6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 143

[EPA-HQ-OW-2015-0680; FRL-10012-43-OW]

RIN 2040-AF55

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing changes to existing regulations to protect the public from lead in plumbing materials used in public water systems or

residential or nonresidential facilities providing water for human consumption. The changes in this rule codify aspects of the Reduction of Lead in Drinking Water Act of 2011 (RLDWA) and the Community Fire Safety Act of 2013 (CFSA). The RLDWA amended section 1417 of the Safe Drinking Water Act (SDWA), which 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 of plumbing products; and established a statutory method for calculating lead content. EPA is also establishing new requirements for manufacturers or importers that introduce into commerce products that must meet lead free requirements to certify such products as being in compliance with the lead free requirements in Section 1417 of the SDWA, as well as other changes to existing regulations to assist in implementation of Section 1417 of the SDWA, as amended. EPA expects that these requirements for lead content in plumbing materials used in new installations and repairs will result in fewer sources of lead in drinking water and, consequently, will reduce adverse health effects associated with exposure to lead in drinking water. The **SUPPLEMENTARY INFORMATION** section details EPA's changes to existing regulations as authorized under the SDWA as amended.

DATES: This final rule is effective on [**Insert date 30 days after date of publication in the Federal Register**]. The compliance date for the product certification requirements in 40 CFR 143.19 is [**Insert date 3 years after date of publication in the Federal Register**]. For purposes of judicial review, this rule is promulgated as of [**Insert date of publication in the Federal Register**].

ADDRESSES: EPA has established a docket for this action under Docket ID No. **EPA-HQ-OW-2015-0680**. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. This material can be viewed at the Water Docket in the EPA Docket Center, EPA/DC, EPA West William Jefferson Clinton Bldg., Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading room is 202-566-1744, and the telephone number for the Water Docket is 202-566-2426. Publicly available docket materials are available electronically through https://www.regulations.gov.

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. Additional information may also be obtained from the following website: https://www.epa.gov/dwstandardsregulations/use-lead-free-pipes-fittings-fixtures-solder-and-flux-drinking-water**.**

SUPPLEMENTARY INFORMATION:

Abbreviations and Acronyms

AFS – American Foundry Society

ANSI – American National Standards Institute

CBI – Confidential Business Information

CFR – Code of Federal Regulations

CFSA – Community Fire Safety Act of 2013

FAQs – Frequently Asked Questions

NAICS – North American Industry Classification System

NSF – NSF International

O&M – Operations and Maintenance

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

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I. General Information

The United States has made tremendous progress in lowering children's blood lead levels. As a result of multiple federal laws and regulations, including the 1973 phase-out of lead in automobile gasoline, the 1978 federal regulation banning lead paint for residential and consumer use, the 1991 Lead and Copper Rule (LCR), and the 1995 ban on lead in solder in food cans, the median concentration of lead in the blood of children aged 1 to 5 years dropped from 15 micrograms per deciliter in 1976–1980 to 0.7 micrograms per deciliter in 2013–2014, a decrease of 95 percent.

Although childhood blood lead levels have been substantially reduced as a result of these actions, some children are still exposed to high levels of lead. Sources of lead include lead-based paint, drinking water, and soil contaminated by historical sources. The Federal Action Plan (Action Plan) to Reduce Childhood Lead Exposures and Associated Health Impacts, issued by the President's Task Force on Environmental Health Risks and Safety Risks to Children, December 2018, provides a blueprint for reducing further lead exposure and associated harm through collaboration among federal agencies with a range of stakeholders, including States, Tribes, and local communities, along with businesses, property owners, and parents. The Task Force comprises 17 federal departments and offices, including the Department of Health and Human Services (HHS) and the Department of Housing and Urban Development.

Through the Action Plan, EPA is committed to reducing lead exposures from multiple sources, including paint, ambient air, and soil and dust contamination, especially exposures of sources to children who are among the most vulnerable to the effects of lead. EPA is also focused on conducting critical research and improving public awareness by consolidating and streamlining federal messaging.

To reduce exposure to lead through drinking water, the Action Plan highlights several key actions, including EPA's commitment to updating the Lead and Copper Rule, making regulatory changes in this final rule to protect the public from lead in plumbing materials, and assisting schools and childcare centers with the existing 3Ts approach (Training, Testing and Taking Action) for lead in drinking water. The Action Plan also highlights EPA's continued support to States and communities by providing funding opportunities through the Drinking Water State Revolving Fund and the Water Infrastructure Finance and Innovation Act loan program for updating and replacing drinking water infrastructure. For more information about the Federal Lead Action Plan, see https://www.epa.gov/sites/production/files/2018-12/documents/fedactionplan_lead_final.pdf.

The Reduction of Lead in Drinking Water Act of 2011 (RLDWA) amended section 1417 of the Safe Drinking Water Act (SDWA) to revise the definition of "lead-free" to: (1) lower the allowable maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of pipes, fittings, and fixtures; and (2) specify a required method for calculating lead content. In addition, the RLDWA created exemptions from the prohibitions in section 1417 of the SDWA (these prohibitions are also referred to as "lead free requirements") for plumbing

products that are used exclusively for nonpotable services as well as for other specified products. The Community Fire Safety Act of 2013 (CFSA) further amended section 1417 of the SDWA to exempt fire hydrants from these requirements.

A. Does this action apply to me?

The statutory prohibitions on use and introduction into commerce of certain products that are not lead free, which are codified by this final rule, apply to any "person" as defined in the SDWA. This final rule applies to any person who would introduce plumbing products into commerce, such as manufacturers, importers, wholesalers, distributors, re-sellers, and retailers. It also applies to any person who would use plumbing products in the installation or repair of a public water system, such as an installation contractor, or in a residential or nonresidential facility providing water for human consumption, such as a plumber. 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 codifying revisions to the SDWA's prohibition on use and introduction into commerce of certain products that are not lead free (hereafter referred to as the SDWA lead prohibitions). The SDWA lead prohibitions, first enacted in 1986, were amended in 1996, and most recently in the RLDWA and the Community Fire Safety Act of 2013 (CFSA). This codification will further assure consistent implementation and enforcement of the SDWA lead prohibitions on use and introduction into commerce of certain products that are not lead free. EPA is also establishing requirements to certify plumbing products introduced into commerce to

help ensure that only lead free pipes, fittings, and fixtures are used in repairs and new installations of a public water system or in a residential or nonresidential facility providing water for human consumption (i.e., potable use applications).

The SDWA, section 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 nonresidential facility providing water for human consumption that is not "lead free" as defined in section 1417(d). Section 1417(a)(3) of the SDWA further 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 (1) lower the maximum lead content from 8.0 percent to a weighted average of 0.25 percent of the wetted surfaces of pipes, fittings, and fixtures; (2) specify a required method for the calculation of lead content; and (3) eliminate the requirement that lead free products be in compliance with voluntary standards established in accordance with the SDWA, section 1417(e), for leaching of lead from new plumbing fittings and fixtures. In addition, the RLDWA created two categories of exemptions from the prohibitions on the use or introduction into commerce for

(1) “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”; and (2) “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, sections 1417(a)(4)(A) and (B)). The CFSA further amended section 1417(a)(4)(B) of the SDWA to add fire hydrants to the list of excluded devices. By this regulation, EPA is identifying several additional types of products (e.g., clothes washing machines) that are exempt from the lead free requirements, which will decrease burden for manufacturers without endangering public health and safety.

In addition to codifying the revised requirements under RLDWA and CFSA, EPA is establishing regulations for product certification and information collection to help ensure consistent implementation and enforcement of the SDWA lead prohibitions. The final rule does not require the marking and labeling of lead free pipes, fittings, or fixtures as EPA had initially proposed. Having reviewed public comments on this issue, EPA has reconsidered the matter, and EPA anticipates that the final rule’s certification provisions, combined with the widespread practice of voluntary labeling by firms that obtain third party certification, will likely result in the marketing of many potable use plumbing products in a way that communicates the lead free status of the products to the purchaser without the burden of regulatory requirements to do so.

EPA expects that this final rule will result in fewer sources of lead in drinking water and, consequently, will reduce adverse health effects associated with exposure to lead in drinking water.

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

EPA's authority for this final rule is the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.* including sections 1417, 1445, 1450, and 1461 of the SDWA, 42 U.S.C. 300j-6, 300j-4, 300j-9, and 300j-21. The SDWA, section 1450, authorizes EPA Administrator to "prescribe such regulations as are necessary or appropriate to carry out his functions" under the SDWA. 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, or the introduction into commerce prohibitions, which were established in the 1996 amendments to the SDWA. This final rule amends those regulations to reflect current law. In addition, EPA is adopting additional regulatory provisions to aid in the implementation and enforcement of the requirements of the SDWA, section 1417, and to identify additional products as exempt.

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

EPA conducted an incremental compliance cost analysis of this final rule. For detail on the cost analysis see sections V and VI of this preamble. The Final Rule Technical Support Document (USEPA, 2020) prepared for this final rule is available in the docket for this rule. It contains the detailed economic analysis for this rule including the description of the cost assessment. EPA did not quantify or monetize benefits for this final rule, but a qualitative

discussion of the benefits attributable to this final rule can be found in section VII of this preamble and in the Final Rule Technical Support Document.

Total annualized costs for this final rule range from $7 million discounted at three percent to $12 million discounted at seven percent. These costs include administrative requirement costs, third party and self-certification costs, and the costs of responding to EPA data requests.

This final rule will help ensure that only lead free plumbing products and components of public water systems are used in repairs and new installations in potable use applications. The benefits of this final rule are the resulting incremental reduction in exposure to lead in drinking water. The 2013 Integrated Science Assessment for Lead (USEPA, 2013) and the U.S. Department of Health and Human Services' National Toxicology Program Monograph on Health Effects of Low-Level Lead (National Toxicology Program, 2012) have examined the health effects of lead. In these documents, lead has been associated with adverse cardiovascular effects (both morbidity and mortality effects), renal effects, reproductive effects, immunological effects, neurological effects, and cancer.

II. Background

Lead can be introduced into drinking water by corrosion of plumbing products and components of public water systems (pipes, pipe and plumbing fittings, and fixtures, solder, and flux). The greatest risk associated with lead exposure is to infants, young children, and pregnant women. Scientists have linked lead exposure to lowered IQ in children, as compared with children exposed to lower levels of lead.

In 1986, Congress amended the SDWA to prohibit the use of pipes, solder, or flux that are not "lead free" in the installation or repair of public water systems or plumbing in facilities providing water for human consumption. In doing so, Congress intended "to eliminate the future use of lead in water supply distribution systems." H.R. Rep. No. 99-575 (1986) (Conf. Rep.) as reprinted in 1986 U.S.C.A.A.N. 1592, 1602. At the time, the SDWA defined lead free as solder and flux having no more than 0.2 percent lead, and defined lead free pipes as having no more than 8.0 percent lead.

In 1996, Congress further amended the SDWA to clarify that its "lead free" prohibition on the use of pipes, solder, and flux also applies to pipe fittings, plumbing fittings, and fixtures (referred to in this document as "fittings and fixtures"). The goal of the legislation was described similarly to the purpose articulated in the 1986 legislative history: "The focus of these changes is to prevent the contamination of the drinking water supply by lead that has leached from pipes, faucets, and other fixtures incidental to the delivery of potable water. It is the intent of the Committee that the terms pipe and plumbing fittings, and fixtures in the legislation are in reference to drinking water applications." H.R. Rep. 104-632(I), at 39, as reprinted in 1996 U.S.C.A.A.N.1366, 1402. The 1996 amendments also revised the definition of lead free to require new plumbing fittings and fixtures be in compliance with a lead leaching standard established in accordance with section 1417(e) of the SDWA.

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. Additionally, the RLDWA revised the definition of lead free to remove the requirement that new plumbing fittings and fixtures be in compliance with standards established in accordance with the SDWA, section 1417(e), for the leaching of lead from new plumbing fittings, and fixtures.

The RLDWA also established two new categories of exemptions from the 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 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, section 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, section 1417(a)(4)(B)). The RLDWA

established a prospective effective date of January 4, 2014, which provided a 3-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 released the "Summary of the Reduction of Lead Drinking Water Act and Frequently Asked Questions" to help the public, including manufacturers, retailers, plumbers, and consumers in understanding the changes to the law (USEPA, 2013a). In this Frequently Asked Questions (FAQ) document, EPA stated its intention to further evaluate and refine topics in the FAQ and other issues in a future rulemaking.

On January 17, 2017, EPA published in the *Federal Register* a proposed rulemaking – "Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water" (USEPA, 2017, 82 FR 4805). The proposed rulemaking contained several major provisions. EPA proposed to codify various statutory provisions, including the definition of lead free; the prohibition on introducing into commerce pipes, fittings, or fixtures that are not lead free; and the prohibition on the use of any such products in the installation or repair of any public water system or any plumbing in a residential or nonresidential facility providing water for human consumption. EPA also proposed labeling requirements to differentiate plumbing materials that are required to meet the lead free requirements from those that are exempt from the requirements. In addition, EPA proposed requirements that lead free products would need to be certified by an American National Standard Institute (ANSI) accredited third party certification body, unless they are made by manufacturers having fewer than 100 employees, in which case they could be self-

certified as lead free. Other provisions were included in the proposal to aid in implementation, such as defining certain terms used in the statute or the proposed regulation and provisions to ensure compliance.

In the *Federal Register* publication for the proposed rulemaking (USEPA, 2017, 82 FR 4805 (January 17, 2017)), EPA requested comments on a number of specific questions concerning provisions in the proposal and possible alternative provisions or criteria. In response to requests from the public, EPA extended the 90-day public comment period by an additional 30 days; the comment period closed on May 17, 2017 (82 FR 17406, April 11, 2017). EPA received 25,858 comment submissions, of which 25,751 were identical or nearly identical because they were submitted as part of a mass mailing public comment campaign (5,212 of the 25,751 comments included unique statements in addition to the identical comment). A detailed listing of public comments received and EPA's responses to comments are available in Docket ID EPA-HQ-OW-2015-0680 at https://www.regulations.gov.

III. Summary of Data Used

This final rule is supported by a number of documents. The Technical Support Document and additional records are available in the public record for this final rule under Docket ID No. EPA-HQ-OW-2015-0680 at https://www.regulations.gov.

A. Characterization of the Affected Industry

EPA used a number of data sources 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 nonpotable 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 final rule. These data were supplemented with information from various additional sources. Dun & Bradstreet data were obtained for those firms that were identified by the North American Industry Classification System (NAICS) and Standard Industrial Classification (SIC) code classifications as potentially producing products that would be affected by the final 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 to reflect the 0.25 percent lead content limit, which was later established as a new NSF/ANSI Standard 372. Additional information was gathered from the website of the Plumbing Manufacturers International (PMI), 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. These data sources are referenced in the Final Rule Technical Support Document and other supporting documents available in Docket ID No. EPA-HQ-OW-2015-0680 at https://www.regulations.gov.

B. Determining Baseline Industry Practices and Potential Costs of Compliance

EPA conducted calls with representatives of both the PMI and the American Foundry Society (AFS) industry associations and held a stakeholder webinar in 2015 to obtain information on current practices 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, PMI and AFS 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, EPA obtained data from various independent and 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 rule. EPA also contacted the eight firms currently accredited to certify plumbing components for compliance with NSF/ANSI Standard 372, to obtain information on the cost of certification and the technical process for testing and certifying products to meet the standard. These calls with PMI and AFS and other data sources are referenced in the Final Rule Technical Support Document and other supporting

documents available under Docket ID No. EPA-HQ-OW-2015-0680 at https://www.regulations.gov.

IV. Final Rule

This section includes a summary of the requirements of this final rule, the significant changes from the proposed rulemaking, and the rationale for those changes. A detailed listing of public comments received and EPA's responses to comments are available in Docket ID EPA-HQ-OW-2015-0680 at https://www.regulations.gov.

A. Applicability and Scope

1. Final Rule Requirements:

This final rule amends the Code of Federal Regulations (CFR) at 40 CFR part 143 by retitling it as Other Drinking Water Regulations; creating a subpart A, to consist of the existing National Secondary Drinking Water Regulations; and creating a Subpart B, Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water, pursuant to, *inter alia*, sections 1417, 1461, and 1450 of the SDWA. EPA has included a Scope/Applicability section in subpart B as 40 CFR 143.10 of this final rule. Subpart B states that "[t]his subpart establishes regulations pertaining to pipes, pipe or plumbing fittings, or fixtures, solder, or flux pursuant to, *inter alia*, section 1417 and 1461 of the SDWA (42 U.S.C. 300g-6 and 300j-21). It applies to any person who introduces these products into commerce, such as manufacturers, importers, wholesalers, distributors, re-sellers, and retailers. It also applies to any person who uses these products in the installation or repair of a public water system

or a residential or nonresidential facility providing water for potable uses." The product certification requirements in 40 CFR 143.19 for lead free pipes, fittings, and fixtures in this final rule apply to manufacturers and importers. The terms "manufacturer" and "importer" are defined in 40 CFR 143.11. A manufacturer is defined as a person or entity who: processes or makes a product; or has products processed or made under a contractual arrangement for distribution. An importer is any person who introduces into commerce any pipe, fitting, fixture, solder or flux entering the United States; or any "importer" as defined in 19 CFR 101.1; or both. EPA does not consider plumbers or entities that design and build public water systems to be manufacturers of pipes, fittings, and fixtures, but rather as persons who use or assemble pipes, fittings, and fixtures in the installation or repair of a public water system or a residential or nonresidential facility providing water for potable uses. This final rule requires that new or replacement pipes, pipe or plumbing fittings, or fixtures, solder and flux used in providing water for potable uses must be lead free, except for certain exemptions.

There are six components of the definition of "lead free" in 40 CFR 143.12(a) through (f) of this final rule, based on the statutory definitions of lead free in sections 1417 and 1461 of the SDWA. In 40 CFR 143.12(a), EPA specifies the maximum allowable lead content as follows: (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. In 40 CFR 143.12(b), this final rule includes the statutorily prescribed calculation of the weighted average lead content. In 40 CFR 143.12(c) and (d), EPA specifies how to use the required calculation method when a coating or liner is used in manufacturing a product. (This final rule defines the terms "coating" and "liner" in 40 CFR 143.11.) Similarly, in 40 CFR 143.12(e), EPA specifies how to calculate lead content if a fixture consists of any media (e.g., activated carbon, ion exchange resin) contained in filters.

In 40 CFR 143.12(f) of the final rule, EPA defines "lead free" for drinking water coolers. In addition to meeting the weighted average of 0.25 percent lead when used with respect to wetted surfaces, additional limits specific to drinking water coolers are placed on their storage tanks and individual parts or components, consistent with the definition of "lead free," and applicable to drinking water coolers in section 1461(2) of the SDWA. This final rule addresses this requirement in 40 CFR 143.12(f) as follows: In addition to the definitions of "lead free" in 40 CFR 143.12(a) through (e), 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.

As with all pipes, fittings, or fixtures, this final rule does not require the removal and replacement of existing drinking water coolers that do not meet the maximum 0.25 percent weighted average lead content of the wetted surfaces of the entire product. However, this final rule does require that if any new drinking water coolers are installed, or if existing drinking water coolers are removed and replaced, with a new or replacement device, the new and replacement products must meet the requirements of this final rule.

2. Changes from Proposed Rule and Rationale

Some public commenters requested that EPA clarify that this final rule encompasses products such as those used in municipal drinking water distribution and plumbing products that convey drinking water. EPA added a new section, 40 CFR 143.10 Applicability and Scope, to this final rule to provide a brief description of the rule and to whom it applies. 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 final rule applies 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 are 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: (1) any

public water system; or (2) any plumbing in a residential or nonresidential facility or location providing water for human consumption.

Section 143.12(e) was added to this final rule to exclude media in filters, such as activated carbon, from the calculation used to determine the wetted surface area of the entire product. This change was made because such filter media should not contain lead, yet the surface area of the filter media would be very large and could be difficult to determine; therefore, including it in the calculation of the weighted average of the lead content of the product would allow other components in the product to contain high levels of lead while still meeting the definition of lead free.

EPA requested comment concerning whether a specific provision needed to be included in this final rule to define "lead free" for drinking water coolers because of the different definitions in sections 1417 and 1461 of the SDWA. EPA received several public comments about this issue, most of which supported the inclusion of a specific provision pertaining to drinking water coolers. This final rule includes 40 CFR 143.12(f) to address the specific treatment of drinking water coolers under the SDWA. 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 not more than 8 percent lead except that no drinking water cooler that contains any solder, flux or storage tank interior surface that may come into contact with drinking water shall be considered lead free if the solder, flux, or storage tank interior surface contains more than 0.2 percent lead." The

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 a "fixture" under this final rule and as that term is generally understood; and, therefore, subject to the definition of lead free in the SDWA, section 1417. The "parts or components" in drinking water coolers constitute an important source of lead in drinking water coolers. Accordingly, this final rule defines "lead free" for drinking water coolers to give effect to both statutory definitions of lead free. In practice, drinking water coolers need to comply with the most restrictive of the requirements in sections 1417 and 1461 of the SDWA. For clarity and consistency with statutory requirements, EPA addressed the requirements of the SDWA, section 1461, in this final rule by including regulatory text in 40 CFR 143.12(f). If the section 1461 requirements were not incorporated into this rule, a drinking water cooler could potentially have a small part with lead content that is much greater than 8 percent as long as the weighted average lead content of wetted surfaces of the whole device did not exceed 0.25 percent lead. The effect of this change in the rule is to further reduce potential public exposure to lead from any new or replacement drinking water coolers.

Based on public comment, this final rule includes a minor correction to address concerns with placement of the rule in 40 CFR part 143 as it relates to the mandatory nature of this rule. The National Secondary Drinking Water Regulations that are

currently already in 40 CFR part 143 are not federally enforceable as stated in existing 40 CFR 143.1. This final rule revises 40 CFR part 143 to designate the National Secondary Drinking Water Regulations as subpart A of part 141 and the lead free requirements in this rule as subpart B. Therefore, EPA also revised the statement about non-enforceability in 40 CFR 143.1, to clarify it only pertains to the National Secondary Drinking Water Regulations by removing "part" and replacing it with "subpart" in the first sentence of the paragraph.

B. No Labeling Requirement for Potable Use Products

1. Final Rule Requirements

This final rule does not require any marking or labeling of lead free pipes, fittings, or fixtures on products or packages. However, EPA continues to recommend marking and labeling of lead free products and packages to indicate compliance with the SDWA, section 1417.

2. Changes from Proposed Rule and Rationale

EPA proposed 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. EPA did not propose a specific phrase to be required on products or packages, but rather a performance standard -- that each package, and each product (unless the product is too small), clearly convey to users that the product is in compliance with the lead free requirements of the SDWA.

EPA is not requiring any lead free labeling or marking of potable products in this final rule. Several commenters made the point that labeling is not necessary if third party certification is required, because the certification itself provides adequate assurance of compliance and, therefore, the cost of labeling is not worth any incremental benefits of labeling a product that has been verified as lead free. EPA found that many manufacturers already utilize a combination of product marking and/or package labeling to indicate that the product has been certified to be lead free for marketing reasons and to demonstrate that the products can be used in compliance with State and local plumbing codes. EPA anticipates that this final rule's certification provisions, combined with the widespread practice of voluntary labeling by firms that obtain third party certification, will likely result in the marketing of many potable use plumbing products in a way that communicates the lead free status of the product to the purchaser without the burden of regulatory requirements to do so. Accordingly, the final rule does not require the marking and labeling of lead free pipes, fittings, or fixtures.

C. Exemptions

1. Used Exclusively for Nonpotable Services

a. Final Rule Requirements

The RLDWA established two new categories of exemption from the lead free requirements. One category exempts pipes, pipe fittings, plumbing fittings, or fixtures 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." EPA has also provided examples of products that could be considered as "used exclusively for nonpotable services" in 40 CFR 143.16(a). The second exemption category consists of specifically named product classes. These specifically listed exempt products are codified in this final rule and discussed in section IV.C.2. of this preamble.

b. Changes from Proposed Rule and Rationale

EPA has removed the definition of "used exclusively for nonpotable services" that was contained in the proposed rulemaking. The proposed regulation had defined the term "used exclusively for nonpotable services" by specifying two ways to meet this exemption: (1) The product is incapable of use in potable services (e.g., is 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. In the final rule, as opposed to defining the term "used exclusively for nonpotable services," EPA has provided examples of products that could be considered as "used exclusively for nonpotable services" in 40 CFR 143.16(a).

EPA received numerous comments on the proposed definition with a very wide range of perspectives, examples of which are summarized in this section. Some commenters supported the definition as proposed, with some stating the requirement is critical to human health. Some commenters requested EPA remove the option of qualifying for the exemption through labeling products with a warning, and instead require such products be made physically incompatible with potable water plumbing. Other commenters stated that many fittings and components, such as automotive parts and HVAC valves, are physically compatible with potable use plumbing products because the pipe threads are compatible and that to extend the labeling requirement to anything which could be made to fit onto a potable use plumbing product would drastically increase the rule cost to many manufacturing sectors. Other commenters contended that EPA has no authority to regulate non-potable use products or that such a requirement was beyond the intent of the SDWA. EPA's proposed option to allow the use of labeling to qualify for the "used exclusively for nonpotable services" exemption was not a requirement to label exempt products; it was an option EPA proposed be made available to manufacturers that elected to use it in order to establish that pipes, fittings, and fixtures intended, designed and marketed for use in nonpotable services or in applications other than delivery of water products would be considered "used exclusively for nonpotable services" and therefore exempt from the prohibitions. It would have been within EPA's authority to finalize such a requirement in order to clarify the meaning of the exemption for regulated entities. However, due to the numerous and widely differing

perspectives and reasons expressed by commenters, it became clear that the definition could be interpreted to be both over-inclusive and under-inclusive. Therefore, in the final rule EPA is not including a definition of "used exclusively for nonpotable services" but EPA is providing examples of products that could be eligible for the exemption. These examples are not intended to create binding criteria for eligibility (or ineligibility) for the exemption. Therefore, EPA will continue to rely on manufacturers and importers, in the first instance, to determine which products are "used exclusively for nonpotable services." Because any person, including a manufacturer or importer, could be subject to enforcement if the person introduces into commerce non-lead free products that could be used in potable services, it is in such person's interest to make accurate determinations about the potential use of their products in order to maintain compliance with the SDWA. As previously discussed, EPA recognizes that situations exist in which a particular product's primary use in most circumstances is expected to be for nonpotable use, but in which the same product may be anticipated to be used for potable use in some circumstances. Examples may include hose bibs and yard hydrants. The primary use of these products in most situations is likely outdoor watering and irrigation. However, they are sometimes observed to be installed and in use as a source of potable water for cooking and drinking, such as in campgrounds and RV parks. If used for cooking or drinking, the products are not used exclusively for nonpotable services. To protect public health, EPA advises that manufacturers exercise caution in anticipating how a product that is introduced into commerce may be used in various circumstances. Likewise, EPA

advises caution in anticipating product usage by persons involved in the installation or repair of any public water system, or of any plumbing in a residential or nonresidential facility providing water for human consumption. For non-lead free products that are very similar in form to, and that may be confused with, lead free potable use counterparts, EPA recommends that manufacturers, importers, and other suppliers either reformulate the product to be lead free or clearly label the non-lead free product with a phrase such as "Not for use with water for human consumption."

2. Specifically Listed Exempt Products

a. Final Rule Requirements

This final rule codifies the statutory exemption for specific products by name in the SDWA, section 1417(a)(4)(B), to include toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, fire hydrants, shower valves, service saddles, and water distribution main gate valves that are 2 inches in diameter or larger. In addition to the specific plumbing devices excluded in the SDWA, the final rule is also excluding clothes washing machines, emergency drench showers, emergency face wash equipment, eyewash devices, fire suppression sprinklers, steam capable clothes dryers, and sump pumps because these products are not designed or used for any potable application as potable uses as defined for this final rule. These products do not provide water for human ingestion. The Use Prohibitions in 40 CFR 143.13 or the Introduction into Commerce Prohibitions in 40 CFR 143.15 do not apply to these specifically exempted products; therefore, these exempt

products do not need to meet the definition of lead free in 40 CFR 143.12, and manufacturers and importers of these products do not need to meet the certification provisions in 40 CFR 143.19.

b. Changes from Proposed Rule and Rationale

For the specific product exemptions listed in 40 CFR 143.16(b) and (c), EPA retained the exempted products listed in the proposed rulemaking either because they are explicitly identified as exempt in statute or because the product is not used for any potable purpose. In this final rule, EPA added two product categories to the list of exempt products as follows: "emergency face wash equipment" and "steam capable clothes dryers."

Emergency face wash equipment may be combined with eyewash devices, and neither the equipment nor the devices are used for a potable purpose that involves the ingestion of water. Steam capable clothes dryers, like clothes washing machines, are used for laundering clothing; they are not used for the ingestion of water, and, therefore, are not used for any potable purpose as defined in this final rule.

EPA is clarifying in this final rule that exempt products do not need to comply with the certification provisions of 40 CFR 143.19. Such products either (A) are not potable use products or (B) are specifically exempted by the RLDWA.

D. Product Certification

1. Final Rule Requirements

The final rule establishes certification requirements for manufacturers and importers to demonstrate that the maximum lead content of the wetted surfaces of their plumbing products (i.e., pipes, fittings, and fixtures) does not exceed a weighted average of 0.25 percent using the method for the calculation of lead content specified in this final rule. This final rule requires manufacturers with 10 or more employees, and importers entering products purchased from or manufactured by manufacturers with 10 or more employees, to obtain third party certification by an ANSI accredited third party certification body to demonstrate that, with some exceptions, any pipe, pipe or plumbing fitting or fixture introduced into commerce meets the definition of lead free. This final rule requires manufacturers with fewer than 10 employees, and importers entering products purchased from or manufactured by manufacturers with fewer than 10 employees, to demonstrate compliance either through third party certification by an ANSI accredited certification body or through self-certification as described later in this section. This final rule also requires manufacturers of all sizes and importers entering goods manufactured by or purchased from entities of all sizes to certify custom fabricated products either through an ANSI accredited certification body or through self-certification as described later in this section. A requirement for recordkeeping pertaining to product certification is described in section IV.E.2. of this preamble.

Third party certified plumbing materials in covered plumbing projects are currently required for certain products under model plumbing codes, which are often

adopted in whole or in part by States or municipalities. The most recent version of the single most widely adopted model plumbing code, the *2018 International Plumbing Code* (published in 2017), requires pipe, pipe fittings, joints, valves, 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 needs to be evaluated by an ANSI accredited third party certification body. These bodies are independent organizations that test a product, review a product's manufacturing process, and determine whether the product complies with specific standards for safety, quality, sustainability, or performance (e.g., 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 the Water Quality Association.

For manufacturers with fewer than 10 employees and importers entering products manufactured by or purchased from manufacturers with fewer than 10 employees, this final rule provides the flexibility of allowing these entities to demonstrate product compliance either by using an ANSI accredited third party certification body or by self-certification of the products. Firms with fewer than 10 employees are more likely to operate on a limited scale with a lower volume of production, including those that serve only local or regional markets, which would make third party certification not

as cost effective as it is for larger firms; the cost of certification per unit produced could be much higher.

Therefore, this final rule provides the option for firms with fewer than 10 employees to self-certify their products. Those eligible manufacturers that opt for the self-certification are required to develop a "certificate 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 and importers eligible for self-certification, this final rule requires the certificate of conformity to be posted to a web site with continuing public access in the United States, unless it is distributed by other means (e.g., electronically or in hard copy) with the product through the distribution channel for final delivery to the end use installer of the product.

The certificate of conformity is required to include the following information: 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 (e.g., the manufacturer has fewer than 10 employees or the product is custom fabricated), 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 confirmation (by some method described in the statement) that all source materials used in manufacture were less than 0.25 percent lead. EPA anticipates that firms will develop the certificate of conformity to work best with their individual circumstances. For example, a manufacturer may list multiple product numbers or models on a certificate of conformity for use with all products within a similar product family, provided that all of the similar products meet the lead free requirements.

EPA anticipates that some firms having fewer than 10 employees will utilize third party certification rather than self-certification in cases where a large quantity of a specific product is produced. Some firms will do so because many State and local plumbing codes require the use of third party certified plumbing products in projects covered by the codes.

This final rule also requires firms that expand to 10 or more employees to obtain third party certification within 12 months, to allow a reasonable transition time for obtaining third party certification of products. Third party certification should be easily attainable in such situations without the need to modify or reformulate products if the products were accurately self-certified as lead free.

The certification requirement will help ensure that only lead free plumbing materials are introduced into commerce or used in new installations or repairs of any public water system or any plumbing in a facility providing water for human

consumption. The third party certification requirement leverages the resources of the third party certification bodies as well as manufacturers to help parties in the supply chain ensure that they are not violating the requirements of the RLDWA when they introduce the product into commerce or use it in new installations or repairs. Increasing the number of products that are third party certified will provide small businesses such as plumbers and builders better assurance that they are complying with the federal requirements to use lead free plumbing products. The self-certification requirement, which is applicable to manufacturers with fewer than 10 employees or for custom fabricated products, also helps to ensure that products sold by those smaller manufacturers or those products that are custom fabricated are lead free without imposing a significant burden on the smallest manufacturers.

This final rule also allows any manufacturer of custom fabricated products to opt for self-certification for custom fabricated products. EPA has defined "custom fabricated product" in 40 CFR 143.11. For custom fabricated products, EPA anticipates that firms may develop and use a certificate of conformity that covers a range of products within a product family, provided that all the products meet the lead free requirements.

This final rule includes three exclusions from the certification requirement for those products required to be lead free: (A) product components of assembled pipes, fittings, or fixtures do not need to be individually certified if the entire product in its final assembled form is lead free certified; (B) direct replacement parts for previously

installed lead free certified products do not need to be individually certified if the weighted average lead content of the wetted surface area for the part does not exceed the weighted average lead content of the original part; and (C) dishwashers.

2. Changes from Proposed Rule and Rationale

In the proposed rulemaking, EPA proposed certification requirements for manufacturers and importers to demonstrate that 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. For products that are required to meet the SDWA section 1417 lead free requirements, EPA proposed to require manufacturers with 100 or more employees or importers sourcing products from or representing manufacturers with 100 or more employees to demonstrate compliance with the lead free definition by obtaining third party certification by an ANSI accredited third party certification body. EPA proposed to require manufacturers with fewer than 100 employees, or importers sourcing products from or 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 later in this section. As evidenced by California's product testing program, there has been significant noncompliance with California's definition of lead free, which was the basis of the RLDWA lead free definition (CalEPA, 2013). A third party certification requirement leverages the resources of the third party certifiers as well as the supply

chain to help the market police itself and assure compliance. This final rule also lowers the maximum number of employees allowed for a manufacturer or importer to self-certify products to apply to manufacturers with fewer than 10 employees, and importers entering products purchased from or manufactured by manufacturers with fewer than 10 employees.

EPA made this change after taking into consideration issues raised in public comments regarding both the proposed requirements for labeling and marking (pertaining to section IV.B of this preamble) and the proposed requirements for self-certification. After careful review of comments, EPA determined that the objectives achieved through labeling and marking can more effectively be achieved through requiring more widespread use of third party product certification. EPA proposed labeling and marking requirements with the intent of clearly conveying to users that a product is in compliance with the lead free requirements of the SDWA. However, the third party certification requirement assures users in the supply chain that they are not violating the requirements of the RLDWA when they introduce a product into commerce or use it in new installations or repairs. Thus, the final rule does not require any marking or labeling of lead free pipes, fittings, or fixtures on products or packages. Rather, this objective of the rule is achieved by relying more heavily on third party certification.

EPA is ensuring that there will not be a significant impact on small entities by allowing the self-certification option for firms with fewer than 10 employees or for

any custom fabricated product. Reducing the employee threshold for self-certification from less than 100 employees in the proposed rulemaking to less than 10 employees in the final rule, will reduce the number of self-certified products in the market. EPA chose this cut-point to avoid imposing a burden on the smallest firms that would be disproportionate to the incremental benefits of third party certification as compared to self-certification. The employee threshold of 100 would have allowed a much larger share of the market to avoid third party certification, reducing the benefits of a widely applicable regulatory requirement for third party certification. Increasing the number of products that are third party certified will provide small businesses such as plumbers and builders better assurance that they are complying with the federal requirements to use lead free plumbing products. The self-certification requirement, which is applicable to manufacturers with fewer than 10 employees or for custom fabricated products, also helps to ensure that products sold by those smaller manufacturers or those products that are custom fabricated are lead free without imposing a significant burden on the smallest manufacturers.

EPA received a number of comments supporting a requirement for third party certification of products and opposing any provisions allowing for self-certification. The comments opposing any self-certification were submitted from a wide range of sources (e.g., plumbing manufacturing industry representatives, public water system interests, consumer advocacy groups, and individuals). Many of these comments object to the use of manufacturer size or employee numbers as a criterion for self-

certification for various reasons. Many of these comments state that because many plumbing codes require the use of third party certified products, many firms with less than 100 employees presumably already have their products certified by a third party in order to be in conformance with plumbing codes and sell in these areas. For example, the most recent version of the model plumbing code, the 2018 International Plumbing Code, requires pipe, pipe fittings, joints, valves, faucets, and fixture fittings used to supply water for drinking or cooking purposes to comply with the NSF/ANSI 372 standard for lead content. As a result, products sold in States or municipalities that have adopted such a model plumbing code are likely to be certified, regardless of the size of the firm.

Some commenters stated that small businesses that had already committed to third party certification of their products would be harmed by competitors that undercut prices by self-certifying products. Other comments expressed concern that a small entity exemption from third party certification could lead to abuse by over-seas providers that already present a more challenging category of manufacturer for regulators to monitor and that this could harm U.S. manufacturers. Thus, those commenters believe that there is no need to allow firms having fewer than 100 employees to self-certify their products and that doing so would create unfair market conditions and the introduction of products that are not lead free.

Some commenters addressing the proposed product label and marking requirements, indicated that EPA should not require product labeling or marking, but

rather should rely more heavily on third party certification to implement the intent of the rule. Several commenters made the point that labeling is not necessary if third party certification is required, because the certification itself provides adequate assurance of compliance and, therefore, the cost of labeling is not worth any incremental benefits of labeling a product that has been verified as lead free. One comment states opposition to any use of self-certification but indicates that if EPA nevertheless allows self-certification in some cases, it should do so at a lower employee threshold to reduce the volume of products eligible to be self-certified. This commenter asserts that as proposed, almost one fifth of the total volume of products produced would be eligible to be self-certified. In contrast, very few comments requested that self-certification be allowed for any firm and only one comment suggested a higher employee threshold level be specified. Of the very few comments that cited a need for self-certification, almost all suggested the use of criteria such as product characteristics (e.g., product complexity or type of material) rather than employee numbers to determine eligibility.

In making this change to the size of the firms that are eligible for self-certification from firms with fewer than 100 employees to firms with fewer than 10 employees, EPA has considered these comments and has also sought to avoid significant burdens upon the smallest plumbing manufacturers, those with less than 10 employees. EPA made this decision in tandem with the decision to not require the marking and labeling of lead free pipes, fittings, or fixtures as EPA had initially proposed. EPA

anticipates that the certification provisions in the final rule, which increase the volume of third party certified products, combined with the widespread practice of voluntary labeling by firms that obtain third party certification, will likely result in the marketing of more potable use plumbing products in a way that communicates the lead free status of the product to the purchaser without the burden of regulatory requirements for labeling.

EPA analyzed the costs of requiring third party certification for all firms regardless of the number of employees. Based on this analysis of the costs, EPA determined that requiring third party certification for all manufacturers would have resulted in a significant impact upon a substantial number of small manufacturers. Therefore, EPA is not requiring third party certification for all size firms. EPA specifically requested comment on the appropriate break point for number of employees, e.g., based on other categories of Census Bureau's Statistics of U.S. Business, for allowing self-certification. Census Bureau statistics include firm size categories for less than the following number of employees: 500, 100, 20, 10, and 5. EPA evaluated each of these potential firm size category break points. A summary of this analysis is included in the Final Rule Technical Support Document, Section 6.4 (USEPA, 2020). Based on this cost analysis, EPA determined that the most appropriate break point for self-certification eligibility is firms having fewer than 10 employees, which avoids significant impacts on small manufacturers.

Manufacturers having fewer than 10 employees often may serve only local or regional markets and are more likely to operate on a limited scale with a low product volume per firm, reducing the cost effectiveness of third party certification. EPA determined that the use of this break point would not be expected to result in significant cost impacts – i.e., costs exceeding 1 percent of revenues for any small businesses. In comparing this impact to that of the proposed rulemaking, EPA found that the proposed rulemaking would have impacted 29 small entities (2% of the total number of small entities) with costs exceeding 1 percent of revenues, whereas the final rule is expected to impact no small entities (0% of small entities) with costs exceeding 1 percent of revenues. Note that the 1 percent of revenue threshold is based on EPA's Regulatory Flexibility Act guidance and represents a revenue level that if exceeded could result in a significant impact on a small business. However, if third party certification had been required for all firms regardless of the number of employees, and assuming no product marking or labeling were required, EPA projected that 37 percent of small businesses would have been impacted with costs exceeding 1 percent of revenues. EPA estimated that manufacturers of covered products having fewer than 10 employees account for 39 percent (representing 855 manufacturers) of the total number of such manufacturers (2,193 manufacturers), but only produce 1 to 2 percent of the total volume of products. In contrast, EPA estimated that manufacturers of covered products having fewer than 100 employees account for 72% of the total number of such manufacturers and produce an estimated

5 to 18 percent of total product volume. EPA did not find that the economic impacts on firms with fewer than 10 employees would justify the incremental benefits of third party certification for the estimated 1 to 2 percent volume of covered products produced by these firms. EPA determined that, for these firms, the option to self-certify in the final rule is effective in assuring lead free products are produced, because many of the firms with fewer than 10 employees may operate in limited local or regional markets, may be custom fabricators, or may be assemblers of products made from certified components.

This final rule includes the addition of a provision specifying that any manufacturer or importer, regardless of employee numbers, is eligible to self-certify custom fabricated products rather than obtaining certification from an accredited third party certification body. For clarity, a definition of "custom fabricated product" is included in 40 CFR 143.11 of this final rule. EPA requested comment in the proposal concerning whether self-certification should be allowed as an option based on whether a product is mass produced or custom fabricated. EPA received one comment stating that self-certification should be allowed for custom fabricated products and that custom fabrication should be defined. In evaluating the comment, EPA determined that third party certification for custom fabricated products is impractical because obtaining the certification could take significant time and custom fabricated products are often needed for repairs when there is no existing product available for use. Moreover, third party certification for custom fabricated products is

not as cost effective as it is for mass produced products; the cost per unit produced would almost certainly be much higher for custom fabricated products. Therefore, the final rule allows self-certification for any custom fabricated product (that meets the definition of such a product defined in this final rule) regardless of the firm's number of employees.

In the proposed rulemaking, manufacturers and importers using the self-certification process would have been required to post the certificate of conformity on a web site with continuing public access in the United States. In this final rule, manufacturers and importers may elect to distribute an electronic or hard copy version of the certificate of conformity through the distribution channel for final delivery to the end use installer of the product if it is not posted to a website. EPA has provided this flexibility in the final regulation to firms with fewer than 10 employees, because EPA determined that some firms with fewer than 10 employees do not maintain a website. For administrative ease, the final rule provides this flexibility to all manufacturers and importers who use the self-certification process for custom fabricated products as well. In addition, providing a copy of the certificate of conformity to end use installers is also an effective means of communicating the lead free status of a product to all the parties in the supply chain. A public comment requested the need for EPA to specify a transition period for entities that may expand their number of employees to greater than the level allowable to self-certify products, and therefore would be no longer eligible for self-certification of non-custom

fabricated products. Based on the comment, EPA included a provision in 40 CFR 143.19 (c)(1) to provide for a 12 month transition period of time.

Three provisions were added to this final rule to allow certain exclusions from the certification requirement for those products required to be lead free. These products excluded from certification requirements include: (A) product components of assembled pipes, fittings, or fixtures do not need to be individually certified if the entire product in its final assembled form is lead free certified; (B) direct replacement parts for previously installed lead free certified products do not need to be individually certified if the weighted average lead content of wetted surface area for the part does not exceed the weighted average lead content of the original part; and (C) dishwashers.

EPA added the first two provisions in response to comments that the RLDWA recognizes the concept of area weighted average lead content, and, therefore, that the third party certification requirements apply only to the entire final end use product assembly and not individual sub-components, including any repair parts or repair kits. EPA agrees with commenters that the method for calculating lead content in the statutory definition of lead free contemplates that an assembled product could satisfy the requirement even if some components of the assembled product would exceed the maximum weighted average lead content of 0.25 percent if they were evaluated separately. Similarly, EPA agrees with commenters that certification of direct replacement parts for previously installed lead free certified products is unnecessary,

provided that the lead content of the wetted area for the replacement part does not exceed such lead content of the original part. EPA has added the third provision excluding dishwashers from certification requirements based on consideration of information provided in public comment. In the proposal, EPA solicited comment on the product certification provisions of the proposed rulemaking and asked if any product certification should be required. A commenter opposed mandatory third party/self-certification requirements, stating they were unnecessary for home appliances, including dishwashers. The commenter provided information from manufacturers representing about 80% of the dishwashers shipped in 2013. EPA had examined this information previously and concluded that "dishwashers as a class appear to easily meet the definition of lead free (a weighted average of 0.25%)" for wetted surfaces. The commenter also stated that the water film remaining on dishes at the end of the rinse cycle of a dishwashing machine is minimal. The commenter argued that the information provided should support an exemption from the requirements of the rule. After considering this information, EPA has determined that certification is not warranted to confirm that dishwashers are in compliance with the lead free requirements of the Reduction of Lead in Drinking Water Act. In view of the information previously submitted to EPA in 2013 about component materials used and the comparative surface areas of the components in dishwashers, the Agency has determined that it is not necessary for a manufacturer to undertake a certification process to demonstrate that these devices meet the lead free requirements. EPA also

notes that exposure to water remaining on items cleaned in a dishwasher is relatively low in comparison to other potable use products. EPA agrees with the commenter that the water film remaining on dishes at the end of the rinse cycle of a dishwashing machine is minimal and reduces the risk of exposure to lead resulting from water remaining on washed items that may be ingested. In addition, due to the large surface area of low-lead components (e.g., the plastic or stainless steel tub), it is unlikely for dishwashers to exceed the RLDWA lead limit compared with other potable use product types. Even if other component parts, such as fittings, were to contain lead, these components have a minor surface area compared with the wetted surface of the entire dishwasher device, which is consistent with the conclusion noted above that dishwashers as a class appear to easily meet the maximum weighted average lead content threshold of 0.25 percent. Therefore, the final rule provides an exclusion from product certification requirements for dishwashers.

EPA contacted eight ANSI accredited certification bodies prior to publication of the proposed rulemaking to obtain estimated cost for certifying products to ANSI/NSF Standard 372 and to obtain information on any time limits on the validity of the certification before renewal would be required by the certifying bodies. As EPA explained in the proposed rulemaking, while the period of time before the expiration of a certificate varies among certification bodies, the longest period of time is five years (USEPA, 2017; 82 FR 4817, January 17, 2017). Accordingly, EPA chose the minimum document retention time of five years from the date of last sale so as to

be consistent with the maximum effective duration time for a third party product certification.

E. Other Regulatory Requirements and Clarifications

1. Definitions

a. Final Rule Requirements

To clarify the requirements, set forth in the RLDWA and this final rule, EPA defined terms in 40 CFR 143.11 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 this final rule. Other terms defined in this final rule include: "accredited third party certification body," "Administrator," "affiliated," "alloy," "coating," "custom fabricated product," "drinking water cooler," "importer," "introduce into commerce," "lead free," "liner," "manufacturer," "nonpotable services," "person," "pipe fitting," "plumbing fitting," "point-of-use treatment device," "potable uses," "product," "public water system," United States," and "water distribution main." EPA defines "product" to mean a pipe, fitting, or fixture. This term was defined to reduce the number of repetitive references to pipes, fittings, and fixtures that would otherwise be necessary throughout this final rule. For similar reasons of conciseness, EPA defined "fitting" to mean a pipe fitting or plumbing fitting.

By removing section 1417(d)(3) from the definition of lead free in the 2011 amendments to the SDWA, Congress eliminated distinctions between "pipes," "pipe fittings," "plumbing fittings," and "plumbing fixtures." As a general matter, EPA finds that Congress intended that the prohibitions in Section 1417 broadly apply to pipes and plumbing materials that may provide water for human consumption with the goal of minimizing or eliminating lead in the wetted surfaces of these conveyances, thus reducing exposures to lead in tap water. Therefore, in the case of the definitions of "fixture," "pipe fitting," and "plumbing fitting," this final rule contains broad working definitions that also include illustrative examples of these plumbing and water system products. EPA included some plumbing appliances or devices, such as drinking water coolers, water heaters, and water pumps, as examples in the definition of "fixture." EPA did so because these products are often used in systems that supply potable water. These examples in the definitions are not intended to limit or exclude other types of pipes, fittings, or fixtures that are not specifically listed.

b. Changes from Proposed Rule and Rationale

Additional definitions were added to this final rule for clarity. These definitions included "point of use treatment device" and "public water system," because these terms are defined in 40 CFR part 141, where this final rule was previously located, but would not otherwise be defined in 40 CFR part 143, Subpart B.

"Water meters" were added to the list of example products included in the definition of "fixture" to clarify that these in-line devices comprising numerous internal parts are required to meet the definition of lead free in their assembled form, and that it is not the case that each individual component contained therein must meet lead free requirements. EPA revised the definition of "nonpotable services" ("all uses of water that are not potable uses") to refer to "all product uses and applications that are not potable uses" because some nonpotable uses of the products do not involve the use of water. Based on public comment, the definition of "pipe" was expanded to include permanently attached end fittings, which EPA finds is a common product form. The definition of "pipe fitting" was amended to remove washers as one of several examples of those products. Washers may be components of plumbing fittings, or fixtures, but EPA does not consider individual washers to be pipe fittings. Manifolds were added to the definition of "plumbing fitting" because these products are becoming more commonplace as a means to control directional flow of potable water in homes and other buildings. In calculating the "wetted surface area of the product," surfaces that are not exposed to liquid water, such as those surfaces in refrigerator ice dispensers, would not be "wetted" and, therefore, should not be considered in the calculation. In addition, because ice is either cubed or crushed, there is limited contact between the surface of the ice and the surface of the cubed or crushed ice as it sits in the bin or passes through the discharge chute. Including ice bins and

ice discharge chutes in the calculation of the wetted surface area of combination ice and water dispensers would dilute the calculated wetted average lead content of the other components that are “wetted” and, therefore, are more likely to be a source of lead.

In 40 CFR 143.11, a definition of “custom fabricated product” was added to this final rule to clarify the products for which self-certification is an option for manufacturers and importers described in 40 CFR 143.19, Required Certification of Products.

In 40 CFR 143.11, the definition of “importer” was modified to mean any person who introduces into commerce any pipe, any pipe or plumbing fitting or fixture, or any solder or flux entering the United States; or any “importer” as defined in 19 CFR 101.1; or both. This change from the definition in proposed rulemaking was made to harmonize the definition of this final rule with that included in 19 CFR 101.1 by cross referencing it. That definition in Title 19 is as follows: "*Importer*" means the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf. The importer may be:

(1) The consignee, or

(2) The importer of record, or

(3) The actual owner of the merchandise, if an actual owner's declaration and superseding bond has been filed in accordance with 40 CFR 141.20 of this chapter, or

(4) The transferee of the merchandise, if the right to withdraw merchandise in a bonded warehouse has been transferred in accordance with subpart C of part 144 of this chapter.

2. Recordkeeping Provisions

a. Final Rule Requirements

This final rule requires manufacturers or importers to maintain documentation to substantiate product certification for at least five years from the date of the last sale of the product by the manufacturer or importer. The manufacturer or importer must keep records for all products certified by an accredited third party certification body, which include, at a minimum, documentation of certification, of dates of certification, and of expiration. This documentation must be provided upon request to the Administrator as specified in 40 CFR 143.20(b). For self-certified products, manufacturers or importers 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), records of calculations of the weighted average lead content of the product, documentation of the lead content of materials used in

the manufacture of the product, 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 40 CFR 143.20(b) and must be maintained for at least five years after the last sale of the product by the manufacturer or importer.

b. Changes from Proposed Rule and Rationale

The proposed rulemaking would have required manufacturers or importers of certified products to maintain documentation to substantiate product certification for an unspecified length of time. In this final rule, EPA is requiring manufacturers and importers to maintain such documentation for at least five years from the date of the last sale of the product by the manufacturer or importer (in response to comments requesting that EPA specify a time limit for document retention because it could otherwise be interpreted to be an on-going, continuous requirement). EPA contacted the eight ANSI accredited certification bodies prior to publication of the proposed rulemaking to obtain estimated cost for certifying products to ANSI/NSF Standard 372 and to obtain information on any time limits on the validity of the certification before renewal would be required by the certifying bodies. As EPA explained in the proposed rulemaking, while the period of time before the expiration of a certificate varies among certification bodies, the longest period of time is five years. (USEPA, 2017; 82 FR 4817, January 17, 2017). Accordingly, EPA chose the minimum document retention time of five

years from the date of last sale to be consistent with the maximum effective duration time for a third party product certification.

3. Compliance Provisions

a. Final Rule Requirements

To effectively enforce the lead free requirements of the SDWA and the regulatory provisions, this final rule provides EPA with the ability to obtain, 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, and certification documentation. This final rule contains a provision in 40 CFR 143.20(b) 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 the statutory authority contained in section 1445(a)(1) of the SDWA. This final rule also includes a provision in 40 CFR 143.20(a) indicating that noncompliance with the SDWA or this subpart may be subject to enforcement. Enforcement actions may include seeking injunctive or declaratory relief and civil penalties or criminal penalties. This provision is based on authorities including section 1414 of the SDWA and section 1001 of Title 18.

b. Changes from Proposed Rule and Rationale

Clarification changes were made to the language in 40 CFR 143.20 of the proposed rulemaking to further specify that enforcement actions may also seek declaratory relief in addition to injunctive relief. These provisions will help EPA to effectively enforce the requirements of SDWA section 1417 and of this final rule.

4. State Enforcement of Use Prohibitions

a. Final Rule Requirements

This final rule contains language in 40 CFR 143.14 to clarify that SDWA section 1417(b)'s direction 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 (PWSS) grant allocation. Under the SDWA, section 1417(b)(1), the State enforcement provision applies only 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 does it apply to the final rule requirements for product certification.

b. Changes from Proposed Rule and Rationale

No changes were made in 40 CFR 143.14 from the proposed rulemaking. The regulatory provision is based on the statutory direction in section 1417(b) of the SDWA for States to enforce the statutory use prohibition through State or local plumbing codes or such other means as the State may determine to be appropriate.

Similar regulatory language in current 40 CFR 141.43 is being replaced by this final rule.

5. Removal of Lead Leaching Standard from Definition of Lead Free

a. Final Rule Requirements

The final rule does not include a requirement for certification of plumbing fittings and fixtures to a lead leaching standard.

b. Changes from Proposed Rule and Rationale

No changes were made to the proposed rulemaking. Many comments were received requesting that EPA require the lead leaching standard and associated certification requirements that were incorporated into the definition of lead free in section 1417(d) of the SDWA, prior to the amendment by the 2011 RLDWA. These comments were made in a mass public comment campaign submitted by 24,751 signatories as well as in some other individual comments, including two submitted by members of Congress. Some commenters suggested that EPA should require products to be certified to the NSF/ANSI 61 Standard to address lead leaching.

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 plumbing fittings and fixtures be in compliance with

voluntary standards established in accordance with SDWA section 1417(e) for leaching of lead from new plumbing fittings and fixtures. While EPA supports the industry's voluntary use of a lead leaching standard and certification to that standard, a requirement for plumbing fittings and fixtures to be in compliance with it is not necessary or appropriate to implement section 1417 of the SDWA, because the requirement was specifically eliminated in the 2011 RLDWA.

F. Implementation Schedule

1. Final Rule Requirements

The RLDWA, including the revised definition of lead free, has been in effect since January 4, 2014. See the **DATES** section of this document for effective and compliance dates for this final rule.

2. Changes from Proposed Rule and Rationale

No change was made to the compliance date for the rule's certification requirement. The proposed compliance date for labeling requirements was removed because EPA is not finalizing those requirements.

V. Costs

The primary cost estimate for this rule calculated according to the E.O. 13771 accounting standards—that is, as an annualized value over a perpetual time horizon, in 2016$, discounted to its 2016-equivalent using a 7% discount rate is $7.1 million. The quantitative cost estimates in the Final Rule Technical Support Document (USEPA, 2020) primarily focus on the

discretionarily-imposed costs, and thus reflect a post-statute baseline. Because this rule codifies the RLDWA's statutory requirements, assessment relative to a pre-statute is also appropriate (and required by OMB Circular A-4). In analyses such as this one, in which impacts are assessed relative to multiple baselines, it is important to compare costs relative to the same baseline. EPA lacked data to conduct a quantitative pre-statutory baseline of costs but has included a qualitative discussion of the pre-statutory baseline in the Technical Support Document.

Based on state and industry action prior to the RLDWA and economic theory, EPA's best estimate of the pre-statutory baseline (the world in the absence of the Federal RLDWA) is that states across the nation would have continued to implement their own lead-free standards, and industry would have made the decision to manufacture and market a single lead-free line of product meeting these state standards, if possible. There is also the possibility that these state standards might have varied leading to a patchwork of lead-free standards that would have been costly to comply with. Therefore, the most likely outcome of the self-implementing portions of the statute that created a single national standard, and in turn those components repeated in this rule, was a reduction in production costs due to increased conformity in lead free requirements.

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 is 1.3 billion units.

There are 2,193 firms producing plumbing products impacted by this final 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.1 also breaks down production into product

subcategories and provides EPA's estimated annual production values for each subcategory, the NAICS code assigned to the subcategory, 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 Countertop 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 Heaters and Boilers	Combi Boiler Market	55,527	333999	15
	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: Final Rule Technical Support Document, Exhibits 3-3 and 3-9 (USEPA, 2020)

EPA developed cost estimates for the final rule along with three additional regulatory alternatives. The four alternatives that were considered are presented in Table V.2. Alternative C is the regulatory option selected for the final rule. The Final Rule Technical Support Document (USEPA, 2020) provides more detailed information on the costing methodology and a discussion of the uncertainties and limitations of this assessment.

Table V.2: Comparison of Final Rule to Alternatives Considered

Alternatives Considered	Description
A	• Product marking **and** package labeling for potable use products • Third party certification required for all firms
B **Proposed Rule**	• Product marking **and** package labeling for potable use products • Self-certification or third party certification for < 100 Employees • Third party certification only for ≥ 100 Employees
C **FINAL RULE**	• No required product marking, no required package labeling for potable use products • Self-certification or third party certification for < 10 Employees and for custom fabricated products • Third party certification only for ≥ 10 Employees (unless custom fabricated product)
D	• Product marking **or** package labeling 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. For the final rule, EPA estimated that it would take each firm an average of 8 hours to read and understand the rule. This time estimate, when multiplied by an average labor rate of $71.72 and the number of firms affected by the rule (2,193), results in a total cost of $1.26 million, which was then annualized at 3 percent and 7 percent discount rates.

Table V.3 provides the initial rule implementation annualized cost ranges by firm size category. 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 $0.07 to $0.11 million.

Table V.3: Final Rule Initial Administrative and Initial Implementation Annualized Costs, in millions (2014$)

Manufacturer Size Based	Read and Understand the Rule and Initial Rule Implementation

on Number of Employees	Discount Rate	
	3%	7%
<10	$0.027	$0.039
10-99	$0.023	$0.033
100-499	$0.011	$0.016
≥ 500	$0.008	$0.012
All Sizes	$0.070	$0.101

Source: Final Rule Technical Support Document, Exhibit 4-5 (USEPA, 2020).

B. Labeling Potable Use Products

The final rule does not require any product marking or package labeling of potable use products to indicate lead free status; therefore, there is no cost for marking or labeling. EPA did consider alternative options that would have required product marking or package labeling or both. Table V.4 provides a summary of product labeling costs for this final rule with the other alternatives that were considered for comparative purposes for the various regulatory options that EPA considered. Since the final rule has no labeling costs, the methodology for estimating these costs for various alternatives is not provided in this document. However, it is included in the Technical Support Document for the Proposed Rule (USEPA, 2016) available in the docket for this rule.

Table V.4: Total Annualized Present Value Costs for Lead Free Labeling of Potable Use Products on Product and Package for Final Rule and Alternatives Considered, Millions (2014$)

Alternatives Considered	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: FINAL RULE No product messaging No package messaging	$0	$0

D: Product **or** package messaging	$1.17 – 1.28	$1.14 – 1.26

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

C. Product Certification

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 compiled information on plumbing manufacturers' use of third party certification by reviewing current State laws requiring certification for NSF Standards 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. Based on the collected information, EPA assumed that 90 percent of manufacturers with 100 or more 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 developed 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 certification bodies. Table V.5 summarizes the third party certification baseline assumptions EPA used in the development of regulatory costs. Under all regulatory alternatives considered, certification costs would be attributable to only those manufacturers that do not already use these third party certification bodies.

Table V.5: 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
<10	25%	50%
10 - 99	25%	50%
100-499	10%	10%
≥ 500	10%	10%

Source: Final Rule Technical Support Document, Exhibit 4-6 (USEPA, 2020).

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 down 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. 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 certification bodies 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. 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 NSF/ANSI Standard 372. Costs varied based on the product type and certification body. One of the responding certification bodies required re-certification annually. The other four certification bodies require renewal on a less frequent basis, the longest being every five years. EPA determined a 5-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.

The final rule and Alternatives B and D allow for some firms to self-certify to comply with the lead free requirements. EPA estimated that each manufacturer would require 40 hours of labor to initially develop the certificate of conformity (the rule requirement for 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. This time is used to update the certificate of conformity and to perform recordkeeping activities. This means that the

unit cost of annual self-recertification is $449 per product family for the final rule, as well as for Alternatives A and D.

Table V.6 provides EPA's estimated total annual cost ranges for potable use product certification requirements of the final rule and other alternatives that were considered. Unit certification costs were multiplied by the number of firms and average number of product families. The final rule requires third party certification for firms with 10 or more employees and gives the option of self-certification to firms with fewer than 10 employees. Annualized certification cost for the final rule ranges from $6.67 million to $12.24 million`. EPA did not assess any cost savings to firms that would no longer choose to have products third party certified because EPA assumed that firms that were already having their products third party certified would continue doing so after rule implementation.

Table V.6: Total Annualized Present Value Costs for Demonstration of Compliance Requirements for Final Rule and Alternatives Considered, Millions (2014$)

Alternatives Considered	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: **Proposed Rule** Third party for ≥ 100; Choice of self-certification for <100	$2.82 - $4.14	$2.93 – $4.31
C: **FINAL RULE** Third party for ≥ 10; Choice of self-certification for <10 and for custom fabricated products	$6.66-$11.82	$6.89-$12.23
D: Third party certification or self-certification	$1.52 - $2.84	$1.59 - $2.98

Source: Final Rule Technical Support Document, Exhibits 4-12a and 4-12b (USEPA, 2020).
Note: Under Alternatives B, C, and D, all manufacturers eligible for self-certification are assumed to select the less costly choice of self-certification.

D. Response to EPA Data Request Costs

Under all four of the final regulatory alternatives that were considered, manufacturers will be required to respond to EPA's requests for product information (see section IV.E.2 of this preamble 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 approximately $1,400. 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, 5 percent of requests would be to firms with 10 to 99 employees, and firms with fewer than 10 employees would receive the remaining 5 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.7 shows the total annualized costs of EPA data request responses 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.7: Total Annualized Present Value Costs for Responding to Data Requests, in Millions (2014$)

Manufacturer Size Based on Number of Employees	3% Discount Rate	7% Discount Rate

< 99	$0.0006	$0.0006
100-499	$0.0025	$0.0024
≥ 500	$0.0087	$0.0083
All Sizes	**$0.0124**	**$0.0119**

Source: Final Rule Technical Support Document, Exhibit 4-14 (USEPA, 2020).

VI. Economic Impact Analysis

EPA assessed the social costs and the projected economic impacts of the final rule and the other regulatory alternatives that were considered. This section provides an overview of the methodology that EPA used to assess the social costs and the economic impacts of the final rule and summarizes the results of these analyses. The Final Rule Technical Support Document (USEPA, 2020), 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 final rule and regulatory alternatives' 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, 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 not on an annual basis were annualized over a specific useful life, implementation, and/or event recurrence period (e.g., 10 years for mold modifications), using discount rates of

3 and 7 percent. EPA added up the annualized capital, initial one-time costs, and the annual and non-annual portion of 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 final rule and regulatory alternatives that were considered. As shown in the table, total annualized compliance costs for the final rule are estimated to range between $7 million to $12 million. Estimated annualized costs for other alternatives considered ranged from $3 million and $36 million for Alternatives D and A, respectively.

Table VI.1: Total Annualized Social Costs for Final Rule and Alternatives Considered (Millions, 2014$)

Alternatives Considered [1]	3% Discount Rate	7% Discount Rate
A: Label product and packaging; third party certification for all manufacturers	$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 those <100	$11.8 - $14.8	$14.5 - $18.3
C: **FINAL RULE**: No labeling product or package; third party certification for manufacturers ≥ 10 employees and third party or self-certification for those <10 and for custom fabricated products	$6.7 - $11.9	$7.0 - $12.3
D: Label product or packaging; third party or self-certification for all manufacturers	$2.9 - $4.5	$3.0 - $4.6

Source: Final Rule Technical Support Document, Exhibit 4-16 (USEPA, 2020).

1. Table includes annualized costs for rule implementation, certification of potable use products, and EPA requests

for data. Lead-related messaging for potable use products and products eligible for the "used exclusively" exemption that was in the proposed rule is included in Alternatives A, B, and D only, but not applicable for the final rule C.

B. Economic Impacts – Cost-to-Revenue Analysis

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

To conduct the cost-to-revenue test, EPA developed a list of 2,193 manufacturers that participate in the production of specific types of products that are principally used for potable use and those that might not be used exclusively for nonpotable services. These firms were assigned to a NAICS code based on the type of 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, EPA derived the number of firms in each of the 14 NAICS codes broken down by the seven employee size categories each (i.e., 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). 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 alternative considered. 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; consequently, 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 with 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 were assumed to be impacted at the 3 percent level. Impacted firms were 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 final rule as compared with the three other regulatory alternatives that were considered. The table shows only the largest impact scenarios analyzed, based on upper bound compliance cost estimates and a 7 percent discount rate. For the lower bound cost and 3 percent discounted impact results, see the Final Rule Technical Support Document (USEPA, 2020). For the final rule (which includes rule implementation costs, third party certification costs for firms with 10 or more employees and third party or self-certification costs for firms with fewer than 10 employees, and data request costs), EPA estimates that all plumbing manufacturing firms subject to the regulations will incur annualized costs amounting to less than 1 percent of revenue. No small manufacturers had impacts between 1 and 3 percent of revenue. The analysis of the final rule also found that no large entity had impacts between 1 and 3 percent of revenue.

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

Alternatives Considered	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	1,976	783	27	40%	1%	217	0	0	0.0%	0.0%

	all manufacturers										
Proposed Rule 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	0	0	0.0%	0.0%
FINAL RULE C	No Product or Package Costs, 3rd Party Cert for ≥ 10 employees, Self or 3rd Party Cert <10 employees and custom fabricated products	1,976	0	0	0.0%	0.0%	217	0	0	0.0%	0.0%
D	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: Final Rule Technical Support Document, Exhibit 6-7 (USEPA, 2020).

1. All alternatives considered also include implementation and data request costs. For Alternatives B and C, EPA assumes that manufacturers <100 employees or < 10 employees, respectively, choose the least-cost option of self-certification. For Alternative D, EPA assumes all manufacturers pick the least cost option of self-certification. In addition, for Alternative D, 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.

VII. Benefits

EPA did not quantify the expected reduction in adverse health effects associated with the final regulation nor with the enactment of the RLDWA. The adoption of lead free plumbing materials likely occurred as a result of plumbing manufacturing industry response to requirements enacted in some states as early as 2006 (see the Final Rule Technical Support Document for more discussion). The changes made by plumbing manufacturers to reduce lead content of plumbing materials likely resulted in much greater lead exposure reductions than this regulation. EPA believes that there will be benefits of the final regulations from the improved implementation of the requirements of the RLDWA and greater consistency in assuring that plumbing products are lead free, which will minimize the likelihood that non-lead free products would be sold or used for potable use applications. This improved implementation and consistency in conformity may result in some reductions to drinking water lead ingestion, however EPA cannot estimate the magnitude of those reductions. EPA qualitatively assessed the health effects associated with reductions in lead ingestion 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). These two sources have both documented the association between lead and adverse cardiovascular effects, renal effects, reproductive effects, immunological effects, neurological effects, and cancer. EPA's

Integrated Risk Information System (IRIS) Chemical Assessment Summary provides additional health effects information on lead (USEPA, 2004). For a more detailed explanation of the health effects associated with lead for children and adults see Chapter 5 and Appendix C of the Technical Support Document for the Final Rule (USEPA, 2020).

VIII. Statutory and Executive Orders Review

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an economic analysis of the potential costs and benefits associated with this action. The economic analysis is included in the "Technical Support Document for the Final Rule: Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water," which is available in Docket ID No. EPA-HQ-OW-2015-0680, and is briefly summarized in section V of this preamble.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 regulatory action. Details on the estimated costs of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action in sections V through VII of this preamble and in the Technical Support Document for the Final Rule.

C. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number. 2040-NEW. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized in this section. The information collection requirements are not enforceable until OMB approves them.

The PRA requires EPA to estimate the burden on manufacturers complying with the final rule. For the first three years after publication of the final rule in the *Federal Register*, manufacturers will incur burdens to conduct the following rule compliance activities:

- Reading and understanding the rule requirements.
- 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 and importers

entering products purchased from or manufactured by manufacturers of plumbing products for potable use.

Respondent's obligation to respond: Mandatory (Safe Drinking Water Act Section, 42 U.S.C. 300f et seq.)

Estimated number of respondents: 2,193 firms.

Frequency of response: Once for obtaining initial third party or self-certification activities to indicate that a product meets the lead free requirements and occasionally, as needed, for EPA requests for information.

Total estimated burden: Estimates for average annual burden ranges from 42,990 to 77,838 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Estimates for average annual costs range from $6.69 million to $11.58 million (per year) and include $5.23 to $9.14 million in annualized capital or operation and maintenance.

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. When OMB approves this ICR, EPA will announce the approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities in this final rule.

D. 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 systems, or any plumbing in a residential or nonresidential facility or location that provides water for human consumption, and 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 final rule vary across NAICS categories and range from firms with fewer than 500 employees to firms with fewer than 1,250 employees (See Table VIII.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 out of 2,193 plumbing product manufacturers potentially subject to this final rule meet the small business definitions. EPA's analysis of

projected impacts on small entities is described in detail in section VI.B (Economic Impacts) of this preamble. EPA projects that none of the 1,976 affected small entities would 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 Final Rule Technical Support Document, available in the docket, for the final rule.

E. 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 final rule places no federal mandates on State, local, or Tribal governments. The mandated annual cost to the private sector is estimated to be between $6.7 and $12.3 million and the highest single year nominal cost is $15.4 million, which is below the $100 million UMRA threshold.

F. 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.

G. 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 final 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.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may be 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 Executive Order 13045 does not apply, EPA does anticipate that the product certification requirements associated with this final rule will limit the use of leaded plumbing products, thereby reducing the exposure of children to lead in drinking water.

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

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule implements statutory requirements for lead content limits of pipes, fittings, and fixtures

for installation or repair of public water systems and plumbing that supplies potable water and provides for verification of lead content. The lead content of these manufactured materials would not have a significant impact on the supply, distribution, or use of energy

J. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. EPA is establishing a requirement that can be satisfied, depending on the size of the regulated entity or whether products are custom fabricated or not, either by 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 final rule, EPA is establishing the use of several technical standards that meet the new definition of lead free as a means of demonstrating compliance with this rule.

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

EPA has determined that this action does 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 final rule that codifies existing requirements set forth by Congress regarding the allowable levels of lead in plumbing products, and includes additional provisions intended to aid in the implementation of those requirements.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined in 5 U.S.C. 804(2). 2018.

IX. References

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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.

USEPA, 2017. Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water – Proposed Rule. Federal Register. Vol. 82, No. 10. P. 4805. January 17, 2017.

USEPA, 2020. Technical Support Document for the Final Rule: Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water. EPA 810-R-20-001. June 2020.

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.

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR 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.

Subpart E—Special Regulations, Including Monitoring

2. Amend the heading for Subpart E by revising it to read as set forth above.

§ 141.43 [Removed]

3. Remove § 141.43.

PART 143—OTHER SAFE DRINKING WATER ACT REGULATIONS

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

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

5. Revise the heading for part 143 as set forth above.

§§ 143.1 through 143.4 [Designated as subpart A]

6. Designate §§ 143.1 through 143.4 as subpart A, and add a heading for newly designated subpart A to read as follows:

Subpart A—National Secondary Drinking Water Regulations

§ 143.1 [Amended]

7. Amend § 143.1 by removing the text “part”, “These regulations”, and “The regulations” and adding in their places “subpart”, “The regulations in this subpart”, and “The regulations in this subpart” respectively.

§§ 143.5 through 143.9 [Added and Reserved]

9. Add and reserve §§ 143.5 through 143.9.

10. Adding 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

§ 143.10 Applicability and Scope.

(a) This subpart establishes regulations pertaining to pipes, pipe or plumbing fittings, or fixtures, solder and flux, pursuant to, *inter alia*, sections 1417 and 1461 of the Safe Drinking Water Act (42 U.S.C. 300g-6 and 300j-21). It applies to any person who introduces these products into commerce, such as manufacturers, importers, wholesalers, distributors, re-sellers, and retailers. It also applies to any person who uses these products in the installation or repair of:

(1)Aa public water system; or

(2) A residential or nonresidential facility providing water for human consumption.

(b) Reserved.

§ 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.

Custom fabricated product means a product that:

(1) Is manufactured on a case-by-case basis to accommodate the unique needs of a single customer;

(2) Does not have a Universal Product Code (UPC) assigned to the product;

(3) Is not stocked by and is not available through inventory from a manufacturer, importer, wholesaler, distributor, retailer, or other source for distribution; and

(4) Is not cataloged in print or on the Internet with a specific item number or code.

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 treatment devices, coffee makers, and refrigerator ice and water dispensers; and

(3) Water heaters, water meters, 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 entering the United States; or any "importer" as defined in 19 CFR 101.1; or both.

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 otherwise 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 the person's or entity's brand name or trademark.

Nonpotable services means all product uses and applications 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, conductor, tubing, or hose and may also include permanently attached end fittings.

Pipe fitting means any piece (such as a coupling, elbow, 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, manifolds, and valves.

Point-of-use treatment device means point-of-use treatment device as defined in § 141.2 of this chapter.

Potable uses, for purposes only of this subpart, 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, or fixture.

Public water system means a public water system as defined in § 141.2 of this chapter.

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.

State means state as defined in § 142.2 of this chapter.

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.

(e) If a fixture contains any media (e.g., activated carbon, ion exchange resin) contained in filters, the media are not to be used in determining the "total wetted surface area of the entire product" in paragraph (b) of this section.

(f) In addition to the definitions of "lead free" in paragraphs (a) through (e) of this section, 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.

§ 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 the 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.

(a) No person may 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) No person engaged in the business of selling plumbing supplies in the United States, except manufacturers, may sell solder or flux that is not lead free; and

(c) No person may 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 Exemptions.

The prohibitions in §§ 143.13 and 143.15 and the product certification requirements in § 143.19 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. Additional products that could be "used exclusively for nonpotable services" include:

(1) Products that are clearly labeled, on the product, package, 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;

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

(3) Products that are plainly identifiable and marketed as being solely for a use other than the conveyance of water (these other uses include conveyance of air, chemicals other than water, hydraulic fluids, refrigerants, gasses, or other non-water fluids).

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

(c) Clothes washing machines, emergency drench showers, emergency face wash equipment, eyewash devices, fire suppression sprinklers, steam capable clothes dryers, and sump pumps.

§ 143.17 [Reserved].

§ 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, except as provided in paragraphs (a)(1) through (3) of this section, that the products are certified to be in compliance as specified in paragraphs (b) and (c) of this section by [**Insert date 3 years after date of publication 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 for at least 5 years from the date of the last sale of the product by the manufacturer or importer.

(1) Product components of assembled pipes, fittings, or fixtures do not need to be individually certified if the entire product in its final assembled form is lead free certified.

(2) Direct replacement parts for previously installed lead free certified products do not need to be individually certified if the weighted average lead content of wetted surface area for the part does not exceed such lead content of the original part.

(3) Dishwashers do not need to be certified.

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

(c) Products may be self-certified by manufacturers or importers as provided in paragraph (c)(1) or (c)(2) of this section. Such manufacturers or importers electing to self-certify products must comply with paragraphs (d) through (g) of this section.

(1) Manufacturers having fewer than 10 employees, or importers entering products purchased from or manufactured by manufacturers having fewer than 10 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. Any such firms that subsequently expand employment to 10 or more employees, based on the most recent 12-month average number of persons employed, are no longer eligible to self-certify products and must obtain third party certification within 12 months of having 10 or more employees.

(2) Manufacturers or importers may elect to self-certify any custom fabricated product in lieu of obtaining certification from an ANSI accredited third party certification body, regardless of the number of persons employed by the manufacturer.

(d) In order for eligible manufacturers or importers to self-certify products, such manufacturers or importers must attest that products are in compliance with the definition of

"lead free" in § 143.12 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 site with continuing public access in the United States, unless it is distributed by other means (e.g., electronically or in hard copy) with the product through the distribution channel for final delivery to the end use installer of the product.

(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;

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

(3) A brief listing of the products to include, when applicable, unique identifying information such as model names and numbers;

(4) 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;

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

(6) 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 a proprietor, the name and position of the officer, 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, records of calculations of the weighted average lead content of the product, documentation of the 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) and must be maintained for at least five (5) years after the last sale of the product by the manufacturer or importer.

(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 or declaratory relief, civil penalties, or criminal penalties.

(b) The Administrator may, on a case-by-case basis, request any information, such as records 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. Information, such as records requested, must be provided to the Administrator at a time and in a format as may be reasonably determined by the Administrator.