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Regulatory Alert: FDA Publishes FSMA Voluntary Qualified Importer Program Draft Guidance

Requirements for Expedited Entry of Food Shipments Spelled Out

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On June 4, 2015, FDA published draft guidance on the Food and Drug Administration's (FDA) Voluntary Qualified Importer Program (VQIP). The Food Safety Modernization Act (FSMA) required FDA to establish VQIP. VQIP is a voluntary, fee-based program that provides for expedited review and importation of foods from importers who import food from facilities and farms that have been certified under FDA's Third-Party Auditing regulations, and take additional measures to ensure the safety and security of the foods they import. **The VQIP program will not be available until the Third-Party Auditor Rule is finalized and implemented (with auditors/certification bodies accredited).** Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information.

Key Questions and Answers

Benefits

What are the benefits of participation in VQIP?

- FDA will expedite entry into the U.S. for all VQIP foods. FDA will set screening in its PREDICT import screening system to recognize VQIP foods to expedite entry. The system is designed to recognize the information and immediately release the shipment, unless examination and sampling are necessary for public health reasons.
- FDA will limit examination and/or sampling of VQIP food entries to "for cause" situations (i.e. public health) to obtain statistically necessary samples and audit VQIP.
- FDA will expedite lab analysis of "for cause" or audit samples of VQIP entries.
- FDA will maintain a VQIP Importers Help Desk for VQIP importers.

FDA notes that they may suspend any or all of these benefits as necessary to protect public health or in the event of an emergency.

When do importers receive VQIP benefits?

October 1 following the acceptance of the importer into the program, and benefits will last through September 30 of the following year with certain exceptions.

What information should be submitted at entry to identify a VQIP food?

A VQIP Affirmation of Compliance code and the VQIP application number to identify the entry as a VQIP food.

Will FDA expedite entry of a VQIP food that is part of an entry with non-VQIP food?

FDA will expedite only the line entry associated with the VQIP food. Entry may not be expedited in instances where VQIP foods cannot be readily separated from non-VQIP foods to allow for examination or sampling of the non-VQIP foods.

Definition of VQIP Importer

Who can be a VQIP importer?

A VQIP importer is defined as the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the U.S. A VQIP importer may be located outside of the U.S. Persons who may be a VQIP importer include the manufacturer, owner, consignee, and importer of record.

Must a VQIP importer be the importer of record for an entry?

No. A VQIP importer may be, but is not required to be, the importer of record.

Is the VQIP importer the same as the FSVP importer or importer under the Juice and Seafood HACCP rules?

No. An FSVP or HACCP importer must be located in the U.S. A VQIP importer may be a foreign importer. A VQIP importer may be an FSVP or HACCP importer in many circumstances (if it is a U.S. person).

Eligibility

What are the eligibility criteria for VQIP participation?

1. At least a 3-year history of importing food into the U.S.
2. A D-U-N-S number
3. Use of a paperless filer/customs broker who received a passing rating during their last FDA filer evaluation
4. No food you import, including a food you do not intend to include under VQIP is subject to a Class 1 recall or import alert
5. Neither you nor the non-applicant entities associated with a VQIP food are subject to an ongoing FDA administrative or judicial action (e.g., Import Alert, injunction, and debarment), or have a history of significant noncompliances relating to food safety. Non-applicant entities include the FSVP or HACCP importer of the food, the foreign supplier, and the filer/customs broker.
6. If you are the FSVP or HACCP importer for a VQIP food, you are in compliance with the supplier verification and other importer responsibilities under the applicable FSVP or HACCP regulations. If you are not the FSVP or HACCP importer for a VQIP food, you identify the FSVP or HACCP importer for the food and ensure they are in compliance with those regulations as applicable.

7. You have a current facility certification for each foreign supplier of food you intend to import under VQIP.
8. You develop and implement a VQIP Quality Assurance Program.
9. Within the past 3 years, you have not been the subject of any CBP penalties, forfeitures, or sanctions that are related to the safety and security of any FDA-regulated product that you imported or offered for import.
10. You pay the annual VQIP user fee before October 1 of the year in which you intend to participate.

What are the estimated user fees for VQIP?

FDA has estimated an annual user fee of $16,400.

Facility Certification

What certification for a foreign supplier is required for a VQIP food?

A certification issued by a third-party auditor/certification body which has been accredited pursuant to FDA's Third-Party Auditing Rule. Registered food facilities and farms may be certified. Facilities and farms must be recertified at least annually.

Application

What is the VQIP application process?

Applications must be submitted electronically via the FDA Industry Systems Website at www.access.fda.gov. Applications must be submitted between January 1 and May 31 to participate in VQIP during the next fiscal year (beginning on Oct. 1). A new application must be submitted every year.

What information is needed to complete the VQIP application?

The application is divided into seven sections:

a) Applicant and Firm information
b) FSVP Responsible Contact
c) VQIP Quality Assurance Program
d) Filer/Broker Information
e) Foreign Supplier Facility and Products
f) Comments
g) Review Application

VQIP Quality Assurance Program

What is the VQIP Quality Assurance Program (QAP)?

The QAP is a compilation of the written policies and procedures used to ensure adequate control of over the safety and security of foods you import.

What should be included in the QAP?

a) Table of contents
b) Corporate quality policy statement
c) Organization structure and functional responsibilities
d) Food safety policies and procedures
e) Food defense policies and procedures
f) Experience and training (of employees responsible for implementing the QAP)
g) QAP implementation procedures (auditing, updating)
h) Recordkeeping procedures
i) Definitions
j) References (i.e. to information and sources used)

FDA Review of VQIP Application

How will FDA review the VQIP application?

FDA will review the application for completeness and data accuracy. FDA will review the compliance history of the importer and all foods and foreign suppliers listed, as well as customs brokers. FDA will review the QAP and may examine CBP audit reports related to food defense if you are a C-TPAT participant. FDA will review all the labels of all of the VQIP foods.

Will FDA conduct and inspection of an importer before conferring VQIP benefits?

FDA will ordinarily conduct a VQIP inspection after an application is approved and prior to October 1 of the first year that an importer participates in VQIP. However, receipt of benefits will not be delayed if FDA does not complete the VQIP inspection prior to October 1 of the first year an importer participates in VQIP, unless the inspection is delayed because of the importer or by restrictions in travel that prevent FDA inspection of a foreign VQIP importer.

How often will FDA reevaluate VQIP participants?

At least once every 3 years.

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