GUIDANCE DOCUMENT

Guidance for Industry: FDA's Voluntary Qualified Importer Program

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Final

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Issued by:

(/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program)
Center for Veterinary Medicine
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition

The FDA Food Safety Modernization Act (FSMA) (/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma) (Pub. L. 111-353) enables the Food and Drug Administration (FDA or the Agency) to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Under FSMA, those that import food have a responsibility to ensure that their suppliers produce food that meets U.S. safety standards.

FSMA also requires FDA to establish 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. This control includes importation of food from facilities that have been certified in accordance with FDA's program for Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (see FDA's third-party certification regulations at 21 CFR part 1, subpart M), as well as other measures that support a high level of confidence in the safety and security of the food they import. Expedited entry incentivizes importers to adopt a robust system of supply chain management and further benefits public health by allowing FDA to focus its resources on food entries that pose a higher risk to public health.

This guidance document describes FDA's policy regarding participation in FDA's Voluntary Qualified Importer Program (VQIP) (/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip) by importers of food for humans or animals. This document provides guidance on:

- The benefits VQIP importers can expect to receive;
- The eligibility criteria for VQIP participation;
- Instructions for completing a VQIP application;
- Conditions that may result in revocation of participation in VQIP; and
- Criteria for VQIP reinstatement following revocation.

This guidance document is presented in question and answer format. This guidance document may be modified (in accordance with FDA's good guidance practice regulation (21 CFR 10.115)) as VQIP is implemented and evaluated. FDA's guidance documents, including this guidance, do not

establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required. This guidance represents FDA's current thinking regarding what will be considered for participation in VQIP and how VQIP will expedite entry of imports. However, we will consider alternative approaches and, as further discussed in this document, we retain our full authority with regard to import sampling and entry decisions.

The pronouns "I," "me," "you," and "your" are used in this guidance to refer to the importer who may want to participate in VQIP. "Agency" and the pronouns "we" and "our" are used to refer to FDA. The term "food" has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(f)), except that, for the purposes of VQIP, food does not include pesticides as defined in 7 U.S.C. 136(u).

Download the Guidance (/media/92196/download?attachment)

Related Information

- Fact Sheet on the Guidance (/food/food-safety-modernization-act-fsma/fact-sheet-final-guidance-industry-fdas-voluntary-qualified-importer-program)
- VQIP Program Main P (/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip)age (/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip)

- VQIP Portal User Guide (/media/113346/download?attachment)
- Public List of Approved VQIP Importers (/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip-public-list-approved-vqip-importers)
- Outlining the Benefits of the Voluntary Qualified Importer Program (/food/food-safety-modernization-act-fsma/outlining-benefits-voluntary-qualified-importer-program)
- Food Safety Modernization Act (FSMA) (/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma)

Meetings & Webinars

- Final Guidance for VQIP Webinar (/food/food-safety-modernization-act-fsma/final-guidance-voluntary-qualified-importer-program-vqip-webinar)(November 2016)
- Focus on Strategic Implementation of Prevention-Oriented Import Safety Programs (/food/food-safety-modernization-act-fsma/fsma-public-meeting-focus-strategic-implementation-prevention-oriented-import-safety-programs) (June 2016)
    - Report on Regional FSMA Import Safety Meetings (/media/99946/download)

Translations of the Guidance Document

- French (PDF: 500KB) (/media/121389/download?attachment)

- Spanish (PDF: 586KB) (/media/121391/download?attachment)
- Traditional Chinese (PDF: 733KB) (/media/121390/download?attachment)

Translations of the Fact Sheet

- French (PDF: 190KB) (/media/121392/download?attachment)
- Hindi (PDF: 374KB) (/media/121393/download?attachment)
- Portuguese (PDF: 195KB) (/media/121394/download?attachment)
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You can submit online or written comments on any guidance at any time (see 21 CFR 10.115(g)(5))

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
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All written comments should be identified with this document's docket number: FDA-2011-N-0144 (https://www.regulations.gov/docket/FDA-2011-N-0144).

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