



Foreign Supplier Verification Programs

What Do Manufacturers/Processors Covered by the PC Supply-Chain Program Need to know about FSVP?

A manufacturer/processor subject to the preventive controls (PC) requirements that uses imported raw materials or other ingredients may also be an importer covered by the Foreign Supplier Verification Programs (FSVP) rule. It's important for these manufacturers/processors to know that:

- they can be deemed in compliance with most of the FSVP requirements for foods they import if they implement preventive controls for the hazards in the food in accordance with applicable requirements or comply with the PC supply-chain program requirements, and
- they will still need to provide certain identification information when importing the food, as required in the FSVP rule. For example, they will need to provide a unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.

The first major compliance date for FSVP is May 30, 2017. Compliance dates for both FSVP and the PC supply-chain requirements are staggered, based on the size of the supplier.

For more information on PC compliance dates

Human Food:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>

Animal Food:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food>

For more information on FSVP compliance dates:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/compliance-dates-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and>

How do I know if I am subject to the FSVP rule?

You are subject to the FSVP rule if you meet the definition of importer under that rule. The FSVP importer is the

U.S. owner or consignee of the food offered for import (i.e., owns the food, has purchased it, or has agreed in writing to purchase it at the time of U.S. entry). If there is no U.S. owner or consignee at time of entry, the FSVP importer is the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent.

What is required if I am an importer under the FSVP rule?

Like the supply-chain program requirements in subpart G of 21 CFR part 117 (for human food) and subpart E of 21 CFR part 507 (for animal food), the FSVP rule provides that supplier verification activities must provide assurance that the hazards requiring a control in the food have been significantly minimized or prevented. In order not to impose duplicative requirements, manufacturers/processors are deemed in compliance with most FSVP requirements if:

- they have established and implemented a supply-chain program in compliance with subpart G of 21 CFR part 117 (for human food) or subpart E of 21 CFR part 507 (for animal food);
- they implement preventive controls for the hazards in the food in accordance with 21 CFR 117.135 (for human food) or 21 CFR 507.34 (for animal food); or
- they are not required to implement preventive controls under the preventive controls rules in certain specified circumstances. Examples of such circumstances include when the type of food (e.g., such as coffee beans) could not be consumed without application of a preventive control, or when the customer will be significantly minimizing or preventing identified hazards,. The circumstances are specified in 21 CFR 117.136 (for human food) and 21 CFR 507.36 (for animal food).

Although a manufacturer/processor that is also an FSVP importer will be deemed in compliance with most of the FSVP requirements as specified above, under the FSVP rule, it still needs to provide its name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.

(Note that manufacturers/processors subject to the preventive controls requirements have a choice about whether they wish to comply with the supply-chain program requirements in the preventive controls regulations, or if they prefer to comply with supplier verification requirements under the FSVP rule. Under the preventive controls regulations, receiving facilities that are importers in compliance with the FSVP requirements and have documentation of activities conducted under section 1.506(e) need not conduct verification activities for that raw material or other ingredient (see sections 117.405(a)(2) and 507.105(a)(2))).

What is a UFI and how should an importer go about getting one?

The FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP. DUNS numbers, assigned and managed by DUN & Bradstreet, are available free of charge to importers by visiting <https://www.dnb.com/duns.html>. For more information, see **Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation** (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recognition-acceptable-unique-facility-identifier-ufi-foreign-supplier>).

FDA issued updated guidance in April 2022 that removes the temporary policy of permitting the use of the entity role code “UNK” in lieu of a DUNS number. The guidance states that beginning on July 24, 2022, FSVP importers must comply with the requirement in 21 CFR 1.509(a) of providing a unique facility identifier recognized as acceptable by FDA (i.e., DUNS number) when filing entry with CBP. For more information, see **Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs for Food Importers Regulation** (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-compliance-providing-acceptable-unique-facility-identifier-foreign-supplier>).