



## Consumer Federation of America

December 15, 2014

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

**RE: Docket No. FDA 2011-N-0143**

Consumer Federation of America appreciates the opportunity to comment on the Food and Drug Administration's supplemental notice of proposed rulemaking on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals [Docket No. FDA 2011-N-0143]. This rule is fundamental to the prevention of human illnesses from contaminated imported food.

CFA appreciates the efforts FDA has made to draft this rule, seek stakeholder input through public meetings and the public comment process, and remain open to ideas and suggestions to improve the rule. CFA's comments on the supplemental proposal follow.

**Definitions of Very Small Importer and Very Small Foreign Supplier**

FDA proposes to revise its definitions of very small importer and very small foreign supplier as such entities with annual food sales of less than \$1 million. CFA reiterates our opposition to FDA's decision to define these entities and strongly urges FDA to delete the definitions of very small importer and very small foreign supplier, which would exempt these entities from most requirements of the Foreign Supplier Verification Program (FSVP) rule. Congress did not provide an exemption for small importers or foreign suppliers and FDA should not create one. In some countries a foreign supplier with \$1 million in food sales could be considered quite large and could produce a substantial amount of food. Providing an exemption for small importers would undermine the integrity of the FSVP and allow businesses to alter their structures in order to ensure that the importing entity was exempt from the rule. If FDA does move forward with definitions for these entities, FDA should limit annual food sales to \$250,000, consistent with our recommendations on the Preventive Controls Rule and Produce Rule.

**Food and Foreign Supplier Risk Evaluation**

CFA agrees that importers should consider both food and supplier risks, in addition to a supplier's compliance status, in developing their supplier verification plans. This would require importers to consider:

- The entity that will be applying controls for the identified hazards, such as the foreign supplier or foreign supplier's raw material or ingredient supplier;
- The foreign supplier's procedures, processes and practices related to the safety of the food;
- Applicable information regarding the foreign supplier's compliance with food safety regulations, including whether the supplier is the subject of an FDA warning letter or import alert;

- The foreign supplier's food safety performance history, including testing results, audit results and corrective actions;
- Any other relevant factors, including but not limited to storage and transportation practices.

FDA should develop guidance on the specific information that should be considered under each factor to help reduce misinterpretation.

CFA further agrees that an importer should reassess the effectiveness of its FSVP when it becomes aware of new information about potential risks associated with the food or foreign supplier, and that an importer should update its risk evaluation for a food and foreign supplier during an FSVP reassessment. However, FDA should also require that importers conduct a reevaluation of food and supplier risks annually, similar to the requirement that preventive control plans be reevaluated annually. This would provide greater assurance that these risks are being reviewed, at least on an annual basis, and that necessary adjustments are being conducted. Otherwise, importers could go for years without reevaluating food and supplier risks and claim that they had no information to otherwise reevaluate. Further, an annual reevaluation is not overly burdensome; if no changes were required, the importer could simply note that and no more action would be necessary.

### **Hazard Analysis**

CFA agrees that hazards that are intentionally introduced for purposes of economic gain should be included under the types of known or reasonably foreseeable hazards that an importer must consider in its hazard analysis. This is especially important considering high-profile incidents such as the adulteration of milk products and pet food with melamine, particularly for foods or regions in which it is generally known that economic adulteration occurs.

CFA supports the requirement that the hazard evaluation must also include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment to minimize the pathogen. However, consistent with our comments on the preventive controls supplemental proposal, FDA should not limit its requirement for an evaluation of environmental pathogens to ready-to-eat foods. FDA should expand its proposal to require an evaluation in any circumstances in which there is a risk of contamination by an environmental pathogen.

### **Supplier Verification**

CFA agrees that that importers should be required to ensure that a foreign supplier is producing food in compliance with the preventive controls or produce safety regulations, as applicable, as well as with sections 402 (adulteration provision) and 403(w) (allergy labeling) sections of the FD&C Act. This change more closely aligns supplier verification activities with the requirements under FSMA.

FDA proposes that if an importer determines that there are no significant hazards, the importer is not required to conduct any verification activities under 1.505 and 1.506. We believe that a determination that there are no significant hazards would be rare. Even if the product had no inherent hazard, the importer must still consider the condition, function and design of the foreign supplier's procedures, processes and practices; the supplier's compliance history and food safety performance history, as well as other relevant factors. FDA should provide guidance on examples of food in which hazards are not likely to occur, but should note that these other factors may introduce a hazard to the food.

FDA should carefully review any determination by any importer that there is no significant hazard to verify that the agency agrees with that determination. Experience from the Food Safety and Inspection Service's implementation of HACCP showed that many establishments did not identify a significant hazard in their HACCP plans despite FSIS' consideration that all products under its jurisdiction would carry some type of microbiological hazard. This occurred in the early days of HACCP all the way through to more recent years and has led to foodborne illness outbreaks because the hazards were not appropriately identified. Considering this, even if FDA finalizes this provision, importers should have to conduct annual reevaluations to determine whether their finding of no significant hazard is still relevant.

### **Hazards Controlled by the Foreign Supplier**

FDA proposes to require importers to conduct and document one or more supplier verification activities – onsite auditing, sampling and testing of food, review of the foreign supplier's food safety records, or some other appropriate risk-based verification activity. FDA requires importers to conduct this activity initially before importing food and periodically thereafter.

For hazards for which there is a reasonable probability of serious adverse health consequence or death to humans or animals (SAHCODHA), FDA proposes to require importers to conduct initial and annual onsite auditing of the foreign supplier, unless the importer determines that other supplier verification activities or activity frequencies provide adequate assurances regarding the safety of the food.

We reiterate our support for annual onsite audits of foreign suppliers, particularly for SAHCODHA hazards. Onsite inspection of foreign suppliers is essential to provide assurance that the foreign supplier is adequately addressing food safety hazards. As we know from inspection results, onsite verification can identify potential problems in ways that paperwork reviews cannot. Seeing how a foreign supplier is conducting their business onsite is critical.

FDA's allowance of alternative activities assumes that the importer will always choose the best verification option to assure the food is safe rather than a lower level of verification that might cost less. Considering the financial pressures facing food importers, it is easy to envision multiple scenarios when a lower level of verification would be chosen that saves the importer money but is inappropriate for a SAHCODHA hazard.

If FDA does move forward with this proposal, we urge the agency to consider annual onsite audits for SAHCODHA hazards the default action and require importers to affirmatively inform FDA if they are opting to perform any type of variation (another activity or a different activity frequency) from an annual onsite audit. Importers must be able to justify and document how a chosen variation provides the same level of assurance as an annual onsite audit. If FDA permits importers to conduct other types of verification activities or conduct activities at frequencies other than annually, FDA should specify the type of documentation required in order for the agency to determine whether those activities are in compliance with the law and are sufficient to protect the public health.

### **Documentation of Foreign Supplier Verification Audits**

FDA has revised its requirements regarding documentation of supplier verification activities to provide more specifics on what documentation should entail. CFA agrees that the information specified in the proposed rule is important and should be documented and available for review by FDA. For other supplier verification activities that aren't spelled out in the regulations, importers should document the activity, the date it occurs, the findings from the activity, any corrective actions taken, and justification

that this activity provides the same level of assurance as other specified activities, particularly for SAHCODHA hazards.

**Food from Countries with Officially Recognized or Equivalent Food Safety Systems**

If an importer is importing food from a country with an officially recognized or equivalent food safety system, FDA proposes to exempt that importer from all requirements of the FSVP rule except 1.509 and 1.510. CFA reiterates our opposition to this approach.

Regardless of where the importer imports food, the importer should have to implement and maintain an FSVP. This is a best practice and an important way to assure the safety of the supply chain. Just because a country has been deemed comparable by FDA does not mean that everything in that country's food safety system is operating perfectly all the time.

A comparability determination also does not mean that the foreign country is inspecting each supplier on a regular basis. Under FSMA FDA is required to inspect high risk facilities every 3 years and non-high risk facilities every 5 years. It is unclear whether the inspection frequency in "comparable" countries is similar. Regardless, inspection once every three years (or longer) is an insufficient frequency upon which an importer should reliably assess a supplier. The initial FSVP proposed rule proposed annual checks on suppliers. Oversight by the importer of its suppliers through an FSVP is essential, even in countries which FDA has officially recognized. We strongly urge FDA to require all importers to maintain and implement an FSVP regardless of the country from which their suppliers originate.

CFA appreciates the opportunity to provide comments on this important proposed rule. We urge FDA to finalize the rule as soon as possible.

Sincerely,



Chris Waldrop  
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Consumer Federation of America