ROMAINE CALM: FSVP IS APPROACHING

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Does FSVP Apply to You?

Are you the importer, consignee, or agent for food imported into the United States? If so, the Foreign Supplier Verification Program for Importers of Food for Humans and Animals (FSVP), a key element of the Food Safety Modernization Act (FSMA), likely applies to you. Implementation of the FSVP will begin on May 30, 2017, but categories of companies or foods may be subject to later compliance deadlines. Where do you fit?

The FSVP regulations aligns with key components of the FDA's overall food safety plan for facilities that manufacture, process, pack or hold food which must now establish and follow the regulations regarding current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food and animal food (Preventive Controls or PC).

What Is FSVP?

FSVP is a program that requires an importer to verify the foreign supplier produces food using processes that achieve the same level of public health protection as the PC or Produce Safety Regulations in the U.S. See *FSMA Final Rule for Preventive Controls for Human Food*, the same for animal food, and *FSMA Final Rule on Produce Safety*.

Further, the importer must ensure the supplier's food is neither adulterated nor misbranded with respect to allergen labeling. See 21 U.S.C. §§ 342 and 343, respectively.

The FSVP regulations focus on known or reasonably foreseeable food safety hazards, identified and considered through a hazard analysis and evaluation process, rather than all forms of adulteration as specified in 21 U.S.C. § 342.

For these purposes, there are several different types of hazards importers are expected to plan for, by way of example:

- Biological hazards, including parasites and disease-causing bacteria,
- Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved food or color additives, and food allergens,
- Physical hazards, such as glass,
- Formulation and composition, including substitution of ingredients, and
- Sanitation and transportation.

A full discussion about all the possible hazards to be concerned about can be found here and here.

Who Is The FSVP Importer?

The importer of record for Customs entry purposes may, but is not necessarily, the FSVP importer. Rather, the FSVP importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the FSVP importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, and must provide an annual signed statement agreeing to perform that role. The FSVP agent is accepting full responsibility for meeting the FSVP requirements and is the party to whom the FDA will turn if there are questions. Parties with no direct financial interest in the food offered for import are not FSVP importers, which is why it is not likely agents such as customs brokers, warehouses, etc., are likely willing or able to act as the FSVP importer.

Qualified Individual:

An importer accomplishes compliance with the FSVP by relying on verification activities by qualified individuals. FDA's FAQs describe a "qualified individual" as follows:

"Please note, however, that importers will not be required to have their qualified individuals who perform FSVP activities take … any … particular training … when it becomes available. Importers may rely on training on supplier verification (and related FSVP activities, such as hazard analysis) that is available from other sources to ensure that persons conducting FSVP activities for the importer have the necessary education, training, or experience (or a combination of those factors) to perform a particular activity required by the FSVP regulation. In addition, it might also be possible for a person to obtain the necessary expertise to serve as a qualified individual through experience or education" [emphasis added].

Must All Importers Comply?

No. There are exceptions and some instances where modified requirements apply.

Importers also operating as manufacturers/processors may be deemed in compliance with most FSVP requirements, if they comply with the supply-chain program under the PC; or they implement PC for hazards in the food; or they are not required to implement PC in certain specified circumstances. Some examples include types of food that cannot be consumed without application of a PC, such as coffee beans, or when a subsequent entity in the supply chain minimizes or prevents identified hazards by processing for food safety. There are also requirements for disclosures and written assurances.

Requirements for dietary supplements vary based on factors, such as whether the import is a finished product or an ingredient/component. A dietary supplement importer is not mandated to comply with most of the FSVP requirements if he establishes and verifies compliance with certain specifications concerning dietary supplement components and packaging. These are required under separate, pre-existing dietary supplement CGMP. In addition, an importer whose customer provides written assurance that it complies with and meets such specifications may also be exempt from most FSVP requirements. Importers of other dietary supplements, including finished products, are subject to most of the standard FSVP requirements, other than hazard analysis, but their verification activities focus on dietary supplement CGMP. The terms "hazard analysis" and "verification" are explained in the FSVP Requirements section below.

Very small importers and importers of food from certain small suppliers are subject to modified requirements. For example, those importers may verify their foreign suppliers by obtaining written assurances from the individual suppliers, rather than having to conduct hazard analyses. The FSVP and PC definitions of "very small importer" are consistent: a yearly sales ceiling of $1 million for human food and $2.5 million for animal food, averaged over three (3) years, but there is conjecture whether those numbers are limited only to sales in the U.S. or worldwide. Small suppliers are either exempt from the underlying FDA food safety regulations, or are subject to modified requirements because of their size:

- Facilities are subject to modified requirements under the PC because they are qualified facilities;
- Farms which are not "covered farms" under the Produce Safety Rule because they average $25,000 or less in annual produce sales or because they meet the requirements for a qualified exemption; and
- Shell egg producers with fewer than 3,000 laying hens.

Certain types of food from foreign suppliers in countries where the food safety systems are recognized by FDA to be comparable to that of the United States, right now Canada, New Zealand and Australia, are also excluded from most of the standard FSVP requirements, including hazard analysis and verification that hazards are minimized or prevented, provided:

- The food falls within the relevant official recognition or equivalency determination;
- The importer determines the foreign supplier is in good standing with the relevant food safety authority; and
- The food is not intended for further processing in the United States before consumption, e.g., packaged food products and raw agricultural commodities.

Are All Foods Subject To The FSVP?

No. There are a few categories of food not subject to the FSVP. These include:

- Juice, fish and fishery products, and certain ingredients for use in juice and fish and fishery products, in compliance with FDA's HACCP regulations;
- Food for research or evaluation or for personal consumption not intended for or sold to the public – which must be properly labeled as such;
- Alcoholic beverages and certain ingredients for use in alcoholic beverages;
- Food that is transshipped through the United States or imported for processing and future export;
- Food manufactured/produced, grown or raised in the United States, exported and returned without further manufacture or processing in a foreign country;
- Low-acid canned foods (LACF), such as canned vegetables, and certain ingredients for use in LACF, but only with regard to microbiological hazards otherwise regulated; and
- Certain meat, poultry and egg products regulated by the U.S. Department of Agriculture at the time of importation.

Does FSVP Apply To You?

In addition to the guidelines mentioned above, the FDA has provided a decision tree that is quite helpful, see *Am I Subject to the FSVP*.

FSVP Requirements

Importers are required to develop, maintain and follow an FSVP for each food brought into the United States and the foreign supplier of that food, unless an exemption applies. If the importer obtains a certain food from a few different suppliers, a separate FSVP is required for each supplier.

The rule requires importers to verify that food imported into the United States was produced in a manner that meets the applicable U.S. safety standards by performing risk-based activities, that include:

- Appointing a qualified individual to develop an FSVP and perform the related activities;
- Determining known or reasonably foreseeable hazards with each food, by performing hazard analysis;

- Evaluating the risk posed by a food, based on the hazard analysis, as well as the foreign supplier's performance;
- Using the evaluation of risk posed and the supplier's performance to approve suppliers and determine appropriate supplier verification activities;
- Conducting supplier verification activities to ensure hazards have been minimized or prevented, such as audit by a qualified auditor, sampling and testing, and reviewing supplier safety records;
- Conducting prompt corrective actions and evaluating the adequacy of the FSVP; corrective action may be triggered by the review of consumer, customer or other complaints related to food safety, verification activities or other information;
- Reevaluating the food and supplier at least every three (3) years, or when new information comes to light about a hazard or the foreign supplier's performance;
- Identifying the FSVP importer at the line level on the import entry, providing the name, contact information, the FDA registration number and any other information required at the time of entry.
- Maintaining records of FSVP activities.

FSVP importers may rely on analyses and evaluations carried out by others, but must review and assess the relevant evaluation or determination. The importer must approve its own foreign suppliers. Importers must establish and follow written procedures to ensure they import food only from approved suppliers, based on the evaluation of the risk posed by the food and the supplier's performance. As such, the foreign supplier verification activities must be determined and documented, including the frequency of conducting them. Importers may import food from unapproved foreign suppliers, on a temporary basis when necessary, provided adequate verification activities are performed before importing it.

DUNS Number:

Acknowledging the current state of confusion, FDA on May 4, 2017 announced by way of CBP's CSMS (Cargo System Messaging Service) 17-000255, it will temporarily allow "UNK" (unknown) for the DUNS number of the FSVP importer during the "onboarding" period which starts on May 30th. CBP also stated that UNK should only be used if the 9 digit site specific DUNS number is not available at time of import. So if you have it, use it! The CSMS provides a portal address where DUNS numbers can be looked up or obtained – http://www.fdadunslookup.com. CBP also stated it will send another CSMS when the grace period expires.

Importers are reminded the correct DUNS number is the one associated with where the FSVP importer maintains his records.

Key Dates:

In an attempt to make the various deadlines as clear as possible, FDA published a list, which can be seen here.

1) FSVP importer whose foreign supplier is not subject to the PC or Produce Safety Rules: May 30, 2017;

2) FSVP importer whose foreign supplier is required to comply with the PC rule for human food – when the foreign suppliers are in these categories;

- Small businesses as defined in 21 CFR 117.3: March 19, 2018;
- Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 117.3: March 18, 2019;
- Suppliers subject to the Pasteurized Milk Ordinance: March 18, 2019;
- "All Other" Businesses Suppliers: May 30, 2017.

3) FSVP importer of animal food whose foreign supplier is subject to the CGMP requirements in subpart B of 21 CFR part 507 in the PC rule for animal food.

- Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 507.3: March 19, 2018;
- Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: March 18, 2019; and
- "All Other" Businesses: May 30, 2017.

4) FSVP importer whose foreign supplier is required to comply with the animal food preventive controls requirements in subpart C of part 507 of the PC rule for animal food, but that is not required to comply with the CGMP requirements in subpart B of 21 CFR part 507.

- Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 507: March 18, 2019;
- Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: March 17, 2020; and
- "All Other" Businesses: March 19, 2018.

5) FSVP importer whose foreign supplier is required to comply with the produce safety rule, except for the requirements applicable to sprouts in subpart M of 21 CFR part 112.

- Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: July 29, 2019;
- Very Small Businesses as defined in as defined in 21 CFR 112.3: July 27, 2020; and
- "All Other" Businesses: July 26, 2018.

6) FSVP importer whose foreign supplier is required to comply with the requirements in the produce safety rule applicable to sprouts in subpart M of 21 CFR part 112.

- Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: July 26, 2018;
- Very Small Businesses as defined in 21 CFR 112.3: July 29, 2019; and
- "All Other" Businesses: July 26, 2017.

7) FSVP importer whose foreign supplier is subject to the produce safety rule and eligible for a qualified exemption (other than when the foreign supplier is a farm producing sprouts).

- Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: July 29, 2019; and
- Very Small Businesses as defined in 21 CFR 112.3: July 27, 2020.

8) FSVP importer whose foreign supplier is a farm producing sprouts that is eligible for a qualified exemption under the produce safety rule.

- Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: July 26, 2018; and
- Very Small Businesses as defined in 21 CFR 112.3: July 29, 2019.

If you are still not sure how you are impacted, the November 27, 2015 final rule is posted here.

If you are not ready by May 30th and are not otherwise subject to a later deadline, you can expect FDA will start to enforce the law. It is not likely shipments will get held at the border, at least not at first. Rather, FDA is expected to start asking importers for their FSVP documentation post-importation. If those documents cannot be provided or they are inadequate, the importer and supplier will likely go on Import Alert and the related food facility registration suspended. FDA may also require the imported food to be recalled. If all else fails, civil penalties may be imposed.

On top of that, additional inspections can be expected. Those inspections will likely be for cause, to follow-up on perceived FSVP problems, importers whose foreign suppliers have been inspected by the FDA, and then there are the VQIP standards!

Do you know when you must comply? Are you exempt? Is your deadline delayed for at least some of your foreign suppliers? If so, until when? Do you have the needed preventive controls/hazard analysis plan ready? Has it been implemented? Do you have the needed provisions in your contracts? Are your suppliers ready? Who is your FSVP importer? Who is your FSVP Qualified Individual? If you have multiple importers, have you worked out with them whether each is his own FSVP importer or there is someone who will take the role on for all of them? All of these questions and many more should be well on their way to be answered, if you are to be ready by May 30th. Given

these regulations have been on the books since November 2015, food importers should anticipate FDA is serious about enforcing these requirements as soon as they take effect.

Just by way of a quick summary, FDA issued a recent reminder that if you fit into one of these categories, you must be ready by May 30th:

"The first FSVP compliance date is May 30, 2017 **for importers whose foreign supplier falls into one of these categories**. The supplier:

- Will not be covered by the FSMA preventive controls or produce safety rules;
- Is subject to the Preventive Controls for Human Food rule, and is not a "small business," "qualified facility," or subject to the Pasteurized Milk Ordinance; or
- Is subject to current good manufacturing requirements in the FSMA Preventive Controls for Animal Food rule, and is not a "small business" or "qualified facility"".

If you do not fit into these categories, you are still subject to the FSVP regulations as explained above, but simply have more time – so breathe a sigh of relief – and then get ready! Given the heightened scrutiny food safety is getting, even if the FDA gives you more time, it is reasonable to expect that other types of commercial and consumer claims are coming! Are your defenses ready?