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BY EMAIL SUBMISSION

February 23, 2023

Jennifer C. Trodden MS, CSP
Deputy Commissioner
NYS Department of Agriculture and Markets
10B Airline Drive
Albany, NY 12235

Re: Response to New York State Input and Feedback Request on the Proposed Recall Action Level for Lead in Spices

Dear Deputy Commissioner Trodden,

Thank you very much for the opportunity to submit this response to the Department of Agriculture and Markets (AGM) on the Input and Feedback Request regarding the proposed recall action level for lead in spices. Also, thank you for the 90-day deadline extension of the due date for our response. We appreciate the additional time to prepare and submit our comments.

The American Spice Trade Association (ASTA) represents the United States' spice industry in the global market. The highest priority of ASTA and our nearly 200 members is ensuring the supply of pure, safe spice to American consumers. Further, ASTA promotes the value of spices in health, culture, and the economy.

Spices are a flavorful part of a healthy diet, and there is a growing body of research on the potential for certain spices to improve health. Spices are also an integral part of the broader food and agricultural sector, which accounts for about one-fifth of the U.S. economy, supporting jobs and economic growth in both the developing and developed world through farming and trade. ASTA ensures spices remain integral within the American market to preserve meaningful cuisine and cultural experiences for all.

We appreciate the opportunity to address the following feedback requests **(set in bold)** sought by AGM.

- **"We encourage businesses that have data to support that the proposed action level for lead is not achievable to send such data, with proprietary information removed, together with the associated detailed laboratory analyses, to AGM for review and consideration."**

While the industry appreciates the opportunity to provide information to help inform AGM's proposed action level for lead, unfortunately any data collected by the businesses who were invited to provide data on this submission (retailer, spice manufacturer, or spice distributor) regarding achievability of the action level is inherently proprietary – i.e., the information is necessarily specific to each company, such

that it is impossible to remove proprietary information. As such, AGM should not expect to obtain any data in response to this request.

Instead, the industry recommends that New York State leverage publicly available data, such as the data available from the European Food Safety Authority (EFSA), the World Health Organization Global Environmental Monitoring (WHO GEMs) database, and the published scientific literature.

Although company-specific data is likely not feasible to obtain, ASTA is committed to providing helpful, available information to AGM. With that goal in mind, ASTA is providing a summary of background levels of lead in spices in Table 1 below. ASTA conducted a search of the scientific literature to identify studies that investigated and reported on the level of lead in spices available on the U.S. market and within the European Union (EU). The search focused on those studies that collected spice samples through a market-basket or store-based survey design to represent spices available for purchase in both the U.S. market as well as in EU markets. Studies or data within studies that focused on spice samples suspected of adulteration or implicated in lead poisoning and/or those that were purchased abroad and brought into the U.S. were excluded, as these studies would likely report artificially high levels due to lead-based dyes versus environmental background levels. In addition, a summary of the background lead levels in spices as summarized by the Codex Committee on Contaminants in Foods (CCCF) and the EFSA are included in this table.

Table 1. Summary of background levels of lead in dried spices as measured and reported in publicly available literature and references

			Lead level in spices			
Citation	**Sample description**	**Spice name**	**Number of samples**	**Mean (mg/kg)**	**90th percentile (mg/kg)**	**Maximum (mg/kg)**
Angelon-Gaetz et al 2023	Market basket survey of 50 spices from 9 grocery stores in/near Raleigh, NC	Asafoetida	2	0.18		0.29
		Chili powder/red pepper	6	0.15		0.31
		Cinnamon	5	0.07		0.07
		Turmeric	13	0.12		0.28
		Whole chili peppers	4	0.07		0.07
Hore et al 2019	Spices purchased in the US (result of case investigations for lead poisoning)	All spices (store survey)	102	1.0 (GM)	4.0	21
		Turmeric	28	1.0 (GM)	4.2	6.7
		Hot pepper, chili powder, paprika	24	0.4 (GM)	0.6	1.0
Lin et al 2010	Market basket survey in/around Boston. Spices sampled include: garlic powder,	All spices	38	2.6		7.6
		US brand spices	10	0.19 (95%CI: 0.1-0.28)		0.41

			Lead level in spices			
Citation	**Sample description**	**Spice name**	**Number of samples**	**Mean (mg/kg)**	**90th percentile (mg/kg)**	**Maximum (mg/kg)**
	black pepper, fennel powder, fenugreek, ginger powder, coriander, garam masala, turmeric, chili powder, paprika, and cardamom	Indian brands spices	10	0.45 (95%CI: 0.17-0.73)		1.54
Codex Alimentarius 2022	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	Culinary herbs (dried)	1,012	0.5	1.65*	
		Aril spices	15	0.26	0.70*	
		Floral parts (flower, stigma, bud)	59	0.34	1.14*	
		Fruits and berries	2,546	0.23	0.57*	
		Rhizomes, bulbs and root	550	2.04	1.92*	
		Bark	448	0.67	2.48*	
		Dried seeds	860	0.22	0.76*	
Winiarska-Mieczan et al 2022	Fresh and dried herbs and spices purchased in markets in Lublin, Poland	Oregano	15	0.69		
		Lovage	8	0.57		
		Rosemary	9	0.38		
		Basil	16	0.71		
		Coriander, cilantro	11	0.51		
		Thyme	15	0.40		
		Marjoram	11	0.72		
		Tarragon	7	0.64		
		Savory	8	0.30		
		Turmeric	12	0.06		
		Allspice	10	0.16		
		White pepper	9	0.02		
		Black pepper	12	0.07		
		Rose pepper, pink pepper	10	0.13		
		Cayenne Pepper	13	0.145		
		Paprika	10	0.048		
		Coriander	9	0.042		

			Lead level in spices			
Citation	**Sample description**	**Spice name**	**Number of samples**	**Mean (mg/kg)**	**90th percentile (mg/kg)**	**Maximum (mg/kg)**
		Cumin	11	0.041		
		Ginger	10	0.10		
		Cinnamon	15	0.03		
		Bay leaf	8	0.025		
		Cloves	11	0.03		
Kowalska et al 2021	Imported spices purchased in supermarkets in Lublin, Poland	Sage	4	2.21		2.55
		Thyme	3	ND		ND
		Basil	3	1.66		1.92
		Turmeric	3	0.138		0.256
		Black pepper	26	0.159		0.74
		Peppers	8	0.338		0.775
		Allspice	3	0.361		0.422
		Cumin	3	0.43		0.55
		Fennel	3	0.321		0.382
		Fenugreek	3	0.173		0.202
		Clove	3	0.343		0.422
Harangozo et al 2018	Select spices purchased in three local markets in Slovak Republic (grown outside)	Black pepper	ns (20 total)			0.05
		Paprika				1.5
		Basil				5.5
		Marjoram				4.78
Reinholds et al 2017	Survey of select spices from German collaborated; spices on the European market	Black pepper (Brazil, Vietnam)	50	0.28		0.44
		Paprika (Brazil, China)	50	0.42		0.75
		Nutmeg (Indonesia)	50	0.13		0.37
		Thyme (Poland)	50	0.79		1.04
		Basil (India)	50	0.48		1.2
		Oregano (Turkey)	50	0.42		0.71
Bua et al 2016	Market basket survey of 7 samples of 3 spices from local Italian markets	Cinnamon (Indonesia)	1 (5 reps)	0.766		0.792
		Cinnamon (Madagascar)	1 (5 reps)	0.294		0.384
		Cinnamon (Vietnam)	1 (5 reps)	2.224		2.923

			Lead level in spices			
Citation	**Sample description**	**Spice name**	**Number of samples**	**Mean (mg/kg)**	**90th percentile (mg/kg)**	**Maximum (mg/kg)**
		Turmeric (India)	1 (5 reps)	0.171		0.179
		Turmeric (Sri Lanka)	1 (5 reps)	1.383		1.402
		Ginger (India)	1 (5 reps)	0.327		0.346
		Ginger (Japan)	1 (5 reps)	1.15		1.154
EFSA 2012	Analytical results submitted by EU member states and Norway	Chervil	4	0.073		
		Chives	69	0.027		0.069
		Dill	45	0.053		0.172
		Parsley	215	0.093		0.33
		Thyme	21	1.11		3.6
		Basil	72	0.08		0.5
		Tarragon	9	0.391		0.923
		Paprika	271	0.318		0.95
		Chili powder	24	0.257		
		Anise seed	9	0.095		
		Caraway	6	0.079		
		Cayenne	8	0.492		
		Cinnamon	30	0.438		2.2
		Cloves	5	0.119		
		Coriander seed	13	0.115		
		Cumin seed	36	0.127		0.38
		Ginger	29	0.95		3.22
		Nutmeg	98	0.106		0.4
		Pepper, black and white	168	0.195		0.731
		Turmeric	15	0.407		

GM: geometric mean; ND: non-detect; ns: not specified
*95th percentile

The proposed Class II recall action level of lead in spices of 0.21 ppm is well below the upper percentile lead levels (i.e., the 90th or 95th percentile level) for nearly all spices where this data was publicly reported. In addition, the majority of the mean levels also exceed 0.21 ppm, indicating that there is a large proportion of the spice samples that do not meet this proposed level.

Of critical importance, what is considered achievable is entirely based on how achievability is being defined. Until agreement on this definition is reached, it is not possible to have a meaningful discussion about achievability.

ASTA strongly advises that a threshold of 90-95% achievability should be used as the basis for the state's recall action level for lead in spices. A 90-95% achievability threshold would significantly minimize disruption in the supply chain. This is likely why leading regulatory authorities, such as FDA, Codex, and the EU typically use this threshold as the definition of "as low as reasonably achievable" to establish action levels. In fact, New York State even used this threshold in the establishment of its action levels for cadmium and inorganic arsenic. In contrast to the 90th percentile of achievability used for the state's action levels for cadmium and inorganic arsenic, less than 50% percent of spices in general would be able to meet the proposed action level for lead (and much higher percentages of specific types of spices would not meet this level). To be consistent with its action levels and to ensure achievability and minimize disruption, the state should set the action level for lead based on at least the 90th percentile of achievability or higher.

Furthermore, in light of the recently signed domestic mutual reliance partnership agreement between FDA and New York State, there is further reason for New York to be in alignment with the FDA when it comes to addressing achievability of lead levels. FDA typically uses a 95th percentile of achievability, as evidenced by recent guidance levels that have been set under the FDA's Closer to Zero action plan. In fact, the FDA's January 26, 2023 announcement of draft guidance for industry on action levels for lead in baby foods set the action level for lead based on an achievability range of 90-95%. FDA also used this threshold to set guidance levels for lead in juices that published in April 2022.

The American Spice Trade Association's response to New York State's new regulatory policies for heavy metals in spices (the "Letter"), published in Volume 10, Issue 1 (2022) of the *Journal of Regulatory Science*, outlines how the action level proposed by New York State is not achievable. Further, in the Letter, ASTA and its scientific experts provide a critique of the scientific approach undertaken by AGM, which served as the basis for NYS's recommended lead limits for spices and herbs and highlight critical considerations that New York State failed to address, both of which impact the conclusions reached by AGM. A copy of the Letter accompanies this response and is incorporated by reference.

Since the publication of the Letter, ASTA has posted guidance levels for lead in spices on its website. These levels are based on what is globally achievable for specific categories of spices and align with those established by the EU and under consideration by the WHO.

- **"Based on industry feedback, AGM is taking an additional 36 months to collect samples of individual spices commonly consumed by children. We encourage individual stakeholders to send any concerns or additional questions they have regarding this additional research or extended implementation timeline to AGM directly."**

ASTA applauds AGM for conducting additional research on individual spices. The industry appreciates the additional consideration that AGM will engage in prior to implementing limits.

ASTA has a number of questions pertaining to this research and the extended timeline.

It is our understanding, that new levels will not go into effect until after the additional research is completed, which will not be completed for 36 months, or until at least fall 2025. Our questions include:

- Is the state willing to meet with ASTA to discuss the research goals and study design in the early stages of the research?
- What steps will the state take once the research is completed?
- At what point will the research be shared with industry stakeholders with an opportunity to comment?
- Will proposed levels be updated based on the research findings and will the basis for this update be shared with stakeholders with an opportunity to comment? At what point after the research is completed will this occur?
- Does the state intend to publish final levels along with an implementation period for the industry to come into compliance?
- How long will the implementation period be once the research is completed?

It is ASTA's understanding that the purpose of this research is to evaluate achievability of spices on an individual basis. We understand that the state is focusing this research on spices commonly consumed by children. In correspondence with ASTA, AGM has indicated that the final levels will apply to all spices, not just those commonly consumed by children. As such, it is not clear why the state is focusing the research on spices commonly consumed by children. The evaluation of achievability should be for any spice that is subject to the levels.

Additionally, during this time period, ASTA encourages AGM to compare exposure from all sources of dietary intake and drinking water to that from spices in order to determine the true contribution of spices to overall dietary exposure for heavy metals.

ASTA also encourages AGM to more clearly distinguish 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. In its Letter, ASTA summarized a variety of studies that demonstrate spices purchased abroad directly by consumers are more likely to exceed limits for lead than spices purchased domestically. These studies support the conclusion that spices purchased in the U.S. have notably lower levels than those purchased in foreign markets, highlighting the success that U.S. importers and regulators have had in implementing standards that keep heavy metal levels in spices on the U.S. market low.

Since the publication of the Letter, additional studies have been published that support this conclusion. One study of spices in North Carolina found that spice products purchased in India contained more than triple the median lead levels of those purchased in the U.S. (Angelon-Gaetz et al 2023). Another recent report from the health department of Douglas Country, Nebraska linked spices to lead poisoning in children in 2021 (Gaarder 2023). However, the department's findings concluded that most of the impacted children were refugees from Afghanistan who consumed products purchased from their home country that the refugees themselves brought into the U.S. Notably, the action taken by New York state will not address the real issue with lead in spices sold overseas. In fact, it is only likely to increase that likelihood that citizens choose to purchase spices from these countries due to the lack of availability of affordable spices in the state that are able to meet the new recall action level.

ASTA would appreciate the opportunity to meet with the state to learn more about the goals and design of the research share perspectives for consideration.

- **"This proposed action level and associated research apply solely to spices sold in retail stores as a food commodity or ingredient that is added to foods. We encourage feedback regarding**

the preventative and mitigating measures that companies who process, distribute and or sell retail spice products will need to adopt to comply with the proposed action level."

It remains unclear how spices used as ingredients by food manufacturers and restaurants will be impacted by this action. Although AGM has repeatedly indicated that the research to support this action only applies to spices sold in retail stores or an ingredient that is added to foods, this remains confusing for the industry. Especially considering essentially all spices are used as "an ingredient that is added to food" and the consumption data relied on by AGM does include spices consumed from all sources, including spices used in packaged food products, such as cereals, snacks, etc.,[1] clarity is needed on what products are covered by the proposed action. Furthermore, the public health justification for targeting only spices sold directly to consumers is unclear. Spices used by manufacturers and restaurants account for the majority of spices that are sold and consumed. There are also no significant differences in the way in which spices are consumed within these products. In fact, spices used in home cooking are added to the food in similar small amounts (typically <1% of the total product) as to packaged and restaurant foods.

Given the continued lack of clarity, AGM is requested to answer the following questions in the affirmative or negative:

- Do the recall levels apply to restaurant preparing food with spices purchased at retail market?
- Do the recall levels apply to a supermarket, grocery, etc. that prepares food with spices and sells such food at retail market?
- Do the recall levels apply to a vendor at a farmer's market that prepared a baked good or food product using spices bought at a retail market?
- Do the recall levels apply to a bakery that prepares its food products by using spices that it purchased at a retail market?
- Do the recall levels apply to a food manufacturer such as a snack chip maker who uses spices for its food product that it purchased from a wholesaler who also sells the very same spices to retail markets that are purchased by consumers?

Manufacturers who use spices as ingredients in finished food products must comply with the laws and regulations in the states that they operate. The clarification provided by AGM to date does not give sufficient distinction between spices sold directly to consumers and spices used as ingredients by manufacturers, restaurants, grocery stores, and other food service establishments. Without a clear distinction in the published regulations, manufacturers will likely conclude that their ingredients are covered by the action.

Although the U.S. spice industry currently employs a variety of strategies to ensure that the presence of heavy metals is as low as feasible, it will be incredibly difficult to implement additional preventative and

[1] Total spice consumption rates presented in the AGM assessment were based on the Food Commodity Intake Database (FCID). The FCID uses recipes to translate foods as consumed into EPA-defined food commodities. The EPA developed this database to estimate consumption rates at the raw agricultural commodity level. Therefore, the EPA-defined food commodities are the ingredients used in all food consumed, including commercially prepared foods. The spice consumption included in the AGM assessment includes spices used in commercial foods including ready-to eat cereals and snacks (e.g., the cinnamon in an apple cinnamon cereal and granola bars, turmeric in corn chips, etc.).

mitigating measures without additional research at origin. Presently, spice farmers follow Good Agricultural Practices to mitigate uptake during growing. Importers ensure compliance with quality standards and strict specifications by requiring documentation from their suppliers, including testing for heavy metals to achieve the safest supply of spices for consumers. Additionally, manufacturers use cleaning methods to minimize contributions from soil and the environment and adhere to practices that prevent the contribution of heavy metals through processing.

As an association, ASTA has published guidance for the spice industry on heavy metal limits and Good Agriculture Practices to educate spice producers on how to best grow crops, manage irrigation, monitor soils, and safely transport product to minimize toxic element uptake form the environment. Furthermore, the spice industry works with producers and other partners, such as the Sustainable Spice Initiative, around the world to provide training on these practices.

However, much is still unknown about the mechanisms through which spices take up heavy metals from soil and groundwater. Additional research is required to better understand these mechanisms before effective intervention strategies can be identified that can be implemented at origin. As such, ASTA has partnered with several NGOs on a research project in Vietnam to understand strategies to mitigate heavy metals in cinnamon. ASTA is also exploring future research opportunities to examine heavy metal uptake in other commonly consumed herbs and spices.

Critically, this is not an issue unique to the spice industry. In fact, the Institute for Advance of Food Nutrition Science (IAFNS) is currently undertaking a study on heavy metal uptake by rice and spinach. Their current research plans demonstrate that the food industry at large is in the early phases of research to understand heavy metal uptake in agricultural commodities, even staple food items. Therefore, it is essential that additional research is conducted to understand what mitigating measures may be taken at origin to limit heavy metal uptake, as well as the implementation timeframe. Research of this nature will take several years to complete, and then additional time to translate to real changes in the supply chain.

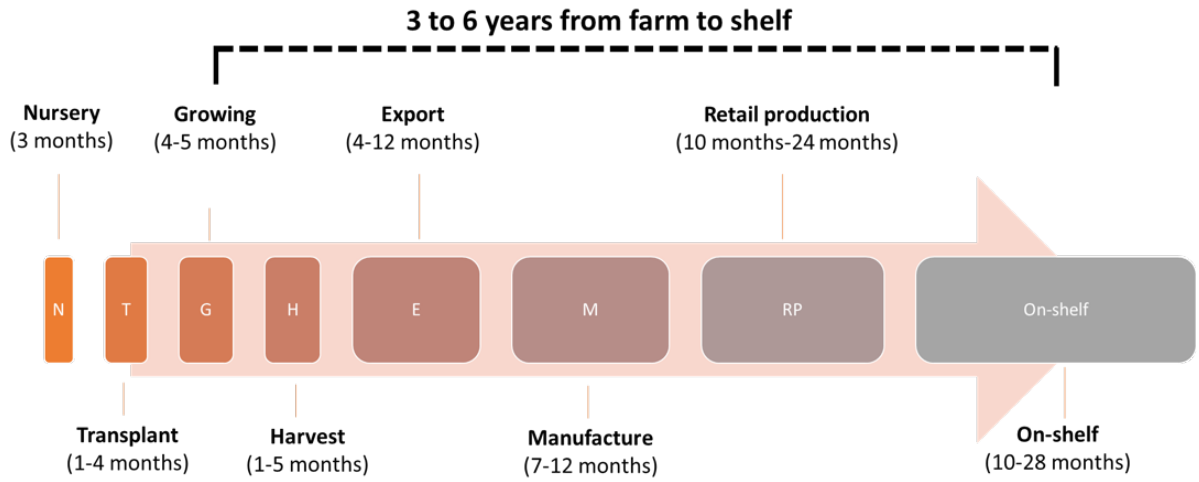
- **"We encourage businesses to provide a detailed description, based on business-specific analytical data, of the supply chain barriers your business will face in order to comply with the proposed action level, and also whether an extended timeline is needed for your business to comply beyond the proposed timeline of 36 months."**

The spice industry is an inherently global industry that supports the livelihoods of farmers in many developing countries. In fact, the vast majority of spices consumed in the United States are imported. The nature of spice supply chains is very complex due to where and how spices are grown.

The spice industry will not be able to meet the current proposed levels. If these levels are finalized, many spices will not be able to be sold in New York. This is likely to result in shortages for some products and cost increases for many others. A revised approach that sets different levels for categories of spices, such as the approach used by the EU, will reduce the impact on the industry. Additionally, an extended implementation timeframe will also reduce the burden.

While the growing and harvesting cycles for each spice crop are unique, the following graphic depicts an example of a typical timeline from the growth of a spice product (specifically paprika) through the end of

its shelf life. It typically takes at least 3-6 years from the time a spice is planted to the expiration of its shelf life.



However, some spices have much longer growing and harvesting cycles. For example, common varieties of cinnamon trees require 10 to 15 years to reach maturation. Unfortunately, spice supply chains cannot quickly be altered to meet the proposed level within the proposed timeframe. As such, the industry will need an implementation timeframe of at minimum six years to implement mitigation strategies, and longer for certain commodities.

In addition to the highly variably production timelines, it is a massive undertaking to obtain changes in growing practices at the farmer level. Spices are typically grown on very small shareholder farms (<10 hectares), which yield relatively low quantities of spices per farm (e.g., only a few hundred pounds annually). Since spice companies need relatively large amounts of spices for their commercial purposes, at least several tons at a time, spices typically need to be consolidated from many farms to obtain commercially viable quantities for importers. Implementing widespread changes to agricultural practices requires communicating with hundreds of thousands of farmers and working with local governments within a given region. Even then, the industry has not yet identified key interventions that farmers can leverage to reduce heavy metal uptake at the grower level, and existing concentrations of heavy metals in soils may not be known by farmers.

Furthermore, many spice growers are subsistence farmers in developing countries who rely on the yield of their crops for the livelihood of their families. In the face of a lack of clear, effective intervention strategies due to the lack of existing research on the uptake of heavy metals by spices, farmers will be unable to produce product that meets the proposed limits. The lack of ability to produce sufficient yields of viable product will threaten spice supply chains and the livelihoods of farmers.

ASTA coordinates with growing regions around the world to provide education on regulatory requirements and promote compliance. It is extremely difficult to coordinate with growers when the

regulatory situation is unclear. For these reasons, the industry needs more clarity on guidance and additional time to ensure compliance with the final levels.

In summary, the preponderance of data demonstrates that the proposed recall action level for lead is unachievable for the spice sector. Instead, an approach that sets levels for categories of spices based on 90-95% achievability would prevent massive disruption to the spice market and would align with the approach taken by FDA and global regulatory authorities. Further, given the lack of evidence on effective mitigation strategies and the complexities of the spice supply chain, the industry will need many years to come into compliance with new levels. If the proposed recall action levels go into effect there will likely be an exclusion of many spice products on the market, widespread shortages, and massive cost increases, which will create a situation that incentivizes immigrant families to source spices from countries that are demonstrated to have much higher lead levels than those in the U.S. Finally, there continues to be confusion within the industry regarding what products are covered by the proposal and questions regarding the research objectives.

Again, thank you for the opportunity to submit this feedback to AGM. We welcome the opportunity to continue our dialogue on this critical issue and are happy to meet to discuss this feedback and answer any questions.

Best regards,

Laura Shumow
Executive Director
American Spice Trade Association

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