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August 19, 2015

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–0144
80 *Federal Register* 32136 (June 5, 2015)

To Whom It May Concern:

We appreciate the opportunity to submit comments under the "Draft Guidance for Industry on the Voluntary Qualified Importer Program for Food Importers and Guidelines in Consideration of the Burden of the Voluntary Qualified Importer Program Fee Amounts on Small Business; Availability", 80 *Fed. Reg*. 32136 (June 5, 2015) in which FDA announced the publication of draft guidance for industry on the Voluntary Qualified Importers Program (VQIP) for importers of human or animal food. The notice includes information on: the eligibility criteria for and benefits of participation in VQIP; submitting an application for VQIP; obtaining facility certification under VQIP; foreign supplier certification; proposed user fees associated with VQIP; conditions that might result in revocation; and, criteria for reinstatement of eligibility.

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, including FDA, as well as 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. With the majority of spices consumed in the United States being imported, insuring the safety of clean, safe spices to be imported is of great interest to our organization, our members, the spice industry and our consumers.

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.

Section 302 of FSMA amended the Federal Food, Drug and Cosmetic Act (FD&C Act) by adding section 806, Voluntary Qualified Importer Program (21 U.S.C. 384b). As proposed, VQIP would establish a voluntary fee-based program for the expedited review of foods from importers who have demonstrated, achieved and maintained a high level of control over the safety and security of their supply chains. Such a program is envisioned 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 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. VQIP would incentivize importers by providing expedited entry to those that maintain a robust system of supply chain management to ensure their food products are safe and allow FDA to focus resources on food shipments that pose higher risk to public health.

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, including food manufacturers, food service, and consumers. Food safety and education are core parts of ASTA's mission and the Association continues to collaborate with FDA on these efforts by remaining actively engaged in the regulatory process by providing comments to FDA. ASTA also provides robust resources to its members which members can share with their entire supply chain, as much as possible. ASTA resources include the *Clean Safe Spices, Guidance from the American Spice Trade Association*, published in March 2011, a tool to assist in the manufacturing, handling and processing of clean safe spices designed to mitigate the risk of filth and microbial contamination. This critical resource was cited as a reference in the proposed FSMA rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (78 *Fed. Reg*. 3646 at 3666 (January 16, 2013)). ASTA submitted its *Clean Safe Spice* guidance document as part of its FSMA rules comment development packet in order for FDA to include the guidance document in the public domain and broaden the reach of this useful information on spices. Another valuable resource published in April 2015 is the ASTA Good Manufacturing Practices Guide which covers a wide range of issues pertinent to food safety and the manufacturing of spices.

ASTA General Comments on the VQIP Draft Guidance and Proposed User Fees

ASTA generally agrees in principle that a VQIP program could be beneficial as it would provide for expedited entry into the United States for those foods included in an approved VQIP application from importers who have demonstrated, achieved and maintained a high level of control over the safety and security of their supply chains. ASTA further agrees that such a program could 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. ASTA maintains that if

implemented thoughtfully and equitably, VQIP would allow FDA to focus its limited resources on food shipments that pose a higher risk to public health while providing expedited entry to those that maintain a robust system of supply chain management to ensure their food products are safe. However, ASTA requests FDA consider the following comments:

VQIP application procedures and fee structure should incentivize participation from all importers maintaining a robust system of supply chain management and food safety – not just from large importers

It is imperative that VQIP be developed in such a way that access to the program is equitable and allow for unencumbered trade. The VQIP application procedures and fee structure should not be so onerous as to place smaller companies at a competitive disadvantage relative to those larger importers better able to absorb the administrative and/or monetary costs associated with VQIP than their smaller competitors. A level playing field for applicants of all sizes that have demonstrated, achieved and maintained a high level of control over the safety and security of their supply chains is critical. Costs, including both tangible and indirect, associated with the application preparation and submission as well as the monetary costs of the fees imposed for entry into the program should be manageable and not prevent smaller entities from participation.

Meeting and exceeding food safety compliance standards should be rewarded. Food safety does not discriminate. Just as compliance should not be minimized or a lower standard created for smaller companies to achieve, entry and accessibility into a program to reward good behavior should not discriminate based on company size but instead on the record of ensuring an adequate supply of safe food.

Accessibility to VQIP should be affordable

The cumulative costs of applying for the VQIP program as currently outlined are prohibitive for most companies. FDA estimated that the agency's total costs to administer VQIP in fiscal year 2018 will be $3.4 million. Based on this estimate, FDA proposed a flat $16,400 fee to be paid by all VQIP participants. (*see* 80 *Fed. Reg*. 32136 and 32137-32138 (June 5, 2015)). ASTA members, primarily smaller companies, believe fees at that level are greater than the perceived benefit and would deter applicants, even those that meet the high bar of providing adequate assurances for food safety that FDA envisions.

FDA requested feedback on the proposed user fees associated with the VQIP application. As we suggested above, a flat $16,400 fee for all participants may pose a burden on smaller importers. Therefore, we request that FDA consider a fee structure based on volume of product to be imported into the US under the VQIP Program. For example, fees could be based on the number of entries expected annually as extrapolated from previous year's data. The higher the number of shipments would result in a higher fee while a company with a lower number of shipments, would pay a lower application fee. A graduated cost structure could be employed being capped at the proposed $16,400 fee. This approach could attract and incentivize a larger range of importers that meet and exceed food safety compliance required under FSMA and who would be willing and able to apply to participate in the voluntary program.

Application submission and records, streamlined processes and confidentiality

FDA should eliminate or minimize the duplication of work required to complete the VQIP application and comply with other FSMA regulations. FSMA requires a great deal of record keeping in a variety of contexts, with each of the major FSMA rules setting specific requirements that when combined with the six other rules is overwhelming, especially for small businesses.

FDA should consider minimizing duplication whenever possible to meet requirements of other FSMA rules or provide a mechanism that would recognize compliance. For example, a signed affidavit could be submitted as part of the VQIP application to demonstrate the applicant has met the records requirements of FSMA preventive controls and foreign supplier verification program, and thus the VQIP program. Streamlining the required FSMA paperwork would provide a more seamless process and eliminate duplicative efforts that could free up resources to focus on ensuring a safe food supply. In the economic analysis FDA estimates it will take applicants 80 hours to complete the VQIP application. Dedicating 80 staff hours to complete a single VQIP application presents a significant burden especially for small importers with limited staff. We ask that required documentation be streamlined as much as possible to minimize that burden without eliminating the information FDA needs for VQIP administration.

Confidentiality of business information must be maintained as required by all applicable federal laws. The risk of a breach or disclosure of confidential business information increases as the volume of records and regulatory submission grows, despite the good faith efforts of FDA to maintain proprietary business information as confidential. There have been significant data breaches across federal agencies in recent years. If additional records and confidential business information are to be required for submission then the appropriate level of safeguards to maintain confidentiality must also be expanded. In an environment of fiscal instability, flat to modest increases to fund FSMA, and an ever-expanding portfolio of responsibilities that FDA must juggle, it is imperative that resources be utilized as efficiently as possible. Streamlining records requirements among VQIP and the other FSMA food safety rules and the utilization of existing data capture would benefit the FDA and allow the agency to focus efforts on food safety instead while relieving some of the unnecessary and duplicative burden on businesses.

Challenges of VQIP participation for businesses that handle a high number of varying spices and the implications associated with VQIP versus non-VQIP foods.

ASTA requests FDA give additional consideration during development of the final guidance for industry and implementation of VQIP as it relates to importers who handle a variety of spices. An importer with a robust system of supply chain management will likely be eligible to participate in the VQIP program for all of the foods it imports, not just a subset. The benefits of the VQIP program, therefore, should run to the importer and not to the individual foods covered under the VQIP application. In instances when an importer handles a significant number of spices, varying food commodities and/or food ingredients, the current proposal is overly complicated and may deter participation specifically if a change is necessary to procure spices in the supply chain or a new spice is added to a company's portfolio.

In the spice industry suppliers typically supply a range of spices. Unforeseen circumstances such as drought, crop failure, and political situations, can bring about the need to add or subtract

particular spices from various suppliers. By requiring any new individual spices to be VQIP certified and having to wait until the next year to be included in the application package, there would be a significant burden for suppliers to ship VQIP and non-VQIP items separately.

Other challenges to consider are the repercussions associated with product shipment and the need to separate out VQIP versus non-VQIP foods. This process of separation of spices into these two categories would result in added costs to business including employee labor hours to physically separate shipments, economies of scale to send separate shipments that would have otherwise been shipped together, and delays associated with these extra steps. These additional costs as well as the costs of the VQIP program fee would ultimately need to be passed along to the consumer resulting in higher food costs.

As currently proposed, the benefits of the VQIP program are tied to the importer for each separate VQIP food covered under the importer's VQIP application. This is an artificial limitation in the scope of VQIP and adds no public health value. Since the FDA will review all aspects of the importer's VQIP application, conduct an inspection to verify program eligibility and will review an importer's import record across all foods imported by the applicant and not just those covered under the VQIP application, FDA will be well positioned to evaluate the overall robustness of the importer's food safety record, not just the importer's success relative to the VQIP foods covered under its application. As a result, we request FDA to modify its VQIP application requirements such that importers be obligated to attest to the general types of products that will be imported, so that the benefits of VQIP participation run to the importer no matter the foods imported.

Conclusion

ASTA and its members thank you for providing an additional opportunity to comment on the VQIP Draft Guidance for Industry and proposed user fees. We are committed to ensuring the safety of spices and are always appreciative of providing constructive dialogue on the FSMA rules and guidance documents for industry.

We thank you for the opportunity to comment on this notice and respectfully request your consideration as you continue to develop the Voluntary Qualified Importer Program.

Sincerely,

Cheryl Deem
Executive Director