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NSMA
National Seasoning Manufacturers Association

January 27, 2014

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

RE: Docket No. FDA-2011-N-0143
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

Submitted via eRulemaking Portal: http://www.regulations.gov

To Whom It May Concern:

The National Seasoning Manufacturers Association (NSMA) appreciates the opportunity to submit comments on the FSMA proposed rule for "Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals" published in the Federal Register on July 29, 2013.

NSMA is a trade association representing the U.S. seasoning industry. Founded in 1973, our membership manufactures more than 98% of seasonings consumed in the United States. The NSMA is composed of member companies that produce food ingredients including but not limited to seasonings, spices, flavorings, additives, and other vegetable ingredients and derivatives. Given the vast array of ingredients incorporated into the products we produce our membership may be greatly impacted by the FSVP rules.

Food Safety – Our Highest Priority

NSMA shares FDA's commitment to food safety. The highest priority of NSMA and its members is providing safe seasoning and spice products to their customers: food manufacturers and consumers. NSMA continues to actively engage in the regulatory process by providing comment to FDA. NSMA also continues to provide needed resources to members to share with the entire supply chain including guidance to assist in the manufacturing, handling and processing of safe seasonings and spices.

NSMA General Considerations on the FSVP Rule

Supply chain management is a key component in the production of safe food and NSMA believes that supplier verification regulations, while needing to be comprehensive, should also be flexible and incorporate current, successful industry practices. In that regard, NSMA presents the following general considerations for the FSVP regulation:

- Supplier verification regulations should incentivize companies to work with their suppliers to drive continuous improvement in food safety and improve public health outcomes.
- Supplier verification needs to establish that suppliers are following effective food safety programs.
- Supplier verification programs should identify and evaluate the risks presented by both the food and the supplier, not just the hazards associated with the food. The historical track record of the supplier is one of multiple factors that can be considered.

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- Audits are a tool in the verification process and not to be overemphasized. To be effective, audits should be risk-based, assess a supplier's food safety system as a whole, and occur at a frequency tailored to the risks presented by both the supplier and the ingredient(s).
- Confidentiality protections are necessary for supplier audits to be effective and to encourage robust scrutiny and an open dialog. FDA's records access should focus on information that demonstrates that significant corrective actions were taken as needed to assure food safety.
- Supplier verification regulations need to foster a culture of prevention and continuous food safety improvements rather than merely compliance with mandatory annual audits and a detailed review of a supplier's regulatory compliance.
- FDA inspections of supplier verification programs should focus on ensuring importers have well-functioning systems in place. Unless there is cause, the importer's determinations about individual suppliers should not be questioned.
- Supplier verification should be the same regardless of whether a supplier is located domestically or internationally. If a supplier was verified under an FSVP, even if by a third-party, the importer should not be required to engage in verification under preventive controls.

NSMA General Comments on the FSVP Rule

Generally speaking, NSMA 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, NSMA 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 cases, NSMA urges FDA take a differing approach than what the FDA has proposed to address some of the specific requirements in the proposed FSVP rule.

NSMA Comments on Specific FSVP Proposed Rule 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. For example, 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 because there is no need to verify suppliers when the hazards are being controlled domestically (i.e. 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 a myriad of 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, NSMA 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.

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Hazards Controlled by the Importer **–** NSMA 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. NSMA fully agrees with this concept. For example, 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 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 has established validated preventive controls to ensure that a 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 seasoning 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 seasoning processor could blend a number of raw spices and verify that their customer has a process validated to adequately reduce *Salmonella.* NSMA firmly believes that the 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. Development of separate or additional documentation for the FSVP would be unnecessary and redundant. NSMA further acknowledges and firmly believes that spices imported as ready-to-eat product that will go directly into commerce should be free from contamination and should be subject to supplier verification (including testing) to verify their safety.

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

Compliance Status Review **–** NSMA 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), NSMA 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.

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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, NSMA 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, overly 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 NSMA urges FDA to implement Option 2.

NSMA 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 NSMA 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. NSMA 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). NSMA 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 **–** NSMA 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

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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.

Records Related Issues **–** NSMA opposes 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 - NSMA agrees with FDA's proposal that would establish modified FSVP requirements for very small food importers and importers of food from very small foreign suppliers (annual food sales of no more than $500,000). The modified requirement would allow these very small food importers and very small foreign suppliers to obtain written assurance describing the process and procedure that the suppliers used to ensure the safety of the food and in these situations the importer would not need to conduct hazard analysis to do so.

Food from Countries with Officially Recognized or Equivalent Food Safety Systems **-** NSMA 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. NSMA 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, NSMA 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.

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Intra-Company Multinational Shipments - FDA requested comment on foreign supplier verification for importing food from companies under the same corporate ownership as the importer. NSMA 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

The above emphasizes our belief that FDA's supplier verification regulations should not be built entirely on a "hazard based" approach. A responsible manufacturer will engage in some level of due diligence for nearly all of their suppliers. Successful practices currently used by industry should be part of verification. The regulations should be flexible and allow facilities to tailor their programs based on risk, evolve their programs in the years to come, and strive for continuous improvement in food safety without requiring future modification to the regulations to adapt to new developments.

The National Seasoning Manufacturer's Association appreciates the opportunity to provide these comments and we respectfully request your consideration of these comments as you draft the final rule on the proposed foreign supplier verification program. Due to the complexities of the proposed FSMA rules and the likely major modifications that these rules will undergo during the promulgation process, NSMA strongly encourages that the rules be re-published for further review before proposing a final rule.

If we can assist the agency with additional information or industry perspective, please do not hesitate to contact us.

Respectfully,

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Executive Director
National Seasoning Manufacturers Association