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

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Abbreviations: American Spice Trade Association (ASTA); Bureau of Toxic Substances Assessment (BTSA); BodyWeight (BW); Codex Alimentarius (Codex) Committee on Contaminants in Foods (CCCF); US Dietary Guidelines for Americans (DGA); U.S. Environmental Protection Agency (EPA); U.S. Food and Drug Administration (FDA); EPA's Food Commodity Intake Database (FCID); gram(g); kilogram (kg); milligram(mg); New York State Department of Agriculture and Markets (NYAGM); parts per million (ppm); parts per billion (ppb); World Health Organization's Global Environmental Monitoring System (WHOGEMS) ; What We Eat In America (WWEIA)

Introduction

The Journal of Regulatory Science recently published an article by Ishida et al. [15] titled "Regulatory policies for heavy metals in spices – a New York approach," which outlines a proposal for New York State (NYS) to reduce its Class II recall action levels for spices by nearly five-fold, from 1.0 part per million (ppm) to 0.21 ppm for lead and inorganic arsenic and 0.26 ppm for cadmium. The American Spice Trade Association (ASTA) and dietary exposure and regulatory experts from the scientific consulting firm Exponent have reviewed the scientific basis for the new action levels as presented in Ishida et al. [15]. This purpose of this letter is to provide a critique of the scientific approach adopted by the authors, which served as the basis for

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NYS's recommended lead limits for spices and herbs, and highlight critical considerations that the authors failed to address, both of which impact the conclusions reached by Ishida et al. [15].

As outlined in Ishida et al. [15], NYS established a Class II recall action level of 1 ppm for spices and herbs in 2016 based on "available academic and federal regulatory information related to heavy metals in food." Ishida et al. [15] state that the "primary objectives of this study were to determine whether NYS should update its state recall action levels for heavy metals in spices." The authors state this update would provide protection to consumers through the reduction of spices as a source of exposure to heavy metals. The authors fail to meet this main objective, since it is not apparent that Ishida et al. [15] evaluated 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. [15] 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 monitoring data recently released in the United States (U.S.) Food and Drug Administration's (FDA) Total Diet Study [8]. Therefore, to support the rationale that targeting spices would have a meaningful impact on reducing exposure to heavy metals, the authors should evaluate and present the relative contribution of spice consumption to total dietary lead exposures. The relative contribution of spices to overall lead exposure was not quantified, nor was the relative impact of the proposed new recall action levels on reducing lead exposure.

Ishida et al.'s [15] proposed revisions to Class II recall action levels is limited to spices, and definitively states that any level should be set "as low as achievable." However, while achievability was the basis for the proposed cadmium and inorganic arsenic action levels, it is not clear if an achievability assessment was completed to inform the setting of the proposed action level for lead. Absent an exposure assessment, a focus on the ability of the regulated industry to meet the proposed levels would be appropriate, as was done for arsenic and cadmium.

Through this letter, we aim to present our critique of the assessment conducted by Ishida et al. [15] and discuss the impact this proposed policy would have on industry's ability to meet the proposed New York State limit. The discussion presented herein are the opinions of the authors.

Background on heavy metals in spices and herbs

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 [2]. Heavy metal content in spices varies based on how the plant takes up and stores substances from the soil and from which part of the plant the spice is derived. Roots and bark naturally concentrate heavy metals from soils, resulting in higher metal levels than spices derived from other parts of the plant. 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 [16].

The variability in background heavy metal levels of spices is noted in the publicly available data and published literature [10, 24]. 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 Codex Committee on Contaminants in Foods (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 calculated background levels for spices for the following 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. [10, 24]

Table 1 shows the natural heterogeneity of environmental background lead levels found in spices based on plant parts. Based on Codex Alimentarius 2022, Table B1 [11].

Table 1. Summary of background levels of lead in spices [11]

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

It is unclear whether Ishida et al. [15] recognized or considered the inherent background variability in lead levels in herbs and spices when establishing the action levels. Ishida et al. [15] states that background levels were calculated to "understand what levels of specific heavy metals the spice industry could achieve (data not shown)"; however, it is unclear if that assessment took into account the natural variability of background levels of heavy metals between different types of spices. Ishida et al. [15] does not provide any discussion of this variability, nor were data presented on lead levels by spice type. The results of the analysis conducted by Ishida et al. [15] is limited to the observation that in most cases, lead levels in spices were below 1 ppm (89% of samples). The failure to consider the inherent variability of lead levels across different spices from different origins will result in a *de facto* ban of spices with higher natural background levels of lead (e.g., spices derived from roots, bark, etc.).

Exposure Assessment

An exposure-based dietary risk assessment should consider the levels of a contaminant observed in the food, as well as the pattern of consumption. Based on the data presented in Ishida et al. [15][2], total spice intake represents approximately 0.1% of total food intake among children. This calls into question the overall exposure impact should proposed new action levels be implemented in New York State. Given that Ishida et al. [15] use a safety benchmark for lead as the basis of their level-setting process, it is reasonable to expect the presentation of an exposure assessment. Furthermore, there are a number of flaws with the approach to the derivation of the

[2] Per 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 in [20]; and the total spice intake estimated by Ishida et al. of 114.0 mg/kg bw/day (see Supplemental Material in [15])

lead action level presented by Ishida et al. [15]. A brief discussion of key considerations and flaws with the methodology used to derive the lead action follows.

Derivation of the health-based guidance value

Ishida et al. [15] derived a health-based guidance value for lead based on an equation that includes two key data inputs developed by NYS's Bureau of Toxic Substances Assessment (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 led health-based guidance value serves as the basis for the reduced Class II recall action level. This approach to establishing the health-based guidance value by the authors is atypical as it embeds an existing reference dose into an equation that also includes the consumption rate and relative contribution factor. This approach is aligned with establishing a concentration limit rather than a health-based guidance value. Furthermore, this approach is not consistent with guidance published by the WHO on how to derive health-based guidance values for the risk assessment of chemicals in food[3] [23].

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. In the analysis conducted by Ishida et al. [15], 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

[3] Per the recommendation of WHO, health-based guidance values (HBGVs) are derived from either the NOAELs or BMDs (BMDLs), often called the point of departure (POD) or reference point, from animal toxicity studies, and are derived as: HBGV = POD/ UFs where UF is the uncertainty factor, a term often used synonymously with safety factor.

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 critical.

Factors that impact spice consumption include the frequency, level, and duration of consumption, as well as the commodities that are considered spices. When using food consumption surveys, risk assessors need to be aware that they are limited to short-term consumption and do not capture intra-individual variability that will affect long-term averages. Additionally, dietary patterns may change over time (e.g., an individual may consume different ethnic foods as they grow up) and, therefore, there is a lot of uncertainty in estimates of heavy metal exposure via the dietary route. However, this uncertainty is not considered by the study authors.

The methodology relied upon by Ishida et al. [15] to estimate total spice consumption is flawed and does not follow standard approaches used by U.S. regulatory authorities – including the FDA and U.S. Environmental Protection Agency (EPA) – to estimate cumulative (i.e., total) intake of a commodity group such as spices. 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, Ishida et al. [15] 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, Ishida et al. [15] is assuming that each child consumes all eight commodities every day. An alternate approach would be to use the same consumption database Ishida et al. [15] rely upon to estimate the *cumulative* spice intake, 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[4] and would result in a health-based value of 1.2 ppm versus 0.21 ppm (See Example #1, Table 2).

Ishida et al. [15] also state 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. Instead, 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 [6] 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 [15] 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 empirically or anecdotally. Published studies,

[4] https://fcid.foodrisk.org/percentiles

instead, support the fact that consumption of individual spices does not occur every day, but rather is episodic [3, 5, 14, 17].

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. [15] and BTSA is based on consumption data from surveys conducted in 2005-2010 [4]. 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.

Spice selection and grouping

Ishida et al. [15] 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 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 [4].

While Ishida et al. [15] states that they relied on FDA's definition of spices (21 C.F.R. § 101.22)[5] to select spices for inclusion in the BTSA assessment [4] "pepper, bell" is not included

[5] 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.

in the list of spices in this definition. Further, FDA's Compliance Guide 525.750 states "sesame seeds…are not considered to be spices" [22]. 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 proposed new guidance value of 0.21 ppm (See Example #2 Table 2). This example illustrates the impact the selection of spices has on the calculation of the health-based guidance value. Including or excluding spices – or in the case of Ishida et al. [15], including commodities that are *not* spices – will ultimately impact the action level. 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 [15] assessment [21] included the following:

- "Herbs and Spices" FCID category, which covers 22 spices and herbs
- 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." Based on food availability data from the U.S. Department of Agriculture's Economic Research Service, the majority of spices in the U.S. food supply are imported.[6] Furthermore, while Ishida et al. [15] assigned an "imported" status to products that had countries

[6] Source: Calculated by ERS/USDA based on data from various sources [19]. Data last updated Feb. 1, 2017.

of origin clearly labeled on the packaging, this approach may not accurately capture all spices that are grown overseas. What is not considered is that many imported spices are exempt from the country-of-origin labeling requirements[7]. Therefore, Ishida et al. [15]'s reported distribution of samples (337 domestic, 455 imported, 302 unspecified origin) may not reflect products that are grown overseas and may legally be labeled as a product of the U.S. (additional concerns with regards to representative of the sampling database are provided below).

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. 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 reported to be 0.10 mg/kg bw/day based on the WWEIA/FCID 2005-2010 database [20]. 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 2).

A summary of the examples cited and the impact on the health-based guidance value for lead is provided in Table 2.

[7] 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).

Table 2. 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. [20]

Example #2: consumption rate based on reported spice intake excluding sesame seeds as reported in [4]; 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. [20]

*Calculated using the following formula [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) [4].

Key concerns and outstanding questions regarding achievability

Inconsistency between consideration of achievability for lead versus cadmium and inorganic arsenic

While Ishida et al. [15] based its new proposed recall action limits for cadmium and inorganic arsenic on the estimated 90th percentile of achievability and state the lead levels should be “as low as achievable,” achievability was not a component of the scientific basis for the proposed lead level ([15]; Table 3). The cadmium and inorganic arsenic levels follow the recommendation made by BTSA within the NYS Department of Health for the derivation of health-based guidance values for heavy metals in spices that “[New York State Department of Agriculture and Markets] rely upon the distribution of background metal levels in spices that NYAGM has compiled and that might be available from other sources.” [4; see also supplemental material in 6]. 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 proposed new Class II recall action level of 0.21 ppm. While Ishida et al. [15] 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 16 and 4], the recommendation does not appear to have been included in the setting of the proposed new recall action level for lead in spices.

Thresholds for achievability

Based on the limited information provided in Ishida et al. [15], it appears that 1,094 samples of spices were analyzed for lead (Figure 1 in [15]). Ishida et al. [15] 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. [15], this threshold for achievability (i.e., ~50%) is inconsistent with standard regulatory practices. For example, Codex's "As Low as Reasonably Achievable" standard is set at meeting a 95% global compliance rate for the commodity under evaluation. Likewise, the European Union and the FDA have set action levels for spices and/or other commodities at similar levels of achievability. While the 90th percentile achievability approach leveraged for arsenic and cadmium would be more consistent with the approaches undertaken by other regulatory jurisdictions, this 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 fact, 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 [9]. Further, while FDA considered setting a single action level for all juices, it decided to set multiple action limits for different types of juices based on the variability in the background levels and differences in consumption patterns. This framework can be directly applied to spices.

In instances where FDA has established action levels that correspond to achievability rates of less than 95%, ASTA understands that 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 its 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 Good Manufacturing Practices and selective sources, it would be possible to achieve these levels.

Ishida et al.'s [15] 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.

Design and Representativeness of Sampling methodology

Under its commodity-based targeted sampling program, Ishida et al. [15] collected samples from the NYS market. Results from a commodity-based targeted sampling program were used to establish a baseline on the range of heavy metals 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 proposed reduced Class II recall action levels. Sampling from a wide array of spices and herbs from multiple origins is needed to ensure that the data are representative.

Spices purchased in U.S. versus international markets

It appears that Ishida et al. [15] does not draw the appropriate distinction between spices purchased outside of the U.S. directly by consumers and spices grown outside of the U.S. that are subsequently imported for sale. Despite the assertion by the authors that imported spices are at an increased risk of heavy metal contamination, no data are presented detailing the distribution of heavy metals in spices based on origin. Instead, the authors reference a paper by [13] 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 [13] 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 supported by studies that showed that turmeric sold in local

Bangladeshi markets had higher lead levels – due to adulteration with lead chromate – than product exported to foreign markets [12] and that purchasing spices in the U.S. may lower consumer lead poisoning risk compared to purchasing spices abroad [1]. Therefore, these studies show that spices 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 [13].

This reality also raises the potential concern that if certain spices become unavailable in NYS due to the inability to achieve these proposed new standards, 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. [15].

Consideration of the public health impact of lowering recall action levels

Beyond the risk noted above of the potential for consumers to purchase spices overseas with higher heavy metal content, there are additional public health considerations that may result from the proposal to lower NYS's action levels. 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 [18] The DGA also recommends the use of spices and herbs to "add to the enjoyment of nutrient-dense foods, dishes, and meals" [18]. A *de facto* ban on certain spices may inadvertently alter people's dietary patterns to move away from healthy food options. As stated in FDA's Closer to Zero Action Plan [7]:

> "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."

Ishida et al. [15] did not consider these potential unintended public health consequences of the proposed new action limits.

Conclusion

While Ishida et al. [15] based its proposed recall action levels for cadmium and arsenic in spices on a 90th percentile of achievability, it does not appear that achievability was considered for the proposed lead level. Publicly available data demonstrates that levels of heavy metals in spices vary significantly by spice type and that the proposed new recall action level for lead is not achievable. The implementation of the proposed level for lead would have an immediate and significant negative impact on the spice industry due to the realities of supply chains and other business planning considerations. As one brief example, a cinnamon tree requires 10 to 15 years to reach maturation and, therefore, spice supply chains cannot be quickly altered to meet the proposed level within the proposed time frame, even if it was feasible to do so.

Moreover, it is undeterminable whether the proposed new levels would meaningfully reduce heavy metals in the diet of New Yorkers since Ishida et al. [15] did not present an analysis on the current contribution of spices to total dietary lead exposure or the impact on reducing exposure among children. Given the significant flaws in the health-based guidance value presented in Ishida et al. [15] and the lack of an achievability assessment, the proposed recall action levels are not scientifically justified.

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