LONG POINT advisors

By Email

July 7, 2022

Kevin King
Deputy Secretary, Agriculture and Markets
Office of New York State Governor Kathy Hochul
NYS Capitol Building
Albany, NY 12224

Dear Deputy Secretary King,

Thank you for taking the time to meet with my client the American Spice Trade Association (ASTA), some of its members, New York Food Industry Alliance, and the Consumer Brands Association, on June 17 (the "June 17th Meeting"). We appreciate the Administration's willingness to discuss our concerns with New York State's proposed new class II recall action levels for heavy metals in spices. While the group that met with you represents a diverse and wide-ranging segment of New York businesses and industries, they are united in their worries about the impact that these proposed new levels would have on the lives of New Yorkers and on businesses that operate in New York. It is ASTA's mission to ensure the supply of safe and pure spices, and ASTA and the representatives who met with you all share New York State's goal in protecting public health.

However, this group, and others with whom you have previously corresponded, have many concerns and outstanding questions about the proposed new levels for spices. As discussed in the June 17th Meeting, there has not been a public opportunity for stakeholders to formally submit written comments, questions, concerns, or objections to the proposed levels prior to their adoption. It was relayed to us at the meeting, however, that parties could submit comments to the proposed levels via letter. Accompanying this letter at Exhibit A is a written memorandum and a scientific report prepared by ASTA outlining its concerns. I have also attached several exhibits to this letter in support of our position. We respectfully request that the Administration, the Department of Health (DOH), and the Department of Agriculture and Markets (DAGM) take account of all of this correspondence and documents as comments when considering future actions regarding the proposed recall action levels.

ASTA's questions regarding, concerns about, and an alternative approach to the new levels proposed by New York State are summarized below.

<u>Outstanding Questions Regarding the Status of the New Levels</u>

- *Are the levels proposed or adopted?* Agriculture and Markets Deputy Commissioner Jennifer Trodden stated during the June 17th Meeting that the class II action levels for heavy metals are, in fact, "proposed" and not yet adopted. New York State, however, has published documents, such as its Food Recall Manual (revised May 27, 2021), the written materials for DAGM's May 25, 2001 Webinar,[1] and the study by Ishida et al. (2022) that publicly maintain that the State's recall policy *has been updated* to lower the recall action levels to these levels. Copies of these documents are attached as Exhibit B. These inconsistencies have created confusion among

[1] https://agriculture.ny.gov/system/files/documents/2021/06/heavymetalspresentation.pdf

consumers and businesses about status of these levels. New York State should revise all references to the levels to clearly and consistently communicate that they are, in fact, only proposed.

- *Do the levels apply to all uses of spices?* There remains confusion regarding whether the new proposed levels apply to spices used as ingredients for commercial purposes (e.g., commercially prepared foods, restaurant prepared meals, bakery goods) or only to spices for retail sale (i.e., those sold in stores to individual consumers). The uncertainty was underscored at the June 17th Meeting when representatives of New York State stated that the "intent" of the new proposed levels is to apply only to retail spices. At one point in the meeting, Deputy Commissioner Trodden stated that regulatory action would be taken against spices used as ingredients in processed foods if the level was exceeded and suggested that companies could not produce or manufacture foods in New York State that used spices that exceed the proposed new levels. She then subsequently indicated that the "focus" of the new proposed levels was only for retail spices.

  The policy, as currently drafted, fails to clearly make this distinction and exposes companies using spices as ingredients in processed or restaurant-prepared foods to possible liability even if the state does not intend to focus on enforcement of this use. Moreover, it is unclear from a public health standpoint why the proposed levels would target spices sold for retail sale. These spices represent a tiny fraction of the overall spice consumption and are used in similar minor quantities in home-cooked products as are present in processed or restaurant food products. We request that New York State both clarify if all spices are subject to the new policy and if not, justify the different standard.

- *When do the levels go into effect?* We understand that New York will require compliance 18 months after the State announces to the industry that it is ready to begin the new levels. Eighteen months is an insufficient timeline for the industry to comply with a new action level for spices. Among other concerns: (a) the shelf life of spices is typically at least two years so food will already be in commerce that was produced before the new levels took effect, and (2) companies need an additional two to four years, at minimum, to work with suppliers to either source product that would meet the level (for those spices that this is technically feasible, as discussed below) or, to cease the sale of products in the state.

- *What details can be shared about New York's additional on-going research?* In February 2022, Deputy Commissioner Trodden advised ASTA about additional research being conducted on this issue. ASTA applauds such research endeavors and raised questions about such research in a subsequent email. To date, New York State has not provided a response to ASTA's questions. A copy of this correspondence is attached as Exhibit C.

<u>Concerns with the Proposed New Levels</u>

- *The levels are not achievable.* Due to challenges in conducting a health-based determination for lead levels, most regulatory authorities, including in New York State, opt to set levels as low as achievable. The detailed report set out in Exhibit A, among other things, outlines the concerns regarding the industry's inability to meet the proposed new levels; explains that background levels of heavy metals in spices vary substantially by the type of spice; and highlights that the preponderance of publicly available evidence demonstrates that New York State's proposed new levels would not be achievable by the spice industry. This report further outlines that achievability is a key consideration for the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO) when those highly credible authoritative bodies set action levels for lead and other contaminants in food.

- *Research does not support the health-based lead value.* In its presentation on December 9, 2021, ASTA shared several concerns with DAGM and DOH regarding the scientific basis of the analysis to determine the health-based value. A copy of this presentation is attached as Exhibit D. ASTA's concerns are further explained in the report attached as Exhibit A, which outlines the flaws in the state's consumption analysis for spices and lack of an adequate exposure assessment. We respectfully request that DAGM and DOH review this research and take it into account as the agencies continue to undertake additional research on the issue.

- *The policy is unlikely to be effective at reducing exposure to lead.* The new heavy metal policies would not be effective at meaningfully reducing exposure to heavy metals, since neither the DOH nor the DAGM conducted any exposure assessment to determine the contribution of spices to overall lead exposure among children. Given that spices represent approximately 0.1% of food intake, it is unclear why New York proposed new levels that are approximately five times lower than other food commodities with higher contributions to food intake among children. Further no data has been provided to support the rationale for focusing on spices when intake contributes minimally to total dietary intake

- *New York regulators misapplied a NYCDOH study to justify the new levels and the proposed action will likely result in unintended consequences.* Reference was made to a New York City Department of Health (NYCDOH) study (Hore, et al) (the "Hore Study") as a basis for these new levels. It is critical to understand that this study provides that lead-based paints and occupational lead hazards "remain the primary sources of lead exposure among New York City children and men." While this study acknowledges that spices can be "identified as potential lead sources associated with elevated blood lead levels," researchers found that "lead content in the spices was significantly higher for spices **purchased abroad** [emphasis added] than in the United States." A copy of the Hore Study is annexed as Exhibit E. These findings *do not show* that spices grown overseas and imported into the U.S. for commercial sale contain excessive levels of heavy metals, but rather that this problem arises from spices in unmarked/unbranded containers purchased by consumers directly in foreign countries and carried home in their luggage. Moreover, the study findings demonstrate that the U.S. regulatory framework is effective, and that meaningful action must be targeted at the global supply chain. By misapplying this NYCDOH study, New York State has proposed new levels that would create a *de facto* ban on spices when more stringent restrictions are unnecessary and are not supported by sound science. In fact, New York's proposed new levels would make it so that immigrant families living in New York would be unable to access safe and affordable spices in the state. The unintended consequence may be that these families would source spices from overseas from the countries that have the highest levels and that have not been imported through the regulated commercial channels.

Alternative Approaches

As a part of ASTA's core work, the U.S. spice trade industry collaborates with global regulatory and spice production counterparts around the world on research and educational programs intended to promote the safety of spices. With respect to heavy metals, specifically, ASTA partners with NGOs, governmental agencies, and industry groups worldwide to understand the sources of uptake in spices grown overseas and promote effective mitigation strategies. ASTA also publishes guidance on good agricultural practices, regularly presents at global spice conferences on this topic, and collaborates on spice famer training program. ASTA welcomes collaboration with New York State on research and education programs with our global counterparts.

To that end, ASTA is supportive of regulatory levels for heavy metals in spices that are protective of public health when the levels are based on science and that are technically and scientifically achievable. For instance, New York State could utilize the approach recently adopted by the European Union and those under consideration by the Codex Alimentarius Committee on Contaminants in Foods. Notably, these levels differ based on the type of spice. This approach allows for appropriate consideration of differing consumption patterns of various types of spices, as well as the variability in naturally-occurring background levels of heavy metals. ASTA believes that adoption of these levels would allow New York State to balance the public health protection of its residents with the needs of New York families, businesses, and industries.

EU Lead Levels for Spices, Adopted in 2021

Category	Lead Level (mg/kg)
Fruit spices	0.6
Root and rhizome spices	1.5
Bark spices	2.0
Bud spices and flower pistil spices	1.0
Seed spices	0.9

It is my understanding that DAGM is seeking certain data from ASTA regarding lead levels in spices. Please note that in response to concerns about New York State's new heavy metal levels for spices, ASTA previously provided DAGM confidential, trade secret information on the achievability of the new levels on a spice-by-spice basis for select spices. This information was covered in the PowerPoint slides presented to DAGM and DOH on July 29, 2021 (See Exhibit F). In the attached correspondence with Deputy Commissioner Trodden in February 2022, additional data was requested from ASTA, but as noted in ASTA's response, data was not collected on other spices (See Exhibit C). Regardless, this type of blinded consolidated industry data should not be a basis of governmental action, but rather was intended to illustrate the variability and impact of proposed new levels on a spice-by-spice basis.

As an alternative data source, we suggest that DAGM look to its own database and/or the publicly available literature, including more than 5,000 datapoints in the WHO's Global Environment Monitoring System (GEMS) database, as summarized in the scientific report attached as Exhibit A. These data demonstrate that heavy metal levels in spices vary by the type of spice and that the new levels proposed by New York State are both unachievable and inconsistent with other U.S. and global regulatory frameworks.

In summary, New York State has yet to justify the need to establish heavy metal levels that depart from existing regulatory frameworks established by U.S. and International authorities that represent the gold standard for food safety. We look forward to continuing the dialogue with your office and New York State on this issue.

Very truly yours,

Hon. Craig M. Johnson
Chief Executive Officer
Long Point Advisors

Cc: Micah Lasher, Director of Policy
Angela Profeta, Deputy Secretary of Health
Laura Shumow, Executive Director, ASTA

EXHIBIT A

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Technical Questions and Concerns Arising from the Meeting on June 17, 2022

ASTA has prepared the attached report, which outlines concerns with the achievability and scientific basis of New York State's "proposed" class II recall action levels for heavy metals for spices. These concerns were also raised during meetings with Department of Agriculture and Markets (DAGM) and the Department of Health (DOH) on July 29 and December 9, 2021.

Following the meeting on June 17, several additional questions and concerns have come to light, which are highlighted in this memo.

Achievability

The proposed levels for inorganic arsenic and cadmium are based on a 90th percentile of achievability determined by background levels of heavy metal in spices, but despite the state's assertion that action levels should be "as low as achievable", **it does not appear that an achievability assessment was conducted for lead.**

The attached report demonstrates that background levels of heavy metals in spices vary substantially by the type of spice and that the preponderance of publicly available evidence demonstrates that New York State's recall action levels for lead will not be achievable for many spices. This report further outlines that a 95th percentile is used by FDA and Codex as an achievability threshold and that other regulatory authorities have established higher maximum lead action levels for spices, which vary on a spice-by-spice basis for different spice categories.

We understand that additional research that is being conducted by DAGM as described by Deputy Commissioner Jennifer Trodden during the meeting on June 17 and in the email communications with ASTA in February 2022 to evaluate the achievability of the new levels for spices commonly consumed by children. However, there are still many outstanding questions regarding this research, which were not answered by email or during the meeting:

- **Will New York State adjust its lead level if the results of the study determine that the proposed level is not achievable by the market? What threshold of achievability will be used? Will this be consistent with the 90th percentile used as the basis for cadmium and inorganic arsenic action levels and if not, why?**

- We understand that New York State is planning to focus on 16 "spices" that are "commonly consumed by children", including several commodities that are excluded from the FDA's definition of spices (such as bell pepper and sesame seeds), and a "spices, other" category. **Is the intention that the new recall action levels for lead in spices would only apply to these 16 spices? If so, how will New York State address the "spices, other" category which includes 20+**

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spices including many that seem unlikely to be commonly consumed by children (e.g. juniper berries, lovage seed, caper, etc.)?

Exposure Assessment

During the meeting, ASTA members and allied food organizations questioned the scientific basis for the 0.21ppm lead limit for spices, versus the 1ppm limit for "other food products" outlined in the May 27, 2021 version of the New York State's food recall manual. Since spices represent a small percentage (approximately 0.1% per the attached report) of food intake, it is unclear why the limit established for spices is so much lower than that for other foods. An exposure assessment would demonstrate the relative contribution of spices to lead exposure versus other sources and the resulting impact of the new proposed level on total exposure.

While it appears that no such exposure assessment was conducted by DOH, during the meeting, Gary Ginsberg, Director of the Center for Environmental Health explained that the policy was based on a publication by Hore et al. (2022). This paper reported that spices purchased abroad by consumers and carried home in their suitcases, particularly from Georgia, Bangladesh, Pakistan, Nepal, and Morocco, contained much higher levels of lead than spices available for purchase in the United States. As such, Hore et al. (2022) conclude that local and national policies are unlikely to be effective at addressing the challenge. Rather, the authors recommend that policymakers work with global partners in the spice trade and initiate educational programs that warn consumers about the risks posed by purchasing spices from countries that have the highest levels of lead. **What impact will the proposed levels have on the risk of consumers purchasing spices overseas with elevated lead levels?**

Consumption rate of spices

During the meeting, there was a lengthy discussion regarding the applicability of the proposed levels to spices used as ingredients for processed or restaurant foods versus spices sold directly to consumers at retail. Gary Ginsberg inaccurately stated that the consumption data used to support the state's health-based assessment only applies to retail spices. The EPA and CDC databases used to estimate consumption of the eight (8) commodities used in the state's assessment includes spices used as ingredients in processed food products. Moreover, this rationale raises the question of if the proposed levels only apply to the eight commodities used in the health-based assessment. **Since the health-based assessment is only based on an evaluation of eight (8) commodities, is the intention that the policy only applies to these commodities?**

The attached report also outlines additional concerns with the selection of these eight (8) commodities and other flaws with the state's consumption analysis. For example, the analysis inaccurately assumes that every child consumes every spice, every day, despite the fact that scientists and regulators from New York State have stated that duration and frequency of exposure are important determinants of

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human exposure to metals and should be considered. Given New York States direct reliance on the consumption rate of spices to calculate the recall level for lead, the methodology and data sources used to estimate consumption of spices among children are impactful. The attached technical report demonstrates the impact incorrect use of the consumption data will have on derivation of the action level for lead with alternative action levels ranging up to 1.2ppm (i.e., six times higher than the proposed recall action level and consistent with the existing limit of 1ppm).

The American Spice Trade Association's response to New York State's new regulatory policies for heavy metals in spices

Abbreviations:

ASTA - American Spice Trade Association
BTSA - Bureau of Toxic Substances Assessment
bw - bodyweight
CCCF - Codex Alimentarius (Codex) Committee on Contaminants in Foods
NYS – New York State
DGA - U.S. Dietary Guidelines for Americans
EMA - Economically Motivated Adulteration
EPA - U.S. Environmental Protection Agency
FDA - U.S. Food and Drug Administration
FCID - EPA's Food Commodity Intake Database
g - gram
GAP - Good Agricultural Practices
GMP - Good Manufacturing Practices
kg - kilogram
mg - milligram
NYAGM - NYS Department of Agriculture & Markets
ppm – parts per million
ppb – parts per billion
WHO GEMS - World Health Organization's Global Environmental Monitoring System
WWEIA - What We Eat In America

Introduction

The Journal of Regulatory Science recently published an article by Ishida et al. (2022) titled **"**Regulatory policies for heavy metals in spices – a New York approach," which outlines the state's plans to reduce its Class II recall action levels for spices by nearly five-fold, from 1.0 parts per million (ppm) to 0.21 ppm for lead and inorganic arsenic and to 0.26 ppm for cadmium. The American Spice Trade Association (ASTA) has evaluated the basis for the new action levels presented in Ishida et al. (2022). This report provides a discussion of ASTA's review and additional information to support a basis for recommending that further considerations be taken prior to implementing new action levels for heavy metals in spices and that the new levels be revoked in the interim.

The U.S. spice industry has made significant changes to their standards of practice to meet the New York State (NYS) Class II recall action level of 1.0 ppm for lead that was established in 2016. NYS's new action levels of 0.21 ppm for lead and inorganic arsenic and 0.26 ppm for cadmium represent the most stringent levels globally. Unfortunately, the ability of the spice industry to achieve the new lead level was not considered in the assessment presented in Ishida et al. (2022). For those spices for which the new heavy metal action levels are not achievable, the new reduced Class II recall action levels will result in a *de facto* ban in NYS. Furthermore, the relative contribution of spices to overall lead exposure was not quantified nor was the relative impact of the new levels on reducing lead exposure. The new action levels would essentially ban spices that have heavy metals that are naturally incorporated by the plants from which they are sourced, and are not removable by the spice industry, without resulting in measurably lower consumer exposures.

ASTA supports regulatory limits for heavy metals in spices that are based on science and that are technically achievable, such as those recently adopted by the European Union and those under consideration by the Codex Alimentarius (Codex) Committee on Contaminants in Foods (CCCF). It is a standard practice to engage public stakeholders, including the regulated industry, in the process of establishing new regulatory requirements. This approach helps to inform effective policies and achieve compliance. NYS did not provide a meaningful or public opportunity for stakeholder input prior to publishing the new reduced action levels for heavy metals in spices (Ishida et al. 2022). Such input would provide NYS with important insights into the relative impact to exposure and the feasibility of the proposed actions.

While no public comment period was offered, NYS Department of Agriculture & Markets (NYAGM) did notify the regulated industry of its new levels during a webinar held in May 2021. Moreover, in July and December 2021, the authors of Ishida et al. (2022) met with ASTA to address questions and concerns regarding these levels, which are summarized in this public letter, along with ongoing questions for clarification on the assessment presented by Ishida et al. (2022) and proposed alternative approaches to setting levels for heavy metals in spices.

Ishida et al. (2022) focuses only on spices and states that the Class II recall action level for lead should be set "as low as achievable." However, it does not appear that an achievability assessment was completed to inform the setting of the new level for lead. It is critical to consider achievability since the ubiquitous nature of these compounds renders it impossible to avoid small levels of uptake and accumulation in the plants from which spices are derived. Based on the last correspondence with the NYAGM, it is our understanding that the state plans to conduct additional research on the heavy metal content found in spices commonly consumed by children and the achievability of the new limits on a spice-by-spice basis. We support this additional research that will build upon the database described in Ishida et al. (2022) and would appreciate the opportunity to work with NYSAGM on an alternative approach to establishing recall action levels informed by the additional data. Considering that we have raised significant scientific and practical questions, we believe NYS should remove the new recall action levels presented by Ishida et al. (2022) from the NYSAGM website and its regulatory policy manual until the additional data is collected and analyzed.

Ishida et al. (2022) states that by reducing the existing Class II recall action level, NYS would be better protecting "NYS consumers by reducing spices as a source of heavy metal contamination in the human body." However, it is unclear from Ishida et al. (2022) if they evaluated (i) the relative contribution of spices to overall lead exposure from all sources, (ii) the relative contribution of spices to all dietary sources of heavy metals, and (iii) the relative impact of the new levels on reducing lead exposure, with an emphasis on children. Ishida et al. (2022) note that they targeted spices because heavy metals have been observed in spices. Yet, heavy metals have been observed for decades in a wide variety of foods, including foods consumed by children such as fresh fruits and vegetables, as evidenced by the U.S. Food and Drug Administration's (FDA) Total Diet Study. Therefore, this is not sufficient scientific justification for Ishida et al.'s (2022) sole focus on spices.

Further, exposure-based dietary risk assessment should consider the levels of a contaminant observed in the food, as well as the pattern of consumption (including both amount and frequency). Based on the recommended total food intake rate for children of 79 grams/kg bw/per day (Mean total food intake among children 3 to <6 years of age, Table 14-1; EPA 2011) and the total spice intake estimated by Ishida et al. (2022) of 114.0 mg/kg bw/day (see Supplemental Material), total spice intake represents approximately 0.1% of total food intake among children. In addition, the assessment conducted by NYS is flawed in that the methodology used incorrectly assumes that every child consumes every spice every day and inaccurately defines spices, which will result in an overestimation of exposure. Nonetheless, it is not clear why Ishida et al. (2022) established levels for lead in spices that are five times lower than action levels for all other products except ready-to-drink juices and children's candy (New York State 2021), when other food and beverage commodities that contain lead are consumed in greater quantities and noted to be significant contributors to dietary lead exposure (Spungen 2019). Any reduction in lead exposure resulting from these new levels is likely negligible given the minor contribution spices make to the overall diet in children.

NYSAGM should (i) consider the relative contribution of spices to heavy metals exposure from the diet, (ii) work with food industry stakeholders to establish achievable action levels on a spice-by-spice basis that would be in line with global regulatory standards, (iii) address serious concerns related to the methodology used to derive the reduced action levels, and (iv) consider alternative approaches to regulating heavy metals in spices. A detailed discussion of the importance of considering all these points prior to establishing reduced action levels follows.

Additionally, the potential unintended consequences of these regulatory actions should be considered. For example, New York consumers may be incentivized to source spices directly from countries that have no regulatory standards in place, for which heavy metals are documented to be much higher. Other concerns include the impact on cultural culinary practices and the beneficial role of spices in supporting a healthy diet.

Background levels of heavy metals in spices

Naturally occurring versus economically motivated adulteration

It is critical that a distinction be made between naturally occurring (low) levels of heavy metals that are present in agricultural products and high levels that are likely the result of economically motivated adulteration (EMA). There are known historical incidents in which lead chromate and other lead-based colorants have been added to spices to enhance color in the developing countries from where they are sourced. These added colorants are used to improve the perceived quality of the spice and, thus, increase its value. This form of adulteration has been known to result in high levels of heavy metals, reaching as high as 48,000 ppm in foreign markets (Hore et al. 2019).

The prevention of EMA incidents has been a major area of focus of the spice industry and regulatory authorities to reduce lead in spices to as low as feasible. The U.S. spice industry has put in place supply chain verification measures to mitigate the potential presence of illegal dyes that may contain lead, such as those outlined in ASTA's Identification and Prevention of Adulteration Guidance (ASTA 2016). These practices include the development of specifications, vulnerability assessments, supplier verification activities, and testing programs. The interventions outlined in this guidance, which are consistent with supplier verification requirements in FDA's Preventive Controls for Human Food regulation, have been effective in preventing the availability of dye-laced spices on the U.S. market. As Ishida et al. (2022) notes, the differences in lead levels observed between spices in U.S. versus foreign markets demonstrate the effectiveness of the measures that U.S. regulators and industry have undertaken to mitigate the issue of lead-based colorants in domestic spices.

The issue of lead-based colorants is distinct from the potential for spices to contain naturally occurring heavy metals from the environment (Table 1). As the FDA notes, heavy metals including lead, arsenic, and cadmium, are naturally found in the Earth's crust and are present in the environment in soil and ground water due to volcanic activity and industrial releases. As a result, any plant that is in contact with soil or ground water has the potential to take up trace amounts of metals which cannot be removed. Factors such as climate, soil conditions, and a particular plant's cultivation and harvesting time impact the level of naturally occurring heavy metals in each spice. Although the spice industry employs a variety of tactics to reduce environmental heavy metal contamination, such as the use of Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and monitoring, it is infeasible to avoid uptake and accumulation of trace levels in spices due to persistent levels of heavy metals in the environments where spices are grown. While background levels of heavy metals in spices vary by the specific commodity as outlined below, naturally occurring heavy metal concentrations in spices are much lower than those observed through EMA (see Table 1).

Table 1. Characteristics of Economically Motivated Adulteration vs. Naturally Occurring Sources of Lead in Spices

Characteristics	Economically Motivated Adulteration (EMA)	Lead from the Environment
Source	Lead in the form of lead chromate or other lead-based dyes is used to enhance color or increase weight	Lead present in the environment through soil, water, and air is absorbed by plants
Concentration in Spices	Reported concentrations of 34.78 ppm (Cowell, 2017), 99.5 ppm (Cowell, 2017), 609 ppm (Forsyth, 2019), 1152 ppm (Forsyth, 2019) in turmeric, and 48,000 ppm (Hore et al, 2019) in saffron	95^{th} percentile background levels in WHO GEMs reported at 0.23-2.48 ppm (Codex 2022)
Stage of Lead Introduction	Can occur at any stage of the supply chain, but most typically during grinding and processing	Occurs during the growing of spices
Driving Factors	Economic factors	Environmental factors including presence in earth's crust, pollution, fossil fuel emissions
Key Prevention Strategies	Vulnerability Assessments, Supplier Verification, Chain of Custody, Testing Programs	Good Agricultural Practices, Good Manufacturing Practices, Testing/Monitoring

Variability by spice type

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 (Table 2). 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 example, within most plant species approximately 95% of absorbed lead is accumulated in the roots, with less than 5% translocated to the aerial plant parts (Pourrut et al. 2011).

Table 2. Examples of spices derived from different parts of plants

Part of Plant	Spice
Aril	Mace
Bark	Cinnamon
Berry	Allspice, juniper, pepper (black, white, green, pink)
Bud	Cloves
Flower	Chamomile, lavender
Fruit	Anise (star), capsicums, cardamom, paprika, vanilla
Leaf	Balm (lemon), basil leaf (sweet), bay leaves, chervil, chives, cilantro, dill weed, marjoram, oregano, parsley, peppermint, rosemary, sage, savory, spearmint, tarragon, thyme
Root	Galangal, ginger, horseradish, turmeric
Seed	Anise seed, caraway seed, celery seed, coriander, cumin seed, dill seed, fennel seed, fenugreek seed, mustard seed, nutmeg

The variability in background heavy metal levels of spices is noted in the publicly available data and published literature. For this reason, global regulatory authorities have recognized the need to stratify limits for heavy metals, particularly lead, in spices based on the part of plant from which they are derived. For example, the CCCF recently considered proposed limits for lead in spices and herbs. In its analysis of 3,409 data points for culinary herbs and 5,224 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 was able to calculate background levels for spices for the following spice categories: floral parts; fruits and berries spices; rhizomes, bulbs and roots; bark; seed spices; and celery seeds. The Committee considered lead limits in these categories ranging from 0.4 ppm to 3.5 ppm.

Table 3 shows the natural heterogeneity of environmental background lead levels found in spices based on plant part (based on Codex 2022, Table B1).

Table 3. Summary of background levels of lead in spices (Codex 2022)

Food	Samples (N+ / N)[1]	Mean (mg/kg)	Median (mg/kg)	95th percentile (mg/kg)
Culinary herbs (fresh)	1,111/1,452	0.07	0.03	0.23
Culinary herbs (dried)	757/1,012	0.5	0.14	1.65
Aril spices	13/15	0.26	0.21	0.70
Floral parts (flower, stigma, bud)	43/59	0.34	0.11	1.14
Fruits and berries	1,954/2,546	0.23	0.11	0.57
Rhizomes, bulbs and root	502/550	2.04	0.12	1.92
Bark	402/448	0.67	0.26	2.48
Dried seeds	625/860	0.22	0.12	0.76

[1]N+/N = positive (i.e., detectable) samples/total samples

Similarly, recognizing the difference in background levels of lead in various spices and the need to consider achievability, the European Union established new limits for lead in spices categorized by type of spice (Table 4).

Table 4. Limits for Lead in Spices as Established by the European Union (Regulation 2021/1317)

Category	Lead Level (mg/kg)
Fruit spices	0.6
Root and rhizome spices	1.5
Bark spices	2.0
Bud spices and flower pistal spices	1.0
Seed spices	0.9

The categorized approach employed by the European Union and Codex allows for a more accurate description of background levels of heavy metals in spices. This is because this approach acknowledges that different types of spices have variable uptake and accumulation mechanisms in addition to geographical factors that result in varying naturally occurring levels.

The categorized approach taken by the European Union and Codex is consistent with the established approach FDA would take to evaluate the potential for recalls or import alerts for spices. 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, which 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 a recall situation for product already in the marketplace or refusal of entry for imports.

Based on the collective data provided, it is clear that NYS's existing Class II recall action level of 1.0 ppm established in 2016 effectively prohibits the sale of products containing elevated levels of lead due to EMA (which typically result in levels much higher than 1.0 ppm), and in some instances excludes spices with higher natural background levels of lead (e.g., spices derived from roots). Further, the reduced Class II recall action levels presented by Ishida et al.

(2022) are far more stringent than those established by other regulatory authorities and demonstrate a lack of understanding of the inherent variability in spices when viewed as a single commodity group.

Key concerns and outstanding questions regarding achievability

Achievability

The role of achievability is commonly recognized in connection with regulatory action levels. FDA's regulations provide that manufacturers are expected to utilize quality control measures that will reduce contamination to the lowest level currently feasible (21 CFR § 109.7(b)). Consistent with these principles, FDA also considers achievability in the establishment of action levels. Additionally, Codex's "As Low as Reasonably Achievable" standard is set at meeting a 95% global compliance rate for the commodity under evaluation. The European Union and the FDA have set action levels for spices and/or other commodities that reflect what they have determined to be as low as reasonably achievable. In contrast, while Ishida et al. (2022) considered achievability in its assessment of cadmium and inorganic arsenic recall action levels, it does not appear that achievability was considered for lead.

To illustrate the standard of practice, FDA recently published draft action levels for lead in apple juice (10 parts per billion; ppb) and other juice and juice blends (20 ppb). In the supporting documentation, FDA explained that it selected these levels based on the ability of 95% of apple juice and 97% of other juice and juice blends to meet these new draft levels (FDA 2022). Specifically, the FDA draft guidance states (FDA 2022): "FDA's reevaluation has focused on the review of U.S. data to determine if lower levels were achievable and if lower levels would reduce lead exposure in vulnerable populations." Further, while FDA considered setting a single action level for all juices, its decision was ultimately based on the variability in the background levels and differences in consumption patterns. The FDA acknowledged that while a single action level would be "…easier to implement than multiple action levels, it did not consider the relative consumption of different juice types." FDA's approach illustrates the importance of considering achievability combined with a recognition that not all juices can be evaluated the same way. This reasoning can be directly applied to spices.

Ishida et al. (2022) relies in part upon an assessment conducted by the Bureau of Toxic Substance Assessment (BTSA) within the New York State Department of Health for the derivation of health-based guidance values for arsenic, cadmium, and lead in spices used in food preparation (BTSA 2019; see also supplemental material in Ishida et al.2022). The Class II recall action levels for arsenic and cadmium were based on the estimated 90th percentile of the background levels of each metal in the spices sampled (Ishida et al. 2022; Table 3). This approach follows the recommendation made by BTSA that "NYAGM rely upon the distribution of background metal levels in spices that NYAGM has compiled and that might be available from other sources." (BTSA 2019). However, in contrast to the approach used for arsenic and cadmium and in opposition to the recommendation made by BTSA, the health-based guidance value for lead was solely based on a risk assessment with no discussion of the 90th percentile lead level or how that aligned with the new Class II recall action level of 0.21 ppm. While Ishida et al. (2022) does restate BTSA's recommendation that "…it is prudent to reduce risks for Pb exposure through consumption of spices by adopting screening or action levels as low as achievable" (see Footnote 1 of Table 3 in Ishida et al. 2022 and BTSA 2019), the recommendation does not appear to have been included in the setting of the new recall action level. A summary of the background level distribution for lead should be provided to allow stakeholders the ability to identify where the new reduced recall action level of 0.21 ppm of lead falls among the spices sampled to understand what percent of the spice market in NYS may not be available to consumers should it be enforced.

Based on the limited information provided in Ishida et al. (2022), 1,094 samples of spices were analyzed for lead (Figure 1; Ishida et al. 2022). Ishida et al. (2022) states that if the reduced class II recall action levels were in effect during the sampling period "…there would have been 509 recalls for [lead]…in the period 2014-2019". Assuming that the 509 potential recalls refer exclusively to the samples discussed in Figure 1, this would indicate that approximately half (46.5%) of spice samples would fail to meet the reduced action level for lead. However, it is unclear what types of spices were included in that database, what percentage of spices within various categories would not be able to meet the limit, or if an achievability assessment was completed for individual spice types.

If we assume that 46.5% of spices being removed from the market was acceptable to Ishida et al. (2022), this threshold for achievability (i.e., ~50%) is inconsistent with standard regulatory practices. While the 90th percentile achievability approach leveraged for arsenic and cadmium would be more consistent with the 95th percentile approaches undertaken by other regulatory jurisdictions as outlined above, NYAGM's approach has not evaluated achievability among the specific types of spices. Considering the extensive variability between different types of spices as outlined above, achievability should be evaluated for individual spice types.

In instances where FDA has established action levels that correspond to achievability rates of less than 95%, the potential for the future market supply to meet the market demand was considered. For example, in 2014, FDA established a limit for inorganic arsenic in infant rice cereal of 100 ppb, for which 47% of samples tested would be able to comply. However, through FDA's detailed and transparent achievability assessment, FDA concluded that rice low in inorganic arsenic content was available to infant rice cereal manufacturers, and that through use of GMPs and selective sources, it would be possible to achieve these levels. This notion was borne out as sampling after the establishment of the action level showed higher and higher percentages of samples were meeting the action level of 100 ppb. Ishida et al.'s (2022) inattention to achievability as it pertains to lead in spices is not consistent with global regulatory standards, nor is it consistent with their own approach for other heavy metals.

In conclusion, before it implements any amendment to the existing 2016 recall action level for spices, NYAGM should conduct an achievability assessment to support the state's policy that action levels are set "as low as achievable." This assessment should include an evaluation of achievability for lead, cadmium, and arsenic by different types of spices.

New York State's approach fails to acknowledge market realities

Ishida et al. (2022) demonstrates a misunderstanding of the spice supply chain through its consideration of domestic, imported, and unknown-origin products, and frequency of heavy metal contamination in imported products. While NYAGM assigned an "imported" status to products which had countries of origin clearly labeled on the packaging, this approach does not accurately capture all spices that are grown overseas, as many imported spices are exempt from the country-of-origin labeling requirements[1]. The reality is that nearly all spices available in the U.S. are imported, which is not consistent with Ishida et al.'s (2022) reported distribution of samples (337 domestic, 455 imported, 302 unspecified origin). Furthermore, it appears that Ishida et al. (2022) does not draw the appropriate distinction between spices purchased outside of the United States (U.S.) directly by consumers and spices grown outside of the U.S. that are subsequently imported for sale in the U.S.

Despite the assertion by the authors that imported spices are at an increased risk of heavy metal contamination, no data is presented detailing the distribution of heavy metals in spices based on origin. The authors explain that based on data from their sampling program from 2014-2019, 89% of samples complied with the 1 ppm lead limit (Ishida et al. 2022, Table 3). The authors do not specify whether the 11% of samples exceeding this limit were from domestic, imported, or an unspecified origin. Instead, the authors reference a paper by Hore et al. (2019), which found that the average lead level was significantly higher in spices purchased outside of the U.S., and higher still from countries that have limited laboratory testing surveillance programs. According to Hore et al. (2019), spices purchased abroad directly by consumers were three times more likely to exceed the reference level of 2 ppm than spices purchased domestically (45% versus 13%, respectively). This observation is echoed by Forsyth et al. (2019), who concluded that turmeric sold in local Bangladeshi markets had higher lead levels due to EMA with lead chromate than product exported to foreign markets.

The literature indicates the risk of spices purchased by U.S. consumers directly from foreign markets, not of spices imported from overseas for sale in the U.S. Rather, the spices

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[1] 9 U.S.C. 1304 subsections (a) and (b) pursuant the amendment of the labeling statute within Section 14 of the Miscellaneous Trade and Technical Corrections Act of 1996, Pub. L. 104-295, 110 Stat. 3514 (October 11, 1996).

purchased in the U.S. are demonstrated to have notably lower levels than those purchased in foreign markets, highlighting the success that U.S. importers and regulators have had in implementing standards to keep heavy metal levels in spices on the U.S. market low. This reality also raises the potential concern that if certain spices become unavailable in New York because the NYS standards cannot be met, consumers may rely more on purchasing spices directly from those countries where heavy metal levels are highest. The risk of elevating exposure by encouraging import or purchase from countries without regulatory standards was not evaluated by Ishida et al.

Outstanding questions regarding NYS commodity sampling program

Under its commodity-based targeted sampling program, Ishida et al. (2022) collected samples from the NYS market. NYS leveraged its results from its commodity-based targeted sampling program to establish a baseline on the range of heavy metals ordinarily found in commercially available spices. However, questions remain as to how samples were selected and grouped:

- Does the database include samples from different brands?
- Does the database include duplicate samples from the same lot?
- Does the database include multiple lots for a selected brand/manufacturer?
- Does the database include multiple brands/manufacturers per spice?
- Do the spices sampled provide a valid representation of the spice market in NYS?
- How was sample size determined? How many samples per spice per year per region, etc.?
- Was there an attempt to look at trends to see if decreasing levels is possible?

Greater transparency and additional details that address the population of spices sampled and the ability to generalize these results to the entire NYS market are needed to support the basis of the reduced Class II recall action levels.

Comments on the health-based guidance value

Ishida et al. (2022) derived a health-based guidance value for lead based on an equation that includes two key data inputs developed by BTSA: total spice consumption among children 0-6 years of age and the non-cancer toxicity value (i.e., the reference dose) for lead. This lead health-based guidance value serves as the basis for the new reduced Class II recall action level and did not take into account the achievability of meeting this level. Further discussion on the two key data inputs and the impact on the resulting health-based value are provided below.

Spice consumption

When conducting a dietary exposure assessment for purposes of understanding safety and characterizing risk, determination of the estimated consumption rate is a critical step. The consumption rate of spices is inversely proportional to the health-based guidance value. In other words, higher estimated consumption rates result in lower health-based guidance values. Given this direct reliance on the consumption rate of spices in the determination of the health-based guidance value for lead, the methodology and data sources used to estimate consumption of spices among children are impactful.

Comments on methodology

The methodology relied upon by Ishida et al. (2022) to estimate total spice consumption is flawed and does not follow standard approaches used by US 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. The approach incorrectly assumes that every person consumes every spice every day. Based on the available consumption data, this assumption is not correct and will significantly overestimate consumption. Given the inverse relationship between consumption rates and health-based guidance values, an overestimation of spice consumption will reduce the derived health-based value and result in an erroneously low recall action level.

In estimating cumulative intake of the eight commodities selected to represent total spice consumption among children 0-6 years of age, NYS summed the per user mean intakes from each of the eight commodities. Adding the mean intake across individual commodities on a per user basis is mathematically flawed. Individuals who are a "user" of one spice may not be a "user" of another spice. By doing so and representing it as the per user mean cumulative intake, NYS is assuming that each child consumes all eight commodities every day. An alternate approach would be to estimate the cumulative spice intake using the same consumption database, which allows for the direct estimation of the per user cumulative mean intake of all eight food categories at the person level. This calculation does not assume that each child consumes each of the eight commodities every day. Instead, it uses actual data from consumption reports of surveyed children and would result in a health-based value of 1.2 ppm versus 0.21 ppm (See Example #1, Table 5).

Ishida et al. (2022) also states that duration and frequency of exposure are important determinants of human exposure to metals and should be considered; however, the authors fail to do so in their analysis as they used spice consumption based on a single day (24-hour) of dietary records. Consumption estimates based on one or two days of dietary intake are generally not reflective of usual intake where frequency of exposure is considered. FDA's Guidance for Industry: Estimating Dietary Intake of Substances in Food (FDA, 2006) notes that for many foods, especially among infrequently consumed foods, one or two days of intake will overestimate consumption among consumers and thus provide a conservative (i.e., high) estimate of exposure. For this reason, both the frequency of consumption, as well as the amount consumed, should be used to estimate intake. Hence, Ishida et al.'s (2022) use of consumption data from a single day results in inaccurate and unrealistic estimates of the habitual consumption pattern for contaminants such as lead. The assumption that every child 0 to 6 years of age consumes each of the eight commodities every day is not supported or realistic. Published studies, instead, support the fact that consumption of individual spices does not occur every day, but rather is episodic (Blanton 2020; Isbill et al. 2018; Siruguri and Bhat 2015; Carlsen et al. 2011).

Further, default body weight values were used to estimate total spice consumption despite the availability of individual body weights in the consumption database. Therefore, the use of a default bodyweight adds an unnecessary additional degree of uncertainty in the spice consumption rate used to derive the lead action level.

Finally, the assessment relied upon by Ishida et al. (2022) (BTSA 2019) is based on consumption data from surveys conducted in 2005-2010. These surveys are continuously updated and are currently available up through 2018. Moreover, the recipes included within the recipe database used (i.e., EPA's Food Commodity Intake Database or FCID) should be updated and/or incorporated into the more recent surveys. It is also important to note that the spice consumption estimates relied upon by Ishida et al. (2022) include both home use of spices (i.e., spices sold at retail) as well as spices used in commercial food products (e.g., cinnamon in a commercial cinnamon cereal).

Spice selection and grouping

Ishida et al. (2022) states that total daily spice consumption was used to calculate the health-based guidance values. However, this is a misrepresentation, as the assessment relied upon by the authors (BTSA 2019) was limited to a select group of eight commodities, not all of which are spices: 1) cinnamon, 2) pepper, black and white, 3) spices, other, 4) turmeric, 5) pepper, bell, dried, 6) pepper non-bell, dried, 7) sesame seed, and 8) ginger, dried.

While Ishida et al. (2022) stated that they relied on FDA's definition of spices (21 C.F.R. § 101.22)[2] to select spices for inclusion in the BTSA assessment (2019), "pepper, bell" is not included in the list of spices in this definition. Further, FDA's Compliance Guide 525.750 states "sesame seeds…are not considered to be spices". The inclusion of sesame seeds greatly impacts the health-based guidance value since the consumption rate of spices including sesame seeds (114 mg/kg bw/day) is more than twice the rate when it is excluded (47 mg/kg bw/day). Using the consumption rate excluding sesame seeds results in a health-based guidance value for lead of 0.51 ppm which is more than double the new guidance value of 0.21 ppm (See Example #2 Table 5). This example illustrates the impact the selection of spices has on the calculation of the health-based guidance value. Including or excluding spices will ultimately impact the action level and therefore, the criteria for both should be clear and defensible.

The search parameters to estimate spice consumption from the consumption database used in Ishida et al.'s (2022) assessment (What We Eat In America (WWEIA)- FCID from 2005-2010) included the following:

- "Herbs and Spices" FCID category, which covers 22 spices and herbs

[2] Spices specifically listed in 21CFR101.22(2) include: Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, and Turmeric.

- Sixty individual spices (including cinnamon and turmeric, which are not included in the FCID group “Herbs and Spices”)
- For all commodities, those labeled as “fresh” or “herb” were excluded along with any baby food uses
- Exclusions included spices 1) that are “unlikely imported” (e.g., dried basil leaves, lemongrass, parsley, dill seed, peppermint), 2) that are fresh (basil leaves, herbs other, lemongrass, pepper/bell, pepper/non-bell), 3) with a low number of eaters (chives, dill seed), or 4) for an unknown reason (e.g., marjoram, savory, coriander seed)

It is unclear what data was used to support the determination that certain spices were “unlikely imported.” In fact, nearly all spices consumed in the U.S. are imported. Additionally, the rationale for the exclusion of spices based on a low number of eaters was not clear, and the criteria for what constitutes a low number was also not stated. Further, a low number of eaters for an individual spice would not impact the reliability of the cumulative (total) intake estimate from all eight “spices” if estimated using typical methods and therefore, the rationale for excluding is inappropriate.

Finally, given the variability in background levels of lead by category of spices, it is essential to also consider consumption patterns by spice (e.g., cinnamon) or spice group (e.g., bark spices). For example, cinnamon consumption alone among children 0-6 years of age is 0.10 mg/kg bw/day based on the WWEIA/FCID 2005-2010 database. If the consumption pattern of this specific spice was considered, as opposed to the cumulative intake from the eight selected “spices,” the health-based guidance value for cinnamon would be 2.4 ppm, compared to NYS’s 0.21 ppm (See Example #3, Table 5).

A summary of the examples cited and the impact on the health-based guidance value for lead is provided in Table 5.

Table 5. Summary of examples to illustrate the impact of spice consumption rate on the health-based guidance value for lead

Input/method	Ishida et al. 2022; BTSA 2019	Example #1	Example #2	Example #3
Commodity	Eight select "spices"	Eight select "spices"	Seven select spices (excluding sesame seed)	Cinnamon
Consumption (mg/kg bw/day)	114	20	47	10
Health-based guidance value for lead (ppm)*	0.21	1.2	0.51	2.4

Eight select spices: 1) cinnamon, 2) pepper, black and white, 3) spices, other, 4) turmeric, 5) pepper, bell, dried, 6) pepper non-bell, dried, 7) sesame seed, and 8) ginger, dried.
Example #1: consumption rate based on the cumulative intake of the eight spices included by BTSA following the standard approach (i.e., added at the individual level) to estimate cumulative intake from multiple commodities using WWEIA/FCID 2005-2010; single-day, eaters-only, children 0-6 years of age.
Example #2: consumption rate based on reported spice intake excluding sesame seeds as reported in BTSA 2019; supplemental table 11.
Example #3: consumption rate based on the estimated single day intake of cinnamon using WWEIA/FCID 2005-2010; single-day, eaters-only, children 0-6 years of age.
*Calculated using the following formula (BTSA 2019): [Non-cancer toxicity value (0.00012 mg lead/kg bw/day) / spice consumption rate (mg spice/kg bw/day)] x relative source contribution (20%) x conversion factor (1 x 10^{-6} mg spice/kg spice).

Consideration of the public health impact of lowering recall action levels and effectively banning certain spices

Both heavy metals and essential minerals, such as iron and zinc present in water and soil, are taken up by plants via similar processes. Therefore, foods that are grown in soil, such as fruits, vegetables, grains, and spices all contain detectable levels of metals and essential minerals. Since spices and herbs are used to flavor food and are used to support a healthy diet, raising concern to the public about naturally occurring levels of heavy metals may inadvertently alter people's dietary patterns to move away from healthy food options. The U.S. Dietary Guidelines for Americans (DGA) recommends the use of herbs and spices as a strategy to reduce sodium intake by increasing cooking at home and using these food products to flavor food (USDA, 2020). The DGA also recommends the use of spices and herbs to "add to the enjoyment of nutrient-dense foods, dishes, and meals" (USDA, 2020). FDA states in its Closer to Zero Action Plan:

> "It is crucial to ensure that measures to limit toxic elements in foods do not have unintended consequences—like limiting access to foods that have significant nutritional benefits by making them unavailable or unaffordable for many families. There is also the potential of unintentionally increasing the presence of one toxic element when foods are reformulated to reduce the presence of another."

Dietary exposure to these heavy metals from consumption of spices contribute minimally to total exposure from all dietary sources and reflect their ubiquitous and natural environmental occurrence. Raising concern over naturally occurring background levels of lead in spices may very well result in unintended changes in dietary behavior among consumers with unknown short- and long-term health impacts.

Conclusion

ASTA supports policies to minimize heavy metal contamination in spices and stands ready to work with NYAGM on policies that are protective and achievable. However, at this time, the science demonstrates that it is not possible for the spice industry to comply with a 0.21 ppm recall action limit for lead across all spices. Furthermore, we affirm that NYAGM's existing limit of 1.0 ppm is achievable and provides sufficient protection to both adults and children given the relatively low consumption rate of spices. Moreover, it is undeterminable whether NYAGM's new limits will meaningfully reduce heavy metals in the diet of New Yorkers given NYAGM's lack of analysis on the current contribution of spices to total dietary lead exposure.

Although NYAGM anticipates that the new Class II recall action level will not go into effect until 2023 at the earliest, the continued publication of these levels will have an immediate and significant impact on the spice industry due to the realities of supply chains and other business planning considerations. Some spices take years to grow. For instance, cinnamon requires 10 to 15 years to reach maturation, meaning that spice supply chains cannot be quickly altered to meet these lower standards within the proposed time frame even if it was feasible to do so.

We encourage NYAGM to continue engaging in dialogue and collaborate with the food industry to consider alternative approaches to regulating heavy metals in spices to better align with those leveraged by global regulatory agencies. Until NYAGM completes its additional research on the heavy metal content found in spices commonly consumed by children to support its achievability framework, we respectfully recommend that NYAGM remove any mention of these new levels from the state website and its regulatory policy manual. Otherwise, the result will be continued confusion among consumers and in the marketplace, with no meaningful positive effect on public health.

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EXHIBIT B

FOOD RECALLS

Revised May 27, 2021

WHY RECALL

A RECALL IS INITIATED TO REMOVE PRODUCT FROM COMMERCE WHEN THERE IS REASON TO BELIEVE IT MAY BE ADULTERATED OR MISBRANDED.

RECALL CLASSIFICATION

***"RECALL CLASSIFICATION"* MEANS THE NUMERICAL DESIGNATION, i.e., I, II, OR III, ASSIGNED TO A PARTICULAR PRODUCT RECALL TO INDICATE THE RELATIVE DEGREE OF HEALTH HAZARD PRESENTED BY THE PRODUCT BEING RECALLED.**

MOST RECALLS ARE VOLUNTARILY CONDUCTED

THIS DEPARTMENT CANNOT MANDATE A FIRM TO INITIATE A RECALL ON A PRODUCT. UNDER SECTION 206 OF THE FEDERAL FSMA REGULATION, FDA DOES HAVE MANDATORY RECALL AUTHORITY.

RECALL CLASSIFICATION

CLASS II

A SITUATION IN WHICH USE OF, OR EXPOSURE TO, A VIOLATIVE PRODUCT MAY CAUSE TEMPORARY OR MEDICALLY REVERSIBLE ADVERSE HEALTH CONSEQUENCES OR WHERE THE PROBABILITY OF SERIOUS ADVERSE HEALTH CONSEQUENCES IS REMOTE.

EXAMPLES OF CLASS II
<u>RECALL SITUATIONS</u>

- NON FD&C CERTIFIED COLORS (E DESIGNATIONS) AND UNDECLARED FD&C YELLOW #5 AND #6
- ALL UNDECLARED CERTIFIED COLORS
- BOTULINUM POTENTIAL
- NORWALK VIRUS (SEAFOOD)
- UNDECLARED SULFITES (3.7 - 9.9 MG. PER SERVING)
- UNDECLARED WHEAT, OATS, CORN OR SESAME SEEDS.
- UNAPPROVED ADDITIVES/ INGREDIENTS
  (i.e., Coumarin, Nitrates in Certain Species of Fish, Ponceau 4R, Artificial Sweetener, Alcohol, Industrial Dyes)
- NOT SHELF-STABLE (Requires Refrigeration)
- LEAD CONTAMINATION*
  Children's Candy (100 ppb)
  Ready to Drink Juice (50 ppb)
  Spices (0.21 ppm)*
  Other products (levels below 25 ppm but greater than 1ppm)
- INORGANIC ARSENIC*
  Rice Cereal for Infants (100 ppb)
  Apple Juice (10 ppb)
  Spices (0.21 ppm)*
- OTHER HEAVY METAL CONTAMINATION*
  (specific levels vary based on product and individual metal)
  Cadmium in Spices (0.26 ppm)*

** Note: Action levels in spices will be implemented on a date TBD but not prior to 1/1/2023.*

Regulatory Policies For Heavy Metals In Spices – A New York Approach

New York State Department of Agriculture and Markets

Division of Food Safety and Inspection

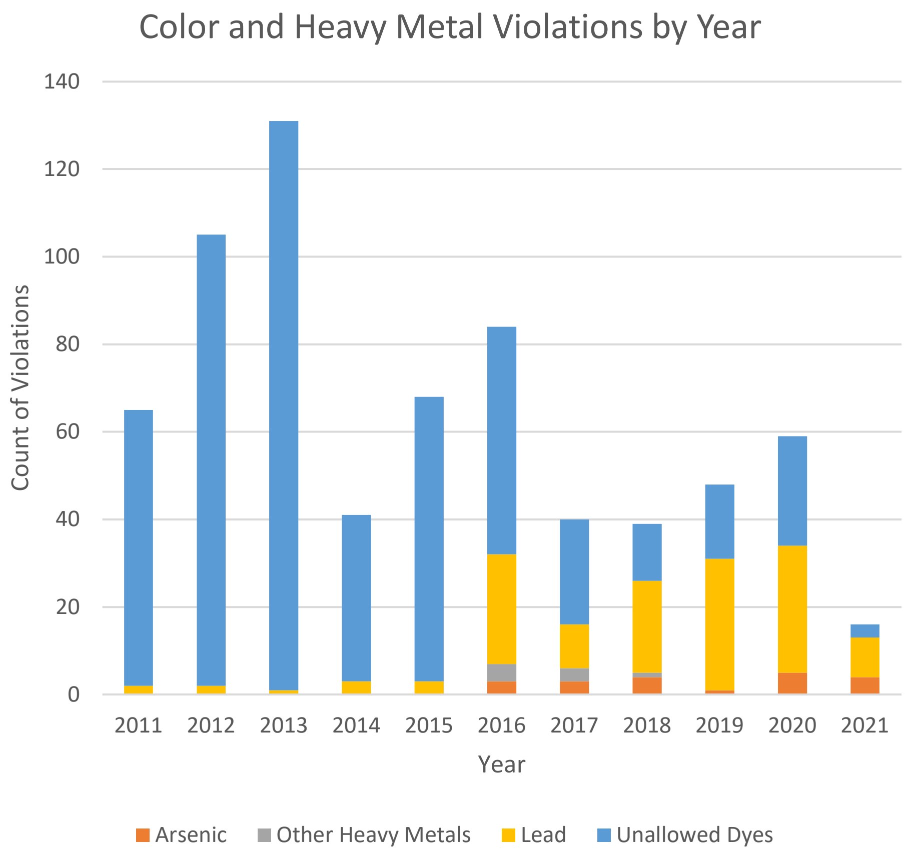
Background

- The New York State Department of Agriculture and Markets (NYSAGM) Division of Food Safety and Inspection is responsible for the safety of food manufactured and sold in New York State.
- That responsibility covers the routine inspection of food, retail, storage and distribution food facilities, as well as the routine sampling of food to check for chemical, physical or biological contamination.
- If contamination or “adulterants” are found, the Department recalls, destroys and/or removes such products from commerce.

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Background

- Over the past 10 years, through the Department's routine food surveillance program, Food Laboratory analysts noticed an increase in the number of spices containing non-food-grade dyes.
- Such non-food-grade dyes were found to contain lead and chromium pigments.
- As a result of these findings, the Department began to target the collection and analysis of spice samples for heavy metals.



Background

- There are no federal action levels for heavy metals in spices.
- In 2016, using results from a devised targeted sampling plan, the Department instituted a State Class II action level of 1 ppm for Inorganic Arsenic, Cadmium and Lead and a State Class I action level of 25 ppm for Lead in spices.

Recall Classifications

- Class I Recall: Dangerous or defective products that predictably could cause serious health problems or death.

- Class II Recall: Products that might cause a temporary health problem or pose only a slight threat of a serious nature.

Background

Since 2016, over 1,000 spice samples analyzed resulted in the recall and removal of over 100 spices from the marketplace.

Background

While the State action levels have resulted in the recall of over 100 spices, a health-based assessment of heavy metals in spices was needed to ensure the appropriate action levels were protecting the people of NY state from this potential source of heavy metal exposure.

Background

In 2018, NYSAGM and the New York State Department of Health's Bureau of Toxic Substance Assessment (NYSDOH) formed an interagency collaboration to determine actionable limits of contaminants commonly found in spices, particularly heavy metals.

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AGM – DOH Interagency Collaboration

Focus areas:

- Through this collaboration, we reviewed laboratory surveillance data, as well as toxicity data and spice consumption rates to identify which heavy metals were commonly found and, of those, which pose a risk to human health;
  - Inorganic Arsenic, Cadmium and Lead were determined to be the heavy metals of concern
- We also evaluated whether additional domestic and non-domestic spice samples should be collected.

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AGM – DOH Interagency Outcome

- NYSDOH-BTSA performed oral exposure and toxicological assessments to derive health-based guidance values for Inorganic Arsenic, Cadmium, and Lead in spices used in food preparation.
- Informed by these assessments and sampling data on concentration of heavy metals in spices, NYSAGM lowered the State's Class II action levels for Inorganic Arsenic, Cadmium and Lead in spices by a factor of almost 5 times.

Action Levels for Heavy Metals

New York is the first State in the nation to establish action levels for heavy metals in spices providing better protection to New York State consumers

Analyte	Class II Recall Action Level (ppm)
Lead (Pb)	>0.21
Cadmium (Cd)	>0.26
Inorganic Arsenic (As)	>0.21

New York State *Updated* Recall Policy for Heavy Metals in Spices (effective *TBD*)

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Class II Recall Action Levels

Lead: Class II recall action level selected is based on the NYSDOH derivation of a noncancer health-based guidance value for Lead in spices used in food preparation. It is important to recognize that this assessment differs from other noncancer assessments because of the absence of a threshold for the effects of Lead on the developing central nervous system of children. While the health-based guidance value is based on health protective methods and assumptions, the absence of a threshold means that we cannot assume that exposure below the health-based guidance value is without risk as we would for other noncancer health-based guidance values. Due to absence of a threshold for the noncancer health effects of Lead, and the presence of many other potential sources of exposure to Lead (e.g. soil, indoor dust, water), it is prudent to reduce risks for Lead exposure through consumption of spices by adopting screening or action levels as low as achievable.

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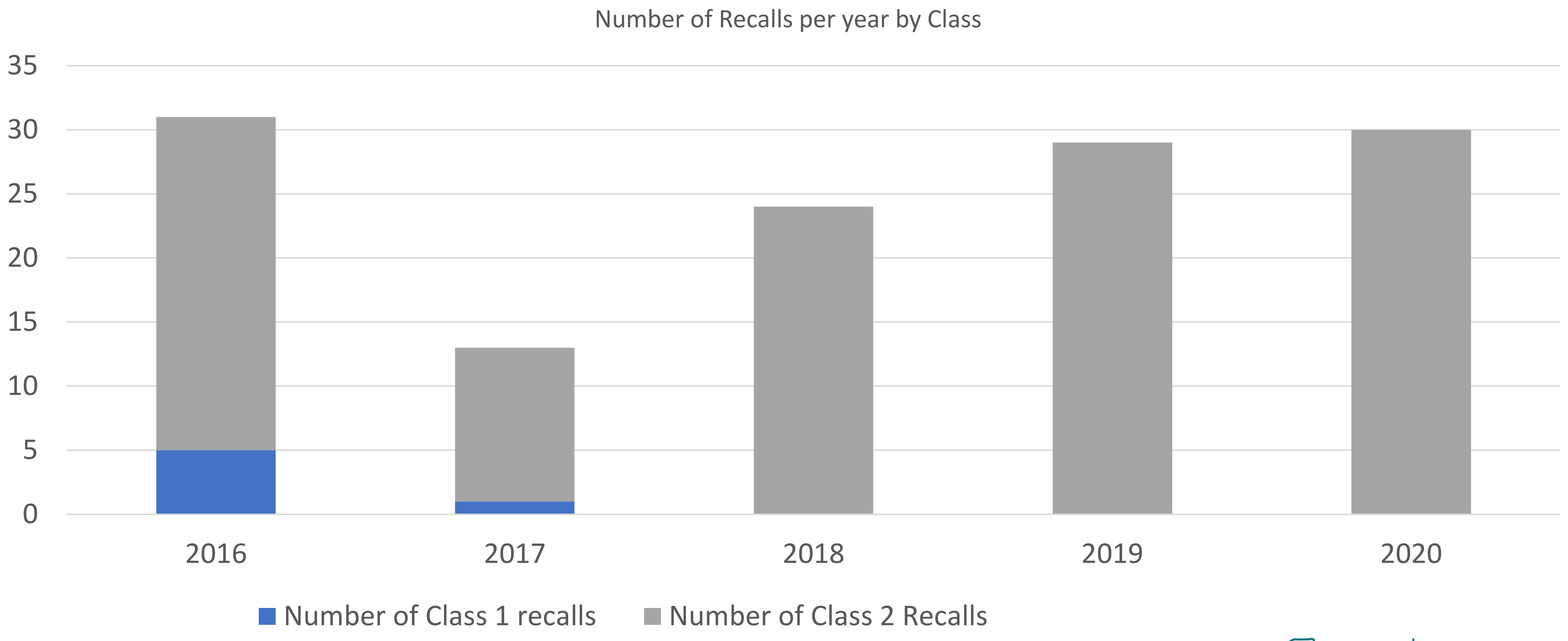
Class II Recall Action Levels

Cadmium: Class II recall action level is based on the 90th percentile of Cadmium concentrations detected in sampled spice products, which was used as a surrogate for background Cadmium concentrations found in spices and is also set as close as feasible to the health-based values for Cadmium in spices.

Class II Recall Action Levels

<u>Inorganic Arsenic</u>: Class II recall action level is based on the 90th percentile of Inorganic Arsenic concentrations detected in sampled spice products, which was used as a surrogate for background inorganic arsenic concentrations found in spices, and is also set as close as feasible to the health-based values for Inorganic Arsenic in spices.

Spice Samples Violative for Lead



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Historical Samples for Lead and Cadmium

2016 Policy for both Lead and Cadmium:
Class 2 = > 1 ppm Class 1 = 25 ppm

		# of tests	Class 2 > 1 ppm	Class 1 > 25 ppm		# of tests	Class 2 > 1 ppm	Class 1 > 25 ppm
2014	**Cadmium**	12	0	0	**Lead**	38	5 (13%)	2 (5.3%)
2015	**Cadmium**	37	1 (2.7%)	0	**Lead**	59	7 (12%)	0
2016	**Cadmium**	226	0	0	**Lead**	239	28 (12%)	3 (1.3%)
2017	**Cadmium**	166	2 (1.2%)	0	**Lead**	167	12 (1%)	1 (0.6%)
2018	**Cadmium**	284	2 (0.7%)	0	**Lead**	284	24 (9%)	0
2019	**Cadmium**	309	0	0	**Lead**	309	33 (11%)	2* (0.6%)
2020	**Cadmium**	173	0	0	**Lead**	173	29 (17%)	0
Totals	**Totals**	1207	5 (0.4%)	0	**Totals**	1269	138 (11%)	8 (0.6%)

*Both 2019 samples>25 ppm were from a health investigation into elevated blood lead levels linked with a non-commercially available product.
**Arsenic was not included in the table because the metal was not detected for every sample or speciated as inorganic As (toxic form). Inorganic As is speciated only if total As is 1 ppm or higher.

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Updated Recall Policy Implementation

- Public health and the protection of New York's consumers is our top priority and effective implementation of its public health mission is vital.
- In order to successfully implement the State's update recall policy and subsequent enforcement activities, NYSAGM will use a phased approach over the span of an 18-month period.
- Currently, NYSAGM has a Class II recall action level of 1 ppm for Pb, that was put into place in 2016. As part of the State's implementation strategy NYSAGM will monitor and document violations of the new Class II recall action level policy (e.g. >0.21 ppm Pb) by sending warning letters to those responsible for the violation (unless actionable under the current Class II recall action level, i.e. Pb ≥ 1 ppm).
- This approach will afford importers, distributors, co-packers, manufacturers of spices and retailers the opportunity to implement additional controls that may be needed to comply with the new Class II recall action levels in the future.

Stakeholder Input

- NYSAGM also intends to work closely with retailers, importers, wholesalers, manufacturers (spice manufacturers and those using spices as ingredients in their finished products), and any other relevant industry partners during the 18-month implementation period.
- It will engage in various forms of comprehensive outreach and education sessions by speaking at national and regional food safety conferences, hosting in-person meetings, and providing those affected by this change various forms of written communication to ensure they are aware of this change.

Protecting Public Health

- NYSAGM's goal is to ensure that all stakeholders affected by this updated policy are adequately prepared once the change becomes effective, while ensuring that the implementation of this updated recall policy efficaciously protects public health.
- For this project to have a broad impact, NYSAGM will share this information with state departments of health and agriculture, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to serve as a national model for appropriate action concerning spices contaminated with heavy metals.

Publication: Journal of Regulatory Science

- A copy of the manuscript prepared for this project is currently going through scientific-peer review
- We will share the final copy of this manuscript once it is published

Regulatory policies for heavy metals in spices – a New York approach

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Abstract

The New York State Department of Agriculture and Markets (NYSAGM) Division of Food Safety and Inspection (NYSAGM-FSI), observed high levels of heavy metals in spices through its routine food surveillance program. There are no federal action levels for heavy metals in spices. In consultation with the NYSAGM Food Laboratory (NYSAGM-FL) and using results from a devised targeted sampling plan, NYSAGM-FSI instituted a State Class II action level of 1 ppm for Pb, arsenic (As) and cadmium (Cd) and a State Class I action level of 25 ppm for Pb in spices. In 2018, NYSAGM and the New York State Department of Health's Bureau of Toxic Substance Assessment (NYSDOH-BTSA) formed an interagency collaboration to determine actionable limits of contaminants commonly found in spices, particularly heavy metals. NYSDOH-BTSA

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Questions?

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Regulatory Policies for Heavy Metals in Spices – a New York Approach

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Abstract

The New York State Department of Agriculture and Markets (NYSAGM) Division of Food Safety and Inspection (FSI) observed high levels of heavy metals in spices through its routine food surveillance program. There are no federal action levels for heavy metals in spices. Based on available academic and federal regulatory information related to heavy metals in food, FSI instituted a State Class II action level of 1 ppm for lead (Pb), inorganic arsenic (iAs), and cadmium (Cd), and a State Class I action level of 25 ppm for Pb in spices. In 2018, NYSAGM and the New York State Department of Health's (NYSDOH) Bureau of Toxic Substance Assessment (BTSA) formed an interagency collaboration to determine actionable limits of contaminants commonly found in spices, particularly heavy metals. BTSA performed oral exposure and toxicological assessments to derive health-based guidance values for iAs, Cd, and Pb in spices used in food preparation. Based on these assessments and sampling data on concentration of heavy metals in spices, NYSAGM lowered the State's Class II action levels for Pb, iAs, and Cd in spices by, in some cases, a factor of almost five times. New York is the first state in the nation to establish action levels for heavy metals in spices, providing better protection to New York State consumers.

Keywords:
spices, regulation, action level, heavy metals, lead, arsenic, cadmium

1. Introduction

NYSAGM is the primary food safety regulatory authority in New York State and, as such, is responsible for the regulatory oversight and inspection of food manufacturing, food warehousing facilities, and retail food establishments. The agency also monitors imported and domestic foods, including spices, for the presence of adulterants and verifies that food products are labeled correctly. If through analytical testing such products are found to be adulterated or misbranded, NYSAGM removes such products from commerce using a recall classification system. The numerical designation of a recall is relative to a degree of health hazard presented by the product being recalled. For example, a Class I recall is for products where reasonable probability exists that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. A Class II recall is used when a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

In 2016, absent a federal action level or federal guidelines on the allowable level or limit of heavy metals in spices, NYSAGM using a targeted sampling plan devised State action levels for Pb, iAs, and Cd in spices. Based on available academic and federal regulatory information related to heavy metals in food, NYSAGM devised a State Class II recall action level of 1 ppm for iAs, Cd, and Pb, and a State Class I recall action level of 25 ppm for Pb. Since that time, the Division of Food Laboratory (FL) has tested and analyzed over 1,000 samples of spices for contaminants such as non-food-grade dyes and heavy metals. This extensive targeted sampling plan has resulted in the recall and subsequent removal of close to 100 spice lots from the marketplace. In addition to the presence of heavy metals, some spices also were removed from the marketplace due to the presence of unallowable food dyes (Class II recall).

In 2018, the NYSAGM and the NYSDOH formed an interagency collaboration to further address the growing public safety concern about heavy metals in spices. The interagency collaboration is comprised of food research subject matter experts such as food safety and public health professionals, chemists, and toxicologists from both agencies, with the primary goal of

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reducing spices as a source of heavy metal contamination in the human body. This collaborative group, with each agency focusing on specific tasks relative to their respective areas of expertise, focused on the following key areas:

1. reviewing laboratory data from several years of surveillance to identify which heavy metals were commonly found and, of those, which pose risks to human health;

2. evaluating whether additional domestic and non-domestic spice samples should be collected; and

3. performing health-based evaluations of heavy metals in spices, including exposure and toxicological assessments, and derivation of health-based guidance values (as described in the Supplemental Materials).

In this study, the NYSAGM chose to research iAs, Cd, and Pb as primary contaminants of concern. These heavy metals and iAs were chosen as they are often found in spices and because oral exposure to elevated levels of them can pose health risks to humans, particularly children. Heavy metals, such as those that are the focus of this study, are naturally occurring elements that are found throughout the earth's crust. Historically, humans were exposed primarily while performing metal extraction activities such as mining or smelting. Exposure has increased due to the use of heavy metals in other industrial and technological applications, with the contamination of houses/buildings from lead-based paint, water, soil, air, and food now an ecological, health, and agricultural concern. Regardless of chemical availability, exposure does not result only from the presence of harmful agents within the environment. Duration and frequency of exposure should also be considered as important determinants of total human exposure to heavy metals. Since minimum duration of exposure causing illness is often not known, it is important to evaluate exposure over both long and short periods [3].

According to the U. S. Department of Agriculture (USDA), the U.S. is the world's largest importer of more than 40 distinct spices from more than 50 countries, most notably from Indonesia, Mexico, India, Canada, and China. The increase in spice ingestion trends is partly due to growing recognition of aroma, palatability, and general enjoyment of ethnic food, while at the same time thought to be used to reduce fat and salt intake in the U.S. diet [1, 14]. Others add spices to their daily routine as part of a home remedy, without consulting a physician and ignoring the lack of available studies to support the health improvement claims made on the label. Whatever the ingestion reason or pathway, studies regarding the presence of heavy metals in food have identified spices and herbs as the potential source of numerous human poisonings [12, 26]. It is for this reason that scientists are working to further understand this issue [2, 5, 8, 10, 11, 12, 13, 16, 27].

Food fraud, the deception of consumers through the intentional adulteration of food, has been going on for centuries. In the case of spices, one adulterant that the FL has detected in spices is Pb chromate, which is thought to be added to spices such as chili powder [15] and turmeric [7] to enhance the appearance (color) of a substandard product. And while the product may become more appealing to the buyer, the addition of such a filler results in the product being contaminated with Pb. Such contaminated spices easily enter markets in developing countries due to their limited ability to test for heavy metals, causing adulterated spices to become a widespread global issue [4]. Ziyaina et al. (2014), studied Cd and Pb levels in select spices sold in Libya and found high variation among spice samples. This study also indicated that the highest levels of Pb were found in spices sold in wholesale markets, and levels of Cd exceeded the Food and Agriculture Organization of the United Nations (FAO) recommended level of 0.2 ppm [27]. A more recent study by Hore et al (2019) determined that more than 50 percent of the spice samples in New York City had detectable Pb, and more than 30 percent had Pb concentrations greater than 2 ppm. Additionally, this study found that the average Pb content was significantly higher in spices packaged or grown outside the U. S., and even higher from countries that have limited laboratory testing surveillance programs, with the highest concentrations of Pb found in spices imported from Georgia, Bangladesh, Pakistan, Nepal, and Morocco [10]. As described by Goswami & Mazumdar (2014) in their study of spices in India, the toxicity of Pb remains a matter of public health concern, and the awareness about its toxic effects at observed exposure levels has gained substantial attention in recent years. Despite setting a regulatory Class II recall action level of 1 ppm of heavy metals in spices, further assessment of this Class II recall action level was necessary to verify and ensure that New York State was appropriately protecting its food supply.

With clear evidence that heavy metals are found in spices, and given that oral exposure to elevated levels of these metals can pose health risks, the primary objectives of this study were to determine whether New York State should update its State recall action levels for heavy metals in spices. This would provide better protection to New York State consumers by reducing spices as a source of heavy metal contamination in the human body and the State's food supply, and raise national awareness about the presence of heavy metal contamination in spices. As the first State in the nation to establish science-based action levels for heavy metals in spices, New York State believes this study will serve as a model that can be adopted and applied by other states, as well as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), when taking appropriate action concerning spices contaminated with heavy metals.

2. Materials and Methods

2.1. Sampling

FSI collected spice samples using standard sample collection techniques and shipped the samples to the laboratory via overnight courier to be analyzed for heavy metals. Two sampling approaches were taken: 'for cause' and commodity-based targeted assignments. During the 'for cause' sampling approach, FSI inspectors selected samples based on: (1)

Table 1: Microwave parameters

Ramp Time (mins)	Temp (°C)	Hold Time (mins)
20	75	20
20	180	20

historical information, selecting products from countries with an increased number of recalls; (2) appearance (bright or heavily colored products may indicate the addition of fillers or illegal dyes); and (3) price. Price differential was selected as part of the surveillance since lower priced products historically were found to contain additional ingredients and contaminants, including heavy metals, not identified on the label. The commodity-based targeted sampling approach was used to establish a baseline on the range of heavy metals ordinarily found in commercially available spices. FSI inspectors were also tasked with collecting spices from well-known domestic brands, independent of origin, appearance, or price. Product origin was defined as domestic, imported, or unknown, with domestic samples being any spice (domestic or imported) packed in the U.S. Imported samples were from countries where the county of origin is clearly labeled, indicating they are imported into the U.S. Unknown samples did not have a country of origin clearly labeled.

2.2. Heavy Metals Analysis

Heavy metals analysis was performed based on Gray et al (2015). For this work, the elements tested were total As, Cd, and Pb. iAs was determined when total As concentration was higher than 1 ppm. The samples collected were inspected prior to weighing the test portions. Some spice samples (spice mixes) needed to be further ground to a fine uniform particle size using a cryomill (model SPEX 687OD). Test portions of 0.5 g were weighed into CEM Mars™ Xpress vessels. The actual weights of the samples were recorded to the nearest 0.001 g. Then, 8 mL of $D-HNO_3$ and 1 mL of H_2O_2 were added to the vessels. The vessels were capped and inverted to mix the samples. If excessive foaming occurred, the samples were vortexed until foaming subsided. The samples were allowed to pre-digest before microwaving to prevent loss of the sample during the microwaving process. If the samples reacted vigorously upon addition of the acid, a longer pre-digestion time was allowed. When the reaction subsided, the vessels were capped and placed in the microwave. Sample digestion occurred using the following microwave program settings described in Table 1.

When the vessels cooled, the digestates were poured into 100 mL plastic "class A" volumetric flasks containing 2 mL HCl, 0.89 mL of DI/Trace metal grade (TMG) HNO_3, and approximately 1 mL of reversed osmosis de-ionized (RO/DI) water. Volumes were adjusted to 100 mL with RO/DI water and mixed thoroughly. Samples were poured into 50 mL plastic centrifuge tubes and centrifuged for 10 minutes at 3,000 rpm.

A Thermo Scientific I-Cap Q inductively coupled plasma mass spectrometry (ICP-MS) single quadrupole was used for determination of Pb in spice samples. Pb isotopes of 206, 207 and 208 were monitored and an internal standard of 175Lu – 209Bi was used to correct for signal drift and matrix effects present in the samples. The instrument was run in KED (Kinetic Energy Discrimination) mode with a dwell time of 0.01 seconds for all isotopes. An SC-4 DX FAST autosampler using a high-flow vacuum pump was used to rapidly deliver the samples to the ICP-MS. An interference equation of (208 = (208) x 1 + (206) x 1 + (207) x 1) was used to account for the varying isotope ratios of Pb in different samples. The concentration of each element, in ng/g, was calculated as follows:

$c = C * V * D/m$

where C = concentration in the sample (ng/g); c = concentration (ng/mL) of the element in the digest solution; V = volume (mL) of the test solution being made up (100 mL); D = dilution factor of the test solution; m = weight of the sample (g).

Analytical working standards were prepared by diluting a stock solution to 10 ug/mL. Seven concentrations of working standards were generated by adding the appropriate amount of stock solution to 100 mL "class A" plastic volumetric flasks, containing 2 mL of trace metal grade HCl, 10 mL RO/DI water and 8.89 mL of $D-HNO_3$. The resulting calibration curve yielded a correlation coefficient of >0.995, and all samples were calculated using the curve for total As, Cd, and Pb.

3. Results and Discussion

NYSAGM has been sampling products for the presence of adulterants in imported spices for decades. Initially, testing for adulterants primarily focused on testing for unallowable dyes and allergens. Around the same time FL analysts had become aware of Pb based adulterants being reported in spices in other countries and started testing spice samples received in the laboratory for heavy metals, to see if they would observe similar findings. In 2014, high levels of Pb (52.8 ppm and 146 ppm) were detected from two distinct samples of turmeric powder (data not shown). The use of Pb chromate was suspected to be added to the products and was confirmed via subsequent laboratory analyses. A sample of saffron (Kasubha) was also found to contain a Pb level of 14.4 ppm. Several targeted samples of black cumin, black salt, cumin powder, and paprika, among others, were all analyzed and found to contain Pb and/or Cd at varying levels (data not shown). Based on laboratory findings and absent a federal action level or federal guidance on heavy metals in spices, NYSAGM devised a State Class II recall action level of 1 ppm for spices. This Class II recall action level of 1 ppm, recommended by FL, was based on action levels for

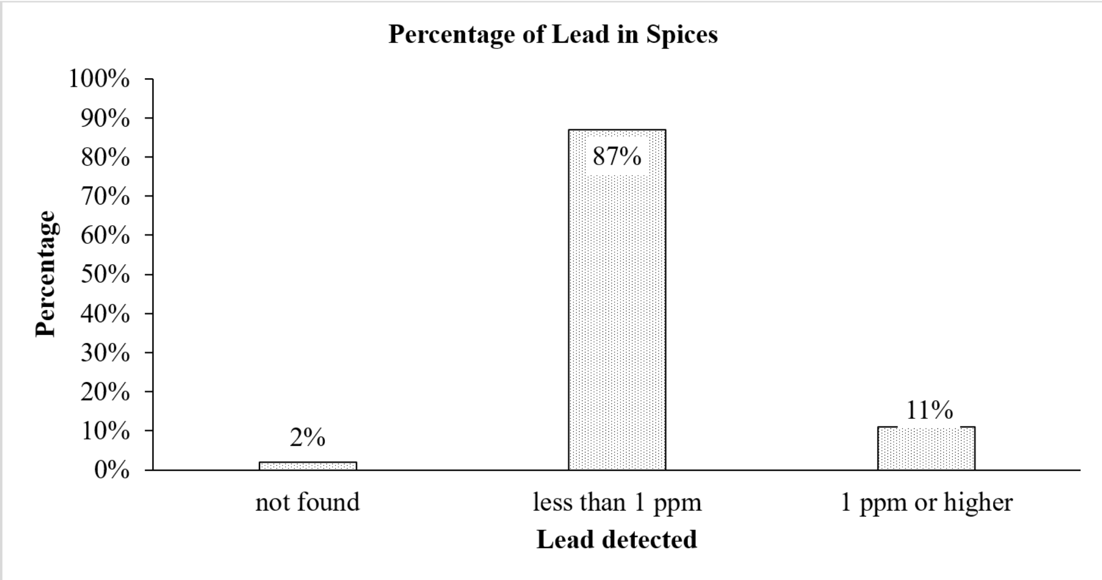

Figure 1: Percentage of lead (Pb) in spices found by the NYSAGM from 2014 to 2019 (n=1094).

other commodities, such as juices, as proposed by FDA guidelines [17, 18, 19, 20, 21, 22]. It was recognized that ingestion patterns for juices are different from those of spices, but taking this step allowed NYSAGM to either proactively remove several thousand pounds of product that were contaminated from New York's marketplace. If the contaminated product is distributed in other states, it triggers NYSAGM to notify them. Each state will apply what regulatory action is appropriate for their program. NYSAGM used a conservative and proactive approach at first by only initiating Class II recalls for the presence of unallowable dyes. FSI then developed a commodity-based targeted sampling surveillance program to systematically target imported spices, and in 2016 adopted a Class I recall action level of 25 ppm for Pb after reviewing FDA 2013 Class I recall for powder turmeric containing 28 ppm of Pb [6]. In 2019, FSI utilized a commodity-based targeted sampling approach to establish a baseline of heavy metals ordinarily found in well-known domestic spice brands, independent of origin, appearance, or price. While in most cases the heavy metals contamination was low (below 1 ppm), the information was used to establish background levels of heavy metals in spices and understand what levels of specific heavy metals the spice industry could achieve (data not shown).

Although a range of toxic metal elements were tested, Cd and Pb were the elements that were most commonly detected. iAs was not often detected, because the total As threshold of 1 ppm was not reached to trigger As speciation. From all samples tested ('for cause' and/or targeted), 337 were domestic products, 455 were imported, and 302 did not specify their origin.

Imported spices came from Bangladesh, Barbados, Canada, China, Croatia, Dominican Republic, Ecuador, Georgia, Germany, Ghana, Guyana, Hong Kong, Hungary, India, Indonesia, Israel, Italy, Ivory Coast, Jamaica, Japan, Jordan, Korea, Lebanon, Malaysia, Mexico, Morocco, Nepal, Nigeria, Pakistan, Peru, Philippines, Poland, Russia, Spain, Taiwan, Thailand, Trinidad & Tobago, Turkey, United Arab Emirates, Vietnam, and Yemen. Figure 1 shows the number of samples collected over a 5-year (2014-2019) period and what percentage of those contained Pb below or above 1 ppm. From 2016-2019, NYSAGM removed over 95 different types of spices from the marketplace using Class I or Class II recall methodology due to Pb concentrations being above 1 ppm (Table 2). Additionally, and based on NYSAGM action, the FDA issued several import alerts; (#28-13) list [25] for ground turmeric (tested in 2016), ground cumin (tested in 2017), and galanga powder (tested in 2020).

Following FSI's creation of the targeted sampling surveillance program and subsequent expansion of its enforcement policy, a noticeable decrease in the number of tested samples containing Pb above 1 ppm was observed. In 2014, 2015, and 2016, the percentage of spices containing Pb concentration more than 1 ppm were 18, 12, and 13 percent, respectively. While in 2017, 2018, and 2019, the percentage of spices with Pb above 1 ppm slightly decreased to 8, 8, and 11 percent, respectively. While the NYSAGM leading regulatory approach to contamination in spices has proved to be effective, to reduce human exposure to heavy metals from imported spices to below health-based and background levels a global, more comprehensive approach, must be adopted [10]. This comprehensive approach would ensure national, state, and local public health professionals and healthcare providers work together to carefully consider unconventional sources such as food and imported spices when investigating heavy metal poisoning cases [10, 12, 26].

Figure 2 gives an overview of the percentage of Cd in spices. Samples collected were initially flagged for the presence of unallowable dyes or other metals but were subsequently tested for the presence of Cd. Residues of Cd in spices (red pepper, black pepper, turmeric, and mixed spices) were also studied by Ziyaina et al. (2014) in Libya because of its

Table 2: Violative spices removed from marketplace due presence of lead (Pb) above 1 ppm

Product Type	**Product**	**Lead (Pb) concentration in ppm**	**Country of Origin**	**Recall Class Type (I or II)**[1]
Aniseed	Aniseed Powder	4.83	China	II
	Dried Aniseed	7.67	China	II
	Star Aniseed Powder	6.06	China	II
	Ground Star Anise	1.74	China	II
Chili	Chili Powder	1.66	Domestic	II
	Red Chili Powder	1.11	Pakistan	II
Cinnamon	Cinnamon Powder	1.13	India	II
	Cinnamon Powder	3.6	Domestic	II
	Cinnamon Powder	4.27	Domestic	II
	Dried Cinnamon Powder	5.39	China	II
	Dried Cortex Cinnamon Powder	2.61	China	II
	Ground Cinnamon	3.50	Not Listed	II
	Ground Cinnamon	4.49	Domestic	II
	Ground Cinnamon	1.01	Not Listed	II
	Ground Cinnamon	1.04	Domestic	II
	Ground Cinnamon	1.13	Indonesia	II
	Ground Cinnamon	1.22	Not Listed	II
	Ground Cinnamon	1.53	Not Listed	II
	Ground Cinnamon	2.07	Not Listed	II
	Ground Cinnamon	2.74	Not Listed	II
	Ground Cinnamon	2.98	Not Listed	II
	Ground Cinnamon	3.91	Not Listed	II
Coriander	Coriander	13.7	Not Listed	II
	Coriander	1.66	Not Listed	II
Cumin	Cumin Powder	1.12	Hong Kong	II
	Cumin Powder	1.34	China	II
	Dried Cumin	1.13	China	II
	Dried Cumin Powder	1.8	China	II
	Comino Molido/Ground Cumin	1090[2]	India	I
	Ground Cumin	1.57	Domestic	II
	Ground Cumin	2.2	Not Listed	II
	Ground Cumin	1.12	Domestic	II
	Ground Cumin	1.33	Not Listed	II
	Ground Cumin	2.41	Mexico	II
Curry	Curry Powder	1.31	Not Listed	II
	Curry Powder	1.33	Not Listed	II
	Curry Powder	2.50	Domestic	II
	Hot Jamaican Curry Powder	18.6	Domestic	II
	Hot Jamaican Curry Powder	25.3	Not Listed	I
	Jamaican Curry Powder	4.49	Not Listed	II
	Jamaican Curry Powder	1.07	Domestic	II

Product Type	Product	Lead (Pb) concentration in ppm	Country of Origin	Recall Class Type (I or II)[1]
Curry	Jamaican Curry Powder	1.18	Domestic	II
	Jamaican Curry Powder	2.37	Domestic	II
	Jamaican Curry Powder	2.79	Domestic	II
	Jamaican Curry Powder	21.5	Domestic	II
	Jamaican Curry Powder	22.6	Domestic	II
	Jamaican Curry Powder	35.0	Domestic	I
	Jamaican Curry Powder	19.7	Not Listed	II
Ginger	Dried Ginger Powder	1.13	China	II
	Ginger Ground	1.03	Domestic	II
	Ginger Powder	1.06	Domestic	II
	Ginger Powder	2.48	Domestic	II
	Ground Ginger	1.05	Not Listed	II
	Ground Ginger	1.14	Domestic	II
	Ground Ginger	1.03	Not Listed	II
Five Spice	Dried Five Spice Powder	1.95	China	II
	Dried Five Spice Powder	6.91	China	II
	Dried Five Spice Seasoning Powder	2.4	China	II
	Dried Five Spiced Powder	3.71	China	II
	Five Spice Powder	11.9	China	II
	Five Spice Powder	1.26	Taiwan	II
	Five Spice Powder	1.73	China	II
	Five Spice Powder	1.82	Thailand	II
	Five Spice Powder	1.82	China	II
	Five Spice Powder	4.33	China	II
	Five Spice Powder	5.72	Hong Kong	II
	Five Spice Powder	3.59	China	II
	Five Spice Powder	11.3	China	II
	Five Spice Powder	1.05	Not Listed	II
	Five Spice Powder	2.02	Hong Kong	II
	Five Spice Powder	2.14	Hong Kong	II
Red Hot Pepper	Red Hot Pepper	1.02	Turkey	II
	Red Pepper Powder	1.40	Taiwan	II
	Spice Powder	1.06	China	II
	Spice Powder	2.54	China	II
	Spice Powder	4.24	China	II
	Spice Powder	4.55	China	II
Turmeric	Turmeric Powder Pepper	2.03	Vietnam	II
	Ground Turmeric	54.1[2]	Domestic	I
	Ground Turmeric	2.03	Domestic	II
	Ground Turmeric	2.19	Not Listed	II
	Turmeric Powder	1.25	Thailand	II

Product Type	Product	Lead (Pb) concentration in ppm	Country of Origin	Recall Class Type (I or II)[1]
Turmeric	Turmeric Powder	1.56	Thailand	II
	Turmeric Powder	2.30	Vietnam	II
	Turmeric Powder	5.00	Bangladesh	II
	Turmeric Powder	15.8	Not Listed	II
	Turmeric Powder	2.00	Thailand	II
	Turmeric Powder	2.40	India	II
	Turmeric Powder	3.57	Not Listed	II
Others	Aborrotera Central Tequesquite	2.21	Mexico	II
	Clavo Molido	1.2	Not Listed	II
	Fennel Powder	1.88	China	II
	Garam Masai Powder	1.41	India	II
	Garam Masai Powder	1.41	India	II
	Grey Salt with Black Summer Truffles	3.09	Italy	II
	Ground Cloves	1.60	Not Listed	II
	Pashupati Lapsi Powder	1.77	Nepal	II
	Ramirez Produce Tierra Santa Holy Land	4.6	Not Listed	II
	Suya Khebab Powder	2.16	Ghana	II

[1] Recall action levels were set at 1 ppm for a Class II recall and 25 ppm for a recall Class I
[2] After traceback activities, the FDA issued an import alert (#28-13) based on NYSAGM findings (US FDA 2016-2019)

potential toxic effects.

The effectiveness of the NYSAGM leading regulatory approach was further substantiated by the study conducted by Hore et al. (2019), where authors observed that spices purchased in stores in New York City that are under the regulatory authority of NYSAGM were less likely to have elevated Pb concentrations when compared to similar spices purchased abroad. Additionally, Cowell et al. (2017) recommended and supported NYSAGM's efforts to implement targeted sampling assignments to help understand overlooked food safety problems. These authors also encouraged the FDA to use portable, fast, inexpensive, and reliable heavy metal screening tools such as X-ray fluorescence spectroscopy (XRF) instruments at major ports of entry, to quickly and easily identify problematic products before entering U.S. commerce.

NYSAGM currently uses handheld XRF units to screen spices for several heavy metals. The use of the XRF unit for screening purposes has resulted in NYSAGM increasing its ability to prioritize which samples to both collect (FSI) and analyze (FL), adding efficiency to both divisions.

4. Conclusions

4.1. NYSAGM recall policy update

With public health and safety its priority mission, and absent federal action levels for heavy metals in spices, NYSAGM has elected, based on the health-based guidance values developed by the BTSA (see Supplemental Materials) and by the range of heavy metal concentrations from spice sampling data provided by the FL, to lower the State's Class II recall action level for heavy metals in spices and subsequently update its recall policy (Table 3). The reduction of Class II recall action level from 1.0 ppm to >0.21 ppm for Pb, >0.26 ppm for Cd, and >0.21 ppm for iAs, represent, in the case of Pb, approximately a five-fold reduction from the original Class II recall action level devised by NYSAGM in 2016. Had these levels been in effect, there would have been 509 recalls for Pb and 68 recalls for Cd in the period 2014-2019. New York State determined that these new action levels for Pb, Cd, and iAs meet the criteria for a Class II recall, a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote [23] but did not meet the criteria for a Class I recall, a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death [24]. Once these new action levels are exceeded, a Class II recall will be initiated. A Class II recall requires firms recalling a product to remove the contaminated product from the marketplace. Using these updated Class II recall action levels, NYSAGM will lead the nation in proactively protecting its food supply against heavy metal spice contamination.

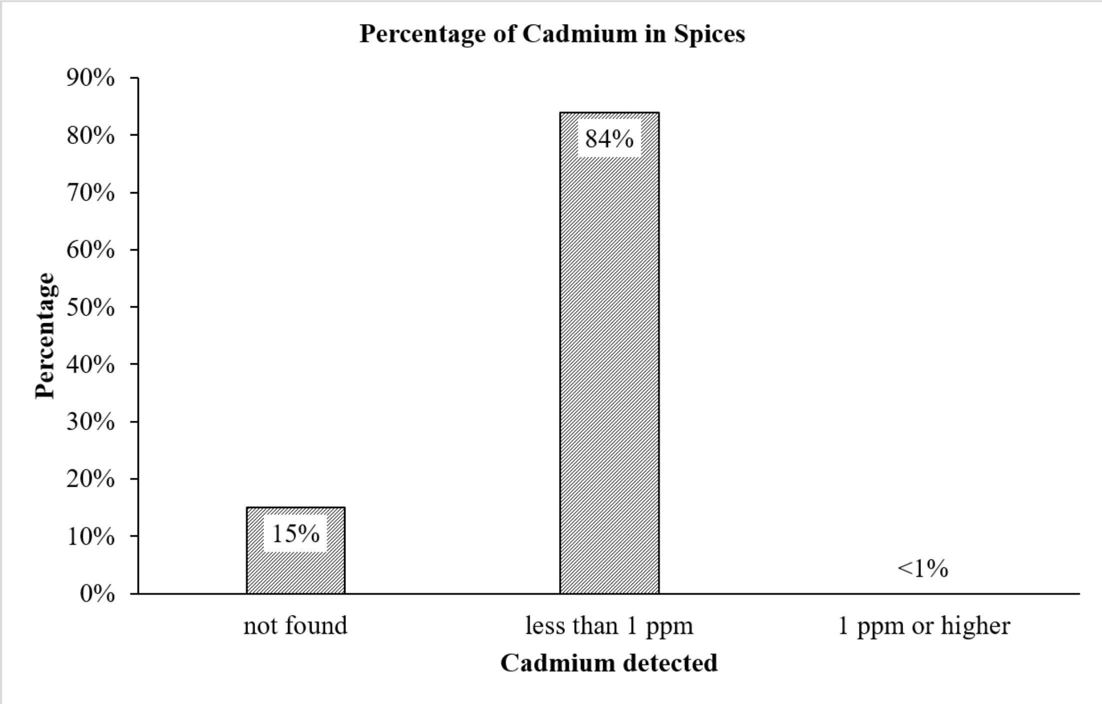

Figure 2: Percentage of cadmium (Cd) in spices detected by the NYSAGM from 2014 to 2019 (n=1041).

4.2. Update recall policy implementation

Protecting New York's consumers is the State's top priority, and effective implementation of its public health mission is vital. In order to successfully implement the State's updated recall policy and subsequent enforcement activities, NYSAGM will use a phased approach over the span of at least an 18-month period. Currently, NYSAGM has a Class II recall action level of 1 ppm for Pb that was put in place in 2016. As part of the State's implementation strategy, NYSAGM will monitor and document violations of the new Class II recall action level policy (e.g. >0.21 ppm Pb) by sending warning letters to those responsible for the violation (unless actionable under the current Class II recall action level, i.e., Pb (≥ 1 ppm). This approach will afford importers, distributors, co-packers, manufacturers of spices, and retailers the opportunity to implement additional controls that may be needed to comply with the new Class II recall action levels in the future.

NYSAGM also intends to work closely with retailers, importers, wholesalers, manufacturers (spice packers and those using spices as ingredients in their finished products), and any other relevant industry partners during the 18-month implementation period by engaging in various forms of comprehensive outreach and education sessions; by speaking at national and regional food safety conferences; by hosting in-person meetings; and by providing those affected with various forms of written communication to ensure they are aware of the change.

NYSAGM's goal is to ensure that all stakeholders affected by the updated policy are adequately prepared once the change becomes effective, while ensuring that the implementation of the updated recall policy efficaciously protects public health. Finally, for this research to have a broad impact, NYSAGM will share the information provided in this paper to State departments of health and agriculture, to the Centers for Disease Control and Prevention (CDC), and to the Food and Drug Administration (FDA) to serve as a national model for appropriate action concerning spices contaminated with heavy metals.

5. Declaration of Conflicting Interest

The authors declare no conflicts of interest.

6. Acknowledgements

This work would not be possible without overwhelming support from Department of Agriculture and Markets staff (R. Ball, J. McCormick, R. Gonzalez, G. Palmer, E. Sawyer, L. Shephard, D. McCarthy) and Department of Health (acknowledged below). Special recognition to technical collaborative work from NYSAGM Food Safety inspectors (various), Food Laboratory analysts (T. Tarantelli and W. Hoek), who conducted sampling and testing of heavy metals in spices, NYSDOH staff (A. Candara, L. Marquez-Bravo, T. Johnson, H. Spliethoff, M. Hughes, G. Recer, G. Ginsberg) for supporting and performing a risk assessment of heavy metals in spices as summarized in the Supplemental Materials.

7. Article Information

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Table 3: New York State *Updated* Recall Policy for Heavy Metals in Spices

Analyte	Class II Action Level (ppm)
Lead (Pb)	>0.21(1)
Cadmium (Cd)	>0.26(2)
Inorganic Arsenic (iAs)	>0.21(3)

(1) Class II recall action level selected is based on the NYSDOH derivation of a noncancer health-based guidance value for Pb in spices used in food preparation (see Supplementary Materials). It is important to recognize that this assessment differs from other noncancer assessments because of the absence of a threshold for the human health effects of Pb; for effects on the developing central nervous system of children. While the health-based guidance value is based on health protective methods and assumptions, the absence of a threshold means that we cannot assume that exposure below the health-based guidance value is without risk as we would for other noncancer health-based guidance values. Due to absence of a threshold for the noncancer health effects of Pb, and the presence of many other potential sources of exposure to Pb (e.g., air, soil, indoor dust, water), it is prudent to reduce risks for Pb exposure through consumption of spices by adopting screening or action levels as low as achievable.
(2) Class II recall action level is based on cadmium concentrations detected in sampled spice products, which were used as a surrogate for the 90th percentile of background cadmium concentrations found in spices, and is also set as close as feasible to the health-based values for cadmium in spices described in the supplemental materials.
(3) Class II recall action level is based on arsenic concentrations detected in sampled spice products, which were used as a surrogate for the 90th percentile of background arsenic concentrations found in spices, and is also set as close as feasible to the health-based values for arsenic in spices described in the supplemental materials.

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9. Supplemental Materials

9.1. *Summary of New York State Department of Health (NYS-DOH) Bureau of Toxic Substance Assessment (BTSA) Derivation of Health-Based Guidance Values for Metals in Spices*

At the request of the New York State Department of Agriculture & Markets (NYSAGM), BTSA derived health-based guidance values for inorganic arsenic (iAs), cadmium (Cd), chromium (Cr) compounds, and lead (Pb) in spices using procedures consistent with the general risk assessment paradigm [1, 2, 3]. A summary of the risk assessment methods used to develop these health-based guidance values is presented below, with more details presented elsewhere [3]. The latter document also describes the FDA Interim Reference Level for lead and provides additional details on the methods described in this supplement to derive an acceptable daily lead exposure level for young children.

9.1.1. *Hazard Identification*

Summary of Health Effects. BTSA reviewed information on the long-term health effects of iAs, Cd, Cr compounds, and Pb, based on animal and human toxicity studies.

9.1.2. *Dose-Response Assessment*

Selection of Cancer and Noncancer Toxicity Values. BTSA obtained cancer and noncancer oral toxicity values from authoritative assessments (i.e., done by environmental and public health agencies) on iAs, Cd, Cr compounds, and Pb. These values were based on quantitative dose-response relationships between oral exposure to these metals and the incidence or severity of adverse health effects reported in animal or human toxicity studies. BTSA evaluated and selected toxicity values (e.g., oral reference doses and cancer potency factors) for each metal based on the strength of the underlying toxicity data and the consistency of the methods used by the authoritative bodies with generally-accepted risk assessment practices. For Pb, the noncancer toxicity value was based upon integrated exposure uptake biokinetic (IEUBK) modeling to determine the exposure from food associated with a 1-point drop in the average IQ in children through ingesting spices [3].

9.1.3. *Exposure Assessment*

Estimation of the Total Daily Spice Consumption. To characterize the potential for oral exposure to the metals of concern in spices used for food preparation, BTSA estimated rates of daily consumption of spices for children and adults from different race/ethnic(ity) groups using data from the scientific literature and other authoritative sources [4, 5, 6, 7, 8, 9, 10, 11]. For use in deriving health-based guidance values, BTSA estimated central tendency (mean) and high-end (90^{th} percentile) total spice consumption rates for children and adults based on daily ingestion of eight of the most common spices, using individual spice consumption data from the Food Commodity Intake Database [4] and body weight data from the United States Environmental Protection Agency Exposure Factors Handbook [12].

9.1.4. *Risk Characterization*

Derivation of Health-based Guidance Values. BTSA used the selected cancer and noncancer toxicity values for each metal and estimates of total daily spice consumption to calculate the concentration of each metal in spices that would result in a daily dose corresponding to the oral noncancer toxicity value and the one-in-one million cancer risk level. These health-based guidance values represent concentrations of metals in spices that are expected to be without an appreciable risk of deleterious noncancer effects and a *de minimis* level for cancer risk (e.g., one-in-one million cancer risk level), assuming mean or high-end (90^{th} percentile) estimates of daily consumption of spices in food. After considering differences in spice consumption rates across the various exposure groups, BTSA selected mean consumption estimates for children (averaged from birth to < 7 years of age) for all race/ethnic(ity) groups and genders, and mean consumption estimates for adults (all race/ethnic(ity) groups, all genders) as the basis for recommended health-based guidance values for metals in spices. Table 4 presents the recommended noncancer and cancer health-based guidance values for metals in spices. Since children are estimated to consume more spices per unit body weight than adults, the noncancer health-based guidance values based on spice consumption in children are lower and more protective for the general population than values based on spice consumption in adults, and therefore these values are presented. The cancer health-based guidance values for spices are calculated using adult spice consumption rates.

9.1.5. *Recommendations*

BTSA evaluated Pb in this assessment and proposed a noncancer health-based guidance value in Table 4. It is important to recognize that the derivation of the health-based guidance value for Pb differs from the other noncancer assessments because of the absence of a threshold for Pb human health effects, particularly for effects on the developing central nervous system of

Table 4: Summary of Noncancer and Cancer Health-Based Values for Metals in Spices Used in Food Preparation [a]

Metals	**Noncancer Health-Based Spice Guidance Value (mg/kg) [b,c]**	**Cancer Health-Based Guidance Value (mg/kg) [d,e]**
Arsenic (inorganic)	0.53	0.0030
Cadmium	0.019	0.45
Chromium (hexavalent)	1.6	0.058
Lead	0.21	2.64

[a] Units in mg/kg represent milligrams of metal per kilogram of spice (mg_{metal}/kg_{spice}), which is equivalent to units expressed in parts per million (ppm).
[b] Noncancer Health-Based Guidance Value = (reference dose/child total spice consumption rate) x (1 x 10^6 mg_{spice} / 1 kg_{spice}) x 0.2 (relative source contribution). Considering that other possible exposure sources (e.g., water, soil, consumer products) can contribute to overall exposure to the metals of concern, NYSDOH-BTSA used a default relative source contribution of 20 percent.
[c] Total spice consumption rate for children = 114 mg_{spice}/kg_{bw}/day
[d] Cancer Health-Based Guidance Value = [(1 x 10^{-6} / cancer potency factor) / adult total spice consumption rate] x (1 x 10^6 mg_{spice} / 1 kg_{spice})
[e] Total spice consumption rate for adults = 32.9 mg_{spice}/kg_{bw}/day

Equation 1: Calculation of Total Spice Consumption Rate for Children

$$CR = \sum_{i=1}^{m}\left(\sum_{j=1}^{n}\left(\frac{\bar{I}R \times ED}{AT \times BW \times CF}\right)\right)$$

Where,
CR = total spice consumption rate for children (mg_{spice}/kg_{bw}/day)
i = spice (unitless)
m = maximum number of spices considered
j = age (in one-year intervals)
n = maximum number of age intervals considered
$\bar{I}R$ = ingestion rate of spice (g/d); mean for central tendency estimates and 90^{th} percentile for high-end estimates from the Food Commodity Intake Database [4]
ED = exposure duration for interval j (one year)
BW = assumed body weight (kg) at year j from the United States Environmental Protection Agency Exposure Factors Handbook [5]
AT = averaging time (seven years)
CF = conversion factor (10^{-3} g/mg)

Equation 2: Calculation of Total Spice Consumption Rate for Adults

$$CR = \sum_{i=1}^{m}\left(\left(\frac{\bar{I}R}{BW \times CF}\right)\right)$$

Where,
CR = total spice consumption rate for adults (mg_{spice}/kg_{bw}/day)
i = spice (unitless)
m = maximum number of spices considered
$\bar{I}R$ = adult (age 21 to <78) ingestion rate of spice (g/d) from the Food Commodity Intake Database [4].
BW = 80 kg
CF = conversion factor (10^{-3} g/mg)

children. The absence of a threshold for health effects of Pb in children means there is no level of exposure to Pb in children without an increased risk for health effects. Given the toxicity of Pb and the presence of many other potential sources of Pb exposure (e.g., air, soil, indoor dust, water), BTSA recommends that exposure to Pb in spices used in food preparation be minimized to the greatest extent practical. From a strictly health-based perspective, the lowest value for each metal in Table 4 would be considered the most protective against health effects from long-term exposure to metals in spices used for food preparation. BTSA recommends adoption of action levels for each metal that are as close as possible to the lowest corresponding health-based guidance value, taking into account background concentrations of the metals in spices and technical feasibility.

9.1.6. References

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EXHIBIT C

From:	Laura Shumow
To:	Trodden, Jennifer (AGRICULTURE)
Subject:	Re: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar
Date:	Tuesday, February 8, 2022 4:04:21 PM

Hi Jen,

Thank you for sharing and thank you for the clarification below. Just confirming that with that clarification, you are comfortable with me sharing this information with my membership. I actually just got a question from a company today regarding the compliance timeframe.

Wow, yes that is a lot of spices. Per my question below, are you planning to include all 20+ of those spices in the first implementation round? I thought when we spoke yesterday, you mentioned that you would focus on 8 spices in the first round and then other spices in a subsequent round, but I am a bit confused as these all seem to be in the "spices, other" category.

Also, would you adjust the limit if the data demonstrated that the 0.21ppm was not achievable?

Warm regards,
Laura

Laura Shumow
Executive Director
American Spice Trade Association
630-542-3482

From: Trodden, Jennifer (AGRICULTURE) <Jennifer.Trodden@agriculture.ny.gov>
Sent: Tuesday, February 8, 2022 3:26 PM
To: Laura Shumow <lshumow@astaspice.org>
Subject: RE: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

Hi Laura,

Here is what is included in the "other spices" list, which is why we will need some time to collect and analyze samples to populate the new dataset we are building.

"Other spice":

Allspice
Anise, seed
Anise, star
Annatto, seed
Caper, buds
Caraway
Caraway, black
Cardamom
Cassia, buds
Celery, seed
Clove, buds
Cumin
Fennel, common
Fennel, Florence, seed
Fenugreek, seed
Grains of Paradise
Juniper Berry
Lovage, seed
Mace
Mustard, seed
Nutmeg
Poppy, seed
Saffron
Vanilla

Minor edit below, as we have already evaluated the data, using spices as a single category, to determine feasibility.

Jen

From: Laura Shumow <lshumow@astaspice.org>
Sent: Tuesday, February 8, 2022 2:32 PM
To: Trodden, Jennifer (AGRICULTURE) <Jennifer.Trodden@agriculture.ny.gov>
Subject: Re: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

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Hi Jen,

Oh I see. We did not collect data on any other spices initially, so I don't have anything else at this time. Let me look into it and see what we can do. It may be challenging to do this at this time, but I will look into if we can do it and get back to you. I also have the WHO and EU data, which we could look at as well.

Could you clarify how "spices, other" is being defined as this is in the first group? It seems challenging to deal with that category in that way and it perhaps needs to be broken out.

I also had a few questions below about if I understood correctly what you are doing and if I may provide updates to my membership.

Warm regards,
Laura

Laura Shumow
Executive Director
American Spice Trade Association
630-542-3482

From: Trodden, Jennifer (AGRICULTURE) <Jennifer.Trodden@agriculture.ny.gov>
Sent: Tuesday, February 8, 2022 2:23 PM
To: Laura Shumow <lshumow@astaspice.org>
Subject: RE: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

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HI Laura,

Thanks for the data you provided, however we were hoping for additional data for all spice types I shared that are listed below.

My apologies if I wasn't clear.

Thanks.

Jen

From: Laura Shumow <lshumow@astaspice.org>
Sent: Tuesday, February 8, 2022 2:00 PM
To: Trodden, Jennifer (AGRICULTURE) <Jennifer.Trodden@agriculture.ny.gov>
Subject: RE: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.

Hi Jen,

Thank you so much for taking the time yesterday and for the follow up. I really appreciate the update and the list below. I wanted to confirm with you my understanding of the plan and ask if it is ok for me to share this update with my membership.

As I understood from our call yesterday, Ag and Markets and DOH are building a database of 16 spices commonly consumed by children per the FCID. This database will include Ag & Markets Food Lab surveillance data on these spices, and where there are gaps in the data, NYS will be doing additional sampling. The purpose of the dataset is to further validate ~~evaluate~~ feasibility on a spice by spice basis against the 0.21ppm standard. For this purpose, feasibility is defined as at least 50% of the samples being able to meet the standard.

Further, the implementation timeline will not begin until this database is complete, which is anticipated to take some time. Once it is complete, the results will be shared with industry and implementation will begin in a phased approach. Enforcement against the new 0.21 standard will begin no sooner than 18 months after the database is completed and shared with industry (in the meantime, the 1.0ppm standard for lead will apply). Enforcement will begin against the top 8 spices consumed by children after the first 18 month, followed by the subsequent 8 and other spices in the second phase, which will begin 18 months after the first phase.

Is that all correct?

If so, I have a few questions.

- First of all, if your data were to show that <%50 of spices could meet the lead standard, would you modify the standard for that spice so that it was achievable per this standard?
- It appears that the 90th percentile was used for cadmium and inorganic arsenic. Could this standard be applied for lead as well in NY's analysis?
- Also, I see you have "spices, other" listed in the first round - so would the first implementation timeframe include all spices other than those listed separately in the list? And if so, how would spices, other be defined (as NYS is not aligned with the the standard FDA definition of spices)?

I am re-sharing the chart that was included in the presentation we provided in July. This is information I am sharing with you on a confidential basis as it includes protected business information. It seems that this table includes all of the headers you list below, except the 95th percentile, which I could add in if that would be helpful.

CONFIDENTIAL - BUSINESS INFORMATION

				90th		

Spice	N	Average (ppm)	Median (ppm)	Percentile (ppm)	% >0.21 ppm	% >1.0 ppm
Cinnamon	3095	0.81	0.66	1.6	86%	28%
Ginger	441	0.76	0.68	1.3	95%	18%
Turmeric	550	0.29	0.17	0.67	44%	3%
Basil	34	0.27	0.20	0.62	47%	0%
Oregano	121	0.54	0.37	0.94	79%	9%

I also wanted to address the issue of this 50% feasibility standard.

New York State stated that they chose the 0.21 ppm class II recall level for lead although only approximately 50% of the spices sampled as part of their assessment could meet the level. In justifying the level, they cited FDA's setting of 100 ppb inorganic arsenic action level for infant rice cereal. FDA's data on inorganic arsenic level in infant rice cereal showed that only 47% of the samples could meet the action level in 2014. This neglects the fact that FDA had designed a study that allowed them, in part, to understand that variability in inorganic arsenic levels in the US market. In particular, FDA has a large amount of data on inorganic arsenic levels in rice that showed that rice low in inorganic arsenic content was available for infant rice cereal manufacturers to enable them to meet the 100-ppb action level. Under 21 CFR 109.7, a manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible. Sourcing of rice that has low inorganic arsenic content would be a quality control procedure that infant rice cereal manufacturers can use to lower the inorganic arsenic content of their product.

It is true that at the time FDA proposed a 100-ppb action levels for inorganic arsenic in infant rice cereal, data on levels of inorganic arsenic in 76 samples of infant rice cereal (sampled in 2014) showed that nearly half (47%) of infant rice cereals could meet the agency's proposed action level and a large majority (78%) was at or below 110 ppb inorganic arsenic. In the supporting document that was issued with the proposed action level, FDA stated "FDA believes that industry use of good manufacturing practice, in particular selective sourcing, could allow all manufacturers to achieve lower levels of inorganic arsenic in infant rice cereals, and specifically to achieve a 100-ppb action level of inorganic arsenic in infant rice cereal." This is because, based on its extensive sampling of rice and rice products for arsenic, the agency was aware that rice that is low in inorganic arsenic was available to infant rice cereal manufacturers.

Indeed, in its sampling of infant rice cereal in 2018 (149 samples) 76% of the samples met the 100- ppb action level. This shows that, following issuance of the proposed action level, infant rice cereal manufacturers had started to use incoming rice that was low in inorganic arsenic. In the supporting document that accompanied the final action level of 100 ppb, FDA again reiterated, "Selective sourcing, i.e., buying rice from growers or mills with consistently lower levels of inorganic arsenic than in the general rice supply, will lower inorganic arsenic in infant rice cereals."

From the current understanding of the database developed by NYS, this consideration of evaluating the market supply of spices in NYS was not conducted. While the 90th percentile cut-off for cadmium and arsenic reflects some understanding of the achievability approach, this was not the case for lead.

Thank you again. I look forward to continuing the dialogue with you on this.

Warm regards,
Laura

Sent from Mail for Windows

From: Trodden, Jennifer (AGRICULTURE)
Sent: Tuesday, February 8, 2022 12:14 PM
Subject: RE: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

Good afternoon Laura,

It was great catching up yesterday. Below are the spices that have been identified as commonly consumed by children:
Most Ingested to Least w/Phase
1 Sesame, seed
1 Pepper, nonbell, dried
1 Parsley, dried leaves
1 Dill, seed
1 Spices, other
1 Marjoram *
1 Basil, dried leaves
1 Savory*
2 Cinnamon
2 Turmeric
2 Pepper, bell, dried
2 Pepper, black and white
2 Ginger, dried
2 Coriander, seed
2 Chive, dried leaves
2 Peppermint *

The headings for the data we are sorting through for each one of these spices are as follows:

- Number of Samples
- Mean
- % greater than 210ppb

- 90th % Value
- 95th % Value

As we discussed, please share the summarized data you have and we will see if we can use it to bolster our dataset.

Thanks so much.

Jennifer C Trodden MS, CSP
Deputy Commissioner

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From: Trodden, Jennifer (AGRICULTURE)
Sent: Wednesday, February 2, 2022 3:05 PM
To: 'Laura Shumow' <lshumow@astaspice.org>
Subject: RE: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

Hi Laura,

Thanks so much for reaching out.

Do you have any availability next week to discuss the questions you pose below further?

Some times/dates I have available are as follows:
2/7 1-5pm
2/8 9-1pm

From: Laura Shumow <lshumow@astaspice.org>
Sent: Wednesday, February 2, 2022 12:54 PM
To: Trodden, Jennifer (AGRICULTURE) <Jennifer.Trodden@agriculture.ny.gov>
Subject: RE: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

Hi Jennifer,

I hope you are well. Thank you for sharing the new publication. I have circulated it to my members.

I am curious about what you mean regarding the database and about the implementation strategy and timeline. Can you please expand upon what the database entails and how it will be used to assess feasibility? Additionally, I would appreciate any information you can share on the anticipated implementation timeline.

Warm regards,
Laura

Sent from Mail for Windows

From: Trodden, Jennifer (AGRICULTURE)
Sent: Tuesday, February 1, 2022 4:36 PM
Subject: New York State Action Limits for Heavy Metals in Spices - External Stakeholder Webinar

Good afternoon,

We wanted to take a moment to share that the Journal of Regulatory Science has finally published the manuscript we referenced in the New York State Action Limits for Heavy Metals in Spices stakeholder webinar we hosted in May, 2021. This manuscript summarizes our collaborative work with NYSDOH regarding heavy metals in spices. The manuscript is titled “Regulatory policies for heavy metals in spices – a New York approach” and can be found in the link below.

Additionally, since our last meeting, and based on the feedback we received, we have been working with our partners at NYSDOH to build out the dataset we have on spices, focusing specifically on spices commonly consumed by children. Once that dataset is built, we plan to host an additional webinar to share a more specific implementation strategy and timeline with you all.

https://journals.tdl.org/regsci/index.php/regsci/article/view/149

Thanks so much for your input and for your continued collaboration.

Jennifer C Trodden MS, CSP
Deputy Commissioner

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EXHIBIT D

The Expert Voice of the U.S. Spice Industry in the Global Market

ASTA Meeting with NY State on Class II Recall Action Limits

December 9, 2021

Agenda

- Overview of Concerns with NYS Class II Limits
- Scientific Questions and Discussion
- Consumption & Exposure Analysis Issues
- Feasibility Assessment
- Procedural Concerns
- Consideration of Alternative Approaches

Key Concerns

- U.S. spice industry cannot meet new action limits
  - Feasibility issues have not been addressed
- Significant concerns/questions with NY State's risk assessment
  - Problematic consumption methodology
  - Spices contribute minimal exposure relative to other dietary sources
  - Health-based guidance value for lead does not align with standard dietary risk assessment approach or federal agency recall procedures
- Limit established without formal rulemaking – no opportunity for public comment
- ASTA requests that NYS revoke the new action limits and work with stakeholders on an alternative approach

Consumption & Exposure Assessment Considerations

Questions & Discussion

NY State Class II Limits for Lead in Foods

LEAD CONTAMINATION*
Children's Candy (100 ppb)
Ready to Drink Juice (50 ppb)
Spices (0.21 ppm)*
Other products (levels below 25 ppm but greater than 1ppm)

Excerpt from latest NY State Recall Manual – May 27, 2021

Action levels for spices do not align with exposure from other food products

Food product/commodity	NYS Class II recall action levels (ppb)	FDA Reference Amount Customarily Consumed[a] (grams)	Lead exposure (ug/day)
Children's candy	100	30	3
RTD juice	50	120	6
Spices	***210***	***0.5***	***0.105***
Other products (e.g., breakfast cereal)	1000 (1 ppm)	40	40
Other products (e.g., breakfast cereal)	25,000 (25 ppm)	40	1000

Lead exposure permitted to be 10,000X higher for other commodities versus spices

[a]Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category: (fda.gov)

Action Levels for Spices are Discriminatory

Using the same exposure assessment approach to establish a limit for apples would result in a guidance value of 0.036ppm, but NY State provides a 1-25ppm limit for foods other than spices, candy and juice

Input/method	Current NYS approach	Example using non-spice commodity
Commodity	8 select spices	Apples
Consumption (mg/kg bw/day)	114	6670
Guidance value for lead (ppm)*	0.21	0.036

Limits for Spices are Discriminatory

- Reducing spice class II action limit has a nominal impact on overall exposure to lead

Spices already contribute a fraction of the lead contributed from drinking water

Population	Diet source	Regulatory Limit	Regulatory/Action Level (ppm)	Per User Mean Consumption Estimates	Estimated exposure to lead from diet source at regulatory/action level	% of exposure from bottled water	% of exposure from drinking water
			- - - - ppm - - - -	- - - - g/day - - - -	- - - -µg Pb/day - - -		
Children 1-6 y	Bottled water	FDA Water Quality Standard	0.005	328	1.6	--	--
Children 1-6 y	Drinking water	NYS Drinking water standard	0.015	1000	15	--	--
Children 1-6 y	All spices (FCID)	Current NYS Class II Recall Level	1	0.05	0.1	3.1%	0.3%
Children 1-6 y	All spices (FCID)	Proposed NYS Class II Recall Level	0.21	0.05	0.01	0.65%	0.07%

Other Dietary Sources Are Much Higher Contributors

- Fruits, grains, and dairy products are top contributors to total dietary lead exposure among children
  - Grains: 27.5%
  - Fruits: 24.7%
  - Dairy: 16.8%
- Based on 2005-2010 WWEIA FCID, individual spices with 1 ppm lead would contribute <0. 1% to total dietary lead exposure among children 1-6 years of age as estimated by Spungen (2019)

Food Additives & Contaminants: Part A

Taylor & Francis

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Children's exposures to lead and cadmium: FDA total diet study 2014-16

Judith H Spungen

To cite this article: Judith H Spungen (2019) Children's exposures to lead and cadmium: FDA total diet study 2014-16, Food Additives & Contaminants: Part A, 36:6, 893-903, DOI: 10.1080/19440049.2019.1595170

To link to this article: https://doi.org/10.1080/19440049.2019.1595170

Table 4. Total diet study food group intakes and contributions to lead and cadmium exposures, children 1–6 years.

	Food Intake*	Dietary Lead Exposure[a]		Dietary Cadmium Exposure[a]	
Food Group	g/day	µg/day	% total	µg/day	% total
Baby Food	18	0.02	1.6	0.03	0.5
Beverages	299	<0.01	0.3	0	0
Dairy	428	0.19	16.8	0.16	2.4
Eggs	16	0	0	0	0
Fats/oils	2	0.01	0.8	0	0.1
Fruits	243	0.29	24.7	0.2	3
Grains	131	0.32	27.5	2.1	31.8
Legumes, nuts, seeds	11	0.02	1.8	0.42	6.4
Meat, poultry, fish	66	0.03	3	0.25	3.8
Mixtures	147	0.18	15.5	1.92	29.1
Sweets	17	0.04	3.5	0.08	1.2
Vegetables	66	0.05	4.7	1.44	21.8
Total	1444	1.2	100	6.6	100

[a]Data sources: Toxic element concentrations in foods: FDA Total Diet Study, 2014–16 (analysis method: inductively coupled plasma mass spectrometry, or ICPMS), arithmetic mean concentrations. Food consumption: What We Eat In America (WWEIA)/National Health and Nutrition Examination (NHANES) 2009–14. Estimated exposures do not include contributions from breast milk or from tap water, and are based on lower bound mean concentrations (values < limit of detection set to zero) in other foods.

Key Concerns with Spice Consumption Analysis

- Inclusion/exclusion rationale is unclear
- Total spice consumption estimated based on commodities that are not spices per FDA definition (sesame seeds and dried bell pepper)
- Spice consumption rate includes spices used in commercial foods
  - E.g., cinnamon included in cinnamon breakfast cereal
  - Cinnamon would be recalled if lead levels >0.21 ppm
  - Cinnamon breakfast cereal would be recalled if lead levels >1 ppm
  - Exposure to lead from cinnamon is <<< exposure to lead from breakfast cereal

Key Concerns with Spice Consumption Analysis

- Methodology to estimate consumption rate:
  - Sum of per user mean intakes among the 8 commodities to estimate consumption rate is not statistically correct
    - FCID allows for estimation of mean and 90th percentiles from cumulative sources
  - Default body weight used instead of individual's own body weight
- Assumes every child 0 to <7 years of age consumes every spice every day at that rate
  - Studies show this is not a realistic consumption pattern for any spice
- **FDA's Guidance for Industry: Estimating Dietary Intake of Substances in Food**[1]
  - Provides lead as an example of a "persistent and ubiquitous contaminant"
  - "As the various food-consumption databases provide only snapshots of food-consumption for limited periods of time, intake estimates based on these databases are generally conservative as measures of average daily chronic intakes or average daily intakes over a lifetime for individuals within the surveyed population."

Impact on Guidance Value on Incorrect Consumption Analysis

The assumptions and methods used to estimate consumption rate of spices is a ***critical component*** in the calculation of the health-based guidance value – need to be supported

Input/method	Current NYS approach	Spice Sensitivity #2 – excluding sesame seeds	Spice Sensitivity #1 – cumulative intake at individual level
Commodity	8 select commodities	7 select commodities	8 select commodities
Cumulative intake method	Sum of per user means over 1 year age interval	Sum of per user means over 1 year age interval	Cumulative intake and body weight at individual level
Consumption (mg/kg bw/day)	114	47	20
Guidance value for lead (ppm)*	0.21	0.51	1.2

*Calculated using the following formula: $\frac{Reference\ dose\ (0.00012\ mg\ per\ kg\ per\ day)}{Consumption\ rate}\ x\ Relative\ source\ contribution\ (20\%)$

Lack of Alignment Definition of Spices

- NYS Commodities:
    - Cinnamon
    - Ginger
    - Pepper, black and white
    - Pepper, non-bell dried
    - Pepper, bell, dried*
    - Spices, other
    - Turmeric
    - Sesame seeds*

*Not included in 21CFRSec.101.22 (2)(2)
FDA explicitly excludes sesame and nutritive vegetables, such as bell peppers from the definition in regulations and compliance guide - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-525750-spices-definitions

Lack of Alignment with Established Methods

- The methodology used by NYS to estimate total spice consumption is not consistent with how FDA would estimate cumulative intake of a commodity for risk assessment purposes
- Approach is inconsistent with FDA and USDA methodology to determine recalls for heavy metals in foods
- FDA and USDA use RACC and IRL to determine recalls for foods

Analysis Based on Individual Spices

- An alternative approach is to consider spices on a spice-by-spice basis
- Considering the differences between spices in origin/source, use, and consumption, it is appropriate to view spices on an individual basis

Input/method	Current NYS approach	Individual spice
Commodity	8 select spices	Cinnamon
Cumulative intake method	Sum of per user means over 1 year age interval	Body weight at individual level
Consumption (mg/kg bw/day)	114	10
Guidance value for lead (ppm)*	0.21	2.4

Feasibility Considerations

Questions on methodology for lead health-based guidance value

- Table 2 – Footnote: "…it is prudent to reduce risks for Pb exposure through consumption of spices by adopting screening or action levels as low as achievable."
    - What achievability assessment was done to support this statement?
- Figure 1 – What % of the samples had levels <0.21 ppm?
- Was any analysis done to confirm this proposed level is achievable for individual spices versus considering all spices as one commodity group?

Additional Questions on Feasibility Assessment

- How were the included commodities selected and why?
- Did the spices sampled match the 8 included commodities used to estimate spice consumption rate?
- Does the database include samples from different brands?
- Does the database include duplicate samples from the same lot?
- Does the database include multiple lots for a selected brand/manufacturer?
- Does the database include multiple brands/manufacturers per spice?
- Do the spices sampled provide a valid representation of the spice market in NYS?
- How was sample size determined? How many samples per spice per year per region, etc.?
- Was there an attempt to look at trends in levels to see if decreasing levels is possible (similar to what FDA did with inorganic arsenic in rice)?

Arsenic Example

- Although FDA's 2014 study showed that only 47% of samples could meet the 100ppb action level, FDA had conducted a study to understand variability in inorganic arsenic levels in the US market
- FDA had a large amount of data on inorganic arsenic levels in rice that showed that rice low in inorganic arsenic content was available for infant rice cereal manufacturers to enable them to meet the 100-ppb action level
- This is not the case for the lead assessment for spices

Existing Limit is Already Effective

- NYS has already recalled over 100 spice products since 2016 in accordance with existing limit
- New limit would result in ~50% of all spices not being in compliance and 95% of ginger, 86% of cinnamon and 79% of oregano being removed from the market

Regulatory & Procedural Concerns

Recall Level Should be Established by Rulemaking

- Establishing a regulatory limit solely through the publication of a scientific article is unusual
- Typically the public is provided advanced notice and opportunity for comment
- ASTA believes that Article 2 of the New York State Administration Procedure Act requires that any action levels for heavy metals in spices must be established through rulemaking
  - To satisfy state procedural law, AGM should withdraw the heavy metal action levels from its Recall Manual and instead issue a proposed rule for public comment

Questions Regarding Timing of Implementation

- NYS previously indicated that the levels will not go into effect until at least 18 months after publication of peer-reviewed article
- The article has yet to clear peer review or be published
- Is this still the planned timing for implementation?

Consideration of Alternative Approaches

AST Stands Ready to Work with NY State

- ASTA remains committed to minimizing contamination and adulteration and keeping heavy metals as low as possible
- We stand ready to work with NY State on an approach that is achievable and protective

Targeting Products with Lead-Based Dyes

- In background information regarding NY State’s decision to establish the recall action limit, the state indicated that initial goal of the program was to identify spices containing lead-based dyes
    - These products can have extremely high levels of lead – 10,000ppm
- Was consideration given to policies to target this practice?
- Did the state consider changes to Class I action limit?

EXHIBIT E

OPEN

SDC

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

Paromita Hore, PhD, MPH; Kolapo Alex-Oni, MPH; Slavenka Sedlar, MA; Deborah Nagin, MPH

ABSTRACT

Context: While lead-based paint and occupational lead hazards remain the primary sources of lead exposures among New York City's lead-poisoned children and men, respectively, these are not the only possible lead sources. Certain consumer products are often implicated. Between 2008 and 2017, the New York City Department of Health and Mental Hygiene tested more than 3000 samples of consumer products during lead poisoning case investigations and surveys of local stores, and of these, spices were the most frequently tested (almost 40% of the samples).

Objectives: To describe spice samples—types, origin, lead concentrations, and the implication of findings for public health programs and global food safety regulations.

Design: Descriptive study of lead contamination in spices systematically collected as part of lead poisoning investigations.

Setting and Participants: A total of 1496 samples of more than 50 spices from 41 countries were collected during investigations of lead poisoning cases among New York City children and adults and local store surveys.

Results: More than 50% of the spice samples had detectable lead, and more than 30% had lead concentrations greater than 2 ppm. Average lead content in the spices was significantly higher for spices purchased abroad than in the United States. The highest concentrations of lead were found in spices purchased in the countries Georgia, Bangladesh, Pakistan, Nepal, and Morocco.

Conclusions: Certain commonly used spices, particularly those purchased abroad in Georgia, Bangladesh, Pakistan, Nepal, and Morocco, can have very high lead levels, which can contribute to lead body burden. This underscores the need to develop comprehensive interventions that educate consumers and initiate intergovernmental efforts for stricter global food regulations.

KEY WORDS: Georgia, lead-contaminated spice, South Asia, turmeric, yellow flower

As blood lead levels of children and adults in the United States continue to decline,[1] the epidemiological evidence of adverse health effects from lower levels of lead exposure continues to grow. It has now been widely acknowledged that there is no known level of lead exposure that can be considered safe.[2] In children, a particularly vulnerable group due to their behavior and neurological development,[3] the adverse effects of lead exposure on learning and behavior have been well documented.[4-8] In adults, lead exposure can increase risk of hypertension, peripheral neuropathy, renal dysfunction, and adverse reproductive outcomes.[9-11] Pregnant women present a unique concern because lead exposure can affect the health of both the woman and the fetus.[3] Since symptoms of lead poisoning are often not observed, and many adverse health effects are irreversible, preventing exposure is the only effective way to avoid

Author Affiliations: *Bureau of Environmental Disease and Injury Prevention (Dr Hore and Mss Alex-Oni, Sedlar, and Nagin), New York City Department of Health and Mental Hygiene, New York City, New York.*

This work is partially supported by the Lead Poisoning Prevention and Surveillance grant from the Centers for Disease Control and Prevention (6NUE1EH001275-03-01) and a contract with New York State Department of Health, Lead Poisoning Prevention Program (DOH01-C30933GG-3450000).

The authors acknowledge the contributions of the Bureau of Environmental Disease and Injury Prevention's staff—including inspectors, nurses, and other valued members of the bureau—for their tireless work around identifying lead sources for New York City's lead-poisoned children and adults.

The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (http:// www.JPHMP.com).

Correspondence: *Paromita Hore, PhD, MPH, Bureau of Environmental Disease and Injury Prevention, New York City Department of Health and Mental Hygiene, 125 Worth St, CN34C, New York, NY 10013 (phore@health.nyc.gov).*

DOI: 10.1097/PHH.0000000000000876

the health consequences of lead poisoning for children and adults.

The average blood lead levels of New York City's (NYC's) children and adults follow the pattern of national decline[1]; however, lead poisoning continues to be an important public health concern. In 2017, there were more than 5000 children and 2000 adults with blood lead levels at or above the Centers for Disease Control and Prevention's reference level of 5 μg/dL.[12,13] While lead-based paint and occupational lead hazards remain the primary sources of lead exposure among NYC children and men, respectively, these are not the only possible lead sources. Consumer products, such as certain supplements or remedies, cosmetics, religious powders, and spices, are often identified as potential lead sources associated with elevated blood lead levels.[14] Between 2008 and 2017, the NYC Department of Health and Mental Hygiene (DOHMH) tested more than 3000 samples of consumer products during investigations of lead poisoning cases and surveys of local stores. Of these samples, spices were the most frequently tested—more than 40% of all analyzed samples were spices.

The potential for lead exposure from spices has been previously documented. However, the few published reports either focused on a single spice type or a single country of origin or presented limited case studies.[15-17] The purpose of this article is to describe the characteristics of a variety of spices tested by DOHMH during the 10-year period between 2008 and 2017. Given the diversity of NYC's population, the spice samples analyzed by DOHMH provided a unique opportunity to examine spices commonly available and used around the world.

Methods

Case investigations and sample collection

DOHMH receives all blood lead test results for NYC residents and routinely conducts investigations of child and adult lead poisoning cases.[14] During these investigations, DOHMH collects samples of products suspected to contain lead and reportedly placed in the mouth or ingested by the lead-poisoned individual. Samples are analyzed for lead by an accredited laboratory using the Environmental Protection Agency (EPA) Inductively Coupled Plasma Mass Spectrometry Method SW6020 or Atomic Absorption Method SW7420 following acid digestion via EPA Method 3050. If a product is found to contain elevated lead concentrations, DOHMH visits local stores to determine availability and purchase samples of the implicated product, or similar products, for lead testing.[14] Laboratory results for each sample collected during case investigations and store surveys, along with a description of each sample, as reported by the family or retrieved from product packaging, such as the product name, origin, amount used, and frequency of use, are documented electronically in a proprietary SQL Server database. This public health activity is not subject to DOHMH Institutional Review Board review, as the scope is limited to public health practice, and all activities are authorized and conducted by DOHMH, a public health authority.

Statistical analyses

We calculated descriptive statistics for lead concentration in spices. Chi-square tests were used to compare frequencies of samples of different origin exceeding guideline lead levels; the Mann-Whitney U test was used to compare distributions of lead concentrations for spices purchased abroad and in the United States, and independent-samples t tests were used for mean comparisons of log-transformed concentrations of samples with detectable levels purchased abroad and in the United States. All analyses were conducted using IBM SPSS version 23.

Results

Lead concentration by type of spice

Table 1 presents lead concentrations by type of spice. Between 2008 and 2017, DOHMH analyzed 1496 samples of more than 50 types of spices. More than half of the samples (n = 797) had detectable lead concentrations, and 31% exceeded the reference limit of 2 ppm—a permissible limit for lead in certain food additives that is used by DOHMH as a guidance value (for information on spices exceeding other reference limits, see Supplemental Digital Content Table 1, available at http://links.lww.com/JPHMP/A524).[18,19] The highest lead concentration (48 000 ppm) was observed for the Georgian spice *kviteli kvavili*, also known as yellow flower or Georgian saffron. All samples of *kviteli kvavili* had detectable lead levels (geometric mean [GM] = 240 ppm; geometric standard deviation [GSD] = 63 ppm); 84% exceeded the reference level of 2 ppm. Other spices and spice mixes typically used in Georgian cuisine, such as *khmeli suneli* or *kharcho suneli*, *svanuri marili* or *svaneti* salt, *utskho suneli* or fenugreek, *adjika* and *kvliavi*, also known as *dzira* or caraway, measured high as well, with maximum lead concentrations ranging from 1400 ppm (*kvilavi*) to 17 000 ppm (*khmeli suneli*). The majority of Georgian spice samples had detectable lead levels, with average concentrations ranging from 8.9 to 291 ppm

TABLE 1
Lead Concentration by Type of Spice[a]

Spice	Number of Samples	Lead Concentration Percentiles, ppm: Median, all Samples	75th	90th	Maximum	Geometric Mean (GSD) of Samples With Detectable Lead	Percentage[b] of Samples With Lead Concentration Above a Reference: Above Detection Limit, %	Above 2 ppm, %
Total all spices	1 496	0.4	0.4	4.0	48 000	9.5 (20.2)	53	31
Kviteli kvavili/yellow flower/Georgian saffron	32	227.5	17 750	25 500	48 000	240.1 (63.1)	100	84
Curry	67	0.3	1.2	6.0	21 000	2.4 (13.2)	51	18
Khmeli suneli/*kharcho suneli*	41	1.7	175	6 340	17 000	21.6 (36.1)	85	49
Bouillon/broth/soup spice	17	ND	ND	1 921	9 600	8.6 (109.6)	24	6
Svanuri marili/svaneti salt	32	525	1 900	4 310	7 100	291.4 (16.7)	88	78
Utskho suneli or fenugreek	38	3.1	77.0	455	3 500	11.8 (14.6)	84	58
Adjika	10	58.0	1 062.5	3 290	3 400	78.3 (28.8)	80	60
Masala	40	ND	1.3	21.9	2 700	2.8 (10.6)	50	13
Turmeric	252	0.7	230	770	2 700	32.3 (22.0)	56	39
Hot pepper, chili powder, paprika	284	ND	3.3	27.0	2 400	4.9 (7.5)	48	30
Kvliavi/*dzira*/caraway	9	4.8	14.5	…	1 400	8.9 (9.7)	89	78
Cumin	127	ND	1.0	4.4	1 200	2.3 (6.2)	46	19
Cinnamon	19	2.0	4.8	9.6	880	3.8 (6.1)	74	53
Salt	11	ND	0.6	364	410	35.6 (34.6)	27	18
Tamarind	2	114.5	…	…	230	230 (0.0)	50	50
Spice mix	7	0.6	1.3	…	170	2.1 (12.1)	71	14
Coriander	102	0.6	2.5	17.4	79	3.0 (4.4)	55	26
Thyme	11	2.4	6.6	18.0	19	2.9 (3.0)	91	55
Mole	6	ND	9.1	…	17	10.4 (2.0)	33	33
Epazote	5	ND	11.5	…	13	11.4 (1.2)	40	40
Ginger	7	1.2	4.3	…	9.6	2.9 (2.7)	57	29
Berberis berries	2	5.1	…	…	9.4	2.8 (5.4)	100	50
Onion	4	ND	5.4	…	6.9	2.4 (4.4)	50	25
Okra	4	ND	3.9	…	5.5	5.5 (0.0)	25	25
Cilantro	3	1.3	…	…	4.6	2.4 (2.4)	67	33
Asafetida/hing	4	0.4	3.1	…	3.6	2.5 (1.7)	50	25
Tikka	3	1.8	…	…	2.5	2.1 (1.3)	67	33

Abbreviations: GSD, geometric standard deviation; ND, nondetectable; ppm, parts per million.

[a] Included in analyses spices with 2 or more samples. Shown only spices with geometric mean of samples with detectable levels of at least 2 ppm; for the full list of spices see Supplemental Digital Content Table 1 (available at http:// links.lww.com/ JPHMP/ A524).

[b] Represents row percentage.

(*kvilavi* and *svanuri marili*, respectively). Between 49% (*khmeli suneli*) and 78% (*kvilavi* and *svanuri marili*) of the samples exceeded the reference level of 2 ppm. Spices and spice mixes commonly used in South Asian cuisine such as curry, masala, and turmeric were also found to contain elevated lead levels, with maximum concentrations ranging from 2700 ppm (turmeric and masala) to 21 000 ppm (curry). About half of these spices had detectable lead, with average concentrations exceeding the reference level of 2 ppm. Various other spices and seasonings used widely in different cuisines, such as bouillon cubes and powders, broth, or soup spices, as well as hot pepper, chili powder, and paprika, were also found to have detectable levels of lead exceeding the reference limit of 2 ppm.

Qualitative data on frequency and quantity of use of spices were analyzed. The daily use of 1 teaspoon of spices in food preparation was most frequently reported. On average, 3 different spice samples were collected from each home.

Lead concentration in spices by country of purchase

The purchase country was reported for 88% (n = 1 311) of the samples (Table 2). More than half of the spices were purchased outside the United States (n = 792), altogether representing spices from 41 different countries. Bangladesh (n = 275) and Georgia (n = 210) were the most commonly reported countries of purchase; spices purchased in these 2 countries represented 61% of all samples purchased abroad. South Asian countries India, Pakistan, and Nepal were also frequently reported countries of purchase, as were Mexico, Morocco, and Jamaica. The majority of the spices purchased abroad were in unmarked packaging without brand name information.

Lead was more commonly found in spices purchased abroad than in those purchased in the United States (66% vs 40% with detectable lead concentrations, respectively; $P < .001$). This difference was even greater for the proportion of samples exceeding the reference level of 2 ppm. The spices purchased abroad were more than 3 times as likely to exceed this value compared with the spices purchased in the United States (45% vs 13%, respectively; $P < .001$). Spices purchased in Georgia were most likely to exceed the reference level of 2 ppm (70% of samples were above the limit), followed by spices from Bangladesh (54%), Morocco (48%), Nepal (30%), and Pakistan (25%). Spice samples from Georgia measured up to 48 000 ppm, from Pakistan up to 7100 ppm, from Nepal up to 2700, from Bangladesh up to 2000 ppm, and from Morocco up to 120 ppm. Samples purchased in India, Mexico, and Jamaica were less likely to exceed the reference level of 2 ppm, although some extreme concentrations were found in samples obtained in India

TABLE 2
Lead Concentration in Spices by Country of Purchase[a]

			Lead Concentration Percentiles, ppm				Geometric Mean (GSD) of Samples With Detectable Lead	Percentage[b] of Samples With Lead Concentration Above a Reference	
	Number of Samples	%	Median, All Samples	75th	90th	Maximum		Above Detection Limit, %	Above 2 ppm, %
Grand total	1 496	100	0.4	4.0	330	48 000	9.5 (20.2)	53	31
Country of purchase									
Unknown	185	12[c]	ND	1.0	4.4	4 400	4.1 (12.6)	36	16
United States	519	35[c]	ND	0.8	3.2	21 000	1.9 (6.4)	40	13
Store survey	102	20[d]	ND	0.6	4.0	21	1.0 (3.9)	49	13
Case investigation	417	80[d]	ND	0.8	3.0	21 000	2.3 (7.1)	38	14
Foreign country	792	53[c]	1.3	35.8	920	48 000	20.2 (23.3)	66	45
South Asia	412	52[e]	1.1	12.8	596	7 100	14.1 (15.4)	62	42
Bangladesh	275	35[e]	2.5	69.0	700	2 000	16.8 (14.4)	73	54
India	76	10[e]	ND	ND	3.3	690	3.3 (7.5)	24	13
Pakistan	51	6[e]	0.5	2.4	940	7 100	10 (25.7)	55	25
Nepal	10	1[e]	1.0	205.8	2 510	2 700	16.6 (35.8)	60	30
Georgia	210	27[e]	13.5	925	10 860	48 000	58.6 (31.1)	90	70
Mexico	39	5[e]	ND	0.7	6.4	17.0	2.4 (4.1)	31	18
Morocco	21	3[e]	1.4	6.6	56.6	120	5.2 (5.5)	67	48
Jamaica	12	2[e]	ND	ND	0.4	0.4	0.4 (1.2)	17	0
Other countries (N = 32)	98	12[e]	0.1	1.7	230	33 000	6.6 (30.4)	51	23

Abbreviations: GSD, geometric standard deviation; ND, nondetectable; ppm, parts per million.

[a] Countries were included if, on average, at least 1 sample per year was reportedly purchased there between 2008 and 2017. For additional reference levels see Supplemental Digital Content Table 2 (available at http://links.lww.com/JPHMP/A525).

[b] Represents row percentage.

[c] Represents percentage of the grand total.

[d] Represents percentage of the samples purchased in the United States.

[e] Represents percentage of the samples purchased in foreign countries.

(maximum = 690 ppm). Among other countries, an extreme concentration of 33 000 ppm was found in an unlabeled spice purchased in Belarus; however, spices from Belarus were not frequently sampled. Although a maximum of 21 000 ppm was found in a spice reportedly purchased in the United States, similar levels were never observed in spice samples purchased in local store surveys (maximum = 21 ppm), indicating a possible case of misreported country of purchase.

Comparison of lead concentration in select spices purchased during local store surveys and abroad

A comparison of select spices purchased during local store surveys (n = 88) and the same spice types purchased abroad (n = 466) showed significantly lower concentrations of lead in the spices obtained locally (GM = 31.6 ppm vs 1.1 ppm, respectively; $P < .001$; Table 3). Samples of *khmeli suneli* or *kharcho suneli* spices with detectable lead levels purchased in the United States had significantly lower average lead concentrations than those purchased in Georgia or Russia (GM = 0.8 ppm vs 82.9 ppm, respectively; $P < .001$). Maximum lead concentration for the samples of *khmeli suneli* or *kharcho suneli* purchased in local stores did not exceed 10 ppm, whereas a sample of the same spice purchased abroad had a maximum lead concentration of 17 000 ppm. Turmeric samples with detectable lead levels bought in local stores had a significantly lower average lead concentration than turmeric purchased abroad in Bangladesh, India, Nepal, Pakistan, and Morocco (GM = 1.0 ppm vs 152.3 ppm; $P < .001$). The maximum lead concentration of turmeric purchased abroad was 2700 ppm, whereas turmeric purchased locally did not exceed 10 ppm. Hot pepper, chili powder, and paprika samples purchased locally also had significantly lower lead concentrations than similar spices purchased abroad (GM = 0.4 ppm vs 8.0 ppm; $P < .001$). The maximum lead concentration for the locally purchased samples of hot pepper, chili powder, and paprika never exceeded the permissible level of 2 ppm, whereas the maximum concentration of lead for samples purchased abroad was 2400 ppm. Similarly, the maximum lead concentration for the locally purchased kviteli kvavili (21 ppm), utskho suneli (3.6 ppm), and curry (20 ppm) were much lower than the maximum lead concentrations for the same spices purchased abroad (48000 ppm, 1883 ppm, and 570 ppm, respectively), although the number of samples purchased locally were too small for reliable statistical comparisons (data not shown in Table 3).

TABLE 3

Comparison of Lead Concentration in Select Spices Purchased in the United States and Abroad[a]

Spice	Country of Purchase for Spices With Detectable Lead	Number of Samples[c]	Percentage[b] With Detectable Lead	Lead Concentration Percentiles, ppm: Median, All Samples	75th	90th	Maximum	Geometric Mean (GSD) of Samples With Detectable Lead	P
Khmeli suneli or *kharcho suneli*	Georgia, Russia	28	89	58.0	1 195	11 300	17 000	82.9 (29.1)	<.001
	United States	12	75	0.5	0.9	5.2	6.9	0.8 (2.4)	
Turmeric	Bangladesh, India, Nepal, Pakistan, Morocco	105	72	160	710	1 140	2 700	152.3 (12.1)	<.001
	United States	28	43	ND	0.5	4.2	6.7	1.0 (3.2)	
Hot pepper, chili powder, paprika	Algeria, Pakistan, Bangladesh, Nepal, Morocco, Tunisia, Georgia, Bulgaria, Mexico	147	61	1.3	9.8	58.6	2 400	8.0 (7.1)	<.001
	United States	24	33	ND	0.3	0.6	1.0	0.4 (1.6)	
All spice types[c]	Other countries	466	0	2.7	170.0	1 130	48 000	31.6 (22.3)	<.001
	United States	88	53	0.3	0.7	4.9	21.0	1.1 (3.9)	

Abbreviations: GSD, geometric standard deviation; ND, non-detectable; ppm, parts per million.

[a] *Spices were included if there were at least 10 samples of the same type obtained during a store survey as well as reportedly purchased outside the United States. For spices obtained outside the United States, listed are only the countries where the samples with detectable lead were purchased. Shown* P *values of the independent-samples* t *test comparing means of log-transformed lead concentrations for samples with detectable lead levels. The Mann-Whitney* U *test comparing full distributions of the samples purchased abroad and locally also showed that the distributions were significantly different;* P *values identical to those shown.*

[b] *Represents row percentage.*

[c] *The aggregate number includes all spice types with at least 1 sample purchased abroad and 1 sample purchased locally. Included in the aggregate but not shown in the table are: kviteli kvavili, svaneti salt, utskho suneli, curry, berberis berries, coriander, tequesquite, black or white pepper, and bouillon or soup spice.*

Discussion and Conclusion

To our knowledge, this is the first time such an extensive database of spices, systematically collected over a decade-long period as part of lead poisoning investigations, has been analyzed for lead content. These samples provided a unique insight into spices of diverse origins and types.

One of our main findings was that spices purchased abroad were more likely to have elevated lead concentrations compared with similar spices purchased locally in the United States. The greatest proportion of spices exceeding reference limits were those purchased in the countries Georgia, Bangladesh, Pakistan, Nepal, and Morocco. Earlier studies have described the potential of foods and spices from Georgia and South Asia to contain elevated lead levels, and cases of lead poisoning associated with spices obtained in Georgia and South Asia have also been documented.[15,17,20] In NYC, Georgians and South Asians are disproportionately represented among lead-poisoned children and pregnant women,[21,22] and although spices may not be the only source of lead exposure for these populations, it is an important risk factor to consider during lead poisoning investigations of these at-risk groups.

Adulteration of spices can occur at any point along the supply chain due to the intentional or inadvertent addition of lead. Lead may be added as a coloring agent, or to add weight for products sold by weight, or it can be introduced because of poor processing equipment; the presence of lead in air, dust, or soil where food is grown or processed can also contribute toward contamination.[23] In addition, poor regulatory controls in some countries can further impact the safety of food supplies. Although some of the countries have established guidelines for allowable lead concentration in foods, our findings show that a large proportion of the spices purchased in these countries may surpass the country's regulatory limits. For example, in Georgia, the permissible limit for lead in food is 5 ppm (National Food Agency of Ministry of Agriculture of Georgia, e-mail communication, 2017), which was exceeded in our study by more than 60% of the spices purchased there (see Supplemental Digital Content Table 2, available at http://links.lww.com/JPHMP/A525), indicating a need for tougher quality control and enforcement of standards.

In the United States, local and national surveillance and regulatory controls are in place to curtail the sale and distribution of contaminated products (eg, routine surveillance and enforcement conducted by DOHMH, New York State Department of Agriculture and Markets, US Customs and Border Protection, and the US Food and Drug Administration [FDA]).[14,24,25] These actions have led to national alerts and recalls and, in some cases, investigative and auditing activities in the products' countries of origin.[26,27] The finding that spices purchased in the United States were less likely to have elevated lead concentrations compared with similar spices purchased abroad further speaks to the effectiveness of existing processes. Nevertheless, the regulatory structure could always be strengthened. For instance, although FDA routinely monitors levels of heavy metals in certain food items through the Total Diet Study, a market basket survey of foods representative of the diet of the US consumer, the list of foods typically does not incorporate spices.[28] In addition, although FDA has established a federally recommended maximum level for lead in candy, a similar limit has not been set for lead in spices; providing such a guidance may enhance regulatory procedures.[29] Current surveillance and border control protocols are also ineffective when addressing transfer of contaminated spices brought into the United States by travelers for personal use. In this study, the spices purchased abroad were often in unmarked packaging, without any brand name information, and many times reported to be either custom-ground or from an open market. The purchase of spices from open markets presents a challenge, as trace-back mechanisms to stop the sale of these contaminated products may not be easily employed. Farmers and processors play a key role in the spice production supply chain. It is critical to engage these stakeholders by providing not only information about the health risks of spice adulteration and food safety challenges, but also access to modern, low-cost technologies that may help reduce inadvertent introduction of contaminants. On the regulatory end, routine monitoring and auditing of these nonconventional outlets, along with an emphasis on good agricultural practices, may also help curb both intentional and unintentional contaminations.[30]

In addition to regulatory controls, raising awareness about the possibility for lead contamination in spices among at-risk populations is critical. DOHMH has implemented a multifaceted, data-driven approach incorporating both local enforcement and education and dissemination of information nationally and internationally by engaging foreign consulates and regulatory authorities.[14] DOHMH has also developed linguistically and culturally appropriate educational materials for routine dissemination of health messages through respected and trusted entities such as community- and faith-based organizations and continues to work with community stakeholders to identify innovative and practical avenues to reach target populations. DOHMH's approach has been instrumental in triggering national and international investigations around lead hazards in spices and other

Implications for Policy & Practice

- Our findings highlight the importance of communicating the risks for lead contamination in spices purchased abroad, particularly to individuals who recently traveled to or emigrated from Georgia, Bangladesh, Pakistan, Nepal, or Morocco and may have obtained their spices in these countries.
- Public health professionals and medical providers should also be aware of spices as a potential risk factor for lead exposure and screen at-risk populations, especially those with Georgian, Moroccan, or South Asian ancestry.
- Adopting a comprehensive approach to identify hazardous products and documenting findings systematically can help lead poisoning prevention programs effectively respond to emerging and existing lead hazards.[14]
- Overall, a solely localized or national approach to address spice contamination will not be adequate, as the problem is global. Our results demonstrate the need for more stringent quality control and enforcement of standards globally. Although local authorities cannot mandate another country to impose stricter regulations for reducing lead contamination in spices, intergovernmental efforts can be effectively initiated by a local government agency.[31] Improving food safety standards and ensuring their effective implementation through a regulatory framework are paramount to address the issue of lead-contaminated spices.

consumer products. This process hinges on the identification of hazardous products during lead poisoning case investigations and systematic cataloguing of relevant data about these products. A similar approach can be adopted by other jurisdictions, which will improve the capacity to effectively address emerging and existing hazardous products.

Our findings had several limitations. The absence of product labeling introduced uncertainty into the data due to possible errors in reporting of spice names and origin. The spices in this study may not be representative of the spices available in the US marketplace, nor of the spices available in the countries mentioned here. They may represent worst-case scenarios since they were collected and tested as part of lead poisoning investigations. A small sample size for some spices purchased during store surveys was also a limitation in our comparison of lead concentrations between spices purchased abroad versus those purchased locally in the United States, although this difference holds for spice types with larger sample sizes, as well as across sample types overall. Despite the limitations, this study provides an informative snapshot of the various types of spices that have been found to contain elevated lead concentrations and were associated with lead-poisoned children and adults in NYC.

Our findings clearly suggest that users of spices purchased in Georgia, Bangladesh, Pakistan, Nepal, and Morocco may be at an increased risk for lead exposure. This is of concern, as previous studies have shown high bioaccessibility of lead from contaminated spices[15,26] and that chronic ingestion of such spices can lead to increased blood lead levels.[16] Although further evaluation of the association between spice ingestion and blood lead levels in children and adults is needed, our findings underscore the need to develop comprehensive intervention efforts that engage local, state, federal, and international governmental entities to implement stricter regulations, quality control, and enforcement of standards that safeguard the integrity of global food supplies.

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EXHIBIT F

AMERICAN SPICE TRADE ASSOCIATION

Presentation for New York State Department of Agriculture

Confidential – Business Information

ASTA Overview

1907: ASTA is formed to ensure that members had resources to comply with new regulations and work closely with regulatory agencies globally and federally

1906: Pure Food and Drug Act

2021: 200 members including growers, importers, processors, and users of spices. Members include large multi-national companies and small, locally owned businesses.

Spices & New York State Economy

26 companies

560 employees

>$550 million worth of spices imported annually through New York state ports

Essential for restaurants, bakeries, and retailers

ASTA's Mission & Vision

- ***ASTA shares New York State's mission of protecting public health***
- ***Existing limits for spices are protective***
- ***New limits pose significant feasibility concerns and will result in a ban of many spices***

Achievability Assessment: Determination of Proposed Class II Recall Action Levels

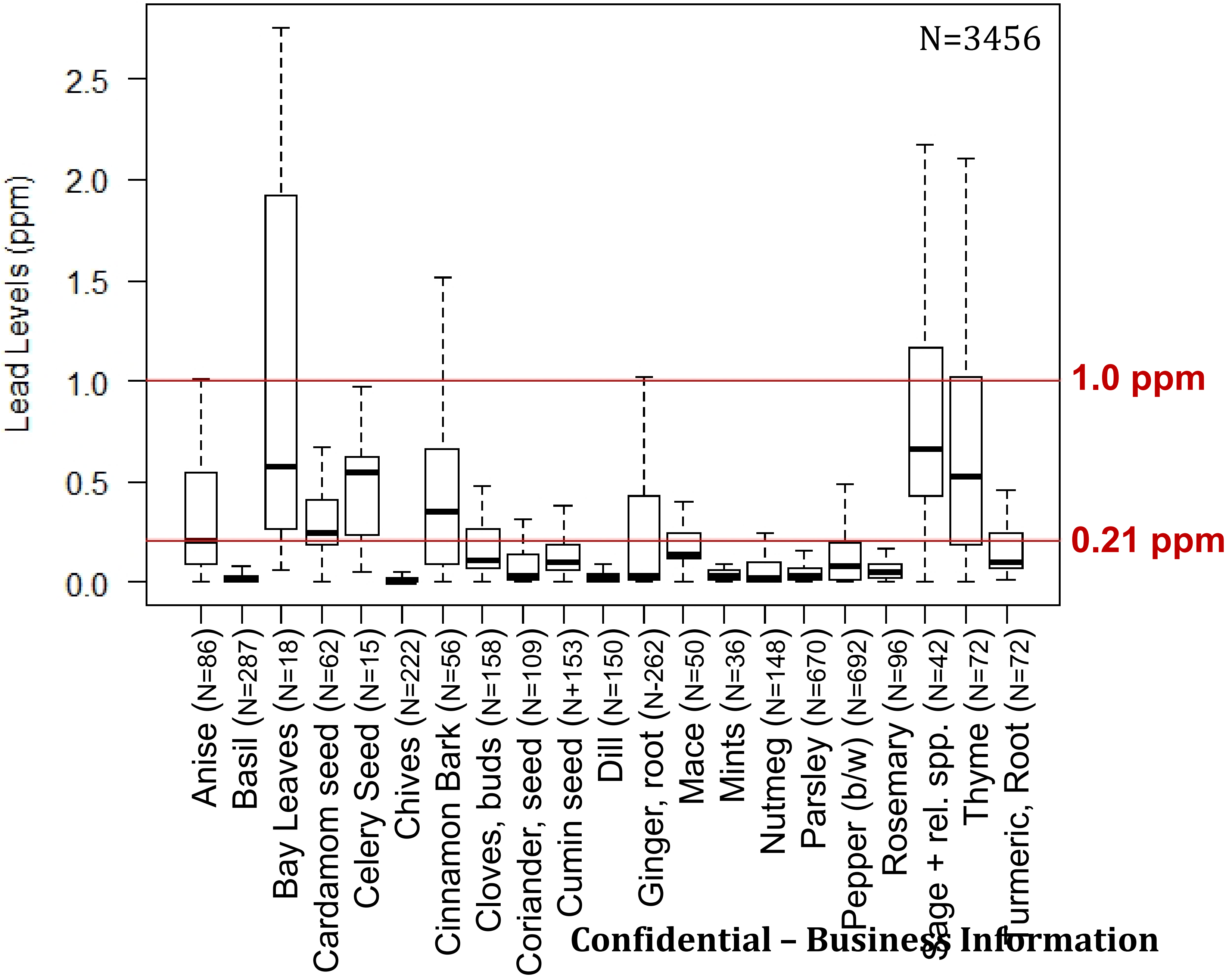
- Inorganic arsenic/Cadmium: 90th percentile of distribution of levels
- Lead: "Health-based guidance value"

Class II Recall Action Levels

Lead: Class II recall action level selected is based on the NYSDOH derivation of a noncancer health-based guidance value for Lead in spices used in food preparation. It is important to recognize that this assessment differs from other noncancer assessments because of the absence of a threshold for the effects of Lead on the developing central nervous system of children. While the health-based guidance value is based on health protective methods and assumptions, the absence of a threshold means that we cannot assume that exposure below the health-based guidance value is without risk as we would for other noncancer health-based guidance values. Due to absence of a threshold for the noncancer health effects of Lead, and the presence of many other potential sources of exposure to Lead (e.g. soil, indoor dust, water), it is prudent to reduce risks for Lead exposure through consumption of spices by adopting screening or action levels as low as achievable.

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

"as low as achievable"



Distribution of Lead Levels Among Spices (WHO GEMS, 2020)

3900+ data points available on 31 spices and herbs for 2020.

Figure represents the top 20 spices in the database for the US market.

Confidential – Business Information

Under the new class II action limits, cinnamon, ginger, and oregano will no longer be available

Spice	N	Average (ppm)	Median (ppm)	90th Percentile (ppm)	% >0.21 ppm	% >1.0 ppm
Cinnamon	3095	0.81	0.66	1.6	86%	28%
Ginger	441	0.76	0.68	1.3	95%	18%
Turmeric	550	0.29	0.17	0.67	44%	3%
Basil	34	0.27	0.20	0.62	47%	0%
Oregano	121	0.54	0.37	0.94	79%	9%

This data was anonymously consolidated and blinded from samples throughout the global spice supply chain, including raw materials and finished products.
Non-detects set to 1/2 LOD; if no LOD was provided, assumed an LOD of 0.005 ppm.

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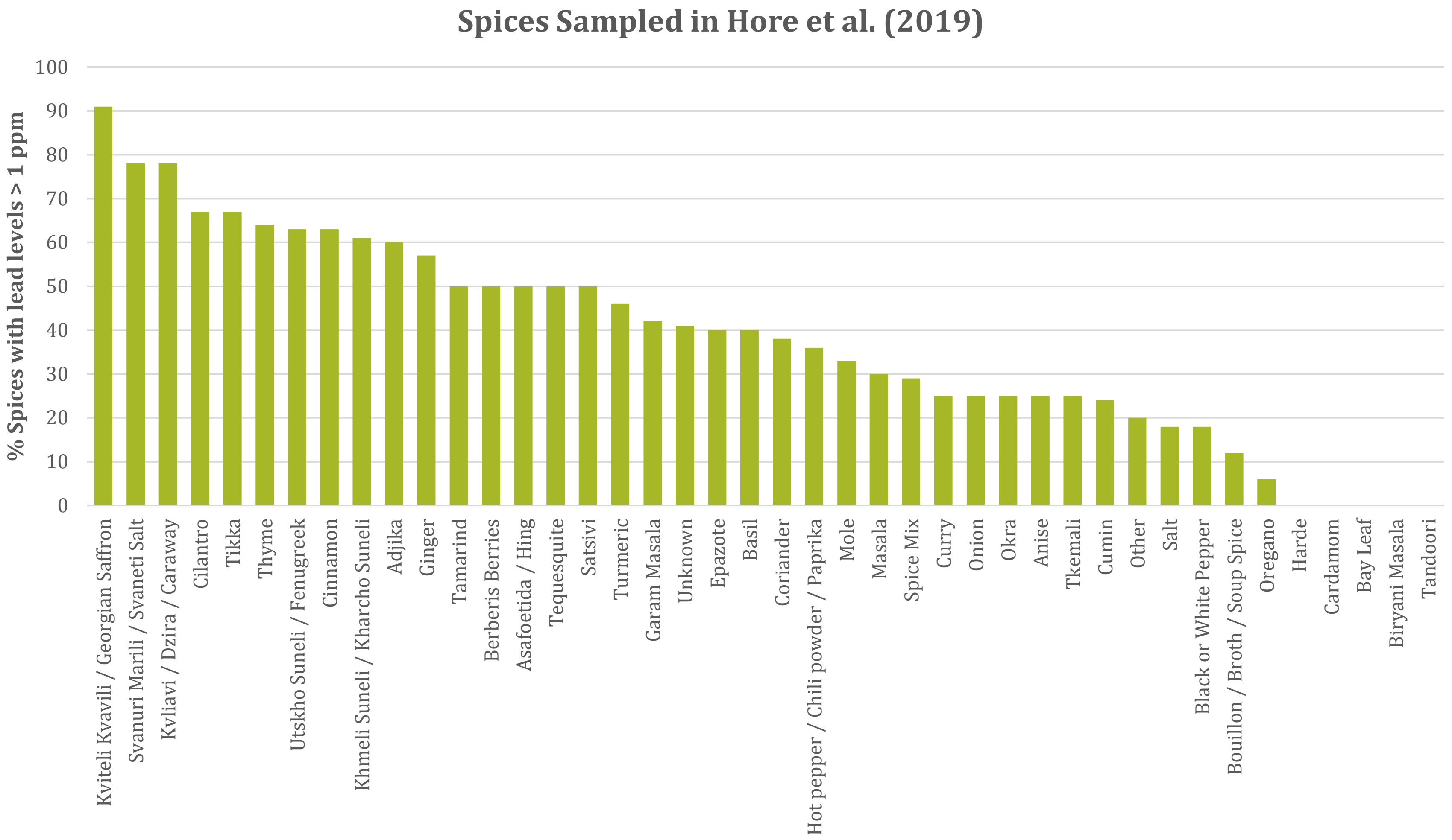
Consequences of Banning Spices in New York

- Spices are an important part of the American diet and ethnic cuisines
- According to the Dietary Guidelines for Americans, spices are healthful ingredients that promote healthy eating practices
    - "Spices and Herbs can help flavor foods when reducing added sugar, saturated fat, and sodium, and they also can add to the enjoyment of nutrient-dense foods, dishes, and meals that reflect specific cultures"
- Ban on spices would have downstream impacts on restaurants, bakeries, packaged foods, and retailers

Spice Industry Efforts to Reduce Heavy Metals

- **Farmer training on Good Agriculture Practices** – suppliers are trained in growing, harvesting, and storage techniques that are known to minimize heavy metal uptake from the environment.
- **Adherence to Good Manufacturing Practices** - Manufacturers use cleaning practices to minimize contributions from soil and the environment and adhere to practices to prevent the contribution of any heavy metals through processing.
- **Monitoring and Compliance -** Specifications and testing on heavy metals to ensure compliance with strict internal quality standards
- **Key Challenges –** Spices come from many different crops grown in developing nations with differing environmental risks based on region and botanical nature of the commodity (roots, bark, seeds, etc.)

New York City Publication Data

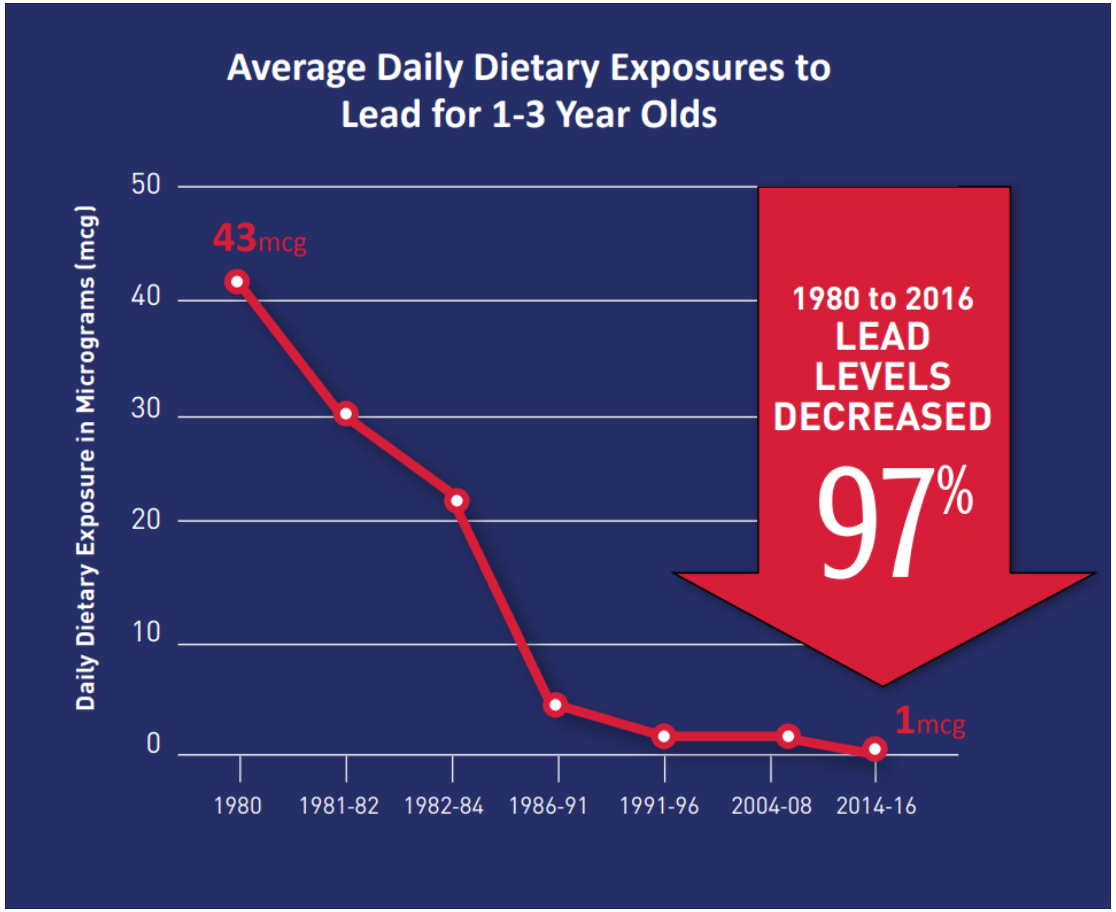


- Of the 50+ spice categories sampled (n=1496), 38% had lead concentrations above 1 ppm
- Highest concentrations of lead were found in Georgian saffron, of which 91% of samples exceed 1 ppm
- Only 21% of US spices exceeded 1 ppm compared to 66% of foreign samples

US and International Efforts to Reduce Dietary Exposure to Metals

- FDA, through the US delegate to the Codex Committee on Contaminants in Foods (CCCF), participates in international standard setting activities of the Codex Alimentarius Commission.
- Many health protective standards have been set for lead, arsenic, and cadmium in foods.
- FDA monitors levels of metals in foods, including foods intended for infants and toddlers, to inform policies it establishes in the form of regulations or guidance for industry
- FDA's Closer to Zero – An Action Plan for Baby Foods
- Codex has elaborated Codes of Practice to minimize levels of metals in foods

Lead exposure among children has declined significantly over last 40 years



Source: [Closer to Zero - Trends in Exposure to Toxic Elements from Foods for Babies and Young Children (Infographic) (fda.gov)]

Spice consumption (grams per day)

	Estimated daily consumption*			
	Per Capita		Per User	
	- - - - g/day - - - -			
Population subgroup	Mean	90th Percentile	Mean	90th Percentile
Children 1-6 y	0.02	0.05	0.05	0.15
Children 7-12 y	0.04	0.11	0.08	0.21
WCBA 14-49 y	0.06	0.13	0.16	0.46

*Two-day average consumption estimates based on NHANES 2005-10 and U.S. EPA's What We Eat in America – Food Commodity Intake Database, 2005-10 (WWEIA-FCID 2005-10) recipes
G: grams; WCBA: women of child bearing age; y: years

Spice consumption as % of total diet

		Per Capita Mean Consumption Estimates*	
Population subgroup	**Diet component**	**- - - - g/day - - - -**	**g/kg-bw/day**
Children 1-6 y	Total diet	1674	103
Children 7-12 y	Total diet	2037	56
WCBA 14-49 y	Total diet	2963	42
Children 1-6 y	All spices	0.02	0.001
Children 7-12 y	All spices	0.04	0.001
WCBA 14-49 y	All spices	0.06	0.001
Children 1-6 y	% spices of total diet	0.001%	0.001%
Children 7-12 y	% spices of total diet	0.002%	0.002%
WCBA 14-49 y	% spices of total diet	0.002%	0.002%

*Two-day average total diet consumption estimates based NHANES 2005-2010; spice consumption based on U.S. EPA's WWIEA-FCID 2005-10 recipes.

G: grams; kg-bw: kilogram bodyweight; WCBA: women of child bearing age; y: years

Dietary lead exposure among children

- Fruits, grains, and dairy products are top contributors to total dietary lead exposure among children
  - Grains: 27.5%
  - Fruits: 24.7%
  - Dairy: 16.8%
- Based on 2005-2010 WWEIA FCID, individual spices with 1 ppm lead would contribute <0. 1% to total dietary lead exposure among children 1-6 years of age as estimated by Spungen (2019)

Food Additives & Contaminants: Part A

Taylor & Francis

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Children's exposures to lead and cadmium: FDA total diet study 2014-16

Judith H Spungen

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Table 4. Total diet study food group intakes and contributions to lead and cadmium exposures, children 1–6 years.

	Food Intake*	Dietary Lead Exposure[a]		Dietary Cadmium Exposure[a]	
Food Group	g/day	µg/day	% total	µg/day	% total
Baby Food	18	0.02	1.6	0.03	0.5
Beverages	299	<0.01	0.3	0	0
Dairy	428	0.19	16.8	0.16	2.4
Eggs	16	0	0	0	0
Fats/oils	2	0.01	0.8	0	0.1
Fruits	243	0.29	24.7	0.2	3
Grains	131	0.32	27.5	2.1	31.8
Legumes, nuts, seeds	11	0.02	1.8	0.42	6.4
Meat, poultry, fish	66	0.03	3	0.25	3.8
Mixtures	147	0.18	15.5	1.92	29.1
Sweets	17	0.04	3.5	0.08	1.2
Vegetables	66	0.05	4.7	1.44	21.8
Total	1444	1.2	100	6.6	100

[a]Data sources: Toxic element concentrations in foods: FDA Total Diet Study, 2014–16 (analysis method: inductively coupled plasma mass spectrometry, or ICPMS), arithmetic mean concentrations. Food consumption: What We Eat In America (WWEIA)/National Health and Nutrition Examination (NHANES) 2009–14. Estimated exposures do not include contributions from breast milk or from tap water, and are based on lower bound mean concentrations (values < limit of detection set to zero) in other foods.

Comparison of NYS spice level versus other regulatory levels

Population	Diet source	Regulatory Limit	Regulatory/Action Level (ppm)	Per User Mean Consumption Estimates	Estimated exposure to lead from diet source at regulatory/action level	% of exposure from bottled water	% of exposure from drinking water
			- - - - ppm - - - -	- - - - g/day - - - -	- - - -µg Pb/day - - -		
Children 1-6 y	Bottled water	FDA Water Quality Standard	0.005	328	1.6	--	--
Children 7-12 y	Bottled water	FDA Water Quality Standard	0.005	479	2.4	--	--
WCBA 14-49 y	Bottled water	FDA Water Quality Standard	0.005	984	4.9	--	--
Children 1-6 y	Drinking water	NYS Drinking water standard	0.015	1000	15	--	--
Children 7-12 y	Drinking water	NYS Drinking water standard	0.015	1000	15	--	--
WCBA 14-49 y	Drinking water	NYS Drinking water standard	0.015	2000	30	--	--
Children 1-6 y	All spices (FCID)	Current NYS Class II Recall Level	1	0.05	0.1	3.1%	0.3%
Children 7-12 y	All spices (FCID)	Current NYS Class II Recall Level	1	0.08	0.1	3.5%	0.6%
WCBA 14-49 y	All spices (FCID)	Current NYS Class II Recall Level	1	0.16	0.2	3.2%	0.5%
Children 1-6 y	All spices (FCID)	Proposed NYS Class II Recall Level	0.21	0.05	0.01	0.65%	0.07%
Children 7-12 y	All spices (FCID)	Proposed NYS Class II Recall Level	0.21	0.08	0.02	0.74%	0.12%
WCBA 14-49 y	All spices (FCID)	Proposed NYS Class II Recall Level	0.21	0.16	0.03	0.67%	0.11%

*Two-day average bottled water consumption estimates based on NHANES 2005-2010; drinking water estimates based on default daily estimates used by the US EPA; spice consumption based on U.S. EPA's WWIEA-FCID 2005-10 recipes.

ppm: parts per million; µg: micrograms; WCBA: women of child bearing age; y: years

Proposed EU Commission Levels (2021)

Category	Level (mg/kg)
Fruit spices	0.6
Root and rhizome spices	1.5
Bark spices	2
Bud spices and flower pistal spices	1
Seed spices	0.9

Proposed Codex Levels (2021)

Category	Level (mg/kg)
Culinary herbs (dried leaves or mixed herbs)	2
Dried bulbs, rhizomes, root spices	2
Bark	2
Dried fruits and berries spices	0.6
Dried seeds spices	0.6
Dried floral parts spices	0.7

International Levels (2021)

Country	Category	Level
Vietnam	Spices; curry powder	2 mg/kg
Hong Kong	All food in solid form	6 ppm
India	Dried herbs and spices	10 ppm
Malaysia	Spices; curry powder	2 ppm
Singapore	Dried herbs and spices (including mustard); curry powder	2 ppm
China	Spices	2 mg/kg
Taiwan	Herbs and spices (fresh)	0.3 mg/kg

Safety of spice consumption

- FDA evaluates food product compliance against the IRL and is unlikely to take regulatory action against spices containing < 1ppm lead
- Estimated daily exposure to lead at current Class II recall level of 1 ppm is << FDA's IRL

Population subgroup	Per user estimated exposure to lead from spice consumption* at 1 ppm Class II Recall (µg/day) Mean	90th Percentile	% of FDA IRL** Mean	90th Percentile
Children 1-6 y	0.05	0.15	2%	5%
Children 7-12 y	0.08	0.21	3%	7%
WCBA 14-49 y	0.16	0.46	1%	4%

*Two-day average consumption estimates based on U.S. EPA's What We Eat in America - Food Commodity Intake Database, 2005-2010 (WWEIA-FCID 2005-10) recipes.
**FDA IRL is currently 3 µg/day for children and 12.5 µg/day for adults (including WCBA).
µg: micrograms; WCBA: women of child bearing age; y: years

Safety of spice consumption

- Change in BLL associated with lead exposure from spice consumption is small and well below the CDC reference level of 5 µg/dL
- Well below 1 µg/dL increase in BLL associated in some evaluations with a 1 IQ point decrease

Population subgroup	Per user estimated exposure to lead from spice consumption* at 1 ppm Class II Recall (µg/day)		Change in Blood Lead Level** associated with lead exposure from spice consumption at 1 ppm Class II Recall Level (µg/dL)	
	Mean	90th Percentile	Mean	90th Percentile
Children 1-6 y	0.05	0.15	0.008	0.023
Children 7-12 y	0.08	0.21	0.013	0.034
WCBA 14-49 y	0.16	0.46	0.006	0.018

*Two-day average consumption estimates based on U.S. EPA's What We Eat in America - Food Commodity Intake Database, 2005-2010 (WWEIA-FCID 2005-10) recipes.
**Calculated assuming a dietary conversion factor of 0.16 µg/dL and 0.04 µg/dL per 1 µg lead/day for young children and adults, respectively (Flannery et al 2020).
µg: micrograms; WCBA: women of child bearing age; y: years

In Conclusion

- New action limit on lead in spice is industry's most significant concern
  - Still evaluating impact of cadmium and arsenic
- New York State's existing limit of 1ppm is already protective of vulnerable populations
  - At 1ppm, spices contribute <0.1% of dietary lead exposure
  - Spice consumption at 1ppm does not elevate BLL enough to result in 1 IQ point drop
- Other foods such as grains and dairy are much greater contributors to dietary lead exposure – limits on these commodities would be more protective of children
  - To meaningfully reduce exposure, NY State will need to set limits on dairy, fruit, grains, drinking water, and baby food
- Many popular spices will no longer be available under the new action limits
  - Industry cannot continue to drive levels lower given sourcing and growing realities
- ASTA supports policies that target lead-containing dyes in spices and stands ready to work with New York State on policies that are protective and achievable

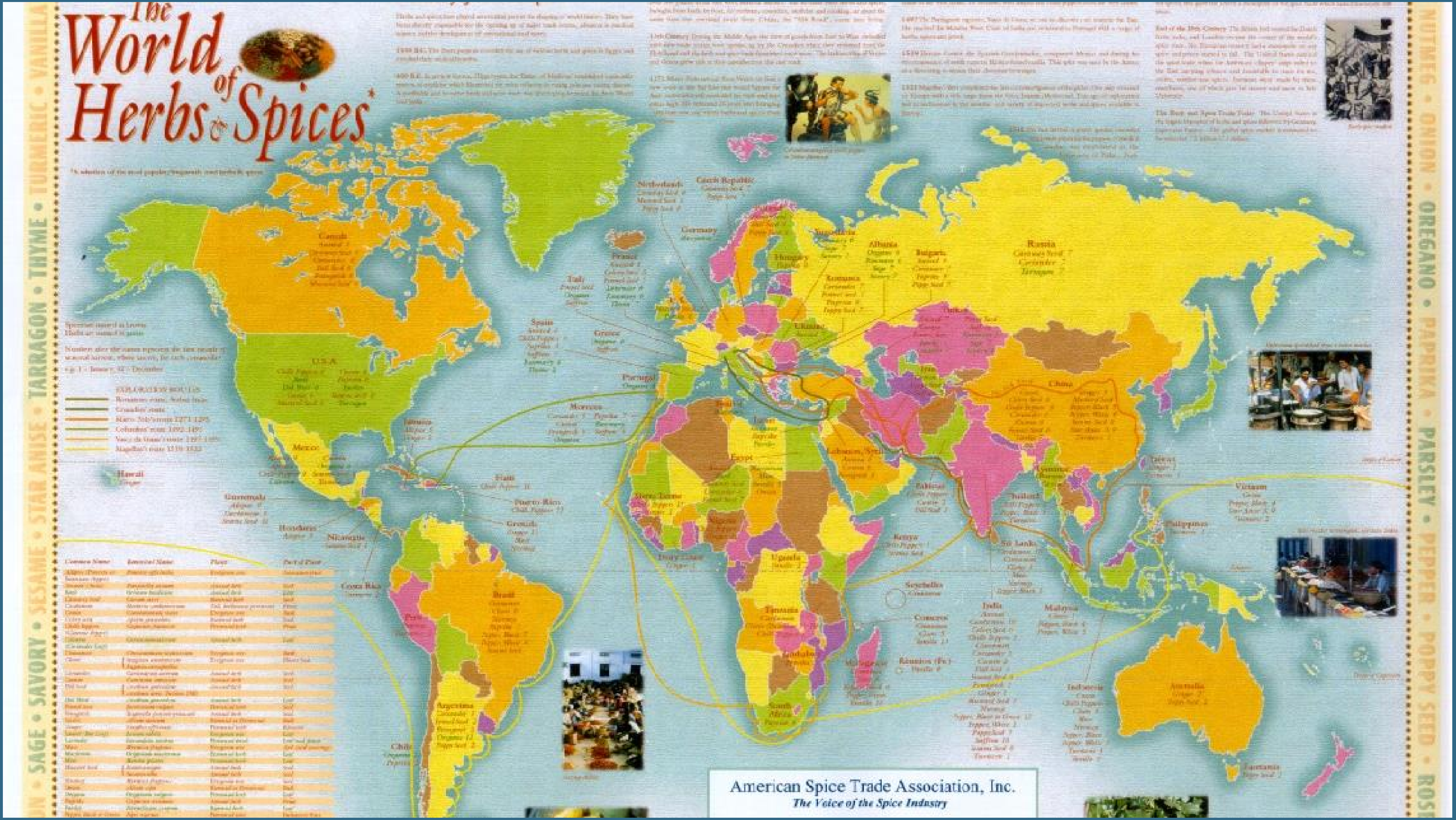
ADDITIONAL/BACKGROUND SLIDES

Sources of Lead in Spices

Characteristics	Intentional Economically Motivated Adulteration	Lead from Environmental Contamination
Source	Lead in the form of lead chromate is used to enhance color or increase weight	Spices can uptake lead from their environment through soil, water, and air
Concentration in Spices	Significantly higher levels (50ppm - 12,000 ppm)	Typically low levels <1 ppm
Stage of Lead Introduction	Can occur at any stage of the supply chain, but most typically during grinding processing	Occurs during the growing and harvesting stage
Driving Factors	Driven by global markets, political unrest, natural disasters	Driven by environmental pollution, fossil fuel emissions, and volcanic eruptions
Key Prevention Strategies	Vulnerability Assessments, Supplier Verification, Chain of Custody	GAPs, GMPs, Testing/Monitoring

New York State's Existing Recall Action Limits Are Protective Against Adulterated Products

- New York State initiated program to target high levels of lead in spices adulterated with lead-containing dyes/colorants
- Existing limit of 1.0 ppm is effective at targeting these products
  - Already resulted in >100 recalls of spice product in New York state
  - Industry has invested significantly in more reliable sourcing and monitoring practices to comply with this limit
- Levels <1ppm occur from unavoidable environmental exposure
  - Roots and bark naturally concentrate heavy metals from soil
  - Spice supply chains cannot be quickly changed to meet lower standards – many spices take years to grow. For example, cinnamon trees take 15 years to reach maturity


The World of Herbs & Spices*
VANILLA • TURMERIC • THYME • TARRAGON • STAR ANISE • SESAME • SAVORY • SAGE
NUTMEG • ONION • OREGANO • PAPRIKA • PARSLEY • PEPPER • POPPY SEED
Canada
U.S.A.
Mexico
Hawaii
Guatemala
Honduras
Jamaica
Haiti
Puerto Rico
Grenada
Costa Rica
Brazil
Peru
Argentina
Chile
Spain
Portugal
Greece
Morocco
Egypt
Kenya
Tanzania
Seychelles
Comoros
Madagascar
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Indonesia
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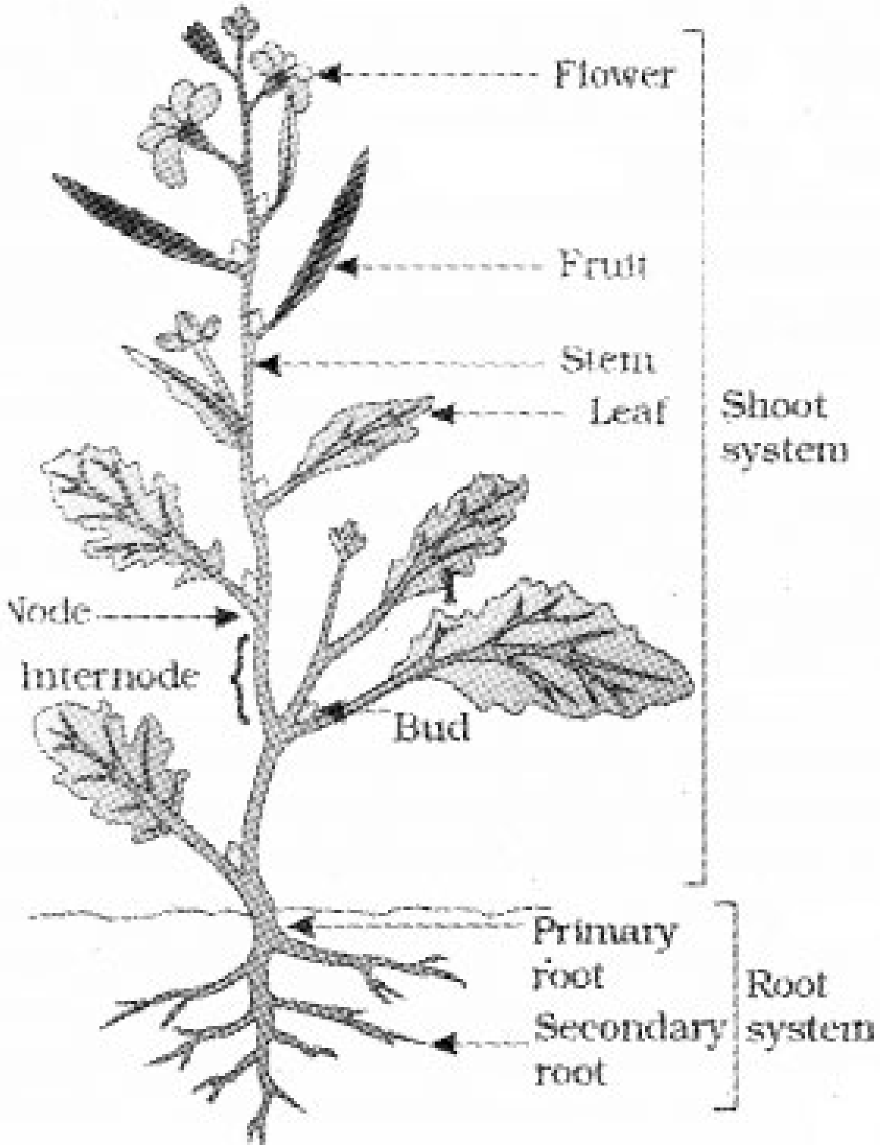
Tasmania
American Spice Trade Association, Inc.
The Voice of the Spice Industry



Spices are derived from many different species and come from various parts of the plant

Part of Plant	Spice
Ariel	Mace
Bark	Cinnamon
Berry	Allspice, juniper, pepper (black, white, green, pink)
Bud	Cloves
Flower	Chamomile, lavender
Fruit	Anise (star), capsicums, cardamom, paprika, vanilla
Leaf	Balm (lemon), Basil leaf (sweet), Bay leaves, chervil, chives, cilantro, dill weed, marjoram, oregano, parsley, peppermint, rosemary, sage, savory, spearmint, tarragon, thyme
Root	Galangal, ginger, horseradish, turmeric
Seed	Anise seed, caraway seed, celery seed, coriander, cumin seed, dill seed, fennel seed, fenugreek seed, mustard seed, nutmeg, poppy seed, sesame

Typical Spice Supply Chain

- Growing/Harvesting
- Drying/Storage
- Sold to local collectors
- Sold to larger collectors
- Trading
- Export/Import
- Processing
- Retailer
- Consumer

Small Remote Farms

Spice farms are typically very small (<10 hectares) with minor yields and farming practices are often very traditional with limited technology.

Multiple Points of Commingling

Spice companies need relatively large quantities for commercial purposes, at least several tons at a time, spices typically need to be consolidated from many farms – in some cases hundreds of farms. This process generally involves multiple points of comingling by various middlemen throughout the process.

Minimal Consumption

Spices are used for seasoning a wide variety of foods but are collectively consumed in very small quantities. According to the USDA's WWEIA database, Americans consume an average of <1 gram of herbs and spices per day.

Environmental Exposure – Sources of Naturally Occurring Lead

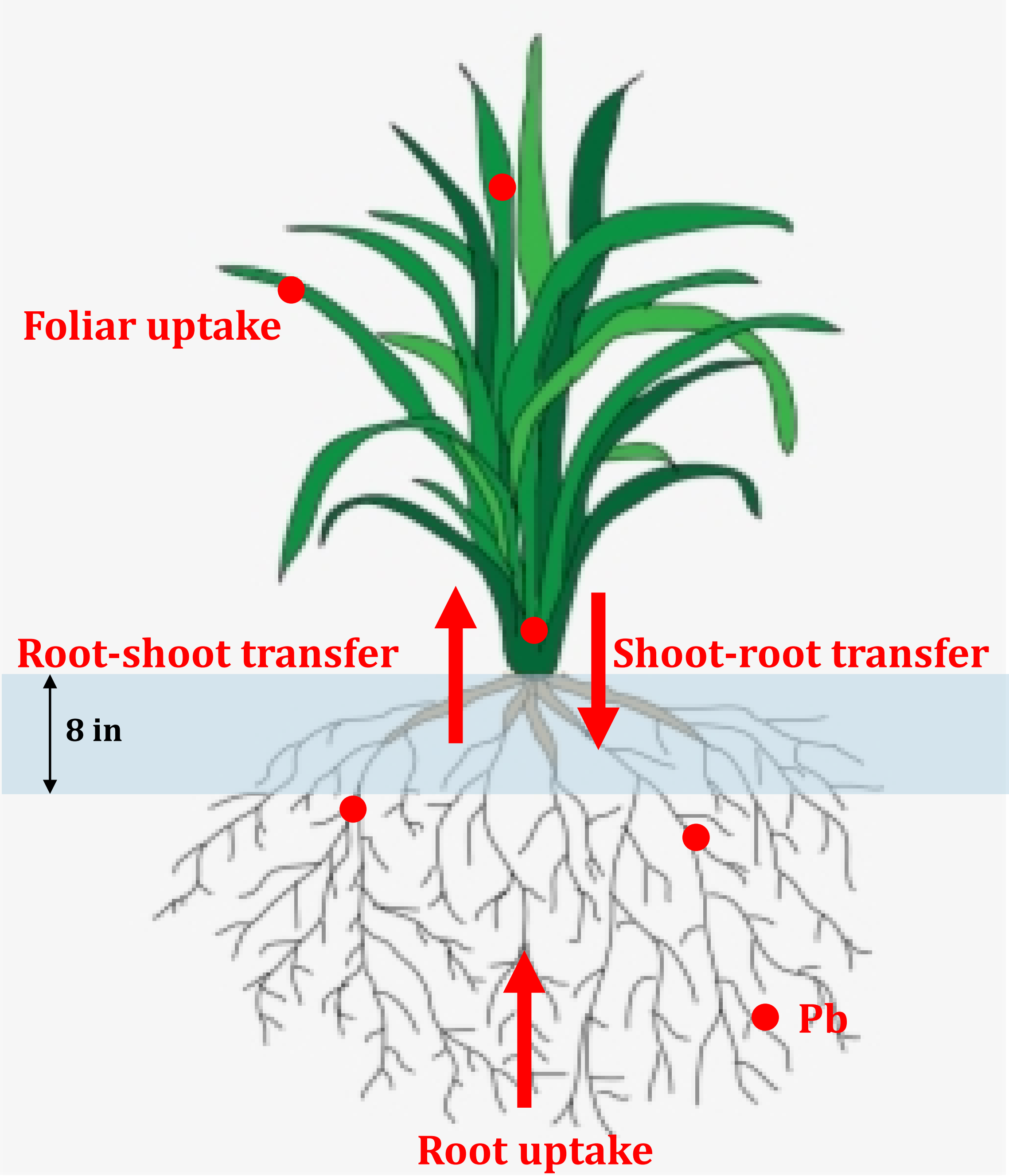
Lead is the most abundant heavy metal in the Earth's crust. Natural levels of lead in soil range from 50-400 ppm (EPA, 2021)

Volcanoes release about 1200 tons Pb/year (Patterson & Settle, 1986)

Industry releases ~300,000 tons of Pb/year (Patterson & Settle, 1986)

Lead may travel long distances in the air before being deposited onto soil

Lead can leech through soil and enter groundwater reservoirs

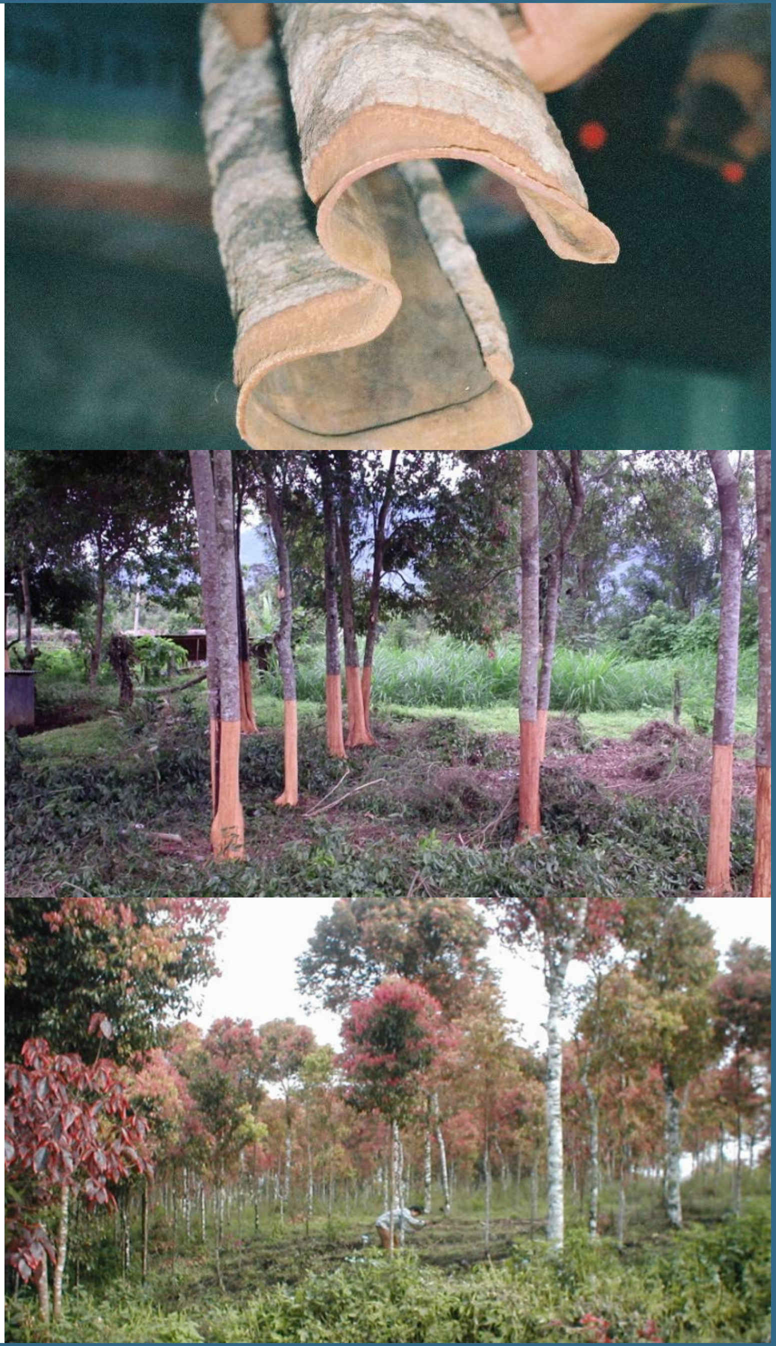


Lead Uptake by Spices

- Lead accumulated in the top 8 inches of soil (Tangahu et al., 2011)
- Plant roots uptake heavy metals from water and soil through rhizofiltration processes
- 95% of absorbed lead is accumulated in the roots (Pourrut et al., 2011)
- Evapotranspiration processes act as a pump translocate heavy metals from the roots to aerial plant parts (Tangahu et al., 2011)
- Factors that influence uptake: species, region, root zone, availability of the heavy metal

Cinnamon Case Study

- Cinnamon is derived from the bark of a tree from the evergreen family (genus *Cinnamonum*)
  - Two main varieties: Cassia and Ceylon Cinnamon
  - Different variators in different growing regions
- Cinnamon trees take at least 15 years to reach maturity
  - Cinnamon quality is based on the volatile oil content, which increases as trees age



Top Imports to U.S. are Indonesia and Vietnam

Cinnamoum

C. cassia/C. aromaticum

C. lourierii

C. zeylanicum /C. verum

C. burmannii

Korintji Cinnamon

85% of the crop comes from Sungaipenuh, the area around the active volcano Mt Korintji from which Indonesian cinnamon gets its name

usiness Information



Korintji Cinnamon Harvesting



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Lead Uptake by Cinnamon Bark

- Bark has the highest capacity for heavy metal sorption of any tree biomass component (Al-Asheh & Duvnjak, 1997; Shin et al., 2007; Boving et al., 2008)
- Lead has the highest binding affinity to bark because of its low hydration enthalpy (Sed et al., 2015)
- Bark is so efficient at heavy metal adsorption that there have been efforts to use it instead of activated carbon in remediation efforts of polluted sites (Sed et al., 2015)
- Factors affecting lead update by bark include pH, bark structure, and temperature. Warmer temperatures increase the adsorption rates of heavy metals into the bark.

AMERICAN SPICE TRADE ASSOCIATION asta