



## Foreign Supplier Verification Programs (FSVP) Instruction Letter

Foreign Supplier Verification Program (FSVP) is a risk-based program mandated by the Food & Drug Administration to verify foreign suppliers and the safety of the food they produce.

The FSVP importer is the US owner/buyer of the food offered for import into the United States. If there is no US owner or buyer at the time of entry, the FSVP importer is the US agent who is a representative of the foreign exporter, as confirmed in a signed statement of consent agreement. The FSVP importer takes responsibility for meeting FSVP requirements, which is to verify that foreign suppliers are using safe processes, procedures, and that the food is not adulterated or misbranded. Food must meet US Food Safety Standards.

By signing this form, you acknowledge that you have read the entire form and understand your responsibilities as the importer of record and to the best of your knowledge, the named FSVP party understands their role and responsibilities in being named the FSVP party for your shipments, has agreed to be your FSVP party, and has an FSVP program in place per FDA regulations. [21 CFR Subpart L 1.500](#).

### Importer of Record Information

Shipment Entry No., Invoice or Reference No.: \_\_\_\_\_

(Single Shipment ONLY, submission of Single Shipment information is preferred)

Annual Certificate Period, covering from (month, year) \_\_\_\_\_ to (month, year) \_\_\_\_\_

(Complete ONLY for Blanket Declarations)

Company Name: \_\_\_\_\_ Account Number: \_\_\_\_\_

Address: \_\_\_\_\_

City, State/Province, and Zip/Postal Code: \_\_\_\_\_

Name of Certifying Individual: \_\_\_\_\_ Title: \_\_\_\_\_

Phone No.: \_\_\_\_\_ Email: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### FSVP Importer Information

Company Name: \_\_\_\_\_ DUNS Number\*: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, and Zip Code: \_\_\_\_\_

FSVP Contact Name: \_\_\_\_\_ Title: \_\_\_\_\_

Phone No.: \_\_\_\_\_ Email: \_\_\_\_\_

\* DUNS Number provided is location where FSVP records are maintained. **Please ensure A.N. Deringer is notified immediately if there are any changes to the above information.**

### Exemptions

If an FSVP Exemption applies, indicate the exemption number from the list on page 2 of this form: \_\_\_\_\_

**DUNS:**

- The FSVP requires the US FSVP importer's unique facility identifier
- At the moment the only data element which satisfies this requirement is the DUNS (Dun and Bradstreet number)
- The number provided should refer to the facility where FDA would physically go to in the event that they wished to inspect records

***If you need a DUNS number or need to verify your DUNS:***

<https://www.dnb.com/duns-number/lookup.html>

***Step-by-step guide on how to look up a DUNS Number:***

<https://www.fdahelp.us/Pdf/how-to-look-up-duns-number.pdf>

**FSVP Exemptions:**

1. Importation by a foreign supplier who has under 500 full time employees as defined in 21 CFR 117.3 (**No longer a valid exemption, expired 2018.**)
2. Certain meat, poultry, and egg products
3. Certain alcoholic beverages
4. Food is exempt if it will only be used for research and development as defined in 21 CFR 1.501 C. The food must be labeled for "research and evaluation." In addition to the country of origin. Affirmation of Compliance is RNE.
5. Juice and seafood from foreign suppliers that are in compliance with the respective HACCP regulations (21CFR part 120 or 123) and certain ingredients that are used by the importer in the manufacturing or processing of juice and seafood products in accordance with the respective regulations.
6. Small quantities of food imported for personal consumption that are not intended for retail sale and are not sold or distributed to the public
7. Food produced in compliance with FDA's low acid canned food requirements in 21 CFR part 113 (exempt with respect to microbiological hazards controlled by 21 CFR part 113 only), as well as certain ingredients for use in LACF products but only with respect to microbiological hazards).
8. Food that is transshipped through the United States or that is imported for future export and not sold or distributed in the United States
9. Food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing.
10. Importation of foods that cannot be consumed without hazards being controlled or for which the hazards are controlled after importation under specified circumstances
11. Importation of dietary supplements and dietary supplement components that will be subject to certain provisions of the dietary supplement Current Good Manufacturing Practice regulation under specified circumstances, or other dietary supplements.



## What are the responsibilities of an FSVP “Qualified Individual”?

21 CFR 1.503 requires that the importer use a **U.S. qualified individual** to perform all FSVP activities, which includes the following:

- Develop FSVP
- Conduct Hazard Analysis
- Evaluate Risks Posed by a Food and Performance of the Foreign Supplier
- Approval of Foreign Supplier
- Foreign Supplier Verification Activities
- Corrective Actions
- Maintenance of Records

FSVP is responsible for ensuring that supplier verification activities are conducted for **each food product imported**.

## Failing to Comply with FSVP requirements:

- Article of food is subject to refusal of admission by FDA
- The importation or offering for importation into the US of an article of food without the importer having an FSVP is prohibited
- In the context of FSVP, including the FSVP requirements, providing false information related to the identification of the importer at the time of entry into the US., might be a criminal offense

## Best Practices:

- Verify DUNS Number provided is location where FSVP records are kept
- Include FSVP details on commercial documents
- Commercial Documents should indicate applicable exemptions

Any questions, please contact your A.N. Deringer Representative or email: [compliance@anderinger.com](mailto:compliance@anderinger.com)

## FSVP Toolkit:

[Am I Subject to FSVP?](#)

[FSVP at-a-glance](#)

[FSVP Fact Sheet](#)

[FSVP Final Rule](#)

[FDA Import Program](#)

[Food Safety Modernization Act \(FSMA\)](#)