

FDA FACT SHEET

“What to Expect During a Foreign Supplier Verification Programs Inspection”

Inspections are an important tool the U.S. Food and Drug Administration (FDA) uses in ensuring human and animal foods are safe for U.S. consumers. The Foreign Supplier Verification Programs (FSVP) rule, which is one of the seven rules that make up the Food Safety Modernization Act (FSMA), requires that importers perform certain risk-based activities to verify that the human and animal food they import into the United States has been produced in a manner that meets applicable U.S. safety standards. This fact sheet provides an overview of steps FDA investigators will take when conducting routine inspections to determine compliance with the FSVP Rule.

An inspection of an FSVP importer to review FSVP records can occur if:

- The importer is subject to routine surveillance and follow-up;
- The importer has an inspectional history that includes a violative inspection and a compliance follow-up inspection is needed to observe voluntary corrections; or
- Products imported by the FSVP importer are associated with a recall, foodborne outbreak investigation, or complaint.

Pre-Inspection Contact

For initial inspections, an FDA investigator will email and/or call the person or entity identified at the time of entry as the FSVP importer.

The investigator will confirm the entity as the FSVP importer for the specific product(s)/foreign supplier(s) assigned to be reviewed, including clarification of the importer’s location and contact information. The investigator will also determine if the FSVP records are in English and available onsite, if they can be retrieved within 24 hours of written request; and if documents are not maintained in English, how soon an English translation can be provided.

Please note that if FDA’s pre-inspection contact attempts are unsuccessful, the FDA will still plan to conduct the inspection at the address transmitted at entry.

How to Prepare for the Inspection

Once contacted regarding an FSVP inspection, the importer should retrieve any records that may be stored offsite so that the documents are ready for the investigator at the start of the inspection. If records are not in English, the FSVP importer should have the records translated into English, prior to the inspection date.

The [FSVP Regulation Records Requirements](#) provide a list of FSVP records the investigator may request to review during the inspection. The list may be used to help the FSVP importer prepare for and facilitate the inspection.

During the Inspection

FSVP inspections are generally conducted at the FSVP importer’s location during normal business hours. When the

investigator arrives, they will ask to speak to the most responsible individual onsite. The investigator will introduce themselves (name, title, agency), provide the reason for the inspection, and show identification. The investigator will also request FSVP records in writing (Form FDA 482d). If the firm is a warehouse, or other type of facility that stores or holds food, the investigator will also issue a Notice of Inspection (FDA Form 482) if a warehouse inspection is scheduled to take place as well. Inspections of warehouses are covered under a different section of the Food Drug and Cosmetic Act.

The owner or the individual responsible for creating and maintaining the FSVP (e.g., a qualified individual) should be present for the inspection. If at the time of the inspection, the owner or the person responsible for creating or maintaining the FSVP is not available in person, he or she should be accessible by telephone. If another qualified entity performed FSVP activities on behalf of the importer, the importer may obtain records from their qualified individual during the inspection.

During the inspection, the investigator will review FSVP records for the product(s)/supplier(s) identified during the pre-inspection contact. They will ask questions and take notes to determine the adequacy of the FSVP records and may ask for copies of the records. They may also ask for labeling, if available, and take pictures.

The amount of time an inspection takes depends on the basis on which the inspection is being conducted, and what is observed during the inspection. The investigator will report their observations to the most responsible individual present during the inspection. The FDA encourages open dialogue among all parties throughout the inspection.

Please note: FSVP inspections may also take place remotely. Under section 1.510(b)(3), if requested in writing by FDA, the importer must send records to the Agency electronically, or through another means that delivers records promptly. This section provides the regulatory basis for conducting remote inspections. For a remote inspection, the FSVP records are reviewed by the investigator at a site other than the importer's premises.

Close of the Inspection

The inspection concludes with an exit interview with the most responsible individual onsite. If the investigator made significant observations during the inspection, they will provide those observations in writing (Form FDA 483a, FSVP Observations), and discuss corrective actions. Less significant observations found during the inspection will also be discussed during the exit interview. For more information about written inspectional observations, please see the [FDA Form 483 Frequently Asked Questions webpage](#).

If the importer responds during the inspection by making corrections to issues pointed out by the investigator, the investigator will take note and collect evidence, if possible. If the deficiency is something that cannot be corrected during the inspection, the investigator should ask the importer about the corrective actions they plan to take. The FDA highly encourages the importer to provide a written response to the FDA within 15 business days following the inspection. The response should include newly created and updated records and evidence of corrections. During the exit interview, the investigator will also answer any additional questions regarding the inspection and next steps.

More information about FSVP can be found on www.FDA.gov/FSMA.