

ASTA Guidance Levels for Heavy Metals in Spices

Introduction

Heavy metals, such as lead, inorganic arsenic, and cadmium, are ubiquitous in the natural environment. These elements are commonly found in the earth's crust, air, and water due to volcanic activity and environmental contamination. As such, any natural product that comes into contact with soil or ground water has the potential to take up trace amounts of metals that cannot be removed by washing or processing. The concentrations of metals in spices, like other common food products, naturally vary due to where and how the spices are grown, climate and soil conditions, as well as harvesting and processing methods.

Although the spice industry employs a variety of tactics to reduce heavy metal contamination, such as the use of Good Agricultural Practices, Good Manufacturing Practices, and monitoring, it is infeasible to avoid uptake and accumulation of trace levels of heavy metals in spices due to their persistent levels in the environments where spices are grown. As such, it is imperative that the spice industry remain vigilant to minimize the concentrations of heavy metals in spices to as low as technically feasible, while recognizing that background levels of heavy metals in spices can vary greatly based on environmental and physiological factors.

ASTA supports limits for heavy metals that are based on science and that are scientifically achievable, such as those recently adopted for lead in 2021 by the European Union (EU). To promote global harmonization with existing heavy metals limits, ASTA recommends the following industry guidance levels for heavy metals in various spice categories. Furthermore, the levels outlined in this document are intended to assist the spice industry to minimize the concentration of heavy metals found in spice products, guide public statement and positions, and demonstrate the industry's commitment to high food safety standards.

Members of the spice trade are encouraged to use this document together with other sources of information to develop and implement programs to ensure that the spices they sell comply with existing standards. It is an individual company's decision how best to use this document in meeting company goals and objectives.

Regulation of Heavy Metals in Spices in the U.S. and Abroad

Spices originate from different parts of a variety of plant crops grown in many different countries around the world. Levels of heavy metals present in the environment vary considerably by geography and the length of time each plant needs to reach maturation for harvest. Moreover, spices are sourced from different parts of the plant, including the roots, seeds, bark, fruit, or leaves. Their heavy metal content varies based on how the plant takes up and stores substances from the soil and from which part of the plant the spice is derived. Roots and bark naturally concentrate heavy metals from soils, resulting in higher metal levels than spices derived from other parts of the plant. For this reason, global regulatory authorities have considered heavy metal limits for spices that are based on natural occurrence, climate, production, and consumption patterns.

International Regulations

I. Lead

In 2021, the European Union (EU) established new limits for lead in spices (Appendix 1) categorized by spice type in <u>EU Regulation 2021/1317</u>. These levels were founded on considerations of achievability and exposure based on occurrence data submitted by the spice industry.

Additionally, several countries, including India, Vietnam, Singapore, China, and Taiwan, have implemented maximum levels for heavy metals in spices and herbs (Appendix 1).

In 2022, the <u>Codex Committee on Contaminants in Foods (CCCF)</u> considered proposed limits for lead in spices and herbs. In its analysis of more than 3,000 data points for culinary herbs and more than 5,000 data points for spices from the World Health Organization's Global Environmental Monitoring System (WHO GEMS) database and an industry call for data, the CCCF working group calculated background levels for spices for the following spice categories: floral parts; fruits and berries spices; rhizomes, bulbs and roots; seed spices; and celery seeds. The Committee considered lead limits in these categories ranging from 0.4 ppm to 3.5 ppm (Appendix 1). Although these levels were not finalized, the dataset compiled by the Committee represents the largest, publicly available dataset available for lead in spices and herbs.

II. Cadmium and Inorganic Arsenic

At present, no regulations exist in the EU that dictate maximum levels of inorganic arsenic in spice commodities. However, <u>EU Regulation 2021/1323</u> establishes a maximum level of cadmium in fresh herbs of 0.20 ppm. No regulations exist that establish maximum levels of cadmium in spices or dried herbs.

United States

I. U.S. Food and Drug Administration (U.S. FDA)

There is currently no FDA-established guideline for heavy metal levels in spices. However, FDA has established maximum limits for lead in a variety of commodities. For example, FDA has established a maximum level for lead of 0.1 ppm in candy likely to be consumed by small children. Similarly, in 2022, FDA introduced maximum levels of lead in apple juice and juice blends as part of its *Closer to Zero* initiative – an action plan to reduce childhood dietary exposure to heavy metals to as low as possible through the establishment of maximum allowable limits. The initiative considers factors that contribute to levels of heavy metals in foods, such as geographical differences, type of crop, and industrial processes, in conjunction with the amount of the commodity consumed. Furthermore, reductions are proposed following active engagement with stakeholders and considerations of industry achievability. To date, FDA has not prioritized spices as part of this initiative.

Although FDA does not have recall levels for lead in spices, it is FDA's practice to evaluate the potential for human health risk from heavy metals in spices on a case-by-case basis. FDA's approach considers exposure based on consumption of the product in question (i.e., a specific spice product such as cinnamon), along with the background levels of that specific commodity in 1) a recall situation for product already in the marketplace or 2) refusal of entry for imports.

II. Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986, also known as California Proposition 65 ("Prop 65"), was adopted through California's public referendum procedure. This Act calls for "clear and reasonable" warnings to be provided by business entities that may expose consumers to substances in consumer products or in the workplace that are determined by the state to be carcinogens or reproductive toxins. The California Office of Environmental Health Hazard Assessment (OEHHA) is the state agency responsible for the administration of Proposition 65.

No significant risk levels (NSRLs), also known as safe harbor levels when established by OEHHA, provide a way in which Prop 65 warnings are not required for exposures to listed substances when the exposures are below a certain level. Safe harbor levels for carcinogens, as established by OEHHA, are referred to as "NSRLs" and as "MADLs" (maximum allowable dose levels) for reproductive toxins. Appendix 2 outlines the safe harbor levels established by OEHHA for heavy metals.

Additional information on California's Prop 65 and its relevance to spices can be found in <u>ASTA's white paper</u> on this topic. ASTA has also published an <u>exposure-based screening tool</u> for lead in five spices (basil, cinnamon, ginger, oregano, and turmeric).

III. New York State

In 2016, New York State established Class II recall action levels of 1.0 ppm for lead. However, in 2021, the state proposed altering the Class II recall action limit to 0.21 ppm for lead and inorganic arsenic and 0.26 ppm for cadmium, representing the most stringent level globally. The state subsequently published 1) this level in its recall manual on its website and 2) an article outlining their approach in the *Journal of Regulatory Science*.

New York regulators derived the Class II recall action limits for inorganic arsenic and cadmium from the estimated 90th percentile of the background levels of each metal in the spices sampled. However, in contrast to the approach used for inorganic arsenic and cadmium, a health-based guidance value was calculated for lead, which was solely based on a risk assessment conducted by the Bureau of Toxic Substance Assessment (BTSA) within the New York State Department of Health. This value was calculated using two key data inputs developed by BTSA: total spice consumption among children 0-6 years of age and the non-cancer toxicity value for lead. However, the methodology employed by New York State to estimate total spice consumption does not follow standard approached used by U.S. regulatory authorities, including the FDA and U.S. Environmental Protection Agency (EPA) to estimate cumulative (i.e., total) intake of a commodity group such as spices. Furthermore, the use of a single limit for lead all spices is a departure from the approaches undertaken by the EU and Codex Alimentarius.

As such, ASTA engaged with the state's Department of Agriculture and Markets, Department of Public Health, and state legislature to explain that the new level is not supported by sound science nor a public health need, and ultimately is not achievable by industry. ASTA also advocated that any limit(s) should consider the relative safety risk of a contaminant, as well as the type of spice, its production processes, origin of purchase, and consumption patterns.

The Department of Agriculture and Markets has confirmed that the implementation of the new limits is on hold while additional research is being conducted to calculate the background levels

of lead in spices commonly consumed by children. Following a meeting with Governor Hochul's head of policy in New York City, the state has also removed the new limits from its food recall manual. However, the state has signaled that it ultimately plans to implement new action levels for spices.

Lead

I. Industry Guidance Levels for Lead

In the absence of a federal limit for lead in spices, and in an effort to promote global harmonization with existing limits for lead in the EU, ASTA recommends the following levels as maximum levels for lead in spices and dried herbs.

Table 1. Industry guidance levels for lead in spices and dried herbs.

Type of Spice (Dried)	Level (ppm)
Fruit spices	0.60
Seed spices	0.90
Bud spices	1.0
Flower pistil spices	1.0
Root and rhizome spices	1.50
Bark spices	2.0
Herbs ¹	

These levels are reflective of achievability considerations, as well as the varying background concentrations of lead in spices due to unavoidable environmental factors and innate uptake and accumulation mechanisms unique to plant types.

¹ No regulatory thresholds currently exist for lead in dried herbs. However, the establishment of a maximum level is under discussion by the Codex Committee for Contaminants in Foods. In 2022, the Committee proposed a maximum level of 2 ppm in dried culinary herbs. In 2023, the Committee proposed a maximum level of 1.5 ppm in dried culinary herbs, which represents the ~97th percentile of lead levels in dried herb samples (n=91). The proposed levels are still in flux. The Committee will consider a final proposed level at its meeting in April 2024.

Other Resources

In 2016, ASTA published its "<u>Identification and Prevention of Adulteration Guidance</u>" which outlines methods to identify and prevent adulteration of spices with contaminants such as heavy metals.

See also:

- ASTA Good Agricultural Practices Guide (GAP Guide)
- ASTA Good Manufacturing Practice (GMP) Guide for Spices
- California Prop 65 and Spices
- ASTA Exposure-based screening tool for contaminants in spices

DISCLAIMER

The American Spice Trade Association (ASTA) provides this guidance document solely to assist its members in addressing issues associated with trading in clean, safe spices. This guidance is not directive in nature and compliance with it is solely at the discretion of the user. ASTA does not provide any warranties of any kind, either express or implied, including but not limited to warranties of merchantability, fitness for a particular purpose, accuracy, design, usage, quality, performance, compatibility, or title. ASTA is not responsible for the use or nonuse of any information presented or discussed in this document. It is the responsibility of each ASTA member to verify information presented in this document before acting on it, and to comply with all relevant federal, state, and local laws. ASTA urges users of any of the information presented in this document to consult with appropriate experts before acting on any of the information in it involving heavy metal concentrations.

Appendix 1. Global Maximum Levels of Lead in Spices & Food.

Age Group/ Sub or Total population	Commodity	Type of threshold	Threshold level	Unit	Regulatory Agency
Total population	Spices (excluding curry powder); curry powder	ML	2	mg/kg	Vietnam Ministry of Health
Total population	Dried herbs and spices	ML	10	ppm	Food Safety and Standards Authority of India
Total population	Dried herbs and spices (including mustard); curry powder	ML	2	ppm	Singapore Food Agency
Total population	Spices	ML	3	mg/kg	China FDA
Total population	Herbs and Spices (fresh)	ML	0.3	mg/kg	Taiwan FDA
Total population	Fruit spices	ML	0.6	mg/kg	EU Commission 2021
Total population	Root and rhizome spices	ML	1.5	mg/kg	
Total population	Bark spices	ML	2	mg/kg	
Total population	Bud spices and flower pistal spices	ML	1	mg/kg	
Total population	Seed spices	ML	0.9	mg/kg	
Total population	Culinary herbs (dried)	ML* proposed	1.5	mg/kg	Codex Alimentarius - Codex Committee on Contaminants in Foods (Proposed) 2023
Total population	Bark spices	ML* proposed	2.5	mg/kg	
Total population	Bud spices	ML* proposed	3	mg/kg	
Total population	Fruits and berries spices	ML* proposed	0.6	mg/kg	
Total population	Rhizomes, bulbs, and roots spices, excluding galangal, asafoetida, coriander root	ML* proposed	2.0	mg/kg	
Total population	Seeds spices	ML* proposed	0.8	mg/kg	

Appendix 2. Safe Harbor Levels for Heavy Metals (Prop 65)

Lead & Lead Compounds

Cancer		
	No Significant Risk Level (NSRL) - Oral	15 μg/day
Reproductive Toxicity	, ,	
	Maximum Allowable Dose level (MADL)	0.5 µg/day

Cadmium

Cancer		
	No Significant Risk Level (NSRL) - Inhalation	0.05 μg/day
Reproductive Toxicity	· .	
	Maximum Allowable Dose level (MADL) 0 Oral	4.1 μg/day

Arsenic (Inorganic Arsenic Compounds)

Cancer	
No Significant Risk Level (NSRL)	10 μg/day (except via inhalation)
No Significant Risk Level (NSRL) - Inhalation	0.06 µg/day