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Via electronic submission through regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry (Chapter 15); Docket No. FDA-2016-D-2343

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Draft Guidance for Industry; Docket No. FDA-2017-D-5225

Dear Sir or Madam:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance documents regarding supplier verification under the FDA Food Safety Modernization Act (FSMA). Specifically, these comments address FDA's draft guidance documents entitled *Chapter 15: Supply-Chain Program for Human Food Products* in FDA's *Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry* (Chapter 15) and *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry* (FSVP Guidance). We commend FDA for issuing thorough and practical guidance documents that will be a useful tool for our members for years to come.

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. ASTA works to ensure the supply of clean, safe spices, shape public policy on behalf of the global industry and advance the business interests of its members. ASTA represents its members' U.S. interests by supporting regulatory compliance and maintaining relationships with U.S. agencies.

ASTA shares FDA's commitment to food safety. The highest priority to ASTA and its members is providing clean, safe spices to customers: food manufacturers and consumers. ASTA continues to engage actively in the regulatory process by providing comments to FDA as it implements FSMA. ASTA also continues to provide needed resources to members to share with the entire supply chain as appropriate, including tools to assist in the manufacturing, handling, and processing of clean safe spices.

We are submitting this comment to address both Chapter 15 and the FSVP guidance because the supplier verification requirements in the Preventive Controls for Human Food (PCHF) and FSVP rules are largely parallel. We ask that FDA make revisions to both of these documents to address our comments.

In our comments that follow, we highlight two particular topics addressed in these draft guidance documents that have a particular impact for our members:

1. More flexibility is needed for performing verification when a control is applied by a facility or farm prior to a supplier (e.g., by a supplier's supplier).

2. FDA should acknowledge that a non-employee retained to perform supplier verification activities on behalf of an importer or receiving facility (e.g., consultant) is not "another entity," so their work does not need to be reviewed and assessed by the importer or receiving facility.

More Flexibility is Needed for Supplier Verification of Indirect Suppliers

The draft guidance documents discuss FDA's expectations for how to manage supplier verification when a hazard requiring a control is managed by an indirect supplier (i.e., a supplier's supplier or another party further back in the supply chain). In Chapter 15, FDA explains that "there is some flexibility in how you could" perform supplier verification if the control is applied by an indirect supplier. However, the examples provided do not provide enough flexibility to be practical, particularly in light of commercial considerations.

Chapter 15 provides the example of a seasoning mix for which certain controls are applied by a supplier to the seasoning mix manufacturer. FDA explains that the entity performing supplier verification either (1) "could rely on documentation provided by Supplier X to you regarding Supplier X's supplier verification activities," or (2) could conduct the appropriate supplier verification activities with respect to the supplier's suppliers itself (i.e., directly verify these suppliers). Neither of these options is practical to implement and, therefore, FDA should provide additional flexibility through the final guidance.

This first option presents a considerable burden for both the verifier and the supplier. Foods such as spices, spice blends, and seasonings often are made from ingredients sourced from numerous suppliers. It would take a tremendous amount of work for the supplier to provide the verifier with all of their supplier verification documents for each of their own suppliers. Correspondingly, it would be very burdensome for the verifier to review all of this documentation. Additionally, the supplier often is prohibited from sharing information received from its own suppliers with third parties (except FDA) due to non-disclosure agreements. So, it often is impossible for the supplier to share specific verification information (e.g., Food Safety Plans; third-party audit reports) with their customer as documentation of its own verification activities.

This second option is not practical because the company purchasing the finished food does not have a direct relationship with these indirect suppliers. The identity of these indirect suppliers will not be known to purchaser of the finished food and their direct supplier is unlikely to be willing to share the indirect suppliers' identities. Moreover, the direct supplier may be prohibited by contract from sharing the identities of its own suppliers with a third-party. Even if the identities of these indirect suppliers are known to

whomever is performing supplier verification for the finished food, the indirect suppliers are unlikely to be willing to share any information about their food safety programs with a company with which they do not do business directly. Because there is no contractual relationship between the indirect supplier and the purchaser of the finished food that is performing supplier verification, there is no obligation for the indirect supplier to share any information regarding their programs or controls. Accordingly, this option is unlikely to ever be viable. Simply put, companies will not send third-parties sensitive information regarding their food safety programs when there is no commercial or regulatory obligation to do so.

ASTA recognizes the important role that supplier verification plays to ensuring that food is safe, but also believes that there are more practical ways to accomplish this goal than what FDA has outlined in the draft guidance documents. Our recommendation is for FDA to provide through this guidance that it would be acceptable for the verifier to review its direct supplier's supplier verification procedure to confirm that they have an appropriate system in place to verify their own suppliers, rather than reviewing specific documentation showing that this procedure has been followed for each of the indirect suppliers that implements a control. This would mean that instead of requiring a supplier to provide the verifier with all of their documentation related to supplier verification for each of the indirect suppliers, the direct supplier can simply provide the verifier with their supplier verification procedure to demonstrate that they have an adequate system in place to perform supplier verification. The verifier then can review this procedure to confirm that their supplier is meeting the requirements under the regulations.

FDA Should Clarify That a Non-Employee Retained to Assist with Supplier Verification is Not "Another Entity" Whose Work Needs to be Reviewed and Assessed

ASTA appreciates that the supplier verification regulations provide flexibility for using a third-party to assist in performing supplier verification on behalf of the importer or receiving facility. *See, e.g.*, 21 CFR §§ 1.504(d), 1.505(d), 1.506(d)(3), § 117.415(a)(3). We also appreciate FDA's recognition in the FSVP draft guidance that it is not always practical or necessary for the importer to review and assess the work of such a third-party, as they may have retained the third-party to perform this work on their behalf. In particular, the FSVP draft guidance states in E.11:

> (If your employee or someone you have engaged to perform an evaluation or reevaluation on your behalf (e.g., a consultant) has conducted the evaluation or reevaluation, you do not need to review and assess it because your employee or consultant would not constitute "another entity" whose actions you must review and assess.)

We agree with this position that is it not necessary to review and assess a supplier evaluation or reevaluation performed by someone the importer has retained to perform the work on their behalf because this person is not "another entity." We ask FDA to include this statement in the final guidance. The same principle should hold true for PCHF, which uses slightly different language to identify another entity ("an entity other than the receiving facility").

We also request that FDA expand on this point and make clear that if an importer or receiving facility has engaged someone (e.g., a consultant) to perform any of the activities under FSVP or Subpart G on their

behalf (when doing so is permitted by the rules), it is not necessary for the importer/receiving facility to review and assess their work. That is, FDA should expand this statement beyond just evaluation and reevaluation and explain that an entity like a consultant is never "another entity" for whom the work must be reviewed and assessed. For example, if a consultant is retained to conduct the hazard analysis, the importer/receiving facility would not need to review and assess their work. This is worthy of a stand-alone question in the FSVP guidance. Discussion of this issue also should be added to the Chapter 15 guidance.

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On behalf of ASTA and its members, we thank you for the opportunity to provide input on this important subject and respectfully request your consideration of our comments.

Sincerely,

Cheryl Deem
Executive Director