

Voluntary Qualified Importer Program (VQIP)

Final Guidance for Industry Overview

Office of Foods and Veterinary Medicine
Food and Drug Administration

What is VQIP?

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Eligibility is limited to importers who demonstrate a high level of control over the safety and security of their supply chains.

Definition of VQIP Importer

- Section 806(g) defines “importer” as “the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”
 - Can include manufacturers, consignees and importers of record for food for humans and animals
 - May or may not be the FSVP importer

VQIP Guidance Eligibility Criteria

- Quality Assurance Program (QAP)
- Assurance of compliance with the supplier verification and other importer responsibilities under the applicable FSVP or HACCP regulations.
- Current facility certification, including farms, issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food in VQIP.

VQIP Guidance Eligibility Criteria (con'd)

- 3+ year history of importing food to the United States.
- No ongoing FDA administrative or judicial action, or other history of non-compliance with food safety regulations by the importer, other entities in the supply chain, or for the food.
- Have a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number.

Elements of a QAP

- Corporate Quality Policy Statement
- Organizational structure and individual responsibilities
- Policies and procedures to ensure food safety from source to entry (e.g., temperature and storage controls), including procedures regarding:
 - Compliance with supplier verification procedures in the FSVP or HACCP rules, if applicable, and maintenance of current facility certifications under FDA's Accredited Third-Party Certification Program
 - Communication of information about potential health hazards to FDA and others
 - Corrective actions to address food and foreign supplier non-compliances that post a risk to public health

Elements of a QAP (con'd)

- Food defense system to protect against intentional adulteration
- Experience and training requirements for employees responsible for implementing the QAP
- Written procedures for establishing and maintaining records relating to the structure and implementation of the QAP

Benefits of VQIP

- Expedited entry into the U.S. for all foods included in an approved VQIP application
- Examination and/or sampling generally limited to “for cause” situations in which there is a potential threat to public health
- Any sampling or examination done at destination or another location chosen by the importer to the extent possible

Benefits of VQIP (con'd)

- Expedited laboratory analysis of any samples
- VQIP Importers Help Desk
- Public posting on the FDA's VQIP web page of approved VQIP importers, if desired

Other Elements of the Guidance

- Application (e.g., submission, timing, amendments, FDA review)
- User Fees
- Revocation Process
- Reinstatement Process

Key Changes

- Ability to add additional food from a foreign supplier from which the importer already imports food under VQIP
- Removes requirement that VQIP applicants must upload food labels for foods included in the VQIP application

Key Changes

- Provides examples of how to ensure that the FSVP or Hazard Analysis and Critical Control Point (HACCP) importer of the food is in compliance with the applicable FSVP or HACCP regulations
- Revises the ‘3-year import history’ eligibility criteria to allow the use of shared importation history of previous or parent companies.

Timing of VQIP Program

- Anticipate first applications January 1, 2018
- Anticipate first benefit period to begin October 1, 2018

Questions

- For more information, visit our website:
<http://www.fda.gov/fsma>

