



EDITION 1

**GREEN PAPERS**

# **fsvp guidance to compliance**

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SHIPPING

# what is fsvp?

## FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

This a set of programs under the Food Safety Modernization Act (FSMA) that importers must have in place to verify that their foreign suppliers are using processes and procedures offering the same level of public health protection as FSMA preventive control (PC) requirements such as current good manufacturing practices for foods (human and animal) and produce, ensure food is not adulterated, and is properly labeled with respect to allergens.

## when did fsvp go into compliance?

The Foreign Supplier Verification Program first went into effect on May 30, 2017. Additional program deadlines are as follows:

SIZE OF BUSINESS	DATE OF COMPLIANCE
<b>Very small business</b> averaging less than \$10 million per year	<b>July 26, 2021</b>
<b>Small business</b> , including any subsidiaries and/or affiliates, with fewer than 500 full-time equivalent employees	<b>July 27, 2020</b>
<b>Other businesses</b> not qualifying for exemptions	<b>July 26, 2020</b>

# am i subject to fsvp?

## REGULATED FOODS

fish/fishery products (in compliance with part 123);

Juice or juice ingredients (in compliance with part 120);

Certain alcoholic beverages;

Food for research;

USDA regulated meat, poultry & egg products

Food imported for personal consumption;

Food that is transhipped;

Food that is imported for processing and export;

U.S. food exported & returned without further processing in a foreign country.

## VERY SMALL IMPORTER

For human food, an importer averaging less than \$1 million per year (or, \$2.5 million per year for animal foods), during a 3-year period, in sales combined with the U.S. market value of food imported, manufactured, processed, packed, or held without sale.

**IF NO,** FSVP does NOT apply to you.

Are you the U.S. owner or consignee of an article of food that is being offered for import into the United States? Or, if there is no U.S. owner or consignee, are you the U.S. agent or representative of the foreign owner or consignee at the time of entry?

**DO YOU ONLY IMPORT ANY OF THESE FOODS?**

**IF YES,** FSVP does NOT apply to you.

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Do you import low acid canned food in compliance with 21 CFR part 113?

**IF YES,** FSVP is applicable.

Are you receiving facility in compliance with requirements in the Preventive Controls for Human or Preventive Controls for Animal food rules?

**IF YES,** Subject to modified FSVP.

Do you import dietary supplements subject to certain dietary supplement current good manufacturing practice requirements in 21 CFR part 111?

**ARE YOU A VERY SMALL IMPORTER?**

**IF YES,** Subject to modified FSVP.

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Do you import food from certain small suppliers (i.e., qualified facilities under PCHF or PCAF, certain farms that are not covered farms under the produce safety regulation, and certain small egg producers)?

**IF YES,** Subject to modified FSVP.

Do you import certain food from a country with an officially recognized or equivalent food safety system?

## FSVP INSPECTIONS

will be based on the review of records, rather than observations of food production.

While most FSVP inspections will be held at the importer's place of business, FDA will also request that some importers provide FSVP records to FDA electronically, as part of a pilot program.

In either case, the investigator will ask to view the importer's FSVP records to determine if there are deficiencies.

In most cases, if any deficiencies are found, the importer will be provided an opportunity to correct them.

## fsvp key requirements

### WHAT IS MY OBLIGATION?

Unless exempt, or subject to modified requirements, an FSVP importer is responsible for:

1. Identifying a qualified individual to develop an FSVP and to perform FSVP activities.
2. Performing a hazard analysis to identify known or reasonably foreseeable hazards associated for each type of food and determining whether they require a control. Potential hazards include:
  - biological hazards, including parasites and disease-causing bacteria;
  - chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved additives, food allergens, and (in animal food) nutrient deficiencies or toxicities;
  - physical hazards, such as glass.
3. Evaluating risks posed by the food and the performance of the foreign supplier, considering:
  - the hazard analysis for the food;
  - the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier;
  - the foreign supplier's food safety practices and procedures;
  - applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert; and
  - the foreign supplier's food safety performance history, including results from testing, audit results, and the supplier's record of correcting problems.

## fsvp key requirements CNTD

4. Conduct appropriate supplier verification activities to provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented. These activities may include:
  - annual on-site audits (must be performed by a qualified auditor);
  - sampling and testing of a food;
  - a review of the supplier's relevant food safety records; and/or o other appropriate activities.
5. Take corrective actions (if necessary) and investigate the adequacy of the FSVP (when appropriate).
6. Reevaluate the food and foreign supplier every three years or sooner if the FSVP importer becomes aware of new information about the hazards in the food or the foreign supplier's performance.
7. Identify the FSVP importer when filing for entry with U.S. Customs and Border Protection using the FSVP importer's name, electronic mailing address, and unique facility identifier (UFI) recognized as acceptable to FDA.
  - The FDA recognizes the Data Universal Numbering System (DUNS), a unique nine-digit business registration number, as an acceptable form of UFI for FSVP.
  - If you do not know your DUNS number, it is available free of charge by emailing [govt@dnb.com](mailto:govt@dnb.com) or visiting [fdadunslookup.com](http://fdadunslookup.com).

## need help with fsvp?

CONTACT GREEN AT  
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