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FDA Publishes Proposal re Foreign Supplier Verification Programs

August 6, 2013

On July 26, 2013, the Food and Drug Administration (FDA) published in the *Federal Register* two (2) proposals. Both are intended to further enhance the safety of the U.S. food supply from imported sources. These proposals are a continuation of the FDA's efforts to implement the Food Safety Modernization Act (FSMA). One proposal addresses foreign supplier verifications and the other third party auditors. Due to the complexity of the foreign supplier verification proposal, importers of FDA regulated food products (and this definition is broad, see below) would be well-advised to start by studying the flow charts which FDA provides as part of its proposal, see <http://www.gpo.gov/fdsys/pkg/FR-2013-07-29/pdf/2013-17993.pdf>. They serve as a sort of roadmap for companies while evaluating the proposal and considering how it might be implemented into their own operations. It is also notable that FDA repeatedly seeks comment from importers as it moves forward with implementation. Since the impact of this proposal is significant, and could well drive many small and medium sized companies out of business due to the added regulatory burden, compliance costs and recordkeeping, do not miss this opportunity to give your input.

FDA has struggled to publish all the required regulations by the original Food Safety Modernization Act (FSMA) deadline in June 2012. When it could not, it found itself on the receiving end of a lawsuit from the Center for Food Safety. The outcome was a holding that FDA had indeed broken the law by not issuing the required regulations within the time dictated by the FSMA. The court eventually acknowledged the complexity of the challenge and agreed to give FDA until November 30, 2013 to publish all the proposed regulations, and until June 30, 2015 to publish all the final rules.

In this Alert, we summarize the Foreign Supplier Verification Programs (FSVP) proposal. In a later Alert, we will address the Third-party Auditor Accreditation proposal.

attorneys

Susan Kohn Ross

practice areas

international trade
regulatory



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Background

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 and made significant changes to the Federal Food, Drug & Cosmetic Act (FDCA). Congress put increased burdens on American food importers, while, at the same time, doing nothing to enhance FDA's ability to conduct more frequent and better inspections of domestic food facilities where the vast majority of the food borne outbreaks have occurred. Every public comment made by FDA touts the way to enhance the safety of food products sold to American consumers in order to put great responsibility on American food importers, while remaining silent about what domestic producers are not doing to meet relevant standards. Put another way, Section 307 of the FSMA, codified in section 805 of the FDCA, requires importers to be held more accountable for the safety of the food products they import and to perform risk-based foreign supplier verification activities to insure that outcome. FDA has proposed the FSVP rule as one means to implement these requirements.

Summary of Major Provisions

The FSVP rule proposes what it calls a flexible, risk-based approach to foreign supplier verification. However, first, it is critical to keep in mind the definition of food is quite broad, i.e., anything covered by section 201(f) of the FDCA [(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.], including dietary supplements, but not pesticides. The proposal does not require a food importer to identify every possible hazard as he conducts his due diligence. Rather, the importer is called upon to focus on foreseeable food safety risks identified through a hazard assessment process. For these purposes, hazard assessment is identical to the long-standing, well-respected Hazard Analysis and Critical Control Point (HACCP) program relied upon with juices, low-acid canned foods and seafood.

Carrying out its flexibility goal, the proposed FSVP regulations would differ depending on the type of the food product, such as raw or processed foods, produce, or dietary supplements; the category of importer; the nature of the hazard in the food product; and who controls the hazard. An importer is here defined as the U.S. owner or consignee of the food product at the time of entry, or, if there is none, the U.S. agent or representative of the foreign owner or consignee.

The proposed FSVP rule would require importers to do much more homework and keep records of such actions as to:

- Review the compliance status of the imported product and the foreign supplier(s), including any FDA warning letter, import alert, or certification requirement issued by the FDA.
- Determine the hazards reasonably likely to occur with each food. Importers will be expected to analyze the hazards associated with each food they import and evaluate the severity of the illness or injury if such a hazard occurred. The more severe the likely hazard, the more robust the effort the importer must have undertaken and documented to insure adequate controls are in place and effective.
- Conduct supplier verification activities. Importers would need to maintain a written list of foreign suppliers and establish written verification procedures. They would also need to verify that hazards identified as



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reasonably likely to occur in a food they import are being adequately controlled. Here again is where flexibility comes into play.

- If the importer or its customer/buyer controls the hazard, the importer would need to document such controls, including obtaining certification from its buyers if they control the hazard.
- If the foreign supplier controls the hazard or the foreign supplier verifies its compliance is being controlled by its raw material or ingredient supplier, there are two options:
 - Option 1 – Importer would be required to conduct on-site auditing of the foreign supplier for hazards to be controlled by the foreign supplier when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death, or hazards in certain raw agricultural commodities. In lieu of onsite auditing, an importer could rely on the result of an inspection by FDA or the food safety authority of a country whose food safety system is officially recognized by FDA. For other hazards, importers would need to choose their verification activity from the following: onsite auditing, periodic or lot-by-lot sampling and testing, periodic review of the supplier's food safety records, or any other appropriate measures. Whichever option he chooses, the importer is required to implement it and then revalidate it at least every few years unless circumstances mandate more frequent action.
 - Option 2 - Importers would be allowed to choose from among the above-stated verification activities for all types of hazards as long as the chosen verification activities are sufficient to ensure the hazards presented are adequately controlled. Again, with this option, there is initial implementation and then periodic validation of the process chosen. In both cases, Option 1 and Option 2, where information comes to light that causes concern, it needs to be investigated promptly and any needed changes implemented to control the new hazard.
- Review complaints, investigate adulteration or misbranding, and take corrective actions in the case of supplier noncompliance, including terminating the supplier.
- Reassess the effectiveness of the importer's FSVP when the importer becomes aware of new information about potential hazards associated with a food, or otherwise every three (3) years.
- Ensure the importer's name and the Dun and Bradstreet Data Universal Numbering System (DUNS) number is provided for each line of food at time of entry.
- Maintain records of the importer's FSVP activities for a minimum of two (2) years (and the start date may not be readily apparent in some circumstances; also the recordkeeping period is longer than two (2) years in many cases). The records can either be maintained on site at the business or must be readily accessible by electronic means. Records about hazard analysis and controls (including supplier verifications of adequacy) must be maintained for so long as not revised or replaced, and then must be held for two (2) more years.



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In addition to the above-stated "standard" requirements, the proposed FSVP rule provides modified provisions for the following circumstances:

- Importation of dietary supplements or their components;
- Importation of food by a very small importer or importation of food from a very small foreign supplier (defined as \$500,000 in annual worldwide food sales); and
- Importation of food from a foreign supplier in good compliance standing with a food safety system the FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

Beside exempting products already subject to existing HACCP plan requirements, the proposal also exempts food imported for personal consumption; alcoholic beverages; food that is transshipped; food that is imported for re-export; and food imported for research or evaluation purposes.

Comments on the proposed FSVP rule are due by November 26, 2013 . FDA is proposing the FSVP rules become effective 60 days after the final rule is published in the *Federal Register*. However, FDA also says it will not make compliance mandatory for an additional 18 months. FDA recognizes it will take some time for industry to be able to adjust business models to properly incorporate these changes. Even this date may be extended if the foreign supplier is subject to the Preventive Controls for Human Food rule.

To its credit, FDA does seem to be taking pains to not force importers to duplicate efforts, meaning if you are subject to one set of controls, you should not have to comply with a different set of controls for a second regulatory regime with vastly different due diligence steps. Nonetheless, there is a presumption in this foreign supplier verification proposal about the extent of influence and control an American importer will have over his suppliers. While the large companies will be able to comply with some adjustments to existing procedures, this proposal is a real headache, recordkeeping nightmare and cost burden for small and medium sized companies. Also, keep in mind, FDA is mandated to develop a list of food importers which it will be publishing on its website. If your company name is readily accessible, you will likely want solid processes and records to back-up your brand.