Introduction to the Foreign Supplier Verification Program

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FSMA Affects the Food Supply Chain

1. Foreign and domestic manufacturers or processors, packers, and holders of foods now must:
   - Assess hazards.
   - Implement preventive controls.
2. Foreign and domestic growers of fresh produce must:
   - Comply with produce safety requirements.
3. U.S. food importers must:
   - Ensure that their foreign food suppliers are sending foods to the U.S. that meet U.S. safety standards.

FSMA Creates New Role for Food Importers

U.S. importers of foods play a vital role in ensuring that their foreign suppliers are:

- Providing the first line of defense in preventing food hazards.

Foreign Supplier Verification Programs Rule

On November 27, 2015 FDA, also published the final FSVP rule:

- Part 1 – *Foreign Supplier Verification Programs* (FSVP) *for Importers of Food for Humans and Animals*

The final FSVP rule was published in the Federal Register, along with its preamble explanations and responses to public comments

Key Principles of FSVP Rule

Importers share responsibility with foreign suppliers to ensure safety of food imported into the U.S.

FSVP requirements are risk-based (according to types of food, types of hazards, and supplier performance).

Importers have flexibility in how they meet requirements.

Purposes of FSVPs

FSVPs are intended to provide adequate assurances that:

- Foreign suppliers produce food using processes and procedures that provide the same level of public health protection as the FSMA Preventive Controls or Produce Safety requirements.
- Food is not adulterated under the FD&C Act or misbranded (*as to allergen labeling, human food only*).

Who is an "Importer" Under FSVP Rule?

Definition: "***Importer*** means the U.S. owner or consignee of an article of food that is being offered for import into the United States…"

Who is an "Importer" Under FSVP Rule? (continued)

"…If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart."

- 21 CFR Part 1, Subpart L, 1.500 Definitions

Determining Who Will Be the FSVP Importer

Often, more than one entity will meet the FDA definition of "importer" for FSVP purposes.

Entities that meet the definition of FSVP "importer" will need to decide among themselves:

- Who will agree to be identified as the FSVP importer for a particular food/foreign supplier, and
- Thus, be responsible for carrying out FSVP obligations.

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Importer of Record vs. FSVP Importer

A key difference between the FSVP "importer" as defined by FDA in the FSVP rule and the "importer of record" (IOR) as defined by Customs and Border Protection (CBP) is that:

- The FSVP "importer" must be someone in the U.S.

If the IOR is located in the U.S., that importer can also be the FSVP importer (assuming that the IOR otherwise meets the FSVP importer definition).

Whoever is the FSVP importer, that person is who FDA will hold accountable if FSVP requirements are not met.

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Who is a "Foreign Supplier"?

Definition: "***Foreign Supplier*** means, for an article of food, the establishment that manufactures/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."

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Who is a Qualified Individual?

Food importers are required to do a number of things that can only be done by persons who meet the definition of "***qualified individual***."

- An FSVP ***Qualified Individual*** is "a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required" by the FSVP rule, "and can read and understand the language of any records that the person must review in performing this activity… ."

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Note: “Qualified Individual” = “Competent Individual”

Previous slide defines “qualified individual”; FDA chose a poor term; confusing with Preventive Controls

Required Tasks Must Be Done by a Qualified Individual

Different FSVP tasks may require different qualified individuals.

Some qualified individuals may be qualified for more than one task, e.g. hazard analysis, determining verification activities.

Qualified individuals may be, but aren’t required to be, employees of the importer.

Qualified auditors are qualified individuals for conducting audits (audits are an example of a verification activity).

Qualified Individual

You will have MANY qualified (competent) individuals, each qualified in different ways to do different things

- Some "QI" tasks may be done by PCQIs
- Other "QI" tasks will require different skills

How is "Food" Defined?

Definition: "Food" is anything that is consumed as food or drink by humans or animals, including:

- Ingredients in food and beverages,
- Food additives and color additives put in food during processing,
- Dietary supplements, and
- Packaging and other food contact substances.

How is "Food" Defined? (continued)

Most food is regulated in the U.S. by FDA, except:

- Most (not all) meat, poultry or certain processed egg products, regulated by the U.S. Department of Agriculture (USDA).

The requirements discussed in this course apply to human and animal foods regulated by FDA.

U.S. Level of Public Health Protection

Your FSVP must ensure that your foreign supplier is:

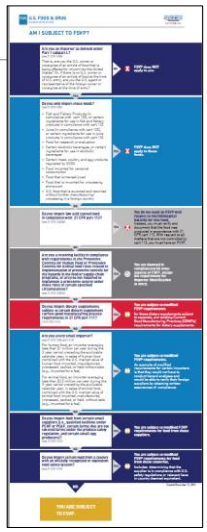
- Producing food using processes and procedures that provide at least the same level of public health protection as required under the FDA rules for risk-based preventive controls or produce safety, if either is applicable; **AND**
- Producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding labeling human food for the presence of major food allergens) of the FD&C Act.

"Not adulterated" (e.g., pesticides that are not harmful): not FDA's priority

- Priority is on public health, so they say

Does FSVP Apply to My Situation?

FDA has provided a flowchart that helps you determine whether or not you are subject to the FSVP rule.



The full version is available on FDA's website at: http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm472461.pdf

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Exempted Foods

Foods under FDA Hazard Analysis Critical Control Points (HACCP) rules

Alcoholic beverages (certain conditions)

Foods not intended for sale or distribution in the U.S.

Certain meat, poultry, and processed egg products (products subject to Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts)

Food manufactured/processed, raised, or grown in U.S., then exported and returned without further manufacturing/processing in a foreign country

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Foods Received and Processed by Importers Who Are Subject to PC Rules

If you are an importer who is a processor/manufacturer subject to and in compliance with the PC rules,

- You are required to employ supply chain preventive controls, as appropriate.
- You do not also have to carry out FSVP requirements.

However, as the importer:

- You must be named on the CBP entry filing as the importer in accord with the FSVP rule.

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Standard Requirements

Conduct a **hazard analysis** of the food, including hazard identification and hazard risk evaluation.

Conduct an **evaluation** of the foreign supplier's food safety performance and risk posed by the food.

Approve the foreign supplier (based on above evaluations).

Establish written procedures to ensure that food is imported only from approved foreign suppliers (with limited exceptions).

Determine and apply appropriate **verification activities** and assess results.

Implement **corrective action(s)**, if needed.

Reevaluate foreign supplier (at least every three years or when reason to).

Identify the FSVP importer at entry.

Keep required **records and documentation**.

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When Do Modified Requirements Apply?

If you are a "Very Small Importer"

If the imported food is from "Certain Small Foreign Supplier(s)"

If the imported food is from foreign supplier(s) in countries with food safety systems recognized by FDA as "comparable" or "equivalent"

If you import dietary supplements or dietary supplement components

Will FDA Inspect FSVP Importers?

FDA has always conducted inspections of food-related operations falling within its jurisdiction to protect public health.

To enforce FSVP, FDA will certainly inspect FSVP importers.

FDA is expected to rely heavily on its authority to access the records that must be kept by FSVP importers to demonstrate compliance with FSVP requirements.

FDA Compliance Activity for FSVP

FDA may:

Conduct an onsite inspection of records.

Request electronic submission of your records.

- FDA review of these records is the same as an onsite inspection.

Request that records kept offsite be made available within 24 hours.

Request that some records be translated into English within a reasonable time.

What to Expect During an Inspection

Generally FDA does not give advanced notice that it is about to carry out an inspection.

FDA will present a formal “Request for FSVP Records” (Form 482d)

You should expect that FDA will:

- Review all of the different types of documentation that relate to your compliance with the FSVP rule.
- Look at your records to determine whether you have maintained them in compliance with FSVP requirements.
- Request copies of some of your records.

FDA will provide you with "FSVP Observations" (Form 483a) that will describe any deficiencies in compliance.

Compliance Dates for FSVP Importers

The compliance date for those FSVP importers whose foreign supplier is not subject to either of the PC rules or the Produce Safety rule is May 30, 2017.

The various compliance dates for the importation of food from a foreign supplier that is subject to the PC rules or Produce Safety rule, vary with the implementation dates of those rules.

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FSVP Training Classes

In contrast to the PC rules for human or animal food and the Produce Safety Rule, the FSVP rule does not require an FSVP "qualified individual" to attend a training program following a "standardized curriculum" recognized by FDA.

Therefore, completing this course is not mandatory.

Attending this course, however, will help course participants understand the FSVP requirements and how those requirements can be met in their particular circumstance.

Typical courses are 2 days long.

https://fspca.force.com/FSPCA/s/course_registration/Course_Registration__c/00B36000007edjpEAA?language=en_US

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Questions

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