FDA Continues FSMA Implementation, Finalizes Guidance on Voluntary Qualified Importer Program to Expedite Food Imports

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The Food & Drug Administration (FDA) released last week a final version of its guidance for industry on the Voluntary Qualified Importer Program (VQIP), which will provide a mechanism for eligible food importers to expedite entry of certain shipments of food into the United States. The finalization of the guidance is the most recent in a long series of steps to implement the Food Safety Modernization Act (FSMA), the sweeping reform of U.S. food safety laws enacted in 2011. In order to participate in the VQIP, an importer must demonstrate that it has established a high level of control over the safety and security of its supply chains, comply with supplier verification requirements, have at least a three-year history of importing food into the United States, and have no ongoing FDA administrative or judicial action, amongst other requirements.

Background

Under FSMA, FDA is required to establish a program "to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program" and "issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with, such program" FDA released a draft form of the guidance in June 2015, which we discussed here. The final version of the guidance is mostly consistent with the earlier draft guidance. Changes include:

- Clarifying that VQIP applicants will not be required to upload food labels for foods included in the VQIP application, but FDA may request a copy of food labels for the foods included in the application to determine if there are labeling violations relating to the risk of the food during a VQIP inspection or audit examinations;
- Providing examples of how to ensure that the Foreign Supplier Verification Program (FSVP) or the Hazard Analysis and Critical Control Point (HACCP) importer of the food (when it is not the VQIP applicant) is in compliance with the applicable FSVP or HACCP regulations; and
- Revising the 3-year import history eligibility criteria to provide for use of shared importation history of previous or parent companies.[1]

Prior to finalizing the guidance, FDA held public meetings in June 2016 in three "strategic regions,"

California, Michigan and New Jersey, to consider the implementation of the import safety programs under FSMA and specifically VQIP, along with the Foreign Supplier Verification Program (FSVP) and Accredited Third-Party Certification. In a report summarizing those meetings, FDA identified significant interest from different industry groups (*e.g.*, food producers, large and mid-sized importers and small importers) in connection with the VQIP. FDA noted that some members expressed hesitation about participation in the VQIP based on the effort and cost to participate, while other members indicated motivation in terms of benefits to reputation and credibility, as well as import efficiency and speed.

Who's an Importer under VQIP?

An importer of food, defined as "the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States," who meets specified criteria is eligible to participate in the VQIP.[2] Note that the definition is broad and includes persons other than the importer of record to the U.S. Customs and Border Protection (CBP). Others eligible to participate in VQIP include the manufacturer, owner, or consignee of the imported food, provided that the importer meets eligible criteria discussed below.

Moreover, an importer need not be based in the United States in order to be eligible to participate in the VQIP. This is distinguishable from FDA regulations in connection with the Foreign Supplier Verification Program (FSVP) and juice and seafood hazard analysis and critical control points (HACCP). Under those regulations, the importer is the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry.[3] While VQIP importers located in the United States may also be the FSVP or HACCP importers, this is not necessarily the case since others are eligible for the VQIP.

Importer Eligibility Criteria

While the definition of "food importer" is fairly broad, the importer must meet a host of requirements in order to be eligible to participate in the VQIP. These include:

- **Foreign supplier facility certification**. The importer must have a current facility certification issued in accordance with FDA's third-party certification program for each foreign supplier of food that will be imported through the VQIP. A facility certification is an attestation by an accredited third-party certification body after a regulatory audit and other necessary activities that the foreign food facility complies with the same food safety requirements as domestic food facilities.

- **3 year history with U.S. food imports**. The importer must have at least a 3 year history of importing food into the United States, although that history may be shared or based on previous or parent companies. The import history may also relate to foods that are not covered by the importer's VQIP application.

- **VQIP Quality Assurance Program (QAP)**. The importer must develop and implement a QAP and submit the written QAP as part of its VQIP application. The QAP is a compilation of written policies and procedures to ensure adequate control over the safety and security of imported food and must include an organization chart that identifies and explains individuals responsible for implementing the QAP, food safety policies and procedures, food defense policies and procedures such as those to protect against intentional adulteration, and procedures for establishing and maintaining records to confirm effectiveness and compliance.

- **No pending import detention, ongoing FDA administrative or judicial action, or history of non-compliance**. The importer cannot have any food subject to detention without physical examination under an Import Alert or a Class 1 recall. Moreover, neither the importer nor the non-applicant entities associated with the VQIP food can be subject to an ongoing FDA administrative or judicial action, or have a history of significant food safety compliance issues. Non-applicant entities associated with the food include but are not limited to the FSVP or HACCP importer, the foreign supplier, and the filer/broker.
- **No recent history of CBP penalties, forfeiture or sanctions related to FDA-regulated products**. The importer must not have been subject to any CBP penalties, forfeitures, or sanctions related to FDA-regulated products within the past three years.
- **Dun & Broadstreet (D&B) Data Universal Numbering System (DUNS) Number**. The importer must have a DUNS number, which is a unique nine-digit business identification number provided by the company D&B. A DUNS number can be obtained by contacting D&B at 866-705-5711 or via e-mail to govt@dnb.com. All entities doing business with the U.S. government can receive a DUNS number free of charge, although it make take up to 45 days or more to process.
- **Compliance with FSVP and HACCP requirements**. If the importer is also the FSVP or HACCP importer for a VQIP food, then they must also comply with applicable FSVP and HACCP regulations. If the importer is not the FSVP or HACCP importer, then they must identify the FSVP or HACCP importer and ensure they comply with applicable regulations.

Benefits to Participation

The final guidance highlights many benefits to participation including:

- Expedited review of foods included in an approved VQIP application based on a unique screening system intended to recognize VQIP foods and release the shipment immediately, unless examination and sampling are necessary for public health reasons.
- Limited examination and sampling of VQIP foods except for “for cause” situations, which shall be expedited to the maximum extent possible.
- For the limited “for cause” examinations and samplings, FDA will attempt to examine the entry at a location preferred by the VQIP importer. If exportation is required, FDA will help the importer coordinate with CBP to export from the port preferred by the importer.
- Access to a VQIP Importers Help Desk to respond to questions and resolve issues associated with the VQIP.
- Optional publication as a VQIP importer on FDA’s VQIP webpage.

Note that FDA will only expedite entry for foods subject to the VQIP. If an importer comingles eligible and ineligible food, FDA will still attempt to expedite entry of the VQIP food but delays may result.

Application, Renewals, and Fees

Importers interested in participating in the VQIP must submit an application between January 1 and May 31 online to FDA’s Industry Systems Website, http://www.access.fda.gov. In conjunction with its

release of the final guidance on VQIP, FDA released a separate guidance, "Instructions for Submission of Voluntary Qualified Importer (VQIP) Application," which provides more detailed guidance on how to establish an account, submit an application, and renew applications in subsequent years.

Approved applications made prior to May 31 will result in VQIP benefits for the following federal government fiscal year from October 1 to September 30. Importers must pay the VQIP user fee before receiving benefits. While the guidance does not specify what the user fee will be for the first year, in its initial Federal Register notice in 2015, FDA estimated that a flat annual fee of approximately $16,400 will be required for all VQIP participants. FDA indicated that it will publish the final fee amount for the first year on or before August 1, 2017 and each year thereafter.

If FDA determines that the importer meets VQIP eligibility criteria and accepts the importer into the program, FDA will conduct a VQIP inspection, which typically will include a review of written procedures and records demonstrating compliance with the VQIP. In the first application year, FDA will review all aspects of an application. FDA will not necessarily re-evaluate an importer's eligibility every year, although it will do so at least once every three years.

FDA will begin accepting applications for VQIP on January 1, 2018 such that the first importers to participate will receive benefits for fiscal year 2019 beginning October 1, 2018. Interested parties can submit comments on the guidance document at any time.

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[1] Voluntary Qualified Importer Program; Guidance for Industry; Availability, 81 Fed. Reg. 79,502, 79,503 (Nov. 14, 2016).
[2] 21 U.S.C. 384b(g).
[3] 21 C.F.R. § 1.500 (FSVP)); 21 C.F.R. 120.3(h) (juice HACCP); 21 CFR 123.3(g) (seafood HACCP)).