Investigating and Addressing Exposures to Lead-Containing Consumer Products

Technical Guide

For more information on these types of consumer products, visit nyc.gov/hazardousproducts. Visit Metal Content of Consumer Products Tested by the New York City Department of Health and Mental Hygiene | NYC Open Data for NYC products testing data.

NYC Health

Navigating the Manual

Background

Despite declines in blood lead levels of children and adults in the United States (U.S.), lead exposures still occur. Evidence of adverse health effects from low levels of lead exposure continues to grow.

In children, lead exposure can negatively impact learning and behavior. For adults, exposure can increase risk of hypertension, kidney disease and cognitive function and result in adverse reproductive outcomes. Exposure during pregnancy can cause high blood pressure and miscarriage and can affect the fetus.

Because of the many harmful health effects of lead exposure, prevention is the most effective measure of protection.

Lead-based paint and occupational lead hazards are commonly identified sources of lead exposure among children and adults who work in the construction industry, respectively. Additionally, across regions, and in varying degrees, lead in soil and water may also contribute to exposure. While these traditional sources may be familiar, there is increasing concern about exposure from lead-containing consumer products. Certain foods, spices, health remedies, traditional cookware/dishware, and cosmetics and cultural powders from around the world have also been associated with elevated blood lead levels in children and adults.

As lead poisoning prevention programs across the country investigate and respond to exposures associated with use of such lead-contaminated consumer products, remedial approaches should be systematic, functional and effective. This can have implications for the integrity of data collection and application, as stronger data can translate to informed policies to protect consumers nationally and internationally from lead-contaminated consumer products.

This document provides technical assistance for the identification, collection, analysis and data interpretation of lead-contaminated consumer products based on information compiled from publications, national alerts and jurisdictional reports. It also provides strategies for education and outreach to stakeholders. Please note that the information provided in this document is only meant to serve as a guide for lead poisoning prevention programs.

Step 1: Identifying Lead-Contaminated Consumer Products

I. Building a knowledge base

The potential for consumer products to contain lead — and other harmful metals — has been known for some time. Over many years, lead poisoning cases associated with the use of lead-contaminated consumer products have been investigated nationally and abroad. These product categories can vary, but they can include certain foods, spices, health remedies, traditional cookware/dishware, cultural powders, toys and jewelry/amulets/charms from around the world *(*Table 1*).* Lead may be unintentionally or intentionally added to these consumer products during manufacturing or processing, or it may be a component of the product itself. It can be difficult to tell whether a product contains lead without laboratory testing, as lead is generally not listed as an ingredient on the product (label).

Lead may be intentionally added to certain products (for example, for perceived therapeutic benefits, as a coloring agent, to add weight to products sold by weight), or inadvertently added along the supply chain (for example, lead contamination of soil where raw ingredients are grown, poor processing equipment).

Table 1. Types of consumer products found to contain elevated lead levels in New York City (NYC)

Product Category	Examples	Potential Uses	Primary Exposure Pathway(s)
Foods	• Candies, snack mixes that use chili or fruit pulps ([for example, chapulines, mole, preserved fruits] Mexico) • Chocolates (Ecuador)	Food/snack items	Ingestion
Spices	• Spices purchased abroad (South Asia, Morocco and the country of Georgia)	Culinary	Ingestion
Health Remedies	• Rasa Shastra Ayurvedic medicines (India) • Traditional Chinese medicines (China) • Calabash Chalk (West Africa) • Tierra Santa/Panito del Señor (Mexico) • Litargirio (Dominican Republic)	Various indications (for example, reproductive, well-being, neurological, digestive, and so on)	Ingestion

Product Category	Examples	Potential Uses	Primary Exposure Pathway(s)
Traditional Cookware/Dishware	• Traditional/handmade ceramicware (Mexico, Ecuador, Turkey, Morocco and Uzbekistan) • Traditional "Kansa"/brass ware (South Asia)	Prepare, cook, serve or store food and drinks	Lead can leach into food or drinks
Cosmetics and Cultural Powders	• Kohl, Kajal, Surma and Tiro (South Asia, Africa and the Middle East) • Sindoor, Tika and Kum Kum (South Asia) • Litargirio (Dominican Republic)	Religious, cosmetic, cultural and medicinal purposes	Hand-to-mouth contact
Toys/Novelty Items	Metal/painted parts of toys and novelty items ([for example, maracas] Mexico)	Items for play, decorative or novelty purposes	Mouthing/ ingestion
Jewelry/ Amulets/ Charms	Metal/painted parts of: • Jewelry • Amulets ([for example, sheesha, tabiz or other metal charms] Bangladesh)	Adornment, speech therapy, good luck and protection	Mouthing/ ingestion

Note: For more information visit, nyc.gov/hazardousproducts.

II. The risk assessment interview

Information on potential lead-containing products can be obtained from a variety of resources. Investigators can learn of these types of products from alerts and reports from national, state and local agencies, alerts from incident reporting agencies (for example, poison control centers) and peer-reviewed or gray literature.

In addition, investigators can identify such products during lead poisoning case investigations. The lead poisoning case investigation process is critical in addressing and reducing exposures to lead. These procedures may vary by program, but they should include an interview component. The interview presents an opportunity for the lead poisoning case investigator to assess possible sources of exposure, which ensures that all contributors are accounted for and, ultimately, that the source of exposure is identified and mitigated.

More holistically, information extracted from the interview can prove vital in expanding the knowledge base around lead exposures, such as newly identified products of concern, emerging at-risk populations and usage and behavioral patterns. It can also inform intervention efforts.

To best achieve this, the development and use of a standardized risk assessment questionnaire is advised. At minimum, the questionnaire should be designed to capture information about potential lead exposure risk factors:

Category	Example Variables
Demographics	• Ethnicity • Country (and region) of birth - If foreign birth, number of years in the U.S. • Primary language • Educational background
Medical Information	• Previous history of elevated lead level(s) • Health insurance availability and type
Occupation and Hobbies	• Job type (of case [if applicable] or household members) • Hobby type (of case [if applicable] or household members) • Duration of employment in industry/engagement in hobby • Use of personal protective equipment
Paint and Nonpaint hazards	• Environmental (for example, peeling/damaged paint) • Use of imported/cultural products • Mouthing or ingestion of nonfood items (pica) • Gunshot injury
Other	• Recent immigrant • Broken bones • Consumption of game meat from animals hunted using leaded ammunition

The risk assessment interview process can also present some challenges. Barriers including language and cultural differences, cross-cultural consumerism, distrust of governmental officials, subjective perceptions of “risky” products, stigma associated with the use of certain products and general miscommunication — particularly if a product has multiple names or uses — can all contribute to difficulty in the identification of exposure sources and may eventually interfere with the lead poisoning case investigation. To overcome these challenges, the following strategies can be employed:

Strategies to enhance the exchange of information and to encourage behavior change during the lead poisoning case interview

Apply cultural sensitivity: Aim to be culturally sensitive and nonjudgmental. Increase your familiarity with the customs and cultures of the case family. This can be critical for gaining trust and obtaining valuable information.

Frame the concern and resolve ambivalence: Explain how lead exposure can harm the health of family members. Emphasize that you are there to help. Assure the family that they will not get in trouble for cooperating during the interview (for example, concerns about immigration status, child protective services, and so on).

Enhance intrinsic motivation: Emphasize the importance of reducing lead exposure. Be specific when possible and provide (linguistically and culturally appropriate) supporting materials when available. Be willing to explore potential exposure information the parents/guardians provide, even if you consider the source to be unlikely. At the least, this can help build partnership with the family in solving the problem.

Ask general questions before probing further: For instance, when trying to assess potential medications as a source of lead exposure, you may want to ask if case uses any products for their health. Follow-up by asking probing questions in multiple ways to help extract more detailed information. Probing is critical for identifying new lead sources. Ask questions multiple times and phrased differently.

Be informed: Review reports of previously documented lead-containing products. As much as possible, be familiar with terms used to refer to a product.

Address cultural products with sensitivity and information: When trying to communicate prevention messaging associated with culturally sensitive products, provide (linguistically and culturally appropriate) supporting materials, when possible, to supplement recommendations to stop use.

Present an alternative: Suggest use of an acceptable substitute. However, if this is not possible (typically due to cultural or religious significance of the product), provide risk management guidance, while reminding the family of the importance of eliminating lead exposure sources.

Encourage blood lead monitoring: Encourage follow-up blood lead monitoring, particularly if the source of exposure cannot be eliminated (for example, use of culturally or religiously significant product).

Be perceptive: This is relevant in instances where the case interview is conducted in person or during a home visit. Watch for potential lead sources and risky behaviors (for example, mouthing nonfood items or hand-to-mouth actions). Additionally, be aware of body language. Maintaining eye contact and having an open posture can help with expressing empathy and engaging the case.

Step 2: Sampling Lead-Contaminated Consumer Products

If a product, which may be mouthed or ingested, is suspected to be a source of lead exposure during the risk assessment interview, a sample of the item should be collected for lead measurement, whether via laboratory testing or screening (for example, using X-ray fluorescence technology or 3M™ LeadCheck™ Swabs). It is important to have

standardized sample collection protocols in place to gather critical information for each sampled product (for example, brand name, product description, usage information, manufacturer, purchase source, and so on). It can help to identify potential source(s) of lead exposure for the individual case(s), assess whether there is a risk for lead exposure from the source(s) and provide insight on how to eliminate or reduce exposure to the source(s). Additionally, integrating a standardized sample collection process into the lead poisoning case investigation can help to identify trends in product use associated with elevated blood lead levels. Detailed documentation of product information can also inform enforcement activities, whether local or federal. Information gathered from each of these steps are essential in developing specific intervention strategies and reduce lead exposures in the future.

I. Determining which samples to collect

Selecting which samples to collect during case investigations can be challenging; however, the following strategies can be used as a guide:

Strategies to Inform the Sample Collection Process

Apply historical knowledge: Ask about use of products historically known to contain high levels of lead. In addition, ask probing questions on use of foreign-purchased or imported products for health, food, cultural or other purposes. Products that are regulated in the U.S. by a federal agency are less likely to be of concern (for example, prescription, allopathic medications, drugstore cosmetics).

Establish linkage of product to the case: Did the case come into contact with the product? Focus on products that are consumed, put in the mouth or used on/by the case in a way that could result in ingestion or hand-mouth exposure (for example, foods, medications, easily dispersible products, like topically applied, fine powders).

Consider routes of exposure*:* Lead is well-absorbed via the gastrointestinal tract. Skin is a good barrier for lead; however, hand-to-mouth exposure can occur with certain products (for example, topically applied, fine powders). Inhalation is not a likely exposure pathway for lead-contaminated products unless such products are burned.

Assess usage patterns: Evaluate case's product use pattern — was the product used recently or on a routine basis resulting in dietary or nondietary ingestion? Also, consider frequency and duration of reported usage in relation to when blood lead level was measured.

Questions to consider:

- Was there contact between the case and the product in question?
- Does the time frame of exposure to the product match the time frame of the elevated blood lead report?
- Has there been exposure to enough amounts to cause the associated elevated blood lead level?
- What was the frequency and duration of the contact?
- Has the product been ingested or mouthed? Is there potential for ingestion or mouthing?

- Is the product a fine powder that is topically applied? Is there potential for hand-to-mouth exposure?
  Where did they get this product? Was it purchased abroad?
- If more than one person in the household is poisoned, what products do they have in common?

II. Collecting and preparing samples for analyses

Once the case investigator has identified samples for collection, they should be collected and processed appropriately for lead analyses. At minimum, this involves collecting sample aliquots, assigning unique sample IDs, photographing the samples and completing appropriate documentation. For each of the samples being collected, some steps to complete are described below:

1. Transfer the product or an aliquot of the product into a clean sampling tube or bag. Take precautions to avoid cross-contamination.

- □ Wear gloves when handling samples.
- □ Collect samples in individual sampling tubes or bags.
- □ Liquid or powder samples should be shaken thoroughly before placing in sampling tubes/bags.
- □ Collect adequate aliquots of samples (for example, if available, 1 to 2 tablespoon of dry powder, 10+ pills or tablets and 5+ mL of liquid). Check with the laboratory for guidance as needed.
- □ When using a sample collection device to collect samples (for example, using a spoon to collect a powder sample), use a new collection device or clean the device before collecting the next sample to avoid cross-contamination.

Sample collection supplies may include:
- ✓ Gloves
- ✓ Sampling tubes and bags
- ✓ Marker
- ✓ Sampling device (for example, spoon, pipette)
- ✓ Camera
- ✓ Disposable wipes

2. Label sampling tube or bag with a unique sample ID

- □ Each sampling bag or tube should be labeled legibly with a unique sample ID. (Verify sample ID has not been used previously.)
- □ Avoid labeling in batch; instead, label each sample with the sample ID immediately after collection. Doublecheck to ensure sample ID matches the corresponding sample.

3. Complete a product sampling form

- □ Standardized documentation and archiving of product-related information can help with the case investigation process from identification to enforcement.
- □ At minimum, systematically document the information below for each sample collected during the investigation:

Variable	Details
Case ID	A unique identifier assigned to the case for sample tracking.
Sample ID	A unique identifier assigned to samples.
Sample Collection Date	Date the sample was collected.
Owner Type	Specify whether sample was collected as part of a case investigation or survey of local shops. If case investigation, specify whether child or adult. If the latter, specify whether nonpregnant or pregnant.
Sample Type	Sample type categories may include foods, spices, health remedies, traditional cookware/dishware, cosmetics and cultural powders, toys/novelty items and jewelry/amulets/charms. There may also be additional categories that may vary with location. A small number of miscellaneous products may best be classified as “other.”
Product Name	Name of product as listed on packaging or how the case refers to the product. If a common name is not available for the product, obtain the best anecdotal name from the case.
Brand Name	Brand name/marketing name/trade name/other brand identifier as written on product package.
Manufacturer Name	Name of manufacturer, as written on product package.
Country of Manufacture	Country where product was manufactured, as written on product package.
Product Details	May include lot number, batch number, date of manufacture and expiration or other product identifiers.
Product Description	Physical description of the product (for example, “ground spice,” "yellow root," " brass bowl," and so on).
Product Usage	How case/family reports using the product (for example, “for fertility,” “for well-being,” “for cooking,” and so on).
Amount Used	Amount of product used by case during a specified period (for example, number of teaspoons of spice per day, number of tablets per day, and so on).
Duration of Use	Timeframe of when the product use started and when last used.
Purchase Source	Type of retail venue from which product was purchased (for example, supermarket, botanicas, online, and so on) or how product was obtained (for example, informal exchange [relative or friend]). If purchased locally or online, document purchase source location/address/website information.
Country and Region of Purchase	Country where product was purchased or obtained. Specify region if available.
Analysis/Screening Method	Lab or screening method used to screen or analyze product sample.

Variable	Details
Analyte	Metal that is measured. Aside from lead, other analytes that may be present in consumer products include mercury, arsenic or cadmium.
Concentration	Concentration of the analyte(s) being measured in the sample.
Unit	Unit of measurement of concentration (for example, parts per million [ppm], milligram per kilogram [mg/kg], microgram per liter [ug/L], microgram per milliliter [ug/mL], microgram per gram [ug/g], milligram per square centimeter [mg/cm^2], and so on)
Reporting Limit	The reporting limit as reported by the lab.
Date of Analysis	Date when the sample was analyzed by the lab.

Notes: If product packaging information is written in a non-Latin alphabet, ask the family to read it. Document the transliterated version in English.

Documenting additional variables such as the blood lead level associated with the lead poisoning case and the case's ethnicity can inform data monitoring efforts.

4. Photograph product packaging and the sampling tube or bag

- □ Take a picture of sample tubes/bags together with product packaging. Make sure sample ID is visible.
- □ Take clear pictures of the product itself (for example, open jar, open bottle, pills, spice, and so on).
- □ Take clear pictures of all sides of the product packaging, if available.
- □ Take a picture of package inserts, if available.
- □ Take pictures of store receipt, or other purchase documentation, with the product, if available.

5. Repeat this process for all samples collected as part of the case investigation. Once all samples have been prepared, complete a chain of custody form.

A chain of custody (COC) form should always accompany samples that have been collected, and it should be properly maintained. Complete a separate COC for *each* case from which samples are collected. Completion of the COC is a critical documentation activity that attests to the proper handling of samples as they move through various channels, such as collection, transportation and storage. Documentation ensuring that proper handling has occurred throughout these activities is also part of the custody record, which provides a mechanism for tracking samples through sample collection, processing and analysis. Custody records document the date and person responsible for the various sample handling steps associated with each sample and provides a reviewable trail for quality assurance purposes and as evidence in legal proceedings. The COC should accompany the sample(s) from collection point to the laboratory, with signatures along each transfer of hands, and it should have the following components:

- **Collector Information**
  - Name
  - Program
- **Case Identifier**
  - Case type
  - Case ID
  - Location tag (for example, ZIP code)
- **Sample Information**
  - Sample ID
  - Sample collection date
  - Sample description
  - Amount sent to lab
- **Laboratory Information**
  - Entity screening or analyzing
  - Signatures and dates for each transfer of hands

III. Maintaining a repository of sampling data

Sample-specific information collected during each case investigation should be systematically tracked and maintained in a repository. Routine monitoring can help to recognize trends in nonpaint lead exposures and identifying new lead sources. Findings can also inform strategies for targeted education and lead poisoning prevention activities as well as provide evidence for national and/or international policies to reduce lead exposures from contaminated products.

Optimally, the data repository selected to house sample data is electronic and searchable, with mechanisms for data backup and recovery (for example, SQL based, Open Data). Case investigators may also find the ability to generate summary reports and provide options to view the data graphically beneficial.

Considerations for quality control should be incorporated during sample collection, preparation and documentation. In addition to sample collectors performing quality assurance checks for each sample, staff members who are not directly involved in initial sampling collection and data entry tasks should review the data for accuracy, whenever possible. Such independent checks will allow for consistent monitoring for data discrepancies, which could illuminate issues. Data errors can not only have important consequences for data interpretation and case management but may also carry downstream legal ramifications. Some examples of quality assurance checks include, ensuring:

- Sample information is accurately documented in the repository (have different staff double-check the data entered)
- Sample IDs are accurate and match on sampling tubes, baggies, products and product packaging
- Product name is documented, even if it is an anecdotal name provided by the case
- Sample type is appropriately categorized to best reflect product type

- □ Sample photographs in the repository match the corresponding sample
- □ Analytical methods pertain to the correct product type

Step 3: Analyzing Lead-Contaminated Consumer Products

I. Choosing a laboratory

Overall, it is advised that laboratories performing nonpaint, consumer product analyses be accredited and have the capacity to conduct metal testing of consumer products in a variety of matrices. When selecting a laboratory, the following considerations may serve as a guide:

Certification and Experience	**Laboratory has:** • National Environmental Laboratory Accreditation Program (NELAP) or state ELAP certification to analyze solid and chemical materials • Proof of certification with detailed list of lab accredited parameters • Experienced technicians • Familiarity with testing methods required to complete analysis

Capacity	**Capacity to test:** • Various consumer products, in a range of matrices for heavy metals, including lead, mercury, arsenic and cadmium • Consumer products using various sensitive analytical methods

Efficiency	**Ability to:** • Provide detailed quality control data for testing conducted, including but not limited to, an analytical quality control summary, run sequence details and calibration data • Meet specified reporting limits for each type of matrix • Receive routine shipments of product samples and retain remnants of tested samples for an agreed period post-analysis • Provide lab results within an agreed upon turnaround time and according to requested format specifications (for example, electronically)

The laboratory report should include information listed in Figure 1. Per request, the laboratory should also be able to provide basic or detailed quality control reports for the sample run as such information may be required by regulatory agencies for further investigations.

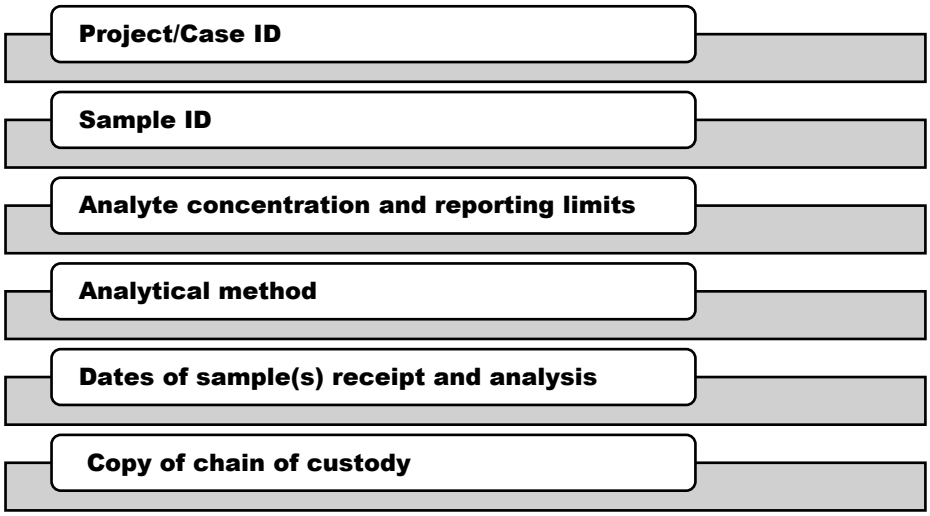

Figure 1. Components of a laboratory report

II. Selecting a screening method

3M™ LeadCheck™ Swabs

3M™ LeadCheck™ Swabs are recognized by the U.S. Environmental Protection Agency (EPA) to reliably determine (when used by a Certified Renovator) that regulated lead-based paint is not present on wood, ferrous metal or drywall and plaster surfaces. Swab results will either be positive or negative for lead, as corresponding lead concentrations are not provided with swab screenings. Although use of such swabs may be able to assist with initial screenings of certain products, such a screening method has not been validated for use on consumer products, such as spices, health remedies and cultural powders.

Sensitivity	• Swabs reliably detect lead in paints at 0.5% (5,000 parts per million [ppm]). 3M™ LeadCheck™ Swabs may indicate lead in some paint films at 0.06% (600ppm).

Protocol	• **Step 1:** Each swab contains two crushable vials, one with a lead-reactive dye, the other with an activator solution. Squeeze and crush points marked “A” and “B” on the barrel of the swab. • **Step 2:** With the swab facing down, shake twice and squeeze gently until the yellow liquid comes to the tip of the swab. The swab is now activated for testing. • **Step 3:** While squeezing, gently rub the swab on the surface of the sample for 30 seconds. If the tip turns red or pink, lead is present. If lead is not detected by the swab, rub the swab on the provided test confirmation card to ensure the swab was correctly activated.

Quality Control	• A test confirmation card is provided as a positive control sample for each 3M™ LeadCheck™ Swab test kit. Per the test kit instructions, this confirmation card is to be used when a positive response is not immediately obtained from the sample being tested.

Handheld X-Ray Fluorescence (XRF) Instruments

XRF instruments are used for measuring metals and other elements in various media. Handheld XRF analyzers are commonly used in environmental and geological studies for a variety of applications, including lead paint analysis, soil analysis and alloy identification. Recently, XRF devices have been used by federal agencies, such as the U.S. Food and Drug Administration (FDA) and the U.S. Consumer Product Safety Commission (CPSC), and state agencies to analyze toxic elements in consumer goods and children's products.

XRF devices that are handheld and field-portable have three major components: (1) an X-ray source, (2) a detector and (3) a software package. The detector converts the X-rays emitted from the sample into measurable energy signals. The device's software package then records the energy signals and calculates the elemental concentrations in the sample. The radiation source that generates X-rays can either be an X-ray tube or a radioisotope. Handheld, X-ray tube-based XRF devices can screen certain consumer products for heavy metals, such as lead, mercury, arsenic and cadmium, in a short time frame. However, there are factors that can impact the precision and accuracy of the XRF measurements. The lower limits of detection (LOD) of the device will vary between brands and models. The following should be considered when screening using an XRF instrument*:

Sample Density	• Samples should be packed tight to maximize the precision of the measurement.
Sample Homogeneity	• More homogenous samples should produce more accurate measurements. The level of homogeneity can vary between replicates of products which can result in variations in measurements.
Measurement Time	• Longer XRF analysis times should yield more accurate and precise measurements. Measurement times can be quite short when the elemental concentration level is high. If elemental concentration is near the LOD, a longer measurement time will be more accurate.
Interference	• Prior to analysis, samples should be transferred to a sampling cup or a thin, clear plastic bag to reduce interference that can be caused by the sample packaging or label. • Various factors, such as interferences due to peak overlaps, can affect XRF sensitivity for certain analytes.
Device calibration	• XRF devices are typically factory calibrated and use proprietary algorithms to estimate elemental concentrations, which can result in variations in measurements across different devices. However, when testing lead-based paint, the EPA and the U.S. Department of Housing and Urban Development require in-house calibration as an accuracy check.

* Follow the manufacturer's instructions for proper operation and maintenance of your XRF device.

III. Selecting a laboratory method

Selecting the appropriate laboratory method to analyze lead-contaminated consumer products is important. Analytical methods can depend on the type of sample being analyzed. Some analytical methods that could be used to measure lead content in consumer products are listed below:

Sample Type	Analysis Methods
Foods and Spices	• U.S. Environmental Protection Agency (EPA) Method SW 6020 • EPA Method 7010 • EPA Method SW7420 • AOAC 2013.06
Health Remedies	• EPA Method SW 6020
Cosmetics and cultural powders	• EPA Method SW 6020 • ISO/TR 17276
Ceramicware (for example, clay pottery, ceramics)	• American Society for Testing and Materials (ASTM) Method C738-94 • Association of Official Analytical Chemists (AOAC) Methods 973.32 and 973.82
Metal ware (for example, “kansa”)	• ASTM Method C738-94 • AOAC Methods 973.32 and 973.82
Toys/Novelty items	• EPA Method SW6020 • ASTM Method E1613-04
Jewelry/Amulets/Charms	• EPA Method SW6020 • ASTM Method E1613-04 • CPSC Test Method CPSC-CH-E1001-08.1 • CPSC Test Method CPSC-CH-E1002-08

Note: Sample preparation methods include EPA Method 3005A, 3050B and 3051A.

Step 4: Interpreting Laboratory Results

I. Regulatory standards and guidance limits

Following receipt of laboratory results comes the task of determining what, if any, risks are posed by use of the implicated product. This decision can be straightforward when regulatory limits — considered to be achievable under good manufacturing practices and protective of public health — have been established.

Challenges arise when no regulatory standards exist for a particular product type. In the absence of existing regulatory standards, consider using proxy values to guide risk management actions:

Risk assessment and risk management should consider the following:

- ✓ Exposure patterns
  - ✓ Frequency of use
  - ✓ Portion size
- ✓ Population
  - ✓ Children
  - ✓ Adult (pregnant or nonpregnant)
- ✓ Lead concentration

Sample Type	Regulatory Standards and Possible Guidance Limits for Lead
Foods	**0.1 ppm** US FDA Lead in Candy Recommended Maximum Level
Spices	**2 ppm** Food Chemicals Codex, Institute of Medicine permissible limit for lead in certain food additives **>0.21 ppm** New York State Updated Recall Policy for Heavy Metals in Spices (proposed)
Dietary supplements	**2 ppm** Food Chemicals Codex, Institute of Medicine permissible limit for lead in certain food additives **10 ppm** World Health Organization limit for lead in herbal medicines and products
Cosmetics and cultural powders	**10 ppm** FDA's recommended maximum level of lead in cosmetic products Note: Per US FDA, cultural products/cosmetics kohl, kajal and surma are banned for sale in the US.
Ceramic cookware/dishware	Contains, upon examination of 6 units, a level of lead exceeding the guideline by category specified: **0.5 µg/mL** (pitchers, cups/mugs) **1 µg/mL** (large hollowware other than pitchers) **2 µg/mL** (small hollowware other than cups and mugs) **3 µg/mL** (flatware) US FDA Regulatory Action Guidance for Ceramic Food Ware

Sample Type	Regulatory Standards and Possible Guidance Limits for Lead
Silver-plated hollowware (metal dish and cookware)	If intended for use by adults, releases in 6 units an average of **≥7 µg/mL** of leaching solution If intended exclusively for use by infants and children, it releases in one or more of 6 units **≥0.5 µg/mL** US FDA Regulatory Action Guidance for Silver-Plated Hollow Ware
Children's products (for example, toys, children's jewelry)	**90 ppm** (paint or similar surface coatings) **100 ppm** (total lead content in accessible parts) US CPSC Federal Lead in Paint Requirements for Lead in Children's Products

Foods and Spices: The Food and Drug Administration (FDA) monitors and regulates levels of lead in certain food wares, foods, dietary supplements and cosmetics. The agency has set a federally recommended maximum level for lead in candy (0.1 ppm or milligram per kilogram [mg/kg]). The FDA also has regulatory oversight for color additives used in foods and, accordingly, has established limits for natural-source food color additives (10 ppm) and diluents in color additive mixtures for food (ranging in values between 0.4 ppm and 10 ppm); however, the FDA has not set a permissible limit for lead in spices. Though, levels of heavy metals in certain food items are routinely measured through the Total Diet Study, which is a market basket survey of foods representative of the diet of the US consumer.

Dietary Supplements: The FDA regulates dietary supplements —a vitamin, mineral, herb or other botanical, amino acid or dietary substance used to supplement the diet—under a different set of regulations than those covering "conventional" foods and drug products. Unlike drugs, supplements are not intended to treat, diagnose, prevent or cure diseases. Manufacturers and distributors of these types of products are prohibited from marketing products that are adulterated or misbranded and are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet regulatory requirements. Overall, the onus falls on the FDA to act on a supplement product found to be adulterated or misbranded after it's marketed. These alerts may come from adverse reports from consumers, health care and public health practitioners and state governmental partners. As with spices, the FDA has not set a permissible limit for lead in dietary supplements.

The FDA assesses whether the amount of lead in a food product is high enough to raise a person's blood lead level to a point of concern. To do this, the Administration calculated a maximum daily intake for lead from food, called the **Interim Reference Level (IRL).** In determining the IRL, the FDA took into account the amount of a particular food a person would need to consume daily, as well as other factors, that would result in blood lead levels of 3.5 ug/dL, the level at which the Centers for Disease Control and Prevention (CDC) is currently recommending clinical monitoring of lead exposure in children.

Example daily intake calculation for a medicine product:
(Pb Concentration) x (# pills/day) x (Weight of each pill)

The FDA calculated the current IRL at 2.2 µg per day for children and 8.8 µg per day for females of childbearing age (updated in 2022). These levels allow for differences across human populations and are set nearly 10 times less than the actual amount of lead intake from food that would be required to reach the CDC's blood reference level. The level for females of childbearing age is to protect against possible fetal exposure in women who are unaware that they are pregnant, and against infant exposure during nursing.

Ceramic and Metal Dishware: Guidance on allowable levels for lead used in glazed ceramicware and metal dishware have been set by the FDA to limit the amount of lead that may leach from these products when preparing, cooking, serving or storing foods. Specific labeling requirements identifying the danger of using such products for culinary purposes have also been established.

Cosmetics and Cultural Powders: As is the case with dietary supplements, cosmetic products do not need to be approved by the FDA premarketing but bringing to market adulterated or misbranded cosmetics is prohibited, and the FDA can pursue enforcement actions against such products. Color additives, however, must have FDA approval for their intended use and most have limits for lead as an impurity (usually no more than 10 or 20 ppm). And, currently, FDA recommends that cosmetic lip products and externally applied cosmetics not contain more than 10 ppm lead as an impurity. The FDA has also lent focus to cultural powders and has identified kohl, kajal, surma and similar materials as illegal color additives. Sale of these products is barred in the U.S. and an Import Alert has been issued.

Toys and Children's Jewelry: CPSC regulates children's products (such as toys and children's jewelry). Children's products are subject to children's product safety rules. A "children's product" is defined as a consumer product designed or intended primarily for children 2 years of age or younger determined through: 1) A statement by the manufacturer about the intended use of the product, including a label on the product, if such statement is reasonable. 2) The product's packaging/display/promotion or advertising its use for 12 years or younger. 3) common recognition by consumers as being intended for use by a child 12 years of age or younger. Per the CPSC, children's products must not contain a concentration of lead greater than 90 ppm in paint or any similar surface coatings and must not contain more than 100 ppm of total lead content in accessible parts. There are no federal regulatory limits for jewelry intended for adults.

II. Communicating Risk

Communicating risk from use of lead-contaminated products can appear a daunting task. Concomitant factors, such as language and literacy barriers, varying perceptions of risk, lack of suitable product alternatives, challenges with translating technical information — like lab results — for the lay public and most significantly, communicating risk to ultimately elicit behavioral change, can impact this process. Like the risk assessment interview, strategies to address some of these challenges include communicating in the case's primary language, employing cultural sensitivity, framing the issue, resolving ambivalence and enhancing their motivation to change harmful behaviors. For instances where it is not possible to eliminate the hazard, emphasizing a risk management approach is recommended. When relaying technical information (for example, lab results and interpretations), using consistent language is key. To achieve this, developing, standardizing and integrating a risk communication script (Figure 2) into the case investigation process can be useful. In addition to providing the lead results to the case, you should also provide specific risk elimination or risk management guidance pertinent to various product types:

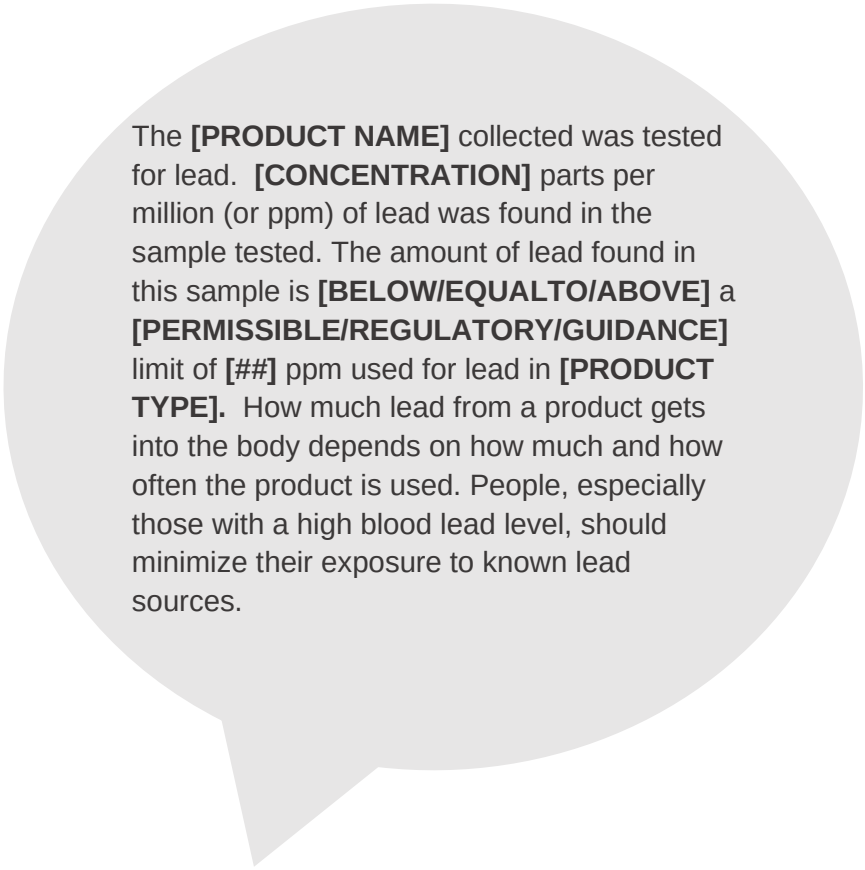

Figure 2. Example risk communication script

Risk Elimination/Management Guidance by Product Type

Foods and Spices:

- Based on available surveillance data, spices purchased abroad are more likely to have high lead levels than similar products sold in the U.S. Buy spices locally instead.
- Avoid eating candies, salt snack mixes and other snacks from Mexico that use chili or tamarind pulp.
- Avoid eating chocolates hand-carried from Ecuador.

Health Remedies:

- A product may contain lead and other heavy metals even if they are not listed as an ingredient on the packaging.
- Avoid using health remedies known to contain lead and other harmful metals.

Cosmetics and Cultural Powders:

- Avoid using cosmetics or cultural powders known to contain high levels of lead.
- If you are unable to stop using a lead-containing product due to religious significance, wash your hands thoroughly after handling such products (for example, kohl, surma, sindoor).
- Wash floors and other surfaces near shrines where such products are routinely used.
- Keep cosmetics and cultural powders away from children.

Traditional Cookware/Dishware:

- Avoid using the following types of cookware/dishware to prepare, cook, store, or serve food and drinks:
  - Cookware/dishware that is labeled for use only as a decorative item. Such items may include a permanent or sticker label with a message such as “Not for Food Use.”
  - Handmade ceramic cookware/dishware with a crude appearance or irregular shape.
  - Damaged or worn ceramic cookware/dishware.
  - Painted and glazed traditional ceramicware that may contain lead.
  - Purchased from flea markets or street vendors where you are unable to determine whether the ceramicware is from a reliable manufacturer.
  - Avoid use of metal ware found to contain lead (for example, certain brass ware known as “kansa”)

Toys/Novelty Items:

- The metal or painted parts of some toys and novelty items (for example, maracas) may contain lead.
- Never buy or give away recalled, broken or damaged toys, especially if there is chipping paint. If a toy is broken, discard it safely.
- If your child often puts toys, including rattles or maracas, in their mouth, ask your child’s health care provider for a blood lead test.

Jewelry/Amulets/Charms:

- Keep amulets and (adult) jewelry away from children when possible.
- If your child wears an amulet or jewelry, place these items on your child in a way so that they cannot be mouthed.
- If your child wears an amulet or jewelry, and puts these items in their mouth, ask your child’s health care provider for a blood lead test.

If you or your child use these types of products, speak with a health care provider, and get a blood lead test. Other household members using these products should also get a blood lead test.

Step 5: Conducting Enforcement Activities

In a best-case scenario, lead-contaminated and other hazardous consumer products, identified through the case investigation process, are removed from commercial circulation, thus preventing exposure for a wider pool of potential users. Such removal actions are ultimately enabled by legally binding federal or local regulations aimed at safeguarding public health.

I. Surveying the local markets

Surveys of neighborhood shops to collect samples of implicated products can be conducted if resources allow. The survey can help to determine the range of availability for such products in the local marketplace. These surveys can be reactive (in response to a lead poisoning case) or proactive (a routine surveillance of the types of products available in the marketplace). Routine and proactive surveys can help to identify previously unrecognized lead-containing consumer products. Product surveillance surveys can be optimized by incorporating the following components:

Undercover: Surveys may prove more forthcoming if staff do not identify themselves in an official capacity.

- Avoid “raising the antennas” of shop stewards.
- Not identifying themselves may allow access to the true landscape of the shop and to the wealth of available products.

Focused: Surveys of businesses should be conducted in commercial areas where likely users of suspect products may shop.

- Concentrate on specific neighborhoods informed by varied sources (for example, anecdotal accounts, census and similar demographic data, business reviews, yellow pages, web searches, and so on).

Informed: Maintain working and historical knowledge of products of concern (noting commonalities in product characteristics of “bad actors”).

- This helps to leverage and maximize use of time and resources.
- Identifying contaminated products is further made difficult because heavy metals are not always listed as an ingredient on product labels. Lead content may also vary considerably between different batches of the same product.

Leveraged:

- Leverage staffing resources: Ask staff to keep a look out for shops that may be selling products of concern.
- Leverage time and travel resources: Along with target products, look for similar or "suspicious" products as informed by previously implicated products (for example, similar uses/indications, manufacturers, distributors, variants of product, and so on).

Documented: Keep transactional records (for example, receipts with store information) and maintain log of survey activities. In addition, make sure to document product details and chain of custody appropriately. This will prove useful for reporting and regulatory purposes.

II. Exploring avenues for enforcement

The removal of lead-contaminated and other hazardous products from the marketplace is a desired outcome in the case investigation lifecycle, and the enforcement of promulgated federal and local regulations bring such outcomes to life. The latter can be especially beneficial when no federal regulations exist. Therefore, local jurisdictions should explore all feasible opportunities to restrict distribution of, and access to, hazardous products in the regional marketplace. Example tactics include:

In NYC, the **NYC Health Code** authorizes the NYC Health Department to seize, embargo or condemn certain products that are unfit for human consumption or use, or "constitutes a danger or nuisance, or is otherwise prejudicial to public health." Rules of the City of New York, Title 24, New York City Health Code §3.03

- □ Working with jurisdictional legal entities (for example, district attorney offices) to establish and codify regulations aimed at protecting public health.
- □ Evaluating the regional legal landscape:
    - □ Establishing partnerships with external agencies (for example, departments of consumer affairs, departments of agriculture, and so on) with enforcement authority or legal structures in place that can be leveraged.
- □ Requiring businesses to label potentially hazardous products with warning messages.
- □ Requiring businesses to post warning signs (meeting language and literacy needs), in a prominent location, alerting customers to the hazard(s) associated with harmful products and encouraging users to contact a health care provider.

Still, if no viable local legislative or authoritative avenues can be identified, then the option remains to rely on "good faith" commitments of businesses to avoid sales or distribution of hazardous consumer products. This will rely considerably on education and outreach activities that raise awareness on the dangers associated with use of these types of products.

III. Reporting findings to relevant stakeholders

The availability and enforcement of federal regulations is preferable, given the limited reach of local enforcement actions, and inversely, the potential to magnify outcomes of such regulatory actions — nationally and internationally. This trajectory often begins with notification activities, as federal regulatory actions can depend on reports from state or local jurisdictions. For instance, reporting a problem to the FDA could help with identifying an unknown risk. Such a report could also help the Administration determine

when to carry out preventive and protective actions, such as issuing safety messages to the public and removing hazardous products from the market.

Prior to reporting findings to the federal government, it is important to gather pertinent product-related information. When forwarding findings from case investigations, at minimum, products associated with poisonings should be reported; at times, however, the determination criteria will be made on a case-by-case basis. The proceeding may serve as a guide for reporting to or notifying relevant stakeholders:

Product-related information to report may include:

- ✓ Product name
- ✓ Manufacturer/Distributor
- ✓ Product details (for example, batch and lot number, manufacturing and expiration dates)
- ✓ Lead concentrations
- ✓ Laboratory analytical

US FDA:

Which products should you report?

- Foods/Spices
- Health Remedies
- Traditional Cookwarew/Dishware
- Cosmetics and Cultural Powders

When should you report?

- **Foods, Spices and Health Remedies:** Consider using Interim Reference Level to make determination
- **Cosmetics and Cultural Powders:** Consider using FDA's recommended maximum level of lead in externally applied cosmetics of 10 ppm
- **Traditional Cookware/Dishware:** Allowable limits exceeded for specific receptacle category (see Step 4: Interpreting laboratory results)

What should you provide?

- Detailed analytical worksheets (for example, data package from laboratory with quality assurance/quality control information)
- De-identified product use details from the case investigation (for example, product name, used for, amount and frequency of use)
- Clear photographs of product packaging (all sides captured)
- Transactional records (proof of supply chain/chain of retail/distribution [if available])

Who can you report to?

- FDA Office of Regulatory Affairs
- FDA Consumer Complaint Coordinators
- FDA Divisional Import Offices
- FDA Center for Food Safety and Applied Nutrition
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- FDA Safety Reporting Portal

US CPSC:

Which products should you report?

- Children's products (for example, toys, children's jewelry)

When should you report?

- Greater than or equal to 90 ppm lead on paint or any similar surface coatings
- Greater than or equal to 100 ppm total lead content in accessible parts

What should you provide?

- Detailed analytical worksheets (for example, data package from laboratory with quality assurance/quality control information)
- De-identified product use details from the case investigation (for example, product name, used for, amount and frequency of use)
- Clear photographs of product packaging (all sides captured)
- Transactional records (proof of supply chain/chain of retail/distribution [if available])

Who can you report to?

Report online at saferproducts.gov

Other Potential Stakeholders:

- Local departments of Agriculture/Markets/Commerce
- Community-based organizations (CBOs) and other community partners in community of concern
- Other jurisdictions
- Supply chain stakeholders (manufacturers, distributors)
- Embassies and consulates

Overall, the reporting and notification structure works best when it is coordinated. And when the baton is passed successfully across the various participatory channels, the results can be counted, including the removal of hazardous products from commercial distribution, as well as recalls and domestic and international investigative and auditing activities. At best, yielded benefits could also include the opportunity to influence consumer behavioral patterns and industry activities towards reducing exposures to lead and other dangerous heavy metals/chemicals from products.

Comprehensive Analytical Laboratory Worksheets or Detailed Quality Control (QC) Reports allow a data validator to evaluate analytical results, QC and sample handling information.

Step 6: Providing Education and Conducting Outreach

I. Resources and Materials

Existent regulatory structures and channels can always be strengthened, and despite best efforts to curb the flow of contaminated consumer products in the commercial sphere, gaps can still exist. For example, there may be a lack of stringent and enforceable standards in countries of origin; individuals may obtain such products abroad — informally or formally — and hand-carry these items into the US; and

products may be available locally, but at unidentified outlets. Thus, risk communication and educational and outreach activities are critical to raise consumers' awareness of identified hazards. Overall, these types of activities help to bridge the gap when enforcement is not possible.

Educating stakeholders, such as the public — especially at-risk populations, health care providers and peers, on the presence of and risks associated with use of hazardous consumer products is key to curtailing exposures from these sources. Because of the varied profiles of these populations, educational outreach strategies and materials are optimal when they have been tailored to suit their diverse needs. At a basic level, however, certain practices, such as a focus on linguistic and cultural competency, can prove useful — no matter the audience.

Useful Practices for Education and Outreach

Linguistic Competence: An important step in education and outreach is ascertaining languages spoken by at-risk populations. In addition to English, providing messaging in a variety of pertinent languages or dialects is recommended. This information can be obtained by researching the population of interest, examining labeling/advertisements of products likely to be used by the population and demographic characteristics of customers who patronize businesses where products may be sold, as well as identifying language(s) through the lead poisoning case investigation. Translations should be accurate and should accurately relay the message being conveyed. In reviewing the latter, leveraging the linguistic and cultural diversity of staff, when possible, is advised.

Considerations for how to reach special populations, such as indigenous persons or individuals with literacy — including health literacy — concerns, should also be factored in. Working with CBOs may prove useful in meeting such challenges, if present.

Cultural Competence: When providing risk communication guidance especially, cultural competence is critical. Along with communicating in preferred languages, a commitment to ensuring cultural sensitivity in messaging can go a long way in making the recommendations digestible — for example, providing guidance based on risk management principles when risk elimination is not an option (for example, Wash your hands thoroughly after handling cosmetics and cultural powders.). As previously mentioned, certain consumer products may be associated with intrinsic cultural, religious or traditional practices, which inhibits the potential effectiveness of hazard elimination messaging. Being aware of certain cultural nuances allows for the development of strategies or recommendations that: 1) work with existing behaviors, 2) advocate for using alternatives when possible and 3) employ practices that avoid use in ways that increase exposure (for example, If your child wears an amulet for "good luck", place it in a way so that it cannot be mouthed.). Further, because messages tied to longstanding uses of cultural products can be nuanced, more conversational (not one-sided) education opportunities, such as "fireside chats," podcasts, social media livestreams, interviews, listening sessions and roundtables may prove beneficial. Selection of the appropriate type of method should be determined by the audience, their needs and their capacities.

Buy-In and Engagement: To ensure that messages are received (and understood), it is important to foster buy-in and engagement within target populations. Buy-in can be aided through the involvement of trusted partners like faith-based and other community leaders. With engagement, which is sometimes difficult to gauge, a good starting point is to meet the intended audience

where they are. Specific strategies may include weaving messages into routine activities and practices, being cognizant of potential barriers hindering the reception of messages — and striving to address them — and encouraging propagation of messages within networks. Overall, striving to ensure long-term sustainability of educational and outreach interventions is key.

Educational messages can be shared using a variety of print and electronic media. Static materials for promoting health communication messages, such as brochures, fact sheets, posters, billboards, newspaper articles, newsletters and pamphlets, are well-established modes of relaying health-related communications and are suitable for the purposes of communicating lead poisoning prevention messages to the public.

Electronic approaches, incorporating the use of social media, radio and television — including ethnic media — continue to be popular choices to reach audiences, and broadcast media can be especially useful in reaching populations with low literacy levels. Identifying well-respected spokespeople in the community can also be useful for outreach. For instance, getting the buy-in of health care providers can be an effective way to provide information to at-risk communities. When feasible, in-person outreach opportunities are optimal. These may include presentations, workshops and "tabling" events at health fairs, community clinics, CBOs, and other venues where at-risk populations may frequent. Potential avenues for outreach and education to various stakeholders can be explored (Figure 3).

Figure 3. Potential avenues for education and outreach

II. In Action: NYC Department of Health and Mental Hygiene (NYC Health Department) South Asian Lead Awareness Campaign

NYC Health Department data shows that NYC's South Asian children and adults are especially at risk for elevated blood lead levels. In addition to lead paint and occupational lead hazards, elevated blood lead levels in this community have been associated with the use of traditional consumer products. To address this issue, the NYC Health Department developed a lead awareness campaign designed to reach this population.

Data were analyzed to identify the target geographic areas for the intervention — high-risk South Asian neighborhoods and associated ZIP codes were selected based on the number and rates of South Asian children and pregnant women with elevated blood lead levels.

The NYC Health Department developed multilingual bus shelter advertisements (Figure 4) and accompanying educational materials to raise awareness about risk factors for lead exposure and provided culturally sensitive risk management guidance to reduce lead exposure.

The NYC Health Department also worked with CBOs in these target South Asian neighborhoods to raise awareness and foster engagement for lead poisoning prevention within this community. Capacity-building activities and tools, such as role play videos and ESL lesson plans were developed. Additionally, train-the-trainer sessions, community workshops and large outreach events — through which lead poisoning prevention messages and materials were disseminated — were also conducted.

The NYC Health Department continues to collaborate with community partners within this community to further promote lead poisoning prevention awareness.

Figure 4. Samples of NYC Health Department multilingual bus shelter advertisements

Source: nyc.gov/hazardousproducts

Summary

Overall, the sequential flow of the case investigation process — from hazardous product identification to removal from commercial circulation — may vary based on factors such as program resources and capabilities. However, a successful approach to reducing exposures to lead-contaminated consumer products is best achieved with elements of the key steps of identification, sampling and analysis, enforcement, as well as education and outreach. Systematic documentation of consumer product-related information and transparency in the data (for example, Metal Content of Consumer Products Tested by the New York City Department of Health and Mental Hygiene | NYC Open Data (cityofnewyork.us)) is also critical for on-going monitoring and triggering broader investigations to ultimately eliminate lead sources locally, nationally and internationally.

Resources

Background

Control of lead sources in the United States, 1970–2017: Public health progress and current challenges to eliminating lead exposure

Continual Decrease in Blood Lead Level in Americans: United States National Health Nutrition and Examination Survey 1999-2014

EPA. 2022. America's Children and the Environment (ACE) Biomonitoring - Lead

Why we need a national repository of consumer product lead surveillance data

Safe Products Awareness Training for Businesses | Registration instructions (PDF)

Step 1: Identifying Lead-Contaminated Consumer Products

Building a knowledge base

Foods and Spices

Examining Lead Exposures in California through State-Issued Health Alerts for Food Contamination and an Exposure-Based Candy Testing Program

Naturally Occurring Lead in Certain Candies – Office of Environmental Health Hazard Assessment

Lead in Spices, Herbal Remedies, and Ceremonial Powders Sampled from Home Investigations for Children with Elevated Blood Lead Levels - North Carolina, 2011-2018

Pediatric lead exposure from imported Indian spices and cultural powders

Childhood lead poisoning in 2 families associated with spices used in food preparation

Elevated Levels of Lead (Pb) Identified in Georgian Spices

A Spoonful of Lead: A 10-Year Look at Spices as a Potential Source of Lead Exposure

Turmeric means "yellow" in Bengali: Lead chromate pigments added to turmeric threaten public health across Bangladesh

Ground Turmeric as a Source of Lead Exposure in the United States

Notes from the Field: Childhood Lead Poisoning Associated with Turmeric Spices - Las Vegas, 2019

Health Remedies

Heavy Metal Content of Ayurvedic Herbal Medicine Products

Lead Poisoning Associated with Ayurvedic Medications --- Five States, 2000--2003

Lead poisoning in pregnant women who used Ayurvedic medications from India--New York City, 2011-2012

Lead, mercury, and arsenic in US- and Indian-manufactured Ayurvedic medicines sold via the Internet

Health Remedies as a Source of Lead, Mercury, and Arsenic Exposure, New York City, 2010–2019 | AJPH | Vol. 112 Issue S7 (aphapublications.org)

Traditional Cookware/Dishware

Notes from the Field: Lead Poisoning in a Family of Five Resulting from Use of Traditional Glazed Ceramic Ware — New York City, 2017–2022 | MMWR (cdc.gov)

Investigating aluminum cookpots as a source of lead exposure in Afghan refugee children resettled in the United States

Metal exposures from aluminum cookware: An unrecognized public health risk in developing countries

Lead leaching from pressure cookers

Lead exposure from aluminum cookware in Cameroon

Cosmetics and Cultural Powders

Lead Content of Sindoor, a Hindu Religious Powder and Cosmetic: New Jersey and India, 2014–2015

Kohl and surma eye cosmetics as significant sources of lead (Pb) exposure

Infant Lead Poisoning Associated with Use of Tiro, an Eye Cosmetic from Nigeria – Boston, Massachusetts, 2011

Toys/Novelty Items

Lead-based paints and children's PVC toys are potential sources of domestic lead poisoning - A review

Death of a Child After Ingestion of a Metallic Charm—Minnesota, 2006

Jewelry/Amulets/Charms

Notes from the Field: Lead Poisoning in an Infant Associated with a Metal Bracelet — Connecticut, 2016

Lead Poisoning of a Child Associated with Use of a Cambodian Amulet --- New York City, 2009

Other

Hunting with lead: Association between blood lead levels and wild game consumption

Examining pica in NYC pregnant women with elevated blood lead levels

Children with Elevated Blood Lead Levels Related to Home Renovation, Repair, and Painting Activities — New York State, 2006–2007

Take-Home Lead Exposure Among Children with Relatives Employed at a Battery Recycling Facility — Puerto Rico, 2011

Blood Lead Levels and Potential Risk Factors for Lead Exposures Among South Asians in New York City

Deaths Associated with Hypocalcemia from Chelation Therapy—Texas, Pennsylvania, and Oregon, 2003–2005

The risk assessment interview

Motivational interviewing and decisional balance: contrasting responses to client ambivalence

Blood Lead Surveillance and Exposure Sources Among Alaska Children

Intervention Model for Contaminated Consumer Products: A Multifaceted Tool for Protecting Public Health

Centers for Disease Control and Prevention Childhood Lead Poisoning Prevention Program

Step 2: Sampling Lead-Contaminated Consumer Products

Agency for Toxic Substances and Disease Registry. 2019. What Are Routes of Exposure to Lead?

Environmental Protection Agency (EPA). Sample Handling and Custody. QA Handbook Vol II, Section 8.0 Revision No: 1. 2008

Step 3: Analyzing Lead-Contaminated Consumer Products

Choosing a laboratory

National Environmental Laboratory Accreditation Program (NELAP)

Selecting a screening method

3M™ LeadCheck™ Swabs Brochure

3M™ LeadCheck™ Swabs Instruction Manual

3M™ LeadCheck™ Swabs Qualitative Spot Test Kit for Lead in Paint

EPA. 2022. Field X-Ray Fluorescence Measurement

Best practices for the use of portable X-ray fluorescence analyzers to screen for toxic elements in FDA-regulated products

EPA Contaminated Site Clean-Up Information: X-Ray Fluorescence

Method 6200: Field Portable X-Ray Fluorescence Spectrometry for the Determination of Elemental Concentrations in Soil and Sediment

Introduction to Energy-Dispersive X-Ray Fluorescence (XRF): An Analytical Chemistry Perspective

Advanced Design Application and Data Analysis for FP-XRF in Soil Matrices, 2010 North American Environmental Field Conference and Exposition

ASTM F2853-10(2015) Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams

Selecting a laboratory method

EPA. 2014. "Method 6020B (SW-846): Inductively Coupled Plasma-Mass Spectrometry," Revision 2. Washington, DC.

EPA. 2007. “SW-846 Test Method 7010: Graphite Furnace Atomic Absorption Spectrophotometry.” Washington, DC.

Pb-Based Paint Laboratory Operations Guidelines: Analysis of Pb in Paint, Dust, and Soil. Washington, DC.

EPA. 2007. “Method 7471B (SW-846): Mercury in Solid or Semisolid Wastes (Manual Cold-Vapor Technique). Washington, DC.

EPA. Hazardous Waste Test Methods / SW-846

ISO/TR 17276:2014. Analytical approach for screening and quantification methods for heavy metals in cosmetics

American Society for Testing and Materials (ASTM) Method C738-94

ASTM E1613-04 – Standard Test Method for Determination of Lead by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES), Flame Atomic Absorption Spectrometry (FAAS), or Graphite Furnace Atomic Absorption Spectrometry (GFAAS) Techniques

Association of Official Analytical Chemists (AOAC) 973.32 and 973. 82-1977(1996), Lead and cadmium extracted from ceramics

AOAC 2013.06-2013 Arsenic, Cadmium, Mercury, and Lead in Foods

FDA. 2005. CPG Sec. 545.500 Silver-Plated Hollowware -Lead Contamination

Consumer Product Safety Commission (CPSC) Test Method CPSC-CH-E1001-08.1

CPSC Test Method CPSC-CH-E1002-08

Elemental Analysis Manual - Section 3.2 (fda.gov)

Step 4: Interpreting Laboratory Results

Regulatory standards and proxy Limits

FDA. 2006. Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA. 2006. Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA. 2020. Lead in Food, Foodwares, and Dietary Supplements

FDA. 2022. Kohl, Kajal, Al-Kahal, Surma, Tiro, Tozali, or Kwalli: By Any Name, Beware of Lead Poisoning

Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level Guidance for Industry

CPSC. Federal Lead in Paint Requirements

Institute of Medicine. Food Chemicals Codex. 5th ed. Washington, DC: The National Academies Press; 2003.

New York State Department of Agriculture and Markets Division of Food Safety and Inspection. Regulatory Policies For Heavy Metals In Spices –A New York Approach

World Health Organization (WHO).1998. Quality control methods for medicinal plant materials.

WHO. 2007. Guidelines for assessing quality of herbal medicines with reference to contaminants and residues

Compliance Policy Guide (CPG) Sec. 545.450 Pottery (Ceramics); Import and Domestic – Lead Contamination

CPG Sec. 545.500 Silver-Plated Hollowware - Lead Contamination

CPSC. Total Lead Content Business Guidance & Small Entity Compliance Guide

Step 5: Conducting Enforcement Activities

Reporting findings to relevant stakeholders

Report a Problem to the FDA | FDA

FDA. 2021. Office of Regulatory Affairs

FDA. 2020. Consumer Complaint Coordinators

FDA. 2021. Import Offices and Ports of Entry

FDA. 2018. FDA Import Contacts and Office Locations

FDA. 2022. MedWatch: The FDA Safety Information and Adverse Event Reporting Program

The Federal Adverse Event Task Force. Safety Reporting Portal

FDA. 2022. Import Program

CPSC. Contact Specific Offices and Public Information

CPSC. Report an Unsafe Product