U.S. Food Imports

1010 Wisconsin Avenue NW, Suite 250
Washington, DC 20007
+1.202.765.1800
+1.202.809.9222
info@usfoodimports.com

Regulatory Alert: FDA Releases Long-Awaited Comprehensive FSVP Guidance

Requirements for Allergen Labeling Reviews, Supplier Monitoring Specified

February 2, 2018

On Wednesday, January 24, 2018, the U.S. Food and Drug Administration (FDA) released long-awaited draft guidance on the Foreign Supplier Verification Program (FSVP) Rule for importers of human and animal food. The FSVP Rule was issued to implement the Food Safety Modernization Act (FSMA).

This U.S. Food Imports (USFI) Regulatory Alert covers key points of the guidance for importers, including food retailers and manufacturers, and foreign suppliers.

I. FSVP Importer

Can a foreign company merely have a mailbox or answering service in the U.S. and serve as an FSVP Importer?

No. The FSVP importer must be located in the U.S. This applies whether you are the U.S. owner or consignee of the food at the time of entry or the U.S. agent or representative of the foreign owner or consignee at the time of entry. An FSVP importer could be a person who resides in the U.S. or maintains a place of business in the U.S. It would not be sufficient to merely have a mailbox, answering service, or some other place in the U.S. where the importer is not physically present.

When can there be multiple entities that meet the definition of "importer" for a particular food?

In some cases, there might be multiple entities that meet the "importer" definition for the same line of an entry of food offered for import into the United States. For example, a U.S. company might purchase olive oil manufactured in Italy and, at the same time, have entered into an agreement to re-sell the olive oil to a U.S. retail store after the product has entered the United States. In this case both the U.S. purchaser and the retail store might meet the definition of importer. Alternatively, a foreign grower of lettuce might arrange for the

importation of the lettuce into the U.S. under written agreements to sell the lettuce to multiple, unaffiliated U.S. buyers once the lettuce has entered this country.

When there are multiple entities that meet the "importer" definition, these entities will need to determine who will be responsible for meeting FSVP requirements for the food (and consequently, who should be identified as the importer of the food at entry). FDA expects that U.S. owners and consignees will address the responsibility for FSVP compliance in their contractual agreements when they have a direct commercial relationship. If there is an agreement between or among multiple U.S. owners or consignees of a food regarding responsibility for FSVP compliance and identification of the importer at entry, the entity identified as the FSVP importer at entry would be the entity that FDA would ordinarily prioritize for possible review under the agency's risk-based compliance assessment program. When there are multiple unaffiliated U.S. owners or consignees for the same line of an entry of a food, FDA anticipates that each entity will develop an FSVP for the food and foreign supplier. However, if one of the entities were willing to serve as the FSVP importer for this food from this foreign supplier, this would be permissible under the regulation. Similarly, if someone (e.g. one of multiple U.S. owners or consignees of a food) fraudulently or unintentionally identified a U.S. owner or consignee of a food as the FSVP importer (contrary to a written agreement regarding responsibility for FSVP compliance), FDA would take this into account in any enforcement action they take with respect to the food.

What does it mean to have "agreed in writing to purchase" a food?
A person has agreed in writing to purchase a food (for the purposes of the definition of "U.S. owner or consignee") when they have entered into a written promise to purchase the food at a later date. Typically, a buyer of a food issues a purchase order to a seller indicating the product to be purchased, the quantity, and the price. When the seller confirms acceptance of the purchase order in writing, there is a written agreement that the buyer will purchase the food. FDA regards agreements entered into electronically (e.g. through online submission and acceptance of a purchase order) as being "in writing."

Would a retailer that places a purchase order with a U.S.-based food distributor be considered the "U.S. owner or consignee," where the retailer does not specify the source of the food and the distributor purchases the food directly from a foreign supplier?

No. If the retailer does not direct the distributor to purchase the food from a particular source or sources, the retailer would not be the "U.S. owner or consignee." For example, if a retailer places a purchase order for bell peppers from a U.S. based distributor without specifying the source of the peppers, the retailer would not own the food, have purchased the food, or have agreed in writing to purchase the food at the time of entry. The retailer would only have placed

an order directing the distributor to obtain peppers, leaving the decision about the source of the peppers to the distributor. At the time of entry, the distributor is the entity that purchased the peppers. Therefore, the distributor would meet the "U.S. owner or consignee" definition in 21 CFR 1.500.

Would a retailer be the "U.S. owner or consignee" if the retailer agrees in writing, three days after the food arrives in the United States, to purchase the food at a warehouse of a U.S.-based distributor?

No. Agreeing in writing to purchase an imported food after the conclusion of the entry process does not cause the retailer to be the "U.S. owner or consignee." The "U.S. owner or consignee" is the entity that owns the food, has purchased the food, or has agreed to purchase the food *at the time of U.S. entry.*

II. Foreign Supplier

Who is the foreign supplier of a food?

The foreign supplier of a food is the establishment that manufacturers/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature. Because of this, your foreign supplier might not be the entity from which you directly obtain the food you import. If you obtain a food from a foreign warehouse, distributor, broker, or other entity that does not perform any manufacturing/processing of a more than de minimis nature, the foreign supplier of the food would be the last entity in the foreign supplier chain that conducts significant manufacturing/processing of the food. For example, if you obtain oranges from a packing house that only packs and holds the oranges (and does not perform manufacturing/processing on the oranges of more than a de minimis nature), the foreign suppliers would be the farms that grew the oranges.

III. Specific Categories of Food Imports

Are grains that are RACs subject to FSVP requirements?

Grains that are RACs including barley, dent- and flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds for oil extraction (e.g. cotton seed, flax seed,

rapeseed, soybean, sunflower seed) – are food subject to the FSVP regulation. However, FDA intends to exercise enforcement discretion with regard to the FSVP requirements for certain importers of grain RACs. This applies to the following importers of grain RACs: (1) those that are solely engaged in the storage of grain intended for further distribution or processing; and (2) those that do not take physical possession of the grain they import, but instead arrange for the delivery of grain to others for storage, packing, or manufacturing/processing.

Are trade show samples subject to FSVP?
Generally yes because food imported for consumption at trade shows is typically sold or distributed to the public (i.e. anyone who attends the trade show).

Are substances that can be used for both food and non-food uses subject to the FSVP regulations?

A substance that can be used for both food and non-food uses is subject to the FSVP regulation if it is reasonably likely to be directed to a food use. Examples of substances that are capable of food and non-food use include the following:

- Dough strengtheners
- pH control agents
- Some seeds
- Food enzymes
- Color additives
- Carbon dioxide

IV. FSVP Activities, Recordkeeping

What does it mean to have an FSVP for "each food?"

You must establish an FSVP for each food you import from each of your foreign suppliers. You do not need to establish a separate FSVP for different versions of the same food from a single foreign supplier when the differences in the foods do not result in different hazards requiring a control. For example, it might be appropriate for you to develop a single FSVP covering several different packaging sizes or formats for a particular food from a particular supplier, provided that the packaging differences do not pose different hazards that need to be controlled by the foreign supplier and addressed through different supplier verification activities. Similarly, you might include different flavor varieties of the same food in a single FSVP provided that the hazards and corresponding controls are the same. Examples of foods that you might address in

a single FSVP (assuming any hazards requiring a control in the different versions of the food are the same) include different varieties of yogurt, cookies, potato chips, chocolate candies, or extruded dog or cat food.

However, if the use of different ingredients to make what is essentially the same food could result in different hazards requiring a control or a need for different types of controls, you should either establish separate FSVPs for these foods or create a single FSVP for the foods that separately addresses the differing hazards or controls required. For example, chocolate chip cookies made with walnuts and without walnuts. The presence of the allergen hazard in the cookies with walnuts would mean that you should either have separate FSVPs for the two varieties of cookies or separately address within a single FSVP the allergen hazard posed by the cookies with walnuts. Your FSVP must be specific to each foreign supplier of a food. Thus, if you obtain a food from multiple foreign suppliers, you must have a separate FSVP for each supplier.

How do I determine whether my potential foreign supplier uses processes and procedures that provide at least the "same level of public health protection" as those required under the preventive controls or produce safety requirements?

The FSVP Rule requires importers to verify compliance with the human and animal food preventive controls regulations and Produce Safety Regulation or processes and procedures that provide at least the same level of public health protection. If your potential foreign supplier uses a process or procedure that varies in some way from the processes and procedures required under the preventive controls regulations in part 117 or part 507 or the Produce Safety Regulation (part 112), you will need to determine whether the process or procedure that the supplier uses provides at least the same level of public health protection as those required under the specified FDA regulations. Importers should make this determination on a case by case basis.

If a foreign country has adopted more prescriptive, stringent or restrictive requirements for a particular concern than those in a relevant FDA regulation, a supplier's compliance with such requirements would likely provide assurance that the supplier's process or procedure provides at least the same level of protection.

You should have adequate scientific data or other information to enable you to conclude that your supplier's use of an alternative process or procedure provides the same level of public health protection as an FDA requirement is intended to address.

With respect to the preventive controls requirements in parts 117 and 507, a foreign supplier might use processes or procedures that are not strictly in accordance with a requirement of those regulations, but still provide at least the same level of public health protection as provided through compliance with the particular requirement. An example of this for the manufacture of human food might be a facility lacking a written hazard analysis describing how the facility determined which hazards require a control but having a HACCP plan identifying appropriate hazards along with controls and management components, and maintaining records documenting the facility's implementation of appropriate hazard controls.

As stated in the preamble to the FSVP final rule, you are not required to document each process or procedure of your foreign supplier that varies from those required under the preventive controls or produce safety regulations but that, in your determination, provides the same level of public health protection. However, when your supplier's use of such a process or procedure is relevant to your evaluation of the supplier's performance under section 1.505 or the performance of supplier verification activities under section 1.506, you must include information about the supplier's alternative processes and procedures in your documentation for these requirements.

Do I need to review labels for compliance with allergen labeling requirements as part of my FSVP?

Yes. As part of your FSVP you should review the label of each human food you import to determine that it complies with the labeling requirements for the major food allergens.

What is meant by "type of food" for the purpose of conducting a hazard analysis?

You must conduct a hazard analysis for each type of food you import that is subject to the FSVP regulation. "Type of food" refers to foods that are similar and for which the same hazards are known or reasonably foreseeable. For example, Brie, Camembert, and Mozzarella are soft-ripened cheeses that are subject to the same hazards. Thus, a hazard analysis for soft-ripened cheeses may cover all three of these cheeses, provided you specify in the hazard analysis the specific soft-ripened cheese you are importing that are covered by the hazard analysis.

May I rely on a hazard analysis conducted by another entity?

Yes. You may rely on a hazard analysis conducted by another entity provided it was conducted by a qualified individual. Your foreign supplier may conduct the hazard analysis.

How should an importer consider the entity or entities other than the foreign supplier?

In the following example, you obtain a seasoning mix from a foreign supplier (Supplier X). Supplier X made the seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z). You identify *Salmonella* as a hazard in the seasoning mix, and you learn from Supplier X (your direct supplier) that they do not apply a control for *Salmonella* in the blending operation. Instead, Establishment Y applies a process control for *Salmonella* in the milk powder and Establishment Z applies a process control for *Salmonella* in the spice blend. Although Supplier X is your "foreign supplier" (as defined in 21 CFR 1.500), Supplier X also is a receiving facility (because Supplier X is a manufacturer) and, thus, would be subject to the supply-chain program provisions of the preventive controls regulation (and therefore would have conducted appropriate supplier verification activities, such as auditing its suppliers or sampling and testing the milk and the spices, to ensure that they have used proper controls). You would have several options for conducting supplier verification activities for Establishment Y and Z because they are entities controlling the *Salmonella* hazard. You could conduct the appropriate supplier verification activities with respect to Establishments Y and Z yourself. You could rely on documentation provided to you by Supplier X regarding Supplier X's supplier verification activities for Establishments Y and Z. You could rely on documentation from Supplier X for some supplier verification activities with respect to Establishments Y and Z and conduct additional supplier verification activities for Establishments Y and Z yourself. You also would determine an appropriate supplier verification activity and associated frequency for Supplier X.

Should an importer review FDA compliance information frequently on foreign suppliers?

Yes. Because FDA makes available warning letters, import alerts, inspection classifications, as well as information on foodborne illness outbreaks and food recalls, the agency believes that importers should maintain an awareness of relevant new information about foods imported and suppliers by frequently checking for new information that the agency posts.

What must an importer do to ensure that it is obtaining food from foreign suppliers that it has approved?

An importer must establish and follow written procedures to ensure that it imports foods only from foreign suppliers it has approved based on the foreign supplier evaluation.

Do I need to have written procedures for conducting foreign supplier verification activities?

Yes. You must establish and follow adequate written procedures for ensuring that you conduct appropriate foreign supplier verification activities with respect to foods imported.

How does a foreign supplier's compliance history relate to determining appropriate verification activities?

A foreign supplier's compliance history, whether positive or negative, could play a significant role in determining appropriate verification measures. A supplier's recent receipt of an FDA warning letter or inclusion in an import alert might warrant taking extra precaution to verify that the supplier has adequate controls in place. On the other hand, a foreign supplier whose recent FDA inspections have found no significant non-compliance might require less verification.

Are annual onsite audits always required for foreign suppliers that control SAHCODHA hazards?

FDA believes that annual onsite auditing of the foreign supplier is appropriate when there is a SAHCODHA (serious adverse health consequences or death to humans or animals) hazard in a food. Under some circumstances it might be reasonable for an importer to determine that annual onsite auditing of a foreign supplier is not necessary even though there is a SAHCODHA hazard in a food. However, in most of these circumstances FDA recommends that supplier verification activities include some frequency of onsite auditing, such as every 2 or 3 years.

Is an accredited laboratory required to be used for testing as part of an FSVP program?

No. A laboratory conducting the tests on which you rely on might be, but is not required to be, accredited.

What verification activities may be appropriate for hazards related to transportation of food?

Your hazard analysis of a food you import might determine that there is a hazard requiring a control that relates to transportation of the food. Examples of foods for which a hazard needs to be controlled during transportation include produce shipped in open or porous containers or crates and soft-ripened cheeses.

If you determine there is a hazard requiring a control in a food you import that relates to transportation practices, you will need to conduct verification activities to provide assurance that the hazard is being significantly minimized or prevented by the foreign supplier or other responsible entity. This verification is in addition to verification of your foreign supplier.

If your foreign supplier is subject to the requirements of the regulation on the Sanitary Food Transportation Act (SFTA) (21 CFR 1.900-1.934), your verification activities may include obtaining written assurance from your foreign supplier that your foreign supplier is complying with SFTA.

If you determine that there is a hazard requiring a control that relates to transportation practices but your foreign supplier is not subject to SFTA because your supplier is not a shipper under the

rule, your verification activities could include obtaining written assurance directly from the actual foreign shipper that it is complying with the sanitary transportation act regulation, if applicable, when it ships the food, or a written assurance from the transporting entity that the food is imported in a manner that significantly minimizes or prevents the hazard (i.e. temperature control and monitoring).

Must I sign and date FSVP records?

Yes. You must sign and date your FSVP records upon initial completion and upon any modification of the FSVP.

Must FSVP records be stored at my place of business?

No, provided that they can be retrieved and provided to FDA within 24 hours of a request for official review. FDA considers electronic records to be available onsite if they are accessible from your onsite location. When an FDA representative makes this request at your place of business, the agency expects the importer to provide requested onsite records while FDA is at your place of business.

U.S. Food Imports LLC provides foreign supplier verification services and other food import compliance solutions. Our proprietary FSMA Cloud® and FDA Cloud™ Software ensures efficient FSVP compliance for you and your suppliers. Please contact Erik Lieberman at elieberman@usfoodimports.com or (202)765-1800 if you have questions or would like additional information.