

Instructions on the Draft NC Guidelines for Lead Investigators on Reporting Lead Contaminants in Food, Spices, Cosmetics, and Medicines

These guidelines are to be followed any time you suspect “food products are suspected to be a source of lead exposure. For the purpose of these guidelines, a **“food product”** is any food, drink, flavoring (e.g. spices), alternative/traditional medicine, medicine, vitamin, herbal remedy, or herbal supplement intended to be consumed orally.

The **“NC CLPPP Reportable Limits”** is the sample result at or above which the NC Childhood Lead Poisoning Prevention Program (NC CLPPP) will report the product information to the US Food and Drug Administration (FDA) for further investigation. Please note that if the laboratory is unable to achieve a precise sample result due to interference (e.g., result is reported as < 4 mg/kg), the result will not be reported to FDA since the actual reportable limit cannot be determined. Only products purchased in the United States or online will be reported to the FDA, as products purchased overseas are out of their jurisdiction. These guidelines are not enforceable on their own but are intended to provide uniform interpretation to remove potential lead hazards from the homes of children with confirmed lead poisoning when sample results indicate lead contamination of edible products.

Risk of lead poisoning for an individual from exposure to a lead-contaminated product will vary depending on the age, size, and metabolism of the individual, the amount consumed, the frequency of consumption, and other factors. Based on current literature, lead may cause behavioral, developmental, and health problems even at low levels in the blood. Because children under age 6 are undergoing critical neurological and physical development, they are especially vulnerable to the adverse effects of lead on the body. Therefore, the NC CLPPP recommends minimizing exposure to lead from all known sources, especially for children under age 6. Unlike lead-based paint, soil, and water, contaminated edible products may be disposed immediately upon receipt of the lead results.

The rationale for disposing of contaminated edible products is similar to that of the EPA’s goal for lead in water. “EPA has set the maximum contaminant level goal for lead in drinking water at zero because lead is a toxic metal that can be harmful to human health even at low exposure levels. Lead is persistent, and it can bioaccumulate in the body over time.” (<https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water>)

Collect the following information about Food, Spices, Cosmetics, and Medicines during the lead investigation because the product may not be in the house by the time the sample results are reported:

- Collect at least 5-10 g (or 5-10 ml) of the product to allow sufficient amount for retesting
- If possible, collect an unopened, sealed package of the product, unless the item is in bulk
- Name of the product and the manufacturer
- When the product was purchased
- City and store where the product was purchased (or website)
- When the product was consumed
- Document everything on the label or container, including product codes, lot numbers, net wt, or identifying marks [Note: do not discard the product packaging and labeling. They provide information that will help FDA investigate the problem]

- If possible, **take photos of ALL parts/sides of the labels.**

Because **Kohl/ Kajal/ Surma is illegal**, any purchased in the US should be reported.

Go to <http://nchealthyhomes.com/lead-poisoning/> for the Spice and Herbal Remedy Survey Tool in multiple languages to use during the investigation to collect this information.

Lead Contaminants in Edible Products and Cosmetics- Draft NC Guidelines for Lead Investigators

Product	Reference Limits	Agency	Reference	NC CLPPP Reportable Limits*
Spices	1 mg/kg	New York State Department of Agriculture (Class II Recall)	https://www.astaspice.org/government-relations-advocacy/public-policy-2/state-regulations/	1 mg/kg
Salts	2 mg/kg	World Health Organization (WHO)	(CODEX STAN 193-1995) http://www.fao.org/fileadmin/user_upload/livestockgov/documents/1_CXS_193e.pdf	1 mg/kg
Maximum daily intake for children from all foods	2.2 µg/ day children 8.8 µg/ day childbearing age	US FDA	https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares	1 mg/kg for any other edible substance
Baby Food	0.01 mg/kg 0.02 mg/kg 0.02 mg/kg	US FDA	<ul style="list-style-type: none"> 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats; 20 ppb for root vegetables (single ingredient); 20 ppb for dry infant cereals. 	0.03 mg/kg 0.04 mg/kg 0.02 mg/kg
Juice, Apple	0.01 mg/kg	US FDA	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice	0.01 mg/kg
Juice, all other types including blends that contain apple	0.02 mg/kg			0.02 mg/kg
Baby Formula	0.02 mg/kg	World Health Organization (WHO)	(CODEX STAN 193-1995) http://www.fao.org/fileadmin/user_upload/livestockgov/documents/1_CXS_193e.pdf	0.02 mg/kg

Product	Reference Limits	Agency	Reference	NC CLPPP Reportable Limits*
Candies likely to be consumed frequently by small children	0.1 mg/kg	US FDA	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children	0.1 mg/kg
Food coloring	2 mg/kg	US FDA	https://www.fda.gov/industry/color-certification/improvements-color-additive-certificates-analysis	1 mg/kg
Alternative Medicines	None found			1 mg/kg
Cosmetics	10 mg/kg for lip products	US FDA	https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/lead-cosmetics	10 mg/kg

*At or above the NC CLPPP reportable limit, NC CLPPP will report the sample results to US Food and Drug Administration (FDA) using their Consumer Complaints portal and copy our FDA state liaison. In NCLEAD, mark this as a Non-property Hazard Definite (Based on sample results from investigation) and attach photos, edible product/cosmetic surveys, and lab results to the Child Event.