



## I'm A FSVP Importer – How Do I Know When I Need To Comply?

That is one of the most common - and difficult questions - to answer when OFW Law teaches a Food Safety Modernization Act Foreign Supplier Verification Programs (FSMA FSVP) course. Determining the compliance dates is typically more challenging for the affected importers. To make it easier, OFW Law has created the following flow diagrams and examples to help the FSVP Importer determine when they must be compliant.

It is important to note that a FSVP Importer must develop a FSVP program based on the foreign supplier and the food being imported. In other words, foreign suppliers are not allowed “general approval” for all foods being produced by them. A FSVP program is for the foreign supplier and the food product being imported.

Also, the FSVP Importer will need to determine if standard or modified requirements to the FSVP rule apply to them based on their size, and their foreign supplier and the food their foreign supplier produces.

The FSVP Importer will need to determine when the FSVP Rule is effective. Compliance dates for the FSVP Rule are dependent on:

- the importer;
- size of the foreign supplier; and
- when the foreign supplier must meet the requirements for the Preventive Control for Human or Animal Food Rules or the Produce Safety Rule.

**Bottom line:** The FSVP Rule goes into effect May 30, 2017, 18 months after the FSVP Final Rule was published, or 6 months after the FSVP Importer’s foreign supplier is required to meet the relevant Food Drug Administration (FDA) FSMA regulations for the food they produce for export.

Essentially, FSVP importers will need to determine when their foreign supplier needs to be compliant with FSMA and add 6 months to that date for their own compliance date to the FSVP Rule.

Example 1: A FSVP Importer’s foreign supplier produces cheddar cheese. The foreign supplier has more than 500 full-time equivalent employees and should have been compliant with Preventive Controls for Human Foods (PCHF) on September 19, 2016. In this situation, while the foreign supplier has been compliant for more than 6 months after FSMA was effective for the foreign supplier’s establishment, the FSVP Rule does not go into effect until 18 months after the publication of the FSVP final rule. So, in this situation, the FSVP importer would have to be compliant to the FSVP Rule on May 30, 2017.

Example 2: A FSVP Importer’s foreign supplier produces cheddar cheese. This time the foreign supplier has less than 500 full-time equivalent employees and is recognized as a small business. Because of this small business distinction, the foreign supplier will need to be compliant with Preventive Controls for Human Foods (PCHF) on September 18, 2017. As a FSVP Importer of a foreign supplier that is considered a small business within the PCHF rule (21 CFR 117.3), the effective date for the FSVP importer is 6 months after their foreign supplier has to comply with PCHF, which would be March 19, 2018.



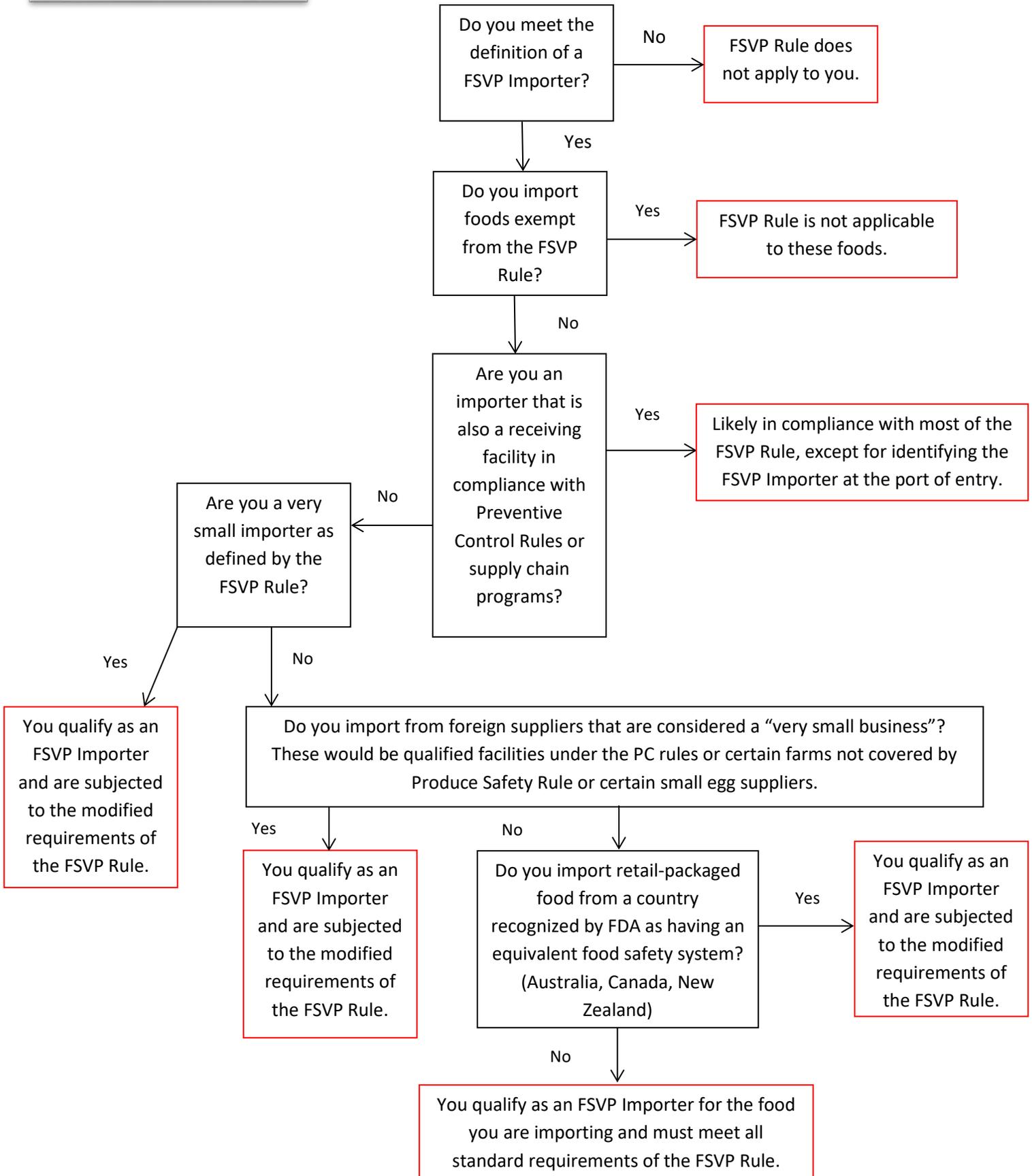
## DEFINITIONS

Within the **Foreign Supplier Verification Programs Rule** ([21 CFR Subpart L § 1.500](#))

- **Facility** means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.
- **Farm** means farm as defined in §1.227.
- **Farm Mixed-Type Facility** means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.
- **Food** has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article), except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).
- **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.
- **Importer** means the U.S. owner or consignee of an article of food that is being offered for import into the United States. 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.
- **U.S. Owner or Consignee** means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.
- **Very Small Importer** means:
  - With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (*e.g.*, imported for a fee); and
  - With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (*e.g.*, imported for a fee).

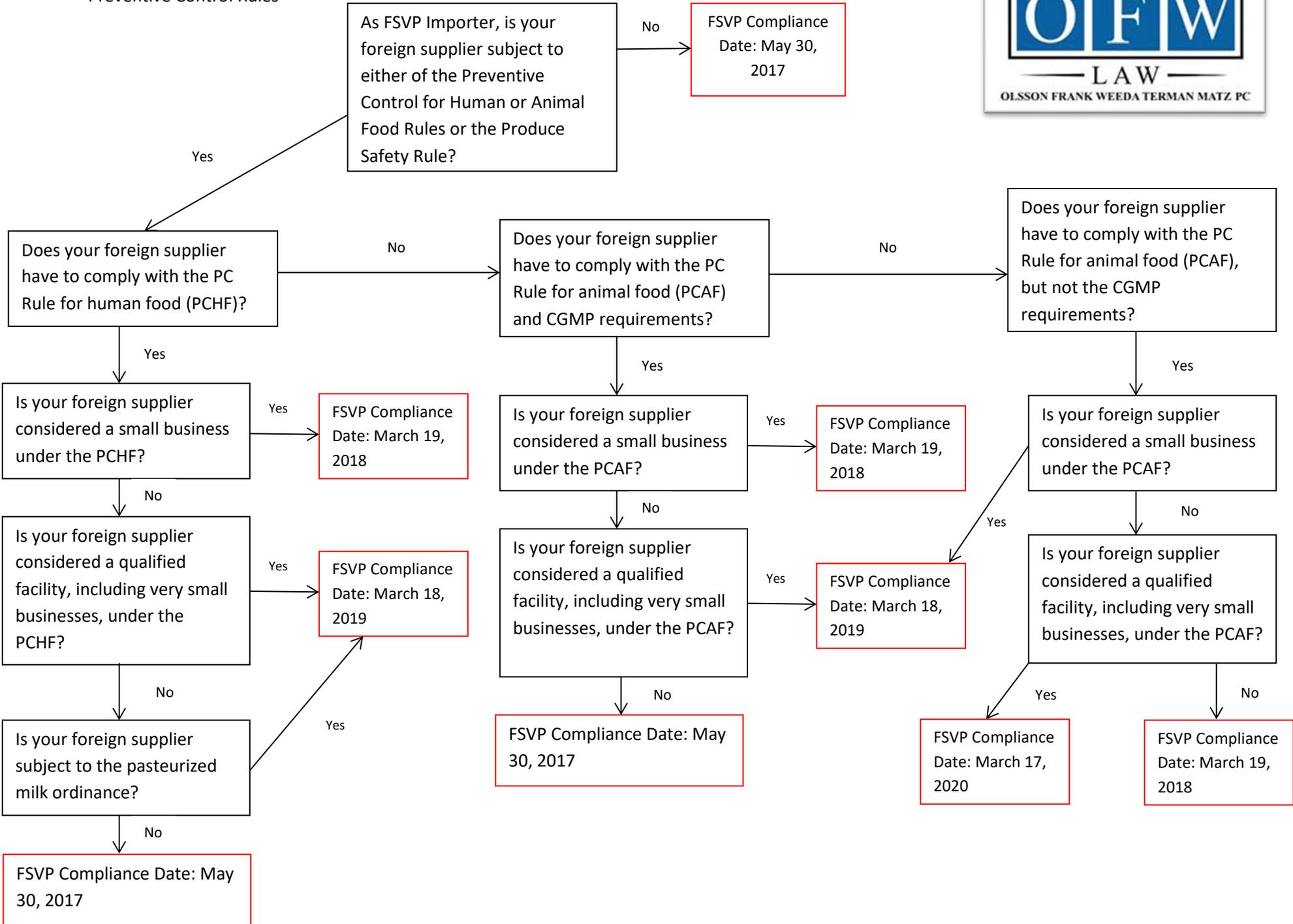


# Am I A FSVP Importer?





Preventive Control Rules





## DEFINITIONS

### Within the **Preventive Controls for Human Food Rule** ([21 CFR 117.3](#))

- **Small Business** means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.
- **Qualified Facility** means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:
  - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
  - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.
- **Very Small Business** means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee).

### Within the **Preventive Controls for Animal Food Rule** ([21 CFR 507.3](#))

- **Small Business** means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.
- **Qualified Facility** means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:
  - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
  - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.
- **Very Small Business** means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale).





## DEFINITIONS

Within the **Produce Safety Rule** ([21 CFR 112.3](#))

- *Small Business* means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business as defined in this section.
- *Very Small Business* means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$250,000.