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MEMORANDUM

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Re: **FDA Issues Draft Guidance on the FSMA Voluntary Qualified Importer Program**

The Food and Drug Administration (FDA) recently issued draft guidance regarding the Voluntary Qualified Importer Program (VQIP) for food importers. The program was created pursuant to a mandate in the FDA Food Safety Modernization Act (FSMA). VQIP 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 the new accreditation program FDA is establishing. 1/ FDA expects to open the program for applications in January 2018.

This memorandum first explains the statutory framework for VQIP and then summarizes the draft guidance. Although comments on guidance can be submitted at any time, FDA requests comments by August 19, 2015 to ensure that they will be considered before the agency completes a final version of the guidance. Comments on the information collection aspects of the draft guidance are due August 4, 2015.

Statutory Framework

Section 302 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding new section 806, entitled "Voluntary Qualified Importer Program" (21 U.S.C. § 384b). The statute directs FDA to establish this voluntary, fee-based program for the expedited review and importation of designated food. FDA additionally is directed to issue a guidance document related to participation in VQIP. Separately, FDA also must establish a process for the issuance of a facility certification to accompany food offered for importation by importers participating in VQIP.

The statute provides several factors that FDA must assess when reviewing applications for participation in VQIP. These factors are:

1. The known food safety risks of the food to be imported;
2. The compliance history of foreign suppliers used by the importer, as appropriate;
3. The capability of the regulatory system of the country of export to ensure compliance with U.S. food safety standards for a designated food;

1/ *See* Hogan Lovells memorandum, *FDA Releases FSMA Proposed Rule on Third Party Accreditation* (August 2, 2013).

4. The importer's compliance with the Foreign Supplier Verification Program (FSVP) requirements;
5. The recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer;
6. The potential risk for intentional adulteration of the food; and
7. Any other factor FDA determines appropriate.

Additionally, importers that qualify for VQIP must be reevaluated at least every 3 years. FDA is directed revoke the qualified importer status of any importer found not to be in compliance with the eligibility criteria.

Overview of Draft Guidance

The draft guidance describes the eligibility criteria for, and benefits of, participation in VQIP, as well as information on submitting an application for VQIP participation, obtaining a facility certification for the foreign supplier of a food imported under VQIP, the user fee, conditions that might result in revocation of VQIP eligibility, and criteria for reinstatement of eligibility. The draft guidance is written in a questions and answers format.

As discussed in more detail below, the core benefits will be expedited entry, reduced sampling, expedited laboratory analysis when sampling occurs, and a designated help desk for import questions and issues. FDA only will expedite the line entry associated with the VQIP food. Thus, importers would need to ensure that VQIP foods can be segregated easily from non-VQIP foods.

The agency anticipates that the participation fee will be $16,400 per importer, annually. Additionally, FDA foresees limiting participation to only 200 companies during the first year that the program is operational. Applications can be submitted between January 1 and May 31 each year. VQIP benefits will run from October 1 through September 30 the following year (starting in 2018).

Key Definitions

VQIP is limited to imports of "food." The term "food" has the meaning given in section 201(f) of the FFDCA, except that for purposes of VQIP "food" does not include food contact substances or pesticides. 2/

Only "food importers" can participate in VQIP. For purposes of VQIP, FSMA defines "importer" as "the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States." A VQIP importer can be located outside of the United States. Persons who may be a VQIP importer include the manufacturer, owner, consignee, and importer of record. Thus, the VQIP importer also may be, but is not required to be, the CBP importer of record or the same "importer" defined in the FSVP regulations or juice and seafood HACCP regulations.

"Foreign supplier" will be defined in the same way as under the forthcoming FSVP final rule.

2/ This is different than the definition of "food" proposed for the Foreign Supplier Verification Program, which includes food contact substances. 78 Fed. Reg. 45730, 45772 (July 29, 2013) (proposed § 1.500). Industry comments on the FSVP requested that FDA exclude food contact substances from this definition and, therefore, the scope of the regulation.

VQIP Benefits

The proposed core benefits of VQIP are:

1. Expedited entry: FDA will set screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening system to recognize shipments of food that are covered by VQIP to expedite their entry.

2. Reduced sampling: FDA will limit examination and/or sampling of VQIP food entries to "for cause" situations (i.e., when the food is or may be associated with a risk to the public health), to obtain statistically necessary risk-based microbiological samples, and to audit VQIP. (The three potential sampling scenarios are discussed in more detail below.)

3. Expedited laboratory analysis: FDA will expedite its laboratory analysis of "for cause" or audit samples of VQIP entries to the extent possible, in accordance with public health priorities.

4. VQIP Importers Help Desk: This contact will be dedicated to responding to questions and resolving issues raised by VQIP importers about VQIP food and the guidance document. Additionally, the Help Desk may be able to help with entry delays by U.S. Customs and Border Protection (CBP) when FDA is in a position to facilitate a resolution.

FDA foresees three situations when the agency will examine or sample VQIP food. First, VQIP food may be subject to "for cause" examination if FDA determines that the food is or may be associated with a risk to public health (e.g., during an outbreak investigation associated with a foreign supplier covered by the VQIP application). Second, VQIP food also may be subject to microbiological sampling related to specific risk-based surveillance assignments, though such food will be a low priority and FDA will collect samples of the food that already are in domestic commerce. Finally, FDA may conduct sporadic audit examinations, which may include some sampling, to verify compliance with VQIP. Additionally, when sampling is required, FDA will examine an entry and collect samples at the VQIP food destination or other location preferred by the VQIP importer.

Eligibility Criteria

FDA has established 10 criteria that must be met to participate in VQIP:

1. Importers must have at least a 3 year history of importing food into the U.S. Additionally, FDA will review the history for all food the importer brought into the U.S. during the past 3 years—not just the food that the importer wishes to import under VQIP.

2. Importers must have a Data Universal Numbering System (DUNS) number.

3. Importers must use paperless filers/brokers who received a passing rating during their last FDA Filer Evaluation.

4. No food that the importer imports, including food that they do not intend to include under VQIP, can be subject to an Import Alert or Class 1 recall.

5. Neither the importer nor the non-applicant entities associated with the VQIP food 3/ can be subject to an ongoing FDA administrative or judicial action (e.g., Import Alert, injunction), or have a history of significant noncompliances relating to food safety (e.g., an "Official Action Indicated" (OAI) FDA inspection classification with no documentation of appropriate corrective actions; one or more voluntary Class 1 recalls relating to food safety).

6. If the VQIP importer also is the FSVP or HACCP importer, the importer must comply with applicable supplier verification regulations. If the VQIP importer is not also the FSVP or HACCP importer, it must identify the party responsible for compliance with the supplier verification regulations and ensure that the FSVP or HACCP importer is in compliance.

7. Each foreign supplier of food that will be imported under VQIP must have a current facility certification issued by an accredited third-party auditor under FDA's new program. Foreign suppliers must be re-certified annually. All foods manufactured or processed at the facility, or grown on a farm, for which a facility certification is issued are within the scope of the facility certification.

8. Importers must develop and implement a VQIP Quality Assurance Program (QAP). Documentation of the QAP must be submitted with the VQIP application. (See additional discussion of the QAP, below.)

9. In the last 3 years, the importer cannot have been the subject of any CBP penalties, forfeitures, or sanctions that are related to the safety and security of any FDA-regulated product.

10. The annual VQIP user fee (estimated at $16,400 per importer) must be paid before October 1 of the participation year.

Application Process

VQIP applications will be submitted online between January 1 and May 31 of each year. The QAP and product label for each food for which the importer is applying for VQIP participation must be included with the application. Additionally, importers must provide their DUNS number and the DUNS number for each non-applicant entity listed in their application (e.g., foreign suppliers, FSVP importers).

When reviewing applications, FDA will consider the applicant's compliance history and the compliance history of all foods, foreign suppliers, a non-applicant entities (e.g., filers/brokers) listed in the application. FDA also will review the QAP to evaluate whether the applicant adequately controls factors relating to the safety and security of the food it intends to import under VQIP. FDA also will review the labels for all VQIP foods to determine compliance with the agency's food labeling regulations. Additionally, FDA may request additional information during the application review, such as asking for a copy of the risk evaluation required under FSVP for a food listed on the VQIP

3/ "Non-applicant entities" are those entities associated with a VQIP food that conduct activities throughout the supply chain necessary for ensuring that the eligibility requirements of VQIP are met. Non-applicant entities associated with a VQIP food include, but are not limited to, the FSVP or HACCP importer of the food (if other than the VQIP importer), the foreign supplier of the food, and the filer/broker.

application or the results of any laboratory tests used to comply with FSVP or HACCP regulations for a food listed on the VQIP application.

FDA ordinarily will conduct a VQIP inspection after an application is approved and prior to October 1 of the first year that an importer will participate in VQIP. The inspection will verify that the VQIP eligibility requirements are met and that the importer has fully implemented the food safety and food defense systems established in their QAP.

After an application is approved, importers are required to "promptly" amend their application to keep it updated. The draft guidance sets forth several actions that trigger the need to amend the application, such as removing a food or foreign supplier listed on the VQIP application that is subject to an ongoing FDA administrative or judicial action (e.g., Import Alert), removing a food label that no longer is applicable to a food and adding a new food label, and updating facility certifications. Notably, importers cannot amend the VQIP application to add any additional food during the VQIP year. New food only can be added when the importer submits their application for the subsequent VQIP year.

VQIP Quality Assurance Program

A VQIP QAP is a compilation of the written policies and procedures that the importer will use to ensure adequate control over the safety and security of the foods it imports. FDA's draft guidance sets out detailed requirements for the QAP. The QAP will include information on the applicant's company profile, organizational structure, quality policy statement, company food safety system, food defense system, training, documentation of contracts that fulfill any task within the QAP, and procedures for record retention. FDA anticipates that development of the QAP will take 160 hours. 4/ VQIP importers are expected to update their QAP on an ongoing basis.

Number of Participants

FDA anticipates that VQIP application review will need to be limited in the program's first year of operation due to the demands on agency resources necessitated by the initial establishment of the program and review of applications. The agency intends to review 200 applications in the first year—but foreshadows that it may not be able to review that many.

User Fees

FSMA directs FDA to collect fees to fund VQIP, which must cover 100% of the costs for the year. The current estimated cost is a flat fee of $16,400 per importer ($3.4 million total for an estimated 200 importers). The final fee schedule will be published at least 60 days prior to the start of the program.

FDA also is required to issue a proposed set of guidelines that consider the burden of the VQIP fee on small businesses and provide of a period of public comment on these guidelines. In the Federal Register notice announcing availability of the draft guidance, FDA sets out several questions about the possible burden of the user fee for small businesses, including whether the agency should

4/ To put this estimate in perspective, the recordkeeping estimate for preparation of a food safety plan under the preventive controls regulation is 110 hours and for preparation of a food defense plan is 40 hours. FDA expects that because the QAP builds on these documents, it would take the VQIP applicant no more than 10 additional hours to provide its company profile, organization structure, quality policy statement, documentation of contracts, and procedures for record retention.

consider charging different fee amounts to different VQIP participants depending on the number of facilities included in the application and/or the number of products included in the application.

Revocation of VQIP Participation

FDA can revoke participation in VQIP and will do so based on evidence that the importer does not meet the VQIP eligibility requirements, or if there is evidence that it participated in smuggling or other fraudulent activities. The draft guidance sets out procedures that FDA will follow to notify participants of potential revocation of their participation, as well as information about applying for reinstatement after a revocation. The agency notes that VQIP importers are responsible for promptly reporting to FDA all deviations that may affect their eligibility to participate in VQIP and their plans for correcting the deviations.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.