

The Agency recognizes that lead and certain lead compounds occur naturally. EPA agrees that industrial activities involving lead do not change the total amount of lead in the earth, and that industrial activities involving lead only affect the type of lead compound and its location in the environment. The Agency believes, however, that while industrial activities do not increase the total quantity of lead in the earth, industrial activities transport lead and lead compounds from one environment to another environment in which the likelihood of exposure to lead in aquatic and terrestrial species, and humans is increased. As discussed in the PBT rulemaking (64 FR 688-729), environmental conditions can vary greatly among geographic locations, even those that are in close proximity to one another. There may be certain geographical areas in which the environmental conditions are such that lead availability from a naturally occurring lead compound may be equal to or greater than that from an industrially produced lead compound.

D. What Comments Did EPA Receive Concerning the Persistence and Bioaccumulation of Lead and Lead Compounds?

In the proposed rule to lower the thresholds of lead and lead compounds, EPA discussed its scientific basis for preliminarily characterizing lead and all lead compounds as highly persistent and highly bioaccumulative. To summarize, the data on lead's persistence in the environment, the observed high bioaccumulation values in aquatic organisms, and lead's ability to accumulate in humans were the basis for EPA's preliminary conclusion that lead and lead compounds are highly persistent and highly bioaccumulative. EPA has also evaluated the bioavailability of lead and lead compounds and has concluded that lead is bioavailable. In the proposed rule the Agency specifically requested public comment on its discussion of the scientific information concerning: (1) The fate, transport and availability of lead in the environment and how this information should be considered in classifying lead as a PBT chemical (Unit V.A.); (2) the bioaccumulation of lead in aquatic organisms, and how this

information should be evaluated in assessing the bioaccumulative potential of lead and lead compounds (Unit V.B.); (3) the bioaccumulation of lead in humans, and how this information should be considered in classifying lead and lead compounds as highly bioaccumulative (Unit V.C.); and (4) abiotic factors (e.g. soil chemistry; pH; water hardness; presence of organic matter in aqueous media) that can diminish the bioavailability of lead in aquatic species.

The Agency received many comments regarding EPA's technical basis for preliminarily characterizing lead and lead compounds as highly persistent, and highly bioaccumulative. These comments were extensively reviewed and considered by the Agency in finalizing the rule. While some of the commenters agreed with the Agency's characterization of lead and lead compounds as highly persistent and highly bioaccumulative, the majority of the commenters disagreed. Most of the comments were similar in content, and pertained to general or specific issues dealing with persistence, bioaccumulation and toxicity, as well as EPA's use of persistence and bioaccumulation data pertaining to lead and lead compounds in characterizing these chemicals as PBT substances. Lead and lead compounds are included on the EPCRA section 313 list of toxic chemicals. EPA is not responding to comments on the toxicity of lead and lead compounds, because their inclusion on the EPCRA section 313 list of toxic chemicals is not at issue in this rulemaking. After consideration of all comments submitted in response to the proposed lead rule, EPA concludes that lead is highly persistent and, at the least, bioaccumulative and defers its determination as to whether lead is highly bioaccumulative. An explanation for EPA's conclusion that lead is at least bioaccumulative is provided below. The basis for EPA's conclusion that lead is highly persistent is provided elsewhere.

In the PBT chemical rulemaking, EPA described bioaccumulation as "the process by which organisms may accumulate chemical substances in their bodies" (64 FR 703) and defined the term as the "net accumulation of a substance by an organism as a result of uptake from all environmental sources." (64 FR 703) EPA has a concern for those toxic chemicals that are bioaccumulative and a particular concern for that subset of PBT chemicals that are highly bioaccumulative.

There are extensive, high quality human data (64 FR at 42230-31) that clearly indicate that lead and lead

compounds bioaccumulate in humans, i.e., humans accumulate lead as a result of uptake from environmental sources. These data include bioaccumulation data on a number of subpopulations of humans, such as children, pregnant women, postmenopausal women, and men. Therefore, these human data support EPA's conclusion, as discussed below, that lead and lead compounds are bioaccumulative. EPA believes that these data would tend to support a finding that lead is also highly bioaccumulative because (1) the data are human data and (2) these data conclusively demonstrate that lead bioaccumulates in humans. EPA believes that these two factors are relevant to a determination that lead and lead compounds are highly bioaccumulative because human data are generally more compelling than animal data, particularly where there are multiple, high quality studies on a broad range of individuals. Thus, these data are sufficiently conclusive that there is no question that lead and lead compounds bioaccumulate in humans.

While evaluation of these data might affect EPA's conclusion as to whether lead and lead compounds are highly bioaccumulative, EPA recognizes that it did not clearly articulate in the proposed rule how human data would be used to distinguish between bioaccumulative and highly bioaccumulative chemicals. Because of this, EPA is deferring at this time the classification of lead and lead compounds as highly bioaccumulative solely on the basis of the extensive human data.

A number of industry commenters have contended that BCFs and BAFs measured for metals (including lead), and in particular essential elements, are not representative of the potential of these substances to bioaccumulate. They claim that the variability of the measured BCFs/BAFs with changing water concentration of the chemical makes it difficult to determine the most representative BCF/BAF value for a particular species. Specifically, these commenters contend that there is an inverse relationship between the measured BCF/BAF values and water concentration. Some commenters assert that only the values measured at higher water concentrations should be used, i.e., the lower BCF/BAF values. Other commenters contend that BCFs and BAFs are not meaningful measures for the bioaccumulation of metals and, therefore, cannot be used.

EPA disagrees that this is the best characterization of the bioaccumulation data for metals, including lead, in aquatic species. While this type of

relationship may exist for some species and/or some metals, for other species and/or metals other relationships are observed: (1) Constant BCFs/BAFs with increasing water concentration; (2) increasing BCFs/BAFs with increasing water concentration; and (3) varying BCFs/BAFs values with constant water concentration.

EPA disagrees that the BCF/BAF data cannot be used to determine the potential for lead, which is not an essential element, to bioaccumulate. EPA recognizes that some data suggest that the relationship between bioaccumulation and water concentration of lead could be characterized as inverse for some organisms, such as fish, algae, and phytoplankton. Such a characterization, however, is incorrect for invertebrates such as snails and bivalves because there is little variation in BCF value with changing water concentration for these species. Further, EPA does not believe that even where the data suggest an inverse relationship, this precludes the use of BCFs and BAFs in assessing the bioaccumulative potential of lead. EPA notes that even for some species in which an inverse relationship is suggested (e.g., algae and phytoplankton), if EPA were to use the BCF or BAF at the highest water concentration measured (i.e., the lowest measured BCF/BAF value) the BCF/BAF values remain over 5,000.

EPA has determined that the data on oysters, snails, algae, phytoplankton, and blue mussels, as well as the human data, clearly support a conclusion that lead and lead compounds are bioaccumulative, and also believes that this information tends to support a finding that lead is highly bioaccumulative. However, during the public comment period and during inter-Agency review, questions were raised challenging the sufficiency of the data to support the conclusion that lead and lead compounds are highly bioaccumulative. Before determining whether lead and lead compounds are highly bioaccumulative, EPA believes that it would be appropriate to seek external scientific peer review from its Science Advisory Board, and EPA intends to do so. The external peer review would address the question of whether lead and lead compounds should be classified as highly bioaccumulative. The external peer review would address the issue of how lead and other, as yet unclassified, metals such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations. After

the completion of the external scientific peer review, EPA will consider and take appropriate action, which could include characterizing lead and lead compounds as highly bioaccumulative and lowering the reporting thresholds for lead and lead compounds to 10 pounds.

Therefore, at this time, EPA concludes that lead is, at the least, bioaccumulative and defers its determination as to whether lead is highly bioaccumulative until further review.

1. *What comments did EPA receive on the environmental fate of lead and lead compounds?* In the lead proposed rule (64 FR 42227) the Agency provided a qualitative environmental fate assessment of lead and lead compounds. Qualitative environmental fate assessments are generally part of a hazard assessment for a chemical. The qualitative environmental fate assessment was not developed, nor was it intended, to be part of an exposure assessment or risk assessment.

An environmental fate assessment for a metal and metal compounds, such as lead and lead compounds, describes the physical, chemical, and biological processes acting upon the metal and metal compound in the environment and the result of these processes. 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 Agency received many comments on its assessment of the environmental fate of lead and lead compounds and the influence of environmental fate on the environmental availability of lead and lead compounds. Commenters contend that normal environmental processes control the availability of lead and lead compounds in water, soil and sediments and concluded that under most environmental conditions lead from lead and lead compounds would not be available for uptake by organisms due to processes including the pH dependent formation and precipitation of insoluble lead compounds in surface waters, and sorption of lead to organic matter and inorganic constituents in soil, surface waters and sediments.

EPA disagrees with these commenters and concludes that processes commonly observed in the environment can result in the formation of available lead where it can be bioaccumulated by organisms. EPA believes that these processes may occur in soil environments with low pH and low levels of clay and organic matter. Lead sorption to soils has been shown to be pH dependent. Decreasing pH can result in increasing concentrations of lead in soil water with

greater availability for uptake by biota. In acidic aquatic environments, low levels of suspended solids and dissolved organic matter can result in increased levels of lead ion in solution where it can be taken up by biota.

One commenter believes that the environmental fate data that EPA used and cites in the proposed rule falls short of what is necessary for a scientifically valid approach to assessing the transformation, specification, and availability of lead in the environment. The commenter argues that the data cited by EPA indicate that very little of the lead released to the environment is likely to be present in a "bioavailable form" (i.e., EPA concluded that less than 1% of lead in soil may be water soluble).

EPA disagrees with the commenter's characterization of EPA's assessment of the environmental fate of lead and lead compounds. EPA asserts that it used reliable data from a variety of credible sources in concluding that lead can be available for uptake by organisms in the environment and that lead is environmentally available. EPA refers the commenter to the discussions of the transformation, speciation, availability and bioavailability of lead in the environment provided in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) and elsewhere in the RTC document for this final rule (Ref. 1). EPA disagrees with the commenter's interpretation of the statement "EPA concludes that less than 1% of lead in soil may be water soluble" to mean or indicate that very little of the lead released into the environment is likely to be present in a "bioavailable form". Simple water solubility is **not** a prerequisite for a metal to become available from a metal compound. It is well established that certain environmental conditions can increase the solubility of a metal compound. Further, as discussed in Unit VI.C.2. of this preamble and in the RTC document (Ref. 1), availability of a metal is not a prerequisite for its bioavailability. Metals may be bioavailable from metal compounds or metal complexes that are not water soluble or in which the metal is not otherwise available. A classic example that illustrates these points are the well documented incidents of childrens' exposure to lead from consumption of soil that contains lead. While less than 1% of lead in soil is typically present as a lead compound that is water soluble (i.e., more than 99% is present as lead compounds that are water insoluble or bound to soils), the lead in soils is still bioavailable in humans.

EPA has concluded that lead released to the environment, whether under conditions where it is available or not, can reasonably be expected to be bioavailable in organisms. EPA's statement "that less than 1% of lead in soil may be water soluble" should not be interpreted to mean that the levels of lead in soils that is available are inconsequential or negligible. On the contrary, because exposure to even low levels of lead are expected to result in its bioaccumulation in many organisms, these levels are still of concern. It should be noted that if 1 percent of soil lead is soluble (i.e., available), this would mean that levels as high as 200 parts per billion (ppb) could be found in soil water (lead is present in many soils at 20 parts per million (Ref. 2) and one percent of this is 200 ppb.)

One commenter believes that the bioavailability of lead and lead compounds is only prevalent in those situations in which an organism would be exposed to continuous, localized influxes of lead compounds, such as near a lead smelter or a highway. The commenter believes that the proximity to sources of lead, such as smelters or highways (influenced by use of leaded fuels), is a prerequisite to high concentrations of the metal in the environment, and thus its potential to bioaccumulate. The commenter cites studies that provide data that show high levels of lead in waters and soils that are in close proximity to sources of lead releases (e.g., smelters, vehicular exhaust), and bioaccumulated lead in freshwater algae, invertebrates, and fish collected near industrialized areas, ponds with high numbers of lead shot, urban areas, lead mines and tailings ponds. The commenter states that although lead may be considered ubiquitous in the environment, its ecological impacts would appear to be significantly influenced by the proximity to sources of lead releases and the public should be aware of this. While the commenter used the term bioavailability, based on the context of the comment, EPA believes the commenter used the term interchangeably with the term environmental availability.

While the concentrations of lead in the environment are more likely to be higher in areas that are in close proximity to facilities that manufacture, process, or otherwise use lead and/or lead compounds, EPA disagrees with the commenter's contention that the availability of lead is only possible in such areas. EPA does not agree with the commenter's position that in order to be exposed to lead an organism needs to be in close proximity to points where lead

is released into the environment. As discussed in Unit V.A. of the proposed rule (64 FR 42227), and in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) many factors influence the mobility and disposition of lead in the environment. Under many environmental conditions lead may become mobile rather than remain stationary. Depending upon prevailing conditions and the method of environmental release, lead may travel within environmental media to areas that are not in close proximity to the point of release. Hence, EPA believes that the presence of lead in the environment, and therewith its availability, is not confined to the areas where lead is released from anthropogenic sources. In addition, any release of lead is important to local communities, because of lead's persistence and bioaccumulative properties. Although EPA disagrees with the commenter's conclusions, the commenter's statement that the ecological impacts of lead are influenced by the nearness to a source of release still provides support for the actions that EPA is taking in this rulemaking.

a. What comments did EPA receive on the abiotic factors that may affect the environmental availability of lead? Several commenters stated that EPA either did not, or should have considered speciation, transformation and bioavailability in its assessment of the persistence of lead and lead compounds. Some of the commenters contend that in most environments lead is either not available or is transformed into forms that are less available. A number of the commenters claimed that the environmental conditions in which lead is mobile or available are rare.

EPA disagrees with the commenters claim that the Agency did not consider speciation, transformation and bioavailability in its characterization of lead and lead compounds as PBT chemicals. As discussed in detail in: Unit V. of the proposed lead rule (64 FR 42222-42243); in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2); elsewhere in this preamble; and in the RTC document (Ref. 1), EPA performed a comprehensive assessment of the environmental fate of lead. The environmental fate assessment embodied an analysis of the environmental variables that affect speciation, transformation, and the availability of lead. These environmental variables include: pH; redox conditions; water hardness; dissolved organic carbon content; and soil properties including cation exchange capacity, organic carbon

content, iron and manganese oxide and phosphorus content. As discussed in Unit VI.D.3., EPA has evaluated the bioavailability of lead and lead compounds and has concluded that lead is bioavailable. From its analysis of the environmental fate of lead, EPA concluded that environmental conditions exist in the United States in which lead may become available or that can increase the availability of lead, even from compounds in which lead, as released into the environment, is not available. From its analysis of the bioavailability of lead, EPA concluded that lead is bioavailable in many aquatic species, and in humans. EPA also concluded that lead compounds that are not available or bioavailable as released may be converted to lead compounds that are available or bioavailable. Thus, after an evaluation of the available data, EPA has determined that the weight of scientific evidence indicates that it is reasonable to conclude that lead in the environment will be available and/or bioavailable from lead and lead compounds.

EPA disagrees with the commenters who claim that the environmental conditions in which lead is mobile or available for uptake are rare. As detailed in Unit VI.C. of this preamble and in the RTC document (Ref. 1), EPA conducted several analyses of large databases containing information on the properties of rivers, streams, lakes, and soils in the United States, with a focus on the properties known to contribute to the availability of lead. Acidity is a particularly important determinant of lead availability: acid conditions (pH < 7) increase lead availability. In water, the solubility and, hence, availability of lead increases linearly as acidity is increased (i.e., from pH 6 to 3). EPA determined that waters of sufficient acidity to favor lead availability, especially in the Mid-Atlantic region of the United States, are not rare. In fact, estimates indicated that almost 11,000 kilometers of streams could have a pH of < 5.5. In addition, as detailed elsewhere in this document, a query of EPA's STORET water quality database indicated that in 1998 pH values of between 5.5 and 5.1 were found in 52 watersheds in the United States. Finally, the commenter asserts that acidic soils in which lead is likely to be available are rare. EPA's analysis of the database of the Soil Survey Laboratory, National Soil Survey Center, discussed in Units VI.C.1. and VI.D.1. of this preamble, found more than 10,000 surface soil samples with low cation exchange capacity and pH values of less than 5.5.

One commenter supports EPA's concern for cross media transport of

chemicals, but believes that it is misleading for EPA to imply that lead is predisposed to find the medium in which it will be transformed into forms that have the "greatest bioavailability (in) man". The commenter agrees that lead cannot be destroyed but, equates this attribute to most elements on the periodic table.

The commenter incorrectly asserts that EPA suggested that lead and lead compounds are released only to, or preferentially partitions to, those environments that are most favorable to enhancing availability or bioavailability of lead. EPA disagrees with the commenter. EPA has not made the claim that lead and lead compounds are released only into those environments where conditions are most favorable to the formation of the most soluble lead compounds. In EPA's discussion of the environmental fate of lead and lead compounds, EPA assessed the availability of the lead and lead compounds under a variety of conditions in water, sediments and soil. As discussed elsewhere, EPA believes that there are many environmental conditions in which lead and lead compounds will be available and/or bioavailable.

b. What comments did EPA receive on the availability of lead in surface waters and sediments. One commenter stated that there are many studies that indicate that lead does not persist in soluble and bioavailable forms in aquatic environments. The commenter cited work reported by May and McKinney (Ref. 33) which, according to the commenter, has shown that the majority of lead entering natural waters will be precipitated to sediments as carbonates or hydroxides (i.e., will be unavailable). The commenter states that even in acidic lake waters, "which according to EPA's own reports are rare", lead can precipitate out of the water, and cites work by White and Driscoll (Ref. 34) to support this position. Another commenter states that there is strong evidence to suggest that under conditions where organic material is present in the water column of an aquatic environment, the organic material will act to reduce the amount of potentially soluble and bioavailable lead. The commenter believes that the wide distribution of organic matter suggests that the potential for the reduction of soluble lead by complexation with organic material is high.

EPA disagrees with the argument that soluble and/or bioavailable lead compounds are irreversibly transformed into insoluble and un-bioavailable lead compounds. EPA discusses below and

elsewhere that many lead compounds that form as a result of conditions in the aquatic environment (e.g., lead-organic matter complexes, inorganic precipitates, carbonates and hydroxides) are not necessarily permanently sequestered as a non-available lead compound, but are subject to processes that can result in their release back into solution. A review of the discussion of the fate of lead in natural waters in May and McKinney (Ref. 33) revealed a single sentence that says: "Upon entering natural waters, most lead is precipitated to the sediment bed as carbonates and hydroxides." While this statement is true for some surface waters in the United States, EPA has concluded for the reasons discussed below and elsewhere in this preamble and in the RTC document (Ref. 1) that lead solubility is greater and precipitation as carbonate and hydroxide is less in acidic waters with low hardness.

White and Driscoll (Ref. 34) observed temporal and spatial variations in the concentration and transport of lead in the acidic Darts Lake in the Adirondacks of New York. Deposition of particulate lead was strongly correlated with aluminum and organic carbon deposition. Increasing metals deposition was observed during periods of increasing pH. The flux of lead into the lake was related to stream hydrology, pH and lead concentration. Stream pH varied seasonally, with a steady pH of 5.1 until spring snowmelt, where pH levels dropped to a minimum of 4.8 in April/May. Increases in pH occurred throughout the summer reaching a maximum of 5.4 in August. High flow periods in the fall and spring were marked by increases in the concentration of dissolved lead in the inlet and outlet streams. Lead flux to and from the lake was greatest during spring and fall periods of high lead concentrations, elevated water discharge, and low pH. The authors explain that even in acidic lake water containing a variety of particle types, oxides and organic films may determine the surface properties of suspended particulate matter. The solid matrix in the lake was probably composed of inorganic hydrous oxides (coatings) and adsorbed or coprecipitated organic matter. The interaction of lead with this matrix appears to be pH sensitive. Changes in pH may affect lead partitioning between the solid and solution through a number of possible mechanisms: matrix formation/dissolution, sorption/desorption of organic complexes and inorganic complexes, and hydrogen ion exchange reactions.

Contrary to the commenter's interpretation, EPA believes that the study by White and Driscoll (Ref. 34) provides evidence that even in the presence of dissolved organic carbon, soluble lead may be present in the water column of acidic waters, possibly through a process of sedimentation and decomposition of organic matter and/or dissolution of redox sensitive hydrous oxides.

Two commenters contend that the majority of lead entering aquatic systems will be removed from solution and become bound to sediments and/or suspended particulate matter. They believe that the lead that partitions to sediments is not expected to be readily bioavailable. The commenters contend that the availability of lead in sediments is controlled by several physicochemical factors including pH, organic carbon (particulate and dissolved), iron and manganese oxyhydroxides, and sulfides. In aerobic sediments, the main factors that drive the formation of insoluble lead are particulate organic carbon and iron/manganese oxyhydroxides. In anaerobic sediments, which represent the overwhelming majority of sediments, acid-volatile sulfides (AVS) are the main binding factor.

The commenter contends that if the concentration of AVS is greater than that of lead that is simultaneously extracted from the sediments, the lead will not be environmentally available. Further they state that EPA is currently considering using this concept to derive national sediment quality criteria for lead and other metals such as zinc, cadmium, and copper. In addition, the commenter contends that although events such as storms or dredging may cause a re-suspension of sediments (thus temporarily changing the physicochemical properties of the sediment), several studies have shown that these events do not have a large impact on the binding of metals such as lead to the sediments, and found that no significant release of lead occurred from dredged sediments being suspended in waters. The commenters claim that other studies have shown only a small portion of metals are released from sediment due to re-suspension and oxidation of the sediments.

EPA agrees that the environmental processes that determine the complexation, speciation, and ultimately the availability of lead in the environment should be considered in its present analysis and asserts that these have been considered. EPA believes that the AVS methodology shows great promise for use in conducting *site-specific* assessments of metals for which

it has been validated. To date, the AVS methodology has not been validated for lead, nor have the generally favorable, albeit substantive technical comments provided by the EPA Science Advisory Board been incorporated into the methodology. Finally, EPA does not believe that a means currently exists to incorporate the AVS methodology into the technical analysis supporting a *nationally* applied regulation such as this rule.

EPA disagrees with the commenter's conclusions regarding sediment-bound metals, and the commenter's inference that once lead becomes bound to sediments it is no longer available. EPA has found that several researchers have investigated the impact of the oxidation of sediment constituents on the release of sediment-bound metals and found that metal availability can increase under these conditions. For example, Zhuang et al. (Ref. 35) found that the aeration of sediment resulted in the rapid oxidation of a major binding constituent, acid-volatile sulfide. In experiments conducted over a 1 month duration, the concentration of cadmium increased 200-400 percent. The oxidation of AVS occurred rapidly with a concomitant decrease in pH, and the release of cadmium from the solid to the liquid phase continued for approximately 2 weeks. The authors noted that aeration of sediments results in only a portion of the associated cadmium, and presumably other toxic metals, being released to water. Sedimentary iron and manganese are transformed to their oxyhydroxides by the oxidation of sulfide. Following the formation of iron and manganese oxyhydroxide, the binding of cadmium is transferred towards these solid phases. Approximately 50% of the cadmium bound in sediments is associated with the extractable iron and manganese components of the sediment following aeration. In addition, oxidation of the sulfidic phase releases other metals that compete with cadmium for available binding sites. EPA believes that it is important to note the following from the authors' conclusions:

Prediction of biological availability of metals in sediments based on the relationship between metal and AVS concentrations may be underestimated if the sediment is subject to aeration.

Thus, experimental data exist that indicate that cadmium, and presumably other toxic metals including lead, bound to sediments can become available. The data also suggest that contrary to what the commenter believes, the AVS methodology does not always provide an accurate estimate of lead availability

when certain, realistic environmental conditions exist.

Other studies demonstrated the availability of lead in aquatic environments. Mahoney et al. (Ref. 36) examined the partitioning of metals, including lead, to organic carbon in 14 different freshwater sediment samples. The metal sorption due to acid volatile sulfide was subtracted from the total sorbed metal to determine the metal bound to other sediment phases (primarily organic carbon). The results indicated that organic carbon partition coefficients for lead were reduced by a factor of 10 with a decrease in pH from pH 7 to pH 6. The authors fit the sorption data to the Langmuir model. The results were consistent with a surface complexation model where binding sites are occupied by either protons (H^+) or metal ions. At lower pHs, the protons compete favorably for the sites, whereas at higher pHs where protons are fewer in number, free metal is removed from solution by organic carbon sorption. This study illustrates that in sediment water systems at pH values in the physiological range, lead can be available for uptake by organisms even in the presence of organic carbon.

Another commenter states organic matter, using as an example humic acids, present in freshwater and marine sediments and in the aqueous phases are capable of complexing variable amounts of metals. The commenter states that most lead entering natural waters is sorbed onto organic ligands and precipitated as insoluble complexes to the sediments as lead carbonate and hydroxide (Ref. 37). The commenter also states that the lead from these complexes may be mobilized and released back into the water column, but only when the pH is decreased suddenly or the ionic composition of the water changes. The commenter claims that both natural soluble organics (e.g., dicarboxylic and amino acids) and synthetic soluble organics (e.g., ethylene diaminetetraacetic acid (EDTA)) act as chelators (i.e., sequestering agents) of lead, and reduce the toxicity of heavy metals such as lead because chelated forms of metals are less toxic than their free, non-complexed forms. The commenter cites work by Canterford and Canterford (1980), which shows that EDTA reduced the toxicity of lead to the diatom, *Ditylum brightwellii*.

EPA believes that the data in Eisler (Ref. 37) cited by the commenter supports EPA's contention that lead can be available in the sediment/water environment under low pH conditions. EPA has discussed the role of organic matter and pH in decreasing the availability of lead and lead compounds

in the aquatic environment elsewhere in this preamble (see also Ref. 2). EPA recognizes the important role of organic matter and pH on the availability of lead and lead compounds in the aquatic environment and the effect of pH on the sorptive behavior of organic matter. However, EPA has commented elsewhere that waters with low organic matter and low pH are widely distributed throughout the United States. EPA believes that lead can be available in such environments. In addition, while EPA believes that lead sorbed onto organic matter may be temporarily unavailable, EPA does not agree that lead sorbed onto organic matter is no longer *bioavailable*. Many aquatic species (e.g., mussels, fish) consume orally as part of their diet organic matter in their environment. Lead sorbed to organic matter may be bioavailable in organisms that consume the organic matter. The same holds true for terrestrial species. Lead sorbed to soils, for example, is bioavailable in humans (See Unit VI.D.2. of this preamble).

c. What comments did EPA receive on the availability of lead in soils. One commenter claims that EPA's data on the fate of lead in terrestrial environments do not support the Agency's conclusion that lead is expected to be bioavailable when in terrestrial environments. The commenter states that EPA fails to provide information about the probability of the natural occurrence of the conditions that could result in the formation of soluble/bioavailable lead species.

EPA believes that soils possessing properties that are conducive to the increased mobility of lead are by no means uncommon. In order to determine the extent to which soil samples collected across the United States possess such properties, EPA conducted a query of the database of the Soil Survey Laboratory (SSL), National Soil Survey Center. The database currently contains analytical data for more than 20,000 pedons of U. S. soils and about 1,100 pedons from other countries. Most of the data were obtained over the last 40 years. Of these, about 75 percent are less than 20 years old. Coverage is for all 50 states, Puerto Rico, Virgin Islands, Trust Territories, and some foreign nations. The search was designed to identify soils with a pH of less than 5.5 and a cation exchange capacity (CEC) of less than 10 milliequivalents (meq) /100 grams. The results of this search identified more than **10,000** samples that meet the criteria.

Many investigators have studied the speciation, mobility, and availability of lead in soils. The EPA concludes from this body of work that although lead binds to many soils, under many natural environmental conditions it will, or at least can be expected to be available for uptake by organisms. Reddy, et al. (Ref. 38) studied the speciation of lead in water extracts from soil samples from the Powder River Basin in Wyoming. Dissolved concentrations of lead were found to be 0.003 to 0.046 mg/L. Chemical speciation indicated that at near neutral pH, dissolved metal concentration in soil water extracts was dominated by dissolved organic carbon-metal complexes. At low pH, dissolved metal concentration in soil water extracts was dominated by free ionic oxidation states, (e.g., Pb^{+2}). The results suggest that as soil pH decreased, the availability and mobility of lead ions increased due to the lead compound in which the metal is present in soil solutions. Wang and Benoit (Ref. 39) investigated the mechanisms controlling the mobility of lead in soils of a northern hardwood forest ecosystem. The authors observed that about 50% of total filtrate lead (passing through a 0.45 um filter) was found to be in the colloidal form below the soil surface organic layer. Colloidal lead concentrations in deeper horizons were less than 10% of the concentrations in the surface layer. Less than 10% of the dissolved lead was found to be complexed to organic substances. A calculated distribution of inorganic lead species indicated that at the pH of the soil solutions tested (4.0 to 4.7), free, dissolved ionic Pb^{+2} dominated and other complexes and ligands were negligible. Low pH resulted in Pb^{+2} desorption from soil solids. However, because both colloidal and dissolved lead were effectively removed during transport down the soil profile, mobilized lead from the surface organic layer was retained in lower soil horizons. Although this study suggests that under the conditions investigated, lead does not migrate to an appreciable extent through the soil profile, EPA believes it gives a strong indication that lead may be available in the acidic organic surface horizon.

The effects of redox potential and pH on the solubility of lead in contaminated soil were investigated by Chuan et al. (Ref. 40). Lead was sparingly soluble at pH 8.0 and more soluble at pH 5.0; solubility increased considerably at pH 3.3. At the same pH, solubility increased as the redox potential decreased. However the effect of pH was more significant than redox

potential. It was proposed that lead in soil was primarily adsorbed to iron-manganese (Fe-Mn) oxyhydroxides and the pH dependent adsorption and dissolution of the Fe-Mn oxyhydroxides under reducing conditions controlled the solubility of lead in soil. EPA believes that the indication of increased lead solubility at pH 5 suggests that in many soils lead could be available for uptake by organisms.

Murray *et al.* (Ref. 41) analyzed the distribution of lead in surface and subsurface soils at an outdoor shooting range in southeastern Michigan that had been in operation for 50 years. It was found that the distribution of lead in the subsurface corresponded to that in the surface soil horizon, suggesting that lead was mobilizing and migrating downward through the vadose zone. Mobilization of lead appeared to be occurring despite the clay-rich nature of the soils, and was thought to be due to the transformation of metallic lead into soluble lead carbonate and lead sulfate. Both compounds were found in crust material coating shot pellets found below a depth of about 5 cm at the site, thus implying a reaction between the metallic lead and the soil. The evidence of the apparent mobility of lead under conditions thought to decrease mobility further indicates that lead is available for uptake in soils.

Laperche *et al.* (Ref. 42) studied the use of soil phosphorous amendments as a means of reducing the availability of lead in contaminated soils. In this study soil contaminated with lead was treated with natural and synthetic phosphorous, and the bioavailability of lead in plants was determined in plant uptake studies with sudax (*Sorghum bicolor*). The lead content in the shoot tissue decreased as the quantity of added phosphorous increased, due to the formation of insoluble lead phosphate compound pyromorphite. However, lead and phosphorous contents in the roots increased as the quantity of added phosphorus increased. The formation of pyromorphite on root surfaces was also observed. It is important to note that in the absence of phosphorous amendments, lead content in the shoot was 170 mg lead/kg dry weight, whereas with the most effective phosphorus treatment, lead content in the shoot was 3 mg lead/kg dry weight. This strongly suggests that in soils with low phosphorus content, lead can be available for uptake by plants.

One commenter believes EPA does not adequately address the important role of cation exchange capacity of soils as it relates to the availability of lead and lead compounds. The commenter states that at pHs of 5 to 9, clays possess

surfaces that are predominantly negative and to which charge-compensating cations are adsorbed. The commenter claims that these cations are not permanently bound to the clays and are being exchanged by other cations, including heavy metals such as lead, copper, and cadmium.

EPA has discussed the effects of pH and cation exchange capacity on the availability of lead in soils in Unit VI.C.2. of this preamble and in the RTC document (Ref. 1). EPA recognizes the important role of cation exchange capacity of soils in the availability of lead and lead compounds, and the effect of pH on the sorptive behavior of clays. The cation exchange capacity of soils is related to the clay content of the soil. Soils with low clay content and low cation exchange capacity are common and widely distributed. EPA has concluded that lead can be available in such soils.

A commenter summarized research results published by Zimdahl and Skogerboe (Ref. 43), and stated that the research showed that soils have a strong capacity to immobilize lead, and that lead tends to become associated with the organic fraction of soil particles. The commenter states that the authors concluded that this sorption is less likely to be affected by low pH (acidification) than would acid ion precipitates (carbonates, phosphates, sulfates, chlorides). The commenter also claims that these investigators concluded that plant uptake studies strongly support their conclusions about the immobilization of lead and its sorption to organic matter in the soil.

EPA reviewed the publication by Zimdahl and Skogerboe (Ref. 43). In the discussion section of this publication the authors provide the following overview regarding the behavior of lead in soils:

* * * the movement of lead in the soil profile and its ultimate fate may be determined by one or more of several processes. These depend largely on the dissolution of the lead particles in the ground water. The lead dissolved may be leached through the soil profile if it remains in a soluble form. It may be immobilized by soil microorganisms, precipitation, sorption or ion-exchange interaction with soil entities (e.g., clays) or fixation by materials such as organic matter. It may also be taken up by plants, thereby entering the food chain. ... The significance of this possibility is reflected in the demonstrated toxicity of lead to corn, beans, lettuce, and radishes in lower concentrations in slightly acidic soil. These and other studies suggest that lead in soil can reach the soil plant root interface and be taken up by plants.

In their investigation of the factors controlling the mobility of lead in soils

the authors developed a correlation function based on the soil properties determined to be most strongly correlated with soil immobilization of lead (pH and cation exchange capacity). Precipitation by carbonate and sorption by hydrous metal oxides appeared to be of secondary importance. They concluded that lead will be twice as mobile (i.e., available) in soil with a pH of 4.1 and a CEC of 13 meq/100 g as in a soil with a pH of 6.8 and a CEC of meq/100 g. EPA believes the findings of Zimdahl and Skogerboe do not conflict with EPA's environmental fate analysis of lead and lead compounds. EPA agrees that the authors determined that some soils have the capacity to decrease the mobility of lead, but equally as important, the study provided a means to estimate the effect that a soil's properties can have on decreasing its capacity to immobilize lead, thereby increasing availability.

One commenter disagrees with the contention of other commenters that lead and lead compounds should not be considered persistent because when released to the soils they will not be bioavailable. The commenter asserts that because metals released into the environment do not always immediately become bound to particles, nor do they remain bound given pH and other changes, and because metals bound to soil particles are ingested by young children, there are strong reasons to be concerned solely about the persistence of toxic metals.

EPA agrees with the commenter that lead released to the environment may not become immediately bound and that there are environmental conditions that will increase the availability of lead in soils. One example is the effect of pH on lead compounds. For example, lead when part of a compound which has low solubility at neutral to basic pH will be converted into soluble compounds when subject to acid mine drainage. The soluble lead compounds will be mobile and may travel through the environment. When these compounds experience higher pH their mobility will decrease and the availability will decrease. However, the availability in many cases will be greater than in the original lead compound. The lead may be part of a lead compound (e.g., carbonate) in which it is much more available than in the original lead compound, even if the pH is the same because the lead will be part of a different molecule and this molecule will react to the environment differently than the original lead compound.

Another commenter contended that EPA should have used the Multimedia Equilibrium Criterion (EQC) model to

estimate overall environmental persistence and partitioning of lead. The commenter stated that in the PBT chemical rulemaking, the Agency discussed how it used this model to evaluate the overall environmental persistence of toxic chemicals subject to the proposal (64 FR 702-703). The commenter believes that the EQC model is ideally suited to model the environmental partitioning and persistence of lead.

The commenter is correct in stating that EPA used the EQC model to evaluate persistence and partitioning of toxic chemicals described in the PBT chemical rulemaking. EPA did not use the EQC model for metals in the PBT chemical rulemaking. EPA agrees that the EQC model is a valuable tool for determining the multimedia fate and transport of chemicals in the environment. As described in the PBT chemical rulemaking, however, the EQC model was only used to model environmental persistence and partitioning of organic chemicals, and not of metals. In the PBT chemical rulemaking, EPA based its determination of whether a toxic chemical is persistent based on half-lives for specific media. For organic chemicals EPA used the EQC model to determine if it were possible that a toxic chemical that is persistent in one medium significantly partitions to another medium in which the toxic chemical rapidly degrades thus providing an overall environmental half-life less than the established criteria. The commenter is also correct in stating that the Agency did not use the EQC model to evaluate the environmental persistence and partitioning of lead and lead compounds. As EPA explained in both the PBT chemical rulemaking and the proposed lead rule, metals are persistent because the metal cannot be destroyed. While the EQC model can be used to model the partitioning of a metal and its compounds from one medium to another medium in the environment, it does not model the destruction of the metal because that *cannot* occur.

The Agency would like to point out, however, that Mackay et al. (Ref. 44) used lead as an example of a "class 2" (nonvolatile) substance for an EQC model run. Because lead is classified as a "class 2" chemical, the EQC model treats volatilization of lead from water to air and from soil to air as negligible. Mackay used an infinitely long degradation half-life for lead (i.e., lead is persistent and is not destroyed). When an infinitely long degradation half life is used (as was used by Mackay, et al. for lead in all media) only non-

destructive removal processes such as loss from the air compartment by deposition of airborne particles to soil and water, soil runoff, advection in sediment (loss from the model environment by burial of sediment-bound lead), and transport of sediment bound lead particles out of the model environment are important. The overall environmental persistence of lead estimated by the model reflects the time necessary for lead to be physically transported from the model environment, not destroyed. Thus the model, in essence, provides information on the partitioning and movement of lead, but inevitably indicates that lead will be persistent in all media.

The EQC level III modeling results for lead showed the importance of deposition from the air compartment to soil and water, at a rate that exceeds the advection rate (rate of non-destructive transport out of the model environment). The main removal mechanism according to the model was advection (burial) in sediment, followed by soil runoff and advection in water. The buildup of the chemical in the model environment was about 1.7×10^{10} kg and its overall persistence was 5.6×10^6 hours (634 years), which is essentially infinite duration. In addition, at steady state the model predicted that lead concentration in the water compartment of the model environment would be 4.27 ug/L. For lead the important transport parameters are those controlling atmospheric deposition and sediment-water exchange. EPA believes that, considering the results above and the discussion of the availability of lead in water, soil and sediments provided elsewhere in these responses to comments, the use of the EQC model would not have provided any information counter to EPA's position that lead and lead compounds are PBT chemicals. Thus, even if EPA had used the EQC model to estimate the environmental persistence and fate of lead, EPA would have drawn the same conclusions stated in the proposed rule. In addition, the Agency would like to emphasize that as discussed in the PBT chemical rulemaking the EQC model was only used as a secondary means to evaluate persistence and partitioning of organic chemical substances, and that unless all of the data inputs to the model were reliable it would not be used by the Agency to override persistence data from individual media.

2. *What comments did EPA receive on the bioaccumulation data for lead and lead compounds?* Some commenters contend that EPA failed to consider the results of more recent studies that

indicate that the accumulation of lead in aquatic organisms is low and that the concentrations of lead found in the environment are lower than previously measured. Commenters also questioned the relevance of laboratory bioaccumulation studies on lead to the bioaccumulation of lead under environmental conditions claiming that under "realistic conditions" lead does not bioaccumulate significantly in organisms. As discussed in detail in this section, none of these issues change EPA's conclusions about the validity of the data. With regard to the results of more recent studies, these studies do not provide information that changes EPA's conclusions that lead and lead compounds are bioaccumulative. EPA also believes that the laboratory bioaccumulation studies for lead are relevant to the potential for lead to bioaccumulate, which is confirmed by the observed bioaccumulation of lead in the environment.

As discussed in Unit VI.B. of this preamble, bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. The propensity of a substance to bioaccumulate in a species depends largely upon the pharmacokinetics of the substance in that species. That is, the extent to which a substance can bioaccumulate in an organism depends upon: (1) Whether the organism can absorb the substance; (2) the extent to which the substance is distributed and metabolized within the organism; and (3) how readily the organism can excrete the substance. The pharmacokinetics of a substance, and therefore the propensity for it to bioaccumulate, can (and often does) vary greatly among different species, even among species within the same trophic level. This is because species differ in their anatomy, physiology, and genetic makeup. These are important variables that govern the propensity for a substance to bioaccumulate, in addition to the substance's physicochemical and other properties. It is well established that a given substance can have different BAF (or BCF) values in different species. Data presented in Table 1 of the proposed rule (64 FR 42230) indicates that lead has different BAF (or BCF) values in different species.

In the proposed lead rule EPA preliminarily concluded that lead and lead compounds are highly bioaccumulative based upon the Agency's review of the bioaccumulation data for lead and lead compounds in aquatic species and in humans. Those who commented on EPA's assessment of the bioaccumulative properties of lead

and lead compounds commented on the aquatic data used by EPA and did not comment on or refute the extensive data in humans. A number of commenters disagreed with the scientific basis that EPA used to support the use of bioaccumulation measurements for lead and lead compounds because they believe EPA's scientific basis: does not use relevant data; is insufficient; does not have a sound scientific foundation; or does not present a balanced view of the scientific literature. Other commenters address the issue of bioaccumulation generically, rather than specifically to lead and lead compounds. EPA responded to the generic issues in the earlier PBT chemical rulemaking (64 FR 58676) and in the associated Response to Comments document (Ref. 15). However, EPA is discussing some general issues here as background for the more specific issues related to lead and lead compounds in order to facilitate EPA's responses. Further, while some commenters agree that lead and lead compounds bioaccumulate, they contend that they are not highly bioaccumulative. A discussion of both the aquatic data and the human data used by EPA, and the issues raised by commenters on EPA's use of these data are provided below. As discussed earlier, after having reviewed and considered all the comments, EPA is finalizing this rule with a finding that lead and lead compounds are bioaccumulative, and is deferring its original conclusion that lead is highly bioaccumulative.

a. What comments did EPA receive on the aquatic bioaccumulation data for lead? Aquatic species have their own unique roles in ecosystems and are important for the subsistence of other species, including consumer and predator species. Thus, the propensity of lead to bioaccumulate in aquatic species is of concern. Among other things, aquatic species comprise components of the food chain that lead to humans. For example, green algae are primary producers in aquatic ecosystems in that, through photosynthesis, they produce oxygen and synthesize carbohydrates and other foodstuffs (Ref. 45). These substances are used by consumer species which in turn serve as the food source for predator species, including fish. Fish in turn, serve as a food source for wild mammals, birds, and man. The survival of a number of terrestrial species, including humans, is at least partially dependent upon aquatic organisms. The Agency for the purposes of EPCRA section 313 believes all aquatic organisms to be equally relevant when

evaluating properties of chemicals to aquatic life forms: i.e., an alga is viewed just as important as an oyster or a fish.

EPA's scientific assessment of lead and lead compounds is based upon relevant data and has a sound scientific foundation. EPA believes that the scientific basis that the Agency used to support its conclusion that lead and lead compounds bioaccumulate in aquatic species is more than sufficient, and presents a balanced view of the scientific literature. The effects of lead and lead compounds on aquatic and terrestrial organisms has been studied extensively since the mid-1920s. A particularly active period for lead research was during the 1970s and 1980s, when dozens of studies were completed. In fact lead was one of the first chemicals extensively tested and monitored in water pollution and water quality studies. Thus, there are a plethora of studies available that investigated the environmental fate, availability, bioconcentration and bioaccumulation of lead and lead compounds. The Agency believes that these studies are relevant to an assessment of lead as a PBT substance, and many of these were reviewed by the Agency for the proposed rule. Each study reviewed by EPA in the development of this rule involving bioconcentration or bioaccumulation testing, was initially assessed by the Agency for quality. Not unexpectedly, the studies were found to vary in quality and test results to the subject organisms. Studies that were found to be most consistent with OPPT test guidelines were deemed valid and selected for use in the assessment. These studies covered a variety of different test species.

The results of EPA's assessment of the bioaccumulation of lead and lead compounds in aquatic organisms are summarized in Table 1 of the proposed rule and in references therein (64 FR 42230). As can be seen from Table 1, the BCF values from these studies range from 390 to over 12,000, additional information on BCF values for lead and lead compounds are contained in EPA's support document (Ref. 6). For a number of aquatic organisms that include: freshwater invertebrates such as mollusks, insects, and daphnid crustaceans; freshwater algae and phytoplankton; marine mollusks, a crustacean, and algae, lead and lead compounds bioconcentrate to levels above the baseline BCF criterion of 1,000 and, for some organisms, at or above 5,000. These values are viewed by the Agency as indicators of the potential for increased exposure due to significant bioaccumulation that could occur in

other organisms in the environment that have not been tested. Based on these data EPA concludes that lead and lead compounds are bioaccumulative, and believes that these data tend to support a finding of highly bioaccumulative.

Where a range of lead BCF values was available for a specific organism, EPA evaluated the scientific validity of the studies reporting BCF values and relied upon those studies that were valid and scientifically sound. If valid BCF values meeting, or surpassing, the bioaccumulation criterion used by EPA in this rulemaking (i.e., BCF or BAF values greater than 1000) were identified for a species, EPA relied on these values as evidence that lead meets the EPCRA section 313 bioaccumulation criterion. Although some species may have a range of reported BCF values, in some cases crossing the bioaccumulation criterion, a study reporting a lower value does not invalidate scientifically sound studies reporting higher values.

The results of the majority of the studies that investigated the bioaccumulation of lead and lead compounds are in general agreement. Thus, although EPA did not review every published lead study as part of its assessment for the proposed rule, the scientific data EPA used to support its assessment of lead and lead compounds were valid, represented the majority of all available data on lead, and provided a representative sample of the available knowledge on lead.

One commenter notes EPA's definitions of BAF and BCF on page 42229 of the proposed lead rule. EPA defines 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." EPA defines 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." The commenter questions the portions of EPA's definitions of BCFs and BAFs that state that the ratios do not change substantially over time (64 FR 42229). Specifically, the commenter claims that "such ratios have little scientific relevance in themselves." The commenter states that available data indicate that the lead BCF may not be a constant for different exposures, species or trophic levels.

EPA agrees with the commenter's statement that a BCF may not be

constant for different species or trophic levels. The Agency also agrees with the commenter's statement that the BAF and BCF of a substance measured in the same species can vary with the level of exposure (the concentration of the substance in ambient water). The Agency, however, believes the commenter has misunderstood the portions of its definitions of BCFs and BAFs that state that the "ratios do not change substantially over time" (64 FR 42229). The definitions of these terms pertain to determinations of BAF and BCF under controlled experimental conditions or field studies, where exposure of the aquatic species to the chemical is kept relatively constant. The phrase "ratios do not change substantially over time" does not refer to different experiments conducted at different concentrations of the test chemical. Thus, the fact that lead BCF values may not be constant for different exposures, species or trophic levels does not mean that lead does not bioaccumulate.

A number of commenters claim that EPA disregarded scientific data or did not use current scientific evidence in its assessment of the aquatic bioaccumulation potential of lead and lead compounds. Most of these commenters point out that EPA based its assessment of lead and lead compounds on studies published no later than the 1980s. These commenters are concerned that the studies EPA used are "out-of-date"; flawed; were not conducted using modern day analytical techniques; and assert that the data provided in these studies should not have been used by EPA in its assessment. These commenters also claim that environmental studies pertaining to lead and lead compounds published in the 1990s indicate that lead and lead compounds are not persistent or bioaccumulative in aquatic species.

While some commenters criticize the Agency for basing its assessment on the studies referenced in the **Federal Register** notice and in the technical support document entitled *Bioaccumulation/Bioconcentration Assessment for Lead and Lead Compounds* (Ref. 6), none of these commenters provide persuasive criticism of the studies used by EPA, or of a particular data point from a study used by EPA. In many cases it is not clear from their comments specifically which studies and data these commenters feel are untrustworthy. It is difficult, therefore, for EPA to provide specific responses to these commenters. In addition, although many of the commenters claim that EPA did not use

current scientific evidence, very few of the commenters provide citations to specific studies that contain more current or more recent scientific data. The Agency recognizes that it did not use results from studies published during the 1990's in its assessment of lead and lead compounds. EPA disagrees with the commenters, however, that the studies used in its analysis are "out-of-date", or that the data are not sufficiently current such that they should not have been used in the assessment. As with all studies used by EPA, the studies EPA used in its assessment of lead and lead compounds were initially reviewed by EPA for scientific credibility, and found to be scientifically valid. Many of the current methods used for biological analyses and conducting ecotoxicity tests are essentially the same as those used in the studies cited by EPA in the proposed rule. In addition, on a more general level, the Agency does not believe that the quality of a study should be judged by the year it was published, or that the results of a more recently published study necessarily has greater scientific validity than a similar study published earlier. The Agency maintains its longstanding position that when conducting a scientific assessment it is scientifically unacceptable to discriminate between study results by the age of the study: the selection of studies for any scientific assessment must be based on scientific merit.

While the Agency did not rely on the specific results from the additional studies referenced and discussed by one commenter to assess the bioaccumulation of lead and lead compounds in developing the proposed rule, the studies published in the 1990s which were referenced by the commenters provide no significant additional information beyond the studies used by EPA in the proposed rule, nor do the results from these studies lead EPA to reconsider the characterization of lead and lead compounds as bioaccumulative.

One commenter claims that more recent aquatic bioaccumulation studies indicate that previously reported concentrations of metals in environmental waters are erroneously high due to sample contamination (i.e., that earlier studies on the concentration of lead in the environment over estimated the actual concentrations of lead in the environment). The commenter believes that this means that previously reported BAF and BCF values would appear lower than if the concentrations of lead had not been overestimated. The commenter states that because of the earlier "erroneous Pb

measurements in water", researchers used higher lead levels in their bioaccumulation studies than they otherwise would have used. The commenter states that no experiments have been conducted at levels close to the actual lead concentrations in "natural waters." The commenter also stated that no data exists on actual lead concentrations for waters associated with highly contaminated sites where the results of the experiments conducted at concentrations above natural waters might apply. The commenter states that recent studies use lead concentrations 3 to 6 orders of magnitude above actual background lead concentrations and that although the data cited by EPA are from studies much closer to levels in natural waters they are still 2 to 4 orders of magnitude greater than typical values of lead in natural waters. According to the commenter this caused higher levels of lead to occur in the organism than would be observed under "actual concentrations of Pb in natural waters." The commenter tries to invalidate the concerns for bioaccumulation by claiming that, even though the BAFs/BCFs used by EPA are high, the absolute amount of lead that would bioaccumulate in organisms is low and does not pose a risk.

EPA disagrees with the commenter's argument that only BAF or BCF values measured at "actual concentrations of Pb in natural waters" are relevant to the bioaccumulation potential of lead and lead compounds. At its foundation the commenter's argument is flawed because under EPCRA section 313 the Agency is collecting data on releases of lead and lead compounds to the environment which are expected to raise lead concentrations above natural background levels. BCF studies that used lead concentrations above natural background levels are valid since they demonstrate that lead can bioaccumulate at lead concentrations that may result from industrial releases. Thus the fact that the experiments on bioaccumulation were conducted at lead levels in excess of those found in "natural waters" does not, in itself, invalidate the results of those studies. As noted in Unit VI.C.3., testing guidelines for bioaccumulation do not state that chemicals should be tested at natural background concentrations, only that the concentrations should be below a level that is detrimental to the test organism. Therefore, even if better data had been available on the background concentrations of lead that does not mean that bioaccumulation studies would have been conducted at those

concentrations. In addition, the commenter admits that higher bioaccumulation values would have been reported in earlier studies if better data on the concentration of lead in the water had been available. EPA fails to see how even higher bioaccumulation values undermine EPA's determination that lead and lead compounds are bioaccumulative. EPCRA section 313 is not a risk-based program, and the Agency is not required to demonstrate a specific risk in order to classify a substance as a PBT chemical. The EPCRA section 313 bioaccumulation criteria does not include a requirement that a chemical must bioaccumulate to some specific absolute amount within an organism in order to meet the criteria. Therefore, EPA disagrees that lead has not been shown to bioaccumulate to a level sufficient for inclusion as a PBT chemical. Even if such evidence were needed, it is available. EPA's database of Fish and Wildlife Advisories (<http://fish.rti.org>) contains 26 advisories for various fish and shellfish, see Unit VI.D.3. This indicates that lead and lead compounds can and do bioaccumulate in aquatic organisms to absolute levels that are of concern for human consumption.

Furthermore, the commenter's contention that previously reported lead concentrations in ambient waters may be erroneously high only serves to support the conclusion that lead and lead compounds are at least bioaccumulative. The commenter agrees that if the previously reported lead concentrations in ambient waters are in fact erroneously high, then the previously reported BAF and BCF values for lead and other metals are erroneously low (because the BAF and BCF values are determined by dividing tissue lead concentrations by environmental water concentrations). Thus, if the commenter's claim about the water concentrations is true, then the propensity for lead and lead compounds to bioaccumulate in aquatic species is actually greater than originally estimated. Based on the commenter's concern for the validity of the water concentrations and the BAF and BCF values reported for lead and lead compounds, EPA re-reviewed the studies it used in its original assessment of lead and lead compounds. EPA is satisfied that the lead water concentrations, BCF values, and BAF values reported in these studies are valid. However, as noted above, EPA is deferring on a final conclusion regarding the classification of lead as highly bioaccumulative based on the

data in these studies, and is concluding in this rule that lead is bioaccumulative.

Two commenters contend that the extent to which a metal such as lead bioaccumulates is dependent upon its concentration in the aqueous habitat of the organism. The commenters state that in most cases where bioaccumulation was noted, the organisms were exposed to artificially elevated lead concentrations in laboratory settings, often where abiotic factors were manipulated to increase lead availability.

The Agency agrees that environmental transformations and the uptake of lead by biota are highly variable and complex. However, these variabilities and complexities can be minimized by testing in the laboratory using a valid method. As discussed in the proposed rule, valid laboratory BCF tests have shown that lead and lead compounds have BCF values in some species well over 1,000. In some of the lead assays, several of the tested species (e.g., mollusks, algae) have very high BAF or BCF values, i.e., 5,000 or greater, indicating that these organisms accumulate or concentrate lead to high levels and eliminate lead very slowly. Thus, in organisms such as these, it would seem logical that the BAF or BCF values obtained at different test chemical concentrations would probably not vary by much. Further, based on its assessment of lead and lead compounds the Agency has concluded that external concentration is only one of several factors that govern the propensity for these substances to bioaccumulate in a given species. As discussed in more detail Unit VI.C.3, pharmacokinetic factors are operative as well.

EPA does not believe that bioaccumulation of lead was documented mostly in cases where the concentrations of lead in the surrounding water were artificially elevated in laboratory settings. This was not the case, for example, in the freshwater and marine algal field studies where BAF or BCF values above 10,000 were documented in actual aquatic environments and the lead levels were not artificially controlled. In addition, the fish advisories discussed in Unit VI.D.3. were based on concerns for lead levels in fish and other species that did not occur as a result of artificially elevated lead concentrations in laboratory settings.

One commenter states that EPA's contention that relatively small releases of lead and lead compounds have the potential to bioaccumulate and cause significant adverse environmental impacts is not supported by the

scientific literature. Another commenter stated that the preponderance of evidence shows that only under very limited conditions will lead and lead compounds be available to bioaccumulate and cause toxic impacts to ecosystems.

EPA disagrees. As discussed elsewhere in this document, there are many studies that show that there are several environmental factors (e.g., pH range of 3 to 6; soils that have low cation exchange capacity; low soil organic matter content) that increase the availability of lead and that, either individually or in combination, commonly exist throughout many geographical locations within the United States. However, even if the conditions under which lead is available were very limited this would not mean that lead would not bioaccumulate. Also, because lead and lead compounds are EPCRA section 313 listed toxic chemicals that EPA has determined are persistent and bioaccumulative, even small releases of lead and lead compounds into the environment persist and have the potential to bioaccumulate and cause significant adverse environmental impacts. Further, EPA notes the data on the bioaccumulation of lead and lead compounds in human (see Unit VI.D.2.b.) and the fish advisories for lead (see Unit VI.D.3.).

b. What comments did EPA receive on the human bioaccumulation data for lead and lead compounds? In Unit V.C. (pages 42230–42231) of the proposed rule, EPA provides a brief summary of available data on the pharmacokinetics of lead in humans. As stated in the proposed rule, EPA concluded that there is a substantial amount of evidence that shows that humans bioaccumulate lead. Unlike the assessment as to whether lead bioaccumulates in aquatic species, which was based on lead bioaccumulation factor (BAF) and bioconcentration factor (BCF) values measured in aquatic species in laboratory or field studies, the assessment of whether lead bioaccumulates in humans cannot be based on an analysis of BAF or BCF values because such values are not available for humans. The assessment of whether lead bioaccumulates in humans was based on the Agency's review of the references cited in Unit V.C. of the proposed rule, which provide a substantial amount of data and information regarding exposure of humans to lead, and the pharmacokinetics of lead in humans. From its review of these references, EPA concluded that humans, particularly

children, bioaccumulate lead to a significant degree. The propensity of lead to bioaccumulate in humans is known to result in toxicity to humans, especially infants and children. While the EPCRA section 313 PBT chemical criteria does not require that toxicity must occur in the same species in which the substance bioaccumulates, or result from bioaccumulation of the substance, those chemicals that persist in the environment, bioaccumulate in humans, and are toxic to humans are particularly problematic in regard to human health. The following information on the accumulation of lead in humans is discussed in the references cited in the proposed rule (Refs. 8, 10, 11, 14, and 25).

Exposure of the general population to lead occurs primarily via the oral and inhalation routes, and data show that in humans lead is absorbed from the gastrointestinal tract and the lung. Absorption of lead from the gastrointestinal tract varies with age. Adults absorb approximately 10% of orally ingested lead, and usually retain less than 5% of what is absorbed. Children absorb up to 40% of ingested lead, and retain more than 5% of the absorbed quantity. Infants retain over 30% of the quantity absorbed following oral exposure. Research indicates that the differences in the extent to which lead is absorbed orally between adults and infants and children may be due to the increased need for calcium in infants and children. In infants, children, and adults, a transport mechanism is involved with the absorption of calcium from the gastrointestinal tract. Infants and children, because they are growing rapidly, utilize calcium for bone formation and growth. Dietary needs for calcium are therefore higher in infants and children than in adults and, consequently, calcium is more efficiently absorbed orally by infants and children than it is by adults. Evidence indicates that lead may be competing with calcium for the transport mechanism involved with absorption of calcium, which could explain why lead is absorbed from the gastrointestinal tract more efficiently in infants and children than it is in adults.

Following inhalation exposure, lead is well absorbed from the lung by all human subpopulations. About 90% of lead particles in ambient air that are deposited in the lung are small enough to be retained within the lung. Lead retained within the lung is essentially completely absorbed from the lung.

In humans, lead is known to bioaccumulate in bone. Following absorption, lead is distributed initially

to the blood and soft tissues (especially the kidney, liver and bone marrow). The biological half-life of lead in blood is generally from 1 to 2 months. Some of the lead in the blood is excreted, predominately in the urine. The extent and rate of excretion is limited, however. Eventually, lead that is not excreted is redistributed from the blood to teeth and bone. Once in bone, the biological half-life of lead can extend beyond 20 years. Following daily exposure to lead, a steady state blood level of lead is achieved after about six months. (A steady state in blood lead is reached when the daily intake of lead approximates the amounts excreted in the urine and partitioned to bone.) Once steady state is reached, the blood level of lead remains essentially constant. However, because the rate and extent of urinary excretion of lead is limited, the concentration of lead in bone tends to continue to increase even though daily exposure remains constant. Also, if the amount of daily intake should increase, the time to accumulate higher levels of lead in the blood and soft tissues shortens disproportionately since renal excretion and deposition into bone occurs too slowly to prevent an accumulation in the blood and soft tissue.

The fraction of lead in bone increases with age from about 70% of total body lead in childhood to as high as 95% of the total body lead during old age. While lead bioaccumulates in bone, lead in bone can remobilize back to the blood. The extent to which lead in bone remobilizes to blood and other tissues is related to conditions that involve calcium resorption from bone. Any conditions that cause calcium to be resorbed from bone into the systemic circulation or other soft tissue will cause lead to resorb from bone. These conditions include: advanced age; osteoporosis; pregnancy; and lactation. Hence, lead stored in bone from exposures that occurred years, even decades, earlier may serve as an internal source of lead exposure later in life. Lead previously accumulated in bone may contribute as much as 50% of blood lead.

Lead in maternal blood can enter the fetus. Lead in fetal tissue is proportional to maternal blood concentration. Inorganic lead (i.e., Pb^0 , Pb^{+2} , Pb^{+4}) does not readily cross the blood brain barrier, and therefore only a small amount of inorganic lead accumulates in the brains of adult humans. Once in the central nervous system, however, lead accumulates in gray matter. The highest concentrations are in the hippocampus, followed by the cerebellum, cerebral cortex, and

medulla. Fetuses, infants and children less than 4 years of age are more predisposed to accumulate inorganic lead in the brain than are adults because in these subpopulations the blood brain barrier is not completely formed. In addition to the ability of infants and children to absorb lead more efficiently from the gastrointestinal tract than adults, it is well established that infants and children are also more sensitive and susceptible than are adults to the neurotoxic effects caused by lead. Mobilization of lead from bone into the blood is of particular concern during pregnancy or lactation.

Based on EPA's findings that in humans lead bioaccumulates in bone, that the concentration of lead in bone tends to continue to increase over the course of a lifetime, and that lead stored in bone from exposures that occurred previously may serve as an internal source of lead exposure later in life, EPA has concluded that lead significantly bioaccumulates in humans. In the proposed rule EPA asked for public comment on the scientific information concerning the bioaccumulation of lead in humans, and how this information should be considered in classifying lead and lead compounds as highly bioaccumulative. Several organizations or individuals provided comments to EPA's request, however none of these comments addressed the scientific information presented by EPA concerning the bioaccumulation of lead in humans, or how this information should be considered in classifying lead and lead compounds as bioaccumulative much less as highly bioaccumulative. While EPA believes that it could have reached a determination of bioaccumulative based on the human data alone, EPA concludes that lead and lead compounds are clearly and properly categorized as bioaccumulative based on the aquatic and human data. EPA further believes that these data would tend to support a finding of highly bioaccumulative.

c. What other general comments did EPA receive on the bioaccumulation of lead? One commenter claimed that EPA's reasoning that lead bioaccumulates is based on many variables, and is not realistic. This commenter refers to EPA's frequent use of the words "may" or "can" throughout the proposal: "EPA believes that processes * * * 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."

The Agency disagrees with this commenter. As described above, EPA's characterization of lead as a highly bioaccumulative substance is based on the Agency's scientific assessment. Also, EPA's use of words such as "may" or "can" is justifiable. EPA's TRI program is a national program and is not limited to specific locations or regions of the country. As discussed in detail in the proposed rule and elsewhere in this document, environmental conditions have a direct influence on the availability of lead and, hence, an indirect influence on the bioavailability and bioaccumulation of lead in aquatic organisms. Environmental conditions vary substantially across the United States and hence the availability of lead in the environment is likely to vary accordingly. To encompass the fact that environmental conditions vary, and that this rulemaking decision will be implemented at the national level, EPA believes its use of words such as "can" or "may" in the proposed lead rule is an accurate characterization of the scientific data. Despite the variations in environmental conditions EPA has concluded that there are many conditions in the United States where lead is available to bioaccumulate. In addition, lead is bioavailable even under environmental conditions where the lead ion may not be readily available in the environment.

Further, there are sufficient experimental data in aquatic organisms, fish advisories, and extensive data in humans, all of which indicate that lead and lead compounds *do bioaccumulate*. Thus, EPA disagrees with the comment that the Agency's conclusion that lead bioaccumulates is unrealistic. To the contrary, EPA has concluded that the available evidence indicates that lead and lead compounds will bioaccumulate in many actual environments.

Several commenters state that there are numerous literature citations that show that lead does not biomagnify in aquatic food chains, and, in experimental trophic chains lead accumulated in decreasing concentration from the lowest to the highest trophic levels. One commenter concludes that bioaccumulation is not relevant unless lead is transferred up the food chain to humans, and that a concept more meaningful than BCF is needed to evaluate the potential risk from lead to public health from ingestion of fish.

EPA disagrees with the commenter's conclusion that bioaccumulation is not relevant unless lead is transferred up the food chain to humans and that BCFs [and BAFs] are not meaningful.

"Transfer up the food chain" is really a biomagnification concern which EPA addressed in the final PBT chemical rule (64 FR 58682) and associated Response to Comment document (Ref. 15, section 2.d), stating that such a process is not relevant to the issue of whether a chemical bioaccumulates. Bioaccumulation is a concern for the organism that bioaccumulates it and any organism that eats such organisms. While available data may indicate that lead does not biomagnify, this has no bearing on the characterization of lead as a bioaccumulative substance because biomagnification is not required in order to have a concern for a chemical that bioaccumulates. While EPA does not have to make such a connection, the commenters' own information provides evidence of a transfer up the food chain. The commenter stated that about 60% of the lead in phytoplankton is assimilated by mussels and that mussels have high BCF values. EPA identified phytoplankton as having high bioaccumulation values so there is the potential for movement of lead in the food chain based on this information. In addition, EPA's database of Fish and Wildlife Advisories (<http://fish.rti.org>) contains 26 advisories for various aquatic organisms including shellfish.

3. *What comments did EPA receive on the bioavailability of lead.* Contrary to some commenters' claims that EPA did not consider relevant data regarding bioavailability, EPA emphasizes that the Agency **did** consider the bioavailability of lead in its evaluation of lead and lead compounds. In addition to the principles described above in Unit VI.C.2. that address the availability and bioavailability of metals, EPA also relied on empirical data regarding the availability and bioavailability of lead. EPA refers specifically to the test data cited in the proposed rule and in the references to the proposed rule that clearly show that lead is bioavailable (Table 1 of the proposed rule (64 FR 42230), and references therein). The fact that lead is detectable in the tissues of snails, algae, plankton, rainbow trouts, blue mussels, oysters, and lobsters exposed to lead provides compelling scientific evidence that lead is bioavailable in these species.

In addition to these test data, EPA examined its public National Listing of Fish and Wildlife Advisories database (see <http://fish.rti.org/>) to see whether lead has been detected in fish under actual environmental conditions. The individual states have the primary responsibility for protecting residents from the health risks of consuming contaminated noncommercially caught fish and wildlife. Individual counties

monitor local fish and wildlife for the presence of chemical contaminants, including lead. Fish consumption advisories warn the public that high concentrations of chemical contaminants have been found or are suspected in fish from local waters and that consumption of these fish may pose health risks. The advisories may recommend to limit or avoid consumption of specific fish species, or to limit or avoid consumption of fish from specific water bodies. It is important to emphasize that while a single advisory has one geographic location (e.g., a portion of a river or lake), it can contain information about several fish species (e.g., carp, largemouth bass, shrimp), several pollutants (e.g., mercury and PCBs), and several "populations" (e.g., no consumption for at risk subpopulations such as pregnant women and/or restricted consumption for general populations). There are 26 reports that show that lead is or has been detected in different aquatic species located in various areas within the United States. The fact that lead is detected in fish shows that lead is bioavailable in fish under actual and varying environmental conditions. Being within the purview of state and local governments, there is some variation in fish advisory policies and procedures across the United States. Thus, not all counties monitor fish and wildlife for chemical contaminants, and some counties may not monitor for lead contamination. Therefore, there may be additional geographical locations within the United States, not listed in the National Listing of Fish and Wildlife Advisories database, where the fish are contaminated with lead.

Some commenters state that EPA should evaluate each individual member of the lead compounds category on a case-by-case basis because the availability of lead from lead compounds differs among lead compounds and lead is unavailable from certain lead compounds. As explained in Unit VI.C.1., the Agency has concluded that there is a scientific basis for evaluating lead compounds as a category rather than individually because the bioavailability of a lead compound is not necessarily dependent upon the availability of lead from the compound. That is, the parent lead compound may be bioavailable as is or, if not itself bioavailable, could be converted in the environment into a another lead compound that is bioavailable or from which lead is bioavailable. As discussed in Unit VI.D.1, EPA's environmental fate assessment indicates that there are

many conditions under which lead from lead compounds can become available in the environment. Further, most lead compounds provide bioavailable lead when ingested. Thus, after an evaluation of the available data, EPA has determined that the weight of scientific evidence indicates that it is reasonable to conclude, based upon similarities between the compounds, that lead in the environment will be available and/or bioavailable from all lead compounds.

In addition, regardless of the relative environmental availability of lead from one lead compound to another, the lead compounds all add to the environmental loading of lead. Thus, even if under the same environmental conditions the lead from compound A is 10 times less available than the lead from compound B, compound A would introduce the same amount of available lead if its releases are 10 times greater. If lead compounds are evaluated individually based on relative environmental availability then the additive effect of the loading of lead from these compounds would be ignored.

E. What Comments Did EPA Receive on Its Proposed Threshold for Lead and Lead Compounds?

EPA received a range of comments on the thresholds proposed for lead and lead compounds similar to those it received on the thresholds proposed for the PBT chemicals in its earlier rulemaking. Many commenters contended that EPA should not consider burden in choosing thresholds. They believe that EPA should set a threshold of 1 pound for lead because it was proposed as falling within the subset of PBT chemicals that are both highly persistent and highly bioaccumulative. Numerous commenters believe that the threshold for reporting should be zero. Other commenters believe that burden should have been a greater consideration in EPA's choice of reporting thresholds. Many of these commenters also stated that EPA should set thresholds based on some percentage of releases that would be reported.

With few exceptions, the comments EPA received failed to take into account the analyses EPA laid out in the final PBT chemical rule. As explained in the preamble to that rule, the analyses in that rulemaking relied on the characteristics and policy considerations surrounding PBT chemicals in general. The analyses were not dependant on the specific chemical properties of the particular, individual chemicals addressed in that rulemaking,

but were tied more closely to the overall characteristics of PBT chemicals generally. For example, as part of the explanation for the Agency's decision to establish two categories of thresholds an order of magnitude apart, EPA noted:

EPA then considered the relative degree of persistence and bioaccumulation between the two classes of chemicals. EPA wanted to establish two sets of revised thresholds with the same approximate relationship to each other, as the relative exposure potentials of PBT chemicals to that subset of highly persistent and highly bioaccumulative PBT chemicals. Simply stated, chemicals with half-lives of 6 months or greater and a BAF/BCF of 5,000 or greater have a higher exposure potential than chemicals with half-lives of 2 months or greater and a BAF/BCF of 1,000 or greater. However, although, as discussed below, EPA could establish a qualitative relationship, the Agency could not reliably quantify the relative exposure potential across the board for all of the members of both classes. Therefore, in attempting to translate the qualitative exposure potential of PBT chemicals to that subset of PBT chemicals that are highly persistent and highly bioaccumulative into a qualitative *threshold* relationship, EPA considered both the attributes of these chemicals and factors specific to thresholds. 64 FR 58690.

And as EPA also explicitly noted in the preamble, EPA established the revised thresholds with the intention that they would be generally applicable to future members of the two PBT categories. See 64 FR 58691. Thus, absent some strong technical or policy concern to the contrary—a topic on which the public would have the opportunity to present information and otherwise provide comments—the revised thresholds were anticipated to be applicable to future candidate PBT chemicals. EPA requested commenters to submit such technical and policy concerns in its proposed rule for lead and lead compounds. See 64 FR 42224. This, the commenters have failed to do. In addition, in the proposed lead rule, EPA identified an additional factor for use in determining whether a chemical is, at the least, bioaccumulative. EPA explained that there is clear and convincing evidence that lead is bioaccumulative in humans. EPA also requested comment on the human data and on how such data should be considered in determining whether a chemical should be classified in that subset of PBT chemicals that are highly bioaccumulative. Therefore, consistent with the factors laid out in its previous rulemaking, and with its determination that lead and lead compounds are highly persistent and bioaccumulative toxic chemicals, EPA is setting the thresholds for lead and lead compounds

at 100 pounds. As discussed elsewhere, following its review of the comments, EPA is deferring on its proposal to classify lead and lead compounds as highly bioaccumulative.

Consistent with EPA's approach to revise thresholds for PBT chemicals, EPA began with the premise that for lead and lead compounds, assuming no unique circumstances, a threshold of either 100 or 10 pounds would be warranted. The choice of threshold was dependent on whether the data indicated that lead and lead compounds were PBT chemicals, or fell within the subset of highly persistent and highly bioaccumulative toxic chemicals. In this rulemaking EPA has concluded, through application of PBT criteria as discussed in the PBT final rule and the proposed lead rule, that lead and lead compounds are highly persistent and bioaccumulative. At this time, EPA is deferring on a final conclusion as to whether lead and lead compounds are highly bioaccumulative, and is deferring on whether lead and lead compounds are appropriately classified in that subset of toxic chemicals that are highly persistent and highly bioaccumulative. Thus, based on EPA's conclusions, a 100 pound threshold for lead and lead compounds is warranted.

EPA has considered the same factors for lead and lead compounds that it had considered for the individual PBT chemicals included in its previous rulemaking. To determine whether the additional reporting burden associated with lowering the thresholds for lead and lead compounds presented any unique concerns, and to ensure that the 100 pound threshold would capture significant information from a range of covered industry sources, EPA analyzed the number of reports that would be submitted by each industry sector for the following potential thresholds: 1 pound, 10 pounds, 100 pounds, and 1,000 pounds.

EPA's analysis confirmed that 100 pound threshold achieves the appropriate balance of the various factors laid out in the preamble to the final PBT rule. EPA therefore finds that establishing the threshold at 100 pounds will not be unduly burdensome, and ensures that the resulting reporting will provide the public with information from a range of covered industry sectors, and that the information will contribute significantly to providing the public with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems.

F. What Comments Did EPA Receive on Its Proposed Treatment of Lead Contained in Stainless Steel, Brass, and Bronze Alloys?

The commenters on this issue generally agree with EPA's proposed limitation on the reporting of lead contained in stainless steel, brass, and bronze alloys, but felt that it should be expanded. Some commenters suggest that all alloys should be included, while others cited various types of alloys that they believed should also be included, e.g., aluminum, copper, zinc, tin, iron, all steels, carbon and low alloy steels, leaded steel, and galvanized and drawn steel wire. Some commenters also suggest that other metals be included in a broader alloy reporting exemption and that the exemption should be for all reporting, not just for the lower reporting thresholds. Some commenters claim that EPA's reasoning in drafting the alloys exemption is that lead incorporated into an alloy does not pose the same hazard as unincorporated lead, is not bioavailable, does not exert toxic effects, is not available for exposure, and that this reasoning holds true for lead contained in other alloys. Commenters also contend that alloys have significantly different bioavailability, bioaccumulation, and toxicity characteristics than other forms of metals, and thus should be treated separately. Some comments state that an alloys exemption would enhance the ability of TRI to provide meaningful information to the public regarding the risk associated with the release and handling of toxic materials. Several commenters requested an exemption for the use of lead and lead compounds in wire soldering operations. Some commenters state that lead contained in primary aluminum and aluminum alloys is incidental and that the concentrations are significantly lower than that found in stainless steel, bronze and brass alloys, which intentionally contain lead, and therefore lead in aluminum alloys should not be regulated any more stringently than those alloys. One commenter states that EPA failed to demonstrate that lead is bioavailable in any metal alloy and illegitimately provided a preferential exemption only to certain metal alloys. The commenter contends that EPA has failed to show any rational basis for excluding other metal alloys from such an exemption and that limiting the exemption to stainless steel, brass, and bronze alloys is arbitrary and capricious and should be expanded to all, metal alloys, including aluminum alloys.

EPA does not believe that it currently has any information that would support

a decision to extend to other types of alloys, its deferral of a decision on a lower threshold for lead when contained in stainless steel, brass, and bronze alloys. EPA's proposed deferral was based on the fact that it is currently evaluating a previously submitted petition, as well as comments received in response to previous petition denials, that requested the Agency to revise the EPCRA section 313 reporting requirements for certain metals contained in stainless steel, brass, and bronze alloys. Contrary to the commenter's allegations, EPA has not determined that lead is neither toxic nor bioavailable when contained in these or any other alloys. Nor did EPA imply that lead or other metals contained in these or any other alloys are less hazardous than metals not contained in alloys, or that lead or other metals cannot exert toxic effects, or that lead or other metals are not available for exposure when contained in an alloy. Rather, the deferral is simply based on the fact that for stainless steel, brass, and bronze alloys, EPA is currently reviewing whether there should be any reporting changes. In light of that review, EPA has decided to maintain the status quo for lead when contained in these alloys until the review is complete.

Lead is an EPCRA section 313 listed toxic chemical, and lead contained in all alloys are therefore subject to the EPCRA section 313 reporting requirements. As discussed above, EPA did not illegitimately provide a preferential exemption only to stainless steel, brass, and bronze alloys. EPA is merely maintaining the status quo with respect to the alloys that are the subject of the pending review. Other alloys are not part of that review. Because the commenters have submitted no information or data that would allow the Agency to conclude that lead in all other alloys are similarly situated, in light of its scientific findings in this rule with respect to lead and lead compounds, EPA has no basis for extending its deferral.

With respect to the request for an exemption for lead soldering, EPA does not believe that the commenter's allegation that lead may not be released during these processes, such as wire soldering, provides an adequate basis for excluding that activity from threshold determinations and release reporting requirements. Under EPCRA section 313, whether an activity must be counted towards an EPCRA section 313 reporting threshold is based on whether the activities fall within the definition of manufacturing, processing, or otherwise use, not on whether the

activity actually, or potentially, results in releases. Additionally, because even low amounts of releases are of concern for PBT chemicals like lead and lead compounds, it is not appropriate to exclude a reportable activity merely because releases from that activity may be relatively low.

In addition, this rulemaking is specific to lead and is not the appropriate forum to address the issue of limitations or exemptions for other metals contained in these or other alloys; nor was comment on such issues requested in the proposed rule. EPA will be issuing a report on its review of the data for stainless steel, brass, and bronze alloys and will be asking for comments on the report.

The comment that an alloys exemption would enhance the ability of TRI to provide meaningful information to the public regarding the risk associated with the release and handling of toxic materials is not relevant to the issue of whether or not there should be reporting changes for any alloys. As EPA has previously discussed (64 FR 58592), EPCRA section 313 is a hazard-based program, not a risk-based program. As such, EPCRA section 313 does not directly provide any risk information to its users, but rather provides basic release and other waste management information on chemicals that meet the criteria in EPCRA section 313(d)(2). Congress established these criteria as the sole standard for listing decisions. Therefore, any final determination on whether there should be changes to the reporting of alloys will be based on whether the alloys meet the criteria of EPCRA section 313(d)(2).

One commenter stated that EPA's limitation on the reporting of lead contained in alloys should apply to all alloys to be consistent with that proposed for cobalt and vanadium in the January 1999 proposal for other PBT chemicals.

EPA disagrees that it must extend its deferral to all lead alloys to be consistent with its past actions on cobalt and vanadium. With respect to cobalt, in the October 29, 1999 final PBT chemical rule (64 FR 58666), EPA only changed the reporting requirements for vanadium not cobalt. Regarding vanadium, the original vanadium listing contained the qualifier "fume or dust;" thus the status quo was that unless the vanadium alloy was converted to a fume or dust form, the vanadium in any alloy was not reportable. In the October 29, 1999 final rule, EPA added all forms of vanadium, except vanadium contained in alloys, to the list of TRI chemicals. EPA deferred its decision to add vanadium contained in alloys until it

had resolved the pending petition. EPA explained its decision as follows: "At this time, while EPA is in the process of a scientific review of the issues pertinent to alloys, the Agency is not prepared to make a final determination on whether vanadium in vanadium alloys meet the EPCRA section 313(d)(2) toxicity criteria" (64 FR 58711).

At the time EPA made its determination with respect to vanadium, EPA chose not to add vanadium contained in any alloys to the EPCRA section 313 list of toxic chemicals. This decision excluded from a listing decision more than just the three classes of alloys specifically addressed in the alloys project out of concern that the project could be expanded to similar alloys. However, at the time of the lead proposal, EPA identified a potential concern with proposing a similarly broad deferral for lead since lead is used in many types of alloys that are not similar to stainless steel, brass, and bronze alloys. Because these other alloys, such as lead solder, are not being reviewed, and are currently subject to reporting under EPCRA section 313, EPA believes that the Agency has no basis to defer lowering thresholds for these other alloys. In light of the Agency's conclusions with respect to lead, EPA will review its October 29, 1999, vanadium decision and determine whether vanadium contained in alloys, other than the three classes of alloys currently under review by the Agency, should be added to the EPCRA section 313 list of toxic chemicals.

None of the commenters who supported a limitation for lead in other alloys submitted any data on which the Agency could rely to create such a limitation, or to extend the alloys review to encompass lead when contained in alloys other than stainless steel, brass, or bronze. As explained above, EPA believes that it has no basis to defer lowering thresholds for other alloys that are not currently being reviewed. If the commenter has data to support a revision to the reporting requirements for lead when contained in alloys other than stainless steel, brass, and bronze the commenter can submit it as part of a petition to delist lead contained in such alloys from the EPCRA section 313 list of toxic chemicals.

One commenter contends that EPA has exempted steel, brass and bronze alloys from reporting for lead with the implication being that these alloys do not yield sufficient lead to be a significant risk. The commenter stated that there are many products containing trace amounts of lead which are at least

as stable as bronze or steel alloys. The commenter contends that EPA provides no explanation for why these other products were not also provided an exemption and that EPA sets forth an artificial and unfair distinction. The commenter cites colored plastics, vinyl siding, ceramics, paints and inks as examples of products that do not leach lead in sufficient quantity to pose a risk to the community. The commenter contends that there is an assumption implicit in the proposed rule, that steel alloys containing lead are sufficiently safe and non-toxic to avoid reporting under the TRI, while all other forms of lead, lead compounds and thousands of products which may contain trace quantities of lead and lead compounds are not and that this is unsubstantiated in the record for this rulemaking.

EPA is not providing an "exemption" to lead contained in stainless steel, brass and bronze alloys. As EPA discussed in other responses in these section, EPA is merely deferring a final decision on lowering thresholds for lead contained in these alloys until the scientific review of the alloys petition is complete. EPA has made no determination, implicit or otherwise, that lead contained in any alloy is safe, non-toxic, or without significant risk. Lead contained in other non-alloy products is currently reportable and since these other non-alloys are not part of the review of stainless steel, brass, and bronze alloys EPA did not include any similar deferral for these other products. With regard to these other lead containing products, if the commenter has data that indicate that the lead contained in these products cannot become available through any abiotic or biotic processes, then they may wish to provide these data in a petition to have the lead in such products delisted from the EPCRA section 313 listed toxic chemicals. In addition, under certain conditions, some of the products mentioned by the commenter (such as vinyl siding, colored plastics, and ceramics) may be eligible for the article exemption (see 40 CFR § 372.38 (b)) and thus would not be subject to reporting in any case.

Two commenters requested that lead and lead compounds contained in glass, ceramic enamels, and ceramicware be excluded from reporting. One commenter stated that EPA's limitation on the reporting of lead in stainless steel, brass, and bronze alloys, is apparently justified because alloys have significantly lower potential for bioavailability, bioaccumulation, and toxicity than other forms of metals and are less likely to affect organisms than non-alloy forms of metals and that these

compounds are extremely stable and virtually unable to interact with organisms. The commenter contends that ceramic enamels share similar properties with alloys and that the way that they are manufactured and used results in little or no releases or exposures. The commenter stated that these enamels are as insoluble as possible and bind the lead compounds in such a way that their use in glazing and decorating ceramicware or glass would strictly limit the potential exposure of the community to releases from a glazing or decorating process.

As discussed in detail in the responses contained in the previous section, EPA has not determined that lead is neither toxic nor bioavailable when contained in these or any other alloys. Nor did EPA imply that lead or other metals contained in these or any other alloys are less hazardous than metals not contained in alloys, or that lead or other metals cannot exert toxic effects, or lead or other metals are not available for exposure. EPA is merely deferring a final decision on lead contained in these alloys until the Agency completes its current review of the alloys petition. The commenter has provided no data to support expanding its alloys review to these materials so the basis for the deferral for lead in certain alloys does not apply to these other materials. If the commenter has data to support such an extension, then they may wish to provide this data in a petition to have the lead in such products delisted from the EPCRA section 313 listed toxic chemicals. In addition, under certain conditions, glass and ceramic products may be eligible for the article exemption (see 40 CFR § 372.38 (b)) and thus would not be subject to reporting in any case.

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

EPA has prepared an economic analysis of this action, which is contained in a document entitled *Economic Analysis of the Final Rule to Modify Reporting of Lead and Lead Compounds Under EPCRA Section 313* (Ref. 46). This document is available in the public version of the official record for this rulemaking. The analysis assesses the costs, benefits, and associated impacts of the rule, including potential effects on small entities. The major findings of the analysis are briefly summarized here including responses to some of the major comments EPA received.

A. What Is the Need for the Rule?

Federal regulations exist, in part, to address significant market failures.

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

This action 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 1998, EPA received TRI data on the release and other waste management of over a billion pounds of lead and lead compounds from approximately 1,900 facilities. EPA believes that there are many additional facilities 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 estimate the total multi-media releases or other waste management quantities from these additional facilities without additional TRI reporting. Since even small amounts or concentrations 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 action, 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 are the Potential Costs of this Action?

This action will result in the expenditure of resources that, in the absence of the regulation, could be used for other purposes. The cost of the rule is the value of these resources in their best alternative use. Most of the costs of the rule will result from requirements on industry. Approximately 9,800 facilities are expected to submit additional Form R reports on an annual basis as a result of this action. The estimated composition of this reporting, by industry, is shown in Table 1. This table also displays the estimated costs for this action, which includes costs of compliance determination for all potentially affected facilities, and rule familiarization, report completion, and mailing/recordkeeping for facilities that are expected to file additional reports. Aggregate industry costs in the first year for the selected alternative are estimated to be \$80 million; in subsequent years they are estimated to be \$40 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 satisfy reporting requirements by updating or modifying information from the previous year's report. EPA is expected to expend \$1.2 million in the first year, and \$775,000 in subsequent years for programmatic, compliance assistance, and enforcement activities as a result of the rule.

TABLE 1. SUMMARY OF ESTIMATED ADDITIONAL REPORTING BY INDUSTRY

| SIC Code—Industry | Estimated Number of Additional Reports | Estimated Industry Costs (thousand \$ per year) | |
|-------------------|----------------------------------------|-------------------------------------------------|----------|
| | | First Yr. | Sub. Yr. |
| 10—Metal Mining | 127 | \$756 | \$459 |
| 12—Coal Mining | 314 | \$1,782 | \$1,163 |
| 20—Food | 291 | \$2,857 | \$1,380 |
| 21—Tobacco | 29 | \$170 | \$106 |
| 22—Textiles | 184 | \$1,359 | \$761 |

TABLE 1. SUMMARY OF ESTIMATED ADDITIONAL REPORTING BY INDUSTRY—Continued

| SIC Code—Industry | Estimated Number of Additional Reports | Estimated Industry Costs (thousand \$ per year) | |
|-----------------------------------|----------------------------------------|-------------------------------------------------|----------|
| | | First Yr. | Sub. Yr. |
| 23—Apparel | 16 | \$1,339 | \$371 |
| 24—Lumber | 107 | \$1,998 | \$744 |
| 25—Furniture | 60 | \$958 | \$377 |
| 26—Paper | 211 | \$1,938 | \$894 |
| 27—Printing | 41 | \$2,646 | \$755 |
| 28—Chemicals | 497 | \$3,327 | \$1,968 |
| 29—Petroleum | 95 | \$589 | \$364 |
| 30—Plastics | 84 | \$1,685 | \$613 |
| 31—Leather | 18 | \$185 | \$87 |
| 32—Stone/Clay/Glass | 186 | \$1,889 | \$898 |
| 33—Primary Metals | 1,945 | \$11,931 | \$7,049 |
| 34—Fabricated Metals | 267 | \$3,865 | \$1,577 |
| 35—Machinery | 53 | \$3,083 | \$892 |
| 36—Electrical Equipment | 3,501 | \$25,957 | \$12,737 |
| 37—Transportation Equipment | 347 | \$2,462 | \$1,409 |
| 38—Measure./Photo. | 7 | \$723 | \$197 |
| 39—Miscellaneous | 58 | \$1,103 | \$380 |
| 4911/4931/4939—Electric Utilities | 574 | \$3,025 | \$2,069 |
| 4953—Refuse Systems | 107 | \$561 | \$385 |
| 5169—Chemical Wholesale | 0 | \$299 | \$75 |
| 5171—Bulk Petroleum | 616 | \$3,539 | \$2,293 |
| 7389—Solvent Recovery Services | 78 | \$417 | \$283 |
| Total | 9,813 | \$80,441 | \$40,287 |

A number of commenters contend that EPA's analysis of affected industry sectors for the proposed rule failed to include sectors that would be affected by the rule. These commenters suggest that the following industries would be affected by the rule: metalworkers; glaziers; lead crystal glassware manufacturers; animal feed producers; metal platers; brass and copper fabricators; stained glass manufacturers; organ makers and manufacturers of other musical instruments; dye makers and manufacturers of dye-containing products including businesses in the leather, garment, and textile industries; pigments and coatings companies; metal finishers; medical and dental equipment manufacturers; makers of sporting and recreational equipment; precision metal

components, mirrors, stabilizers, fertilizer; and numerous ceramic decorative art manufacturers and studios; art pottery and art pottery supply firms; ink formulators; print shops; product painting/coating/refinishing businesses; and packaging or packaging coating firms, and other businesses that use or manufacture materials that contain small amounts of lead.

In the economic analysis for the proposed rule (Ref. 16), EPA estimated the additional TRI reporting that would be expected from a number of industry groups that are subject to EPCRA section 313 at four lower reporting thresholds considered for lead and lead compounds. EPA also identified other industry groups, which are also subject

to EPCRA section 313, but for which EPA lacked sufficient information to generate quantitative estimates of additional reporting. In the proposed rule, and in a subsequent notice announcing public meetings, EPA solicited additional information to allow EPA to quantify the number of additional reports in all industry groups that are subject to EPCRA section 313. In response, EPA received comments that varied greatly in detail and utility for making quantitative estimates of additional reporting.

In some cases, in addition to asserting that an industry sector would be affected by the rule, commenters also provided detailed information on the activity in the industry sector associated with lead or lead compounds, the

amount or concentration of lead associated with industrial materials, the lead usage per employee, the prevalence of the lead-related activity within the industry, or other information that allowed EPA to confirm the potential for additional reporting in that industry at the various proposed lower reporting thresholds. This information, in conjunction with additional research and industry contacts, allowed EPA to revise or generate estimates for many of the additional industry sectors that commenters identified. These sectors include galvanizers, stained glass manufacturers, metal finishers, animal feed producers, organ manufacturers, and other industry sectors described in Appendix A of the economic analysis of the final rule (Ref. 46).

In other cases, commenters asserted a potential impact on an industry without providing information that would allow EPA to confirm the potential for additional reporting as a result of the rule, or to make a quantitative estimate of additional reporting at any of the lower reporting threshold options that EPA considered. Table A-73 in the economic analysis of the final rule lists industries that may be affected by the rule, but for which existing data are inadequate to make a quantitative estimate of additional reporting.

EPA fully considered the information from the commenters on the potential for additional reporting from industries that were not identified in the economic analysis of the proposed rule, or for which EPA was unable to make quantitative estimates at the time of the proposal. As a result of the comments, EPA revised its estimates for a number of potentially affected industry groups. The revised estimates are described in Appendix A of the economic analysis of the final rule. While the estimates of additional reporting for some industry groups changed substantially as a result of the comments, the net effect on EPA's estimates of additional reporting was less pronounced because estimates for some industry sectors increased while others decreased. (Additional details are available in Appendix A of the economic analysis of the final rule.)

With regard to the potential for additional reporting, a number of commenters cite the following footnote to Table A-45 in Appendix A of the economic analysis of the proposed rule:

Zero facilities are predicted to report for lead due to natural gas combustion given the uncertainty regarding concentration data for lead in natural gas. Assuming available concentration data are accurate, an estimated 35,376 additional facilities would report at the proposed threshold.

The commenters note that this estimate for natural gas users would greatly increase the number of additional reports that EPA estimated for the proposed rule. Although one commenter notes that EPA explained that "concentration data for natural gas are considered unreliable," the commenters ask that EPA explain why it chose to reject the available concentration data for lead in natural gas, but not the data it used for lead in other fuels.

The footnote cited by the commenters reflects EPA's assessment of the quality of available information on the presence of lead as a trace contaminant in natural gas at the time of proposal. Because of uncertainties about the presence or absence of lead as a trace contaminant in natural gas, EPA did not include any reporting due solely to natural gas combustion in its quantitative estimates of additional lead and lead compound reporting at the lower reporting threshold options.

For the economic analysis of the proposed rule, EPA consulted two references for information on lead in natural gas: *Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds* (Ref. 47) and *Study of HAP Emissions from Electric Utility Steam Generating Units: Final Report to Congress* (Ref. 48). These references provided emission factors for lead from natural gas combustion based on a very limited number of observations. The observed emissions of lead do not necessarily indicate that lead was present as a trace contaminant in natural gas. For example, the lead measured in emissions from natural gas combustion may have originated from lead-containing oil residues in combined-cycle combustion units. In this case, the effect on additional reporting would have been captured in EPA's estimate of reporting due to lead levels in residual or distillate fuel oil. Due to this uncertainty about the origin of lead emissions from natural gas combustion, EPA estimated the potential number of additional reports based on the lead emission factor for natural gas, but did not include these reports in the quantitative estimate of additional reporting at the lower reporting threshold options. For other fuels, EPA was able to locate typical concentration values for lead contained in those fuels a trace contaminant. Therefore, for fuels other than natural gas, EPA included estimates of additional reporting due to fuel combustion at the lower reporting threshold options.

As a result of public comments on this issue, EPA sought additional

information to verify if lead is found as a contaminant in natural gas. EPA located a report that characterizes the presence of hazardous air pollutants in natural gas (Ref. 49). According to this report, lead was not detected at a detection limit of 0.9 micrograms per cubic meter of natural gas. Assuming, as an illustrative example, that lead was present at the detection limit concentration, the facility at the 90th percentile of manufacturing facilities using natural gas would only have a lead throughput of 0.05 lbs per year based on natural gas throughput data presented in the economic analysis of the final rule. Because the currently available data reviewed by EPA on trace levels of lead and lead compounds in natural gas indicate that very few, if any, facilities would be affected by any of the lower reporting threshold options as a result of natural gas combustion, EPA has estimated in the economic analysis of the final rule that no additional reports on lead and lead compounds will be submitted solely as a result of natural gas combustion.

Commenters assert that EPA underestimated the burden associated with the proposed rule because they believe that EPA's estimates of burden consider only those facilities expected to file reports under the proposed lower reporting thresholds. The commenters state that many facilities will be affected by the rule because they will have to make threshold determinations, even though they will not exceed the reporting threshold. The commenters contend that these facilities will incur the unit costs that EPA has quantified in the *Economic Analysis* for compliance determination and rule familiarization. The commenters contend that because the proposed thresholds are very low and material use varies from year to year, these determinations would occur annually, not just in the first year.

In estimating the cost of the rule, EPA considered facilities that make threshold determinations but do not exceed the reporting threshold. EPA estimated the costs to facilities of determining whether a report must be filed for lead and/or lead compounds as part of "compliance determination." EPA agrees that a compliance determination will be made annually at all facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA section 313, and the economic analysis of the rule reflects this.

Compliance determination should occur annually at all facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA section 313. In this respect, compliance

determination for lead and lead compounds is similar to compliance determination for all other EPCRA section 313 chemicals. However, lead and lead compounds are a small part of the list of over 600 EPCRA section 313 chemicals. Therefore, it is reasonable to expect that the typical *incremental* compliance determination costs specifically for lead and lead compounds at a lower reporting threshold would be less than current compliance determination costs for the entire list of EPCRA section 313 chemicals.

Compliance determination costs are described in Chapter 4 of the economic analysis. The economic analysis of the final rule estimates that compliance determination for the changes in TRI reporting will take an average of 1.6 hours in the first year of reporting and 0.4 hours in subsequent years. These estimates are incremental to the time currently required each year for compliance determination for other EPCRA section 313 chemicals. The lower burden hour estimate for subsequent years reflects the decline in burden hours after the necessary inputs to the threshold calculation are identified at each facility.

EPA does not agree that facilities will incur "rule familiarization" costs after the first year of reporting, especially if these facilities do not exceed any applicable reporting thresholds. Rule familiarization is related to the time that facilities spend learning how to fill out the reporting form. Once a facility determines that a report is not required, the subsequent costs of reporting (rule familiarization, report completion, and mailing/recordkeeping) are not incurred. Facilities are expected to incur costs of rule familiarization only if they are reporting under EPCRA section 313 for the first time. At a minimum, rule familiarization involves reading the instructions to the *Toxic Chemical Release Inventory Reporting Form R*, however, it may also involve consulting EPA guidance documents, attending a training course, and/or calling the EPCRA technical hotline. In subsequent years, staff are already familiar with the requirements that apply to their facility, apart from any minor changes to interpretive guidance that may occur in the intervening year.

C. 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. EPCRA section 313 has empowered the Federal

government, State governments, industry, environmental groups and the general public to participate in an informed dialogue about the environmental impacts of toxic chemicals in the United States. EPCRA section 313's publicly available data base provides quantitative information on toxic chemical releases and other waste management practices. Since the TRI program's inception in 1987, the public, government, and the regulated community have had the ability to understand the magnitude of chemical releases in the United States and to assess the need to reduce the uses 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 under EPCRA section 313 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 reporting under EPCRA section 313: those resulting from the actions required by the rule (such as reporting and recordkeeping), and those derived from follow-on activities that are not required by the rule. Benefits of activities required by the rule include the value of improved knowledge about the release and waste management of toxic chemicals, which leads to improvements in understanding, awareness and decision-making. It is expected that this rule will generate such benefits by providing readily accessible information that otherwise would not be available to the public. The rule will benefit ongoing research efforts to understand the risks posed by lead and lead compounds and to evaluate policy strategies that address those risks.

The second type of benefit derives from changes in behavior that may result from the information reported

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

Commenters point out that EPA has not quantified the benefits of the proposed rule. The commenters assert that not quantifying the benefits of the rule severely inhibits the public's ability to evaluate and comment upon this proposed rule.

EPA notes that the state of knowledge about the economics of information is not highly developed. Because of the inherent uncertainty in the subsequent chain of events following TRI reporting, EPA has not attempted to predict the exact changes in behavior that result from the information, or the resultant monetized benefits. EPA does not believe that there are adequate methodologies to make reasonable monetary estimates of either the benefits of the activities required by the proposed rule, or the follow-on activities. The economic analysis of the proposed rule, however, does provide a qualitative discussion along with illustrative examples of how the proposed rule will improve the availability of information on lead and lead compounds. EPA described how consumers, industry, the financial and business community, academics, environmental groups, communities, and the media are expected to use the results of TRI reporting on lead and lead compounds. Based on the number and variety of comments, it appears that this information was adequate to allow the public to evaluate and comment on the benefits of the proposed rule.

A number of commenters request that EPA quantify the releases expected to be captured by the proposed rule and address whether a substantial majority of lead and lead compounds releases are already captured by current TRI reporting. Other commenters state that EPA cannot estimate the quantity of lead and lead compounds that are released or transferred without the additional data that would be collected by the rule. These commenters assert that estimates about releases or transfers would be "fundamentally flawed" due to a reliance on unsupported assumptions about facility operations, not on actual data. The commenters note that while it is possible to estimate how many facilities might be impacted

by having to report a particular substance, estimating quantities at a particular facility is extremely difficult because of differences in operations even among facilities in a narrowly-defined four-digit SIC code. The commenters express a concern that any release estimate made by EPA of an "average" facility is likely to be highly inaccurate and biased toward known sources of lead releases, and that those communities with large numbers of facilities with small releases would be adversely affected by this approach.

EPA agrees with the commenters who describe the practical difficulties in making reasonable, reliable estimates of the quantity of lead and lead compounds that are released or transferred without the additional reporting data that would be collected by the rule. EPA has not estimated the total national releases to all media for this rule (and in previous TRI rules) because EPA believes that there is insufficient information on the numerous processes and associated waste management techniques in the affected sectors to generate a comprehensive release estimate.

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

Historical attempts to estimate the releases expected to be reported to TRI prior to actual reporting have been imprecise to the point of being misleading, particularly in respect to estimates of releases per report or per facility. EPA notes that there were various reports and studies about air emissions of toxic chemicals prior to TRI, but the collection of facility-level data showed that actual releases were much different from what had been anticipated. EPA has not seen any evidence to indicate that the TRI

releases that will be reported as a result of the this action can be predicted any more accurately now than the quantities reported as a result of the original TRI rule could have been predicted prior to 1987.

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

EPA does not believe that inaccurate or incomplete estimates of releases and other waste management activities would aid the decision-making process for the rule. Therefore, EPA has not estimated the releases and other waste management activities that would be reported as a result of the rule.

Commenters assert that the cost of the rule would outweigh the benefits because the proposed 10 pound reporting threshold for lead and lead compounds will not capture "significant" amounts of releases, while substantially burdening thousands of facilities.

Although the reporting threshold for lead and lead compounds in this action is 100 pounds, EPA does not agree with the comment. The commenters do not define what constitutes "significant" amounts of releases of lead and lead compounds. Absent this definition, it is unclear what amount of unreported releases the commenters believe would justify the cost of additional reporting. The implication of the comment is that there is minimal benefit to any reporting that does not constitute a large proportion of total national releases. EPA does not agree. EPA notes that the inherent persistence, bioaccumulation, and toxicity of lead and lead

compounds create concern about human health and environmental effects in even the smallest amounts or concentrations. EPA believes that information on small amounts of lead or lead compounds (either in absolute or relative terms) is important. Even if a single facility or industry is not responsible for a high percentage of total national loadings, the releases from that facility or industry may still be of concern to the public. The percentage of total national releases that an individual facility or industry represents does not reflect the potential human health and environmental effects of even small amounts of lead and lead compounds, especially when multiple facilities release lead and lead compounds that persist and bioaccumulate. EPA also believes that focusing exclusively on releases ignores the value of other data elements on TRI reporting form, such as quantities of waste otherwise managed on-site and transferred for off-site management and qualitative information on source reduction activities.

Aside from the issue of whether comprehensive release estimates for such a rulemaking can reliably be predicted, EPA notes that pounds of releases and other waste management activities (even if known) are not a reasonable proxy for the benefits of the information being provided. This is because the benefits of an informational regulation are not systematically related to the magnitude of the data elements being reported. For example, automobile manufacturers are required to provide information about fuel economy on the stickers for new cars. Assuming that the quantity reported is a direct measure of the value of the information would lead to the mistaken conclusion that there is 100 percent difference in the benefit of requiring the information to be provided on a car that gets 15 miles per gallon compared to another car that gets 30 miles per gallon. To use another example, nutritional labels are required on food packages. Assuming that the benefits of information provision are linearly related to the quantity that is reported would yield the conclusion that if one product has 6 grams of fat per serving and another has 2 grams, the benefit of the nutritional labeling requirement are three times higher for the former than the latter.

One of the central purposes of TRI data is to inform the public about releases and other waste management of EPCRA section 313 listed toxic chemicals in their community and nationally so that the public can form its own conclusions about risks. The amount of releases and other waste

management activities that a community may find relevant or useful will vary depending on numerous factors specific to that community, such as the toxicity of the various chemicals, potential exposure to these toxic chemicals, and the number of other facilities in the area that release EPCRA section 313 listed toxic chemicals. Section 313(h) of EPCRA states that the data are "to inform persons about releases and other waste management activities 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." Pounds of releases and other waste management activities reported does not measure how the data perform these functions, and thus is not a measure of benefits. EPA disagrees with the implicit assumption by commenters that the benefits of information from different facilities is strictly and systematically related to the quantity reported as being released. Finally, EPA notes that while the proposed reporting threshold for lead and lead compounds was 10 pounds, the final rule (and associated economic analysis) reflect a reporting threshold of 100 pounds. This further reduces the relevance of the comment.

D. What are the Potential Impacts of This Action on Small Entities?

In accordance with the Regulatory Flexibility Act (RFA) and the Agency's longstanding policy of always considering whether there may be a potential for adverse impacts on small entities, the Agency has evaluated the potential impacts of this rule on small entities.

This rule may affect both small businesses and small governments. No small non-profit organizations are expected to be affected by the rule. For the purpose of its small entity impact analysis for the final rule, EPA defined a small business using the small business size standards established by the Small Business Administration (SBA) at 13 CFR part 121. [On October 1, 2000, the new SBA size standards for small businesses based on the North American Industry Classification System (NAICS) took effect (65 FR 30836, May 15, 2000). These replaced the previous size standards established under the Standard Industrial Classification (SIC) system. EPA has concluded that the conversion to the new classification system will have no substantive impact on the conclusions of the Agency's small entity impact analysis for this action (Ref. 53)]. EPA

defined small governments using the RFA definition of jurisdictions with a population of less than 50,000. EPA analyzed the potential cost impact of the rule on small businesses and governments separately in order to obtain the most accurate assessment for each. EPA then aggregated the analyses for the purpose of determining whether it could certify that the rule will not 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 this certification statement. EPA believes that the statutory test for certifying a rule and the statutory consequences of not certifying a rule all indicate that certification determinations should be based on an aggregated analysis of the rule's impact on all of the small entities subject to it.

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. Potential small entity impacts were calculated for both the first year of reporting and subsequent years. First year costs are typically higher than continuing costs because firms must familiarize themselves with the requirements. Once firms have become familiar with how the reporting requirements apply to their operations, costs fall. EPA believes that subsequent year impacts present the best measure to judge the impact on small entities because these continuing costs are more representative of the costs firms face to comply with the rule.

The incremental burden of the additional reporting at the facility level is low. This burden is associated with labor that will be expended by facility staff to conduct the reporting activities to file one TRI report. By statutory requirement, the smallest possible facility that could be affected by this action must have the equivalent of at least 10 full-time employees. On a yearly basis, this means that there are at least 20,000 labor hours expended at the smallest potentially affected facility (10 FTEs x 50 wks/year/employee x 40 hours/wk = 20,000 labor hours/year). EPA estimates that typical reporting burdens as a result of this rule will be up to 110 hours per facility (in the first year of reporting for a first-time TRI reporter), and that in subsequent years

typical reporting burden will be approximately 50 hours. Based on these reporting burdens, the average impact of TRI reporting ranges from 0.25 to 0.55 percent of available labor hours for the *smallest* facility affected by this rule. The impact would be even less for facilities with more than 10 full-time employees, or for facilities that take less than the average time to report.

EPA examined annual compliance costs as a percentage of annual company sales to assess the potential impacts of this rule on small businesses. Based on its estimates of additional reporting as a result of the rule, the Agency estimates that approximately 5,700 businesses will be affected by the rule, and that approximately 4,100 of these businesses are classified as "small" based on the applicable SBA size standards. EPA estimates that fewer than 250 small businesses (approximately 5% of all affected small businesses) will bear annual costs between 1–3% of annual revenues in the first reporting year, and that no small businesses will bear annual costs above 1% of annual revenues in subsequent reporting years. These results are not significantly different from those derived in the economic analysis of the proposed rule; the main difference is a "non-zero" result for the number of small businesses predicted to experience an annual cost impact above 1% of annual revenues in the first year of reporting. These estimates, and their derivation, are described in the economic analysis of the final rule (Ref. 46).

A number of commenters submitted comments on EPA's methodology for assessing small entity impacts in the economic analysis of the proposed rule. One commenter asserts that the Agency's analysis of potential impacts of the proposed rule on small business is lacking because it does not examine the large number of industrial sectors that may be affected by this reporting requirement. The commenter states that EPA's findings about the widespread and persistent nature of lead in the environment are not in accord with the "very limited effort" to identify affected sectors (especially small business sectors).

EPA disagrees with the commenter's characterization of the effort made to identify affected sectors. In the economic analysis for the proposed rule, EPA made quantitative estimates of the number of additional TRI reports that would be expected at four lower reporting thresholds for lead and lead compounds from industry groups that are subject to EPCRA section 313 and for which EPA could locate the information necessary to make

quantitative estimates of facility level lead usage. EPA also identified a number of industry groups which are also subject to EPCRA section 313, but for which EPA lacked data on lead throughput to generate quantitative estimates of additional reporting.

In the proposed rule, and in a subsequent notice announcing public meetings, EPA solicited additional information to allow EPA to quantify the number of additional reports in all industry groups that are subject to EPCRA section 313. EPA fully considered information from the commenters on the potential for additional reporting from industries that were not identified in the economic analysis of the proposed rule, or for which EPA was unable to make quantitative estimates at the time of the proposal. As a result of the comments, EPA revised its estimates for a number of potentially affected industry groups. The revised estimates are described in Appendix A of the economic analysis of the final rule. While the estimates for some industry groups changed substantially as a result of the comments, EPA's estimate of the total number of additional reports remained relatively stable. At a 100 pound reporting threshold for lead and lead compounds, EPA estimates that approximately 9,800 facilities will submit additional reports.

EPA's economic analysis of the proposed rule modeled the revenue characteristics of affected firms to evaluate the potential impact on small businesses. Commenters assert EPA's analysis produced biased results by combining manufacturing industries (SIC codes 20-39) that are unrelated in most aspects. Commenters assert that EPA made faulty assumptions by "grouping together small business with large manufacturers." One commenter asserts that EPA's analysis considered the aggregate cost of the proposal to each industry group surveyed, ignoring individual businesses with costs above and below the aggregate value.

In the economic analysis of the proposed rule EPA modeled revenues for small firms with low, medium and high revenues in the manufacturing industries (i.e., SIC codes 20-39). EPA's RFA/SBREFA guidance states that "In assessing the impact of a rule on small businesses, it may be appropriate to analyze the rule's impact on each kind of business separately, particularly where the rule may impose significantly higher costs on some kinds of businesses than on others" (Ref. 50). However, there is no guidance as to the specific SIC code level that is appropriate (e.g., 2-digit vs. 3-digit vs. 4-

digit vs. 5-digit, etc.). For the small entity analysis of the proposed rule, EPA analyzed impacts separately for the following "kinds of businesses": mining, manufacturing, electric utilities, commercial hazardous waste treatment, chemical and allied products-wholesale, petroleum bulk terminals, and solvent recovery services. EPA does not believe that this approach biased the results of the small entity impact analysis for the proposed rule.

EPA did not group small businesses together with large businesses in the manufacturing industry as the commenter asserts. EPA constructed separate revenue models for large firms and small firms. For small firms within each industry group, EPA compared typical reporting costs with the revenues available to small firms with low, medium, and high revenues. EPA's analysis was not based on an aggregate cost to each industry group, but rather on the cost to individual firms. For the economic analysis of the final rule, EPA developed revenue profiles at the 2-digit SIC code level (20, 21, 22, etc.) for small businesses within the manufacturing industries to provide for additional disaggregation. This approach was taken to address the comment that EPA would reach a different determination if impact estimates for the manufacturing SIC codes were presented at a greater level of disaggregation. Contrary to the comments on this issue, the disaggregated analysis does not change the ultimate conclusion about small entity impacts.

In the small entity impact analysis for the proposed rule, revenues of potentially affected small businesses were modeled using revenue data for small businesses that own or operate facilities that currently report to TRI on any chemical. EPA developed separate revenue profiles based on "small" current filers and "large" current filers. Within these profiles, EPA looked at companies with low, medium, and high revenues. Commenters contend that EPA's use of current TRI filers as a representative cohort for estimating the proposed rule's impacts on small businesses is flawed since current TRI filers may not be representative of facilities that report to TRI for the first time as a result of the rule. The commenters assert that facilities reporting as a result of this rule are very different in terms of size and revenues from their counterparts that currently use lead, or other EPCRA section 313 listed toxic chemicals, in amounts greater than 25,000 pounds. The commenters contend that current TRI filers are, for the most part, the largest members of their sectors with the

highest revenues. As a result, the commenters contend that EPA underestimated the proposal's impact on small businesses. The commenters state a belief that an assessment of the rule's potential impact on small businesses should not be based upon its impact on current TRI filers. The commenters suggest an alternative methodology of assessing how the smallest facilities in each potentially impacted small business sector would be impacted by the proposed rule in order to make a SBREFA determination.

EPA disagrees that using small businesses that own current TRI filers as a representative cohort for estimating the proposed rule's impacts on small businesses is flawed methodology for assessing whether the rule would have a significant economic impact on a substantial number of small entities. First, it should be noted that current TRI filers span the range of employment, from companies with 10 employees to those with thousands of employees. As noted in the economic analysis for the proposed rule, almost 70 percent of current TRI reporters are small businesses. Therefore, small businesses have substantial representation in current TRI reporting. Second, additional reporting on lead and lead compounds will not be limited to small facilities, or to facilities filing their first TRI reports. Additional reporting on lead is expected to come from facilities with a mix of size characteristics, including large facilities that currently report other EPCRA section 313 chemicals but not lead. Third, current TRI filers in the manufacturing industries tend to be found in capital-intensive industries rather than in labor-intensive industries. Based on EPA's research, it appears that most facilities that file additional lead reports will also be from capital-intensive industries like the ones that predominate in current TRI reporting. Since additional lead reporting will come mainly from: (1) Current filers (who file on other chemicals) and (2) new filers in capital-intensive industries, EPA believes that it is valid to assume that first-time filers under this rule will be like current filers in terms of employment and revenue.

To evaluate the possibility that first-time TRI filers in the manufacturing sector would be so dissimilar to current TRI filers as to change EPA's small entity impact findings, EPA conducted a sensitivity analysis (Ref. 51) to estimate the potential impact on the smallest facilities in each potentially impacted small business sector for the proposed reporting threshold. This analysis estimated the average potential impact of the proposed rule on facilities

in various employment size classes within each of the twenty 2-digit manufacturing SIC codes (and certain 4-digit SIC codes). The analysis revealed that average potential impacts are higher for facilities with fewer employees and lower annual revenues, but the potential cost impact is still less than 1 percent of average annual revenues for every employment size class in every manufacturing SIC code.

Even information submitted to EPA by industry does not indicate that a substantial number of small businesses would have costs above 1% of annual revenues. In an informal survey conducted by the IPC the Association Connecting Electronics Industries, IPC asked its member companies in the printed wiring board industry to indicate if the proposed rule would result in regulatory costs exceeding 1% of annual revenues (Ref. 52). IPC received 300 responses, of which 260 were from self-identified small businesses. Of these 260, only 5 claimed that the proposed rule would impose costs greater than 1% of their annual revenues. This survey indicates that less than 2% of affected small businesses in this sector believe that they would experience an economic impact of greater than 1% of annual revenues as a result of the proposed rule. Furthermore, IPC's survey was based on the proposed reporting threshold of 10 pounds. This final rule incorporates a reporting threshold of 100 pounds, which will result in less regulatory impact to facilities in this sector.

To further address the issue of differing revenue characteristics between current and first-time TRI filers, EPA revised its method for modeling the revenues of affected small businesses. In the small entity impact analysis for the final rule, EPA modeled revenues of small first-time filers using revenue data for small businesses that own facilities that do not currently file TRI reports. EPA modeled revenues of small current filers using revenue data on small businesses that own current TRI-filing facilities. Contrary to the comments on this issue, using this method to model revenues does not change the ultimate conclusion about small entity impacts.

A commenter asserts that EPA's conclusion about the impact of the rule on small businesses was based on an erroneous assumption about the percentage of additional reports that would be received from new filers. The commenter asserts that EPA "seriously" underestimated the number of first-time filers to TRI that would result from the proposed rule. The commenter notes that approximately 10% of printed

wiring board facilities currently report to TRI and few of the facilities report for lead, but that this proposal would trigger lead reporting for virtually all companies. In this industry, approximately 80% to 90% would have to report to the TRI for the first time. The commenter notes that EPA estimated that first-time filers under the rule would comprise only 38.3% of affected manufacturing facilities.

The estimate for first-time TRI filers cited by the commenter is an average for the entire manufacturing sector. For individual SIC codes within manufacturing (such as printed wiring boards), the percentage of first-time TRI filers may be higher or lower. For the economic analysis of the final rule, the estimate of first-time filers was revised based on an SIC code-by-SIC code approach that assumes current TRI filers will file the first additional reports in each SIC code, and that the remaining additional reports will be filed by facilities that are new to TRI reporting (i.e., first-time filers). Rather than using an average number of new filers for manufacturers as a class, this approach estimates the number of new filers at the 2-, 3-, or 4-digit SIC code level. Using the revised approach, the total estimated percentage of first-time filers increased to approximately 40% of all affected facilities, with substantial variation at the 2-digit SIC code level as indicated by the commenters. Therefore, EPA does not believe that the number of first-time filers was "seriously" underestimated in the economic analysis of the proposed rule.

In assessing the potential impact of the rule on small entities, EPA searched for situations in which the annual cost of reporting for a business would exceed a small fraction of annual revenues. Commenters assert that 1% of annual sales (one of the indicator values used by EPA) is not a good measure of impacts on small businesses. The commenters assert that the 1% metric is arbitrary and argue that it may not be a good measure of impact across different industry sectors. The commenters state that some industries may have profits that are only a few percent of total revenue, in which case, costs that are close to one percent of revenue would be a very large percent of profit, while other industries may have profits that are a much higher percent of revenue.

Contrary to the commenters' claim, EPA did justify its choice of revenue-based impact metric for assessing small entity impacts. As EPA stated at 64 FR 42238, "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."

The commenters suggest that EPA should use profits as a measure of impact. EPA, however, believes that there are several advantages to the use of revenue data. The advantage of using revenue to measure impacts is that it is a stable, easily accessible, and easily understood measure which provides a basis for comparing this rule to other rules. Unlike profit information, the definition is consistent and not subject to the widely varying accounting definitions and interpretations of terms that affect "profit" measures. Another advantage is that revenue data, unlike profit data, are widely available. The proportion of firms for which revenue data are available generally greatly exceeds the proportion of firms for which profit data are available. Many information sources, including the Census of Manufactures, collect and publish revenue data but not profit data.

Furthermore, revenue data are easily understood. For example, if the impact of compliance costs on a firm is 1% of revenue, a firm would need to raise its prices 1% to cover the costs of the regulation. This is a clear, easy to understand measure that can help decision-makers determine whether additional measures to reduce the impact of a regulation are warranted. In addition, EPA has a long history of using the relationship between the annual cost of compliance with a regulation and total annual revenue of the firm to determine whether a regulation may have a significant economic impact on substantial number of small entities.

EPA believes that the revenue-based impact calculation used in the analysis of this rule is preferable to a profit-based calculation because it is simple to apply and based on readily available data, which allows consistent application of the methodology from rule to rule. Although the commenters suggest other metrics such as profit margins, they do not provide any indication of how this data could be obtained or what impact levels would indicate a "significant" impact. The commenters note that profit

margins are variable, but do not provide profit margin data for all affected industry sectors.

In addition to small businesses, the rule is also expected to affect certain small governments. To assess the potential impacts of the final rule 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 8 publicly owned electric utility facilities, operated by a total of 8 municipalities, may be affected by the rule. Of these, an estimated 7 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. Therefore, 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) because only certain small businesses are expected to experience impacts above 1% of revenues in any year.

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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 a "significant regulatory action". This action was submitted to the Office of Management and Budget (OMB) for

review, and any substantive changes made during that review have been documented in the public version of the official record.

EPA's cost-benefit analysis for the proposed rule was contained in a document entitled *Economic Analysis of the Proposed Rule to Modify Reporting of Lead and Lead Compounds Under EPCRA Section 313 (Ref. 16)*. The economic analysis contains a quantitative estimate of the costs and a qualitative discussion of the benefits of the proposed rule. This document, and its supporting documentation, were included in the public docket for review and comment. EPA has prepared an economic analysis of the impact of this final rule, which is contained in a document entitled *Economic Analysis of the Final Rule to Modify Reporting of Lead and Lead Compounds under EPCRA Section 313 (Ref. 42)*. This document is available as part of the public version of the official record for this action, and is briefly summarized in Unit VII.

Commenters assert that the proposed rule did not meet Executive Order 12866 requirements to consider costs and benefits, including the alternative of not regulating. The commenters assert that the Agency has not given adequate consideration to the baseline option of existing TRI reporting thresholds of 25,000 and 10,000 pounds, under which EPA has received reporting on release and other waste management of over one billion pounds of lead and lead compounds per year. The commenters assert that the alternative of the current reporting thresholds of 25,000 and 10,000 pounds is generally not included in the text and tables of the preamble and Economic Analysis.

EPA did consider the option of not regulating, and addressed what would happen in the absence of this rule. As EPA noted in the **Federal Register** notice for the proposed rule, "If EPA were not to take this proposed action to lower 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" (64 FR 42237). The discussion of costs and benefits in the economic analysis and preamble are all relative to the baseline of not regulating beyond the current reporting thresholds for lead and lead compounds. Chapter 6 of the economic analysis of the proposed rule contains a discussion of current reporting on lead and lead compounds at existing reporting thresholds, as well as a discussion of information that would be collected as a result of the proposed rule. Furthermore, current TRI

reporting on lead and lead compounds was summarized in Tables A-3 and A-4 of the economic analysis of the proposed rule.

Commenters assert that EPA has not met requirements of Executive Order 12866 because EPA has not quantified benefits of the proposed rule and has not estimated the amount of releases expected to be reported.

EPA believes that the proposal is consistent with Executive Order 12866, because EPA proposed the regulation upon a reasoned determination that the benefits justify the costs. The commenters imply that EPA must quantify benefits to comply with Executive Order 12866. However, Executive Order 12866 recognizes that it may not be feasible to derive quantitative estimates of benefits in all cases. Section (1)(a) of Executive Order 12866 states that "Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider." The Executive Order goes on to state in section (1)(b)(6) that "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." EPA's economic analysis has addressed the costs of the proposal in a quantified manner and the benefits in a qualitative manner. Because the state of knowledge about the economics of information is not highly developed, EPA has not attempted to quantify the benefits of the rule as monetized net benefits. EPA notes that Executive Order 12866 does not require that benefits be quantified for every regulation, or that agencies should predict the answers to a data collection (in this case, the "per facility" releases and other waste management of lead and lead compounds) prior to the actual collection of the data.

EPA notes that comparing the cost of the reporting to the quantity of releases that would be reported does not compare costs and benefits. Section 313(g) of EPCRA states that the data are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities, to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons

in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. The quantity of releases reported does not measure how well the data perform these functions, and thus releases are not a measure of benefits. The benefits of the rule include improvements in understanding, awareness, and decision making related to the provision of information. Even if reliable estimates of releases were possible, pounds of releases would not measure the value of the information provided. Improvements in understanding are not measured in pounds, nor are improvements in awareness or decision making.

While it is not possible to quantify the benefits of the rule with monetized estimates, EPA has qualitatively examined the benefits of the rule. Based on this review, EPA believes that the benefits provided by the information to be reported under this rule will significantly outweigh the costs. Upon review of this evidence, EPA has made a reasoned determination that the benefits of the regulation justify its costs. Therefore, EPA believes it has followed the principles and met the requirements of Executive Order 12866.

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

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the EPA Administrator hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is presented in the small entity impact analysis prepared as part of the *Economic Analysis* for this final rule (Ref. 46), which is discussed in detail in Unit VII, and contained in the public version of the official record for this rule. Further support for this determination can be found in the sensitivity analysis (Ref. 51) that was conducted to assess the analytical methods used in the small entity impact analysis of the proposed rule. Information relating to this determination has been provided to the Chief Counsel for Advocacy of the Small Business Administration, and is included in the public version of the official record for this rulemaking. The following is a brief summary of the Agency's factual basis for this certification.

For the purpose of analyzing potential impacts on small entities, EPA used the RFA definition of small entities in section 601(6) of the RFA. Under this section, small entities include small

businesses, small governments, and small non-profit organizations. [On October 1, 2000, the SBA size standards for small businesses based on the North American Industry Classification System (NAICS) took effect (65 FR 30836, May 15, 2000). These replaced the previous size standards established under the Standard Industrial Classification (SIC) system. EPA has concluded that the conversion to the new classification system will have no substantive impact on the conclusions of the Agency's small entity impact analysis for this action (Ref. 53)]. EPA defined a small business using the small business size standards established by the Small Business Administration (SBA), which are generally based on the number of employees or annual sales/revenue a business in a particular industrial sector has. EPA defined small governments using the RFA definition of jurisdictions with a population of less than 50,000. No small non-profit organizations are expected to be affected by this final rule.

EPA estimates that approximately 4,100 small businesses will be affected by the rule. The incremental burden of the additional reporting at the facility level is associated with labor that will be expended by facility staff to conduct reporting activities. Based on typical reporting burdens of approximately 110 hours (in the first year of reporting for a first-time TRI reporter) and 50 hours in subsequent years, the impact of this action ranges from 0.25 to 0.55 percent of available labor hours for the smallest affected facility. The impact would be even less for facilities with more than 10 full-time employees, or for those that take less than the average amount of time to report.

EPA estimates that the final rule would have an annual cost impact between 1-3% of annual revenues on fewer than 250 small businesses (approximately 5% of all affected small businesses) in the first year only. After the first year of reporting, the annual cost impact as a percentage of annual revenues is estimated to be below 1% for all affected small entities.

Commenters assert that this rule will have significant impacts on small businesses, and that EPA improperly certified the proposed rule. The commenters assert that a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel must be completed to determine the "true" impact of the proposed rule on small businesses.

EPA believes that its certification of the proposed rule as not having a significant economic impact on a substantial number of small entities was proper. In the **Federal Register** notice

for the proposed rule, EPA described a quantitative small entity impact analysis that EPA placed in the official version of the public record. The results of this analysis indicated that the proposed rule would not have a significant economic impact on a substantial number of small entities. Based on public comments, EPA revised this quantitative analysis and arrived at the same conclusion for the final rule. Furthermore, EPA notes that while the proposed reporting threshold for lead and lead compounds was 10 pounds, this final rule incorporates a reporting threshold of 100 pounds. This threshold further reduces the potential regulatory impact on small entities as indicated in the economic analysis of the final rule.

EPA does not agree with the comment that a SBREFA panel must be completed to determine whether this, or any, proposed rule will have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act (RFA) to require EPA to convene a Small Business Advocacy Review Panel for any proposed rule for which EPA is required to prepare an initial regulatory flexibility analysis (IRFA). The RFA requires that EPA prepare an IRFA for all rules for which EPA is required by statute to publish a notice of proposed rulemaking unless the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." The panel is an additional means for small entities to participate in the rulemaking process, but the certification provision of the RFA as amended by SBREFA indicates that panels are not appropriate for every rulemaking. The panel requirement only applies to proposed rules that the Agency ultimately determines will not be certified under the RFA.

Commenters also assert that EPA failed to provide a "meaningful" opportunity for small businesses to participate in the rulemaking process. The commenters asserted that EPA did not conduct outreach to small businesses prior to the proposal, and that any outreach after rule proposal is inadequate and cannot remedy EPA's "lack of outreach" to small entities early in the regulatory development process. The commenters assert that "EPA's failure to contact small business sectors early in the rulemaking process" led to "significant flaws" in EPA's SBREFA determination because it failed to consider "more than two dozen small business sectors that would be impacted by the proposed rule" and failed to consider the significance of the impact on small businesses. Specifically the

commenters mention printed circuit board manufacturers, metal finishers, foundries, and dentists as affected sectors. As a result, the commenters contend that the Agency did not comply with SBREFA, and violated the analytical and outreach requirements of the RFA. The commenters also contend that EPA did not comply with the Agency's own internal guidance related to RFA/SBREFA compliance. One commenter contends that EPA's failure to conduct appropriate outreach misled the Agency to certify that the rule has no significant impact on small business. Therefore, the commenter suggests that the EPA conduct additional outreach with small business, followed by a thorough SBREFA panel process. The commenter contends that outreach to small business would have revealed that the proposed rule affects more than "two dozen small business sectors that the agency failed to consider." As one example, the commenter asserts that dentists would have to report because they accumulate lead in the form of used x-ray film backing that they store and recycle. The commenter also mentions metal finishing and the printed circuit board industry.

EPA complied with internal guidance and the requirements of the RFA as amended by SBREFA and conducted its analysis in accord with the Agency's internal guidance. EPA's actions provided a meaningful opportunity for small businesses to participate in the rulemaking process. EPA initially alerted the potentially affected community to EPA's intention to review lead and lead compounds for lower reporting thresholds in the proposed rule to lower the EPCRA section 313 reporting threshold for certain PBT chemicals that are subject to reporting under EPCRA section 313 (64 FR 688). That **Federal Register** notice stated that "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" (64 FR 717, January 5, 1999). As part of the PBT rulemaking process, EPA held three public meetings in San Francisco, CA; Chicago, IL; and Washington, DC. Numerous commenters on the PBT rule requested that EPA classify lead and lead compounds as PBT chemicals.

EPA published a notice of proposed rulemaking for lead and lead compounds on August 3, 1999. EPA

requested comment on this rulemaking and provided an initial 45 day comment period. Subsequently, EPA extended the comment period twice for a total of 90 additional days. In addition, EPA held public meetings with special emphasis on potential small business impacts in Los Angeles, CA; Chicago, IL; and Washington, DC. EPA also met with representatives of small business trade organizations who expressed a desire for additional meetings.

EPA notes that a number of small businesses participated in the rulemaking process by attending public meetings and submitting comments on the proposed rule. EPA has considered these comments and updated its economic analysis with information provided by these commenters. EPA believes that these activities, along with the written public comment process, provided ample opportunities for small businesses to participate in the rulemaking process.

EPA does not agree that its rulemaking process led to significant flaws in EPA's certification that the proposed rule would not, if promulgated, have a significant economic impact on a substantial number of small businesses. EPA conducted an extensive economic analysis that included a quantitative small entity impact analysis. EPA made this analysis available as part of the public record for the rulemaking. The public comment process has provided an opportunity for small businesses to comment on this analysis, and to provide additional information to refine this analysis. Further, even though EPA extended the public comment period twice and held three public meetings, EPA did not receive additional information that would lead it to change its determination.

Although some commenters assert that EPA failed to identify certain potentially affected sectors leading to a flawed certification, EPA does not agree. EPA conducted an extensive economic analysis. Specifically, EPA did identify printed circuit board manufacturers, metal finishers, foundries, and other industries as potentially affected sectors in the economic analysis of the proposed rule. Dentists were not identified as potentially affected because they are not in a SIC code that is subject to TRI reporting. EPA cannot evaluate the accuracy of generic comments that assert EPA missed potentially affected industries when commenters do not identify these industries by name, or provide evidence to support the assertion for each additional identified industry. If EPA failed to identify certain sectors as

potentially affected, this a reflection of the lack of publicly available information on lead and lead compounds. The lack of publicly available information on lead and lead compounds speaks more to the need for the rule than to the quality of EPA's analysis.

In conclusion, EPA believes that it has followed the requirements of the RFA and that it has properly certified that the rule will not have a significant impact on a substantial number of small entities.

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

The information collection requirements contained in this final rule have been submitted to OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), and in accordance with the procedures at 5 CFR 1320.11. OMB has approved the existing reporting and recordkeeping requirements for the EPA Toxic Chemical Release Inventory Form R (EPA Form No. 9350-1), supplier notification, and petitions under OMB Control No. 2070-0093 (EPA ICR No. 1363). EPA has prepared an amendment (EPA ICR No. 1363.11) to the existing Information Collection Request (ICR) to include the burden associated with lower reporting thresholds for lead and lead compounds. A copy may be obtained from Sandy Farmer, Office of Information Collections, U.S. Environmental Protection Agency (2137), 1200 Pennsylvania Ave., NW., Washington, DC 20460, by calling (202) 260-2740, or electronically by sending an e-mail message to "farmer.sandy@epa.gov."

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 a currently valid OMB control number is displayed. The OMB control numbers for EPA's regulations, after initial publication in the Federal Register, are maintained in a list at 40 CFR part 9. The information requirements contained in this final rule are not effective until OMB approves them.

EPCRA section 313 (42 U.S.C. 11023) requires owners or operators of certain facilities manufacturing, processing, or otherwise using any of over 600 listed toxic chemicals and chemical categories in excess of the applicable threshold quantities, and meeting certain requirements (i.e., at least 10 Full Time Employees or the equivalent), to report certain release and other waste management activities for such chemicals annually. Under PPA section

6607 (42 U.S.C. 13106), facilities must also provide information on recycling and other waste management data and source reduction activities. 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 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 (based on typical unit burden estimates for Form R completion and recordkeeping/mailling requirements), 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 rule is estimated to result in additional reports from approximately 9,800 respondents. Of these, approximately 3,600 facilities are estimated to be reporting to TRI for the first time as a result of the rule, while the remainder are currently reporting facilities that will be submitting additional reports. The 9,800 respondents will each submit an additional Form R. This rule is estimated to result in a total burden of 1.2 million hours in the first year, and 0.6 million hours in subsequent years, at a total estimated industry cost of \$80 million in the first year and \$40 million in subsequent years. The existing ICR will be amended to add 790,000 burden hours (annual average burden for the first 3 years of ICR approval).

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide

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

A commenter asserts that EPA failed to meet Paperwork Reduction Act requirements because it has not provided Form R reporting instructions for the proposed changes to the TRI reporting requirements for lead and lead compounds. The commenter contends that the proposed rule requires significant changes in the information submitted by regulated industry sectors on the Form R. The commenter asserts that OMB's Information Collection Review Handbook requires that materials submitted for review under the Paperwork Reduction Act must be accompanied by the documents to be used in the collection of information (i.e., forms, schedules, questionnaires, handbook, manual, interview plan or guide, rule, regulation, or other document), and any other explanatory material to be given or sent to prospective respondents. The commenter asserts that the current Form R reporting instructions do not provide the guidance necessary for reporting lead and lead compounds at the lower reporting thresholds with elimination of exemptions such as the *de minimis* exemption and changed rules for reporting. The commenter asserts that EPA has not issued guidance regarding how to comply under the proposed lower reporting thresholds, indicated what its plans are for issuing such guidance, or allowed formal opportunity for stakeholders to review and comment.

EPA disagrees with the commenter. EPA did not propose significant changes in the types of information to be reported by industry. EPA proposed using the existing Form R for reports that would be required under the lower reporting threshold. Since EPA did not propose to amend the Form R, and the existing Form R was already approved

by OMB, EPA was not required to submit the Form R separately with the ICR amendment at the proposed rule stage. Nevertheless, the proposed ICR amendment that EPA submitted to OMB included a copy of the existing ICR approved by OMB, along with a copy of the Form R. The existing ICR also specifically describes all of the existing reporting elements on Form R.

EPA strongly disagrees with the suggestion that it has circumvented the notice and comment process. The preamble to the proposed rule, the economic analysis, and the proposed ICR amendment all specifically describe EPA's proposal to lower reporting thresholds, and to change the reporting requirements so as not to allow use of the *de minimis* exemption, range reporting or Form A for reports submitted under the lowered thresholds. The **Federal Register** provided public notice and specifically solicited public comments on the changes to reporting requirements and reporting instructions that were being considered, as well as on the Agency's associated burden estimates. The Agency provided a functional description of the changes in reporting that would result from his rule. Therefore, EPA was in compliance with the PRA and with OMB requirements.

D. What are the Determinations Under the Unfunded Mandates Reform Act and Executive Order 13084?

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4), EPA has determined that this action does not contain a "Federal mandate" that may result in expenditures of \$100 million or more for the private sector in any 1 year, nor will it result in such expenditures for State, local, and tribal governments in the aggregate. The costs associated with this action are estimated in the economic analysis prepared for this final rule (Ref. 46), which is included in the public docket and summarized in Unit VII. of this preamble.

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

Finally, EPA believes this rule complies with section 205(a) of UMRA. The objective of this rule is to expand the public benefits of the TRI program by exercising EPA's discretionary

authority to 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.

As described in Unit VI. of this preamble, EPA considered burden in the threshold selection. The rule also contains reporting requirements that will limit burden (e.g., reporting limitations for lead 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 rule. EPA also will be assisting small entities subject to the rule, by such means as providing meetings, training, and compliance guides in the future, which also will ease the burdens of compliance. Many steps have been and will be taken to further reduce the burden associated with this rule, and to EPA's knowledge there is no available alternative to the rule that would obtain the equivalent information in a less burdensome manner. For all of these reasons, EPA believes the rule complies with UMRA section 205(a).

In addition, today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of 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 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 a significant regulatory action, 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 rule are expected to have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children.

F. What is the Determination under Executive Order 13132?

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implication" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action is expected to have a limited impact on municipal governments that operate electric utilities that may be affected by this action. EPA estimates that there are only 13 publicly-owned electric utility facilities that are potentially affected by the rule. Of these 13 facilities, 8 are expected to file one additional report as a result of this action. Thus, the requirements of Section 6 of the Executive Order do not apply to this rule.

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

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. The

NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

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

H. What are the Requirements of the Congressional Review Act?

The Congressional Review Act (5 U.S.C. 801 et seq.) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

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

Dated: January 8, 2001.

Carol M. Browner,
Administrator.

Therefore, 40 CFR part 372 is amended as follows:

PART 372—[AMENDED]

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

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

2. In § 372.28 by adding one chemical to paragraph (a)(1) alphabetically and to paragraph (a)(2) by alphabetically adding one category to read as follows:

§ 372.28 Lower thresholds for chemicals of special concern.

- (a) * * *
- (1) * * *

| Chemical Name | CAS No. | Reporting Threshold |
|---------------------------------------------------------------------------------------------------------------|-----------|---------------------|
| Lead (this lower threshold does not apply to lead when contained in a stainless steel, brass or bronze alloy) | 7439-92-1 | 100 |

(2) * * *

| Category Name | Reporting Threshold |
|----------------|---------------------|
| Lead Compounds | 100 |

* * * * *