

# ASTA Guidance Levels for Heavy Metals in Spices

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#### 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 agricultural 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 impossible to avoid the natural 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 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 as to how best to use this document in meeting company goals and objectives.

# Background on Heavy Metals in Spices

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, each which have a different propensity to store and accumulate heavy metals. As such, heavy metal content in spices 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. Variability exists in the background levels of heavy metals in spices; however, levels of heavy metals in spices resulting from natural uptake are typically low.

The spice industry is committed to ensuring spices remain safe and that any presence of heavy metals is as low as feasible. The spice industry typically achieves this in several ways. Spice farmers follow Good Agricultural Practices to mitigate uptake of heavy metals during growing. Importers ensure compliance with quality standards and strict specifications by requesting documentation from

their suppliers, including testing for heavy metals to achieve the safest supply of spices for consumers. Additionally, manufacturers use cleaning methods to minimize contributions from soil and the environment and adhere to practices to prevent the contribution of heavy metals through processing.

#### **Lead in Spices**

Publicly available data supports that naturally occurring background levels of lead in spices is relatively low (< 3 ppm), although there is variability depending on the type of spice and origin. In an analysis of 978 data points for culinary herbs and 6,532 data points for spices from the World Health Organization's Global Environmental Monitoring System (WHO GEMS) database, the Codex Committee on Contaminants in Foods (CCCF) calculated background levels of lead in spices based on part of plant. The Committee found that background levels of lead typically ranged from 0.4 ppm to 3 ppm, with the highest levels being recorded in bark spices (i.e., cinnamon).

It is imperative to differentiate between naturally occurring background levels of lead in spices and those found in spices due to economic adulteration. Adulteration is defined as the inclusion in foods of constituents whose presence is prohibited by regulation, custom, and practice as outlined in 21 U.S.C. § 342. Economically motivated adulteration often involves the addition of substances to a food to increase the food's value, such as enhancing a product's appearance. For example, the adulteration of spices with lead-containing compounds, such as lead chromate, has been known or suspected to be used to enhance the color of specific spices, such as turmeric, paprika, and cinnamon.

In cases of economically motivated adulteration, lead may be present in spices at levels that significantly exceed those observed due to natural uptake, leading to adverse health outcomes. In 1994, ground paprika in Hungary was found to be adulterated with lead oxide, causing the deaths of several people and resulting in illness in dozens of others. In 2023, cinnamon adulterated with lead chromate was used as an ingredient in cinnamon applesauce, resulting in over 500 cases of lead poisoning in the United States. Analysis of the cinnamon used in the applesauce demonstrated that lead levels were as high as 2,270 to 5,110 ppm, thousands of times higher than the background levels of lead reported in cinnamon by the CCCF. In countries of origin, lead chromate has been shown to be added to turmeric to provide a brighter, yellow color to the spice (see Forsyth et al., 2019).

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

As noted above, spices originate from many different regions around the world with unique environmental factors and innate physiological properties that influence a spice product's ability and propensity to uptake lead from its surroundings. 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).

#### 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. Although no regulations exist that establish maximum levels of cadmium in spices or dried herbs, the EU permits in the case of dried products (e.g., herbs) the concentration caused by the drying process to be considered when determining the maximum residue limit. Therefore, the maximum level of cadmium in fresh herbs (0.2 ppm) can be extrapolated to individual dried herb commodities upon the application of dehydration factors. The European Spice Association (ESA) <u>recommends</u> specific dehydration factors for dried herbs, which are multiplied by the maximum level of a contaminant in the fresh commodity to derive the corresponding maximum level in a dried herb.

#### Codex Alimentarius

In 2024, the <u>Codex Committee on Contaminants in Foods (CCCF)</u> considered proposed limits for lead in spices and dried 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 proposed lead levels for the following categories: dried seeds, excluding celery seeds; dried celery seeds; dried rhizomes and roots; dried bark; dried floral parts; dried fruit and berries, excluding Sichuan pepper, star anise, paprika, and sumac; dried paprika and sumac; dried Sichuan pepper and dried Star anise; and dried culinary herbs. The Committee forwarded all proposed maximum levels for Step 5/8 for adoption, except for dried bark and dried culinary herbs which were forwarded to Step 5. The proposed levels range from 0.6 to 3.0 mg/kg (Appendix 1). Although these levels are not yet finalized, the dataset compiled by the Committee represents the largest, publicly available dataset available for lead in spices and herbs.

#### **United States**

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

Although there are currently no FDA-established guidelines for heavy metal levels in spices, 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 <u>candy</u> likely to be consumed by small children. Similarly, in 2022, FDA introduced a maximum level of lead of 50 ppb in <u>juice blends</u>. In 2023, FDA introduced a maximum level of inorganic arsenic of 10 ppb in <u>apple juice</u>. Moreover, in 2023, FDA introduced maximum levels for lead in categories of <u>processed baby foods</u>, including 10 ppb for fruits, vegetables, mixtures, yogurts, custards/puddings, and single ingredient meals; 20 ppb for root vegetables (single ingredient), and 20 ppb for dry cereals. These limits were established as part of FDA's <u>Closer to Zero</u> 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 heavy metals 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.

#### Recent Enforcement – Lead in Cinnamon

In late 2023, three brands of cinnamon applesauce manufactured in Ecuador were recalled due to high levels of lead. Analysis of the cinnamon used in the applesauce demonstrated that lead levels were as high as 2,270 to 5,110 ppm. From its investigation, FDA concluded that the cinnamon used in the applesauce was adulterated by an intermediate supplier in Ecuador with lead chromate during processing.

Following the cinnamon applesauce recall, FDA conducted targeted product testing for lead and chromium for ground cinnamon products sold at discount retail stores. In March 2024, the agency recommended voluntary recalls for ground cinnamon products from six distributors whose products were found to have levels over 2 ppm of lead. Additional recalls were announced in July and August 2024.

In <u>meetings with FDA</u>, the agency communicated to ASTA that it will continue to use 2 ppm as the enforcement threshold for lead in cinnamon, although the agency does not plan to codify this level or establish it through guidance.

Notably, the FDA enforcement level for cinnamon (2 ppm) aligns with the maximum level proposed in this document and with current EU regulations.

#### II. Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986, also known as California Proposition 65 ("Prop 65"), is a right-to-know law (not a public health or safety law) adopted through California's public referendum procedure. This Act calls for "clear and reasonable" warnings to be provided by business entities before exposing consumers to substances that are determined by the state to be carcinogens or reproductive toxicants. The California Office of

Environmental Health Hazard Assessment (<u>OEHHA</u>) is the state agency responsible for the administration of Proposition 65.

When exposures are less than no significant risk levels (NSRLs) for carcinogens and maximum allowable dose levels (MADLs) for reproductive toxicants, also known collectively as safe harbor levels, no warning is required for such exposures. Title 27, Cal. Code of Regulations, Sections 25705, 25709 and 25805 summarize the current safe harbor levels established by OEHHA for heavy metals. These levels are expressed on a microgram per day basis and should not be confused for concentrations of the given chemical in the product.

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.

#### III. New York State

In 2016, New York State established Class II recall action levels of 1.0 ppm for lead, inorganic arsenic, and cadmium. 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 90<sup>th</sup> 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 approaches 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 in 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 achievability based on 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. The state has signaled that it ultimately plans to implement new action levels for spices. However, until that time, the Class II recall action level of 1.0 ppm for lead, inorganic arsenic, and cadmium remains in effect.

In 2023, New York State Senator Jessica Ramos (D-13) introduced an ASTA supported-bill in the New York State Senate (\$7036) to establish a standard for lead in retail spices sold in New York that aligns with ASTA's Guidance Levels (Table 1) and the European Union. A companion bill (\$47707) was soon introduced in the New York State Assembly by Assembly Member Monica Wallace (D-143). In June 2024, the New York Senate passed the bill unanimously (61-0). However, the New York Assembly did not advance the companion bill in the 2024 legislative session. ASTA will continue to work with the New York State Legislature and Governor's Office to advocate for clear and achievable limits.

## Heavy Metals & Hazard Analysis

FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry ("PCHF Draft Guidance") (Revised Draft January 2024) is a multi-chapter guidance designed to help food facilities develop their food safety plan, conduct a hazard analysis, and comply with other components of 21 CFR Part 117, Subparts C and G. The document includes "Appendix 1: Known or Reasonably Foreseeable Hazards", which provides guidance for identifying potential biological, chemical, and physical hazards for 16 different food groups, including spices. Appendix 1 is intended to serve as a starting point for hazard analysis, although the inclusion of a potential hazard in Appendix 1 does not mean that the hazard automatically requires preventive control for any particular food.

In Table 2O of the Appendix, arsenic, cadmium, and lead are identified as known or reasonably foreseeable (i.e., potential) chemical hazards in spices. The presence of lead in spices may be due to the uptake of naturally occurring lead in the environment or through economically motivated adulteration.

The PCHF Draft Guidance also addresses spice-specific heavy metal issues more directly. In Chapter 1, the guidance notes that "hazards due to economically motivated adulteration, such as the addition of dyes containing lead to spices to enhance color" should be considered when drafting a food safety plan. Moreover, Chapter 3 of the guidance notes three hazards that may be intentionally introduced to spices for economic gain: (1) lead chromate in turmeric, (2) lead oxide in paprika, and (3) Sudan I in chili powder. In evaluating whether economic gain is a hazard requiring preventive control, FDA recommends considering the country of origin and supplier specific risks.

Per 21 CFR §117.130, food companies must "conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control." Companies are also obligated by 21 CFR § 117.170(b)(2) to reanalyze their food safety plans needed, including "whenever you become aware of new information about potential hazards associated with the food."

In light of the recent recalls of cinnamon applesauce products and ground cinnamon, it is ASTA's recommendation that companies that produce and use ground cinnamon should reanalyze their food safety plans according to CFR §117.170 to ensure that the potential hazard of lead is identified and evaluated in their hazard analysis.

## Industry Guidance Levels for Lead

Herbs<sup>1</sup>

#### 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.

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

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

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.

#### 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:

- IOSTA Good Agricultural Practices Guide (GAP Guide)
- ASTA Good Manufacturing Practice (GMP) Guide for Spices
- ASTA Heavy Metals FAQ
- ASTA Spice Safety Fact Sheet
- ASTA Exposure-based screening tool for contaminants in spices
  - Note: This tool is outdated. Please contact ASTA staff directly for more information.

 $<sup>^1</sup>$  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 (CCCF). In 2024, the Committee proposed a maximum level of 2.5 ppm in dried culinary herbs, which represents the  $^\circ97^{th}$  percentile of lead levels in dried herb samples (n=194). During the  $17^{th}$  meeting of the CCCF, the levels were forwarded to Step 5 for consideration at its subsequent meeting in 2025.

#### 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 or Total population	Commodity	Type of 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	
Total population	Root and rhizome spices	ML	1.5	mg/kg	
Total population	Bark spices	ML	2	mg/kg	EU Commission 2021
Total population	Bud spices and flower pistil spices	ML	1	mg/kg	
Total population	Seed spices	ML	0.9	mg/kg	
Total population	Spices, dried aril	ML proposed	0.9	mg/kg	
Total population	Spices, dried seeds, excluding celery seed	ML proposed	0.9	mg/kg	
Total population	Dried celery seeds	ML proposed	1.5	mg/kg	
Total population	Spices, dried rhizomes and roots	ML proposed	2.0	mg/kg	
Total population	Spices, dried bark	ML proposed*	2.5	mg/kg	Codex Alimentarius - Codex
Total population	Spices, dried floral parts	ML proposed	2.5	mg/kg	Committee on Contaminants in Foods Proposed in 2023, Levels Advanced to Step 5/8 in 2024 *Levels Advanced to Step 5 in 2024
Total population	Spices, dried fruits and berries, excluding Sichuan pepper, star anise, paprika, and sumac	ML proposed	0.6	mg/kg	
Total population	Spices, dried paprika and sumac	ML proposed	0.8	mg/kg	
Total population	Dried Sichuan pepper and dried star anise	ML proposed	3.0	mg/kg	
Total population	Dried culinary herbs	ML proposed*	2.5	mg/kg	
Total population	Cinnamon	Enforcement level	2.0	mg/kg	U.S. FDA
Total population	Spices	Class II Recall Action Level	1.0	mg/kg	New York State

# 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) - 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