VENABLE® LLP

Articles

August 13, 2013

Food for Thought: Understanding FDA's Proposed Rules for Importers of Food and Dietary Supplements and How They May Impact Your Business

AUTHORS

Lindsay B. Meyer
Ashley W. Craig
Matthew R. Rabinowitz
Claudia A. Lewis
Michelle C. Jackson
Todd A. Harrison
Ralph S. Tyler
John G. Moore

RELATED PRACTICES

International Trade and Customs

RELATED INDUSTRIES

Dietary Supplements, Cosmetics and Functional Foods

ARCHIVES

2013 2009 2005
2012 2008 2004
2011 2007 2003
2010 2006

With approximately 15% of all food consumed in the United States coming from overseas, the U.S. Food and Drug Administration (FDA) has renewed its focus on imported food safety and now seeks to place risk-based preventive controls squarely on the importing community. On July 29, 2013, FDA published **proposed rules** entitled *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals and Accreditation of Third Parties to Conduct Food Safety Audits and For Other Related Purposes*.[1] These rules seek to implement a key aspect of FDA's Food Safety Modernization Act (FSMA), and complement the proposed Preventive Controls for Human Food and proposed Produce Safety Rules. *If you are an importer of food and dietary supplement products, take notice. As proposed, these rules define new obligations for ensuring that food is safely imported into the U.S.*

Comments on these Proposed Rules are actively solicited by the FDA. If you want to shape how these rules may be finalized, contact us to discuss how your comments may be submitted and reviewed by FDA before the November 26, 2013 deadline.

What You Should Know about the Proposed Rules

I. Foreign Supplier Verification Programs for Importers

The **first proposed rule** establishes requirements for importers in implementing a Foreign Supplier Verification Program (FSVP). As proposed, the rule requires importers to develop and implement a plan for imported food, including identifying hazards associated with each food that are "reasonably likely to occur." It also requires importers to provide "adequate assurances" that these hazards are being "adequately controlled." As with any new obligation, the devil is in the details and, here, obligations for an "adequate assurance" and "adequate control" may be open to interpretation.

A. Why Require a FSVP?

Although FDA applies the same safety standards to domestic and imported food marketed in the U.S., the logistics associated with conducting foreign inspections raise complications with inspection and enforcement. Domestically, FDA routinely conducts unannounced inspections of registered food facilities. However, these inspections, as well as ''for cause'' inspections, are nearly impossible to conduct abroad. These challenges are further compounded by the sheer number of foreign firms registered with FDA, which currently exceed 250,000 versus the 167,000 domestic registered food facilities. As a practical matter, the FDA is only able to physically examine a small fraction of the food that is imported into this country. Moreover, many foreign firms are located in places with limited infrastructure and where food safety regulations lack requirements for specific risk-based preventive controls or other measures. Accordingly, an FSVP solves these governmental challenges by transferring the burden to provide assurances that foreign firms are meeting the relevant U.S. food safety requirements to the importing community. As FDA notes, this new system deliberately seeks to place "primary responsibility for food safety on industry." 78 Fed. Reg. at 45740.

B. FSVP Requirements

Under the FSVP proposal, importers must be prepared to undertake the following:

- **Compliance Status Review** – Review FDA warning letters, import alerts, etc. concerning the food

and potential foreign suppliers before importing the food, and conduct these reviews periodically thereafter;

- **Hazard Analysis** – Identify the hazards reasonably likely to occur and evaluate the consequences if such a hazard were to occur;
- **Verification Activities** – Provide adequate assurances that the hazards identified are adequately controlled;
- **Corrective Actions** – Review and investigate complaints concerning the foods they import and take corrective action as appropriate;
- **FSVP Reassessment** – Reassess their FSVPs every three years;
- **Importer Identification** – Obtain and use a Dun and Bradstreet Data Universal Numbering System (DUNS) number to file with U.S. Customs; and
- **Recordkeeping** – Keep records of compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and FSVP reassessments.

While the regulations attempt to focus on "foreseeable" food safety risks, rather than all risks covered by the various adulteration or misbranding provisions, the reality is that non-compliance will have significant consequences for an importer. For instance, if an importer fails to comply with these requirements, his imported food and dietary supplements could be refused admission. Additionally, there could be future consequences for the importer's and/or foreign supplier's business.

C. Options for Supplier Verification Activities

The proposed FSVP provides two options for supplier verification activities for hazards that the foreign supplier will control or that the foreign supplier verifies are being controlled by its raw material or ingredient supplier. Option 1 differs from Option 2 in that it requires importers to identify and take specifically-identified measures for hazards where there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA).

Under Option 1, for all SAHCODHA hazards, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier by a qualified individual. Moreover, as proposed, onsite audits must be conducted on at least an annual basis. If you have a substantial number of foreign suppliers, this obligation may strain your current resources. For all non-SAHCODHA hazards, the importer has more flexibility to choose which verification activity it will conduct. For example, the importer can conduct: (1) Periodic or lot-by-lot sampling and testing of the food; (2) Periodic review of the foreign supplier's food safety records; or (3) Any other appropriate procedure based on the risk associated with the hazard.

Under Option 2, for all hazards (SAHCODHA or not), importers would need to choose a verification procedure from the above-listed options, considering risk, probability that exposure would result in serious harm, and the food and foreign supplier's compliance status for activity determination and frequency.

In evaluating both options, we question whether Option 1 is practical for an importer. Whether a hazard could result in SAHCODHA is a subjective standard. Moreover, Option 1 would require onsite auditing for such hazards, which may be difficult to perform. Conversely, Option 2 appears to provide greater flexibility in obtaining supplier verification. To avoid foreclosing on other verification options, under the Proposed Rule as currently written, it appears that importers would be better suited using Option 2 to perform verification activities.

With this as background, it is important to note that FDA has instructed that "a prudent and responsible importer should review readily available information regarding whether the Agency has identified any compliance problems with the food or foreign supplier." 78 Fed. Reg. at 45748. So, what does that mean? Well, get ready to undertake your homework. It appears that these obligations will require an importer for each food and each foreign supplier to assess whether either is the subject of an FDA warning letter, an import alert, or requirement for certification related to the safety of the food, before concluding that it is appropriate to import that food from that foreign supplier. An importer may also need to assess whether there are any recall notices, injunctions or seizures associated with the product. As proposed, not only does the importer need to perform this analysis, he will have an ongoing

obligation to monitor and document compliance, as long as that foreign supplier provides that product. In practice, that seems like an exorbitant amount of work. FDA has asked the trade community to comment as to what compliance information an importer should be required to obtain and maintain. Think about how these new burdens will impact your operations and consider submitting your comments.

D. Are Imported Dietary Supplements Impacted?

While "modified" FSVP requirements apply to the importation of dietary supplements, the associated obligations must also be carefully considered. For dietary supplements and dietary supplement components, importers who establish and verify compliance with certain specifications (such as specifications associated with dietary supplement components, packaging, and labeling) under the dietary supplement CGMP regulations would not be required to comply with most of the standard FSVP requirements, including hazard analysis and standard supplier verification activities. However, importers of *finished* dietary supplements would still be required to comply with most of the standard FSVP requirements, as modified. While importers would not have to conduct hazard analyses, their supplier verification activities would focus instead on verifying that the supplier is in compliance with the dietary supplement CGMP regulations, rather than verifying that hazards identified as reasonably likely to occur are being adequately controlled. As proposed, the "modified" requirements for dietary supplements will vary depending upon whether the dietary supplement will be subject to further processing, to include packaging and labeling, or whether "finished" dietary supplements are sought for importation. Specifically, for dietary supplements that will undergo further processing, FDA is contemplating less burdensome obligations. Importantly, FDA has invited comment as to whether it is appropriate to establish "modified" FSVP requirements for importers of dietary supplements and components thereof when the importer or its customer will be subject to Part 111 of the CGMP regulations. Now is the time to consider how this will impact your business activities and whether your guidance to FDA may favorably shape the final rules.

If you import finished dietary supplements, which are not subject to further processing, FDA acknowledges that foreign suppliers are currently subject to very detailed and comprehensive dietary supplement CGMP requirements. Accordingly, the Proposed Rule would impose that the importer verify its supplier's compliance with Part 111 and not conduct a separate hazard evaluation to determine what to verify, under Option 1. That would not, however, be true if the importer sought Option 2 of the Proposed Rule at section 1.506(g)(1). Nonetheless, as proposed, all importers of *finished* dietary supplements would be subject to rigorous supplier verification requirements. These importers will be required to:

- Maintain a list of foreign suppliers;
- Establish and follow adequate written procedures for conducting foreign supplier verification activities;
- Ensure that there are adequate assurances that the foreign supplier is producing the dietary supplement consistent with the CGMP regulations;
- Conduct enumerated Option 1 or 2 supplier verification activities (*e.g.*, onsite auditing, periodic or lot-by-lot sampling and testing, periodic review of food safety records, and other established procedures) before using or distributing the dietary supplement and periodically thereafter;
- Document and maintain records of such verification activities and promptly review the results, taking appropriate corrective action as warranted; and
- Ensure that any qualified individual who conducts any of the verification activities does not have a financial interest in the foreign supplier and that payment is not related to the results of the activity. (Notably, an importer or its employee is not so prohibited from conducting the verification activity.)

Do you think that these requirements are more appropriately pronounced as part of the CGMP Part 111 regulations rather than under the FSVP requirements? If so, FDA wants to hear your thoughts.

E. Other Exemptions to the Proposed Rule

While the scope of this Proposed Rule is broad, there are certain limited exemptions. Namely, the FSVP explicitly exempts firms that import:

- Juice and seafood from facilities that are in compliance with the Hazard Analysis & Critical Control Points (HACCP) regulations;
- Food imported for research or evaluation purposes;
- Food imported for personal consumption;
- Alcoholic beverages; and
- Food that is transshipped or imported for further processing and export.

Importantly, the first exemption concerning juice and seafood is rather limited. The exemption only applies to facilities with HACCP regulations, which contain their own supplier verification provisions. Therefore, U.S. importers bringing foods from such suppliers will still be subject to FSVP. Similarly, while not fully exempt, regulatory burdens are decreased when importing food from a country with an officially-recognized or equivalent food safety system. In such circumstances, importers are exempt from FSVP requirements, but must still maintain a written list of foreign suppliers, maintain a DUNS number, and comply with recordkeeping provisions.

> TIP: When contemplating these new obligations as they may affect your operations, do you have the contractual provisions in place with your foreign suppliers to access the information? Do you have rights to obtain records, perform on-site auditing or get access to the necessary information? If not, now is the time to get those provisions in place!

II. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

The **second proposed rule** seeks to establish a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. The accredited auditors would conduct food safety audits and issue certifications that FDA may use in deciding whether to admit certain imported food into the U.S. that the Agency has determined poses a food safety risk. The FDA plans to use such third-party certifications for both its Voluntary Qualified Importer Program (VQIP) and FSVP. Although the FSVP proposal does not require the use of accredited third-party auditors, the FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP.

How the Proposed Rules Will Impact Your Business

Think about what steps you will need to take to create an appropriate FSVP plan for your business. The specific food safety protocols in any given FSVP plan will depend upon a variety of factors, including inherent risks associated with the food, the country of origin of the food, and the manufacturers involved in your supply chain. Contemplate whether you have a handful or a hundred foreign suppliers, as your approach may vary accordingly. Either way, ensure that your plan best suits the complexities and challenges of your business model. For instance, if you import a significant number of fruit and vegetable products from overseas, your level of potential risk will likely be greater than one who imports solely dry goods. Conversely, if your product mix includes goods largely exempt from the FSVP requirements, with only a limited-number of food and dietary supplements covered by the new regulations, perhaps you can adopt some of the compliance procedures from your HACCP or CGMP program to align with the goods within the FSVP requirements.

FDA has made clear the proposed rules are part of the entire FSMA framework, and should be reviewed in conjunction with two other proposed rules: (1) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food and (2) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. FDA recently issued its second extension of the comment period for these two rules. The Agency stated it did this to allow interested persons the opportunity to consider the interrelationships between all four proposed rules. The comment period for the proposed rules concerning preventive controls for human food and produce safety have been extended 60 days until November 15, 2013.

Let Your Voice Be Heard.

FDA is openly requesting comments on several aspects of these Proposed Rules. Interestingly, FDA

has sought input from importers who may be subject to both the FSVP and preventive controls regulations, in order to prevent the imposition of any duplicative supplier verification requirements. Therefore, unless further action is undertaken, the final rule on Preventive Controls may likely establish its own, separate supplier verification rules.

In its regulatory impact analysis, FDA assumed that all costs associated with its proposed rules are passed on to U.S. consumers. However, the Agency notes it is possible that some of these costs may not be passed on. Therefore, FDA is seeking comment on the extent to which all of these costs will be passed on to U.S. consumers.

The Agency is also interested in receiving comments from members of the dietary supplement industry. As noted, the Agency specifically requested comment on whether establishing modified FSVP requirements for importers of finished dietary supplements is appropriate and, if so, whether the requirements proposed are appropriate. Additionally, FDA expressed interest in receiving comments on whether there are any other types of food, in addition to dietary supplements, for which it should establish modified foreign supplier verification requirements and, if so, what these requirements should be.

Get Your Operations in Order: How You Can Participate and Potentially Influence the Final Rules

Now is the time to consider your supply chain and affected business activities. Do you have comments that should be shared with the FDA as it seeks to refine and finalize the Proposed Rules? If so, let us know. Our team will be monitoring the upcoming public meetings. We are also available to discuss how these new rules may impact your current operations and assess what steps you need to undertake to get your procedures ready for these anticipated obligations.

Remember: Comments are due by November 26, 2013. We anticipate that the final rules will become effective within 60 days of their publication.

Please contact either Venable's **Dietary Supplements, Cosmetics and Functional Foods Practice Group** or **International Trade and Customs Practice Group** with any questions you might have or for assistance in filing responsive comments.

---

1 *See* Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45729 (July 29, 2013); Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45781 (July 29, 2013).