# *Children's Health Protection Advisory Committee*



September 19, 2024

Administrator Michael Regan
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: UNICEF Lead Toolkits Charge Response Letter

Dear Administrator Regan:

Thank you for the opportunity to comment on the United States Environmental Protection Agency's (U.S. EPA) combined efforts with the United Nations International Children's Emergency Fund (UNICEF) to develop a toolkit to address childhood lead (Pb) exposure in low-and-middle-income countries (LMICs). In this letter, and accompanying appendices, the Children's Health Protection Advisory Committee (CHPAC) presents recommendations alongside case studies that should be considered when developing these toolkits.

Due to the time constraints placed on the CHPAC to develop this letter, the Committee would like to emphasize that it should not be considered a comprehensive overview of recommendations. Instead, this document should be viewed as a compilation of existing information that the CHPAC felt was most important to highlight for LMICs to consider when addressing various issues related to childhood lead exposure.

A common theme stressed in each charge question response is that the economic and health benefits of preventing childhood lead exposure are joined. A few of these benefits include:

- Prevention of reduced intelligence quotient (IQ) loss in children and cardiovascular disease in adults.
- Health impact assessments have proven that exposure prevention is more effective than using children's blood lead levels as a method to guide hazard control efforts.
- Exposure prevention is shown to lead to greater societal savings because intellectual and behavioral consequences of lead exposures in children are far more costly than removing lead from their environments in the first place.

Additional areas of overlap between charge question responses include exposure to lead in consumer products and paint hazards in the home.

Full responses to charge questions 1 – 3 can be found in Appendix B, Appendix C, and Appendix D respectively. Immediately below, please find a condensed

summary of all three charge question responses with a brief note on overlapping themes.

Sincerely,

Shirlee Tan, Ph.D.
Chair

cc: Grace Robiou, Director, Office of Children's Health Protection
Amelia Nguyen, CHPAC Designated Federal Officer, Office of Children's Health Protection

# Summary Recommendations

## Charge Question 1 (see Appendix B)

1. **Determining Sources of Lead Exposure**

    - Emphasis on combining environmental sampling with local blood lead level surveillance.
    - Leveraging of data and support from nearby localities and higher resourced countries to inform local investigations ensures iterative and ongoing evaluation of available data.
    - Case Study Example 1: Data from Other Localities that can Inform Local Investigation.
    - Case Study Example 2: Iterative and On-Going Evaluation of Available Data.

2. **Testing Methods**

    - Highlighted testing methods for lead include virtual assessments, home water pipe scratch tests, colorimetric swabs, X-ray fluorescence (XRF), and the EPA's Inductively Coupled Plasma Mass Spectrometry Method.
    - Case Study Example 1: Spice Testing Method.
    - Case Study Example 2: Low-Cost Hazard Reduction Techniques.

## Charge Question 2 (See Appendix C)

1. **Overview of U.S. Laws and Regulations**

    - Federal, state, and local governments may regulate lead exposure through statutes, regulations, or guidelines.
    - In general, the most effective policies to reduce childhood lead exposure are those that mandate removal of the sources of such exposure before children develop high blood lead levels.
    - Enforcement is an ongoing challenge for under-resourced jurisdictions, even with regulations in place.

2. **Lead in Housing**

    - Lead in residential paint was federally banned in the U.S. in 1978. Known lead hazards in pre-1978 housing must be disclosed to prospective home buyers and in most rental properties at the time of property transfer.
    - Many state and local laws/programs aim to reduce home lead exposure.

3. **Lead in Consumer Products**

    - Various federal, state and local laws regulate lead in cookware, cosmetics, jewelry, spices, toys, and dietary supplements.

- Case Study Example 1: Addressing Lead Adulteration in Spices: Case Studies from the Republics of Georgia and Bangladesh.
- Case Study Example 2: NYC Approach to Addressing Hazardous Consumer Products and Enforcing Elimination of Lead-Containing Consumer Products.

4. **Sharing Information**

- UNICEF should consider creating a database of laws and regulations, including plain language descriptions and culturally relevant information.
    - A resource to help people understand what agency in their country regulates lead in consumer products is also recommended.

## Charge Question 3 (See Appendix D)

1. **Environmentally Sound Management of Lead in Batteries**

- A recent publication by the United Nations (UN) Environment Programme provides excellent advice (and case studies) for the management of lead in battery recycling (formal and informal settings).
- Countries (e.g., the U.S.) are sending batteries to LMICs. Testing has repeatedly shown issues with lead and arsenic soil contamination in communities around lead recycling plants. The CHPAC recommends following guidance such as those from the Centers for Disease Control and Prevention (CDC) to reduce exposure in those living near lead recycling plants.

2. **Lead Exposure Prevention During Pregnancy**

- Federal and state guidance exists to prevent lead exposure during pregnancy. These include guidance from the CDC, Michigan Department of Health and Human Services, and the Canadian government.
- Case Study Example 1: Evaluation of Potential for Take-Home Lead Exposures.

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**Appendix A – Charge Question**

# Children's Health Protection Advisory Committee

UNICEF Lead Toolkits: Charge Questions June 2024

Background:

In 2023, UNICEF established the Children's Environmental Health Collaborative, a multi-stakeholder initiative to protect children's environmental health globally. The purpose of the collaborative is to provide a platform to amplify the work of its partners around children's environmental health.

The objectives of the Collaborative include:

1. Ensuring that children's environmental health is a priority at the national and global levels
2. Sharing data, tools, and educational materials to allow for evidence-based action
3. Bridging the gap between knowledge and action

As part of the Collaborative, UNICEF, in partnership with U.S. federal agencies and other stakeholders, is developing a toolkit to address childhood lead exposure in low- and middle-income countries (LMICs). The toolkit will focus on building national capacity for action in LMICs and will cover a variety of action areas including, but not limited, to:

1. Identifying sources of lead exposure
2. Developing capacities to protect children
3. Communicating about lead
4. Eliminating the sources of lead exposure
5. Developing a country-specific strategy to address lead poisoning

Each tool will be:

- Initially, a concise PDF document drawing from existing resources and expertise. The document will include case-studies, links to global guidance and other resources relevant to the action area. Each tool can be accompanied with an expert video introducing the toolkit.
    - However, the tools will evolve based on feedback from LMICs and other stakeholders (e.g., 15 UNICEF countries implementing children's environmental

programs).

- Hosted on the UNICEF-led Children's Environmental Health collaborative website.

*The toolkit will build on existing resources such as:*

- UNICEF's "Five actions to end childhood lead poisoning" document and country benchmarking survey.
- EPA's Local Lead Action Plan Guide.
- NYC Health Department consumer product resources.

Currently there are plans on developing 10-12 tools as part of the toolkit to address the topic areas above with the goal of releasing six by the end of calendar year 2024.

EPA's role:

The Office of International and Tribal Affairs is coordinating EPA/USG's support to UNICEF on developing this toolkit. This work aligns with EPA priorities as outlined in EPA's Lead Strategy and the Priority Activities Report of the President's Task Force on Environmental Health Risks and Safety Risks to Children (PTF). For example, this toolkit connects with the PTF short-term priority action of the International Lead Exposure Working Group (ILEWG). Both documents cite EPA's work globally to provide guidance to eliminate lead paint and reduce other lead sources, including providing guidance and legal drafting assistance to develop laws to protect children from lead-based paint. This is underscored by the EPA and USAID Administrators signing a Memorandum of Understanding in March 2024 formalizing joint commitment to cooperate in tackling a number of challenges including building capacity in LMICs to reduce sources of lead.

Further, as a partner of the Children's Environmental Health Collaborative, the Office of Children's Health Protection has committed to collaborate on a number of activities including providing technical assistance, expertise and technical resources on children's environmental health topics, (e.g., development of the toolkit).

The charge questions described below are also responsive to the Children's Health Protection Advisory Committee's (CHPAC) February 2024 letter to the EPA Administrator on lead and community engagement. In the letter, CHPAC recommends the Agency enhance external lead collaboration, in turn, encouraging other organizations to locally take measures to reduce lead exposure in children, drawing from lessons learned in EPA actions and building on information disseminated by the EPA. One of the purposes of the tools is to identify existing EPA resources which can be adapted for use in LMICs including the 3Ts for Reducing Lead in Drinking Water, Lead Awareness Curriculum, and resources by EPA partners such as the Pediatric Environmental Health Speciality Units. For example, the core concepts of the current

work being done by the Office of Chemical Safety and Pollution Prevention on community lead awareness and education may be adapted for use in LMICs. The recommendations provided by the CHPAC on the select tools would help the EPA showcase how its best practices for lead exposure reduction in children could be adapted by LMICs.

Children's Health Protection Advisory Committee (CHPAC) Charge:

The EPA is soliciting the CHPAC's expertise on the questions below in order to help inform EPA contributions to the content of the following three specific tools relevant to LMICs:

Tool A: Source assessment

Tool B: Environmental standards, laws, and regulations

Tool C: Environmentally sound management of lead

The formal charge questions are listed below by tool:

TOOL A: SOURCE ASSESSMENT

*Charge question:*

Based on lessons learned in the U.S., what evidence-based information resources could help LMICs:

- Determine sources of lead exposure?
- Test lead in the environment (air, water, soil) given limited resources or testing infrastructure?
- Address lead hazards that might be present in the home?
- Determine the options for product substitution (e.g., lead used in spices, religious/cultural uses, and cosmetics)?

TOOL B: ENVIRONMENTAL STANDARDS, LAWS, AND REGULATIONS

*Charge question:*

- Are there examples of U.S. local and state laws and regulations to address the various sources of lead poisoning such as paint, ceramics and pottery, children's toys, cosmetics, spices, cookware, and traditional medicines, which may serve as a model for LMICs?
    - Are there examples of how to enforce such lead laws and regulations in under resourced communities?

- How can information about these laws and regulations be shared with the public and the regulated community in an easily understood and digestible manner?

TOOL C: ENVIRONMENTALLY SOUND MANAGEMENT OF LEAD

*Charge question:*

- Based on the U.S. experiences, what information and/or resources could help LMICs ensure environmentally sound management of lead in industrial applications, especially the battery recycling industry, to reduce exposure to children?
- What information and/or resources on health guidance could be considered by LMICs to reduce the risk of lead exposure in children, pregnant workers, and workers of reproductive age when working with products where lead is a required component?

## Appendix B – Full Response to Charge Question 1

**Charge Question 1**

**TOOL A: SOURCE ASSESSMENT**

**Based on lessons learned in the U.S., what evidence-based information resources could help LMICs:**

- **Determine sources of lead exposure?**
- **Test lead in the environment (air, water, soil) given limited resources or testing infrastructure?**
- **Address lead hazards that might be present in the home?**
- **Determine the options for product substitution (e.g., lead used in spices, religious/cultural uses, and cosmetics)?**

Recommendations for Charge Question 1 are organized under two categories (see below). Resources to address in-home lead hazards and determine options for product substitution are included with the case examples below.

1.1 Determining Sources of Lead Exposure
1.2 Specific Testing Methods

### 1.1. Determining Sources of Lead Exposure

The CHPAC suggests that when a LMIC is devising a national or subnational source assessment program, the strategy include an emphasis on:

1. A combination of environmental sampling with surveillance blood samples.
2. Consideration of data from other localities to inform local investigations.
3. A commitment to iterative and on-going evaluation of available data, if possible, by leveraging resources from higher resourced countries that are in close proximity or are a destination for many people from the specific country of origin. For brevity, below we offer several salient case examples to support these recommendations.

CHPAC stresses that the only way to identify children with high blood lead is to test blood levels through venous or capillary testing. If resources are limited for robust blood lead surveillance, testing should be prioritized for children in locations or situations where lead risks are highest, and results should be utilized to develop interventions that can be broadly applied to protect children in those locations from further exposures regardless of blood testing status. Risk assessment questions can be used as an educational tool to encourage parents, pediatricians and communities to be aware of need for blood lead testing and methods to reduce exposures to potential sources of lead but should not be offered as a replacement for blood lead testing (e.g., King County risk checklist). Some clinical guidelines such as the one developed for NYC are based on extensive iterative input from blood lead testing and these types of risk assessment questions can be used to complement recommended blood lead testing to determine need for additional testing.[1] As possible, blood lead testing and educational outreach to communities should be guided based on known regional or local sources (summarized in the references provided) and consideration of historical international and local lead policy and practices that affect prevalence of potential sources (i.e. leaded gasoline and lead-based paint bans, e-waste importation, etc.).[2; 3] From that starting point, targeted environmental sampling can complement blood lead surveillance to identify hazards and develop specific clinical screening and testing guidelines as resources permit.

### *1.1.1. Case Study: Data from Other Localities that can Inform Local Investigation*

The NYC Department of Health and Mental Hygiene (DOHMH) is piloting a project to coordinate and implement multi-jurisdictional tracking of consumer products lead surveillance data via the NYC DOHMH tests consumer products, collected during investigations of lead poisonings and market sampling, for lead.[4] Certain consumer products are also tested for other metals such as arsenic, cadmium, and mercury. Spices have been a particular focus; the majority of lead-contaminated spices are hand-carried into the U.S. rather than officially imported.[5]

The dataset available via the NYC Open Data portal contains the laboratory results for the consumer products tested. This work is an outgrowth of a multi-organizational effort to identify consumer product sources of lead poisoning and work with international collaborators to eliminate them.[6-8] In some cases, the lead in a product is serving some function (e.g. increased weight of spices; religious origin connection (kohl, etc); user belief that its presence enhances the taste of food (lead-containing metal or ceramic cooking pots); these should be identified and addressed to support success of a substitution.

### *1.1.2. Case Study: Iterative and On-Going Evaluation of Available Data*

A 2022 publication in the Journal of Exposure Science & Environmental Epidemiology details a multi-year investigation in Washington state by the Hazardous Waste Management Program and the Public Health-Seattle & King County (PHSKC) in response to elevated blood lead levels detected among Afghan refugee children resettled in the U.S.[9] A subsequent 2024 publication describes the in-depth follow-up effort to evaluate metal cookware as a source of lead exposure and identifies stainless steel cookware as a safer alternative to aluminum, brass, and hindalium (an alloy of magnesium and aluminum with a small amount of chromium).[10] This work drove state legislation banning the sale of lead-contaminated cookware, is pushing for federal standards for cookware, and has alerted companies like Etsy and Amazon to remove certain leaded aluminum cookware from online markets.[11]

## 1.2. Specific Testing Methods

The CHPAC provides the following options to consider when developing an environmental testing strategy and prioritizing low-cost assessment. These include both non-quantitative and quantitative assessment methods. While lower resource testing approaches are desirable, no gold standard exists for self-assessment. As mentioned above, blood lead testing (capillary [less reliable but faster and more available] or venous [particularly for confirmatory levels]) is critical for surveillance and to identify sources which can help advance primary prevention efforts to avoid exposures at all.

- Virtual assessment:
  - The Green and Healthy Homes Initiative has developed a free virtual engagement toolkit. While this virtual approach cannot completely replace the need for in-home testing, it can accomplish a preliminary assessment and establish rapport and trust with families.[12]
  - Children's Mercy Kansas City in Missouri has a well-established virtual home assessment program for asthma that is also applicable to lead. The benefits include receptivity of families and lower personnel cost.[13]
- Scratch test for home water pipes as described in this Infographic “Check for Lead in Your Home Plumbing” from the Michigan Department of Health and Human Services.[14]
- Colorimetric swabs are endorsed by some jurisdictions, but swabs have higher false negative results than analytical analysis of dust wipe samples and may not be widely available due to suspension of some production.[15-17]

- XRF is a mobile method that is non-destructive. However, it is not as quantitative as analytical analysis and requires training for safe use and proper calibration.
- The gold standard for detection of lead in paint, dust, soil, water, and products is the EPA Inductively Coupled Plasma Mass Spectrometry Method SW6020 or Atomic Absorption Method SW7420 following acid digestion via EPA Method 3050.[18; 19] This method is destructive, so any items tested cannot be recovered after testing. This method requires a lab that is trained in analytical chemistry techniques and expensive equipment. Equipment maintenance is required, and sample analysis can be expensive for large numbers of tests.

### *1.2.1. Case Study: Spice Testing Method*

Given the emerging evidence of contaminated or adulterated spices as a common source of lead exposure, the international community is increasingly seeking lead assessment methods for powders and roots. No validated method exists for individuals to test their spices at home. Evidence suggests that major brands in the U.S. and to some extent abroad, are more likely to be lead free than small batch sources, but analytical testing remains the only way to be sure a spice product is lead free.[5; 20; 21] Studies assessing the efficacy of both portable X-ray fluorescence (pXRF) analysis and colorimetric testing have shown varying reliability particularly for products with under 30% lead which is concerning as those products can still represent an exposure risk.[22; 23] Analytical testing is the best way to identify spices with high lead levels. If a country has access to a testing laboratory, random sampling of products could reduce the likelihood of adulterated products. Policies aimed at preventing lead in spices at the source are most effective at removing adulterated sources (e.g., see case study on Bangladesh in response question 2)..[24]

### *1.2.2. Case Study: Low-Cost Hazard Reduction Techniques*

A number of resources are available that can help determine best approaches (e.g. paint stabilization, lead dust cleaning, encapsulation, etc.) for addressing known or suspected in-home lead hazards. One such resource is the Alliance for Healthy Homes Report: Innovative Strategies for Addressing Lead Hazards in Distressed and Marginal Housing: A Collection of Best Practices [Revised 2001].[25] Caution should be exercised to ensure that new materials being used (such as with frequent repainting) are not also lead contaminated. And cost assessment should consider durability of the control measures being considered.

## Appendix C – Full Response to Charge Question 2

**Charge Question 2**

**TOOL B: ENVIRONMENTAL STANDARDS, LAWS, AND REGULATIONS**

- **Are there examples of U.S. local and state laws and regulations to address the various sources of lead poisoning such as paint, ceramics and pottery, children's toys, cosmetics, spices, cookware, and traditional medicines, which may serve as a model for LMICs?**
- **Are there examples of how to enforce such lead laws and regulations in under resourced communities?**
- **How can information about these laws and regulations be shared with the public and the regulated community in an easily understood and digestible manner?**

This response considers these related charge questions together and offers examples under U.S. state and local law as well as instructive examples from other countries. We begin by providing a brief overview of laws, regulations, and other standards. We then discuss measures aimed at reducing exposure to lead from paint in residences and efforts to reduce lead exposure from consumer products, including case studies examining efforts by the Republic of Georgia and Bangladesh to reduce lead in spices and efforts in NYC to reduce children's exposure to lead in consumer products. We also consider challenges and limitations to the various approaches for addressing lead poisoning and note that the benefits of lead prevention make such efforts worthwhile. In general, the most effective policies to reduce childhood lead exposure are those that mandate removal of the sources of such exposure before children develop high blood lead levels.

Recommendations for Charge Question 2 are organized into five categories.

1.1 Overview of Potential Structures of Laws and Regulations
1.2 Lead in Housing
1.3 State and Local Laws Addressing Lead in Consumer Products
1.4 Benefits of Preventing Lead Exposure
1.5 Sharing of Laws and Regulations

### 1.1. Overview of Potential Structures of Laws and Regulations

To provide context for the committee's recommendations, this background section briefly describes laws and standards from the U.S.

The U.S. is organized under a system of federalism in which both the federal government and state governments may exercise oversight over lead contamination and poisoning. The states possess an inherent police power that includes the authority to protect public health and welfare, whereas the federal government may exercise only those powers enumerated in the U.S. Constitution. Local jurisdictions may also pass regulations or ordinances to further protect public health.

The federal and state governments may regulate lead poisoning through statutes, regulations, or guidelines. Congress and state legislatures enact statutes, which are relatively difficult to change. Executive branch agencies, such as the U.S. EPA, issue regulations and guidelines, which are easier to change but more vulnerable to judicial challenge. Regulations are legally binding and enforceable; guidelines are non-binding and unenforceable but can guide actors and also assist in implementing enforceable statutes and regulations.

Statutes, regulations, and guidelines often incorporate environmental standards—such as ambient standards, exposure standards, or emission standards. The specific standards chosen may depend on the context. For example, the CDC blood lead reference value for identifying children who would benefit from an individualized intervention is 3.5 micrograms per deciliter. The California Department of Public Health adopts the same standard as a basis for recommending clinical action and follow-up in adults. In comparison, guidance from the World Health Organization recommends 5.0 micrograms per deciliter as a trigger for reviewing a person's sources of lead exposure and taking actions to reduce exposure. The U.S. Occupational Safety and Health Administration's regulations set a much higher blood lead level—40 micrograms per deciliter—as the standard for excessive exposure in the workplace.

Strong laws and regulations are necessary but not sufficient to address lead poisoning, and the existence of legal standards does not ensure that those standards will be met. For example, lead content in new paint samples often exceeds legal limits.[26] One study found that of the 25 countries where paint was tested, at least 10 had laws or regulations in place banning the sale of lead paint. Compare id. Fig. 1 with World Health Org., Legally Binding Controls on Lead Paint. Convenience sampling methods found that all 10 of these countries had paints with lead levels >= 90ppm.

Enforcement is a particular challenge for under-resourced countries or countries without other environmental regulatory interventions.

Public health and environmental protection agencies have long relied on public awareness and education to supplement minimal enforcement of regulations in efforts to minimize lead exposure.

1.2. Lead in Housing

Much childhood lead exposure in the U.S. and worldwide comes from lead paint, especially among low-income children living in rental housing built prior to 1978. The U.S. federal government banned lead in residential paint in 1978, but deteriorating paint continues to expose children to lead in paint flakes and dust. Various laws and programs, some of which may be feasible to adopt in other countries and contexts, aim to reduce this exposure.

At the federal level:

- Federal laws and regulations require sellers and landlords of housing built before 1978 to inform prospective purchasers and tenants of lead hazards. Such disclosure requirements may have limited impact and be less effective for socially vulnerable prospective home buyers, who may have more limited resources, health literacy, and knowledge about the connections between the age of a house, the likelihood that the house has lead-based paint, and risks to human health.[27] Federally owned and federally assisted housing must comply with lead safety requirements, including inspections, maintenance, and hazard reduction.[28] The substantive requirement to reduce lead exposure in federal housing has been more effective in reducing blood lead levels than the mere disclosure requirement generally applicable to pre-1978 housing.[29]
- U.S. EPA regulations establish training requirements, standards, and enforcement mechanisms for renovations that disturb paint in pre-1978 buildings. [https://www.epa.gov/lead/lead-renovation-repair-and-painting-program]

At the state and local level:

- Some states and local jurisdictions maintain registries of lead-safe homes. Examples include:
    - Massachusetts

  - Rhode Island (registry will include all landlords and have information on lead-safe certification)
  - Alameda County, CA
  - Sacramento County, CA
  - Grand Rapids, MI
- Some states mandate lead hazard control measures. For example: Massachusetts: The owner(s) of a dwelling unit or residential premises containing dangerous levels of lead in any paint, plaster or other accessible structural material are required to obtain a Letter of Full Compliance or a Letter of Interim Control when a child younger than six years old resides therein, whether or not the residential premises have been inspected pursuant to M.G.L. c. 111, § 194.
- In some states, local laws also seek to influence property owners' maintenance decisions in high lead-risk housing [pre-1978 rental housing] by mandating inspections periodically, at unit turnover, if a young child or pregnant woman will reside in the unit, or upon tenant request. For a description of these local efforts, see[30; 31]
- Many states have programs that focus on screening children for elevated blood lead levels. While Federal law requires testing for children enrolled in Medicaid, many states rely on guidelines or best practices to encourage lead testing. Some states do require universal testing while others require targeted testing, but most states only recommend testing or have no testing requirements or recommendations at all.[31; 32] Testing requirements are typically enforced through health-care providers or upon school enrollment.[32] States that require testing as a precondition for school enrollment and that require reporting of metrics (measures of health care system quality) have higher testing rates.[33]
- California's Proposition 65 requires businesses with ten or more employees to warn Californians about significant exposures to chemicals that cause cancer, birth defects, or other reproductive harm. Such warnings put pressure on businesses to limit or eliminate the exposures and arguably enable people to make informed decisions about these exposures. The warning requirement may apply to apartments and other residential rental properties that have lead paint and pipes or other sources of lead.

1.3. State and Local Laws Addressing Lead in Consumer Products

Various federal, state and local laws regulate lead in consumer products, a sampling of which is listed below. Implementation and enforcement of these laws vary. The following discussion also includes detailed case studies of efforts to address lead exposure in different jurisdictions: adulterated spices in Georgia (Europe) and Bangladesh, and lead in consumer products in NYC.

**Cookware**

Washington state prohibits the manufacture, distribution, or knowing sale of cookware containing lead or lead compounds exceeding 5 ppm, beginning in 2026, and authorizes state regulators to lower this limit by regulation if a lower limit is feasible and necessary. Violations are subject to a civil penalty of up to $5,000. The U.S. Food and Drug Administration has guidelines for leachate tests of ceramic and metal dishware intended for food use, as well as silverware. See CPG Section 545.450-Pottery.

**Cosmetics**

The federal government recommends a maximum lead concentration of 10 ppm as an impurity in lip products and other externally applied cosmetics. Beginning in 2025, Washington state prohibits the manufacture, sale, or distribution of cosmetics containing intentionally added lead or lead compounds at 1 ppm or above. RCW 70A 560.020v.

**Jewelry**

California law prohibits the manufacture or sale of children's jewelry containing more than 100 ppm lead or a surface coating that contains more than 90 ppm lead. Cal. Health & Safety Code 25241.2(c). The law also restricts the manufacture or sale of non-children's jewelry based on the use of materials containing lead. Cal. Health & Safety Code 25241.2(a). The state has undertaken enforcement efforts against discount stores, department stores, gift shops, and vending machine operators.

New York law prohibits the sale of children's jewelry containing lead exceeding 100 ppm and requires a warning for children's jewelry containing lead between 40 ppm and 100 ppm. New York Environmental Conservation Law 37-0115.

**Spices**

New York's food safety regulations limit lead content in spices and authorize the recall of products exceeding specified limits. NYC's regulated limits for spices are based on a proxy limit from the amount of lead allowed in food additives from the Chemical Food Codex https://www.foodchemicalscodex.org/. State regulators have implemented the limits by screening samples with handheld XRF spectroscopy instruments, sending warning letters to those responsible for violations, and reaching out to retailers, importers, wholesalers, and manufacturers.[34]

**Food**

The U.S. FDA's draft guidance on lead in juice provides an action level for lead of 10 ppb in apple juice (the most commonly consumed juice by young children) and 20 ppb in other juices. The FDA's action levels are intended to inform industry as to the levels of contamination at which the agency regards foods to be adulterated. Id. The FDA's guidance on lead in candy recommends a maximum lead level of 0.1 ppm in candy likely to be consumed frequently by small children. The level of lead present is one factor the FDA considers in taking enforcement actions. Id.

**Toys**

The federal Consumer Product Safety Improvement Act prohibits the sale of toys and other children's products containing lead exceeding 100 ppm. 15 U.S.C. § 1278a. Paint and other surface coatings used for such products may not contain lead exceeding 90 ppm. 16 C.F.R. Part 1303. Manufacturers must certify that their products comply with applicable limits based on testing by a third party. 15 U.S.C. § 2063. See also Total Lead Content.

**Dietary Supplements and Herbal Medications**

Dietary supplements and herbal medications are loosely regulated in the United States (U.S.) by the U.S. Food and Drug Administration via the Dietary Supplement Health and Education Act of 1994 (DSHEA). This law places the responsibility for safety on the manufacturer. While the FDA has the authority to take action on dietary supplements or herbal medications that contain harmful chemicals, enforcement is not standard, and these products often contain lead as an adulterant or even active ingredient. The World Health Organization provides a guideline of 10 ppm limit for lead in herbal medicines and products on lead in dietary supplements. See WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.

India's Ministry of Ayush is responsible for developing education, research and propagation of traditional medicine and has developed guidelines for lead limits in Ayurvedic and other traditional medications via the Drugs and Cosmetics Act of 1940, updated in 2016, also using a 10 ppm limit.

Dietary supplements and herbal medications are often subject to unofficial global transport via travelers or person-to-person shipment and are often not reviewed by regulatory entities. This compounds the challenges of enforcement and underscores the importance of global lead regulations.

### *1.3.1. Case Study: Addressing Lead Adulteration in Spices: Case Studies from the Republics of Georgia and Bangladesh.*

**Introduction:**

Lead enters the food chain in two predominant ways. First, foods can be contaminated when lead is introduced unbeknownst to the grower, processor, or seller of the product. This occurs when produce is grown in contaminated fields, lead-contaminated dust settles on produce during transit or storage and is not washed before processing, and/or lead in grinding and other processing equipment is transferred to the product. In other cases, produce is adulterated by lead, or lead is intentionally introduced because it is thought to improve the end product. It can be added to enhance a color, for expected therapeutic properties, or to increase the weight of the product. While the literature is replete with cases of lead adulteration, few strategies to prevent it have been described. Here we describe two successful interventions that were implemented after more traditional regulatory efforts did not have the desired effect of lowering lead in these products.

**Republic of Georgia:**

In 2019, a representative sample of children in the Republic of Georgia identified that >= 40% of children 2-7 years old had blood lead levels ≥ 5 µg/dL. As a result, investigators conducted a study to determine sources of lead in the children's environments. In total, 25 homes and 4 bazaars across Georgia were studied. A total of 682 pXRF measurements were taken, including those from cookware (n = 53); paint (n = 207); soil (n = 91); spices (n = 128); toys (n = 78); and other media (n = 125) Also, 61 dust wipes and 15 water samples were collected and analyzed (Ericson et al. 2020).

Spice Pb measurements revealed lead concentrations 2,418 to 4,418 times acceptable levels. Median lead concentrations of all other media were found to be within internationally accepted levels, with a limited number of exceedances. Three of 78 toys exceeded the applied standard; four of 61 dust wipes exceeded the applied standard.[35]

This study was conducted in collaboration with the Georgia National Center for Disease Control, and the results were presented to the Director in 2019. As a result, a series of educational efforts were undertaken, including:

1. Investigators met with major spice producers and government officials to map the supply chain, including hubs of spice distribution and sale in the Republic of Georgia.
2. Technical training for food safety regulators was conducted for the Tbilisi's Food Safety Agency and regional government representatives on lead-adulterated spices and pigments, providing guidance on measuring lead in spice, the health hazards of lead, and the related Georgian law.
3. A brochure was developed and distributed to regulators and spice vendors in Tblisi and Batumi, both major spice-producing hubs.
4. Lastly, information on the spice adulteration problem in Georgia was shared with the public through social media.

Results from over 700 samples of spices collected across Georgia from 2020 to 2022 indicated that lead concentrations decreased over time. In the first and second sampling periods, 4 and 6% of samples had elevated lead concentrations, and this decreased to 1% by the last sampling period in 2022. This suggests that the efforts to educate government officials, spice producers, and the public has resulted in a decrease in the use of lead to enhance the color of spices.[36]

**Republic of Bangladesh:**

A series of studies conducted between 2012 and 2018 determined that turmeric was being adulterated with lead chromate pigments across Bangladesh and contributing to human lead poisoning.[37-40] Turmeric is popular in Bangladesh, and daily use is common. It was identified as the primary contributor to elevated blood lead levels among rural Bangladeshi women.[39] A subsequent nationwide investigation of the turmeric supply chain indicated that lead chromate pigments were being added to turmeric during processing at polishing mills to enhance the color and profitability of the roots.[38] The pigment was widely available in 2018 with unrestricted use, and there were no safe food-grade lead-free alternative colorants available in Bangladesh.[38]

In 2019, investigators collected 140 turmeric samples from nine turmeric-producing districts, and an additional 200 turmeric samples from two districts that are not major producers. On average, Pb concentrations were lower in the major turmeric-producing districts, with 11% of samples containing Pb in excess of the Bangladesh Standards and Testing Institution's limit of 2.5 μg/g Pb in turmeric,[21] compared to 26% in the smaller producing districts. The maximum Pb concentration of loose powder was 690 μg/g vs. 1152 μg/g Pb (larger vs. smaller districts, respectively).[38]

Between 2017 and 2021, a comprehensive strategy to reduce use of lead chromate to finish turmeric roots and powder was undertaken.[24] The intervention involved

1. Widespread dissemination of results of scientific studies identifying turmeric as a source of lead poisoning.
2. Public education for consumers and spice producers and sellers using public notices and in-person meetings about the risks of lead chromate in turmeric.
3. Collaboration with the Bangladesh Food Safety Authority to utilize a rapid lead detection technology to enforce policy against turmeric adulteration.

Following the interventions, the proportion of market turmeric samples containing detectable lead decreased from 47% pre-intervention in 2019 to 0% in 2021 ($n = 631$, $p < 0.0001$). The proportion of 33 spice mills with evidence of lead chromate adulteration decreased from 30% 2017 to 0% in 2021 ($p < 0.0001$).

Furthermore, a community-based intervention to reduce lead exposure among children and their caregivers in Bangladesh was effective in raising awareness and changing behavior at the individual and household level. Community health workers gave villagers information about lead and its adverse effects, along with specific recommendations to minimize exposure by avoiding purchases of risky turmeric, avoiding food storage in lead-soldered cans, avoiding consumption of soil or ash during pregnancy, and increasing consumption of foods that decrease lead absorption. Ensuring that behavioral recommendations were feasible, appropriate, and framed to align with caregivers' motivations to raise healthy children contributed to the success of the intervention.[41]

**Conclusion:**

Between 2010 and 2018, the Republic of Georgia adopted a series of lead and regulatory requirements to ensure food safety.[42] However, enforcement of these statutes was essentially non-existent when it came to adulterating spices with lead. In Bangladesh, the practice of polishing turmeric roots with lead chromate was widespread and had been ongoing since the 1980s despite laws forbidding it. As these studies indicate, laws and regulations are necessary but not sufficient to protect public health. In each of the countries described above, developing local data on the prevalence of lead in spices and its relation to blood was the first step. This was followed by widespread education for consumers, producers, sellers, government decision makers, and food inspectors. Enforcement through fines, destruction of adulterated product, and restriction of export provided a foundation for the educational activities.

### *1.3.2. Case Study: NYC Approach to Addressing Hazardous Consumer Products and Enforcing Elimination of Lead-Containing Consumer Products*

**Introduction:**

The scientific literature is replete with reports, case studies, and surveys that identify consumer products as potential sources of lead. These products range from traditional remedies and tonics to toy jewelry, lead contaminated cook and dishware, spices and cosmetics.[43] Many but not all of these products originate in African, Asian, and Central/South American countries and thus are found in the U.S. communities with strong connections to those areas. However, despite strong consumer protection laws in the U.S., some imported products slip into the formal commodity stream. These products have resulted in blood lead levels well above the current reference value of 3.5 µg/dL and have led to numerous cases of lead poisoning and its subsequent adverse impacts.

**Case Findings in NYC:**

In 2009, 24% of the lead-poisoned children interviewed by the NYC DOHMH did not have an identified lead-based paint hazard. During the same year, 15% of men and 89% of women with elevated blood lead levels reported potential non-occupational sources of lead exposure.[5]

**Intervention:**

The DOHMH responded to these findings by implementing the Intervention Model for Contaminated Consumer Products. Over the next few years, the program developed the Model and expanded the DOHMH' s ability to prevent exposure to these potential sources as well as to address current, ongoing exposures to children with high BLLs.[5] The Model has four basic components, including

1. Case finding using reports of assessments of children and adults with high BLLs, health alerts and reports from other jurisdictions, published literature, and media reports.
2. In-person investigations of stores likely to sell products from the same manufacturer, country of origin, and brand. If necessary, inspectors purchase the product and arrange for laboratory testing.
3. Enforcement of the NYC Health Code including production seizure and destruction.
4. Public education to consumers and the general public, businesses, health care providers, churches, and community partners through a variety of media outlets.

**Enforcement and Outreach:**

The NYC Health Code provides that "No person shall manufacture, produce, pack, possess, sell, offer for sale, deliver or give away any food, drug or cosmetic which is adulterated or misbranded." N.Y.C. Health Code § 71.05. The NYC DOHMH is authorized to seize or embargo products deemed dangerous to the public health. It can order businesses to cease sales and properly dispose of contaminated consumer products, including those containing lead. (Rules of the City of New York, Title 24, NYC Health Code §3.03.) This law predates the Model by some years, but enforcement was not consistent until implementation of the Model, which only became possible when a significant increase in resources were provided. Personnel were hired and trained to identify and remove products. Additional linguistically and culturally diverse personnel were needed to reach out to churches and other community-based organizations. The success of the Model also requires intense coordination across NYC agencies, and other local, state, and federal agencies. The Model has resulted in the removal of thousands of contaminated consumer products from local retail and wholesale outlets.

NYC's database of tested consumer products provides a valuable resource for the public, health care providers, regulators, and other jurisdictions to look up specific products and review prior testing done by NYC DOHMH. Efforts to expand this database to include products tested by other jurisdictions is underway, and a larger dataset can help inform decisions for other jurisdictions that may not have the resources to test concerning products.

In addition, NYC DOHMH has published a Technical Guide to "Investigating and Addressing Exposures to Lead-Containing Consumer Products" Investigating and Addressing Exposures to Lead-Containing Consumer Products - Technical Guide. The technical guide offers step-by-step practical guidance to identifying and analyzing lead-contaminated consumer products and conducting enforcement and outreach activities. Enforcement activities described include surveying local markets, identifying and exploring avenues for enforcement, reporting findings to relevant agencies and other stakeholders, and conducting education and outreach.

1.4. Benefits of Preventing Lead Exposure

While many of the efforts described above are labor- and resource-intensive, in addition to the health benefits, there are proven cost benefits of preventing lead exposure in children.

In the U.S., studies of the costs and benefits of associated with preventing childhood lead poisoning conducted since the 1980s have demonstrated that it is far more costly to allow children to be exposed to lead and suffer the intellectual and behavioral consequences than it is to remove lead from their environments. A recent health impact assessment undertaken by the Robert Wood Johnson Foundation found that the benefits of preventing exposure rather than using children's high blood lead levels to guide hazard control efforts results in the greatest savings to society. A suite of policies that would eliminate lead in water, lead paint hazards in homes, and leaded aircraft fuel -- and the widespread adoption of the EPA's lead safe work practices -- was estimated to save U.S. $84 billion for a one-year birth cohort whose blood lead level was never greater than zero.[44]

Two studies have focused on the costs of lead exposure in LMICs. Attina and Trasande evaluated a one-year cohort of < 5 year old children, finding total lifetime losses of $977 billion (2011 Purchasing Power Parity [PPP]) in LMICs.[45]

In a more recent study using less conservative estimates of the impact of lead and including adult health effects, Larsen and Triana-Sanchez estimated that 95·3% of the total global IQ loss and 90·2% of total

cardiovascular disease deaths (CVD) resulting from lead exposure? occurred in LMICs. Globally, the combined cost of IQ loss and CVD was U.S. $6·0 trillion (range 2·6–9·0) in 2019, which was equivalent to 6·9% (3·1–10·4) of the global gross domestic product.[46]

While these studies are compelling and provide evidence that the costs of lead exposure are comparable to other health conditions, more granular estimates, at least at the country level, would provide health and finance ministries with the evidence they need to create local awareness among public and officials on the need to implement lead exposure elimination policies in their jurisdictions.

1.5. Sharing of Laws and Regulations

The sharing of laws and regulations with the public and the regulated community is of utmost importance but will be challenging due to the diversity of a global audience. Differences in languages, cultures, customs, communication methods, and regulatory structures complicate the provision of such information.

One option would be for UNICEF to compile and maintain a database of laws and regulations that affected communities and the public can easily review. Organized by country, a brief description of each law or regulation should be provided to give readers a sense of whether the law or regulation might be relevant to their context, along with links to the laws and further information. Legal language should be minimized, with the descriptions of the laws and regulations in plain language. Consultation or input from the originating country would serve to help ensure the cultural nuances are included. The inclusion of more detailed case studies that illustrate workable and effective approaches to reducing lead exposure and poisoning would also be helpful. Illustrations and infographics improve the effectiveness and reach of public materials and could be considered as accompaniments to the written descriptions.

An additional helpful component in such a database would be information for helping people understand what agency in their country regulates lead in consumer products. This could be in a list format organized by country with internet links if available.

## Appendix D – Full Response to Charge Question 3

**Charge Question 3**

**TOOL C: ENVIRONMENTALLY SOUND MANAGEMENT OF LEAD**

- **Based on the U.S. experiences, what information and/or resources could help LMICs ensure environmentally sound management of lead in industrial applications, especially the battery recycling industry, to reduce exposure to children?**
- **What information and/or resources on health guidance could be considered by LMICs to reduce the risk of lead exposure in children, pregnant workers, and workers of reproductive age when working with products where lead is a required component?**

Recommendations for Charge Question 3 are organized under five categories:

1.1 Battery Recycling
1.2 Benefits of Preventing Lead Exposure in Children
1.3 Case Study: Evaluation of Potential for Take-Home Lead Exposures
1.4 Existing Guidance for Managing Lead Exposure During Pregnancy
1.5 Blood Lead Level Trends, Associated Factors, and Policy Implications in China

### 1.1. Battery Recycling

In the U.S., the Occupational Safety and Health Administration (OSHA) has an online training tool) covering safe battery manufacture, including Oxide and Grid Production, Plate Processing, Battery Assembly, Battery Repair and Reclaim, Environmental Controls, and Maintenance. The section on repair and reclaim reviews safe management of lead. This resource, however, is unlikely to be helpful for LMICs addressing informal battery recycling.

Regarding LMICs, however, the UN Environment Programme's own recent publication, *A Guidance Manual for Policymakers and Regulators for the Environmentally Sound Management of Waste or Used Lead Acid Batteries in Africa*, provides excellent advice (and case studies) for the management of lead in battery recycling (in both formal and informal settings). This resource is available in English and French.

This study reviews some of the issues seen in communities around lead battery recycling facilities and uses baby teeth analyses to assess for exposure. The researchers found there was a correlation between high lead and arsenic in baby teeth and higher levels in soil around their residence, in the community near a large battery recycling facility.[47]

Countries such as the U.S. are now sending batteries to countries with less stringent environmental and worker protections. Testing has repeatedly shown issues with lead and arsenic soil contamination in communities around lead recycling plants. The CHPAC recommends following guidance such as recommendations from the CDC to reduce exposure in those living near lead recycling plants.

### 1.2. Benefits of Preventing Lead Exposure in Children

In the U.S., studies of the costs and benefits of associated with preventing childhood lead poisoning conducted since the 1980s have demonstrated that **it is far more costly to allow children to be exposed to lead and suffer the intellectual and behavioral consequences than it is to remove lead from their environments.** A recent health impact assessment undertaken by the Robert Wood Johnson Foundation found that the benefits of preventing exposure rather than using children's high blood lead levels to guide hazard control efforts results in the greatest savings to society. A suite of policies that would

eliminate lead in water, lead paint hazards in homes, aircraft fuel, and the widespread adoption of the EPA's lead safe work practices was estimated to save U.S. $84 billion for a one-year birth cohort whose blood lead level was never greater than zero.[44]

Two studies have focused on the costs of lead exposure in LMIC. Attina and Trasande evaluated a one-year cohort of < 5-year-old children, finding total lifetime losses of U.S. $977 billion (2011 Purchasing Power Parity [PPP]) in LMICs.[45] In a more recent study using less conservative estimates of the impact of lead and including adult health effects, Larsen and Triana-Sanchez estimated that 95·3% of the total global IQ loss and 90·2% of total CVD from lead exposure occurred in LMICs. Globally, the combined cost of IQ loss and CVD was U.S. $6·0 trillion (range 2·6–9·0) in 2019, which was equivalent to 6·9% (3·1–10·4) of the global gross domestic product.[46]

While these studies are compelling and provide evidence that the costs of lead exposure are comparable to other health conditions, more granular estimates, at least at the country level would provide health and finance ministries with the evidence they need to create local awareness among public and officials on the need to implement lead exposure elimination policies in their jurisdictions.

The EPA should promote the inclusion of guidance and resources regarding preventing and mitigating take-home (or para-occupational) lead exposures among the families of those who work in industries known to involve lead. Such guidance might involve recommending that workers wear appropriate personal protective equipment, that they shower and/or change into clean clothes after working and before entering their home, that work clothes are washed separately from other laundry, and that work shoes be left at the door of the house and not worn inside (see example here). Industries where take-home lead exposures have been documented include electronic scrap recycling, battery recycling, battery smelting, and lead oxide manufacturing. See examples here and here.

The toolkit could include potentially effective approaches towards preventing and addressing take-home exposures: educational sessions as well as incorporation of exposure controls in the workplace and cleaning/remediation of workers' vehicles and homes. See examples here and here.

1.3. Case Study: Evaluation of Potential for Take-Home Lead Exposures

In 2018 – 2022, a pilot program was launched in two counties in Michigan to investigate the county-wide potential for take-home lead exposures across relevant industries. The assessment included the administration of a questionnaire on workplace practices and the wipe sampling of lead dust from workers' vehicles, which revealed the ubiquitous tracking of lead dust out of workplaces. The program was conducted by a single environmental sanitarian, supporting the feasibility of this approach even in the context of limited resources. While the quantification of wipe samples is reliant on analytical instruments, the program could be administered using only a questionnaire if utilization of an analytical laboratory is not possible. Guidance for health departments or other agencies for operationalizing similar programs based on the approach of this pilot was developed, and similar guidance could be incorporated into the UNICEF toolkit and paired with resources for controlling and intervening in take-home exposures as described above. A County-Level Program for the Evaluation of the Potential for Take-Home Lead Exposures Among Children in Michigan - PMC (nih.gov) and Take Home Lead Protocol(1).pdf (msu.edu)

In communities where there is known lead contamination, or where industries use lead, efforts should be made to protect those who are most vulnerable. Children, pregnant workers (and their fetuses), and workers of reproductive age can all be impacted by community use or recycling of lead. To minimize the risk of lead exposure, strategies to decrease take-home exposures should be employed as above. In the

home, steps to decrease the ingestion of dust should be employed, including damp mopping and washing hands with clean water prior to cooking or eating. Strategies to decrease lead absorption include good nutrition, including supplementation with iron and calcium. When a child or pregnant person has been identified as having an elevated lead level, it is reasonable to assume that other family members may as well.

1.4. Existing Guidance for Managing Lead Exposure During Pregnancy

U.S. CDC guidance on lead and pregnancy/childhood:

- Guidelines for the identification and management of lead exposure in pregnant and lactating women (cdc.gov) (guidance doc).
- Are You Pregnant? | Childhood Lead Poisoning Prevention | CDC
- ¿ESTÁ EMBARAZADA? PREVENGA LA INTOXICACIÓN POR PLOMO EMPIECE AHORA (cdc.gov) (*are you pregnant* en Espanol).

Michigan Dept of Health & Human Services:

- Take-home Lead: A Preventable Risk for Your Family (michigan.gov)

Resources from Canada:

- Website for public education
- Example of a municipal programme for consumers
    - Lead in Your Drinking Water | City of Hamilton
- Canadian provincial resource with a lot of good resources
- Example of provincial municipal regulation
- Link to the Canadian Water and Air Quality

1.5. Blood Lead Level Trends, Associated Factors, and Policy Implications in China

See the following references for further information regarding lead policy and outcomes in China.[48-51]

Potential regional sources of lead exposure in LMICs (from UNICEF's own *Assessing Environmental Lead Exposure in Resource-Constrained Settings*):

**Table 1: Regional sources of lead exposure identified in the literature compiled from multiple sources**

| Subregion | Identified sources of lead (Pb) exposure |
|---|---|
| Eastern Africa | automobile repair; battery manufacture or recycling; dietary sources, including spices; mixed industrial sources |
| Middle East and North Africa | automobile repair; battery manufacture or recycling; ceramics; cosmetics; dietary sources, including spices; mining and smelting; mixed industrial sources |
| Southern Africa | mining and smelting; mixed industrial sources |
| Western Africa | automobile repair; battery manufacture or recycling; cosmetics; e-waste recycling; lead-based paint; mining and smelting; mixed industrial sources |
| Caribbean | battery manufacture or recycling |
| Central America | battery manufacture or recycling; ceramics; mining and smelting |
| South America | battery manufacture or recycling; ceramics; dietary sources, including spices; lead-based paint; mining and smelting; mixed industrial sources |
| Central Asia | mining and smelting |
| Eastern Asia | battery manufacture or recycling; dietary sources, including spices; e-waste recycling; mining and smelting; lead-based paint; mixed industrial sources; traditional medicines |
| South-Eastern Asia | battery manufacture or recycling; ceramics; dietary sources, including spices; mining and smelting; mixed industrial sources |
| Southern Asia | automobile repair; battery manufacture or recycling; cosmetics; dietary sources, including spices; lead-based paint; mining and smelting; mixed industrial sources; traditional medicines |
| Western Asia | aluminum cookware; automobile repair; battery manufacture or recycling; ceramics; dietary sources, including spices; mining and smelting; mixed industrial sources |
| Eastern Europe | mixed industrial sources |
| Southern Europe | mining and smelting; mixed industrial sources |

Source: Ericson et al., 2021; Obeng-Gyasi, 2019; Hore et al., 2019.