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

Re: Food and Drug Administration, HHS
Docket No. FDA–2011–N–0143-0023
78 *Federal Register* 45730 (July 29, 2013)

To Whom It May Concern:

We appreciate the opportunity to submit comments under the "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals," 78 *Fed. Reg*. 45730 (July 29, 2013) in which FDA proposes to adopt regulations on foreign supplier verification programs (FSVPs) that importers must create and follow to help ensure the safety of imported food.

American Spice Trade Association

The American Spice Trade Association (ASTA) was established in 1907 to provide representation for the American spice trade. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. On behalf of its members, ASTA works with federal and state regulators and legislators and assists its members in addressing a variety of technical issues to help members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

FDA Role to Protect Public Health and the Food Supply

Passage of the FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, underscored the role of the Food and Drug Administration (FDA) to protect human health and the critical mission it plays in ensuring that our nation's food supply is safe. The proposed rule on FSVPs is intended to provide adequate assurances that food imported into the United States is produced in a manner that provides the same level of public health protection as foods produced domestically as required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the Federal Food Drug, and Cosmetic Act (FD&C Act), as appropriate, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C

Act. The FSVP will operate in conjunction with other proposed FSMA rules to build a food safety system that makes science-, and risk-based food safety programs the norm across all sectors of the food system.

Food Safety – Our Highest Priority

ASTA shares FDA's commitment to safety. The highest priority of ASTA and its members is providing clean, safe spices to their customers: food manufacturers and consumers. ASTA continues to actively engage in the regulatory process by providing comment to FDA. ASTA also continues to provide needed resources to members to share with the entire supply chain as possible including tools to assist in the manufacturing, handling and processing of clean safe spices. We recently published *Clean Safe Spices, Guidance from the American Spice Trade Association* to provide industry with information and tools to mitigate the risk of filth and microbial contamination. This critical resource was cited as a reference in the proposed FSMA rule for preventive controls for human food. ASTA has submitted this document as part of the preventive controls rule comment submission.

ASTA General Comments on the FSVP Rule

Generally speaking, ASTA agrees with FDA's overall principle that supplier verification should follow a flexible risk-based approach that is built on proven and well-accepted supplier assessment principles. The FSVP should align with successful programs already in place by leading performers in industry, without being overly burdensome and restricting trade. However, ASTA urges that FDA be focused on measuring the outcomes achieving the standard as opposed to being overly prescriptive in mandating specific steps that must be carried out to get there as one size does not fit all. In some aspects of the FSVP rule, we urge a different approach than what FDA has proposed.

FSVP Proposed Regulation Requirements

Hazard Analysis and Evaluation – FDA should simplify its approach to supplier verification by eliminating the requirement to conduct a hazard analysis of the "hazards reasonably likely to occur" for the imported food and food ingredients. Instead, importers should take a more holistic approach and consider both ingredient risk and supplier risk for the foods that they import. Importers should be given the flexibility to conduct their own analysis or review as appropriate for their product and process. The risk analysis should identify, for example, whether the imported product is raw and will be processed in the U.S. or already ready-to-eat such that the foreign supplier is responsible for controlling the hazards. Many imported spices are raw agricultural commodities that will be further processed in the U.S., such that the importer controls the hazards. In these situations, an understanding of who controls the hazard should be sufficient without requiring further evaluation or application of verification activities. Thus, we support FDA's proposed focus on who controls the hazards (whether biological, chemical, physical, or radiological) because there is no need to verify suppliers when the hazards are being controlled domestically, here in the U.S.

We agree that it would be best to address intentionally introduced hazards as part of a separate rulemaking and not in this proposal

With regard to hazard evaluation, FDA's proposal lists myriad factors that would need to be evaluated. Although the list of factors is a good start to provide as example of what types of factors should be considered in hazard evaluation, ASTA urges caution in mandating a specific "check list" of hazard evaluation. Instead, FDA should provide industry the ability to make these decisions based on their unique circumstances and these decisions should be risk based.

Hazards Controlled by the Importer – ASTA recognizes that certain hazards associated with an imported food will many times be controlled through actions that an importer takes after the food is brought into the United States. ASTA fully agrees with this concept, as many of our members control the hazards in spices themselves after the product is imported to the U.S., which mitigates the need for supplier verification. Proposed § 1.506(e) states that for a hazard that the importer has identified as reasonably likely to occur (RLTO)[1] with a food that the importer itself will control, the importer must document, at least annually, that it has established and is following procedures that adequately control the hazard. If the importer of a food concludes that a hazard is not RLTO or has established validated preventive controls to ensure that an RLTO hazard is adequately controlled, there would be no need for the importer to conduct a foreign supplier verification activity with respect to that hazard.

As an example many times raw agricultural commodity spices are imported for use as an ingredient in other products that will undergo further processing and are not intended to go directly into commerce. In these instances it is likely that the importer would identify *Salmonella* as a hazard reasonably likely to occur in the raw agricultural commodity spice and the importer in this scenario would not need to conduct a verification activity with respect to the *Salmonella* hazard if the importer itself will be treating the raw agricultural commodity spice using a process validated to adequately reduce *Salmonella*. Alternatively, a spice processor could blend a number of raw spices and verify that their customer has a process validated to adequately reduce *Salmonella.* ASTA firmly believes that importers that control the hazards in these spices that they import should document their, or their customer's, control of the hazards. However, it should be adequate that the Food Safety Plan demonstrates control of the hazards regardless where the control is performed. Development of separate or additional documentation for the FSVP would be unnecessary and redundant. ASTA further acknowledges and firmly believes that spices imported as ready-to-eat product that will go directly into commerce should be free from any RLTO hazards and should be subject to supplier verification (including testing) to verify their safety.

ASTA has developed a pilot to differentiate between raw agricultural commodity spices intended for further processing and ready-to-eat spices at the time of entry. This has been shared with FDA's Center for Food Safety and Applied Nutrition staff on April 15, 2013. ASTA urges that FDA move forward with this important delineation to allow for resources to more efficiently and effectively be focused when conducting border inspections. ASTA stands ready to work with FDA on this important matter.

Also, when considering whether a supplier is controlling a hazard, ASTA urges FDA to provide additional clarification and better define validation and publish guidance on this subject. One of the five key recommendations in ASTA's Clean, Safe Spices Guidance is to use validated microbial reduction techniques. As a tool for the spice industry, ASTA has published a white paper that provides an overview of essential elements for companies to consider in developing programs to validate the microbial reduction processes they use. ASTA urges that FDA recognize and accept this important resource in the published guidance.

Foreign Supplier – Under the proposed definition of "foreign supplier," our members sometimes would need to go more than one-step back in the chain to engage in supplier verification. In some instances, they may have to go all of the way back to the farm, even though there are often middle entities like brokers before the spice reaches the importer. We are concerned that this requirement exceeds FDA's legal authority for traceability. Every party in the supply chain should only be required to go one step back to their

[1] Our preventive controls comments urged the agency to use the phrase "known or reasonably foreseeable" instead of "reasonably likely to occur." However, we are using the term "reasonably likely to occur" here because it is used in the FSVP proposed rule. Nevertheless, a wording change in this regulation would be appropriate for the same reasons discussed in our preventive controls comments.

immediate supplier. Part of this verification should consider whether that supplier has its own supplier verification program.

Compliance Status Review – ASTA agrees that as part of a verification system companies should take into consideration a potential supplier's track record to confirm they are in good standing with FDA. However, we are concerned with the proposed requirement to conduct this review on an "ongoing" basis because that implies that constant review in perpetuity. We also are concerned by the challenges of finding relevant information on the agency's website and the potential penalties for failing to identify relevant information that is difficult to locate.

The agency specifically requests comments on "what compliance information about a food or foreign supplier an importer should be required to obtain and consider as part of its food/supplier compliance status review. We also request comment on whether this information should include information about a foreign supplier's compliance standing with the food safety authority of the country in which it is located." 78 Fed. Reg. 45749. As currently drafted, the proposed rule misses a critical component. A regulatory action involving a supplier should not automatically disqualify them from being a supplier. In as much as it is important to review compliance information in the public domain (e.g., Warning Letters, Importer Alerts), ASTA believes that it is even more important to assess the potential supplier's response to any compliance action and assess the supplier based on their corrective actions and subsequent track record. As this information is not typically available from FDA, it will need to be requested from the supplier when relevant regulatory findings are identified. Moreover, FDA compliance history is only one aspect of "supplier risk" and should be subsumed within that broader framework.

Verification Activities – Of the two options presented by FDA for foreign supplier verification activities, ASTA supports Option 2 and strongly opposes requiring Option 1 for all importers.

First, Option 2 would provide needed flexibility for importers to determine what appropriate verification activities are necessary for each unique supplier based on FDA regulatory compliance history, their "track record" as a supplier, intended use, and other factors. Option 1 is a more straightforward "check the box" approach" that may be easier for some smaller companies that lack the knowledge about how to truly assess supplier risk—but this does not mean it is the right approach for food safety. Option 1 is too broad because mandating mandatory on-site auditing of every ingredient supplier that controls a significant hazard on an annual basis – into perpetuity – is unachievable, over burdensome and costly. In particular, this Option does not account for the supplier that has a robust food safety program and, based on its track record, does not warrant an annual audit.

We are also concerned that many supplier risks would be overlooked if the system achieves FDA's goal of a single, "gold standard" annual audit. Instead, a comprehensive approach is needed where each supplier is audited when appropriate and necessary, based on a combination of ingredient risk and supplier risk. This approach would allow oversight of suppliers to be properly titrated according to need. For these reasons ASTA urges FDA to implement Option 2.

ASTA urges that FDA continue to provide flexibility to choose verification activities. These activities could include onsite auditing of the foreign supplier, periodic or lot-by-lot sampling and testing, periodic review of the supplier's food safety records, and any other procedure that an importer has established as being appropriate to verify adequate control of a hazard. However, again ASTA reiterates that the importer is in the best position to determine the appropriate steps necessary for their unique situation and the rules should be results based as opposed to overly prescriptive.

Qualified Auditors – FDA requests comment regarding whether to only allow FSVP audits to be conducted by FDA-accredited third-party auditors. ASTA opposes such a requirement. FSVP audits should be able to be conducted by any appropriately qualified auditor, regardless of whether they are accredited by FDA.

List of Foreign Suppliers – Proposed § 1.506(a) would require importers to maintain a written list of the foreign suppliers from whom they are importing food and FDA requests comment on how the information should be identified. In the Federal Register notice, FDA indicates this information would be accessible to the agency under proposed § 1.510(b) and requests comment on whether the identity of the foreign supplier of the food should be provided when the food is offered for import, along with the importer information that must be provided under proposed § 1.509(c). ASTA considers the identity of the supplier to be confidential business information. We strongly oppose a requirement to provide FDA with this proprietary information that is safeguarded under intellectual property protections on a routine basis. FDA should only access this information in emergency situations under FD&C Act section 414 (Bioterrorism Act). As long as the company is keeping the written list and can quickly provide it to FDA in the event of a public health incident, this information should be securely and confidentially kept. Confidentiality is critical in the supply chain.

Reassessment – ASTA supports FDA's position in regards to reassessing the effectiveness of a company's FSVP on a regular basis or when the company becomes aware of new information about potential hazards associated with a food. It is important that processes are in place to insure necessary steps are being taken to provide a safe food supply. Requiring review every three years, however, seems arbitrary. Instead, reassessment simply should be required as new information arises about a change in a potential hazard associated with that particular food. We believe this approach would reserve the flexibility necessary for each company to tailor its program to its own circumstances.

DUNS Number – Instead of requiring DUNs numbers as has been proposed in the FSVP rule, ASTA suggests that FDA should use an existing resource. We are concerned that DUNs do not provide adequate protections for confidentiality and also question whether FDA has the legal authority to require importers to engage in this additional registration step. The Prior Notice form can serve as a source of identifying the importer as opposed to requiring what amounts to a new registration requirement for importers. The Prior Notice form that is required of all food imports lists the name of the U.S. owner and consignee. This information can be imported into an FSVP system just like the DUNs would while eliminating a potential and unnecessary burden to business created by the use of DUNs numbers. Further, to identify the U.S. agent for FSVP where necessary, another box could simply be added to the Prior Notice form.

Records Related Issues – We oppose the requirement to provide FDA with remote access to an importer's FSVP records because there is no legal authority for doing so. We also oppose the requirement to maintain FSVP records in English, as some importers do not speak English as their first language. We also support an exemption for electronic FSVP records from 21 CFR Part 11.

Confidentiality – Supplier records are typically held in strict confidence. FDA should train investigators to understand the broad scope of supplier verification materials protected from public disclosure under the Freedom of Information Act. We also encourage the agency to apply special protections for audit reports, so that FDA auditors do not review these reports during inspections. Otherwise, there will be a strong disincentive for suppliers to allow thorough audits. Instead, FDA should only be able to review information about the most significant corrective actions from supplier audits.

Modified Requirements for Very Small Food Importers and Importers of Food from Very Small Foreign Suppliers

ASTA includes members of the spice industry from small, family owned businesses to large food companies, and many that fall in between. ASTA reiterates our commitment to food safety and urges FDA to be mindful of the challenges for very small foreign suppliers and very small importers to come into compliance with the FSVP regulations. We urge the agency to consider giving these entities additional time to comply, beyond the three years proposed, and also to commit to engaging in capacity building and education to help improve their knowledge and performance. Food safety does not discriminate between suppliers based on size, so everyone in the food chain needs to do their part to make food safe. We urge FDA to work with very small importers that will require assistance in developing their verification programs.

Food from Countries with Officially Recognized or Equivalent Food Safety Systems

ASTA fully supports FDA's position to allow modified FSVP requirements for foods in good compliance standing with a country's food safety authority that has been officially recognized or deemed equivalent by FDA as meeting the same food safety standard of the United States. ASTA also urges FDA to continue to look for opportunities to continue these partnerships. We also encourage FDA to expedite its efforts in this area to conduct additional assessments, beyond New Zealand, as soon as possible.

Compliance with International Agreements

In light of the enormous mandate of insuring a safe supply of imported foods combined with the Congressionally-mandated increase of foreign inspections that must be conducted, ASTA believes it is critical for FDA to focus inspection resources based on risk. Furthermore, whenever possible, acceptance of Codex Alimentarius Commission (Codex) and industry accepted practices will be critical in implementation. It is also critical to note that requirements placed on imports be equivalent to domestically produced standards to alleviate any trade issues and potential World Trade Organization (WTO) disputes. Therefore, if a supplier has been verified under the FSVP they should not also have to be verified under the preventive controls regulation. Furthermore, FDA agrees that "FSMA also states (in section 404) that the provisions of the act and any amendments to the FD&C Act may not be construed in a way that is inconsistent with the agreement establishing the World Trade Organization (WTO) or any other treaty or international agreement to which the United States is a party. The FSVP provisions in FSMA ensure that U.S. importers, who are domestic entities, share responsibility for food safety with the foreign suppliers of those foods by requiring that importers perform risk-based supplier verification activities. This requirement, in conjunction with FDA oversight of importers, is vital to ensuring a consistent level of protection for domestic and imported foods." 78 Fed. Reg. 45740.

Intra-Company Multinational Shipments

FDA requested comment on foreign supplier verification for importing food from companies under the same corporate ownership as the importer. ASTA strongly urges that since the food is within the possession of the same company that it would make sense that verification of foreign supplier would not be necessary in this case. This is an unnecessary step as a company would be verifying themselves as the supplier and resources should be spent on risk-reducing verification activities.

Summary

ASTA and its members are committed to ensuring the safety of spices. Due to the complexities of these proposed FSMA rules and the likely major modifications that the rules will undergo during the promulgation process, ASTA strongly encourages that the rules be re-published for further review before proposing a final rule.

We thank you for the opportunity to comment on this proposed rule and respectfully request your consideration as you draft the final rule on the proposed foreign supplier verification program.

Sincerely,

Cheryl Deem
Executive Director