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FDA Releases Final Guidance for Industry on Voluntary Qualified Importer Program for Food

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Food, Drugs, and Devices

On November 10, 2016, the Food and Drug Administration (FDA) released its final guidance for industry on the voluntary qualified importer program (VQIP). The final guidance builds upon draft guidance issued in June 2015, as part of FDA's implementation of the FDA Food Safety Modernization Act of 2011 (FSMA) mandate to establish a voluntary, fee-based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 final guidance addresses the following aspects of VQIP:

- Benefits of VQIP participation;
- Eligibility criteria for participating in VQIP;
- Instructions for completing a VQIP application; and
- Revocation and reinstatement of VQIP participation.

In its final guidance, FDA made very few changes from the draft guidance. FDA clarifies that during a fiscal year a VQIP importer may add additional food from a foreign supplier from which the importer already imports food under VQIP. The guidance further clarifies that applicants for VQIP will not be required to upload food labels for foods included in their applications, and that applicants' 3-year import history eligibility can include shared importation history of previous or parent companies. Finally, the guidance provides examples of how importers may ensure that non-applicant importers of food are in compliance with the Foreign Supplier Verification Program (FSVP) or the seafood or juice Hazard Analysis and Critical Control Point (HACCP) requirements.

VQIP will begin in the 2019 fiscal year, which runs from October 1, 2018 through September 30, 2019. Applicants may begin applying on January 1, 2018 through May 31, 2018. This client alert includes a summary of the VQIP guidance and key issues that potential applicants should consider prior to the application deadline.

Highlights of VQIP Final Guidance

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. If 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. In its final guidance, FDA clarified that importers may amend their VQIP applications during a fiscal year to add a food from a foreign supplier included in the VQIP during a fiscal year. Importers may not amend their applications in a given fiscal year to add a new food from a foreign supplier not included in the VQIP, but may add a supplier in VQIP applications for subsequent fiscal years.

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 on the VQIP website (although 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.

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 of the importer's foreign suppliers, the compliance history of the importer with requirements under FDA's foreign supplier verification program,[1] 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 guidance establishes a number of specific eligibility criteria for participation in VQIP. 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. In its final guidance, FDA clarified that the 3-year history can consist of an importer's shared importation history with previous or parent companies. FDA will review the history for all food that an importer has imported into the U.S. during the past 3 years, 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,[2] 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 it imports, including food that would not be included in VQIP, is subject to an import alert or a Class 1 recall. Further, 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 non-compliances relating to food safety. Finally, importers must not

[1] FSMA required 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 final rule for the foreign supplier verification program in November 2015. Click here for our client alert summarizing the final rule.

[2] FSMA required FDA to establish a program for the accreditation of third-party certification bodies (i.e., third-party auditors) to conduct food safety audits of foreign food facilities and issue certifications. FDA published its final rule for the third-party accreditation system in November 2015. Click here for our client alert summarizing this rule.

have been the subject of any U.S. Customs and Border Protection (CBP) penalties, forfeitures, or sanctions related to the safety or security of any FDA-regulated product imported or offered for import within the past 3 years.

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 (including the certification number assigned by the accredited certification body who issued the facility certification), and the foods that the importer would like to import through VQIP. In its final guidance, FDA clarified that applicants are not required to submit a copy of food labels for the foods included in VQIP applications, although copies of such labels may be requested by FDA.

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: a corporate quality policy statement explaining the importer's quality policy related to food safety; an organizational chart or written explanation of the management structure; a description of the importer's food safety policies and procedures, including compliance with FSVP or HACCP regulations;[3] a description of the importer's food defense system for supplier compliance with intentional adulteration regulations (if applicable);[4] implementation and records procedures for the VQIP QAP; and qualification and training requirements for employees implementing 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 fiscal 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 may ask applicants to submit additional documentation, such as food labels or copies of hazard analyses required under FSVP or HACCP regulations. Additionally, FDA will 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. Any delay in FDA's ability to conduct the VQIP inspection will not delay VQIP benefits beyond October 1.

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[3] In its final guidance, FDA provided additional examples of how to ensure that non-applicant importers of food are in compliance with FSVP and HACCP. The guidance requires that VQIP applicants include procedures for ensuring compliance such as determining that an FSVP or HACCP importer is not subject to an FDA enforcement action, or obtaining annual written assurance that the importer is in compliance with FSVP or HACCP regulations.

[4] FSMA required FDA to establish regulations for help protect food against adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism. FDA published its final rule on mitigation strategies to protect against intentional adulteration in May 2016. Click here for our client alert summarizing this rule.

In the first year that an importer submits a VQIP application, FDA will review all aspects of the application and conduct an inspection. Thereafter, FDA will reevaluate an importer's eligibility to participate in VQIP at least once every 3 years. Changes in compliance history, risks 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. Further, changes in QAP food safety or food defense policies and procedures could trigger a requirement for importers to amend their applications. Importers may also be required to amend their applications in order to remove foods or foreign suppliers subject to ongoing FDA administrative or judicial action.

Revocation of VQIP Participation and Reinstatement

FDA may revoke participation in VQIP based on either (1) evidence that the importer does not meet one or more of the VQIP eligibility requirements, or (2) evidence that the importer participated in smuggling or other fraudulent activities. Revocation applies to all foods imported under VQIP. Reinstatement of participation in VQIP is only permitted where revocation was based on failing to meet VQIP eligibility requirements and the problems have been corrected.

Key Issues for Industry

VQIP participation will be available for the 2019 fiscal year. As of January 1, 2018, eligible importers will be able to apply for participation in the program by visiting the FDA Industry Systems website and submitting a "Notice of Intent to Participate" in VQIP. FDA has not yet finalized the user fee for January 2018 applications but will publish the fee amount in the Federal Register on or before August 1, 2017. In its draft guidance for VQIP, FDA had previously estimated that the flat annual fee for VQIP participants would be approximately $16,400.

Eligible importers should review FDA's evaluation criteria for VQIP participation and begin assembling the required documentation. As noted, for first time applicants FDA will review the application and conduct an inspection to verify the importer's eligibility. Following this initial review, FDA will reevaluate eligibility at least once every three years. Events such as outbreaks or recalls linked to a food product included in the VQIP application may lead to additional reevaluation and inspection by FDA.

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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