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MEMORANDUM

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Re: **FDA Finalizes Guidance on the FSMA Voluntary Qualified Importer Program**

The Food and Drug Administration (FDA) recently finalized its guidance regarding the Voluntary Qualified Importer Program (VQIP) for food importers. Enacted under the FDA Food Safety Modernization Act (FSMA), VQIP is a fee-based program that provides expedited entry for food from importers who have a high level of control over the safety and security of their supply chains. Participation is limited to food from foreign facilities that are certified by an accredited third-party auditor under FDA's final rule on accreditation of third-party certification bodies. 1/ FDA will begin accepting applications for VQIP on January 1, 2018 and the program will start operating during fiscal year 2019 (October 1, 2018 through September 30, 2019). The agency has not yet finalized the program fee.

This memorandum provides an overview of the VQIP requirements and benefits, as explained in FDA's VQIP guidance, as well as next steps for implementation of the program. Below we summarize the benefits of VQIP, the eligibility criteria for participation, the application components, how VQIP applications will be reviewed, and VQIP inspections. The guidance also details the procedures FDA will follow in revoking or reinstating participation in VQIP, which are not summarized herein.

VQIP Benefits

The major benefit of VQIP is that FDA will expedite entry into the U.S. for all foods included in an approved VQIP application. This means that FDA will set up its import screening system to recognize shipments of food that are under VQIP and, in most cases, immediately release the shipment after the receipt of entry information. However, if a mixed entry is presented (i.e., an entry that includes VQIP food and food that is not covered by VQIP), FDA will only expedite the VQIP food. This means that combining VQIP and non-VQIP foods into a single entry may slow the entry of the VQIP food.

1/ *See* HL Memo, *FDA Releases FSMA Final Rule on Accreditation of Third Party Certification Bodies* (November 30, 2015).

FDA will examine and sample VQIP entries in limited situations—"for cause" situations in which there is a potential threat to public health, to obtain statistically necessary risk-based microbiological samples, and to audit VQIP. Any sampling results will be expedited. FDA also will post a publicly available list of approved VQIP importers on its website, but an importer may opt out of this listing.

VQIP Eligibility

VQIP is open to an "importer" of food, which for this purpose is 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." This is a different definition than FDA used for "importer" under the Foreign Supplier Verification Program (FSVP) regulations and the juice and seafood HACCP regulations. For example, the VQIP importer need not be located in the U.S., but the FSVP and HACCP importers must be located in the U.S.

The draft guidance sets out the following eligibility requirements for the importer:

1. The importer must have at least a 3-year history of importing food into the United States. This may be based on the shared importation history of previous or parent companies, such as those that have been involved in a merger.

2. The importer must have a Dun & Bradstreet Data Universal Numbering System (DUNS) number.

3. The importer must use paperless filers/brokers who received acceptable results during their last FDA Filer Evaluation.

4. None of the food imported by the importer (including foods that the importer does not include in their VQIP application) may be subject to a detention without physical examination under an Import Alert or a Class I recall at the time the VQIP application is submitted.

5. The importer and any "non-applicant entities" associated with a VQIP food may not be the subject of an ongoing FDA administrative or judicial action (e.g., an Import Alert, injunction, debarment) or have a history of significant non-compliances relating to food safety (e.g., an "Official Action Indicated" (OAI) FDA inspection classification with no documentation of appropriate corrective actions; or, significantly, one or more voluntary Class I recalls relating to food safety). A "non-applicant entity" includes any entity in the supply chain that conducts activity necessary to ensuring the eligibility requirements of VQIP are met, including the FSVP or HACCP importer of the food, the foreign supplier of the food, and the filer/broker.

6. If the importer also is the FSVP or HACCP importer for a VQIP food, the importer must be in compliance with any obligations under FSVP or applicable HACCP regulations. If the importer is not the FSVP or HACCP importer for the VQIP food, the importer must identify the FSVP or HACCP importer of the food and ensure the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP regulations.

7. Each foreign supplier of food the importer intends to import under VQIP must have a current facility certification issued in accordance with FDA's third-party certification program.

8. The importer must develop and implement a VQIP Quality Assurance Program (QAP), and submit the written plan with the VQIP application. (See below for further discussion of the QAP requirements.)

9. The importer must not have been subject to any Customs and Border Patrol (CBP) penalties, forfeitures, or sanctions related to the safety or security of any FDA-regulated product imported or offered for import in the last 3 years.

10. The importer must pay the annual VQIP user fee before October 1 of the fiscal year the importer intends to participate in VQIP.

It's important to recognize that VQIP importers can only obtain expedited entry for food imported from a facility or farm that has received a certification by an auditor accredited under FDA's final rule on accreditation of third-party certification bodies. Because these certification audits are conducted for a regulatory purpose when used for VQIP, the "bells and whistles" of the third-party accreditation regulation apply. Thus, for any audits conducted for VQIP accredited third party certification bodies must perform unannounced audits, notify FDA upon discovering a condition that could cause or contribute to a serious risk to the public health, and submit their audit report to FDA. To be eligible for VQIP, the foreign supplier also cannot be subject to detention without physical examination under an Import Alert.

VQIP Application

FDA's guidance explains the mechanics of submitting a VQIP application and the information that must be submitted. The application must include QAP, which is a compilation of the written policies and procedures used to ensure adequate control over the safety and security of imported food. The elements of the QAP, and a few notable features of these elements, are as follows:

- Table of Contents
- Corporate Quality Policy Statement
    - This is a statement of the corporate quality policy regarding food safety and security throughout the supply chain.
- Organizational Structure and Functional Responsibilities
    - This includes a written explanation of the responsibilities of the individuals implementing the VQIP QAP, both within the VQIP participant's organization, as well as the non-applicant entities, such as foreign suppliers, who play a role in implementing the importer's VQIP QAP.
- Food Safety Policies and Procedures
    - This is a written description of the policies and procedures for ensuring the safety of the VQIP food from source to entry into the U.S (e.g., procedures for maintaining current foreign supplier certifications; corrective action procedures).
    - Significantly, the VQIP importer must have written procedures for communicating information to FDA relating to food and foreign supplier non-compliances that pose a risk to public health.
    - Also of note, when the VQIP importer is not the FSVP or HACCP importer of the food, they must have procedures for verifying the FSVP and HACCP compliance of

the imported food. This verification obligation may be met with an annual written affirmation.
    - In addition, the VQIP importer must have written procedures for controlling the safety of each VQIP food "throughout the transportation supply chain, including compliance with FDA's sanitary transport rule, if applicable."
- Food Defense Policies and Procedures
    - Importers must provide a written description of their food defense system, as applicable, including procedures for verifying their foreign supplier's food defense system is in compliance with the FSMA Intentional Adulteration rule and procedures for controlling the security of each VQIP food "throughout the transportation supply chain."
    - If the importer's food defense program includes participation in U.S. Customs and Border Protection's (CBP's) Customs-Trade Partnership Against Terrorism (C-TPAT) (Level 2 or 3) and the participation in this program is referenced in the VQIP application, additional information about the transportation food defense procedures is not necessary.
- Qualifications
    - Information about the qualifications of the employees responsible for implementing the VQIP QAP must be provided.
- QAP Implementation
    - Importers should include the procedures for ensuring the VQIP QAP is up-to-date and appropriately implemented, as well as the procedures for auditing and updating the QAP.
- Records
    - This include written procedures for establishing and maintaining record relating to the structure, processes, procedures, and implementation of the VQIP QAP.
- Definitions
    - Applicants should define terms used in their VQIP QAP, as necessary to facilitate understanding.
- References
    - As appropriate, importers should provide references to information or sources used to develop and implement the QAP.

FDA expects that VQIP importers will amend their applications promptly when material information changes, including to remove foods or foreign suppliers that are subject to an FDA administrative or judicial action (e.g., Import Alert, seizure). Additionally, once an importer is accepted to VQIP, they can amend their application to add or remove a food from a foreign supplier already in their VQIP, or add a new foreign supplier that already has a current facility certification for a food already listed in their VQIP. However, if a new food is from a new foreign supplier who is not in their VQIP, this amendment cannot be made until the next program year.

Confidential information in VQIP applications will be protected in accordance with the Freedom of Information Act (FOIA), the Federal Trade Secrets Act, and FDA's FOIA regulations. This information will be shared with other federal agencies, such as Customs and Border Patrol (CBP) to facilitate the entry of VQIP foods.

VQIP applications must be submitted between January 1 and May 31 for the subsequent fiscal year (beginning October 1). An importer must submit a new application for each fiscal year they want to

participate in VQIP. FDA will send VQIP participants an email reminder in December about re-applying for VQIP for the next fiscal year.

VQIP Application Review and Inspections

FDA will review VQIP applications for completeness, and then will evaluate eligibility for participation in the program in light of the criteria set forth in the guidance. FDA will review the compliance history of the importer as well as all non-applicant entities involved with the import within the supply chain for each food. FDA will review the importer's QAP, and if applicable, confirm participation in C-TPAT. During FDA's review, if FDA identifies any deficiencies that an importer may be able to readily correct during the application period, FDA will allow the importer to make such corrections. If the importer is determined to be ineligible for participation in VQIP, or if corrections to a deficient application are not made, FDA will disapprove the application and inform the importer of the reason for disapproval.

Once an application has been approved, FDA will conduct a VQIP inspection prior to October 1, when the VQIP fiscal year begins. VQIP inspections will verify that the importer meets VQIP eligibility criteria and has fully implemented the food safety and food defense systems established in their QAP.

Next Steps – Timing and Costs

FDA will begin accepting applications for VQIP on January 1, 2018 for fiscal year 2019 (October 1, 2018 through September 30, 2019). FDA anticipates receiving approximately 200 applications for participation in the first year of VQIP. FDA has not yet finalized the VQIP user fee. The agency will publish a notice in the Federal Register on or before August 1 each year announcing the VQIP user fee for the next VQIP year. As a point of reference, FDA proposed an annual fee of $16,400 per importer with the draft guidance.

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We will continue to monitor the implementation of the Voluntary Qualified Importer Program. Please contact us if you have any questions.