

By E-mail

November 9, 2022

Dan McCarthy Director of Food Safety and Inspection NYS Department of Agriculture and Markets 10B Airline Drive, Albany, NY 12235

Dear Director McCarthy,

Thank you for your October 24, 2022 response to my letter, on behalf of my client, the American Spice Trade Association ("ASTA"), sent to Deputy Secretary King on July 7, 2022. ASTA and I appreciate the clarity provided by the Department of Agriculture and Markets ("DAM") regarding the additional compliance timeline for the proposed heavy metal levels for spices and DAM's responsiveness to our concerns. In particular, we welcome New York State's announcement that it is conducting additional research on achievability of its proposed heavy metal limits for spices given that ASTA and other organizations, associations, and interested parties have all indicated that new proposed levels cannot be achieved without a significant disruption in the marketplace. We are also pleased to see that New York State has now provided an opportunity for certain stakeholders, such as spice manufacturers and retailers, to provide feedback on the proposed levels.

We note, however, that while your response addressed some of our concerns, it has also left unanswered a number of additional questions we raised in our July letter. Your letter raised a series of new questions, as well. These remaining questions are outlined below. Please note that some of these questions require a timely response given the short comment period DAM has provided to stakeholders other than ASTA itself.

Outstanding Questions Regarding the Status of the New Levels

• Do the levels apply to all uses of spices?

ASTA and I remain unclear about what products are covered by the proposed limits. Based on what was reported in the State's published manuscript that served as a basis for these proposed new limits, we understand that ingredients used by manufacturers were *not* the focus of the targeted sampling. That said, it still remains unclear if the proposed new levels apply to spices used as ingredients by manufacturers, restaurants, or bakeries. This is particularly confusing given that the Spice Input Form (the "Form") sent to ASTA and on the DAM's website set out that the proposed levels apply "solely to spices sold in retail stores as a food commodity or ingredient that is **added** to foods." (Emphasis added). As such, we are seeking clarification on the following questions:



- Do the proposed levels apply to spices used as ingredients by (a) manufacturers,
 (b) grocery stores and supermarkets with respect to their in-store, prepared food products, (c) restaurants, (d) bakeries, or (e) cafes?
- If a food product available for sale in New York State, such as a breakfast cereal or snack chip, contains a spice that exceeds the new proposed levels set by the State, will that product be subject to recall?
- Will a consumer food product manufacturer that uses spices in its manufactured food product be required to comply with the new proposed levels for spices when it manufactures food products in New York State?
- If proposed new levels do not apply to ingredients used by manufacturers, restaurants, or bakeries, will the State ultimately reflect this policy in the final published action levels?
- When do the levels go into effect?

It is our understanding that based on your response, the proposed new heavy metal levels, if any, will not go into effect until after the additional research is completed, which is expected to take 36 months from November 2022. After that point, we understand that research findings will be shared with industry stakeholders. As such, we have additional questions:

- At that time, does the State intend to publish final levels along with an implementation period for the industry to come into compliance?
- If the proposed new levels are not currently in effect and could change based on the new research, will New York State remove the proposed new levels set forth on the DAM website (<u>https://agriculture.ny.gov/heavy-metals-spices</u>) so as not to create confusion in the marketplace?
- What details can be shared about New York's additional ongoing research? We appreciate the overview of the research and look forward to participating in the stakeholder meetings regarding the findings. ASTA posed a number of questions to DAM in February, which were not answered in any subsequent correspondence from DAM, including your letter. These unanswered questions include the following:
 - Will the proposed levels be adjusted if the data demonstrates that they are not achievable?
 - How will achievability be determined?



- Is the intention that the proposed recall action levels would only apply (or be implemented more quickly) for the spices the State has identified as being commonly consumed by children?
- Will New York State plan to target all of the spices in the "spices, other" category, including those that are rarely consumed by children, such as juniper berries?

We would appreciate answers to these questions at this time, so that our public comments for the record may be as complete and comprehensive as possible.

Additional Concerns with the Proposed New Levels

New York regulators misapplied a NYCDOH study to justify the new levels and the proposed action would likely result in unintended consequences.
 The response in the letter does not address the concern that the lack of availability of new proposed recall action levels may drive immigrant families to purchase spices while overseas in foreign markets that have much higher levels of heavy metals. Further, we are interested in the State's finding regarding the likelihood of lower priced spices to have higher levels of heavy metals. This is a new finding offered by the State. Can that data be shared with the industry?

Additionally, the Form notes that DAM "encourage[s] 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." All data created by ASTA member companies as it pertains to the presence of lead in spices is proprietary by its very nature. We are not sure what DAM is seeking to review in connection with non-proprietary information. Please provide some clarification about what specifically DAM is seeking with respect to non-proprietary data.

• The levels are not achievable.

As mentioned above, we appreciate that New York State has now provided an opportunity for impacted stakeholders, including ASTA, to offer feedback on the achievability of the proposed levels. We are troubled, however, that only certain stakeholders are permitted to submit a Form, while excluding other entities such as other trade associations in the food industry, restaurants, bakeries, manufacturers, and consumer groups. All of these key stakeholders are also involved in the spice industry and marketplace and may wish to provide feedback on the proposed levels. Yet apparently these stakeholders – for reasons that are unclear – are precluded from submitting a Form. ASTA strongly believes that any interested parties should be



permitted to submit comments, and the Spice Input Form should be so revised. If DAM does not agree, we respectfully request that DAM provide the legal basis for excluding an interested party from submitting a Form. In short, excluding key stakeholders from DAM's public comment process may undermine what should be an open, transparent, and inclusive public engagement process.

Additionally, Jennifer Trodden granted a 90-day extension to the American Spice Trade Association to submit a Form, such that the Form and supporting documents, if any, would now be due by February 23, 2023. ASTA appreciates the extension and ASTA has been advised that this extension only applies to ASTA and not its individual members. It is ASTA's understanding that its member companies or other stakeholders wishing to submit comments can request an extension. That said, will those requests be granted?

• Research does not support the health-based lead value.

We have raised a number of issues related to the methodological flaws in the consumption analysis and scientific basis of the health-based value. The response provided in your letter provides no justification for the rejection of these numerous concerns. You should be aware that these concerns have now been published publicly in the Journal of Regulatory Science, a copy of which is attached to this correspondence. This is the same Journal in which New York State's study was published. ASTA's letter is a direct response to the study. Will the State be responding to the concerns published in ASTA's letter to the editor of the Journal of Regulatory Science and, if so, through what forum?

• The policy is unlikely to be effective at reducing exposure to lead.

Your letter fails to address our concerns regarding the State's lack of justification for its focus on spices versus other sources of lead and the State's failure to conduct an exposure assessment. Rather, your letter states the implementation of its initial recall level resulted in a reduction of Class I recalls. That is not a credible argument since this matter involves Class II recalls. Moreover, this does not address the issue of exposure to lead from spices versus other food products. In fact, if the measure of whether the new policy is effective is linked to the number of recalls, then the implementation of the new levels is likely to be <u>ineffective</u>, as it will most certainly result in a dramatic increase of products that are subject to a recall and a dramatic reduction in the number of spices available in the New York marketplace.



Once again, ASTA and I appreciate the opportunity to collaborate on the important initiative of ensuring spices are safe. ASTA remains committed to ensuring that levels of heavy metals in spices are safe and as low as feasible.

We look forward to your response, particularly as it applies to the extension of time for submission of the Form by parties other than ASTA.

Very truly yours,

all.V

Craig M. Johnson

CC: Laura Shumow, American Spice Trade Association Deputy Secretary Kevin King Agriculture and Markets Deputy Commissioner Jennifer Trodden