6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 143

[EPA-HQ- OW-2015-0680; FRL-9958-23-OW]

RIN 2040-AF55

Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to make conforming changes to existing drinking water regulations based on the Reduction of Lead in Drinking Water Act of 2011 (RLDWA) and the Community Fire Safety Act of 2013 (CFSA). Section 1417 of the Safe Drinking Water Act (SDWA) prohibits the use and introduction into commerce of certain plumbing products that are not lead free. The RLDWA revised the definition of lead free to lower the allowable maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of plumbing products and established a statutory method for calculating lead content. In addition, the RLDWA created exemptions from the lead free requirements for plumbing products that are used exclusively for nonpotable services as well as for other specified products. The CFSA further amended section 1417 to exempt fire hydrants from these requirements.

EPA proposes to establish new requirements to assure that individuals purchasing, installing or inspecting potable water systems can identify lead free plumbing materials. Specifically, EPA proposes to establish labeling requirements to differentiate plumbing products that meet the lead free requirements from those that are exempt from the lead free requirements and to require manufacturers to certify compliance with the lead free requirements. These proposed requirements would reduce inadvertent use of non-lead free plumbing products in potable use applications and, consequently, reduce exposure to lead in drinking water and associated adverse health effects.

DATES: Comments must be received on or before **[insert date 90 days after publication in the Federal Register]**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ- OW-2015-0680, to the *Federal eRulemaking Portal:* http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system).

For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments,

please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION, CONTACT: Russ Perkinson, telephone number: 202-564-4901; email address: perkinson.russ@epa.gov, Office of Ground Water and Drinking Water, Standards and Risk Management Division (4607), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC, 20460.

SUPPLEMENTARY INFORMATION:

Abbreviations and Acronyms

AFS – American Foundries Society

ANSI – American National Standards Institute

CFSA – Community Fire Safety Act of 2013

CFR – Code of Federal Regulations

FAQs – Frequently Asked Questions

O&M – Operations and Maintenance

NAICS – North American Industry Classification System

NSF – NSF International

PMI – Plumbing Manufacturers International

RFA – Regulatory Flexibility Act

RLDWA – Reduction of Lead in Drinking Water Act of 2011

SDWA – Safe Drinking Water Act

SIC – Standard Industrial Classification

UL – Underwriters Laboratories

Table of Contents

I. General Information

A. Does this action apply to me?

The statutory prohibitions on use and introduction into commerce of certain products that are not lead free codified by this rule apply to "any person" as defined in the Safe Drinking Water Act (SDWA). This rule implementing those provisions applies to any person who would introduce plumbing products into commerce, such as manufacturers, importers, wholesalers, distributors, re-sellers, retailers, and to any person who would use plumbing products in a public water system or in a residential or non-residential facility providing water for human consumption. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is EPA taking?

EPA is proposing this regulation to codify revisions to the SDWA prohibition on use and introduction into commerce of certain products that are not lead free (hereafter termed the SDWA lead prohibitions) as enacted in the Reduction of Lead in Drinking Water Act of 2011 (RLDWA) and the Community Fire Safety Act of 2013 (CFSA). EPA is also proposing requirements to certify and label plumbing products introduced into commerce to assure they are lead free.

SDWA 1417(a)(1) prohibits the "use of any pipe, any pipe or plumbing fitting or fixture, any solder, or any flux in the installation or repair of any public water system; or any plumbing in a residential or non-residential facility providing water for human consumption, that is not lead free" as defined in section 1417(d). Section 1417(a)(3) provides that "it shall be unlawful (A) for any person to introduce into commerce any pipe, or any pipe or plumbing fitting or fixture, that is not lead free, except for a pipe that is used in manufacturing or industrial processing; (B) for any person engaged in the business of selling plumbing supplies, except manufacturers, to sell solder or flux that is not lead free; or (C) for any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption."

The 2011 RLDWA revised section 1417 to redefine lead free in SDWA section 1417(d) to lower the maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of plumbing products; established a statutory method for the calculation of lead content; and eliminated the requirement that lead free products be in compliance with voluntary standards established in accordance with SDWA 1417(e) for leaching of lead from new plumbing fittings and fixtures. In addition, the RLDWA created exemptions in SDWA section 1417(a)(4) from the prohibitions on the use or introduction into commerce for "pipes, pipe fittings, plumbing fittings, or fixtures, including backflow preventers, that are used exclusively for nonpotable services such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption" (SDWA 1417(a)(4)(A)), as well as for "toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, service saddles, or water distribution main gate

valves that are 2 inches in diameter or larger." (SDWA 1417(a)(4)(B)). The CFSA further amended section 1417 to exempt fire hydrants.

In addition to codifying the revised requirements under RLDWA and CFSA, EPA is proposing product certification requirements and data gathering authorities to ensure consistent implementation and enforcement of the SDWA lead prohibition, as well as new labeling requirements to assure that individuals purchasing, installing or inspecting potable water systems can identify lead free plumbing materials. Specifically, EPA proposes to establish labeling requirements to differentiate plumbing products that meet the lead free requirements from those that are exempt from the lead free requirements and to require manufacturers to certify compliance with the lead free requirements. These proposed requirements would reduce inadvertent use of non-lead free plumbing products in potable use applications and, consequently, reduce exposure to lead in drinking water and associated adverse health effects.

The goals of these proposed regulatory provisions are to limit accidental lead exposure by clearly identifying those products to be used or not used for potable services; and to ensure that plumbing products that are identified as lead free for use in potable services meet the requirements of the SDWA lead prohibition.

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

EPA's authority for this proposed rule is sections 1417, 1445 and 1450 of the SDWA, 42 U.S.C. 300j-6, 300j-4, and 300j-9. SDWA section 1417 authorizes the EPA Administrator to "prescribe such regulations as are necessary or appropriate to carry out his/her functions under this subchapter." EPA's current regulations (40 CFR 141.43) codify parts of section 1417 of the SDWA, but they do not reflect the current version of section 1417, as amended by the RLDWA and the CFSA. This proposed rule would amend those regulations to reflect the current law. In

addition, because the RLDWA created exemptions from the use prohibition in section 1417(a)(1) and the introduction into commerce prohibition in section 1417(a)(3), EPA proposes additional regulations to aid in the implementation and enforcement of these prohibitions.

D. What are the costs and benefits of this action?

EPA conducted an incremental compliance cost analysis of this proposed rule. For detail on the cost analysis see sections V and VI of this notice. The Technical Support Document (USEPA, 2016) prepared for this proposed rule and available in the docket for this proposed rule contains the detailed description of the cost assessment. EPA did not conduct a quantified and monetized benefits analysis, but a qualitative discussion of the benefits attributable to this rule can be found in section VII and in the Technical Support Document.

Total annualized costs for the proposed rule range from $12 million discounted at three percent to $18 million discounted at seven percent. These costs include administrative requirement costs, the cost to potable use product manufacturers for both labeling on the product and on the product's packaging, the cost to manufacturers employing the "used exclusively" exemption for package labeling indicating non-potable uses, third party and self-certification costs and the costs of responding to EPA data requests.

The proposed rule would reduce inadvertent use of non-lead free plumbing products in potable use applications and, as a result, would reduce exposure to lead in drinking water. The benefits of this proposed rule would be the resulting incremental reduction in the adverse health effects of low doses of lead, which include adverse neurological, cardiovascular, renal, reproductive, developmental, immunological and carcinogenic effects.

II. Background

Lead can be introduced into drinking water by corrosion of plumbing products (pipes,

pipe and plumbing fittings and fixtures, solder, and flux). Lead exposure causes damage to the brain and kidneys, and can interfere with the production of red blood cells that carry oxygen to all parts of the body. The greatest risk associated with lead exposure is to infants, young children and pregnant women. Scientists have linked the effects of lead on the brain with lowered IQ in children.

In 1986, Congress amended the SDWA to prohibit the use of pipes, solder or flux that are not "lead free" in public water systems or plumbing in facilities providing water for human consumption. At the time, lead free was defined as solder and flux with no more than 0.2 percent lead and pipes with no more than 8.0 percent lead.

In 1996, Congress further amended the SDWA to prohibit the use of pipe and plumbing fittings and fixtures that are not lead free in the installation and repair of any public water system or plumbing in a facility providing water for human consumption. The 1996 amendments also required lead free plumbing fittings and fixtures (endpoint devices) to be in compliance with a lead leaching standard established in accordance with section 1417(e).

The 1996 amendments also made it unlawful for any person to introduce into commerce any pipe, pipe or plumbing fitting, or fixture that is not lead free, except for a pipe that is used in manufacturing or industrial processing. As amended in 1996, SDWA section 1417(a)(3)(B) prohibits "any person engaged in the business of selling plumbing supplies, except manufacturers, to sell solder or flux that is not lead free," and SDWA section 1417(a)(3)(C) makes it unlawful "for any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing of water for human consumption."

In 2011, Congress enacted the RLDWA. It revised the definition of lead free by lowering

the allowable maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of plumbing products. It also revised the definition of lead free to include a statutory method for the calculation of lead content, and eliminated the requirement that lead free products be in compliance with standards established in accordance with SDWA section 1417(e) for leaching of lead from new plumbing fittings and fixtures.

The 2011 RLDWA also established two types of exemptions from the section 1417 prohibitions on the use or introduction into commerce of pipes, pipe fittings, plumbing fittings or fixtures, solder or flux not meeting the statutory definition of lead free. One exemption is for pipes, pipe fittings, plumbing fittings or fixtures, including backflow preventers, that are used exclusively for non-potable services, such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption (SDWA 1417(a)(4)(A)). A second exemption was established for toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, service saddles, or water distribution main gate valves that are 2 inches in diameter or larger (SDWA 1417(a)(4)(B)). The RLDWA established a prospective effective date of January 4, 2014, which provided a three-year timeframe for affected parties to transition to the new requirements. The CFSA further amended SDWA section 1417 to exempt fire hydrants from the prohibitions otherwise applicable under that section.

In anticipation of these changes taking effect, EPA provided a summary of the requirements of the lead ban provisions in SDWA section 1417 and answers to frequently asked questions (FAQs) related to the amendments to assist manufacturers, retailers, plumbers and consumers in understanding the changes to the law (USEPA, 2013a). In this FAQ document,

EPA stated its intention to further evaluate and refine the issues raised in the FAQ in a future rulemaking.

III. Summary of Data Used

A. Characterization of the Affected Industry

A number of data sources were used in the characterization of the plumbing manufacturing industry. GMP Research, Inc., provided a report to EPA in 2014, which included data on the total number of both potable and non-potable plumbing products sold in 2013, distributed across 40 product subcategories, and the market share of the leading suppliers by each product subcategory that may be subject to EPA's proposed rule. These data were supplemented with information from a number of additional sources. Dun & Bradstreet data were obtained for those firms that were identified by North American Industry Classification System (NAICS) and Standard Industrial Classification (SIC) code classifications as potentially producing plumbing products that would be affected by the proposed rule. Additional data for plumbing manufacturers and fabricators were obtained from ThomasNet, a comprehensive online database that provides information on manufacturing firms in the United States. EPA also used NSF International's Certified Drinking Water System Components database, which provides a list of manufacturers who use NSF to certify their products to NSF/ANSI Standard 61, including the subset of products that are certified to Annex G of that standard. Additional information was gathered from the Plumbing Manufacturers International (PMI) website, a plumbing industry trade association. EPA used data on the number of employees and annual receipts for firms from the U.S. Census Bureau's Statistics of U.S. Businesses.

Information used in the development of industry production growth was obtained from both the GMP Research, Inc., report and projections on United States housing growth from IHS

Global Insight. The Technical Support Document (USEPA, 2016) contains more information and data sources used and is available in the docket.

B. Determining Baseline Industry Practices and Potential Costs of Compliance

EPA conducted calls with representatives of both the PMI and the American Foundries Society (AFS) industry associations and held a stakeholder webinar in 2015 in order to obtain information on current practice within the plumbing parts manufacturing industry, in regard to labeling of product packages, marking of the plumbing products themselves, and the technical feasibility and costs associated with making changes to product labeling and marking. Additionally, the two industry associations provided information to EPA on product identification methods, including the estimated percentage of products that currently include lead free identification and general cost information for modifications to package labeling and product marking. Information on the feasibility and time requirements for changing production molds in response to potential regulatory requirements was also discussed, along with plumbing product inventory turnover rates. The trade associations also provided information on the use and costs of third party certification in the industry.

In addition, data were obtained from a number of independent geographically diverse tool and dye firms on the cost of mold modifications. EPA also contacted suppliers to obtain capital equipment and operations and maintenance (O&M) costs to allow the Agency to estimate the economic impact of potential new labeling requirements under the proposed rule. EPA also contacted the eight firms currently accredited to certify plumbing components for compliance with NSF/ANSI Standard 372, for information on the cost of certification and the technical process for testing and certifying products as meeting the standard.

IV. Proposed Regulatory Provisions

A. Scope/Applicability of Proposed Rule

The statutory prohibition on the use or introduction into commerce of pipes, pipe and plumbing fittings, fixtures, solder and flux that are not lead free, and the corresponding requirements described in this proposal would apply to any person. "Person" is defined under the SDWA to include individuals; corporations; companies; associations; partnerships; municipalities; or state, federal or tribal agencies. The statutory ban on selling solder and flux that is not lead free applies only to "any person engaged in the business of selling plumbing supplies." The use prohibition applies only to use in the "installation or repair" of any public water system or any plumbing in a residential or nonresidential facility or location that provides water for human consumption.

EPA solicits comments on all aspects of the proposed approach set forth in this notice. EPA specifically solicits comments, information and data on the following topics:

1. In order to clarify the requirements, set forth in the RLDWA and this proposal, EPA defined terms, such as "pipes," "fittings," "fixtures," "solder," "flux" and several subcategories of these components, which are terms used in the statute, but are not defined within section 1417 of the SDWA. EPA included these and other definitions to provide clarity to provisions of the proposed rule. EPA requests comment concerning the appropriateness of these definitions and any additional terms that should be defined, specifically terms describing exempt products included in section 1417(a)(4)(B) of the SDWA (e.g., water distribution main gate valve).
2. Section 1461 of the SDWA defines lead free with respect to drinking water coolers to mean that "each part or component of the cooler which may come into contact with drinking water contains no more than 8 percent lead" except that any solder, flux or storage tank interior

surface may not contain more than 0.2 percent lead. SDWA section 1461(2) also authorizes the Administrator to establish more stringent requirements for treating any part or component of a drinking water cooler as lead free "whenever he determines that any such part may constitute an important source of lead in drinking water." A drinking water cooler is also a "fixture" under section 1417 of the SDWA; and, therefore, subject to the definition of lead free in section 1417. To give effect to both provisions, in practice, drinking water coolers would need to comply with the most restrictive of the requirements in sections 1417 and 1461 of the SDWA. For clarity, EPA could consider addressing the requirements of section 1461 in the final rule by inserting language such as: "In addition to the definitions of "lead-free" in §143.12(a)(1) and (2), no drinking water cooler which contains any solder, flux, or storage tank interior surface which may come into contact with drinking water is lead free if the solder, flux, or storage tank interior surface contains more than 0.2 percent lead. Drinking water coolers must be manufactured such that each individual part or component that may come in contact with drinking water shall not contain more than 8 percent lead while still meeting the maximum 0.25 percent weighted average lead content of the wetted surfaces of the entire product." Should EPA consider adding such a provision to the rule?

3. The regulatory modifications in this proposal are designed, in part, to make the requirements set forth in section 1417 of the SDWA clearer and easier to implement and enforce in a consistent manner. Are additional clarifications needed to improve the regulation? If so, what specific clarifications are needed?

B. Labeling Potable Use Products

EPA evaluated several options concerning labeling of products that comply with the definition of lead free, including a requirement to label a product's packaging, physically

marking a product, or a combination of both. EPA found that many manufacturers already utilize a combination of package and product labeling to inform product users that the products comply with the RLDWA and several similar state laws. In an effort to reduce consumer confusion and establish a consistent labeling scheme for these products, EPA proposes to require that all lead free products be labeled on the package, container or tag, as well as marked directly on the product, unless the product is too small for a legible marking (in a type approximately 8 point to 14 point depending on the method of marking and roughness of product surface). Direct product marking to indicate lead free status will assist building inspectors in verifying that installations are in compliance with plumbing codes and allow for identification of products if they become separated from packaging prior to installation. Separation from packaging is likely to occur when used products are salvaged and sold or reused. After a product has been installed, a marking on the product itself will aid inspectors in identifying products that are lead free. In the long term, product marking to indicate lead free status will help the metals recycling industry segregate scrap materials that may be used to produce future products with low lead content.

This proposal provides that products that are too small to be marked on the product would be exempt from product marking, but would still need to comply with package, container or tag labeling. Also, when marking a product directly, the manufacturer should, to the extent practical, locate the marking in an area where it would be visible after installation. For those products where visual aesthetics is a factor in marketing and selling the product, the manufacturer may locate the marking in a manner that will not negatively impact the design.

EPA is not proposing a specific phrase be required on products or packages, but rather a performance standard that the phrase clearly conveys to users that the product is in compliance with the lead free requirements of the SDWA. The proposed regulation would include these

examples of acceptable phrases for packaging: “This product conforms to the lead free requirements of the SDWA,” or “Lead Free.” Examples of acceptable product markings include: “Lead Free,” “LF,” or appropriate third party certification markings such as NSF/ANSI 372.

The requirements EPA proposes for lead free products will ensure that purchasers of plumbing products do not inadvertently use products that are not lead free, or re-introduce them into commerce for potable applications (e.g., in the case of a distributor, wholesale supplier, retailer). In addition to the package and product labeling requirement set forth in this proposal, EPA also considered requiring that either the product be marked or the package be labeled, but not both. While this option would decrease the costs and burden on the manufacturer responsible for labeling and marking, EPA is concerned that this option may not provide consumers and others (such as building inspectors) with the information needed to determine that a product is lead free after its initial purchase and installation. If a product is removed from its packaging and stored prior to installation, or if a regulatory body is looking for confirmation after installation that the product meets the lead free requirements, the package labeling would likely be insufficient. Similarly, labeling of a product that is sold in an unlabeled package could also lead to the inadvertent installation of products that did not meet the new definition of lead free for potable purposes. For those reasons, labels on both the package and product are more appropriate (unless the product is too small for a label).

EPA solicits comments on all aspects of the proposed approach set forth above. In addition, EPA specifically solicits comments, information and data on the following topics:

1. Whether the rule should require the specific phrase “lead free” on package labeling and product markings rather than allowing some discretion in the use of phrases.

2. Whether an alternative specific phrase should be required for product and package labeling and, if so, what phrase.
3. If a specific phrase such as "lead free" were required, what period of time should be allowed for a transition period to enable manufacturers to modify their product and packaging to incorporate such phrase?
4. If products were required to use a specific phrase such as "lead free," whether that specific phrase should be required on both the package label and product marking or whether an abbreviated message should instead be allowed on the product.
5. Whether the rule should allow for either package labeling or product marking rather than package labeling and product marking.
6. Whether the rule should require any package labeling or product marking.

C. Exempt Products

As a result of the exemptions created by the RLDWA, there will be plumbing products in the marketplace that are not required to meet the definition of lead free in section 1417(d) of the SDWA. Therefore, without appropriate labeling, there is a risk that non-lead free products will be inadvertently used in potable water applications or re-introduced into commerce for potable applications. There are several points along the distribution chain where EPA anticipates a non-lead free product could be mistakenly identified as a lead free product, including the initial sale of the product and at the time of installation.

Prior to the RLDWA, all plumbing devices were required to contain less than 8.0 percent lead, and certain endpoint devices (e.g., faucets) were required to meet additional standards for lead leaching. The exemptions created in the RLDWA allow for certain pipes, fittings and fixtures to be sold with no limit to the amount of lead they contain.

One of the exemptions allows the use and introduction into commerce of pipes, fittings and fixtures that are used exclusively for nonpotable services. EPA has determined that a plumbing product that is physically incompatible with potable drinking water systems, rendering it impossible to be used for potable service, qualifies for this exemption.

In addition, EPA also proposes a second option for manufacturers to demonstrate that their product is "used exclusively" for nonpotable services and therefore eligible for this exemption (hereafter referred to in this notice as the "used exclusively" exemption). As EPA explained in the RLDWA FAQs, EPA would generally consider pipes, fittings or fixtures to be used exclusively for nonpotable services if they are marketed and sold for use in nonpotable services, and prominently and clearly labeled as illegal for use in potable services and not anticipated for use with water for human consumption. This proposal would codify that interpretation of this exemption by allowing the use of a package label (or the product marking for those products sold without an external package) clearly identifying the product as not for use with water for human consumption. A package label, combined with the labeling requirements for products that must meet the lead free requirements (i.e., package labeling and product marking described in section VI.B of this document and described in §143.17 of this proposed rule), should provide consumers with sufficient information to determine which plumbing products are designed for use with potable water systems; thus significantly reducing the likelihood of improperly installing a non-lead free product.

The products specifically listed as exempt in SDWA section 1417(a)(4)(B) would not be subject to these labeling requirements or any of the other requirements of this proposal. These products are exempt from the requirements of this proposal: toilets, bidets, urinals, fill valves,

flushometer valves, tub fillers, fire hydrants, shower valves, service saddles or water distribution main gate valves that are 2 inches in diameter or larger.

In addition to the specific plumbing devices excluded in the SDWA, EPA is also proposing to exclude clothes washing machines, fire suppression sprinklers, eyewash devices, sump pumps and emergency drench showers, because EPA is not aware of any potable use for these specific products.

EPA solicits comments on all aspects of the proposed approach set forth above. EPA specifically solicits comments, information and data on the following topics:

1. This proposal includes two methods of qualifying for the "used exclusively for non-potable exemption:" a) the product is physically incompatible with potable water systems, or b) the packaging is clearly labeled that it is not for use for water for human consumption. Are the criteria listed above appropriate for qualifying for the "used exclusively" exemption or are there different or additional criteria that EPA should consider?
2. Is there any reason EPA should not extend the used exclusively for non-potable services exemption to plumbing products that are physically compatible with drinking water systems?
3. Will labeling the packaging of pipes, fittings or fixtures as not for use for water for human consumption be sufficient to inform consumers of the appropriate use of the product?
4. In addition to the specific plumbing devices excluded in the SDWA, EPA is also proposing to exclude clothes washing machines, fire suppression sprinklers, eyewash devices, sump pumps and emergency drench showers. EPA is not aware of a potable use for these devices, or of a potable use product that they could be confused with; and as such, requiring a label to qualify for the "used exclusively" exemption could be redundant and unnecessary for those devices.

Is EPA's assumption about the lack of a potable use for these specific plumbing devices appropriate?

5. Are there other specific plumbing devices for which there are no potable uses, nor a potable use product they could be confused with that should be added to the list of excluded products?
6. EPA is proposing to retain the exemption for leaded joints used in the repair of cast iron pipes. EPA interprets the introduction into commerce provision as not prohibiting the sale or distribution of lead which may be used to form leaded joints used in the repair of cast iron pipes. Congress did not remove the statutory exemption for these types of repairs in section 1417(a)(1)(B) in either the 1996 or the 2011 amendments to section 1417 of the SDWA. Therefore, EPA believes that Congress intended to continue to allow the use of leaded joints necessary for the repair of cast iron pipes. EPA is seeking comment on this interpretation of section 1417(a)(1)(B).

D. Product Certification

EPA is proposing certification requirements for manufacturers and importers to demonstrate the maximum lead content of the wetted surfaces of their plumbing products do not exceed a weighted average of 0.25 percent using the method for the calculation of lead content established in the statute by either third party certification bodies or self-certification. For products that are required to meet Section 1417's lead free requirements, EPA proposes to require manufacturers with 100 or more employees or importers representing foreign manufacturers with 100 or more employees to demonstrate compliance with the lead free definition by obtaining third party certification by an American National Standards Institute (ANSI) accredited third party certification body. EPA proposes to require manufacturers with fewer than 100 employees or importers representing foreign manufacturers with fewer than 100

employees to demonstrate compliance either through third party certification by an ANSI accredited certification body or through self-certification as described below.

Third party certification is currently required for certain products in widely adopted model plumbing codes. The most recent version of the single most widely adopted model plumbing code requires pipe, pipe fittings, joints, values, faucets and fixture fittings used to supply water for drinking or cooking purposes to comply with the NSF/ANSI 372 standard for lead content. To meet the NSF/ANSI 372 standard, a product must be evaluated by an ANSI accredited third party certification body. These are independent organizations that test a product, review a product's manufacturing process and determine that the product complies with specific standards for safety, quality, sustainability or performance (i.e., NSF/ANSI 372 standard for lead content). ANSI accredited third party certification bodies currently include NSF International, CSA Group, ICC Evaluation Services, International Association of Plumbing and Mechanical Officials Research & Testing (IAPMO R&T), Intertek Testing Services, Truesdail Laboratories, Underwriters Laboratories and Water Quality Association.

For manufacturers with fewer than 100 employees and importers sourcing products from or representing foreign manufacturers with fewer than 100 employees, the proposed rule provides the flexibility of allowing these entities to demonstrate product compliance by either using an ANSI accredited third party certification body or by self-certification of the products. EPA estimated that manufacturers of covered products having fewer than 100 employees account for 72 percent of the total number of such manufacturers, but only produce 5 to 18 percent of the total volume of products. Small manufacturers that opt for the self-certification option would be required to develop a "certificate of conformity," also known as a declaration of conformity, to attest that products meet the lead free requirements. A similar concept is currently in use for

certain products regulated by the Federal Communications Commission and the Consumer Products Safety Commission.

For manufacturers or importers electing to self-certify products, the proposed rule would require the manufacturer to post the certificate of conformity on a web page with continuing public access in the United States.

As proposed, the certificate of conformity would be required to include: contact information for the manufacturer and any importer, a listing of products, statements attesting that the products meet the lead free requirements and that the manufacturer's or importer's eligibility to self-certify the product is consistent with the regulation (i.e., manufacturer has fewer than 100 employees), a statement indicating how the manufacturer or importer verified conformance, and signatory information. The statement indicating how the manufacturer or importer verified conformance could be a brief overview of the general methodology employed, such as: laboratory testing using X-Ray Fluorescence, other specific technologies, or that all source materials used in manufacture were confirmed to be less than 0.25 percent lead. This proposal would require manufacturers or importers using self-certification to maintain sufficient documentation to confirm that products meet the lead free requirements.

The proposed certification requirements will further reduce the likelihood that non-lead free products will either intentionally or inadvertently be placed into commerce or used in the repair or installation of any public water system or any plumbing in a facility providing water for human consumption. In addition, the labeling and the certification requirements will assist in the enforcement of the SDWA section 1417(a)(3) prohibition of the introduction into commerce of pipes, pipe or plumbing fittings or fixtures that are not lead free. A third party certification requirement leverages the resources of the third party certifiers as well as the supply chain to

help the market meet the requirements of RDLWA. The self-certification requirement, which is applicable to manufacturers with fewer than 100 employees, while not as rigorous as a requirement to obtain third party certification, nonetheless provides an additional assurance that products sold by those smaller manufacturers are lead free.

As an alternative to the proposed product certification requirements previously described, EPA considered requiring all manufacturers to obtain third party certification for products required to meet the lead free requirements. A uniform third party certification requirement would result in a level playing field for all manufacturers and would also make the marketplace consistent when a consumer is shopping for pipes, fittings or fixtures. EPA is not proposing this option because we are concerned about the economic impacts of a mandatory third-party certification requirement on manufacturers with fewer than 100 employees. Some of these manufacturers likely produce or fabricate small quantities of products that may be custom-made for a single specific use with a customer. A requirement for third party certification in these instances may be impractical and costly per unit produced. For those reasons, EPA chose the approach described in this proposal.

EPA also considered the option of allowing all manufacturers the option of electing third party certification or self-certification for their various products. This option would allow maximum flexibility for manufacturers and would likely limit financial impacts to firms that currently do not get their products independently certified. EPA opted not to propose this approach because we found that (currently) the most widely used model plumbing codes require many products to be third party certified, and that there already exists a high level of adoption of third party standards in the plumbing industry. Additionally, requiring all but the smallest firms

to certify their products using third party certification bodies would ensure that the vast majority of products sold in the marketplace are independently verified as lead free.

EPA solicits comments on this aspect of the proposed rule, including EPA's rationale as described in this preamble. In addition, EPA specifically solicits comments, information and data on the following topics:

1. Should third party certification be required of U.S. manufacturers regardless of the number of employees?
2. Should U.S. manufacturers have the option of conducting either third party certification or self-certification for products they produce?
3. Is there a need for some manufacturers to have a self-certification option?
4. Should third party certification be required of importers of foreign manufactured plumbing materials regardless of the number of employees at the foreign manufacturer?
5. Is there a more appropriate break point (e.g., fewer than 20 employees, fewer than 500 employees based on other categories of Census Bureau's Statistics of U.S. Businesses) for allowing self-certification?
6. Conversely, should all importers of foreign manufactured plumbing products be eligible for self-certification?
7. Is the definition of importer in §143.11 of this proposed rule adequate to ensure compliance with the proposed requirements?
8. Are there more appropriate criteria for requiring third party certification for manufacturers based on classes of products that EPA should evaluate, such as more complicated multi-component devices (for example, valves, faucets, pumps, water coolers, etc.), but allowing an option of self-certification for simple single component plumbing pieces (for example, elbow

joint, gasket, pipe, etc.); or alternatively, based on whether a product is mass produced or custom fabricated?

9. Should self-certification be allowed for all products made by any manufacturer if the product is composed of a single material such as pure copper?
10. For self-certification, is the requirement for a "certificate of conformity" and its proposed content appropriate, or should there be another process for self-certification or is there other content for the "certificate of conformity" that would be more appropriate?
11. Should any product certification be required?

E. Other Regulatory Requirements and Clarifications

1. Compliance Information Authority

In order to effectively enforce the lead free requirements of the SDWA and the proposed implementing regulations, EPA needs the ability to obtain, if necessary on a case-by-case basis, certain compliance related information from manufacturers, importers, wholesalers and retailers and others subject to SDWA section 1417, such as information related to the calculation of the weighted average of wetted surfaces, schematics of fittings/fixtures, certification documentation, purchases/sales dates, and examples of lead free product and/or package messaging. This proposed rule contains a provision providing the EPA Administrator with explicit authority to request such information on a case-by-case basis and a requirement for entities to provide the information requested to the Administrator. This provision is based on statutory authority contained in section 1445 of the SDWA.

2. State Enforcement of Use Prohibitions

EPA is proposing language in §143.14 to codify in regulation that the SDWA 1417(b) requirement for states to enforce the use prohibition on pipe, pipe fittings or fixtures, any solder,

or any flux that are not lead free is a condition of receiving a full Public Water System Supervision grant allocation. Under SDWA 1417(b)(1), the state enforcement provision only applies to the use prohibition in section 1417 (a)(1); it does not apply to the introduction into commerce prohibition in section 1417(a)(3) of the SDWA, nor would it apply to the proposed requirements for labeling and certification.

F. Implementation

The revised definition of lead free has been in effect since January 4, 2014, as per the RLDWA and the CFSA. EPA is proposing that labeling and the product certification requirements contained within this proposal will be in effect three years from the date the final regulation is published, consistent with the three-year time period provided under the RLDWA and CFSA. EPA is also proposing that all other provisions are effective 30 days after the date the final regulation is published, because those provisions merely codify statutory provisions already in effect.

EPA solicits comments on all aspects of the proposed implementation period for this proposed rule. EPA specifically requests comments, information and data on whether three years is an appropriate timeframe to achieve compliance with the proposed labeling and certification requirements, or is a different timeframe more appropriate? Is there a need for a different effective date for any other provisions of the rule?

V. Costs

EPA collected data from public sources and private data vendors to develop the estimated rule costs to plumbing manufacturing firms. Annual production of potable use products and products eligible for the "used exclusively" exemption is 1.3 billion units and 500 million units,

respectively. There are 2,193 firms producing plumbing products impacted by this proposed rule, which are spread across 14 NAICS codes. Table V.1 summarizes information for the segment of the industry that produces potable use products. Table V.2 summarizes the data for the segment of the industry that produces products eligible for the "used exclusively" exemption. Both tables break production into product subcategories and provide EPA's estimated annual production values, the NAICS code assigned and the number of manufacturers in the subcategory.

Table V.1. Product Subcategories, Production, NAICS and Number of Manufacturers EPA Identified for Potable Use Products

Product Category	Product Name	Units Produced Annually (2013)	NAICS for Product	Number of Manufacturers for Product
Pipe and Fittings	Copper Tube (< 4" in diameter)	233,049,645	332996	213
	PEX Pipe (< 4" in diameter)	348,583,587	326122	27
	CPVC Pipe (< 4" in diameter)	148,219,048	326122	48
	Copper Fittings (< 4" in diameter)	93,219,858	332913	119
	Brass Fittings (< 4" in diameter)	80,026,241	332913	523
	PEX Fittings (< 4" in diameter)	99,620,061	332913	47
	CPVC Pipe Fittings (< 4" in diameter)	59,287,619	332913	63
	Small and Mid-Diameter PVC Pipe	58,257,345	326122	143
	PVC Pipe Fittings	14,927,862	332913	103
Faucets and Mixers	Kitchen and Bar Faucet Market	8,531,915	332913	74
	Lavatory Faucet	18,635,258	332913	74
Kitchen Sinks and Accessories	Kitchen Sink	4,730,496	332999	24
	Sink Strainer	11,036,332	332999	24
Residential Water Filtration Products	Point-of-entry Residential Water Filtration Market	1,236,699	333318	713
	Point-of-use Counter Top Water Filtration Market	72,857	333318	694
	Point-of-use Under the Sink Water Filtration Market	261,702	333318	704
	Point-of-use Faucet Mount Water Filtration Market	1,707,194	333318	694
Stop Valves, Stainless Steel Braided Hoses, Inline Valves	Stop Valve Market	9,455,319	332911	23
	Stainless Steel Braided Hose Market	9,424,559	333999	204
	Residential Inline Valve Market	30,597,771	332919	204
Water	Combi Boiler Market	55,527	333999	15

Heaters and Boilers	Residential Gas Tankless Water Heater Market	410,831	335228	20
	Residential Gas Storage Water Heaters	4,338,506	335228	11
	Residential Electric Storage Water Heaters	4,061,277	335228	11
	Residential Indirect Fired Water Heater Market	133,647	335228	10
	Residential Electric Tankless Water Heater Market	276,398	335228	19
	Residential Solar Storage Water Heater Market	21,819	335228	42
	Residential Oil Water Heaters	31,692	335228	1
	Commercial Gas Storage Water Heater Market	89,706	335228	11
	Commercial Electric Storage Water Heater Market	70,071	335228	15
Water Coolers / Drinking Fountains / Bubblers	Water Cooler / Drinking Fountain / Bubbler Market	557,244	333415	5
Household Appliances	Refrigerators with Water Dispenser/Ice Making Machinery	4,540,527	335222	7
	Dishwasher Market	5,537,416	335228	5
	Water Softener Market	3,444,782	333318	98
Household & Commercial Appliances	Coffee Makers	234,247	333318	40
Other	Aerator	27,167,173	332913	3
	Backflow preventers/Vacuum Breakers	32,202	332913	11
	Gaskets/O-rings	5,433,435	339991	13
	Pumps	1,808,369	333911	19
	Water Meters/End Point Meters	7,053,100	334514	68

Source: Technical Support Document, Exhibits 3-3 and 3-11 (USEPA, 2016)

Table V.2. Product Subcategories, Production, NAICS and Number of Manufacturers EPA Identified for Products Eligible for the "Used Exclusively" Exemption

Product Category	Product Name	Units Produced Annually (2013)	NAICS for Product	Number of Manufacturers for Product
Pipe and Fittings	Copper Tube (< 4" in diameter)	81,033,435	332996	213
Pipe and Fittings Faucets and Mixers	PEX Pipe (< 4" in diameter)	59,116,515	326122	27
	CPVC Pipe (< 4" in diameter)	39,876,190	326122	48
	Copper Fittings (< 4" in diameter)	32,413,374	332913	119
	Brass Fittings (< 4" in diameter)	27,825,836	332913	523

	PEX Fittings (< 4" in diameter)	16,894,630	332913	47
	CPVC Pipe Fittings (< 4" in diameter)	15,950,476	332913	63
	Small and Mid-Diameter PVC Pipe	68,389,058	326122	143
	PVC Pipe Fittings	35,048,024	332913	103
	Laundry Faucet	1,122,594	332913	72
Stop Valves, Stainless Steel Braided Hoses, Inline Valves	Stop Valve Market	62,175,887	332911	23
Stop Valves, Stainless Steel Braided Hoses, Inline Valves Other	Stainless Steel Braided Hose Market	106,928,024	333999	204
	Aerator	1,122,594	332913	3
Other	Backflow preventers/Vacuum Breakers	79,265	332913	11
	Gaskets/O-rings	224,519	339991	13
	Pumps	21,914	333911	19

Source: Technical Support Document, Exhibits 3-6 and 3-12 (USEPA, 2016)

EPA developed cost estimates for this proposed rule along with two additional regulatory alternatives EPA considered in the development of the proposal. All three regulatory options contain estimates for initial administrative and implementation costs, costs to modify their product and/or package messaging, third party or self-certification costs, and response to data request costs. The three options are presented in Table V.3. Option B is the regulatory option selected for this proposal. The Technical Support Document (USEPA, 2016) provides more detailed information on the costing methodology and a discussion of the uncertainties and limitations of this assessment.

Table V.3: Regulatory Options

Option	Option Description
A	• Product labels **and** package marking for potable use products • Third party certification required for all firms
B	• Product labels **and** package marking for potable use products • Self-certification or third party certification for < 100 Employees; Third party certification only for ≥ 100 Employees
C	• Product labels **or** package marking for potable use products

	• Third party certification or self-certification for all firms

A. Initial Administrative and Initial Implementation Costs

The analysis for initial administrative and implementation costs was conducted at the level of the manufacturing firm. These costs do not vary by regulatory option. EPA estimated that it would take each firm an average of 8 hours to read and understand the rule once promulgated. This time estimate when multiplied by an average labor rate of $71.72 and the number of firms affected by the rule, 2,193, gives a total cost of $1.26 million.

EPA also estimated the cost to manufacturing firms that would have to redesign their product and/or package messaging to include lead-related information. To calculate the cost of package and product messaging redesign, EPA first estimated the total number of product types across 46 product subcategories. A total of 5,705 product types were identified. EPA estimated a percent range of firms that would be required to redesign their product and package in order to comply with this proposed rule. Firms with greater than 500 employees are estimated to redesign 10 percent of product and package messaging. Manufacturers with fewer than 500 employees are assumed to redesign between 25 and 50 percent of their product and package messaging. Redesign was estimated to require 5 hours of labor multiplied by the number of products, giving a total costs range between $0.24 and $0.47 million.

Table V.4 summarizes, by size category, the initial rule implementation annualized cost ranges. The values were discounted at both the 3 and 7 percent rates over the 25-year period of analysis. Annual total initial implementation costs range from $0.08 to $0.14 million.

Table V.4: Rule Initial Administrative and Initial Implementation Annualized Costs, in millions (2014$)

Manufacturer Size (no. of employees)	Read and Understand the Rule		Messaging Design Change		Initial Rule Implementation Cost	
	Discount Rate		Discount Rate		Discount Rate	
	3%	7%	3%	7%	3%	7%
< 100	$0.051	$0.073	$0.011-0.021	$0.015-0.03	$0.061-0.072	$0.088-0.103
100-499	$0.001	$0.016	$0.002-0.005	$0.003-0.007	$0.014-0.016	$0.020-0.023
≥ 500	$0.008	$0.012	$0.001-0.001	$0.001-0.001	$0.009-0.009	$0.013-0.013
All Sizes	**$0.07**	**$0.101**	**$0.014-0.027**	**$0.02-0.038**	**$0.084-0.097**	**$0.121-0.139**

Source: Technical Support Document, Exhibits 4-7a and 4-7b (USEPA, 2016).

B. Labeling Potable Use Products

In order to estimate the potential cost of this proposed rule and the two alternative regulatory scenarios presented in this proposed rule preamble, EPA collected information on current labeling practices to set the regulatory baseline. EPA developed three baseline scenarios characterizing the proportion of firms by size category that either currently have lead free labeling (meeting the requirements of this proposed rule), have product messaging not related to lead free requirements, or have no product messaging. These three scenarios capture the uncertainty surrounding EPA's understanding of current industry labeling practices. Table V.5 presents preexisting labeling assumptions that represent the lower bound for regulatory cost estimates. Table V.6 shows a possible lower level baseline of product labeling. This table represents the upper bound for rule cost estimate. Across both lower and upper bound scenarios, EPA has made the conservative assumption that 5 percent of all firms have no messaging on product or package. Also common across the scenarios, is the concept that firms with greater numbers of employees have larger production totals and serve larger market areas and, therefore, will have a higher probability of selling in markets that already require lead content labeling on

product and package. The upper bound scenario assumes manufacturers with fewer than 500 employees mark products with lead content messaging 50 percent of the time, while in the lower bound scenario, those same firms label 75 percent of products with lead content messaging. Also, firms in the upper bound scenario with less than 100 employees mark 50 percent of their packaging with lead content labeling. The lower bound assumes that firms with fewer than 100 employees label 75 percent of packaging with lead content information.

Table V.5: Estimated Percentage of Potable Use Products with and without Existing Messaging (Lower Bound)

Manufacturer Size (number of employees)	**Percent with Lead-Content Messaging**		**Percent with Existing Messaging but Not Lead-Related** (Incur Partial Messaging Costs)		**Percent with No Messaging** (Incur Total Messaging Costs)	
	Product	Package	Product	Package	Product	Package
< 100	75%	75%	20%	20%	5%	5%
100-499	75%	90%	20%	5%	5%	5%
≥ 500	90%	90%	5%	5%	5%	5%

Source: Technical Support Document, Exhibit 4-8a (USEPA, 2016).

Table V.6: Estimated Percentage of Potable Use Products with and without Existing Messaging (Upper Bound)

Manufacturer Size (number of employees)	**Percent with Lead-Content Messaging**		**Percent with Existing Messaging but Not Lead-Related** (Incur Partial Messaging Costs)		**Percent with No Messaging** (Incur Total Messaging Costs)	
	Product	Package	Product	Package	Product	Package
< 100	50%	50%	45%	45%	5%	5%
100-499	50%	90%	45%	5%	5%	5%
≥ 500	90%	90%	5%	5%	5%	5%

Source: Technical Support Document, Exhibit 4-8b (USEPA, 2016).

Using the assumptions on current industry messaging practices detailed in Tables V.5 and V.6, EPA applied its unit compliance technology costs for both product and package labeling in the following way: (1) firms that currently have lead content messaging on both product and

package are assumed to have no labeling costs in this regulatory analysis; (2) manufacturers that currently mark their product and/or package with some messaging (e.g., company name and marketing materials, a description of how the product is used, installation instructions or other certification and identification information) were assigned a partial cost to implement the requirements of this proposed rule; and (3) firms assumed to have no product labeling on package or product received full capital and O&M costs as part of the regulatory assessment of costs.

Under regulatory options requiring lead free marking on potable use products, EPA assigned to each of the 40 identified product subcategories one of three compliance technologies: printing on product (e.g., copper or plastic pipe), modification of production molds and patterns through the use of electric diode machining (e.g., brass fittings), or attaching a tag with wire or another non adhesive method (e.g., water heaters).[1]

For regulatory costing scenarios that required lead free labeling on product packages, EPA (again) assigned one of three compliance technologies to each of the 40 potable use product categories. The compliance technologies are printing on product box (e.g., faucets), printing on product bag (e.g., copper and brass fittings), or adhesive label (e.g., braided steel hose).[2]

Unit capital and O&M costs for each of the six compliance technologies were derived with information collected from both the PMI and AFS trade associations and information from tool and die firms, product packaging vendors, and printing equipment suppliers.

Table V.7 provides EPA's estimated total annual cost ranges for potable use product lead free messaging on product and/or package for the three options considered as part of the regulatory analysis. For Options A and B, costs include labeling on both the product and package

[1] Small products like gaskets and o-rings are assumed to be bagged with lead free messaging.
[2] Products that are not sold with packaging like pipe are assumed to comply by printing on product.

and range from $8.69 to $13.60 million (2014$) dollars annually. For Option C, which gives producers the choice to label the product or package, EPA assumed that impacted firms would choose the lower cost package labeling alternative; therefore, annual costs range from $1.14 to $1.28 million dollars.

Table V.7: Total Annualized Present Value Costs for Lead Free Labeling of Potable Use Products on Product and Package, Millions (2014$)

Option	3% Discount Rate in Millions (2014$)	7% Discount Rate in Millions (2014$)
A: Product **and** package messaging	$8.69 – 10.34	$11.32 – 13.60
B: Product **and** package messaging	$8.69 – 10.34	$11.32 – 13.60
C: Product **or** package messaging	$1.17 – 1.28	$1.14 – 1.26

Source: Technical Support Document, Exhibits 4-13a and 4-13b (USEPA, 2016).

C. Labeling of Products Eligible for the "Used Exclusively" Exemption

As discussed in section IV.C, EPA has included an additional means of qualifying for the "used exclusively" exemption.

The proposed provision to label products to establish that the products are "used exclusively" in nonpotable services provides a less costly option to persons introducing the product into commerce. If the proposed regulations limited the availability of the "used exclusively" exemption to products that are physically incompatible with potable water systems, then persons introducing non-potable water plumbing products into commerce that are physically compatible and capable of being connected to systems providing water for human consumption would be required to assure that these products meet the lead free requirements, Alternatively, they could or redesign their products to make them physical incompatible with potable water systems. EPA anticipates that the costs associated with designing and applying a label are likely to be less than the costs associated with reformulating the alloy and overhauling the manufacturing processes associated with meeting the "lead free" requirements. Therefore, this

optional compliance alternative will not result in increased costs or burden, and will result in a cost savings for those manufacturers who elect to take advantage of this proposed optional exemption mechanism.

There are six product subcategories that are both physically compatible with potable use applications and would meet the lead content limit of 0.25 percent of wetted surfaces to be considered lead free. In order to develop costs for this requirement EPA first determined the baseline current industry practices when it comes to labeling products eligible for the "used exclusively" exemption and their packaging. Table V.8 shows the lower bound percentage of products by firm size category that currently use lead content messaging, messaging of some kind (e.g., marks, serial numbers, installation instructions), and have no labeling on product or packaging. Table V.9 details the upper bound baseline assumed percentages for labeling by firm size for products eligible for the "used exclusively" exemption.

Table V.8: Estimated Percentage of Products Eligible for "Used Exclusively" Exemption with and without Existing Messaging (Lower Bound)

Manufacturer Size (number of employees)	Percent with Lead-Related Messaging		Percent with Existing Messaging but Not Lead-Related (Incur Partial Messaging Costs)		Percent with No Messaging (Incur Total Messaging Costs)	
	Product	Package	Product	Package	Product	Package
< 100	50%	50%	45%	45%	5%	5%
100-499	75%	75%	20%	20%	5%	5%
≥ 500	75%	75%	20%	20%	5%	5%

Source: Technical Support Document, Exhibit 4-14a (USEPA, 2016).

Table V.9: Estimated Percentage of Products Eligible for "Used Exclusively" Exemption with and without Existing Messaging (Upper Bound)

Manufacturer Size (number of employees)	Percent with Lead-Related Messaging		Percent with Existing Messaging but Not Lead-Related (Incur Partial Messaging Costs)		Percent with No Messaging (Incur Total Messaging Costs)	
	Product	Package	Product	Package	Product	Package
< 100	25%	25%	70%	70%	5%	5%
100-499	50%	50%	45%	45%	5%	5%
≥ 500	50%	50%	45%	45%	5%	5%

Source: Technical Support Document, Exhibit 4-14b (USEPA, 2016).

EPA assumed manufacturers of products eligible for the "used exclusively" exemption that currently do not have lead-related information on their product would use the same compliance technologies that would be used for the labeling of potable use products and packages. For labeling on the product, EPA assigned each of the subcategories as either the printing on product or the mold modification compliance technology.[3] Also, for package compliance, EPA assigned the print on bag compliance technology. Under the "used exclusively" exempt package marking requirements, piping products are required to be printed directly on the product since they are generally not packaged.

[3] Small products like gaskets and o-rings are assumed to be bagged with lead free messaging.

EPA used the same unit cost information that was developed for the potable use labeling requirements. Table V.10 details, by size category, the regulatory annual total cost ranges for labeling those products eligible for the "used exclusively" exemption not for potable use applications. This cost component does not vary by regulatory option. Annual total cost for labeling products that are not for potable use range from $0.14 to $0.22 million.

Exhibit V.10: Total Annualized Present Value Costs for Lead-Related Messaging on Products Eligible for the "Used Exclusively" Exemption on Package or Product, Millions (2014$)

Manufacturer Size (no. of employees)	3% Discount Rate in Millions (2014$)	7% Discount Rate in Millions (2014$)
< 100	$0.03 – $0.03	$0.02 - $0.03
100-499	$0.01 - $0.01	$0.01 - $0.01
≥ 500	$0.11 - $0.17	$0.10 - $0.16
Total Cost	**$0.15 - $0.22**	**$0.14 - $0.20**

Source: Technical Support Document, Exhibit 4-17 (USEPA, 2016), Rule Component All Sizes worksheet

D. Product Certification

In order to develop total compliance costs for third party certification, EPA had to determine the regulatory baseline. This baseline represents the current industry practice with regard to third party certification. EPA collected information on use of third party certification by plumbing manufacturers by reviewing current state laws requiring certification for NSF Standard 61 and 372; reviewing the International and Uniform Plumbing Codes; contacting the two primary industry trade groups, PMI and AFS; and acquiring information from industry third party certifiers (e.g., NSF International, CSA Group, UL, etc.). Based on the collected information, EPA assumed that 90 percent of manufacturers with 100 or greater employees already use an accredited third party agency to certify that their products are lead free. As with potable use product labeling, third party certification costs are a major driver of overall cost to manufacturers; therefore, EPA chose to develop lower and upper bound cost scenarios based on

baseline compliance assumptions for firms having less than 100 employees. Fifty to 75 percent of plumbing manufacturers having fewer than 100 employees are assumed to use third party certifiers. Table V.11 summarizes the third party certification baseline assumptions EPA used in the development of regulatory costs. Under all regulatory options, certification costs would only be attributable to those manufacturers that do not already use these third party certification bodies.

Table V.11: Estimated Percentage of Manufacturers that Do Not Already Use Third Party Certification Bodies

Manufacturer Size (no. of employees)	Percentage of Manufacturers that Currently Do Not Use Third Party Certifying Bodies and to which Certification Costs Would Apply	
	Lower Bound	Upper Bound
< 100	25%	50%
100-499	10%	10%
≥ 500	10%	10%

Source: Technical Support Document, Exhibit 4-18 (USEPA, 2016).

Third party certifying firms usually conduct the certification process according to product families. For NSF/ANSI Standard 372, products of the same material formulation and similar configuration are considered one product family. Thus, certifying costs were developed on a product family basis. EPA estimated that each firm produces an average of three product families, based on an assessment of firm website data for manufacturers across all potable use product subcategories.

Certification costs can be broken into initial assessment and testing costs and annual renewal costs. Most of the accredited third party certification bodies offer an annual renewal based on an audit process for a set number of years after the initial certification year. In order to derive initial and renewal certification unit costs, EPA contacted the eight ANSI accredited third party certification bodies to obtain estimated costs for certifying products to ANSI/NSF Standard 372. The certifiers were asked to provide estimates for four representative product categories

(faucets, fittings, valves and pipes), which are intended to represent the range in complexity of plumbing products.

Four certification bodies provided quotes of sufficient specificity or comparable scope to be used in estimating initial certification costs. None of the firms provided quotes for all four product lines. Costs varied based on the product type and certifying body. EPA used the average of these quotes across firms and product types to derive a composite estimated cost of $6,000 for an initial certification of a single product family. Five of the eight certification bodies provided estimates for annually renewing the third party certification to Standard 372. Costs varied based on the product type and certification body. One of the responding certifiers requires re-certification annually. The other four certification bodies require renewal on a less frequent basis, the longest being every five years. EPA determined a five-year cost stream for each of the third party certifiers and computed a per product family average annual renewal cost of $3,200. In addition to the certifiers' fees, EPA assumed a $224 annualized cost for recordkeeping on the part of the plumbing manufacturing firms.

Both the preferred proposed rule Option B and Option C allow for some firms to self-certify compliance with lead free requirements. EPA estimated that each manufacturer would require 40 hours of labor to initially develop the certificate of conformity (the requirement of the certificate of conformity can be found in section IV.D of this preamble) which certifies a product family as being compliant with the lead free requirements. The unit cost per product family is $1,122. The labor burden for the annual renewal of the self-certification per product family is estimated to be 16 hours. These hours are used to update the certificate of conformity and perform recordkeeping activities. This means the unit cost of annual self-recertification is $449 per product family.

Table V.12 provides EPA's estimated total annual cost ranges for potable use product certification requirements of this proposed rule and other options that were considered. Unit certification costs were multiplied by the number of firms and average number of product families. Option A's cost range of $11.20 to $21.58 million reflects a third party certification requirement for all regulated firms. Option B, the proposed option, requires third party certification for firms with 100 or more employees and gives the option of self-certification to firms with fewer than 100 employees. Annual costs for Option B range from $2.82 to $4.31 million. The analysis of Option C assumes that all firms, when given the less costly self-certification choice, will opt for that compliance path. Therefore, the annual costs that range from $1.52 to $2.98 million reported here are for all firms conducting self-certifications. EPA did not assess any cost savings to firms that would no longer choose to have products third party certified.

Table V.12: Total Annualized Present Value Costs for Demonstration of Compliance Requirements, Millions (2014$)

Option	3% Discount Rate in Millions (2014$)	7% Discount Rate in Millions (2014$)
A: Third party certification only	$11.20 - $20.90	$11.56 - $21.58
B: Third party for ≥ 100; Choice of self-certification for <100 **(Proposed Rule)**	$2.82 - $4.14	$2.93 – $4.31
C: Third party certification or self-certification	$1.52 - $2.84	$1.59 - $2.98

Source: Technical Support Document, Exhibits 4-23a and 4-23b (USEPA, 2016).
Note: Under Option C, all manufacturers are assumed to select the less costly choice of self-certification.

E. Response to EPA Data Request Costs

Under all three of the proposed regulatory options, plumbing manufacturers will be required to respond to EPA's requests for product information (See section IV.E.1.a for a

detailed description of the data request provision). EPA assumed that firms would spend an average of 20 hours responding to each data request, resulting in a unit cost of $1,434. As part of the cost assessment, EPA multiplied the per unit cost by 10 unique data requests per year, starting in the fourth year after promulgation of the final rule and continuing over the 25-year period of analysis. Seventy percent of requests would be to firms with 500 or more employees, 20 percent of requests would be to firms with 100 to 499 employees, and firms with fewer than 100 employees would receive the remaining 10 percent. This breakdown of requests between firm size categories roughly corresponds to the proportion of total products produced by firms in each of the size categories. Table V.13 shows the total annualized cost of EPA data request response by firm size category. Total data request costs range from approximately $12,400 a year discounted at 3 percent to about $11,900 a year when discounted at 7 percent.

Table V.13: Total Annualized Present Value Costs for Responding to Data Requests, in Millions (2014$)

Manufacturer Size (no. of employees)	3% Discount Rate	7% Discount Rate
< 100	$0.0012	$0.0012
100-499	$0.0025	$0.0024
≥ 500	$0.0087	$0.0083
All Sizes	**$0.0124**	**$0.0119**

Source: Technical Support Document, Exhibit 4-25 (USEPA, 2016).

VI. Economic Impacts Analysis

EPA assessed the social costs and the projected economic impacts of the three regulatory options described in this proposal. This section provides an overview of the methodology EPA used to assess the social costs and the economic impacts of this proposed rule and summarizes the results of these analyses. The Technical Support Document (USEPA, 2016), which is available in the docket, provides more details on these analyses, including discussions of

uncertainties and limitations.

A. Annualized Social Costs Estimates

EPA estimated the total annualized social costs to plumbing manufacturers by summing the rule's component costs, which include administrative requirement costs, the cost to potable use product manufacturers for both labeling on the product and on the product's packaging, the cost to manufacturers of products eligible for the "used exclusively" exemption for package labeling indicating non-compliance with lead free requirements, third party- and self-certification costs, and the costs of responding to EPA data requests. EPA annualized the stream of future costs using both the 3 percent (the social discount rate) and 7 percent (opportunity cost of capital) discount rates. EPA annualized one-time costs over the period of analysis, 25 years. Capital and O&M costs recurring on other than an annual basis were annualized over a specific useful life, implementation, and/or event recurrence period (i.e., 10 years for mold modifications), using rates of 3 and 7 percent. EPA added the annualized capital, initial one-time costs, and the non-annual portion of O&M costs to annual O&M costs to derive total annualized compliance costs, where all costs are expressed on an equivalent constantly recurring annual cost basis.

Table VI.1 presents the total annualized compliance costs of the regulatory options. As shown in the table, total annualized compliance costs range between $3 million and $36 million for Options C and A, respectively, with the proposed option (Option B) estimated to have annualized costs of $12 million to $18 million.

Table VI.1: Total Annualized Social Costs (Millions, 2014$)

Regulatory Option[1]	3% Discount Rate	7% Discount Rate
A: Label product and packaging/third party certification	$20.1 - $31.6	$23.1 - $35.5

B: **(Proposed Rule)**: Label product and packaging/third party certification for manufacturers ≥ 100 employees and third party or self-certification for others	$11.8 - $14.8	$14.5 - $18.3
C: Label product or packaging/third party or self-certification	$2.9 - $4.5	$3.0 - $4.6

Source: Technical Support Document, Exhibit 4-27 (USEPA, 2016).

1. Table includes annualized costs for rule implementation, certification of potable use products, lead-related messaging for potable use products and products eligible for the "used exclusively" exemption, and EPA requests for data.

B. Economic Impacts – Cost-to-Revenue Analysis

To provide an assessment of the impact of the rule on plumbing manufacturing firms, EPA used a cost-to-revenue analysis. The cost-to-revenue analysis compares the total annualized compliance cost of each regulatory option with the revenue of the impacted entities. This same analysis is also used under the Regulatory Flexibility Act (RFA) to determine if a rule has the potential to have a significant impact on a substantial number of small entities.

In order to conduct the cost-to-revenue test, EPA developed a list of 2,193 manufacturers that participate in the production of specific types of plumbing products for both potable use and those eligible for the "used exclusively" exemption. These firms were assigned to a NAICS code, based on the type of plumbing product they manufacture. Firm size distributional information, based on number of employees, available from the U.S. Census Bureau's Statistics of U.S. Businesses for the year 2012 was then used to parse the number of entities in each NAICS code into a number of small business and large firm categories. In this way, the number of firms in each of the 14 NAICS codes having seven employee size categories each (e.g., 0-4, 5-9, 10-19, 20-99, 100-499, 500+ to the Small Business Administration (SBA) small business threshold, and large firms above the SBA threshold) was derived. Computation of total average firm cost under each of the NAICS/employee entity size categories was developed by applying the estimated unit

fixed and variable costs to each regulatory option. In order to calculate total average variable costs for each size category, unit variable costs must be adjusted by the units produced and firms producing in each of the NAICS/employee size categories. To determine the number of units produced per NAICS/employee size category, EPA used information from the U.S. Census Bureau's Statistics of U.S. Businesses. The Census Bureau does not provide units produced for each of the NAICS employee size categories, so EPA used the percent of firm receipts by size category as a proxy. The approximated units per size category were then divided by the estimated number of entities in the category (derivation of the number of entities per NAICS/employee size category was previously described) giving average units produced per firm. Average units per firm for each size category was multiplied by unit variable cost to get total variable cost for each NAICS/employees size category. The Census does not provide revenue values by NAICS and employee sizes, so EPA used data on total annual receipts (assuming receipts is an unbiased estimator) by NAICS/employee size categories as a close (although more conservative) approximation of revenue. The total receipts information was divided by the number of firms per category to approximate average revenue.

EPA then compared the computed average annual costs to the average revenue for each of the NAICS/employee size categories. If average cost exceeded revenue by 1 percent, all firms assigned to that category were assumed to incur impacts. Likewise, if average annual cost exceeded revenue by 3 percent in a NAICS/employee size category, all entities in that category are assumed to be impacted at the 3 percent level. Impacted firms are summed across NAICS codes and employee size categories to assess the total impact to the industry

Table VI.2 summarizes the cost-to-revenue analysis results for the three main regulatory options. The table only shows the largest impact scenarios analyzed, based on upper bound

compliance cost estimates, and using a 7 percent discount rate. For the lower bound cost and 3 percent discounted impact results see the Technical Support Document (USEPA, 2016). Under Option B, which represents this proposed rule (which includes costs for rule implementation, potable use labeling costs for both package and product, labeling of products eligible for the "used exclusively" exemption that do not meet lead free requirements, third party certification cost for firms with 100 or more employees and third party or self-certification costs for firm with fewer than 100 employees, and data request costs), EPA estimates that the vast majority of plumbing manufacturing firms subject to the regulations will incur annualized costs amounting to less than 1 percent of revenue (2163 firms, or 98.6 percent of the total 2,193 manufacturers). A total of 29 firms (2 percent of small firms) had impacts between 1 and 3 percent of revenue, and no small manufacturers had impacts above 3 percent, given the costs estimated for Option B. The analysis of Option B also found that 1 large entity (0.5 percent of large firms) had impacts between 1 and 3 percent of revenue, and no large firms were impacted at the 3 percent revenue threshold.

Table VI.2. Summary of Cost-to-Revenue Economic Impact Analysis (Upper Bound Scenario, Small Entities 7% discount rate, Large Entities 3% discount rate)

Option	Option Description[1]	Small Entities (7% discount rate)					Large Entities (3% discount rate)				
		Count[2]			Percentage		Count[2]			Percentage	
		Total	≥1%	≥3%	≥1%	≥3%	Total	≥1%	≥3%	≥1%	≥3%
A	Product and Package Costs for Potable Product *or* Package Costs for "Used Exclusively" Exempt Product, 3rd Party Cert for all manufacturers	1,976	783	27	40%	1%	217	1	0	0.5%	0.0%

B	Product and Package Costs for Potable Product *or* Package Costs for "Used Exclusively" Exempt Product, 3rd Party Cert for ≥ 100 employees, Self *or* 3rd Party Cert for <100 employees	1,976	29	0	2%	0%	217	1	0	0.5%	0.0%
C	Product *or* Package Costs for Potable Product *or* Package Costs for "Used Exclusively" Exempt Product, Self or 3rd Party Cert for all manufacturers	1,976	0	0	0.0%	0.0%	217	0	0	0.0%	0.0%

Source: Technical Support Document, Exhibit 6-7 (USEPA, 2016).

1. All options also include implementation and data request costs. For Option B, EPA assumes that manufacturers <100 employees choose the least cost option of self-certification. For Option C, EPA assumes all manufacturers pick the least cost option of self-certification. In addition, for Option C, EPA assumes manufacturers choose the least cost option for labeling, which is usually package labeling except when the products do not have packaging.
2. Counts of impacted entities are rounded up to 1 if they fall between 0 and 1.

EPA solicits comments on the economic analysis for this proposed rule, including EPA's cost analysis and benefits assessment as described in this preamble and the Technical Support Document (USEPA, 2016) for this proposed rule. Comments are most helpful when accompanied by specific examples or supporting data.

VII. Benefits

EPA did not quantify the expected change in health endpoints for this proposed regulation. EPA assessed the health effects associated with reductions in lead ingestion qualitatively using two main sources: 1) the EPA "Integrated Science Assessment for Lead"

(USEPA, 2013b); and 2) the National Toxicity Program's Monograph on Health Effects of Low-level Lead (USHHS, 2012).

A wealth of information exists on the adverse health effects associated with lead exposure. When ingested, lead is distributed throughout the body and can affect many organ systems. Lead is a highly toxic contaminant that can cause adverse neurological, cardiovascular, renal, reproductive, developmental, immunological and carcinogenic effects. The neurological effects are particularly pronounced in children; however, recent studies in the public health literature have found that a wide spectrum of adverse health outcomes can occur in people of all ages. In 2013, the U.S. Burden of Diseases Collaborators identified lead as one of the top 15 mortality risk factors (and top 10 cardiovascular risk factors) in the country. In addition, a level of lead exposure below which adverse effects do not occur has not been identified. This suggests that further declines in lead exposure below current-day levels could still yield meaningful benefits in the U.S. population, and the reduction in lead exposures from this proposed rule would result in fewer adverse health outcomes and, in turn, decrease societal costs of treatment. Chapter 5 of the Technical Support Document (USEPA, 2016) for this proposed rule contains additional detailed information on the potential health impacts of lead on both children and adults.

VIII. Statutory and Executive Orders Reviews

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2563.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The PRA requires EPA to estimate the burden on manufacturers and primacy agencies of complying with the proposed rule. The information collected as a result of this proposed rule should allow EPA to determine appropriate requirements for specific manufacturers and evaluate compliance with the proposed rule. For the first three years after publication of the final rule in the Federal Register, manufacturers will incur burden to conduct the following rule compliance activities:

- Obtaining certification of products from an accredited third party certification body to document compliance with the lead free requirements as set forth in the SDWA.
- Maintaining record costs associated with the initial certification (conducted by an accredited third party certification body) that potable use products meet the requirements of NSF/ANSI Standard 372.
- Preparing the initial certificate of conformity and maintaining records for potable use products that are self-certified by the manufacturer as being lead free.

Respondents/affected entities: The respondents include manufacturers of plumbing products intended for potable use and manufacturers of some plumbing products eligible for the "used exclusively" exemption that are physically compatible with potable use products. States and local governments are not impacted by the rule. For the first three years after publication of the final rule, EPA is not anticipated to incur any reporting or recordkeeping burden for implementation activities and ensuring compliance.

Respondent's obligation to respond: Compliance with the final rulemaking regulatory requirements would be mandatory. The authority for these requirements comes from EPA's authority for this proposed rule is section 1450 of the SDWA, 42 U.S.C. 300j-9. It authorizes the EPA Administrator to "prescribe such regulations as are necessary or appropriate to carry out his/her functions under this subchapter."

Estimated number of respondents: EPA estimates that 2,193 firms will be affected by the proposed requirements of this regulation.

Frequency of response: The requirements of this proposed rule that occur once during the three year ICR period include: obtaining initial third-party certification or self-certify activities to indicate that a product meets the lead free requirements. Ongoing costs include the third party annual renewal fees, and for all firms annual recordkeeping costs for third party or self-certification. The rule requirement to respond to EPA requests for information is on an ad hoc basis (however, this information collection is not anticipated to occur during the three-year period covered by this ICR).

Total estimated burden: Total three-year burden to manufacturers is estimated to be 162,582 to 318,276 hours, therefore the average annual burden number ranges from 54,194 to 106,092 hours. EPA estimated a range of burden (and costs) based on a lower and upper bound estimate of manufacturers that already include product and/or package lead free messaging that comply with the proposed rule requirements, as well as manufacturers that currently use a third party certifying agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The total costs over the three-year period are between $8.5 and $12.9 million, or an average of $2.8 to $4.3 million per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on EPA's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than [Insert date 30 days after publication in the Federal Register]. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are the manufacturing firms involved in the production of pipe, pipe or plumbing fitting or fixture, flux or solder, which are utilized in public water system or any plumbing in a residential or nonresidential facility or location that provides water for human consumption that meet the SBA's size standards for small businesses. Firms providing these types of plumbing products span fourteen different North American Industrial Classification System (NAICS) categories. The SBA small business definitions used in the analysis of this proposed rule vary across NAICS categories and range from firms with fewer than 500 employees to firm's with fewer than 1,250 employees (See Table XII.1).

Table VIII.1 SBA Small Entity Size Standards by NAICS Code

NAICS Code	SBA Size Standard

326122	750
332911	750
332913	1000
332919	750
332996	500
332999	750
333318	1000
333415	1250
333911	750
333999	500
334514	750
335222	1250
335228	1000
339991	500

EPA has determined that 1,976 plumbing product manufacturers out of 2,193 plumbing product manufacturers potentially subject to this proposal meet the small business definitions. EPA's analysis of projected impacts on small entities is described in detail in section VII (Economic Impacts). EPA projects less than 2 percent of the 1,976 affected small entities may experience an impact of costs exceeding 1 percent of revenue and no small entities would incur compliance costs exceeding 3 percent of revenue. Details of this analysis are presented in Chapter 6 of the Technical Support Document, available in the docket, for the proposed rule.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The proposed rule places no federal mandates on state, local, or tribal governments. The mandated annual cost to the private sector is estimated to be between $11.8 and $18.3 million and the highest single year nominal cost is $53.4 million which is below the $100 million UMRA threshold.

E. Executive Order 13132: Federalism

This action 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.

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

This action does not have tribal implications as specified in Executive Order 13175. It would not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes. This proposed rule contains no federal mandates for tribal governments and does not impose any enforceable duties on tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it implements specific standards established by Congress in statute. While the executive order does not apply, EPA does anticipate that the labeling requirements associated with this proposal will limit the inadvertent use of leaded plumbing products, thereby reducing exposure of children to lead in drinking water.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. The EPA is proposing a requirement that can be satisfied by, depending on the size of the regulated entity, either self-certifying compliance with the SDWA lead prohibition or by achieving a voluntary standard that mirrors the SDWA requirements, such as the NSF/ANSI 372 standard. While EPA is not specifying a technical standard under this proposed rule, EPA is proposing the use of technical standards that will meet the new definition of lead free as a means of demonstrating compliance with this proposal.

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

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, or indigenous peoples as described in Executive Order 12898 (59 FR 7629, February 16, 1994), because this action does not establish any specific regulatory requirements that would affect these communities. Instead, it is a proposed rule that codifies existing requirements set forth by Congress regarding the allowable levels of lead in plumbing products, and also includes additional provisions intended to aid in the implementation of those requirements.

IX. References

USHHS, 2012. National Toxicity Program Monograph on Health Effects of Low-level Lead. U.S. Department of Health and Human Services. June 2012. Available on the Internet at: *https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf*

USEPA, 2013a. Summary of the Reduction of Lead in Drinking Water Act and Frequently Asked Questions. December 2013. Available on the Internet at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100M5DB.txt*

USEPA, 2013b. Final Report: Integrated Science Assessment for Lead. EPA 600-R-10-075F. June 2013. Available on the Internet at: *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=255721*

USEPA, 2016. Technical Support Document for the Proposed Rule: Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water. EPA 815-R-16-009.December 2016.

List of Subjects

40 CFR Part 141

Environmental protection, Chemicals, Indian-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 143

Environmental protection, Chemicals, Indian-lands, Water supply.

Dated: January 4, 2017.

Gina McCarthy,
Administrator.

For the reasons set forth in the preamble, EPA proposes to amend title 40 chapter I of the Code

of Federal Regulations parts 141 and 143 as follows:

PART 141--NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. Revise the subpart heading for subpart E to read as follows:

Subpart E--Special Regulations, Including Monitoring

§141.43 [Removed]

3. Remove §141.43.

PART 143–NATIONAL SECONDARY DRINKING WATER REGULATIONS

4. The authority citation for part 143 continues to read as follows:

Authority: 42 U.S.C. 300f *et seq.*

5. Revise the part heading for part 143 to read as follows:

PART 143—OTHER SAFE DRINKING WATER ACT REGULATIONS

6. Add subpart A to read as follows:

Subpart A—National Secondary Drinking Water Regulations

7. Redesignate §§143.1 through 143.4 as subpart A.

§§143.5-143.10 [Reserved]

8. Reserve §§143.5 through 143.10.

9. Add subpart B to read as follows:

Subpart B—Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

Sec.

Subpart B—Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

§143.11 Definitions.

The following definitions apply to this subpart:

Accredited third party certification body means those bodies that are accredited by the American National Standards Institute (ANSI) to provide product certification to meet the lead free requirements of not more than a weighted average of 0.25 percent lead content when used with respect to the wetted surfaces, consistent with section 1417 of the Safe Drinking Water Act and §143.12, such as certification to the NSF/ANSI 372 standard.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his or her authorized representative.

Affiliated means a person or entity that directly or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the person or entity specified.

Affiliated persons or entities include, but are not limited to: a parent company and all wholly or partially owned subsidiaries of a parent company, or two or more corporations or family partnerships that have overlap in ownership or control.

Alloy means a substance composed of two or more metals or of a metal and a nonmetal.

Coating means a thin layer of material such as paint, epoxy, zinc galvanization, or other material usually applied by spraying or in liquid form to coat internal surfaces of pipes, fittings or fixtures.

Drinking water cooler means any mechanical device affixed to drinking water supply plumbing which actively cools water for human consumption.

Fitting means a pipe fitting or plumbing fitting.

Fixture means a receptacle or device that is connected to a water supply system or discharges to a drainage system or both. Fixtures used for potable uses shall include, but are not limited to: (1) drinking water coolers, drinking water fountains, drinking water bottle fillers, dishwashers; (2) plumbed in devices such as point-of-use water treatment devices, coffee makers, and refrigerator ice and water dispensers; and (3) water heaters, water pumps, and water tanks, unless such fixtures are not used for potable uses.

Flux means a substance used for helping to melt or join metals such as by removal of oxides and other coatings or residues from the metals before joining by using solder or other means.

Importer means any person who introduces into commerce any pipe, any pipe or plumbing fitting or fixture, or any solder or flux that is manufactured by a firm located outside of the United States.

Introduce into commerce or introduction into commerce means the sale or distribution of products, or offering products for sale or distribution in the United States.

Liner means a rigid lining such as a plastic or copper sleeve that is: (1) sealed with a permanent barrier to exclude lead-bearing surfaces from water contact; and (2) of sufficient thickness and having physical properties necessary to prevent erosion and cracking for the expected useful life of the product.

Manufacturer means a person or entity who: (1) processes or makes a product; or (2) has products processed or made under a contractual arrangement for distribution using their brand name or trademark.

Nonpotable services means all uses of water that are not potable uses.

Person means an individual; corporation; company; association; partnership; municipality; or state, federal, or tribal agency (including officers, employees, and agents of any corporation, company, association, municipality, state, tribal, or federal agency).

Pipe means a conduit or conductor, tubing or hose.

Pipe fitting means any piece (such as a coupling, elbow, washer, or gasket) used for connecting pipe lengths together or to connect other plumbing pieces together or to change direction.

Plumbing fitting means a plumbing component that controls the volume and/or directional flow of water, such as kitchen faucets, bathroom lavatory faucets, and valves.

Potable uses means services or applications that provide water for human ingestion such as for drinking, cooking, food preparation, dishwashing, teeth brushing, or maintaining oral hygiene.

Product means a pipe, fitting, fixture.

Solder means a type of metal that is used to join metal parts such as sections of pipe, without melting the existing metal in the parts to be joined. Solder is usually sold or distributed in the form of wire rolls or bars.

United States includes its commonwealths, districts, states, tribes, and territories.

Water distribution main means a pipe, typically found under or adjacent to a roadway that supplies water to buildings via service lines.

§143.12 Definition of lead free and calculation methodology.

(a) "Lead free" for the purposes of this subpart means:

(1) Not containing more than 0.2 percent lead when used with respect to solder and flux; and

(2) Not more than a weighted average of 0.25 percent lead when used with respect to the wetted surfaces of pipes, pipe fittings, plumbing fittings, and fixtures.

(b) The weighted average lead content of a pipe, pipe fitting, plumbing fitting, or fixture is calculated by using the following formula: For each wetted component, the percentage of lead in the component is multiplied by the ratio of the wetted surface area of that component to the total wetted surface area of the entire product to arrive at the weighted percentage of lead of the component. The weighted percentage of lead of each wetted component is added together, and the sum of these weighted percentages constitutes the weighted average lead content of the product. The lead content of the material used to produce wetted components is used to determine compliance with paragraph (a)(2) of this section. For lead content of materials that are provided as a range, the maximum content of the range must be used.

(c) If a coating, as defined in §143.11, is applied to the internal surfaces of a pipe, fitting or fixture component, the maximum lead content of both the coating and the alloy must be used to calculate the lead content of the component.

(d) If a liner, as defined in §143.11, is manufactured into a pipe, fitting or fixture, the maximum lead content of the liner must be used to calculate the lead content of the component.

§143.13 Use prohibitions.

(a) No person may use any pipe, any pipe or plumbing fitting or fixture, any solder or any flux

that is not lead free as defined in §143.12 in the installation or repair of:

(1) Any public water system; or

(2) Any plumbing in a residential or nonresidential facility providing water for human consumption.

(b) Paragraph (a) of this section shall not apply to leaded joints necessary for the repair of cast iron pipes.

§143.14 State enforcement of use prohibitions.

As a condition of receiving a full allotment of Public Water System Supervision grants under section 1443(a) of the Safe Drinking Water Act, states must enforce the requirements of section 1417(a)(1) of Safe Drinking Water Act and §143.13 through state or local plumbing codes, or such other means of enforcement as the state may determine to be appropriate.

§143.15 Introduction into commerce prohibitions.

It shall be unlawful:

(a) For any person to introduce into commerce any pipe, or any pipe or plumbing fitting or fixture, that is not lead free, except for a pipe that is used in manufacturing or industrial processing;

(b) For any person engaged in the business of selling plumbing supplies in the United States, except manufacturers, to sell solder or flux that is not lead free; and

(c) For any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption.

§143.16 Exempt uses and labeling of certain exempt use products.

The prohibitions in §§143.13 and 143.15 shall not apply to the products listed in paragraphs (a)

through (c) of this section:

(a) Pipes, pipe fittings, plumbing fittings, or fixtures, including backflow preventers, that are used exclusively for nonpotable services such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption. For the purposes of this subpart, "used exclusively for nonpotable services" means:

(1) The product is incapable of use in potable services (e.g., physically incompatible with other products that would be needed to convey water for potable uses); or

(2) The product is clearly labeled, on the product, package, container, or tag with a phrase such as: "Not for use with water for human consumption" or another phrase that conveys the same meaning in plain language.

(b) Toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, fire hydrants, service saddles, water distribution main gate valves that are 2 inches in diameter or larger.

(c) Clothes washing machines, fire suppression sprinklers, eyewash devices, sump pumps, and emergency drench showers.

§143.17 Required labeling of products that must meet lead free requirements.

(a) Persons that introduce into commerce products that must meet the lead free requirements of section 1417(a)(3)(A) of the Safe Drinking Water Act and §143.12 must label such products to indicate that it is in compliance with those requirements. Such labeling must occur by **[DATE 3 YEARS AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER]** or prior to introduction into commerce, whichever occurs later.

(b) Labeling or marking as specified in paragraph (a) of this section must be in accordance with paragraphs (b)(1), (b)(2), and (c) of this section:

(1) Packaged, containerized or tagged products must be labeled or marked on the package, container, or tag with a phrase such as: “Conforms with the lead free requirements of the federal Safe Drinking Water Act,” “Lead Free,” or similar terms that clearly convey to users that the product is in compliance with the applicable requirements. Products that are not packaged, containerized or tagged are only required to be marked consistent with requirements in paragraph (b)(2) of this section. Shrink wrapping of bulk products solely for the purpose of shipping or storage does not constitute being packaged, containerized, or tagged.

(2) Products must be directly marked by physically stamping, forging, or printing with indelible ink, except as provided in (b)(2)(i) or (b)(2)(ii) of this section. The marking must clearly convey to consumers that the product is lead free, such as “Lead Free,” “LF,” or certification marks. If the marking is “LF” or another abbreviation, symbol or acronym, the product package, container, or tag must associate that marking with a phrase such as “lead free” or “meets lead free requirements.” Product markings should be located where they are visible after product installation when practical.

(i) If the product is too small for a legible marking in a type face ranging from approximately 8 point to 14 point depending on the method of marking and roughness of product surface, only a product package, container or tag must be labeled or marked.

(ii) If the visible marking on installed products will adversely impact the visual appeal to consumers of the finished product, the product may be marked in a location not visible after installation.

(c) For products certified by accredited third party certification bodies, labeling or marking on the product, package, container, tag or some combination of these locations must include:

(1) The logo or name of the certification body as specified by the specific certification body; and

(2) The specific certification body's required identifier text to convey lead free or low lead content.

§143.18 Required labeling of solder and flux that is not lead-free.

Solder and flux that is not "lead free" as defined in §143.12(a)(1) must bear a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption.

§143.19 Required certification of products.

(a) Manufacturers or importers that introduce into commerce products that must meet the lead free requirements of section 1417 of the Safe Drinking Water Act and §143.12 must ensure that the products are certified to be in compliance as specified in paragraphs (b) and (c) of this section by **[DATE 3 YEARS AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER]** or prior to product introduction into commerce, whichever occurs later. Such manufacturers or importers must maintain documentation to substantiate the certification.

(b) Certification of products must be obtained by manufacturers or importers from an accredited third party certification body, except as provided in paragraph (c) of this section.

(1) Products certified by an accredited third party certification body must be labeled or marked as specified in §143.17(c).

(2) The manufacturer or importers must keep records for all products certified by an accredited third party certification body that include at a minimum: documentation of certification, dates of certification and expiration. This documentation must be provided upon request to the Administrator as specified in §143.20(b).

(c) Manufacturers having fewer than 100 employees or importers sourcing products from or

representing manufacturers having fewer than 100 employees may elect to self-certify products in lieu of obtaining certification from an accredited third party certification body. The number of employees includes any persons employed by the manufacturer and any of its affiliated entities. The number of employees must be calculated by averaging the number of persons employed, regardless of part-time, full-time or temporary status by an entity and all of its affiliated entities for each pay period over the entity's latest 12 calendar months, or averaged over the number of months in existence if less than 12 months. Such manufacturers or importers electing to self-certify products must comply with paragraphs (d) through (g) of this section.

(d) In order for eligible manufacturers or importers to self-certify products, such manufacturers or importers must attest that products are in compliance by developing and maintaining a "certificate of conformity." The certificate of conformity must be:

(1) Signed by a responsible corporate officer, a general partner or proprietor, or an authorized representative of a responsible corporate officer, general partner or proprietor; and

(2) Posted to a web page with continuing public access in the United States.

(e) The certificate of conformity must be in English and include:

(1) Contact information for the manufacturer or importer to include:

(i) The entity or proprietor name,

(ii) Street and mailing addresses,

(iii) Phone number, and

(iv) Email address.

For products imported into the United States, the contact information must also be included for the manufacturer;

(2) A brief listing of the products to include, when applicable, unique identifying information

such as model names and numbers;

(3) A statement attesting that the products meet the lead free requirements of the Safe Drinking Water Act and 40 CFR part 143, subpart B and also that the manufacturer or importer is eligible to self-certify the product consistent with this regulation;

(4) A statement indicating how the manufacturer or importer verified conformance with the Safe Drinking Water Act and 40 CFR part 143, subpart B; and

(5) The signature, date, name and position of the signatory; and if the signatory is an authorized representative of a responsible corporate officer, a general partner or proprietor, the name and position of the responsible corporate officer, a general partner or proprietor.

(f) Manufacturers or importers that self-certify products must maintain, at a primary place of business within the United States, certificates of conformity and sufficient documentation to confirm that products meet the lead free requirements of this subpart. Sufficient documentation may include: detailed schematic drawings of the products indicating dimensions, calculations of the weighted average lead content of the product, lead content of materials used in manufacture and other documentation used in verifying the lead content of a plumbing device. This documentation and certificates of conformity must be provided upon request to the Administrator as specified in §143.20(b).

(g) The certificate of conformity and documentation must be completed prior to a product's introduction into commerce.

§143.20 Compliance provisions.

(a) Noncompliance with the Safe Drinking Water Act or this subpart may be subject to enforcement. Enforcement actions may include seeking injunctive relief, civil or criminal penalties.

(b) The Administrator may, on a case-by-case basis, request any information deemed necessary to determine whether a person has acted or is acting in compliance with section 1417 of the Safe Drinking Water Act and this subpart. Such information requested must be provided to the Administrator at a time and in a format as may be reasonably determined by the Administrator.

[FR Doc. 2017-00743 Filed: 1/13/2017 8:45 am; Publication Date: 1/17/2017]