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Advanced Study Institute of Asia

NO SAFE BLOOD LEAD LEVELS:

UNDERSTANDING THRESHOLDS, COMPLIANCE, AND LEGAL CONSEQUENCES

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WORKING PAPER VERSION 1[1]

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[1] The cover page of the "Lead Poisoning" document uses a bluish-gray color, a common association with lead due to its historical use in blue pigments, to visually represent the topic and create a distinctive identity for the document.

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EXECUTIVE SUMMARY

Blood lead level (BLL) thresholds are essential for assessing lead exposure risks and guiding public health interventions. Key organizations, including the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), have established guidelines for BLLs 5 µg/dL as a critical threshold for assessing lead exposure and initiating further action. The CDC, through its Advisory Committee for Childhood Lead Poisoning Prevention (ACCLPP) and the Lead Exposure and Prevention Advisory Committee (LEPAC), regularly updates these thresholds based on emerging scientific evidence. Blood Lead Reference Value (BLRV) have evolved from 10 µg/dL (100 ppb) in 1991 to 5 µg/dL in 2012, and now revised to 3.5 µg/dL after identifying children with lead levels higher than 97.5% of U.S. children aged 1-5 years, emphasizing the need for stringent regulations to protect at-risk populations. This update reflects a growing consensus that no safe level of lead exposure exists, particularly for children, who are more vulnerable to neurodevelopmental impairments even at lower levels (American Academy of Pediatrics Committee on Environmental Health. (2005), (Lanphear, B. P., et al. (2016).

Rationale Behind BLL Thresholds

However, the rationale behind these thresholds is rooted in the understanding that "no level of lead exposure is considered completely safe", particularly for children. Research has shown that neurodevelopmental impairments can occur at blood lead levels below previously accepted thresholds, with cognitive decline noted at levels as low as 2 µg/dL. This challenges the notion of a "safe" threshold and highlights the need for more stringent regulations to protect vulnerable populations (Steven G. Gilbert and Bernard Weiss (2006). Individual countries set their own legal limits based on local health data, environmental conditions, and public health priorities. For example, as of late 2019, only 38% of UN member countries had established legally binding controls on lead in paints, indicating significant variation in regulatory frameworks globally.

Consequences of Non-Compliance

The consequences of failing to adhere to thresholds can be severe, leading to long-term health issues such as cognitive deficits and developmental delays in children. Non-compliance not only affects individual health outcomes but also places a burden on public health systems and increases healthcare costs associated with lead poisoning treatment and management. While most countries impose fines, legal actions, and reputational risks for non-compliance with lead limits, the enforcement mechanisms and cultural attitudes towards compliance can differ. Internationally, compliance with BLL thresholds also varies. Some countries have established stricter guidelines and intervention levels, while others lag behind, reflecting differences in public health infrastructure and awareness of lead exposure risks. The global community continues to advocate for unified standards and practices to mitigate lead exposure, particularly in vulnerable populations. This working paper highlights the importance of establishing robust compliance programs cannot be overstated, as the costs of non-compliance can far exceed the investments made in compliance efforts.

INTRODUCTION

Lead (**Pb**) is a naturally occurring element found in small amounts in the environment. However, human activities such as mining, smelting, and burning fossil fuels have significantly increased the levels of Lead in the environment.

Lead exposure can occur through various routes, including inhalation of contaminated air, dust, and soil. Children are particularly vulnerable due to their higher likelihood of indirectly ingesting Lead through contaminated food, water, or objects. Lead can also be absorbed through the skin, particularly if the skin is broken or damaged.

Understanding Lead Poisoning and Health Effects

Lead poisoning is a significant public health concern because of the severe and long-lasting effects of Lead exposure on human health. The risk of Lead exposure is particularly high in children, as their developing brains and bodies are more susceptible to negative effects.

Continuous exposure in children can Lead to decreased concentration, difficulty in following instructions, and low IQ. Prenatal exposure is linked to antisocial behavior and schizophrenia, whereas long-term exposure is associated with depression and anxiety disorders. Even low exposure levels can have significant neurotoxic effects and contribute to health problems.

The symptoms of Lead poisoning include abdominal pain, constipation, headache, irritability, memory problems, infertility, and tingling of the hands and feet. If left untreated, it can Lead to intellectual disabilities, such as delays in cognitive and motor skill development, and behavioral problems, such as hyperactivity and aggression. Severe complications of Lead poisoning include neurological damage; decreased vitamin D and hemoglobin synthesis; anemia; acute central nervous system disorders; damage to the kidneys, liver, and other organs; and even death.

No Blood Lead Levels is Safe for Children

The scientific consensus is clear that there is no safe level of Lead exposure. The first breakthrough in understanding the dangers of Lead came from the work of Herbert Needleman, a psychiatrist at the Harvard Medical School, who suspected that even trace amounts of Lead could cause significant harm to children's brains. Needleman's 1979 study, which analyzed the enamel of baby teeth to measure past Lead exposure, revealed that Lead profoundly transformed children's brains, even at levels far below those considered dangerous at the time (Needleman, H. L., Gunnoe, C., Leviton, A., Reed, R., Peresie, H., Maher, C., & Barrett, P. (1979) and Persico, C. (2024).

Despite this, threshold limits for Lead exposure remain in place and are designed to provide a safe threshold for Lead exposure and minimize the risk of harm. Various experts and organizations collaborated to establish these safety thresholds, including the Joint FAO/WHO Expert Committee on Food Additives, the United States (U.S). Public Health Services and Centers for Disease Control. The origins of these limits can be traced back to the 1970s and the 1980s, when the health risks associated with Lead exposure became increasingly evident, as discussed below.

ORIGINS OF BLOOD LEAD REFERENCE VALUE

In 1970, the U.S. Public Health Service established a daily permissible Lead intake of 300 µg/day from all sources for children, based on the assumption that 90% of ingested Lead is excreted and that a total Lead intake of 600 µg/day for an adult or 300 µg/day for a child would not result in increased blood Lead levels. In 1972, **Barltrop** calculated the permissible daily Lead intakes for children of different ages, ranging from 72 µg per square meter of body surface for a newborn to 298 µg per square meter for a 3-year-old child. In 1977, **Mahaffey** recommended that the maximum tolerable Lead intake from all sources should be less than 100 µg/day for infants under 6 months and no more than 150 µg/day for children 6 months to 2 years old. In 1983, **Ryu** found that intake as low as 61 µg/day resulted in increased Lead blood levels in infants, indicating Lead accumulation (WHO. (1986).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) set the Provisional Tolerable Weekly Intake (PTWI) for Lead exposure to assess health risks. PTWI represents the amount of Lead that can be safely consumed by an individual over a week without appreciable health risks. Initially, in 1972, JECFA established a PTWI of 0.05 mg/kg for adults. However, this level does not apply to infants and children because of their increased vulnerability to Lead exposure. Therefore, it was revised in 1986 to 0.025 mg/kg for infants and children to increase their vulnerability to Lead exposure. The current PTWI for Lead is 0.025 mg/kg body weight per week, considering Lead from all sources. The JECFA emphasizes the importance of maintaining low blood lead levels to prevent adverse health effects. Blood lead levels as low as 10 µg/dl have been shown to interfere with enzymes involved in the heme pathway, indicating that there is no threshold for this effect (Joint FAO/WHO Expert Committee on Food Additives (1986) and Joint FAO/WHO Expert Committee on Food Additives. (1999).

The **Centers for Disease Control (CDC)** has established guidelines for blood lead levels to guide policy and interventions. In the 1960s, the CDC set a threshold for "elevated" blood lead levels of 60 µg per deciliter (mcg/dL). This threshold was later lowered to 10 mcg/dL in 1991 (Agency for Toxic Substances and Disease Registry). (2023).

The article by Gilbert Steven G. and Bernard Weiss argues that the Centers for Disease Control and Prevention (CDC) should lower the blood lead action level from 10 micrograms per deciliter (µg/dL) to 2 µg/dL. The authors base their argument on a growing body of evidence that blood lead levels below 10 µg/dL may impair neurobehavioral development in children. They suggest that a level of 2 µg/dL is a useful and feasible replacement for the current action level, which would encourage and accelerate investments needed to protect children from Lead exposure in their homes, schools, and play settings (Gilbert, S. G., & Weiss, B. (2006).

However, the CDC currently considers blood lead levels above 5 mcg/dL as elevated, and since 2021, it has used a blood lead level of 3.5 (µg/dL) for children, based on the top 2.5% of children with the highest blood lead levels in the U.S. population higher than 2 µg/dL (Agency for Toxic Substances and Disease Registry. (2023).

The Lead Exposure in Children Surveillance System (LEICSS) in England, United Kingdom tracks and monitors Lead exposure in children. It identifies cases where a child has a blood lead level of 5 µg per deciliter (µg/dL) or higher, which is detected in a laboratory accredited by the UK

Accreditation Service (UKAS), reported to the UK Health Security Agency (UKHSA) for public health action, and is under 16 years of age at the time of the first elevated blood lead level.

The public health intervention level for Lead exposure in children in England was lowered from 10 µg/dL to 5 µg/dL on July 5, 2021. This change aims to provide earlier intervention and better protection for children exposed to Lead, which can have serious health consequences if left untreated (Government of the United Kingdom. (2023).

RATIONALE BEHIND SETTING LEAD LIMITS

Initially, the focus was on extremely high levels of Lead exposure, which are associated with acute poisoning symptoms. As research has progressed, scientists have begun to recognize the long-term and cumulative effects of Lead exposure, particularly in children.

Previous calculations relied on adult data, but the new guidelines were based on direct measurements in children. These new guidelines are more trustworthy because children absorb Lead more readily and have lower tolerance levels than adults. The gradual lowering of the threshold reflects this growing understanding of the dangers of Lead exposure.

Despite these reductions, the CDC acknowledges that there is no safe Lead level for children, and even low levels can cause developmental and intellectual problems. The blood lead reference value is not a safe threshold but rather a trigger at which public health actions should be taken to identify and mitigate the source of exposure (Persico, C. (2024) and (Ruckart, P. Z., Jones, R. L., Courtney, J. G., et al. (2021).

THRESHOLD LIMIT VALUES (TLVS)

Threshold limit values (TLVs) have their roots in the early 20th century, when concerns about worker health and safety began to grow. Initially, TLVs were based on the concentrations of contaminants that produced clear signs of acute toxicity. However, over time, the focus shifted to establishing levels at which nearly all workers could be exposed without adverse health effects. This shift was driven by the recognition of the potential long-term health effects of chronic Lead exposure.

The development of TLVs involved international cooperation, with organizations such as the American Conference of Governmental Industrial Hygienists (ACGIH) playing a significant role in establishing and maintaining these standards. In the US (US), the legal safe Lead consumption limits are primarily set by two key agencies: the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) (Paull, J. M. (1984).

MULTIPLE THRESHOLDS PERMIT LIMITED LEAD EXPOSURE

Various regulatory and legal standards for lead levels enable some degree of exposure while still prioritizing public health. In the US, these standards are established by multiple federal agencies, including the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA). For instance, OSHA sets a permissible exposure limit (PEL) of 50 µg/m³ for lead in workplace air, while the Japan Society for Occupational Health set the occupational exposure limit (OEL) for lead in air at 30 µg/m³. EPA has established a maximum contaminant level for lead in drinking water at 15 µg/L. The CPSC regulates lead content in consumer products, including a limit of 0.009% in paints intended for residential use.

UNITED STATES

EPA has implemented various regulations to reduce Lead emissions and exposure. Key milestones include:

EPA Ambient Air Quality Standard:

EPA's National Ambient Air Quality Standards (NAAQS) for lead (Pb) for primary and secondary standards are set at 0.15 µg/m for ambient air

- The EPA did set the first reduction standards for lead in gasoline in 1973, aiming to phase it out by 1986.

- 1975: Passenger cars and light trucks are manufactured using catalytic converters that require Lead-free fuel.

- 1978: the initial NAAQS for lead set in 1978 at 1.5 µg/m³, measured as lead in total suspended particulate matter (Pb-TSP).

- EPA also restricts Lead in paint for residences, furniture, and toys to 0.06% or less.

- 1990: *Clean Air Act Amendments ban* the sale of Leaded fuel for on-road vehicles and other uses.

- 1996: Final ban on Leaded fuel for on-road vehicles, aircraft, racing cars, farm equipment, and marine engines.

EPA Drinking Water Regulation:

- 1974: Safe Drinking Water Act gives EPA authority to set limits on Lead for public drinking water systems and other *contaminants in drinking water to be less than 50 µg/L (50 plead).*

- 1986: Amendments to the Safe Drinking Water Act required Lead-free solder, flux, fittings, and pipes as of June 1988.

- The Lead and Copper Rule, adopted in 1991 under Safe Drinking Water Act, requires water utilities to optimize corrosiveness control and monitor tap water Lead levels, *acting if more than 10% of samples exceed the EPA's current 15-plead action level.*

The EPA sets a maximum contaminant level goal for lead in drinking water at **0.015 ppm** (15 µg/L).

EPA Soil Screening Levels:

- 2000: EPA sets standards for Lead in bare soil in play areas (400 ppm) and non-play areas (1200 ppm) for cleanup projects using federal funds.

- 2008: *EPA reduces the allowable Lead level in air from 1.5 micrograms per cubic meter to 0.15 micrograms per cubic meter*, with states given five years to comply (US EPA (1973) and US EPA (1996).

The Food and Drug Administration (FDA), on the other hand, sets limits on Lead levels in food and food packaging. The FDA has set an action level of 0.5 µg/dL for Lead in food products intended for use by infants and children. The agency has also taken actions to reduce Lead exposures from Lead-glazed ceramic pottery, leaded crystal glassware, and lead foil wraps for wine bottles. The FDA established a maximum permissible lead level in glaze for ceramic ware and has proposed regulations to prohibit further use of lead foil wraps on wine bottles. The agency also sets limits on lead levels in wine and has proposed regulations to limit lead in food and bottled water refer to **Table 1. Appendices** (Neltner, T., & Maffini, M. (2024)

The Occupational Safety and Health Administration (OSHA) sets a PEL for lead in workplace air at **50 µg/m³** as an 8-hour time-weighted average (TWA) .

- The action level is defined as **30 µg/m³** over an 8-hour work shift. Employers must begin compliance activities if employee lead exposure exceeds this level.

- OSHA mandates periodic determination of blood lead levels for workers exposed to air concentrations at or above the action level for more than 30 days per year.

- If a worker's BLL exceeds **40 µg/dL**, they must be notified in writing and provided with a medical examination.

- If a worker's BLL reaches **60 µg/dL** or averages **50 µg/dL** or more on multiple tests, they must be removed from exposure until their BLL falls below **40 µg/dL** (US EPA (2024).

Regarding the legal consequences for exceeding BLL thresholds, while OSHA regulations do specify removal from exposure and medical monitoring. However, failure to comply with OSHA regulations can indeed lead to enforcement actions, including fines or penalties.

The Consumer Product Safety Improvement Act (CPSIA) sets strict Lead content limits for children's products. Initially, the maximum allowed Lead content was 600 parts per million (ppm) by February 10, 2009. This limit has revised to 300 ppm on August 14, 2009, and further reduced to 100 ppm on August 14, 2011, unless the Commission determines that it is not technologically feasible to achieve this lower limit. The U.S. Consumer Product Safety Commission (CPSC) enforces these limits through mandatory third-party testing, product determinations, marketplace surveillance, and enforcement actions against non-compliant products. For paint and surface coatings, the limit is 0.009% or 90 ppm Lead, effective August 14, 2009 (U.S. Consumer Product Safety Commission. (2011).

The National Institute for Occupational Safety and Health (NIOSH) recommends a maximum air Lead concentration of 100 µg/m³ to keep blood lead levels (BLLs) at or below 40 µg/dL.

The American Conference of Governmental Industrial Hygienists (ACGIH) has set the following *occupational exposure limits for Lead Threshold Limit Value – Time-Weighted Average (TLV-TWA) to 50 µg/m3 for Lead in workplace air*, except for lead arsenate for an 8-hour workday without adverse health effects. The Biological Exposure Indices (BEI) of 30 µg/dL for blood lead is the advisory level that ACGIH believes workers can be exposed to without adverse effects (Agency for Toxic Substances and Disease Registry (2023).

EUROPE

The European Union (EU) has set the following occupational exposure limits and

biological limits for Lead to protect workers from the negative health effects of Lead since 1982. A revised occupational exposure limit (OEL) for Lead in air of 0.03 mg/m³ as an 8-hour time-weighted average (TWA). A biological limit value (BLV) for Lead in blood of 15 µg Lead/100 ml, with a transitional period until December 31, 2028, during which a limit value of 30 µg Lead/100 ml will apply (International Lead Association. (2024).

JAPAN

Japan's Occupational Lead Exposure Limits for lead, recommending a blood lead level of 15 µg/dL. Japan's OEL for lead in air of 30 µg/m³ is higher than the revised EU limit of 0.03 mg/m³ (equivalent to 30 µg/m³).

The REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) Regulation provides guidelines for the safe handling and use of chemicals, including Lead. It aims to protect workers from exposure to harmful chemicals by encouraging employers to take necessary measures to prevent or reduce exposure. t encourages employers to take necessary measures to prevent or reduce exposure, such as better ventilation, rotating work tasks, PPE, and adequate safety procedures.

EU Drinking Water Directive sets a health limit value for Lead in drinking water at 10 µg/l, aiming to protect human health from adverse effects of Lead contamination. This limit value was established based on the recommendations of the World Health Organization (WHO) and the European Food Safety Authority (EFSA). The directive has undergone revisions, with the most recent one lowering the limit value to 5 µg/l by 2036.

UNITED KINGDOM

Control of Lead at Work Regulations (CLAW)

The UK has specific regulations regarding Lead exposure in the workplace, known as the Control of Lead at Work Regulations (CLAW) 2002. These regulations set out thresholds and compliance requirements for employers to protect workers from the health risks associated with Lead exposure. For women of reproductive capacity, the action level is 25 µg/dL of blood Lead concentration. For young persons, the action level is 40 µg/dL of blood Lead concentration. For other employees, the action level is 50 µg/dL of blood lead concentration. These action levels trigger the employer to take specific actions, such as providing protective equipment and implementing control measures to reduce exposure (LeadSafeWorld. (n.d.).

The Health and Safety Executive (HSE) in 2004 in the UK sets *occupational exposure limits* for various substances to protect workers from hazardous chemicals. For Lead, the HSE *recommends an 8-hour time-weighted average (TWA) of 0.15 mg/m³* and an action level of 25 µg/dL for women of reproductive capacity, 40 µg/dL for people aged 16 or 17, and 50 µg/dL for other employees (Health and Safety Executive (2024).

The Hazardous Waste (England and Wales) Regulations 2005 define hazardous waste as waste that poses a significant risk to human health and the environment. This includes Lead and Lead compounds, but the regulations have been updated to use more general definitions of "harmful" or "toxic" in The Waste (England and Wales) Regulations 2011. Employers have a general compliance requirement to ensure the health and safety of their employees. This includes making a suitable and sufficient assessment of the risks to the health of

employees caused by work involving Lead, identifying, and implementing measures to prevent or control exposure, and recording the findings of the assessment (LeadSafeWorld. (n.d.).

INDIA

The Bureau of Indian Standards (BIS) in 1967 published the Indian Standard Code of Safety for Lead and Its Compounds recommended a TLV of 2 milligrams of Lead per 10 cubic meters of air for most inorganic and organic compounds of Lead, except for lead arsenate, which had a TLV of 0.15 milligrams of lead per cubic meter of air. This standard was part of a series of Indian Standards codes of safety for hazardous chemicals, which aimed to ensure the safety of personnel in industries handling Lead and its compounds (Bureau of Indian Standards. (1967).

Vehicular emission norms in India were first introduced in 1991 and tightened in 1996, requiring catalytic converters and Lead-free, low-sulfur fuels. Refineries supplied unleaded gasoline to NCR and major cities, later expanding nationwide. Fuel specifications based on environmental considerations were notified in 1996 for achievement by 2000, incorporated into BIS 2000 standards (Government of India (2014).

The Drugs and Cosmetics Act in 1940 in India, regulates the import, manufacture, distribution, and sale of drugs and cosmetics including those that use lead compounds for colouring purposes to ensure their safety, quality, and efficacy. The act sets specific limits for the presence of Lead in synthetic and natural organic colours used in cosmetics. *The permissible limit for Lead is not more than 20 ppm.* The act prohibits the import of cosmetics containing Lead compounds for colouring purposes and forbids the manufacture of cosmetics containing dyes, colours, and pigments not specified by the Bureau of Indian Standards and Schedule Q, with the same limits for Lead (The Drugs and Cosmetics Act, 1940 and Rules (1945).

The Factories Act in 1948 regulates working conditions in factories, including safety measures to protect workers from occupational hazards such as exposure to Lead and other chemicals. The act lists industries involving Hazardous processes including non-ferrous metallurgical industries such as those dealing with Lead, and chemical industries involving Lead and its compounds. Threshold The act specifies *Permissible Exposure Limits for Lead in the work environment: Time-weighted average concentration (8 hours): 0.15 mg/m³* Short-term exposure limit (15 minutes): 0.45 mg/m³ (Government of India, Ministry of Labour. (1948).

The Insecticides Act in 1968 regulate the use of certain substances that could potentially contain Lead, such as insecticides and pesticides. The Act requires these substances to be registered and labeled properly to ensure their safe use. The Act does not specify a specific threshold for Lead poisoning (The Insecticides Act (1968).

The Environment (Protection) Act in 1986 provides the framework for regulating activities that have an impact on the environment, including those that contribute to Lead pollution. It empowers the central government to take measures to protect and improve environmental quality. *As per The Environment (Protection) Rules, 1986, standards for emission or discharge of Lead (Lead) should not exceed 0.2 mg/l* **refer Table 2**.

The Manufacture, Storage, and Import of Hazardous Chemicals Rules in 1989 in India, regulate the handling of hazardous chemicals, including Lead compounds. The rules list various Lead compounds, including Lead arsenite, Lead at high temp (molten), Lead azide, Lead styphnate, Tetra methyl lead, and Tetraethyl lead, as hazardous and toxic chemicals. The rules specify *threshold quantities for hazardous chemicals in isolated storage, including: Tetraethyl lead or tetramethyl lead: 5 tonnes for Rules 4, 5, 7 to 9, and 13 to 15, and 50 tonnes for Rules 10 to 12. Lead azide: 100 kg for Rules 10 to 12. Lead styphnate: 50 tonnes for Rules 10 to 12* refer the act from (The Manufacture, Storage, and Import of Hazardous Chemical Rules (1989).

The Chemical Accidents (Emergency Planning, Preparedness, and Response) Rules in 1996 in India, aim to prevent and mitigate chemical accidents and specify emergency planning and response measures for industries handling hazardous chemicals, including lead compounds. The rules list various lead compounds, including inorganic fumes and dusts, Lead Trinitroresorcinoxide (Lead Styphnate), Lead Azide, Tetraethyl Lead, and Tetramethyl Lead, as hazardous and toxic chemicals. The rules specify *threshold quantities for various chemicals, including: Tetraethyl Lead and Tetramethyl Lead: 5 M.T. (metric tons). Lead Azide: 50 T (tons). Lead Styphnate (Lead 2, 4, 6-Trinitroresorcinoxide): 10 T (tons)* refer the act from (The Chemical Accidents (Emergency Planning, Preparedness and Response) Rules (1996).

The Batteries (Management and Handling) Rules in 2001 in India regulate the management and disposal of used lead-acid batteries. emphasizes manufacturers must ensure collection of used batteries back from consumers, maintain accurate records, and transport them to registered recyclers. Importers and recyclers must register with the Ministry of Environment and Forests and ensure compliance with environmental standards. Consumers must return used batteries to dealers or designated collection centers. Dealers must ensure collection of used batteries, provide discounts for returned batteries, and maintain records. Bulk consumers and auctioneers must ensure that used batteries are sold to registered recyclers and maintain records. *The rules specify threshold quantities for hazardous chemicals in isolated storage, including: Tetraethyl lead or tetramethyl lead: 5 tonnes for Rules 4, 5, 7 to 9, and 13 to 15, and 50 tonnes for Rules 10 to 12; Lead azide: 100 kg for Rules 10 to 12; and Lead styphnate: 50 tonnes for Rules 10 to 12* (Central Pollution Control Board. (2001).

The Biomedical Waste Management Rules, 2016 in India regulate the management and disposal of biomedical waste, including hazardous substances like lead, to prevent environmental contamination and protect human health. No specific threshold quantities are mentioned for Lead in the Biomedical Waste Management Rules, 2016. Lead-acid batteries are excluded from these rules and are covered under the Batteries (Management and Handling) Rules, 2001 (Central Pollution Control Board. (2019).

The Central Pollution Control Board set regulations of Lead Contents in Household and Decorative Paints Rules in 2016, prohibits the manufacture, trade, import, and export of household and decorative paints containing lead or lead compounds more than 90 ppm. This regulation was notified by the Government of India in 2016 and came into effect from November 1, 2017. All paints manufactured or imported after November 1, 2017, must be

labelled to indicate that their lead content does not exceed this limit (Central Pollution Control Board (2017).

The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 in India set a threshold for lead poisoning and compliance requirements. The maximum permissible limit for Lead in various types of food products is 0.2 mg/kg **refer Table 3.** (Food Safety and Standards Authority of India (2023).

Food Safety and Standards (Alcoholic Beverages) Regulations in 2018 regulate regulate the production, storage, and distribution of various types of alcoholic beverages. The regulations ensure the safety and quality of alcoholic beverages in India by setting limits for contaminants like lead and other hazardous substances. The maximum permissible limit for Lead in various types of alcoholic beverages is 0.2 mg/l (Food Safety and Standards Authority of India. (2021).

The Occupational Safety and Health Code, 2020, in India, regulates the exposure to hazardous chemicals, including Lead, in various industries involved in hazardous processes dealing with Lead and its compounds. It also covers activities related to, Lead tetra-ethyl. The Code lists Lead poisoning as a notifiable disease, emphasizing the need for proper safety measures to prevent exposure and ensure timely medical intervention in case of poisoning. However, the Code does not specify a specific threshold for lead poisoning (The Occupational Safety, Health, and Working Conditions Code, 2020).

COMPLIANCES

UNITED STATES

The Section 1018 Enforcement Policy, issued by the US EPA, outlines the guidelines for enforcing the Lead-Based Paint Disclosure Rule. This policy applies to federal facilities and government agencies that sell or lease target housing built before 1978. If these entities fail to comply with the disclosure requirements, they can face civil penalties under Section 16(a) of the Toxic Substances Control Act (TSCA). *The maximum penalty for each violation is $10,000* (Hathaway, C. R., Rawson, W. K., Claassen, A., & Hatcher, J. A. (2007).

OSHA sets an Action Level of 30 µg/m³. If an employee's blood lead level (BLL) exceeds 40 µg/dL, they must be notified in writing and provided with a medical examination. If a BLL reaches 60 µg/dL, the employee must be removed from exposure until their BLL falls below 40 µg/dL. *The maximum fine for a serious violation is $13,653, and for a repeat or wilful violation, it is $136,532.* Appeals are heard by the independent Occupational Safety and Health Review Commission (OSHRC).

The Consumer Product Safety Improvement Act (CPSIA) sets strict lead content limits for children's products. If there was non-compliance, there were penalties in place. Failure to report possible product hazards to *the CPSC in a timely manner was increased from $5,000 per violation (with a cap of $1,825,000) to $100,000 per violation (with a cap of $15 million).* Criminal penalties for various prohibited acts, including failure to comply with the act, were increased to include forfeiture of assets and imprisonment for up to five years. The act also protected employees who reported potential violations of consumer product safety laws from retaliation by their employers.

UNITED KINGDOM

Control of Lead at Work (CLAW) Regulations 2002

The Control of Lead at Work (CLAW) Regulations 2002 indeed place a duty on employers to protect employees from lead exposure. Employers must conduct a suitable and sufficient risk assessment to identify and implement measures to prevent or control exposure to lead. They are also required to record the findings of this assessment.

Failure to comply with these regulations can result in fines and penalties, although the frequency and severity of these penalties are not well documented (Health and Safety Executive. (2002).

Hazardous Waste (England and Wales) Regulations 2005

The Hazardous Waste (England and Wales) Regulations 2005 do set out requirements for the management of hazardous waste, including lead-containing waste.

- Schedule II of the regulations includes lead and lead compounds in the definition of 'hazardous'.

- The regulations require producers of hazardous waste, including lead, to register their premises with the Environment Agency and provide quarterly disposal and recovery information (WasteCare. (2023).

EUROPE

The REACH Regulation compliance failure can result in fines, legal action, reputation damage, and health risks for workers. The regulation does not specify specific penalties for compliance failure but emphasizes the importance of adhering to its guidelines to ensure worker safety.

EU Drinking Water Directive compliance is ensured through regular monitoring and testing of drinking water quality. If a water supplier fails to comply with these measures, they may be subject to administrative fines or legal action. However, the specific fines for non-compliance are not explicitly mentioned in the directive (European Parliament, & Council of the European Union. (2020).

INDIA

The Drugs and Cosmetics Act, 1940 ensures compliance through various measures. Penalties impose if anyone who manufactures for sale, distributes, sells, stocks, exhibits, or offers for sale cosmetics deemed spurious or adulterated under the act is punishable with imprisonment for up to three years and a fine not less than fifty thousand rupees or three times the value of the confiscated cosmetics, whichever is higher. For other contraventions of this act or any related rules, the penalty includes imprisonment for up to one year, a fine of up to twenty thousand rupees, or both.

Factories Act, 1948 prohibits or restricts the employment of women, adolescents, and children in certain dangerous operations, including “manufacture and treatment of lead and certain compounds of lead”. The Act requires factories to provide effective arrangements for the disposal of wastes and effluents due to the manufacturing process. The Model Factories Rules under the Act state that lead paint shall not be applied in the form of a spray in the interior painting of any part of a ship or vessel. This indicates an attempt to limit lead exposure from paint. However, the Act and Rules do not specify numerical exposure limits for lead or penalties for exceeding such limits. *The penalties mentioned are general, such as imprisonment up to 3 months or fines up to Rs. 100 for workers who wilfully interfere with safety provisions.* Violation to these can result in

imprisonment for up to seven years and fines up to two lakh rupees, with additional fines for continued violations. If violations persist beyond a year, imprisonment can extend to ten years (Labour Commissioner Government of NCT of Delhi. (2024).

The Insecticides Act, 1968, rules cover various aspects, including the registration of insecticides, labelling requirements, and the powers of Insecticide Inspectors to enforce the Act. The act provides for penalties for non-compliance, including fines and imprisonment. The specific penalties vary depending on the nature of the offense and the level of culpability.

The Chemical Accidents (Emergency Planning, Preparedness, and Response) Rules in 1996 rules emphasize the importance of proper safety measures and compliance with the rules to prevent and mitigate chemical accidents. Non-compliance can result in penalties and other legal actions. The rules cover industries involved in hazardous processes, including those handling hazardous chemicals like lead compounds.

The Batteries (Management and Handling) Rules, 2001 establishing collection centers, ensuring environmentally sound transportation, maintaining accurate records, sending used batteries only to registered recyclers, and creating public awareness about the hazards of lead and the importance of proper battery disposal. Failure to comply with the rules can result in penalties, fines, and legal action. *The specific penalties and fines are not explicitly mentioned in the rules but are governed by broader legal frameworks*. The Battery Waste Management Rules, 2022 notified to regulate lead-acid battery recycling, but implementation remains to be seen.

The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 ensure that their products comply with the specified limits for lead and other contaminants to prevent lead poisoning and protect public health. Regular testing and monitoring of lead levels in the products are crucial to ensure compliance with the regulations. For penalties related to non-compliance, referring to the Food Safety and Standards Act, 2006, which outlines penalty for selling food not of the nature or substance or quality demanded –Any person who sells to the purchaser's prejudice any food which is not in compliance with the provisions of this Act or the regulations made thereunder, or of the nature or substance or quality demanded by the purchaser, shall be liable to a penalty not exceeding 5 lakh rupees (Food Safety and Standards Act, 2006. (2006).

The Regulation of Lead Contents in Household and Decorative Paints Rules, 2016, prohibits the manufacture, trade, import, and export of household and decorative paints containing lead or lead compounds more than 90 parts per million (ppm). However, *the specific penalty for non-compliance with these rules is not explicitly mentioned.*

LEGAL CONSEQUENCES

The rules, regulations, code and guidelines of lead contamination and consumption limits is a complex issue, with multiple thresholds and regulations in place across various jurisdictions. While these regulations aim to protect public health and the environment, their effectiveness is often hindered absence of specific penalties for non-compliance.

In the US, the EPA has implemented various regulations to reduce lead emissions and exposure. Key milestones include the EPA Ambient Air Quality Standard of 0.15 μg/m³ for ambient air and the EPA Drinking Water Regulation of 15 μg/L for public drinking water

systems. The EPA also sets standards for lead in soil, with levels of 400 ppm for bare soil in play areas and 1200 ppm for non-play areas. Despite these regulations, compliance and enforcement remain significant challenges. In the US, the EPA's Section 1018 Enforcement Policy outlines guidelines for enforcing the Lead-Based Paint Disclosure Rule, but civil penalties can be imposed for non-compliance.

In India, several regulations have been implemented to control lead exposure, including the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which set a maximum permissible limit of 0.2 mg/kg for lead in various food products. Similarly, the Central Pollution Control Board's Lead Contents in Household and Decorative Paints Rules, 2016, prohibit the manufacture, trade, import, and export of household and decorative paints containing lead or lead compounds more than 90 parts per million (ppm). However, the effectiveness of these regulations is limited by the lack of specific penalties for non-compliance. For instance, the Food Safety and Standards Act, 2006, outlines a penalty of up to Rs. 5 lakhs for selling food not in compliance with the regulations, but this penalty is not explicitly mentioned in the rules themselves. The Occupational Safety and Health Code, 2020, regulates exposure to hazardous chemicals, including lead, but does not specify a specific threshold for lead poisoning.

The sheer number of regulations and thresholds can create confusion and make compliance difficult. For instance, the various regulations in India, such as the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, and the Central Pollution Control Board's Lead Contents in Household and Decorative Paints Rules, 2016, may have overlapping or conflicting requirements, making it challenging for industries and consumers to comply.

To improve the effectiveness of lead regulations, it is essential to ensure that enforcement mechanisms are in place and that specific penalties are outlined for non-compliance. Additionally, simplifying, and harmonizing regulations across jurisdictions can help reduce confusion and increase compliance. Ultimately, a multi-faceted approach that includes education, awareness, and effective enforcement is necessary to mitigate the risks associated with lead contamination and consumption.

RECOMMENDATIONS

To improve the regulation and enforcement of lead contamination and consumption limits, the following recommendations are provided:

Clear and Consistent Thresholds and Penalties: Establish clear thresholds and specify penalties for Lead only non-compliance, including fines and imprisonment.

Public Awareness and Education: Conduct public awareness campaigns and provide educational materials and training to workers handling lead.

Regular Monitoring and Testing: Regularly test and monitor lead levels in products, water, and air, and implement a system for reporting and tracking lead levels.

Regulatory Harmonization: Harmonize regulations across industries and jurisdictions, and establish a centralized authority to oversee regulatory efforts.

Regulatory Updates and Revisions: Regularly review and update regulations to reflect new findings and advancements, and

ensure regulations adapt to changing circumstances.

Transparency and Accountability: Ensure transparency in regulatory decision-making and enforcement, establish mechanisms for public participation and feedback, and hold regulatory agencies accountable for their actions.

CONCLUSION

In conclusion, the regulations of lead contamination and consumption limits is a critical issue that requires a multifaceted approach. While there are numerous regulations and standards in place, compliance and enforcement remain significant challenges. To effectively curb lead contamination and consumption, it is essential to establish clear and consistent regulations, provide adequate penalties for non-compliance, and ensure effective enforcement mechanisms.

APPENDICES

Table 1: Standards and Regulations for Lead [ACCLPP 2012]

AGENCY	MEDIA	LEVEL	
ACGIH	Air (workplace)	150 µg/m^3 50 µg/m^3	TLV/TWA guideline for lead arsenate TLV/TWA guideline for other forms of lead
ACGIH	Blood	30 µg/dL	Advisory; indicates exposure at TLV*
CDC	Blood	5 µg/dL	Reference range upper value for children's BLL and reference BLL for adults (NIOSH).
CPSC	Paint	90 ppm (0.009%)	Regulation; by dry weight. New standard for lead in household paint and similar surface coatings in children's products, and some furniture, for adult and children, children's toys, jewelry, etc.
EPA	Air (ambient)	0.15 µg/m^3	Regulation; NAAQS; 3-month average
EPA	Soil (residential)	400 ppm (play areas) 1200 ppm (non-play areas)	Soil screening guidance level; requirement for federally funded projects only (40 CFR Part 745, 2001]
EPA	Water (drinking)	15 µg/L 0 µg/L;	Action level for public supplies non-enforceable supplies goal; MCLG
FDA	Food	Various	Action levels for various foods; example: lead-soldered food cans now banned
FDA	Drinking water	5 plead	Bottled water
FDA	Juices	30 plead – 50 plead	Fruit juices
FDA	Candy and Dried fruits	100 plead	Candy and Dried fruits, including raisins:
NIOSH	Air (workplace)	50 µg/m^3	REL (non-enforceable)
OSHA	Air (workplace)	50 µg/m^3 30 µg/m^3	Regulation; PEL (8-hour time weighted average) (general industry) Action level (averaged over an 8hour period)
OSHA	Blood	40 µg/dL 50 µg/dL and 60 µg/dL	Regulation; cause for written notification and medical exam, and return to work after removal Regulation; cause for medical removal from exposure

* Note: BEI and TLV values are intended for use in the practice of industrial hygiene as guidelines or recommendations to assist in the control of potential workplace health hazards and for no other use. These values are not fine lines between safe and dangerous concentrations and should not be used by anyone untrained in the discipline of industrial hygiene.

Table 2. The Environment (Protection) Rules, 1986, standards for emission or discharge of Lead (Lead) should not exceed

INDUSTRY	STANDARD
Electroplating Industries	0.1 Mg/Nm3
Copper, Lead And Zinc Smelting	150 Mg/Nm3
Paint Industry, Waste Water Discharge	0.1 Mg/Nm3
Inorganic Chemical Industry (Waste Water Discharge)	0.1 Mg/Nm3
Dye & Dye Intermediate Industry (Waste Water Discharge)	0.1 Mg/Nm3
Glass Industry (Lead Glass)	20 Mg/Nm3
Common Effluent Treatment Plants	1.0 Mg/Nm3
Organic Chemicals Manufacturing Industry	0.1 Mg/Nm3
Oil Drilling And Gas Extraction Industry	0.05 Mg/L
Pharmaceutical (Manufacturing And Formulation) Industry	0.10 Mg/Nm3
Specifications Of Motor Gasoline For Emission Related Parameters	0.15g/L
Battery Manufacturing Industry	
A) Grid Casting	10 Mg/Nm3
B) Oxide Manufacturing	10 Mg/Nm3
C) Paste Mixing	10 Mg/Nm3
D) Assembling	10 Mg/Nm3
E) Liquid Effluent Discharge Standards	.1 Mg/L
F) Secondary Lead Smelters	10 Mg/Nm3
Water Quality Standards For Coastal Waters Marine Outfalls (Primary Water Quality Criteria For Class Sw-1 Waters)	0.001 Mg/L Values Depend On : (I) Concentration In Salt,Fish And Shell Fish. (Ii) Average Per Capita Consumption Per Day. (Iii)Minimum Ingestion Rate That Induces Symptoms Of Resulting Diseases.

Table 3. Ministry of Health and Family Welfare (Food Safety and Standards Authority of India) Notification

	ARTICLE OF FOOD	PARTS PER MILLION BY WEIGHT (ppm)
(i)	Beverages;	
	Concentrated soft drinks (but not including concentrates used in the manufacture of soft drinks)	0.5
	Fruit and vegetable juice (including tomato juice, but not including lime juice and lemon juice)	1.0
	Concentrates used in the manufacture of soft drinks, lime juice and lemon juice	2.0
(ia)	Baking powder	10
(ib)	Edible oils and fats	0.5
(ic)	Infant Milk substitute and Infant foods	0.2
(id)	Turmeric whole and powder	10.0
(ii)	Other foods	
	Anhydrous dextrose and dextrose monohydrate, edible oils & fats, refined white sugar (sulphated ash content not exceeding 0.03 per cent)	0.5
	Ice-cream, iced lollies and similar frozen confections	1.0
	Canned fish, canned meats, edible gelatin, meat extracts and hydrolysed protein, dried or dehydrated vegetables (other than onions)	5.0
	All types of sugar, sugar syrup, invert sugar and direct consumption coloured sugars with sulphated ash content exceeding 1.0 per cent	5.0
	Raw sugars except those sold for direct consumption or used for manufacturing purpose other than the manufacture of refined sugar.	5.0

	Edible molasses, caramel liquid and solid glucose and starch conversion products with a sulphated ash content exceeding 1.0 per cent	5.0
	Cocoa powder	5.0 on the dry fat free substance
	Yeast and yeast products	5.0 on the dry Matter
	Tea, dehydrated onions, dried herbs and spices flavourings, alginic acid, alignates, agar, carrageen and similar products derived from seaweed	10.0 on the dry Matter
	Liquid pectin, chemicals not otherwise specified, used as ingredients or in the preparation or processing of food	10.0
	Food colouring other than caramel	10.0 on the dry colouring matter
	Solid pectin	50.0
	Hard boiled sugar confectionery	2.0
	Iron fortified common salt	2.0
	Corned beef, luncheon meat, Cooked Ham, chopped meat, Canned chicken, 2.5 Canned mutton and Goat meat and other related meat products	2.5
	Brewed vinegar and Synthetic vinegar	Nil
(iii)	Foods not specified	2.5

ABBREVIATIONS

ACGIH – American Council of Government and Industrial Hygienists

CDC – Centers for Disease Control and Prevention

CPSC – Consumer Products Safety Commission

EPA – EPA

NIOSH – National Institute of Occupational Safety and Health

OSHA – Occupational Safety and Health Administration BLL – Blood Lead Levels

MCLG – Maximum Contaminant Level Goal

NAAQS – National Ambient Air Quality Standards

PEL – Permissible Exposure Level ppm and plead – parts per million and parts per billion

REL – Recommended Exposure Limit

TLV/TWA – Threshold Limit Value/Time Weighted Average µg/dL – micrograms per decilite

CPCB - Central Pollution Control Board under the Environmental Protection Act, 1986

BIS - Bureau of Indian Standards (BIS) guidelines for lead content in consumer products

CPSC - Consumer Protection Council

WHO - World Health Organization

BLL - Blood Lead Levels

FSSAI - Food Safety and Standards Authority of India

JECFA - Joint FAO/WHO Expert Committee on Food Additives

NIOSH - National Institute for Occupational Safety and Health

OSHA - Occupational Safety and Health Administration

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