The Impacts of Changes to Regulatory and Risk Values for Lead

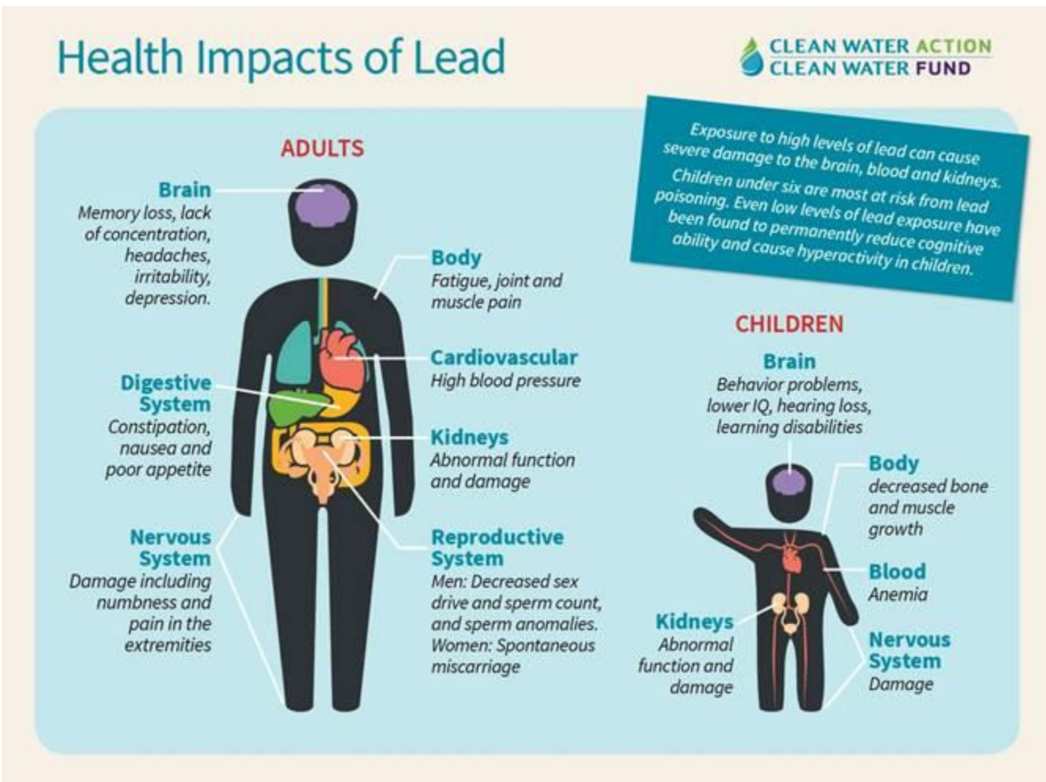
Mark McDaniel, CPSC, and Jonathan Dziekan, EIT, AlterEcho

January 2025

Introduction

Across the United States, lead contamination continues to pose significant environmental and public health challenges—particularly due to its persistence and widespread presence in various forms of media, such as soil, water, air, and dust. Recent scientific advances and evolving health risk data have driven changes in the regulatory landscape for lead, prompting federal agencies such as the U.S. Environmental Protection Agency (EPA) to strengthen screening levels and action limits across several regulatory frameworks. These changes, including updates to soil screening levels, lead action levels for drinking water systems, and dust-lead clearance standards, reflect an urgent need to reduce lead exposure, particularly in vulnerable populations such as children.

This paper examines the risk and regulatory changes concerning lead. It provides a short history of how lead regulatory levels have evolved and explores how recent lead risk values and exposure limits have sparked more stringent cleanup requirements for contaminated sites. Furthermore, by synthesizing recent scientific data and regulatory changes, this paper comprehensively analyzes the evolving landscape of lead regulation.

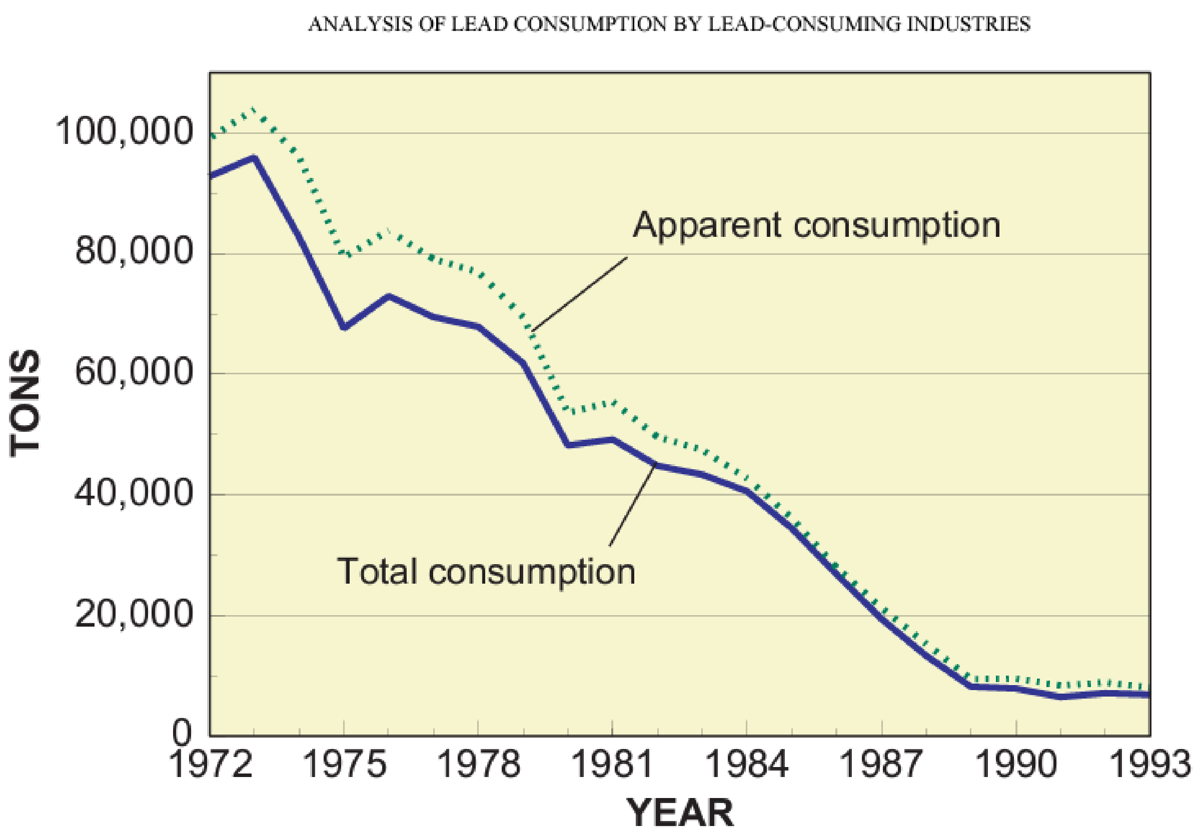


Courtesy of The Water Collaborative/ 2024 Orleans Water Study
https://www.nolawater.org/waternews/2024/invisible-threat-how-lead-exposure-compromises-immunity-and-organ-function

History of lead exposures and government regulation

Prior to the Industrial Revolution, the average human blood lead level (BLL) was estimated to be far less than it is today. Bone lead measurements from two Native American populations living on the Pacific Coast and the Colorado River between 1000 and 1300 C.E. show that BLLs would have been approximately 0.016 µg/dL[1]. Industrialization introduced new sources of lead in man-made materials, including its wide use in paint, gasoline, and solder for canned goods leading up to 1970. Lead use peaked in 1973, driven by tetraethyl leaded gasoline and paint. As lead poisoning reduction efforts grew, U.S. lead consumption dropped steadily over time, beginning in 1973 with U.S. EPA's phase-out of lead in gasoline[2].

Figure 1: Analysis of Lead Consumption by Lead-Consuming Industries in the U.S.[3]



[1] Patterson, Clair; Ericson, Jonathan; Mirela, Manea-Krichten; Shirahata, Hiroshi (1991). "Natural skeletal levels of lead in Homo sapiens sapiens uncontaminated by technological lead". *The Science of the Total Environment*. **107**: 205–236.
[2] USEPA.1973. EPA Requires Phase-Out of Lead in All Grades of Gasoline. Archived press release: https://www.epa.gov/archive/epa/aboutepa/epa-requires-phase-out-lead-all-grades-gasoline.html
[3] Marilyn B. Biviano, Daniel E. Sullivan, and Lorie A. Wagner. Total Materials Consumption An Estimation Methodology and Example Using Lead -- A Materials Flow Analysis. U.S. Geological Survey Circular 1183. 1999.

Initial research into lead uptake, excretion, intoxication, and smog was performed by industry and held that lead existed in equilibrium in the human body. That is, lead was excreted quickly after ingestion and did not accumulate in the body[4]. The research also held that lead was naturally occurring in soil, water, and the body. Historical lead exposure routes include food, wine sweetened with lead, occupational exposures, soil, paint, dust, lead cups and lead crystal glassware, drinking water, toys, jewelry, antiques, cosmetics, traditional medicines imported from other countries, as well as tailpipe emissions from leaded gasoline and aviation gasoline. While humans have been mining, smelting, and using lead for over 6,000 years, the first recorded diagnosis of lead exposure is seen in the literature as early as 250 B.C., when the Greek physician Colophon of Nicander noted colic and anemia from lead poisoning[5]. Heavy lead use in food and wine led to unprecedented epidemics of saturnine gout and infertility among Roman nobility in the first century C.E., but it was not until the 1800s that physicians began to link major symptoms like seizures, neurological issues, and comas to lead exposure.[6] Research into lead poisoning in children in the 1950s focused on children of low-income families who were suspected of eating the paint and plaster in their deteriorated homes. This research resulted in an initial BLL of 60 μg/dL for children set in 1960 and based on observations of acute lead exposure in children, such as abdominal pain, vomiting, and encephalopathy.

However, the research raised questions about the epidemiology of lead poisoning such as:

- What level of lead in blood is safe?
- At what level are there no adverse effects?
- What are the symptoms of lead poisoning?

The scientific and medical community began to question the consensus that a BLL of 60 μg/dL was generally considered safe. What followed were three distinct phases of lead regulation, each having a different approach with advantages and disadvantages[7].

1971-1991 (Medical Approach) During this time, the focus was on medical responses to lead exposure, with blood lead screening identifying children post-exposure. Population-wide representative blood lead surveys from the National Health and Nutrition Examination Survey (NHANES) first appeared in the middle to late 1970s and

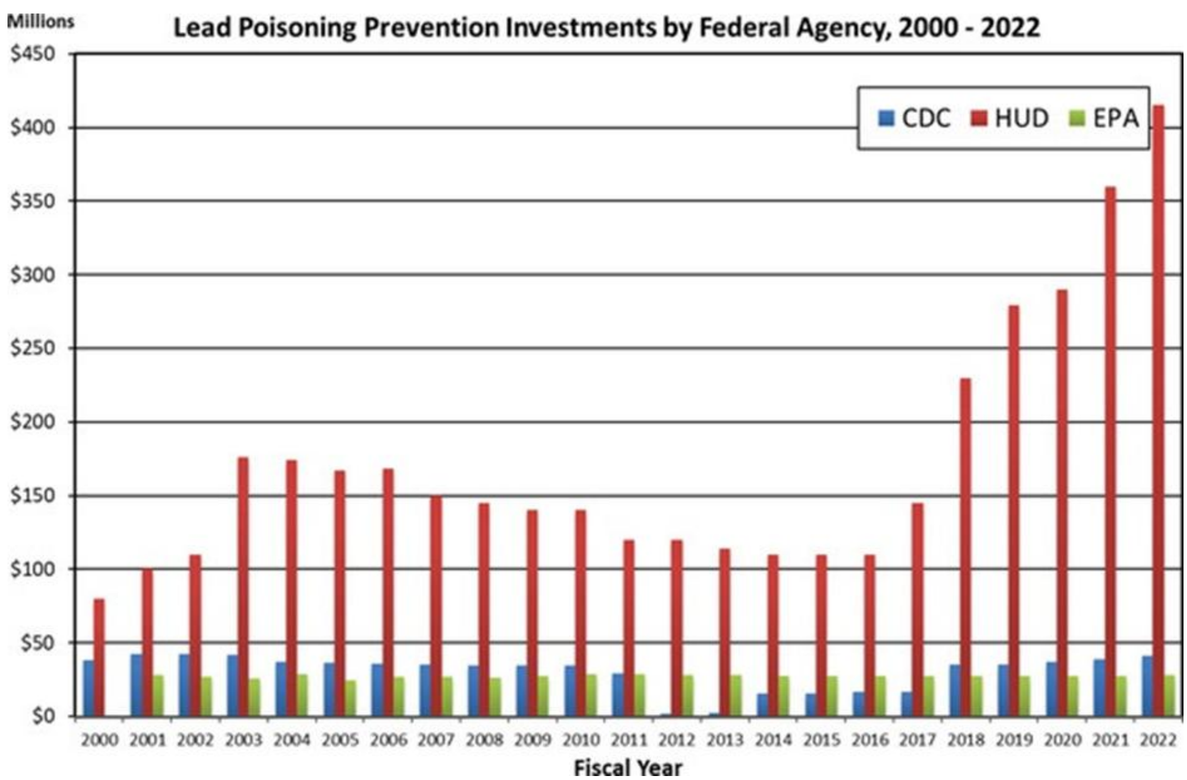
[4] Dr. Robert A. Kehoe Letter to R.M. Palmer Absorption of Ethyl Lead from Gasoline. May 24, 1948. https://findingaids.libraries.uc.edu/repositories/4/resources/63
[5] Needleman, H.L. (1999). History of Lead Poisoning in the World
[6] Ibid.
[7] Round and Round It Goes: The Epidemiology of Childhood Lead Poisoning, 1950-1990. Barney. 1993. The Milbank Quarterly, Vol. 71, No. 1, 1993

alerted epidemiologists to the issue of elevated BLLs in the general population and children[8]. Early regulations targeted lead in products like paint, gasoline, and water pipes. However, remediation efforts were insufficient, with unsafe paint removal practices often increasing lead exposure. During this period, the federal health community used a Blood Lead Level of Concern (BLLC) to flag high levels of lead in blood. Initially set at 60 µg/dL in 1960, it was reduced to 30 µg/dL in 1972 and then to 25 µg/dL in 1985.

1) 1992-2015 (Integrated Housing and Health Approach)

The Housing and Community Development Act of 1992 introduced federal involvement in lead hazard remediation, especially in private housing[9]. Despite some progress, efforts were underfunded, and plans, such as the 2000 federal initiative to eliminate lead poisoning, were never fully implemented for a variety of reasons, including funding cuts, policy shifts, and the logistical and financial complexities of lead abatement in older homes.[10,11] This shift can best be seen in funding for lead abatement via the U.S. Department of Housing and Urban Development (HUD), which began dropping in 2005 and continued to fall until the Flint, Michigan, water crisis reignited concerns for lead poisoning in 2015.

Figure 2: Lead Poisoning Prevention Investments by Federal Agencies 2000-2022[12]



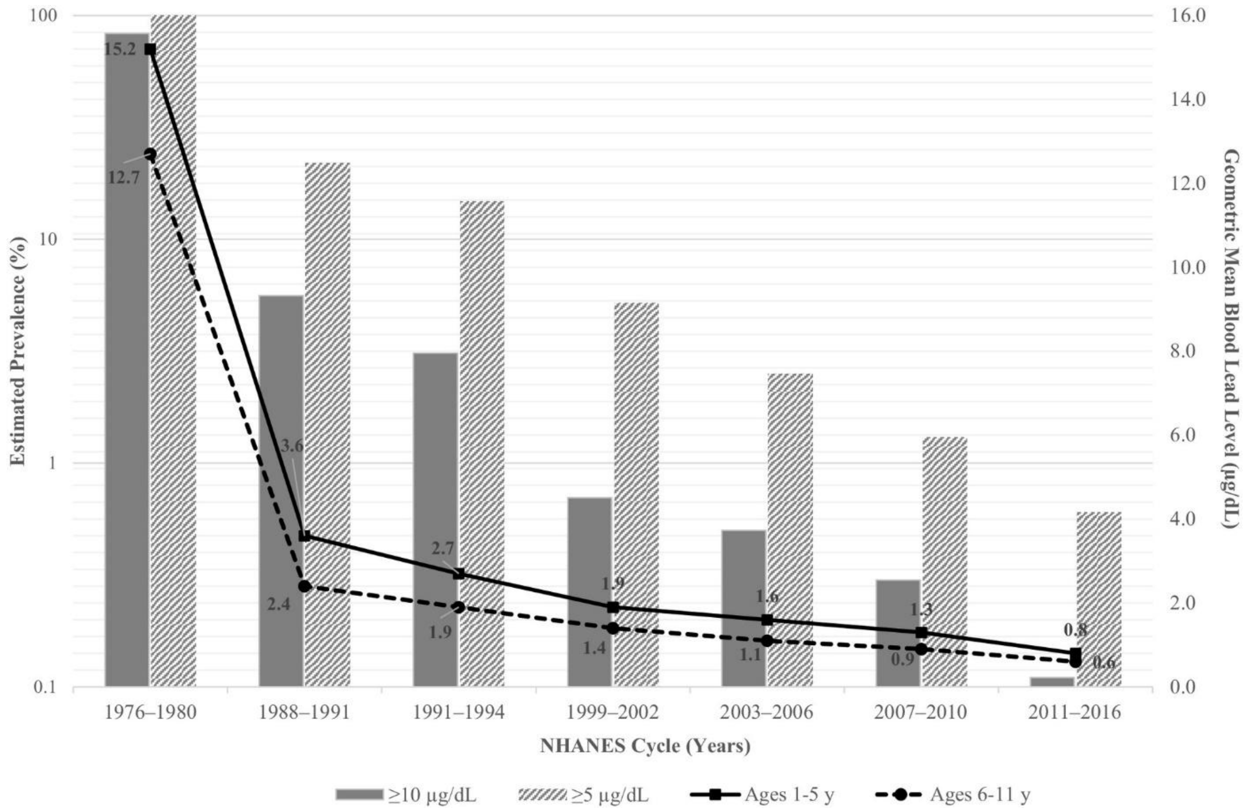
[8] Mahaffey KR, Et al. National estimates of blood lead levels, US 1976-1980. New Eng J Med. 1982;307(10):573–579.
9 Congress.gov. "H.R.5334 - 102nd Congress (1991-1992): Housing and Community Development Act of 1992." October 28, 1992.
[10] Dixon SL, Jacobs DE, Wilson JW, Akoto JY, Nevin R, Scott Clark C. Window replacement and residential lead paint hazard control 12 years later. Environ Res. 2012 Feb;113:14-20. doi: 10.1016/j.envres.2012.01.005. Epub 2012 Feb 10. PMID: 22325333.
[11] Lanphear, B. P., & Roghmann, K. J. (1997). "Pathways of lead exposure in urban children." Environmental Research, 74(1), 67-73.
[12] Jacobs DE, Brown MJ. Childhood Lead Poisoning 1970-2022: Charting Progress and Needed Reforms. J Public Health Manag Pract. 2023 Mar-Apr 01;29(2):230-240. doi: 10.1097/PHH.0000000000001664.

2) 2016-2022 (Scaling Proven Interventions): In 2015, the Flint water crisis reignited national attention on lead poisoning. The U.S. Centers for Disease Control (CDC) surveillance programs had been defunded in 2012-2013, so the problem was noticed only after a local physician found a troubling trend in increased children's blood lead,[13] and the public protested a decline in water quality. Since then, federal funding for lead remediation increased, especially in regard to lead in pipes (service lines and housing) and drinking water. While this crisis helped to create large federal funding increases, the funding was focused on drinking water and lead in pipes. New legislation, like the Infrastructure Investment and Jobs Act (aka, the Bipartisan Infrastructure Law [BIL]), provided billions of dollars of funding for drinking water lead pipe replacement nationwide, but ignored lead paint and other health hazards in housing, such as contaminated soil[14]. A summary of federal agency funding between 2000 and 2022, including the large increases after 2016, is shown in Figure 2. While each phase of lead regulation had its own limitations and shortcomings, the overall effect was positive. Figure 3 shows the dramatic drop in the percentage of the population with elevated BLLs and the geometric mean of BLLs over time, as well as a steady drop in lead exposure and BLLs for the U.S. population since 1976[15].

"Flint drinking water pipes." VCU Capital News Service. May 27, 2017. CC BY-NC 2.0)

[13] Hanna-Attisha M, LaChance J, Sadler RC, Champney Schnepp A. Elevated blood lead levels in children associated with the Flint drinking water crisis: a spatial analysis of risk and public health response. Am J Public Health. 2016;106(2):283–290.
[14] H.R.3684—Infrastructure Investment and Jobs Act, signed into law by President Biden on Nov 15, 2021. https://www.congress.gov/bill/117th-congress/house-bill/3684/text. Accessed October 18, 2022.
[15] Egan KB, et, al. Blood Lead Levels in U.S. Children Ages 1-11 Years, 1976-2016. Environ Health Perspect. 2021 Mar;129(3):37003. doi: 10.1289/EHP7932. Epub 2021 Mar 17. PMID: 33730866; PMCID: PMC7969125.

Figure 3. BLLs in U.S. Population Over Time (NHANES), 1976–2016[16].



Estimated prevalence (%) of blood lead levels ≥10 lg=dL (gray bars) ≥5 lg=dL (hatched bars) among U.S. children ages 1–11 y plotted on the log10 scale; geometric mean blood lead levels (lg=dL) for children ages 1–5 y (squares, solid line) and ages 6–11 y (circles, dashed line) in the National Health and Nutrition Examination Survey (NHANES), 1976–2016, by survey cycle (years).[17]

Specific policies and regulations driving the decrease in BLLs are summarized in Table 1.

Table 1: Federal Lead Poisoning Prevention Policies

Policy or Legislation	**Year**	**Comment**
Lead Based Paint Poisoning Prevention Act	1971	First major lead-based paint legislation; addressed lead-based paint in federal housing.
Phase Out Lead in Gasoline	1973	EPA regulated a phase-out of lead in gasoline.
Ban on Residential Paint	1978	CPSC banned lead paint in residential properties.

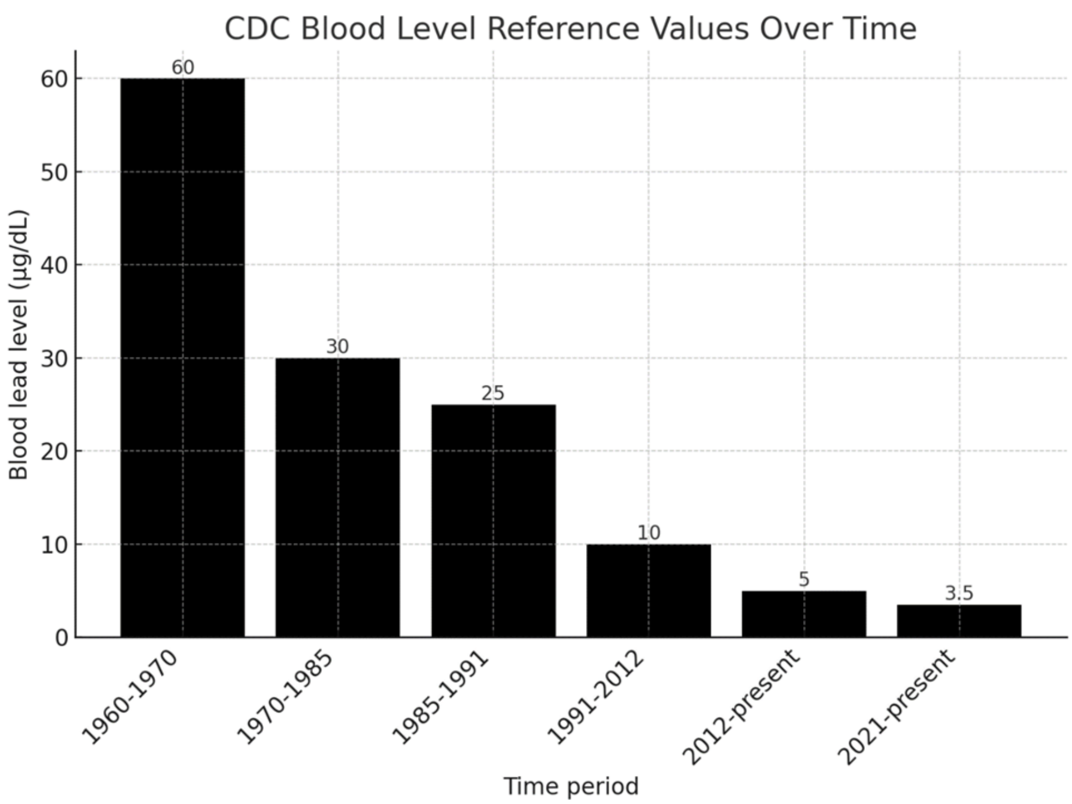
[16] Ibid
[17] Ibid

Safe Drinking Water Act	1986	EPA banned the use of lead pipes and lead solder in plumbing.
Housing and Community Development Act	1987	Highlighted the danger to children of lead-contaminated dust.
Lead Contamination Control Act	1988	Authorized CDC to make grants to state and local programs to screen children and to provide education about lead poisoning.
Residential Lead-Based Paint Hazard Reduction Act, Title X	1992	Established primary prevention of lead poisoning as a national strategy.
Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing	1995, 2012	HUD established guidelines for evaluating and controlling residential lead-based paint hazards.
Ban Lead Solder in Food Cans	1995	FDA amended food additive regulations to ban lead solder from food cans.
Lead Safe Housing Rule	1999, 2012	Regulation issued by HUD setting forth new requirements for lead-based paint notification, evaluation, and remediation.
Hazard Standards for Lead in Paint, Dust and Soil	2001	EPA established a definition of a lead-based paint hazard and standards for paint, dust, and soil in children's play areas.
Consumer Product Safety Improvement Act	2008	CPSC lowered the cap on lead in paint from 0.06% to 0.0009% and incorporated the Lead-Free Toy Act, setting a limit on lead content in toys.
Lead Renovation, Repair and Paint Rule	2010	EPA required contractors working on homes built before 1978 to be certified and follow lead-safe guidelines.

Recent Regulatory Actions to Address BLLs in Humans

As better data and research have advanced, government agencies like the EPA, CDC, and the Agency for Toxic Substances and Disease Registry (ATSDR) re-evaluated risk assessments and issued new guidelines, benchmarks, and risk values—and continue to do. These changes in risk values are the drivers for changing action limits like EPA Regional Screening Levels (RSLs), EPA Regional Removal Management Levels (RMLs), Maximum Contaminant Level (MCL), CalOSHA Permissible Exposure Limits (PELs), lead in pipes, and more. Before 2012, the "blood lead level of concern" for children was considered to be 10 micrograms per deciliter (µg/dL), meaning that a child with a blood lead level at or above 10 µg/dL would be flagged as having elevated lead exposure; this value was used by the CDC to identify children with concerning levels of lead in their blood. In 2012, the CDC and the healthcare community began to use a value called the Blood Lead Reference Value (BLRV) to determine when lead levels in human blood are concerning. The BLRV is based on data showing that 2.5 percent of U.S. children aged 1-5 have lead levels at or above this amount; or conversely, that the child's blood levels are higher than 97.5 percent of other children aged 1-5 in the U.S. While it's not a direct measure of health risk and it is not a health standard, it helps doctors, health agencies, and communities to focus on children who are at higher risk of lead exposure. Over time, epidemiological studies continue to provide evidence of health effects at increasingly lower BLLs. This has resulted in downward trends in the CDC BLRV and other lead action limits[18]. Since the initial value was set at a BLLC of 60 µg/dL in 1960, the CDC has lowered the BLRV five times.

Figure 4. Lowering of BLLC/BLRV (BLLs Considered Elevated) by CDC Over Time [19]



[18] Council on Environmental Health, Bruce Perrin Lanphear, Jennifer A. Lowry, Samantha Ahdoot, Carl R. Baum, Aaron S. Bernstein, Aparna Bole, Heather Lynn Brumberg, Carla C. Campbell, Bruce Perrin Lanphear, Susan E. Pacheco, Adam J. Spanier, Leonardo Trasande; Prevention of Childhood Lead Toxicity. Pediatrics July 2016; 138 (1): e20161493. 10.1542/peds.2016-1493

[19] https://www.atsdr.cdc.gov/csem/leadtoxicity/safety_standards.html

As shown in Figure 4 above, the most recent lowering of the BLRV occurred on October 28, 2021, when the CDC lowered the threshold for what's considered a concerning level of lead in children's blood. This CDC BLRV was reduced from 5.0 micrograms per deciliter (µg/dL) to 3.5 µg/dL. This change also pushes for quicker action to prevent further exposure and reduce health risks for children in this range[20].

These changes in the BLLC/BLRV (BLLs Considered Elevated) by the CDC are directly tied to changes in the Maximum Contaminant Level allowed in drinking water. This is because exposure to lead contamination in drinking water poses the greatest threat to the U.S. population, when considered with all the risk posed by other exposure routes.

Effects of 2011-2016 NHANES Data and lowering the BLRV to lead 3.5 µg/dL

The changes below show the impact of the NHANES lead in U.S. diets and blood studies, as well as CDC's October 2021 lead 3.5 µg/dL BLRV, on the regulatory universe in the U.S.:

- In April 2024, EPA released the new All Ages Lead Model (AALM) Version 3.0, which "rapidly estimates the effect of lead exposures from media such as air, water, food, dust, or soil on lead concentrations in blood, bone, and other human tissues from birth to 90 years of age."[21]
- EPA strengthened residential regulations in 2024 by revising the Dust-Lead Hazard Standards and Dust-Lead Post Abatement Clearance Levels[22]. This would reduce potential lead exposures for approximately 250,000 to 500,000 children annually under the age of 6.
- EPA's January 17, 2024 Lead in Soil Guidance lowered soil screening levels for lead in soil by lowering the Regional Screening Level (RSL) and Removal Management Level (RML) from 400 ppm to 200 ppm for residential soil scenarios and 100 for properties with multiple sources of lead exposure (paint, lead service lines, pipes, dust, etc.)[23,24]. This will have significant impacts to CERCLA and RCRA sites and serve as a potential site reopener impacting 5-year reviews of completed cleanups, as well as expanding removal and remediation actions for lead at these sites.
- Scheduled to go into effect January 1, 2025, California, Cal/OSHA, is lowering the action level for occupational lead exposure from 30 µg/m3 to 2 µg/m3 as an 8-hour time-weighted average[25]. This proposal aims to maintain employee blood lead levels below 10 µg/dL, compared to the previous target of 40 µg/dL.

---

[20] Ruckart PZ, et. Al. Update of the Blood Lead Reference Value - United States, 2021. MMWR Morb Mortal Wkly Rep. 2021 Oct 29;70(43):1509-1512. doi: 10.15585/mmwr.mm7043a4.

[21] USEPA. 2024. All Ages Lead Model (AALM) Version 3.0. https://www.epa.gov/land-research/all-ages-lead-model-aalm

[22] USNIH. 2024. Progress Report on The Federal Lead Action Plan: December 2018-April 2024. https://ptfcehs.niehs.nih.gov/sites/niehs-ptfceh/files/files/progress-report-flap_508.pdf

[23] USEPA. 2024. Regional Screening Levels (RSLs) - What's New. https://www.epa.gov/risk/regional-screening-levels-rsls-whats-new

[24] USEPA. 2024. Regional Screening Levels (RSLs) - Generic Tables. https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables

[25] California. 2023. DEPARTMENT OF INDUSTRIAL RELATIONS Occupational Safety and Health Standards Board Title 8. California Code of Regulations Construction Safety Orders Section 1532.1 And General Industry Safety Orders Sections 5155 And 5198 Https://Www.Dir.Ca.Gov/Oshsb/Documents/Noticeapr2023-Lead.Pdf

- The Maryland Department of Health is following EPA's lead in changing its definition of an elevated blood lead level from 5 µg/dL to 3.5 µg/dL, which was enacted on January 1, 2024[26].
- 2024: EPA's Lead and Copper Rule Improvements (LCRI) lowered the action level for drinking water systems, simplified triggers for action, mandated and provided funding for replacement of lead service lines in the next 10 years, and implemented new sample procedures, locations, and design. The LCRI requires more frequent and targeted testing than the LCRR. Specifically, it established a tiered monitoring system, with the frequency of monitoring depending on the water system's lead and copper levels. The number of sampling locations required depends on the size of the water system. Further, the LCRI strengthened the sampling requirements in high-risk areas, such as service lines that serve schools and childcare facilities.

Overall, these changes reflect a trend toward lowering action levels and reference values for lead exposure, based on growing evidence of health effects at very low levels of exposure, such as damage to the brain and nervous system, slowed growth and development, learning and behavior problems, and hearing and speech problems. These effects can cause lower IQ, decreased ability to pay attention, and underperformance in school[27]. The new action levels are generally 3-5 times lower than previous ones, aiming to protect more people, especially children, from the harmful effects of lead.

A summary of major regulatory changes since 2012 is presented in the table below.

Table 2. Federal Regulatory Changes in Lead Regulations Since 2012

Law or Act	Regulation or Standard	Scope/Details	Changes Since 2012	Level in 2024
Safe Drinking Water Act (SDWA)	**Lead and Copper Rule (LCR)**	Limits lead in drinking water; requires corrective actions for exceedances and lead service line replacements.	Lead and Copper Rule Revisions (LCRR) and introduced in 2021 **testing in elementary schools and child care facilities identification of lead, non-lead, and unknown service lines**	Lead in Copper Rule Improvements (LCRI) **New Action Level: 10 parts per billion (ppb) strengthened lead service line replacement requirements and improved testing protocols**.
Toxic Substances Control Act (TSCA)	**Lead-Based Paint Hazard Reduction**	Regulates lead in paint, particularly for homes built before 1978; includes Renovation,	2021: EPA lowered the clearance levels for residential lead dust: **10 µg/ft² for floors, 100**	2024: Indoor residential lead dust: **any reportable amount** of lead in dust; post-abatement clearance

[26] Maryland Department of Health. 2022. Environmental Health Bureau Childhood Blood Lead Testing in Maryland: Evaluation and Recommendation. https://health.maryland.gov/phpa/OEHFP/EH/Documents/MDLeadTestingEvaluation_122022.pdf
[27] USCDC. 2024 Lead Exposure Symptoms and Complications. https://www.cdc.gov/lead-prevention/symptoms-complications/index.html

		Repair, and Painting (RRP) Rule and Disclosure Rule.	**µg/ft² for window sills. The dust-lead clearance levels for window troughs remained the same at 400 µg/ft²**	levels: **5 micrograms per square foot (µg/ft2) for floors, 40 µg/ft2 for window sills, and 100 µg/ft2 for window troughs.**
Clean Air Act (CAA)	**National Ambient Air Quality Standards (NAAQS) for Lead**	Sets maximum allowable concentration of lead in outdoor air to protect public health and environment.	No changes to the lead standard since the 2008 revision.	**0.15 micrograms per cubic meter (µg/m³) (rolling 3-moth average)**
Resource Conservation and Recovery Act (RCRA)	**Hazardous Waste Regulations for Lead**	Governs treatment, storage, and disposal of lead-containing hazardous waste; requires proper handling to prevent environmental contamination.	Lead classified as hazardous if concentration in waste exceeds **5 mg/L based on the Toxicity Characteristic Leaching Procedure (TCLP) test; residential soil cleanup level at 400 ppm since 1990s.**	New **2024 Residential RSL set at 200 ppm, and 100 ppm at properties with multiple sources of lead exposure.**
Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA/Superfund)	**Lead Remediation**	Manages cleanup of lead-contaminated sites through Superfund; responsible parties required to clean up contaminated soil, water, or waste.	Lead soil cleanup levels: 400 ppm for residential areas where children may play and 1,200 ppm non-play areas.	New 2024 Residential **RSL set at 200 ppm, and 100 ppm at properties with multiple sources of lead exposure and removed "non-play area" language (current EPA RSL)**.

Conclusion

In conclusion, there has been a long history of evaluating the toxic effects of lead on humans, and regulatory actions and removal of man-made sources of lead have resulted in significantly lower BLLs—particularly focused on children. Recent regulatory updates in lead risk values and exposure limits represent a critical enhancement of public health protection. While these enhancements demand considerable financial and operational adjustments from industries and municipalities involved in site remediation to ensure, ensuring safe drinking water and mitigating indoor lead exposures, they underscore regulatory agencies' dedication to implementing science-driven policies that mitigate health risks.

EPA, CDC and other regulatory agencies have indicated that there is no safe level for lead in humans. If historical trends continue, we can expect additional tightening to reduce exposure and sources of lead, including additional regulation, "second looks" at contaminated sites previously thought to be safe, as well as potentially lower BLRVs very soon in the future. Moving forward, the challenge will be balancing the benefits of reduced lead exposure with the logistical and financial demands on industries and regulatory agencies. Continued collaboration between federal, state, and local authorities will be essential to effectively implement regulatory programs and risk-based action levels. Additional financial and legal resources may also be required to support impacted communities and ensure compliance across diverse sectors. Ultimately, these regulatory changes are laying the groundwork for a future where reduced lead exposure contributes to healthier, more resilient communities, closing the gap on health disparities and fostering a safer environment for all.