Fact Sheet on the Final Guidance for Industry for FDA's Voluntary Qualified Importer Program

What is it?

- A voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains.

Who is eligible?

- Importers (defined as the person who brings food, or causes food to be brought, from a foreign country into the United States) should meet several eligibility criteria to participate in the program. These criteria include:

    - Developing and implementing a Quality Assurance Program (QAP) that demonstrates a high level of control over the safety and security of supply chains.
    - Assurance of compliance with the supplier verification and other importer responsibilities under the applicable Foreign Supplier Verification Program (FSVP), juice HACCP (Hazard Analysis and Critical Control Points), or seafood HACCP regulations.
    - A current facility certification issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food intended for importation under VQIP. In the case of raw produce, there must be a certification for the farm.
    - At least a three-year history of importing food to the United States. The import history may be based on the shared importation history of previous or parent companies, such as those that have been involved in a merger. If applicants have imported food for more than three years, the FDA may review additional years as necessary to adequately evaluate compliance history.
    - No ongoing FDA administrative or judicial action (e.g., import alert, injunction, recall), or other history of significant non-compliance with food safety regulations by the importer, other entities in the supply chain (e.g., foreign suppliers, filers/brokers, and FSVP and HACCP importers), or food.
    - Having a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number. To obtain a DUNS number, contact 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.

What kinds of foods are allowed under VQIP?

- Foods from a facility (or farm) certified under FDA's Accredited Third-Party Certification regulations as following appropriate food safety practices.

- No food that an applicant imports, including those not intended for inclusion in VQIP, should be subject to an import alert or Class 1 recall.

Will FDA expedite entry of a VQIP food that is part of a mixed entry (i.e., the entry includes VQIP food and food that is not covered by my VQIP)?

- FDA will only expedite the VQIP food. A non-participating food will be subject to normal FDA review procedures, including routine examination and sampling, when applicable. Therefore, combining VQIP and non-VQIP foods into a single entry may slow the entry of the VQIP food.

Benefits of participating:

- The FDA will expedite entry into the U.S. for all foods included in an approved VQIP application.
- This means that the FDA will set up its import screening system to recognize shipments of food that are the subject of an approved VQIP application and, in most cases, immediately release the shipment after the receipt of entry information.
- The FDA will limit examination and/or sampling of VQIP food entries to "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.
- In the event that FDA examines or samples a VQIP food, the location of such sampling or examination would, to the extent possible, be at the VQIP food's destination or another location chosen by the importer.
- In the event that FDA samples a VQIP food, laboratory analysis of such samples would be expedited.
- The FDA will establish a VQIP Importers Help Desk dedicated to responding to questions and concerns from VQIP importers. The help desk will be available for assistance with completing the VQIP application, facilitating a review of VQIP food that does not receive an immediate release, and answering other questions from VQIP importers related to the program.
- The FDA will post on its VQIP web page a list of approved VQIP importers; however, VQIP importers may choose not to be listed.
- The FDA may suspend any or all of these benefits as necessary to protect public health or in the case of an unforeseen emergency.

What would necessitate a 'For Cause' examination of a VQIP food?

- A shipment from a VQIP-qualified importer may be subject to a "for cause" examination if the food is or may be associated with a risk to public health. For example, if there is an outbreak of foodborne illness that has been linked to the type of food or to a foreign supplier covered in the VQIP application, the FDA may examine and sample the food.

What is my VQIP Quality Assurance Program (QAP)?

- A QAP is a compilation of the written policies and procedures you will use to ensure adequate control over the safety and security of the foods you import. Your QAP, submitted with your VQIP application, should include:

    - A Corporate Quality Policy Statement related to food safety and security throughout the supply chain and an explanation of how this policy is communicated internally.
    - A description of the organizational structure and individual responsibilities.
    - Established policies and procedures that will be implemented to ensure food safety from source to entry (e.g., temperature and storage controls), including

        - Compliance with supplier verification procedures in the FSVP or HACCP regulations, if applicable.
        - Written procedures for maintaining current foreign supplier certifications under FDA's Accredited Third-Party Certification Program,
        - Procedures for controlling the safety of each VQIP food throughout the transportation supply chain, including compliance with FDA's sanitary transport rule, if applicable.
        - Written procedures for communicating information about potential health hazards to FDA and others.
        - Written procedures for corrective actions to address food and foreign supplier non-compliances that pose a risk to public health.
        - A written description of your food defense system to protect against intentional adulteration, if applicable.
- Knowledge and qualification requirements for employees responsible for implementing the VQIP QAP.
- Written procedures for establishing and maintaining records relating to the structure, processes, procedures, and implementation of your VQIP QAP.

How soon will I receive benefits?

- VQIP benefits will begin October 1 following your acceptance into the program and will last through September 30 of the following year (VQIP year).

How do I apply?

- Visit the FDA Industry Systems website to establish an online account.
- From January 1 to May 31 each year, submit online a "Notice of Intent to Participate" in VQIP.
- Your VQIP application must be renewed each year.

Is there a user fee to participate in VQIP?

- Yes. Each importer participating in VQIP must pay a fee to cover FDA's costs of administering the program. The FDA will charge the VQIP user fee on an annual basis. You must pay the user fee by October 1, the start of the VQIP year, in order to receive benefits under the program.
- In the Federal Register of June 5, 2015 (80 FR 32136), FDA estimated that a flat annual fee of approximately $16,400 will be paid by all VQIP participants. FDA has not yet finalized the fee for applications in January 2018, but will publish the fee amount in the Federal Register on or before August 1, 2017, and each year thereafter.

How will FDA evaluate my application?

- FDA will review the application, with all the relevant documents, to determine if you meet the VQIP eligibility criteria.

- If you are accepted into the program, FDA will conduct a VQIP inspection to verify that you meet the VQIP eligibility criteria and have fully implemented the food safety and any food defense systems established in your QAP.

- The inspection will typically include a review of the written procedures and records demonstrating compliance with VQIP. If you are both the VQIP and FSVP/Juice or Seafood HACCP importer for one or more foods you import under this program, FDA may also conduct an FSVP or HACCP importer inspection to assess your compliance with the applicable regulations.

- FDA may also request a copy of food labels for the foods you include in your application, to determine if there are labeling violations relating to the risk of the food (e.g., failure to disclose an allergen). You will be asked to address any label deficiencies. (Food labels do not have to be included in the VQIP application.)

- FDA ordinarily will conduct a VQIP inspection after your application is approved and prior to October 1 of the first year that you participate in VQIP.

How often will FDA evaluate me for VQIP eligibility?

- The first year that you submit a VQIP application, FDA will review all aspects of your application and conduct an inspection to verify your eligibility. Thereafter, we will reevaluate your eligibility at least once every three years that you participate in VQIP.

- An event such as an outbreak or recall linked to a food included in your VQIP application (or a similar food), a new hazard associated with a VQIP food, or intelligence data related to violations associated with one or more entities (e.g., foreign supplier, filer/broker) listed on

your VQIP application may prompt FDA to reevaluate your eligibility, including conducting an inspection, more frequently than once every three years.

What amendments am I permitted to make to my VQIP application for business purposes during the VQIP fiscal year?

- As necessary for your business purposes, you can amend your VQIP application to:
    - Add a food from a foreign supplier already in your VQIP;
    - Remove a food, the foreign supplier of a food, or the FSVP or Juice or Seafood HACCP importer for a food;
    - Replace a foreign supplier or FSVP or Juice or Seafood HACCP importer for a food that is already listed in your VQIP application as long as the foreign supplier has a current facility certification; and
    - Add or remove a filer/broker.

Can the FDA revoke my participation in VQIP and if so how will I be notified?

- Yes. The FDA may:
    - Revoke your participation in VQIP based on evidence that you do not meet one or more of the VQIP eligibility requirements or
    - Immediately revoke your participation in VQIP based on evidence that you participated in smuggling or other fraudulent activities.
- Revocation of your participation in VQIP will apply to all foods you import under VQIP.
- If the FDA has credible evidence that you do not meet one or more of the VQIP eligibility requirements, FDA will send a "Notice of Intent to Revoke" your participation in VQIP by email to the contact person identified in your VQIP application.
- The notice will explain the basis for the proposed revocation and indicate that, within 30 days, you would need to make corrections and provide the FDA with evidence of the corrections to avoid revocation.
- Benefits will continue for those 30 days unless the FDA believes there is a risk to public health.

Can I obtain reinstatement of my participation in VQIP after a revocation?

- When revocation is based upon evidence that you do not meet one or more of the VQIP eligibility requirements, you may ask the FDA to reinstate your VQIP participation and benefits at any time after you have corrected the issues associated with your revocation. Your request should include documentation of actions you have taken to correct or resolve all of the identified issues.