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

Maria L. Ishida[a,*], Virginia Greene[a], Thomas King[a], Jon Greenberg[b], John Luker[b], Debra Oglesby[a], Robert Sheridan[a], Jennifer Trodden[c]

[a]*New York Department of Agriculture and Markets, Division of Food Laboratory, Albany, NY*
[b]*New York Department of Agriculture and Markets, Division of Food Safety and Inspection, Albany, NY*
[c]*New York Department of Agriculture and Markets, Executive Office, Albany, NY*

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

*Corresponding author: Maria L. Ishida,
Email: Maria.Ishida@agriculture.ny.gov

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

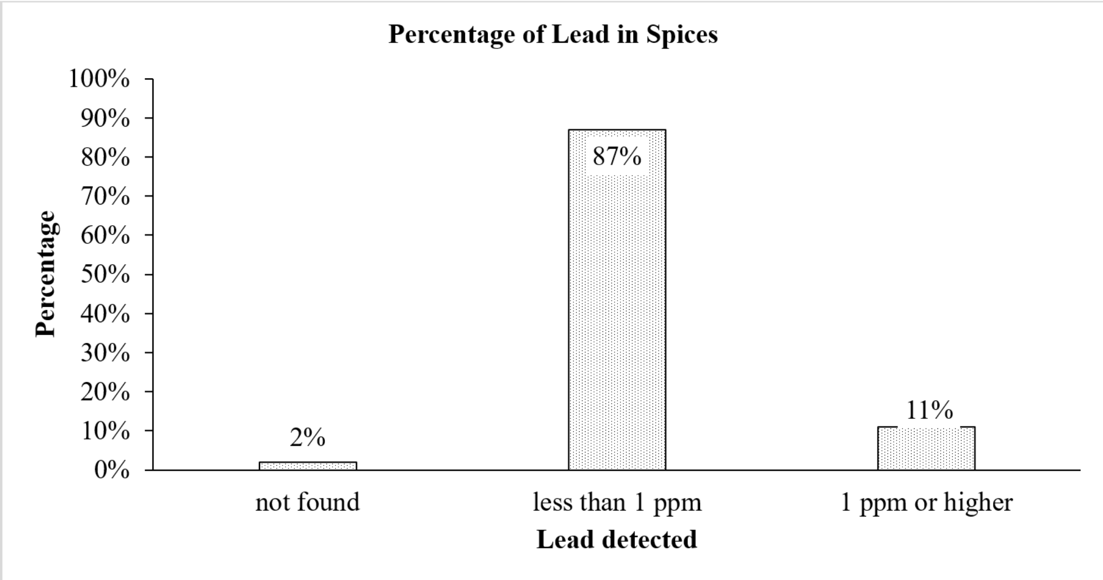

Figure 1: Percentage of lead (Pb) in spices found by the NYSAGM from 2014 to 2019 (n=1094).

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.

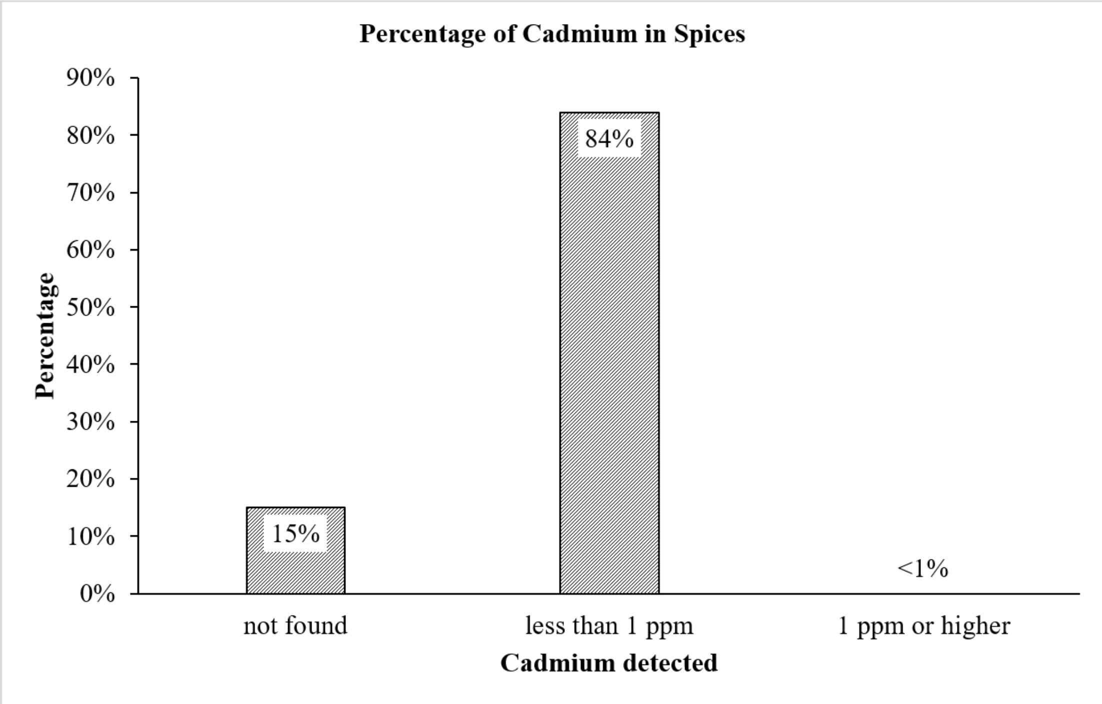

Figure 2: Percentage of cadmium (Cd) in spices detected by the NYSAGM from 2014 to 2019 (n=1041).

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

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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.

8. References

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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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