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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
79 *Federal Register* 58524 (September 29, 2014)

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", 79 *Fed. Reg*. 58574 (September 29, 2014) in which FDA proposes to revise the currently proposed requirements concerning compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities. In the Federal Register notice, FDA indicates coordination with revisions currently being made on the proposed rule on current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food. ASTA strongly supports the concept of a coordinated deliberation of these two integral rules of the Food Safety Modernization Acct.

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

Foreign Supplier Verification Program for importers of food for humans and animals rule 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. Because nearly all spices are grown overseas and imported into the United States, this supplemental proposal is of vital interest to our members.

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, food service, and consumers. ASTA continues to actively engage in the regulatory process by providing comments to FDA. Food safety and education are core parts of our mission and we continue to collaborate with FDA on these efforts. ASTA also continues to provide needed resources to members to share with the entire supply chain as much as possible, including tools to assist in the manufacturing, handling and processing of clean safe spices, including the *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 and will be reiterated in comments on the supplemental proposal addressing the preventive controls rule.

Additionally, since these proposed rules were originally published in 2013, ASTA has provided comments to the FDA on the Draft Risk Profile on Pathogens and Filth in Spices, which we strongly urge FDA also take into account as the FSMA rules are finalized.

ASTA General Comments on the Supplemental Proposal on the FSVP Rule

ASTA agrees with FDA's principle that supplier verification should follow a flexible risk-based approach that is built on proven and well-accepted supplier assessment principles. The supplemental proposal appears to better provide a framework for the FSVP to align with successful programs already in place by leading performers in industry, without being overly burdensome and restricting trade. In our previous comments ASTA urged that FDA be focused on measuring the outcomes achieving the standard as opposed to being overly prescriptive in mandating specific steps required to comply as one size does not fit all. We appreciate the changes to the revised supplemental proposal to simplify the approach, particularly by eliminating the requirement for supplier verification where the hazard is controlled by the importer/receiving company or by a downstream customer and, as appropriate, allowing importers to consider both ingredient risk and supplier risk for the foods that they import.

We agree with FDA that risk analysis for foreign suppliers should identify, for example, whether the imported product is raw and will be processed in the U.S. or is ready-to-eat such that the

foreign supplier is responsible for controlling the hazards. As we have noted in previous comments on the FSMA proposed rules, and in our submission on the Draft Risk Profile, many imported spices are raw agricultural commodities that will be further processed in the U.S., such that the importer or U.S.-based customer 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 on those suppliers which do not take on the role of controlling the hazards. Thus, we support FDA's proposed focus on who controls the hazards (whether biological, chemical or physical) because there is no need to verify suppliers when the hazards are being controlled domestically, here in the U.S.

In regards to FDA's proposal to add hazards that may be intentionally introduced for purposes of economic gain to the types of known or reasonably foreseeable hazards that an importer would be required to consider in hazard analysis under the FSVP rule, ASTA again strongly urges FDA that it would be best to address intentionally introduced hazards (or economically motivated adulteration (EMA) as FDA refers to it in the supplemental proposal) as part of a separate rulemaking and not in this proposal. With regard to the hazard evaluation that would be needed for EMA, FDA's supplemental proposal lists myriad factors that would need to be evaluated. Feedback from our members confirms that it would be difficult if not impossible to differentiate the reason of introduction and that further deliberation will be needed on this topic to adequately address it. Accordingly, we would encourage FDA to defer any regulations addressing EMA until after FDA has completed the 7 major rulemakings.

Point of Agreement with the FDA's Supplemental Proposal

In addition to our strong agreement that supplier verification is not needed when the importer or importer's customer controls the hazard, we agree with FDA on the following elements of the supplemental proposal:

- Focus on Both Food Risk and Supplier Risk: We strongly support FDA's modification to supplier verification responsibilities to focus on both food risk and supplier risk. This is consistent with industry practices and promotes a holistic approach to supplier oversight.

- Ability to Select a Different Approach for SAHCODHA Hazards: We agree with FDA's proposal to provide flexibility in selecting verification activities where the supplier controls a hazard that presents a risk of serious adverse health consequences or death to humans or animals (SAHCODHA). Companies should be able to document their basis for concluding that an approach other than annual onsite audits is appropriate for a supplier controlling SAHCODHA hazards, including the ability to consider the risk profile (such as the track record) of the supplier.

- No Written List of Suppliers: We agree with the agency that companies should not be required to maintain a list of suppliers, but instead should be required to have in place procedures to ensure that food is only received from approved suppliers. We also agree that unapproved suppliers may be used on a temporary basis, when necessary and appropriate, to the extent the food has been verified before use or distribution.

- No Stand-alone Requirement for a Compliance Status Review: We support FDA's deletion of the proposed requirement for a separate compliance status review. The newly proposed requirement to consider compliance history as part of the overall assessment of supplier risk is more appropriate.

- Confidentiality of Audit Reports: We support FDA's recognition that the confidentiality of the full audit report must be maintained to encourage open and honest audits of suppliers. Absent such confidentiality, suppliers may be reluctant to submit to the transparent type of audit needed for a successful supplier verification activity.

- Deemed Compliance: We endorse the approach proposed by the agency for importers that are also subject to the domestic supplier verification program, under which companies in compliance with the domestic supplier verification requirements are deemed to be in compliance with most FSVP requirements. This approach appropriately focuses on food safety and avoids duplication.

FDA's Request for Feedback on Specific Provisions of the FSVP Supplemental Rule

ASTA provides comment to the specific requests for feedback in the Federal Register notice as indicated below.

Hazard Analysis - Intentional Hazards (Revisions Regarding Intentional Hazards)

In the supplemental proposals to the FSVP Rule, FDA is *"proposing to add hazards that may be intentionally introduced for purposes of economic gain to the types of known or reasonably foreseeable hazards that an importer would be required to consider."* 79 Fed Reg. 58581, further stating that "Importers need only consider those economically motivated adulterants that are reasonably likely to harm consumers' health, not economically motivated adulterants that solely affect quality or value."

Potential for Economically Motivated Adulteration (EMA) of Imports

In a report commissioned by the Dept. of Homeland Security and funded by the Natl. Center for Food Protection and Defense (Univ. of Minnesota), Food Fraud (i.e. EMA) was defined as a collective term that encompasses the deliberate substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging, or false or misleading statements made about a product for economic gain. There are numerous examples of EMA throughout history involving many food products including spices and herbs.

The three main categories of EMA in Foods are: (1) Complete or partial replacement of a food ingredient or valuable authentic constituent with a less expensive substitute without the purchasers' knowledge, (2) The addition of non-authentic substance to mask inferior quality ingredient without the purchasers' knowledge, and (3.) Removal of an authentic and valuable constituent without the purchasers' knowledge.

While there are documented examples of each of these types of EMA throughout history, types 1 and 2 above can clearly result in serious public health consequences if the substitute or added

non-authentic ingredient is an undeclared allergen, a non-food grade chemical, a toxic ingredient, etc. In some circumstances, EMA can be food safety risks that, if known, have to be part of a company's raw material risk assessment process for this type of ingredient. As such, the risks inherent in these types of raw materials should be identified in a company's food safety plan and mitigated through the implementation of preventive controls for both raw material sourcing and supplier approval.

As such, ASTA works to provide guidance to members when an occurrence of EMA of spices happens. We work with our Food Safety and Government Relations and Advocacy Committees to formulate courses of action for our membership, including the development of ASTA analytical procedures to detect and identify the adulterant in the spice product. This course of action is followed for all three types of EMA identified above, whether it is a Food Safety issue or a Quality/Value issue.

However, many types of EMA are not food safety issues at all, but are product quality or product value issues. Since many of these types of EMA can be unique to a specific product, from a specific country purchased through a specific vendor that has done business with a specific collector, it is a very complex issue that needs much more than a brief mention within the Preventive Controls and Supplier Verification regulations of the Food Safety Modernization Act (FSMA), and it requires careful thought and deliberation on how to adequately address the issue.

There is an opportunity for ASTA as well as other industry associations to work with the FDA in defining and setting forth reasonable and logical risk assessment guidelines regarding spices as they relate to Food Safety Issues, Economic Adulteration and Quality Issues. We agree with the FDA that any regulations developed to address EMA should only focus on food safety issues and not quality issues.

In summary, EMA of food incidents present a particular challenge to the food industry and regulators alike because they are deliberate acts that are intended to evade detection. It is clear that changes in regulatory systems (i.e. FSMA implementation) and the implementation of novel, non-traditional testing methodologies and other deterrent strategies need to be developed and deployed. As such, ASTA believes the food industry-wide issue of EMA is best served and addressed under a future FDA regulation specific to the unique characteristics surrounding the intentional adulteration of food products, the need for innovative methods for detecting it and for targeting crucial resources toward the riskiest of food products.

<u>Supplier Verification - List of Foreign Suppliers (Revisions Regarding Process for Confirming Receipt of Food from Approved Suppliers)</u>

In the supplemental proposal on FSVP, it is proposed that FDA *"would permit the use of unapproved foreign suppliers on a temporary basis when necessary and appropriate, provided that the importer subjects the food from such suppliers to adequate verification activities before using or distributing the food. The importer's written procedures regarding the use of approved suppliers also would need to address the circumstances under which unapproved suppliers might be used, and the importer would need to document the verification activities it conducts when using unapproved supplies. "*

"*We request comment on circumstances under which it might be necessary and appropriate to receive food from unapproved foreign suppliers and on the types of verification activities than an importer should conduct on food from an unapproved supplier."*

ASTA supports FDA's position that there may be certain circumstances when utilizing unapproved foreign suppliers on a temporary basis may be warranted. Providing flexibility to importers in such circumstances to prevent disruption in the supply chain would be acceptable and welcome, dependent on adequate assurances are in place that the product has been determined safe through appropriate risk assessment.

Supplier Verification - Food from Farms That Are Not Covered Farms Under the Proposed Produce Safety Rule

In the supplemental proposal it indicates "*under §1.506(d)(4) in the revised regulatory text, if a foreign supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with §112.4 regarding the food being imported, the importer would not be subject to the FSVP supplier verification activities in revised §1.506(d)(1) and (d)(2) if the importer…."* FDA goes on to state *"we request comment on the proposed alternative method of supplier verification of obtaining written assurance of compliance with the FD&C Act by these farms."* 79 Fed Reg 58586

ASTA agrees with FDA that where an importer receives food from a supplier that is a farm that is exempt from the requirements for produce safety under FSMA, it should be exempt from conducting supplier verification activities. However, this exemption would be contingent upon obtaining a letter of assurance from each such farm that it is producing the food in compliance with the Federal Food, Drug, and Cosmetic Act.

We have concerns with this documentation requirement as it applies to commingled raw agricultural commodities, because in most cases the identity of the farm supplying the produce is simply not known. Raw agricultural commodities may be grown by hundreds of small farmers and then shipped to a cooperative or distributor, where they are commingled and then shipped to the importer. Neither the cooperative/distributor nor the importer has the ability to trace the individual farms that harvested the produce. Moreover, for produce that is exempt from the produce safety rule, FDA has already made a determination that the produce is of minimal or no risk, thus justifying the exemption. Adopting a documentation requirement for these commodities would therefore not add to food safety, but would impose considerable recordkeeping burdens.

For these reasons, ASTA strongly recommend that FDA delete the proposed requirement in § 1.505(d)(4)(ii) to obtain letters of assurance from farms exempt from the produce safety rule.

Supplier Verification – Criteria for Qualified Individuals Conducting Verification Activities

ASTA urges FDA to provide additional detail and clarity on the qualifications that would be required for a person to be considered adequate to meet the "qualified individual" that is able to

conduct and oversee verification activities as required by FSMA. Companies will need to have a better understanding whether or not their current employees meet this standard and need time to plan accordingly in order to fully comply with the FSVP.

Definitions of Very Small Importer and Very Small Foreign Supplier

FDA requests comment on *"whether the revised proposed monetary value ceiling of $1 million adjusted for inflation, for very small importers and very small foreign suppliers is appropriate, as well as on whether it is appropriate that the ceiling be the same as that specified in the definition of very small business under the preventive controls regulations."* 79 Fed Reg 58588

ASTA reaffirms our position previously submitted that urges FDA to be mindful of the challenges for very small foreign suppliers and very small importers to come into compliance with FSVP regulations. We urge FDA to provide additional time to comply, beyond the three years proposed, and also to commit to engaging in capacity building and education to assist these small entities with the knowledge necessary for them to perform adequately to meet the new mandates. We do however note again that food safety does not discriminate between suppliers based on size so it is imperative that the entire supply chain works toward the safety of the food supply. We continue to urge FDA to work with the very small importers and very small foreign suppliers, many of whom are not ASTA members, which will require additional assistance and guidance in developing appropriate supplier verification activities.

Conclusion

ASTA and its members thank you for providing an additional opportunity to comment on particular portions of the proposed FSVP rule. We are committed to ensuring the safety of spices and are always appreciative of providing constructive dialogue on the FSMA rules.
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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