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To Whom it May Concern:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on the United States (U.S.) Food and Drug Administration (FDA) proposed rule on the Requirements for Additional Traceability Records for Certain Foods in the Federal Register at 85 Fed. Reg. 59984, September 23, 2020, Docket ID: FDA-2017-N-0053.

Introduction

ASTA was founded in 1907 and represents the interests of approximately 200 members, including companies that grow, dehydrate, and process spices. ASTA's members include U.S. based agents, brokers and importers, companies based outside of the U.S. that grow spices and ship them to the U.S., and other companies associated with the U.S. spice industry. ASTA members manufacture and market the majority of spices sold in the U.S. for industrial, food service and consumer use. The highest priority of ASTA and our members is ensuring the supply of pure, safe spice to American consumers.

ASTA appreciates FDA's aspirational vision of achieving end-to-end traceability throughout the entire food supply chain. Although this vision will require many years to ultimately realize, the proposed traceability rule provides a first step towards achieving this goal. ASTA recognizes the complexities and challenges in developing a proposed traceability process for certain foods that furthers public health objectives without being overly burdensome. Upon review of the proposed requirements, the spice industry still has outstanding questions regarding the proposed process. Additionally, since the industry continues to be focused on the COVID-19 pandemic response, it has not been possible to fully engage in the process of reviewing and understanding the implications of the proposed requirements, which are complicated and extensive.

ASTA appreciates that FDA thoughtfully provided exemptions to address many of the aspects of the spice supply chain that would make it difficult for our industry to comply with the proposed requirements, which in effect will mean that dried herbs and spices are not covered by the proposed rule. Dried herbs and spices are not covered commodities on the Food Traceability List (FTL); indeed, we understand that these are separate commodity categories that FDA considered in its Risk-Ranking Model and did not identify as high-risk foods. Even if they were to be added to the FTL, dried herbs and spices would be subject to partial exemptions for commingled raw agricultural commodities (RACs) and products that undergo a kill step.

We nevertheless have an interest in ensuring that the proposed rule's requirements are workable, even among entities not covered by the proposed rule. While dried herbs and spices are not covered by the proposed rule, FDA states that the requirements were "designed to be suitable for all FDA-regulated food products." It is important to recognize that the proposed rule as written is not feasible for the entire food sector. It is unlikely that food companies would be able to voluntarily adopt this approach for many ingredients that are not on the FTL. Companies should not be expected to adopt this approach for their entire range of products. Furthermore, although FDA's New Era for Smarter Food Safety ultimately envisions tech-enabled traceability, the industry does not yet have data harmonization standards in place. It is simply not feasible for cohesive digital data sharing across various information systems platforms at this time, and will not be until significant strides in interoperability are made.

However, with the future in mind, as the industry builds towards more comprehensive traceability efforts, it is important that the proposed requirements should be manageable and achievable for all industries. For this reason, ASTA supports the Food and Beverage Issue Alliance (FBIA) comments that request that FDA adopt a simpler and more achievable approach to the traceability requirements in the proposed rule.

Additionally, ASTA respectfully offers comments on the following topics:

- Support for the FDA clarification of "fresh" on the food traceability list and request for further clarification of covered commodities,
- Support for a complete exemption for foods that undergo a kill step,
- Support for the partial exemption for Commingled Raw Agricultural Commodities and request that FDA clarify it applies to dried herbs,
- Request that FDA engage with foreign suppliers to better understand the potential impact of the proposed traceability requirements,
- Support for a longer phase-in period for new commodities, and
- Request that FDA modify the 24-hour reporting requirement to 72 hours to make it more feasible.

ASTA Supports the FDA Clarification of "fresh" on the Food Traceability List and Requests FDA Clarify Herbs, Peppers, and Tomatoes Destined for Dried Herbs and Spices Are Exempt

We understand FDA views dried herbs and spices as separate commodities from the fresh herbs, peppers, and tomatoes that are included on the FTL, and we appreciate FDA clarifying that only the fresh varieties of herbs, peppers, and tomatoes are included within the scope of the FTL.

However, because the FTL includes both listed foods and foods that contain a listed food as an ingredient, it is unclear how the rule would apply to the fresh herbs, peppers, and tomatoes that are converted into dried herbs and spices. We encourage FDA to clarify that fresh herbs and vegetables destined for used in dried herbs and spices are exempt from the rule and that recordkeeping is not required for these commodities before they are converted into dried herbs and spices.

- Herbs

FDA should exempt herbs destined for conversion to dried herbs because these commodities are grown, processed, and consumed differently than fresh herbs and have notably different food safety risks. ASTA thanks FDA for clarifying the distinction between "fresh" herbs and dried herbs and supports the continued use of this distinction on the FTL. ASTA would recommend that FDA clarify that fresh herbs that are ultimately dried should not be subject to the proposed rule and traceability requirements. The supply chains for dried herbs and fresh herbs are entirely separate. Fresh and dried herbs are grown on different farms because each require distinct growing conditions. In other words, certain herbs are grown specifically for use as dried herbs. As dried herbs, the risk profile is different than for fresh herbs because the drying process lowers the water activity level of the herbs, which can help prevent microbial growth. Dried herbs are consumed in lower volumes than fresh herbs and are typically used in cooked or processed applications. Additionally, dried herbs undergo a kill step such as irradiation, either in the country or origin or after import. Accordingly, fresh herbs grown for use as dried herbs do not present the same potential public health risk as those grown for the fresh market and should not require recordkeeping under the proposed rule.

- Peppers

We similarly encourage FDA to exempt fresh peppers used to make spices from the recordkeeping requirements of the proposed rule. In the spice industry, the term "peppers" can apply to a variety of different commodities. For example, the ASTA black pepper monograph includes a history of the word and derivative uses of pepper:

> Pepper (and its names in all other European tongues) ultimately derives from the Sanskrit name pippali or pippalii (referring properly to long pepper), which was transferred via Greek pééperi and Latin piper. The names of several other spices have in turn been influenced by pepper: For examples, chili ("red pepper"), paprika (from a Serbian word meaning "pepper"), allspice ("Jamaica pepper"), cress ("pepper grass"), peppermint, water pepper and horseradish (called "pepper-root" in Swedish).

Piper nigrum, the plant that is cultivated for production of black, white, and green peppercorns, should not be included on the FTL under the "peppers" designation because it is a product that is not consumed raw and always undergoes a kill step. The berry from the *Piper nigrum* plant is never eaten fresh; it is dried and ground for use as a spice or in a seasoning blend and undergoes a kill step. Black pepper is grown all over the world and is one of the most globally ubiquitous spices. Over 84 million kilograms were imported into the United States just in 2019 from over 35 different countries.[1] Requiring recordkeeping for peppers used to make peppercorns would be overly burdensome and would not serve a commensurate public health benefit. While we view the designation of "fresh" peppers as clarifying

[1] USDA FAS GATS Database.

that *piper nigrum* would not be included on the FTL and that pepper grown to become black pepper is not subject to additional recordkeeping requirements, we encourage FDA to state this distinction expressly to avoid potential confusion.

FDA should also clarify that when the *Capsicum annuum* pepper is grown for use in spices, recordkeeping is not required prior to the pepper being converted into a spice. *Capsicum annuum* is a species of pepper grown around the world for different uses, including to be consumed fresh, dried for use as a spice, and used as an ingredient in a variety of products. Although derived from the same species, fresh capsicums are grown, processed, and consumed differently than the dried capsicums. For example, paprika or chili powder, which are derived from dried and ground capsicum peppers, have supply chains and processing steps distinct from the fresh pepper supply. These capsicum peppers are grown, dried, comingled several times, and further processed before reaching their final destination. Dried capsicums also receive a kill step in the supply chain, either in the country of origin or as part of a further processing step. Accordingly, recordkeeping should not be required for fresh peppers used to make spices.

- Tomatoes

Tomatoes used in spice or seasoning blends should be exempt from recordkeeping requirements for the same reasons. Dried tomatoes used in seasoning blends or as part of a vegetable blend in seasonings have separate and distinct supply chains, a lower risk profile than other fresh tomatoes, and would be subjected to a kill step during processing or when becoming part of a seasoning blend.

In sum, ASTA supports FDA's clarification of "fresh" on the FTL for herbs, peppers, and tomatoes. This distinction is important to the spice industry because it clarifies that spices, dried herbs, and dried vegetables are not included on the FTL. However, FDA should clarify in the final rule that the fresh commodities that are grown and then further processed into dried commodities are not subject to the additional recordkeeping requirements of the proposed food traceability rule. ASTA requests that FDA clarify that records not are not required to be maintained for herbs, peppers, and tomatoes that are subsequently dried, since these commodities have distinct supply chains, end uses, and ultimate public health implications, compared to fresh commodities.

ASTA Supports a Full Exemption for Food that Undergoes a Kill Step

ASTA appreciates that FDA recognizes that the kill step is an important demarcation step for foods on the FTL. However, ASTA questions the reasoning behind requiring strict traceability requirements prior to the application of a kill step. Under FSMA, a company is required to identify a food safety hazard, and then apply a validated preventive control. If a company properly complies with FSMA, the kill step would be effective at eliminating biological contaminants that may be present in the food. The requirement to maintain traceability records from the farm to the kill step therefore would provide no public health benefit, because there would be no need to trace the source of a food prior to the application of a kill step.

Moreover, sufficient records already exist to trace foods that undergo a kill step. Under the Preventive Controls rule, facilities already are required to document the application of a kill step. The Bioterrorism Act's Subpart J recordkeeping requirements similarly require facilities to maintain one up, one back

records for their foods. These records already provide the information needed for a traceback investigation, and requiring further recordkeeping under the rule would not provide any additional public health benefit. Accordingly, we support providing a complete exemption for foods that undergo a kill step.

ASTA Supports the Partial Exemption for Commingled Raw Agriculture Commodities and Requests FDA Clarify it Applies to Dried Herbs

Spices and dried herbs are typically grown on small shareholder farms, where very small quantities of spices are harvested. Then, the spices are consolidated by multiple middlemen prior to further processing. After trading hands multiple times, spices receive a kill step, either at a processing facility located in the country of origin or following import into the U.S. Additionally, spices typically undergo grinding, blending, and other forms of processing at subsequent processing facilities.

ASTA appreciates that FDA's proposed rule recognizes the challenge this type of situation presents for traceability and offers a partial exemption for commingled raw agricultural commodities (RACs) in §1.1305 of the Food Traceability Rule. The proposed partial exemption for comingled RACs applies to any commodity that is combined or mixed after harvesting, but before processing[2] except fruits and vegetables covered by the Produce Safety Rule. Entities that manufacture, process, pack, or hold commingled RACs that are required to register with FDA only need to maintain one up, one back records under the Bioterrorism Act regulations.[3] ASTA supports this partial exemption.

ASTA believes that the intention of the partial exemption in FDA's proposed rule is to apply to commodities like dried herbs that receive subsequent processing and a kill step after multiple stages of commingling. However, ASTA notes that in some cases, dried herbs may receive some rudimentary forms of primary processing on the farms, such as sun-drying or curing. It is ASTA's interpretation that this partial exemption should apply to the entire dried herb supply chain, even if they are sun-dried or subject to similar primary processing on farms prior to commingling. ASTA requests that FDA clarify in the final rule that the exemption for commingled RACs would apply to dried herbs, even when minor primary processing such as sun-drying or curing occurs before they are commingled and subsequently processed.

FDA Should Engage with Foreign Suppliers to Better Understand the Impact of the Proposed Traceability Requirements

Due to the complex nature of their supply chains, it is currently infeasible for the majority of commercially traded dried herbs and spices to be traced back to the farm level. The spice and dried herb categories include a wide array of different commodities that are grown in many different countries (often developing nations, with limitations on technology) around the world, and subsequently imported for processing and use in the U.S. ASTA is concerned that FDA has not actively engaged foreign

[2] 85 Fed. Reg. at 59996.

[3] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58894; October 10, 2003; codified at 21 CFR Part 1, Subpart H.

suppliers to provide education regarding the proposed traceability requirements or to understand their unique challenges with compliance. This sector of the supply chain may represent the entities that require the most assistance with current technological capabilities. For example, in the spice supply chain, many entities continue to rely on paper recordkeeping. Without a robust education and engagement campaign, it is likely that the burden to educate, develop digital capabilities, and promote compliance will fall to industry. Before finalizing the rule, ASTA requests that FDA conduct concerted outreach to foreign entities involved in the supply chain to gain their perspective on the proposed requirements.

Commodities Added to the FTL Should Have a Two-Year Phase-In Period

The FTL was published in September 2020. The commodities on the original FTL have two years after the effective date[4] to come into compliance with the proposed rule. However, in the proposed rule, commodities that are added at a later date to the FTL will only have a one-year phase in period in which to come into compliance. Companies that work with commodities newly added to the FTL likely will need to undergo significant changes to their recordkeeping processes and changes to their supply chain, among other adjustments necessary to comply with the rule's recordkeeping requirements. ASTA would recommend that every commodity added to the FTL be given a two-year phase period with which to come into compliance.

A 24-Hour Period for Industry Reporting is Overly Burdensome

The proposed rule includes a requirement that a company subject to the proposed rule be able to provide data requested by the FDA no later than 24 hours after requested in an electronic, sortable spreadsheet. Depending on the extent of the request, it may require extracting data from several different systems and people working in different facilities (and potentially countries) to collaborate to assemble the requested records into the electronic spreadsheet. Although all of the records would exist and could be accessed within 24 hours, consolidating the data into the correct format will take longer than 24 hours because many companies do not have recordkeeping systems that can download data into a searchable spreadsheet. Moreover, even when a system can produce sortable spreadsheets, the information required by the proposed rule often is stored in multiple different systems that do not necessarily "talk" to each other, and would still require manual consolidation of information into a single spreadsheet. We note that Section 204 of FSMA does not require that data be consolidated in a sortable spreadsheet within 24 hours. Accordingly, we suggest FDA revise the requirement to provide an electronic, sortable spreadsheet and allow 72 hours after receipt of a request to produce the electronic, sortable spreadsheet to FDA.

[4] 85 Fed. Reg. at 60020.

Conclusion

ASTA supports FDA's goal of creating a more traceable food supply to support public health goals. At the same time, the complexities of many supply chains, such as dried herbs and spices, present significant challenges to achieving end to end traceability. The industry will continue to work towards traceability efforts. Recognizing that the proposed food traceability rule provides the basis for a *de facto* traceability standard for all products, not just those included on the FTL, it is essential that FDA make sure that all requirements are manageable and achievable.

ASTA requests that FDA clarify that recordkeeping is not required for fresh herbs, peppers, and tomatoes that are used to make dried herbs and spices. ASTA also requests that FDA clarify that dried herbs fall within the commodities that would be included in the exemption for commingled RACs. Additionally, ASTA supports a full exemption for food that undergoes a kill step in processing. In order to give industry enough time to comply with traceability regulations, ASTA requests that all commodities on the FTL have a two-year phase in period. Finally, the time period for industry to respond to an FDA request for information should be increased from 24 to 72 hours due to current restrictions on technology.

Please feel free to contact me with any questions or follow up.

Sincerely,

Laura Shumow
ASTA Executive Director