Consumer Federation of America

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

RE: Docket No. 2011-N-0143

Consumer Federation of America appreciates the opportunity to comment on the Food and Drug Administration's proposed rule 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.

Introduction

Imported foods make up approximately 15 percent of the average American's diet, and in some categories of FDA-regulated foods, imported products are the majority. About 80 percent of seafood consumed in the U.S. is imported; as is about 50 percent of fresh fruits and 20 percent of fresh vegetables. Food and feed imports originate from more than 250,000 foreign establishments in 200 countries each year. Food imports have grown by an average of nearly 10 percent annually from 2002 to 2009.[1] However, FDA is only able to inspect a small fraction (2 percent) of the foods that are imported in the U.S.

It is critical that these imports meet food safety standards set by the FDA. Each year contaminated food causes 48 million illnesses, 130,000 hospitalizations and 3,000 deaths, some of which are caused by imported products.[2] Recent foodborne outbreaks linked to papayas and cucumbers from Mexico, pine nuts and sesame paste from Turkey, and tuna scrape from India only underline the importance of assuring the safety of imported foods. FDA notes that between 2000 and 2007, between 70 percent and 85 percent of import refusals of produce and seafood were for potentially dangerous violations including the presence of pathogens, chemical contamination, and "other sanitary violations."[3] The Centers for Disease Control and Prevention found that from 2005 to 2010, 39 foodborne illness

[1] Food and Drug Administration, "Ensuring a Safe Food Supply: A Report to Congress."
[2] Comment by Stephen Stich, Director, New York State Department of Agriculture and Markets, that 70 percent of 300 recalls issued by the New York State Department of Agricultural Markets were for imported foods, Meeting Transcript, pp. 172-73, (March 29, 2011); Julie Schmit, U.S. Food Imports Outrun FDA Resources, *USA Today*, March 18, 2007 (quoting New York official that 80 percent of food recalls initiated by the State Department of Agriculture and Markets over two years were for imported products and a corporate vice president for food safety that his company sees no difference in the safety of product produced domestically or overseas).
[3] Food and Drug Administration, "Ensuring a Safe Food Supply: A Report to Congress."

outbreaks and 2,348 illnesses were linked to imported food from 15 countries.[4] CDC found that 17 of the outbreaks occurred in 2009 and 2010 and that fish was the most common source of foodborne disease outbreaks followed by spices. The CDC also found that 45 percent of imported foods causing outbreaks came from Asia.

The Food Safety Modernization Act (FSMA), passed with bipartisan support in Congress and signed into law by President Obama in January 2011, shifts FDA's approach to food safety from reaction to prevention, with the goal of reducing foodborne illness among consumers. One of the key provisions of FSMA is the provision requiring importers to develop foreign supplier verification program to assure the safety of food in their supply chains.

CFA urges the FDA to implement its imported food title consistent with the law's prevention-based, public health focus. It is important to remember that FDA is obligated, under FSMA, to conduct inspections of foreign food facilities. In order to provide assurances that foreign plants are producing food safely, FDA must have some presence in these facilities. The Foreign Supplier Verification Program, Voluntary Qualified Importer Program, and the Third Party Certification program are all additive to a robust government inspection program.

CFA generally supports FDA's proposed Foreign Supplier Verification Program. The following four points highlight key issues raised in CFA's comments on the proposed rule. However, CFA provides comments on numerous other provisions in the proposal where changes should be made to better protect consumers.

1. CFA strongly supports Option 1 which would require importers to conduct onsite audits of foreign suppliers for hazards for which there is a reasonable probability of serious adverse health consequence or death to humans or animals. This will provide the greatest protection for consumers from contaminated food.
2. FDA should not exempt importers from FSVP requirements even if they import food from a country with an officially recognized food safety system. Regardless of the source of the food, the importer should have to implement and maintain a FSVP to assure the safety of the supply chain.
3. Importers should consider hazards that may be intentionally introduced, particularly for foods or regions in which it is generally known that economic adulteration occurs.
4. FDA should delete the definitions of very small importer and very small foreign supplier. Congress did not provide for exemptions for these entities in the import provisions of FSMA and they are likely duplicative with other provisions in the law.

Definitions

CFA 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. An importer for purposes of the rule is the U.S. consignee of the food shipment or, if the food has not been consigned or sold at the time of entry, the "U.S. agent or representative of the foreign owner or consignee." 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. Very small foreign suppliers may already be exempt

[4] Centers for Disease Control and Prevention, "CDC research shows outbreaks linked to imported foods increasing." March 14, 2012 via http://www.cdc.gov/media/releases/2012/p0314_foodborne.html.

from the preventive controls and produce safety rules under the Tester Amendment.[5] These entities do not need a duplicative exemption from the verification steps of their U.S. importers.

General Approach

CFA supports FDA's determination that importers must develop, maintain, and implement a Foreign Supplier Verification Program which provides adequate assurances that each of the importer's foreign suppliers produces food in compliance with processes and procedures that provide the same level of public health protection as those required under the FD&C Act. CFA agrees that importers should be required to review the compliance status of foods and foreign suppliers; conduct an analysis of hazards reasonably likely to occur with foods; conduct appropriate foreign supplier verification activities for foods; review complaints and investigate potential adulteration or misbranding; take corrective actions; reassess the FSVP; ensure that required information is submitted at entry; and document and maintain records. CFA further agrees that these activities should be conducted by a qualified individual as defined in the proposed rule.

Hazard Analysis

CFA supports FDA's proposal that importers must determine and document, for each food imported, the hazards that are reasonably likely to occur and the severity of illness or injury if the hazard were to occur. Importers should consider the effect of the ingredients; the condition, function and design of the foreign supplier's establishment and equipment; transportation practices; harvesting, raising, manufacturing, processing and packing procedures; packaging and labeling activities; storage and distribution; intended use; sanitation; and other relevant factors. CFA agrees with FDA that importers must consider biological, chemical, physical and radiological hazards.

FDA seeks comment on whether importers should be required to consider hazards that may be intentionally introduced for economic reasons. FDA notes that the agency will be developing regulations on intentional contamination to implement Section 106 of FSMA. Considering high-profile incidents such as the adulteration of milk products and pet food with melamine, CFA believes it would be appropriate for importers to also consider hazards that may be intentionally introduced, particularly for foods or regions in which it is generally known that economic adulteration occurs. Seafood would be one area in which fraud is known to occur.[6] Based on past history, dairy products and pet food from China would be another.[7] [8] FDA should ensure that the rulemaking to implement Section 106 is consistent with this rule, the Preventive Controls Rule and the Produce Rule with regards to intentional contamination.

FDA also proposes to permit importers to review and evaluate hazard analyses conducted by the foreign supplier in lieu of conducting a separate hazard analysis. CFA tentatively supports this approach, but encourages FDA to require importers to document that this was done and maintain a copy of the foreign supplier's hazard analysis. That would provide some evidence that the importer actually reviewed the supplier's hazard analysis. However, as noted below, importers should still be required to conduct annual onsite audits to verify that suppliers have adequately identified and controlled for hazards.

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[5] FDA Food Safety Modernization Act, sec. 103, §§ 418(l) and 419(f), 124 Stat. 3892-95 and 3903-04 (2011).

[6] GAO, "FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention." GAO-09-258, February 2009.

[7] Food and Drug Administration, "Melamine Pet Food Recall of 2007", accessed 12/19/13 via http://www.fda.gov/animalveterinary/safetyhealth/recallswithdrawals/ucm129575.htm

[8] Weise E, Schmidt J, "Melamine in Pet Food May Not Be Accidental." *USA Today,* April 20, 2007 via http://usatoday30.usatoday.com/money/industries/2007-04-19-pet-food-usat_N.htm

Foreign Supplier Verification Activities

CFA supports FDA's determination that each importer must maintain a written list of their foreign suppliers. CFA also supports FDA's proposal that importers must establish and follow written procedures for conducting foreign supplier verification activities for the foods they import. Written procedures increase the consistency with which importers conduct these activities and provide FDA with an opportunity to review the importer's procedures to verify their effectiveness.

- **No Hazards Identified**

FDA proposes that if an importer determines that no hazard is likely to occur, the importer must only maintain a list of foreign suppliers of this particular food and reassess that determination every three years. CFA believes that a determination that there are no hazards likely to occur 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 establishment and equipment; transportation practices; harvesting, raising, manufacturing, processing and packing procedures; packaging and labeling activities; storage and distribution; intended use; and sanitation 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 no hazard is likely to occur to verify that the agency agrees with that determination. Experience from the Food Safety and Inspection Service's implementation of HACCP showed that many plants did not identify a 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, CFA does not believe a finding of no hazard should stand for three years, as proposed by FDA. An annual reassessment would be more appropriate and more protective of public health, particularly if the initial determination is incorrect.

- **Hazards Controlled by the Importer or the Importer's Customer**

CFA supports FDA's proposal that the importer would have to document annually that it controls identified hazards, or if the importer's customer is controlling the hazards, obtain written assurance from the customer annually. Since FDA is not requiring the importer to conduct other verification activities in these cases, annual documentation is appropriate. This will provide FDA some assurance that the hazards are being considered and controlled on at least an annual basis.

Hazards Controlled or Verified by the Foreign Supplier – Option 1

CFA strongly supports Option 1 which would require importers to conduct onsite audits of foreign suppliers for hazards for which there is a reasonable probability of serious adverse health consequence or death to humans or animals (SAHCODHA). CFA supports FDA's determination that importers must conduct an initial onsite audit before importing the food from a foreign supplier and at least annually, unless more frequent audits are necessary to adequately verify that the hazard is controlled. This is especially important for importers of raw agricultural commodities so CFA also supports Option 1 for importers of raw produce and agrees that annual audits of foreign suppliers of raw produce are appropriate. For other hazards, CFA agrees that importers must conduct one or more of the following: periodic onsite auditing; periodic lot-by-lot sampling and testing of the food; periodic review of the foreign supplier's food safety records; or another appropriate procedure. The last category is extremely vague. If importers decide to rely on "another appropriate procedure," they should document and justify that procedure as providing adequate verification that the supplier is controlling the hazard.

For some hazards such as *Listeria* in soft cheeses, onsite auditing alone is insufficient to be sure that suppliers are adequately addressing hazards. Importers would need to conduct testing of the environment and product as well as conduct an onsite audit in order to be assured that the hazard was adequately controlled. FDA should delineate similar examples in guidance so that agency expectations are clear.

CFA agrees that onsite audits must be conducted to the requirements of FDA food safety regulations and must include a review of the foreign supplier's written food safety plan and its implementation of that plan. For raw agricultural products, the importer will need to verify that fruits and vegetables are produced in compliance with FDA's produce safety regulations. FDA should provide additional guidance on how importers would do this. For the purposes of this regulation, importers should rely on audit reports that audit to FDA food safety regulations and not to other existing standards. While importers may wish to be assured that suppliers are meeting standards that are stronger than FDA regulation, the suppliers must at least meet FDA regulations for the audit to be acceptable. If an importer relies on an FDA inspection report or comparable foreign country inspection report instead of conducting an onsite audit, CFA agrees that the inspection must have been conducted within one year of the date when the importer reviews the foreign supplier. Any time frame longer than that and the inspection may be substantially less representative of the status of the supplier. CFA notes that FDA maintains that it can only conduct approximately 12,000 foreign audits per year, so it is unclear how often this provision will be used.

Option 1 will provide a clear verification requirement for the most serious hazards and will provide greater protection for consumers from contaminated food than Option 2, which allows the importer to choose any verification activity and does not specify that certain hazards such as SAHCODHA hazards be addressed more robustly. Onsite inspection of foreign suppliers is essential to provide assurance that the foreign supplier is adequately addressing food safety hazards. Onsite inspection will also provide FDA with some assurance that foreign suppliers are being adequately reviewed, particularly for SAHCODHA 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. The purpose of preventive controls and this provision would be defeated if a foreign processor claims to have a food safety plan that it is not actually following and the importer does not visit the processor to determine whether the supplier is implementing the plan it has provided to the importer.

Option 2 relies on more self-regulation with less accountability and will not provide sufficient protection for consumers. Option 2 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 the food hazard. The lack of a clearly enforceable standard under Option 2 will increase the likelihood of contaminated food entering the U.S.

A 2011 GAO report[9] on seafood safety highlighted the importance of onsite verification to ensure that a supplier is operating its food safety plan appropriately. As stated in the report, "According to a senior FDA official, foreign processors can obtain a HACCP plan that is not associated with its own operation,

[9] U.S. Government Accountability Office, "FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources." GAO-11-286, April 2011.

thus defeating the purpose of importers' acquiring a copy of the plan *unless the importers also visit the foreign processor* to validate the information in the plan and that it is being implemented." (emphasis added) FDA should not repeat mistakes that were made in the seafood HACCP program and should implement Option 1 in the final rule.

CFA believes it is premature to allow an importer to rely on an audit conducted in accordance with section 801(q) of the Food Drug & Cosmetic Act. This would allow an importer to rely on an audit conducted by a third party certification body that is certifying certain high-risk foods or facilities participating in the voluntary qualified importer program (VQIP). While this approach may have some attraction in order to connect the regulations closer together, CFA is concerned that the third party certification provision is too new to know whether it would be useful in this context. If the third party certification provision is effective, CFA can see advantages to allowing importer to rely on those audits. However, it is important to know whether the system that FDA is designing works as expected and provides quality results before relying on it for other uses. CFA urges FDA to postpone any decision on this issue until such time when the agency has better data on its third party certification program.

Investigations and Corrective Actions

CFA supports FDA's determination that importers must promptly review customer or consumer complaints to determine whether the complaint relates to the adequacy of the FSVP. Companies review consumer and customer complaints as part of HACCP plans and this can provide another avenue for identifying potential problems.

CFA agrees that if an importer becomes aware that an article of food is adulterated or misbranded, the importer must promptly investigate the cause and take appropriate corrective action. CFA further agrees that the importer must determine whether their FSVP is adequate and modify the FSVP as appropriate. The investigation, findings, corrective actions and any changes to the FSVP should be documented. This is all consistent with activities undertaken by food facilities in carrying out food safety plans and is appropriate as part of an FSVP.

Reassessment of FSVP

It is essential that an importer regularly reassess their FSVP in order to make sure that it is still functioning and effective. Consequently, CFA supports FDA's determination that importers must reassess their FSVP at least every 3 years. If importers become aware of new information about potential hazards with the food, importers should immediately conduct a reassessment and update the hazard analysis accordingly.

Importing from Officially Recognized Country

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 the requirement to maintain a written list of foreign suppliers. CFA strongly disagrees with this approach.

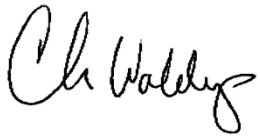
Regardless of where the importer imports food, the importer should have to implement and maintain an FSVP. This is a best practice and an important way to assure the safety of the supply chain. Just because a country has been deemed comparable by FDA does not mean that everything in that country's food safety system is operating perfectly all the time. It should be noted that FDA has chosen to assess a country's food safety system as "comparable", and not "equivalent," as the Food Safety and Inspection Service does for meat and poultry products. GAO has also suggested that an equivalency determination

would provide stronger food safety protections than FDA's comparability approach.[10] CFA believes an equivalency approach is a more robust approach for determining whether the U.S. can rely on another country's food safety system, and even the equivalency approach has its flaws.

A comparability determination also does not mean that the foreign country is inspecting each supplier on a regular basis. Even in the U.S., FDA does not intend to inspect high risk food facilities more often than every three years. FDA estimates that there are approximately 106,000 domestic food facilities.[11] During FY 2011, FDA was able to inspect approximately half of all high-risk domestic food firms.[12] FDA anticipates that all high risk facilities in the U.S. will be inspected within the first 3 years and all non-high risk will be inspected within the first 7 years.[13] 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 FSVP rule itself proposes annual checks on suppliers. Oversight by the importer of its suppliers through an FSVP is essential, even in countries which FDA has officially recognized. CFA strongly urges 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
Director, Food Policy Institute
Consumer Federation of America

[10] U.S. Government Accountability Office, "FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries Oversight Resources." GAO-12-933, September 2012.
[11] Food and Drug Administration, "Report to Congress on Building Domestic Capacity to Implement the FDA Food Safety Modernization Act" via http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM351876.pdf
[12] Food and Drug Administration, "2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices," August 2012 via http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm
[13] Food and Drug Administration, "Report to Congress on Building Domestic Capacity to Implement the FDA Food Safety Modernization Act" via http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM351876.pdf