Voluntary Qualified Importer Program
Draft Guidance At-a-Glance

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) who 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. 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 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.

What kinds of foods are allowed under VQIP?

- Foods from a facility (or farm) certified as following appropriate food safety practices under FDA's Third-Party Certification regulations, which are required under the FDA Food Safety Modernization Act (FSMA).
- No food that an applicant imports, including those not intended for inclusion in VQIP, can be subject to an import alert or Class 1 recall.

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 immediately release the shipment, unless examination and sampling are necessary.
- 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.

    - Location of such sampling or examination would be at VQIP foods destination or another location chosen by the importer.
    - Laboratory analysis of such samples would be expedited.
- The FDA will establish a VQIP Importers Help Desk dedicated to responding questions and concerns from VQIP importers.
- Public posting on the FDA's VQIP web page of approved VQIP importers; however, VQIP importers may choose not to be listed.

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 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 rules, if applicable, written procedures for maintaining current foreign supplier certifications under FDA's Accredited Third-Party Certification Program,
        - 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 post a risk to public health.
    - A written description of your food defense system to protect against intentional adulteration.
    - Experience and training 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?

- It is expected that applications will be accepted beginning in January 2018. 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 (www.access.fda.gov) 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, publishing the amount of the fee in the Federal Register on or before August 1 each year. Then you must pay the user fee by October 1, the start of the VQIP year.
    - For the first year, the FDA is estimating that a flat annual fee of approximately $16,400 will be paid by all VQIP participants. FDA has requested comment on whether and how this amount would be a burden on small business.

Can the FDA revoke my participation in VQIP and 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 must make corrections and provide the FDA with evidence of the corrections.
    - 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 problems.