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# FDA Releases Draft Guidance for Industry on Voluntary Qualified Importer Program for Food

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Food & Drug

On June 5, 2015, the Food and Drug Administration (FDA) issued a draft guidance for industry on the voluntary qualified importer program (VQIP) for public comment, as part of FDA's implementation of the FDA Food Safety Modernization Act of 2011 (FSMA) (the VQIP draft guidance). FSMA requires FDA to establish a voluntary, fee-based program to provide for the expedited review and importation of food from importers who have demonstrated the safety and security of their supply chains. FDA will expedite the entry into the U.S. for all foods included in importers' VQIP applications.

The VQIP draft guidance addresses the following aspects of VQIP:

- Eligibility criteria for participating in VQIP
- Application process for VQIP
- Benefits of VQIP participation
- VQIP fees and small business guidelines

FDA's third party accreditation system[1] must be in place before VQIP can begin, because importers can only participate in VQIP with respect to foreign suppliers that have a current facility certification issued in accordance with FDA's third-party accreditation system regulations. The VQIP draft guidance indicates that FDA currently expects fiscal year 2018 (which runs from October 1, 2017 to September 30, 2018) to be the first year of VQIP. This client alert includes a summary of the VQIP draft guidance and key issues that industry should monitor and consider for comments.

[1] Under FSMA, FDA must establish a third party accreditation system under which accredited third party auditors conduct food safety audits of foreign food establishments. FDA issued a proposed rule for the third party accreditation system in July 2013. Click here for our client alert summarizing this proposal. The final rule for the third party accreditation system is expected to be published in the fall of 2015.

## Highlights of VQIP Draft Guidance

### Eligibility Criteria for Participating in VQIP

FSMA requires FDA to consider the risk of the food to be imported, based on factors such as the known safety risks of the food, the compliance history the importer's foreign suppliers, the compliance history of the importer with requirements under FDA's foreign supplier verification program,[2] the capability of the regulatory system of the country of export to ensure compliance with U.S. food safety standards, and any other factor that FDA deems appropriate.

The VQIP draft guidance establishes a number of specific eligibility criteria for participation in VQIP, most of which are not explicitly provided for under FSMA. Of note, participation would be limited to importers with at least a 3-year history of importing food into the U.S. FDA has concluded that 3 years of import history is the minimum needed to adequately evaluate an importer's eligibility to participate in VQIP. FDA will review the history for all food that an importer has imported into the U.S. during the past 3 years when reviewing an importer's application for VQIP, and it may extend its review to additional years if necessary to fully evaluate an importer's compliance history.

An importer must also have a current facility certification, issued in accordance with FDA's third-party accreditation system regulations, for each foreign supplier of food that the importer intends to import under VQIP. In addition, an importer is only eligible to participate in VQIP if no food they import, including food that would not be included in VQIP, is subject to an import alert or a Class 1 recall, and neither the importer nor any of the entities associated with a food imported under VQIP can be the subject of an ongoing FDA administrative or judicial action or have a history of significant noncompliances relating to food safety.

### Application Process for VQIP

FDA will accept applications to participate in VQIP online. VQIP participation will be for each fiscal year, beginning on October 1, and applications must be submitted between January 1 and May 31 for participation the following October. An importer must re-apply to VQIP each year.

The VQIP application must include information about the importer, the importer's foreign suppliers, and the foods that the importer would like to import through VQIP. The application must also contain a VQIP Quality Assurance Program (QAP), which is a compilation of the written policies and procedures that the importer will use to ensure adequate control over the safety and security of foods they import throughout the supply chain. Specifically, the VQIP QAP should include the following components:

- *Corporate quality policy statement*, which explains the quality policy related to food safety and security throughout the supply chain, how that policy is communicated

[2] FSMA requires FDA to establish requirements for importers to perform risk-based foreign supplier verification activities in order to verify that food imported by the importer is not violative. FDA published its proposed rule for the foreign supplier verification program in July 2013 and a supplemental proposed rule in September 2014. Click here and here for our client alerts summarizing these proposals. The final rule for the foreign supplier verification program is expected to be published in fall 2015.

throughout the organization and to other entities in the supply chain, and what steps the importer will take to ensure that all relevant parties understand the quality policy.

- *Organizational structure and functional responsibilities*, which could include an organizational chart and/or a written explanation of the organization's management structure. This should specifically include the responsibilities of individuals within the organization who will be implementing the VQIP QAP and those of outside entities (e.g., a foreign supplier) under the VQIP QAP.
- *Food safety policies and procedures*, which should ensure food safety from source to entry into the U.S. These could include temperature and storage controls, written procedures for communication with FDA and with foreign suppliers, and written procedures for corrective actions to address food and foreign supplier non-compliances that pose a risk to public health.
- *Food defense policies and procedures*, which should describe procedures for ensuring that each foreign supplier is in compliance with FDA's intentional adulteration regulations (when finalized)[3] and for ensuring the security of each food item throughout the transportation supply chain.
- *Experience and training requirements* for employees responsible for implementing the VQIP QAP, including training related to knowledge of FDA's food safety requirements under the FDCA.
- *Implementation procedures* for the VQIP QAP, which should include procedures for auditing and updating the QAP as necessary.
- *Records procedures* for establishing and maintaining records relating to the structure, processes, procedures, and implementation of the VQIP QAP.

An importer who is re-applying to participate in VQIP would not need to resubmit the VQIP QAP each year; however, the importer would be responsible for submitting any QAP updates to FDA throughout the VQIP year.

FDA will review the VQIP application, including the QAP, and the compliance history of the importer, all of the foods and foreign suppliers listed in the application, and all other entities within the supply chain. FDA will review the labels of all of the foods listed in the application to ensure compliance with FDA's food labeling regulations. FDA will also conduct a VQIP inspection to verify that the importer meets the VQIP eligibility requirements and has fully implemented the policies and procedures in the QAP. FDA will generally conduct a VQIP inspection prior to October 1 of the first year an importer would participate in VQIP; however, any delay in FDA's ability to conduct the VQIP inspection will not delay VQIP benefits beyond October 1.

FDA will review all aspects of the VQIP application and conduct a VQIP inspection the first time that an importer applies to participate in VQIP. Thereafter, FDA will reevaluate an importer's eligibility to participate in VQIP at least once every 3 years. Changes in compliance history, risks

[3] FDA issued proposed intentional adulteration regulations in December 2013, and final intentional adulteration regulations are expected to publish in May 2016.

associated with a certain food type, or risks associated with a certain foreign supplier could all cause FDA to reevaluate an importer's eligibility more frequently.

**Benefits of VQIP Participation**

Importers participating in VQIP will receive a number of benefits. The primary benefits relate to the speed at which entries will enter the U.S. Specifically, FDA will expedite entry for all foods included in an importer's VQIP application, so that those entries will be immediately released unless examination and sampling are necessary for public health reasons. In the event that FDA does examine a participating importer's entry for public health reasons, FDA will expedite all related laboratory analyses and will examine the entry at the location preferred by the importer.

FDA will also maintain a VQIP Importers Help Desk dedicated to assisting participating importers (including outreach to U.S. Customs and Border Protection as necessary), and will post a publicly available list of approved VQIP importers (though any importer can request to not be included on that list). Importers should submit specific information for entries covered by VQIP to help ensure that those entries are appropriately expedited.

**Fees and Small Business Guidelines**

FSMA requires that FDA collect fees from each importer participating in VQIP in a fiscal year to cover the administrative costs of VQIP for that year. FDA will establish fee rates for VQIP each year and publish those rates in the Federal Register on or before August 1 of that year. The Notice of Availability for the VQIP draft guidance includes additional information about VQIP fees. First, FDA estimates that the annual VQIP fee for fiscal year 2018 (which is the first year FDA expects the program to be in place) would be approximately $16,400 per importer, regardless of the number of facilities or number of products the importer includes in its VQIP application. Second, FDA has set forth a proposed set of guidelines in consideration of the burden of fee amounts on small businesses, as required by FSMA.

FDA specifically requests comment on whether and how the VQIP fee might pose a burden to small businesses, and, if it does, whether FDA should consider reducing the fee amount for small businesses and/or increasing the fee for larger importers to ensure that FDA fully recovers the administrative costs of VQIP. FDA also requests comment on how it should define a small business for the purpose of evaluating the VQIP fee. Finally, FDA requests comment on whether it should consider an alternative fee structure under which fee amounts would depend on the number of facilities and/or the number of products included in a VQIP application.

## Key Issues for Industry

The VQIP draft guidance will be open for public comment through August 19, 2015. Stakeholders (including importers and foreign suppliers) may in particular wish to consider submitting comments on the following aspects of the VQIP draft guidance:

1. the eligibility criteria for participation in VQIP, including the requirement that importers have at least a 3-year history of importing food into the U.S.;
2. the various components of the VQIP QAP that FDA has determined are necessary to ensure that an importer has adequate control over the safety and security of foods they import, including the food safety policies and procedures, the food defense policies and procedures, and the experience and training requirements; and

3. FDA's proposed guidelines on the burden of VQIP fee amounts on small businesses, and whether FDA should assess a flat fee or consider an alternate fee structure for the VQIP fee.

Covington & Burling LLP will continue to monitor FDA's implementation of FSMA and advise clients on developments. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:


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