Voluntary Qualified Importer Program (VQIP)



The Voluntary Qualified Importer Program (VQIP) expedites review and import entry of human and animal foods into the United States. Participating importers can avoid unexpected delays at the point of import entry by importing their products more quickly. The resulting safety and security of supply chains benefits consumers.

To participate, importers must meet eligibility criteria and pay a user fee that covers the FDA's administration of the program. Importers interested in applying can set up an account via <u>FDA Industry Systems (https://www.access.fda.gov/)</u>, select VQIP under the FSMA Program options, and then select Notice of Intent to Participate on the VQIP Application Page. Importers applying for the next benefit period should refer to the <u>VQIP Portal User Guide (/media/113346/download?attachment)</u>.

Begin the VQIP Application Process (https://www.access.fda.gov)

Public List of Approved VQIP Importers (/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip-public-list-approved-vqip-importers)

OMB Burden Statement FDA Form 4041 (/food/importing-food-products-united-states/omb-burden-statement-fda-form-4041)

Frequently Asked Questions

Program information and instructions to help you complete the application process.

What are the benefits of participating in VQIP?

Quicker, easier entry

FDA will expedite import entry into the United States for all foods included in an approved VQIP application.

FDA will use its <u>Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) (/industry/fda-import-process/entry-screening-systems-and-tools)</u> import screening tool to recognize shipments of food that are part of an approved VQIP application. The screening tool will be programmed to recognize and, in most cases, immediately release the shipment, unless examination and sampling are necessary for the public health reasons listed below.

Limited examination and sampling

FDA will limit examination and/or sampling of VQIP food entries to the following situations: (1) "for cause" situations (i.e., investigation of an outbreak or illness); (2) to obtain statistically necessary risk-based microbiological samples (when building a product risk profile based on non-biased surveillance sampling); and (3) to audit a small percentage of import shipments covered by VQIP to verify that products declared in a VQIP entry are consistent with products covered in the VQIP application.

FDA sampling at preferred location

When FDA needs to examine an entry covered by VQIP, FDA will attempt, to the extent possible, to examine an import entry and collect samples at the VQIP food destination or other location preferred by the VQIP importer. If import entry to the U.S. is denied, FDA will assist in fulfilling an importer's request to U.S. Customs and Border Protection (CBP) to export the refused products from the port preferred by the importer.

Faster lab results

In the event FDA collects a sample of a VQIP food import entry, FDA's laboratories will prioritize processing of VQIP samples.

Help desk

FDA will maintain a *VQIP Importers Help Desk* connecting importers to FDA staff dedicated to responding to questions and helping to resolve concerns. Contact the help desk at <u>FSMAVQIP@fda.hhs.gov</u> (<u>mailto:FSMAVQIP@fda.hhs.gov</u>), or 1-301-796-8745.

What are the eligibility criteria to participate in VQIP?

- You have a 3-year history of importing food into the United States. Your import history (/food/food-safety-modernization-act-fsma/firmsupplier-evaluation-resources-fsma-rules) is based on importation of all foods, including food that may not be covered under VQIP.
- You have a <u>Data Universal Numbering System (DUNS) number</u>
 (http://www.dnb.com/government/duns-request/duns-request-guide.html)
 (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Don't have a DUNS number, Contact Dun and Bradstreet (D&B) at 866-705-5711 or via e-mail at government@dnb.com
 (mailto:government@dnb.com). All entities doing business with the U.S. government can receive a DUNS number free of charge through D&B using the basic service or pay a nominal fee to expedite service.
- You use paperless filers/brokers who received an acceptable rating during their last <u>FDA Filer Evaluation (/industry/actions-enforcement/filer-evaluations)</u>. The filer/broker is the person responsible for submitting import entry and entry summary data on the food into the <u>Automated Commercial Environment (/industry/import-systems/automated-commercial-environmentinternational-trade-data-system-aceitds) (ACE) and as necessary submitting import documents into the <u>International Trade Auxiliary Communication System (/industry/import-systems/itacs)</u> (ITACS) or through Customs and Border Protection's Document Imaging System (DIS).</u>
- None of the foods you import, including ones you do not intend to include in your VQIP application, is subject to an <u>import alert (/industry/actions-enforcement/import-alerts)</u> or Class 1 recall at the time you submit your application.

- Neither you nor the non-applicant entities associated with a VQIP food are subject to an ongoing FDA administrative or judicial action (e.g., Import Alert (/food/food-safety-modernization-act-fsma/firmsupplier-evaluation-resources-fsma-rules), injunction (/animal-veterinary/compliance-enforcement/drug-residue-injunctions-and-related-actions), and debarment (/inspections-compliance-enforcement-and-criminal-investigations/fda-debarment-list-drug-product-applications/fda-debarments-food-imports)), or have a history of significant non-compliances (http://govdashboard.fda.gov/) relating to food safety (e.g., an "Official Action Indicated" (OAI) FDA inspection classification; one or more voluntary Class 1 recalls relating to food safety) with no documentation of appropriate corrective actions. NOTE: "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 you), the foreign supplier of the food, and the import entry filer/broker.
- If you are the FSVP or HACCP importer (U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the U.S.) for a VQIP food, you are in compliance with the supplier verification and other importer responsibilities under the applicable FSVP, juice HACCP, or seafood HACCP regulations.
 - If you are not the FSVP or HACCP importer for a VQIP food, you must identify the FSVP or HACCP importer
 for the food and ensure that the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP
 regulations.
- You have a current <u>facility certification (/food/food-safety-modernization-act-fsma/fsma-final-rule-accredited-third-party-certification)</u> for each foreign supplier of the food you intend to import under the VQIP.
- You develop and implement a VQIP Quality Assurance Program (QAP). Documentation of your QAP must be submitted with your VQIP application.
- Within the past 3 years, you have not been the subject of any U.S. Customs and Border Protection
 penalties (https://www.cbp.gov/trade/programs-administration/penalties), forfeitures, or
 sanctions (https://www.cbp.gov/trade/priority-issues/revenue/bill-payments/importer-sanctions)
 that are related to the safety and security of any FDA-regulated product that you imported or offered
 for import.
- You must pay the user fee before October 1, the start of VQIP fiscal year, each year that you are approved to participate in the VQIP.

For more information on eligibility requirements, see **Section C. Eligibility** section of <u>FDA's Voluntary Qualified Importer Program Guidance for Industry (/media/92196/download?attachment)</u>.

Why is there a user fee to participate in VQIP?

Annual user fees to participate in VQIP cover FDA's costs for administering the program. These include the costs of reviewing applications; the costs of conducting inspections of importers (both foreign and domestic) accepted into the program; and the annual Information Technology (IT) maintenance costs. The user fee rates are calculated each Fiscal Year and will be posted in a Federal Register notice on or before August 1 each year.

For more information, see:

- Federal Register Notice: Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2024 (https://www.federalregister.gov/public-inspection/2023-15920/food-safety-modernization-act-voluntary-qualified-importer-program-user-fee-rate-for-fiscal-year)
- Federal Register Notice: Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2023 (https://www.federalregister.gov/public-inspection/2022-16175/food-safety-modernization-act-voluntary-qualified-importer-program-user-fee-rate-for-fiscal-year)

- <u>Federal Register Notice: Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2022 (https://www.federalregister.gov/public-inspection/2021-16053/food-safety-modernization-act-voluntary-qualified-importer-program-user-fee-rate-for-fiscal-year)</u>
- Federal Register Notice: Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2021 (https://www.federalregister.gov/documents/2020/08/03/2020-16791/food-safety-modernization-act-voluntary-qualified-importer-program-user-fee-rate-for-fiscal-year)
- Federal Register Notice: Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2020 (https://www.federalregister.gov/documents/2019/07/24/2019-15742/food-safety-modernization-act-voluntary-qualified-importer-program-user-fee-rate-for-fiscal-year)

How do I apply to VQIP?

- Create an account on the FDA Industry Systems website (https://www.access.fda.gov/)
- Submit a Notice of Intent to Participate in VQIP between January 1 and May 31, 11:59pm (EST).
- · Pay the user fee.

Begin the VQIP application process (https://www.access.fda.gov/), which will take you through the above steps.

Check the status of your application on your VQIP Application home page at https://www.access.fda.gov/).

What information do I need to complete VQIP application?

- Information identifying the VQIP Importing Firm
- Foreign Supplier Verification Program (FSVP) Contact Information Documentation of your VQIP Quality Assurance Program (QAP), as specified in <u>FDA's Voluntary Qualified Importer Guidance for Industry</u> (/media/92196/download?attachment)
- Filer/Broker Contact Information
- · Contact information for Foreign Supplier and list of Foods

Contact Us

Email the VQIP Importers Help Desk (mailto:FSMAVQIP@fda.hhs.gov)

Call 1-301-796-8745 for assistance in completing your VQIP application.

Guidance

<u>Guidance for Industry: FDA's Voluntary Qualified Importer Program (/regulatory-information/search-fdaguidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program)</u>

- 英語 (Traditional Chinese) (/media/121390/download?attachment?attachment)
- Français (French) (/media/121389/download?attachment)
- Español (Spanish) (/media/121391/download?attachment)

Fact Sheet: Preparing for the FDA Voluntary Qualified Importer Program (/food/importing-food-products-united-states/preparing-fda-voluntary-qualified-importer-program)

<u>Fact Sheet: FDA's Voluntary Qualified Importer Program</u> (/food/importing-food-products-united-states/fact-sheet-final-guidance-industry-fdas-voluntary-qualified-importer-program-vqip)

- <u>中文 (Simplified Chinese) (/media/121395/download?attachment)</u>
- 英語 (Traditional Chinese) (/media/121397/download?attachment)
- Français (French) (/media/121392/download?attachment)
- <u>हिन्दी (Hindi) (/media/121393/download?attachment)</u>
- Português (Portuguese) (/media/121394/download?attachment)
- Español (Spanish) (/media/121396/download?attachment)

Was this helpful?	Yes	No
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