WHITE PAPER

FSMA, FSVP AND VQIP: AN OVERVIEW

Each year, about 48 million people (one in six Americans) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases.

The FDA Food Safety Modernization Act (FSMA) enables FDA to better protect public health by strengthening food safety and increasing focus on preventing food safety issues rather than just reacting to problems.

FDA created the Accredited Third Party Certification Program to assure increased safety of imported food products. Certification Bodies like NSF can be come accredited to perform FDA regulatory audits of foreign suppliers for eligibility for VQIP and to satisfy FSVP requirements for importers.

FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

Under FSMA, importers are responsible for ensuring the safety of food products they bring into the U.S. for distribution and sale for public consumption. FSVP requires importers to verify that food imported into the U.S. is not adulterated or misbranded with respect to allergen labeling and complies with U.S. product safety standards.

- Importers must evaluate the imported food as well as the supplier's performance every three years. Records of review must be documented.
- Importers must identify and evaluate reasonably foreseeable hazards for each type of food imported to determine whether there are any hazards requiring control and, if so, document them.
- Importers are required to assess vulnerability of materials/products to food fraud.
- Importers are responsible or verifying their foreign supplier on a regular basis. Annual on-site audits of the supplier's facility, sampling and testing, and review of relevant food safety records is required.
- FSVP requires that certain activities must be carried out only by a Qualified Individual (QI).
- Audits conducted by a CB accredited under the FDA Third Party Accredited Program against the FDA regulations can satisfy the FSVP supplier verification activity requirements.

FDA will rely heavily on recordkeeping during inspections to determine compliance with FSVP requirements. **Most businesses were required to comply on July 26, 2018.**

Definitions

Qualified Individual (QI) is someone hired on a full-time basis or sought through an external resource to help you:

- Document and implement the hazard analysis
- Conduct performance evaluation of foreign suppliers
- Approve suppliers
- Document and implement verification activities
- Document and implement corrective actions
- Reevaluate FSVP and document reevaluation
- Maintain records

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Food hazards cause illness or injury to humans or animals that eat the food. Hazards can be biological, chemical or physical threats intentionally or unintentionally introduced. Scope:

- Preventative Control for Human Food
- Preventative Controls for Feed,
- Seafood HACCP
- Juice HACCP
- Produce Safety Rule

VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP)

The Voluntary Qualified Importer Program (VQIP) is a voluntary fee-based program that provides expedited review and import entry of food brought into the United States for participating importers.

Participating importers benefit from increased speed and predictability at point-of-entry. Consumers benefit from increased safety and security of imported foods.

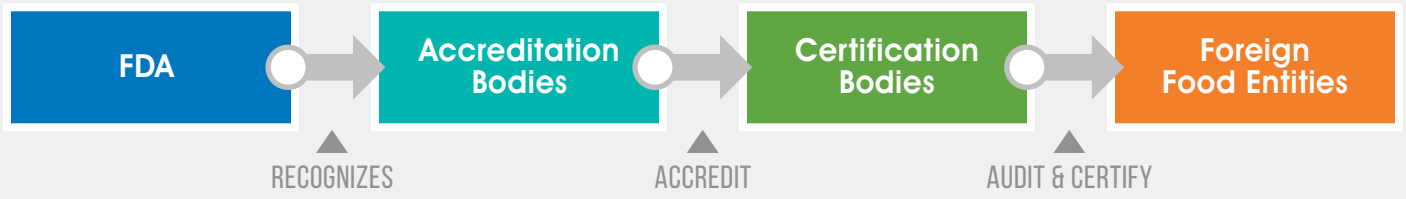
- A site may choose to have a third-party consultative audit prior to the VQIP certification audit to help the site prepare for certification.
- All accredited VQIP certification audits are unannounced.
- The FDA can mandate an import certification (IC) regulatory audit of foreign food suppliers in certain cases it deems high risk. The third-party CB accredited under the FDA Third Party Accredited Program for VQIP audits is also authorized to perform the IC regulatory audits.
- If a supplier undertakes a VQIP or IC audit by an accredited CB, its audit information is shared with the FDA and is listed publicly for its certification status and authorized products for import.
- If a VQIP or IC supplier is involved in a recall, the certification is immediately suspended pending further investigation.
- If a CB observes a critical food safety hazard at the certified site, the FDA is immediately notified and the certification audit is stopped and certification is suspended.

Benefits

- Quicker, easier market entry
- Limited examination and sampling
- FDA sampling at importer's preferred location
- Faster test results
- Dedicated helpline: **FSMAVQIP@fda.hhs.gov** or +1 301 796 8745

Begin your application process with the FDA.

THIRD-PARTY ACCREDITED CERTIFICATION BODIES



NSF has been accredited by ANSI to perform these certification audits for FSVP, VQIP and IC. NSF will begin to offer certification in 2019.

- Establish eligibility for participation in the VQIP, which offers expedited review and entry of food.
- Assist food importers in identifying and addressing potential safety issues before the food reaches the U.S.
- Help ensure imported foods are produced in accordance with the same safety standards required of U.S. foods.

For more information about NSF's import supplier certification or to start your application, visit **www.nsf.org/info/fsma** or email **foodsafetysolutions@nsf.org**.

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