

FSMA accredited foreign supplier facility certification

FDA-Recognized Accredited Third-Party Certification from LRQA for Foreign Suppliers to US Importers

The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) aims to ensure the food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

Perhaps one of the most groundbreaking shifts for the FDA is a much stronger focus on import safety, where importers are now responsible for ensuring that their foreign suppliers have adequate preventive controls in place. FSMA regulations require food imported from abroad to be as safe as domestic food.

To support this requirement, the FDA FSMA rule on Accredited Third-Party Certification has been finalized, and the program is now open for participation. The rule establishes a voluntary program for the accreditation of third-party certification bodies, like LRQA, to conduct food safety audits and issue certifications of foreign entities, including farms, under section 806(d) of FSMA. LRQA is working towards FDA-recognized accreditation to deliver Consultative Audits, Regulatory Audits and Accredited Third-Party Certification under FSMA.

FSMA certifications issued under the US FDA accredited third-party certification program are used:

- By US importers that will use certifications of foreign suppliers, including farms, to help establish their eligibility to participate in the Voluntary Qualified Importer Program (VQIP), which is a voluntary program that provides for the expedited entry of food imported by participating importers.
- For supplier verification activities under the Preventive Controls for Human Food Rules, Preventive Controls for Animal Food Rules, and Produce Safety rules.
- When required by FDA as a condition of entry. For example:
 - safety risks associated with the food product,
 - food safety risks associated with the country, region, or origin of the food, and
 - the capability of the regulatory system of the exporting nation to ensure compliance with FDA safety standards.

What is Accredited FSMA Foreign Supplier Facility Certification?

Under section 806(d) of FSMA, U.S. importers must have a facility certification issued consistent with section 808 of the FD&C Act regarding accreditation of third-party certification bodies, also known as auditors, for each foreign supplier's facility from which they want to import a food under VQIP. The foreign supplier's facility must have a facility certification, which would be issued following a regulatory audit conducted by an accredited third-party certification body that is accredited under FDA's third-party certification regulations (see 21 CFR 1.653). Either the U.S. importer or the foreign supplier may request the regulatory audit required for facility certification.

An FDA inspection of the foreign supplier would not meet the requirement under section 806(d) of FSMA because an FDA inspection does not result in a facility certification consistent with the requirements of FSMA regulations.

What is the difference between Facility Certification and a Regulatory Audit under FSMA?

A facility certification is an attestation issued by an accredited third party certification body after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of FSMA and FDA regulations; any food the importer wishes to be covered under VQIP should be within the scope of the facility certification.

A regulatory audit, for purposes of VQIP, is an audit of a foreign supplier's facility by an accredited third-party certification body, such as LRQA, in accordance with FDA's third-party certification regulation. The results of the audit are used to determine whether a foreign supplier is eligible for a facility certification.

How often must a foreign supplier's facility be re-certified?

Under FSMA regulations, the foreign supplier of a VQIP must obtain re-certification annually, and allows accredited certification bodies, such as LRQA, to issue a certification for a term of up to 1 year. Although it is anticipated that most foreign supplier facility certifications will have a term of 1 year, the certification body may find it appropriate in some circumstances to issue the certification for a shorter term and may require the facility to be re-audited and re-certified more frequently (for example, when there are multiple seasonal productions during a year).

Why is Accredited Foreign Supplier Facility Certification under FSMA VQIP Important?

LRQA issued accredited FSMA certifications under the U.S. Food and Drug Administration (FDA) third-party program may be used:

- By importers for establishing eligibility of foreign suppliers for expedited review of food entry in the United States.
- For supplier verification activities under the Food Safety Verification Program and Preventive Controls rules.
- When required by the FDA as a condition of entry under specific circumstances related to safety risks.
- To determine if an organization is in compliance with applicable U.S. food safety requirements as well as with industry standards and practices.
- To determine if facilities are complying with applicable food safety requirements under the FD&C Act and FDA FSMA regulations.

If you're a foreign supplier into the US, FSMA accredited third party certification under the FDA program can add market and competitive advantage for your organization.

What types of organizations should pursue Accredited Foreign Supplier Certification under FSMA?

All foreign supplier facilities that want to be able to demonstrate their commitment to FSMA and to U.S. food importers should acquire accredited Foreign Supplier Facility Certification to help build credibility and trust that an independent set of food safety expert eyes are helping to assure your organization is fulfilling its responsibilities under FSMA.

In addition, if you know or anticipate the U.S. importer in which your foreign facility supplies may seek participation in VQIP under FSMA, as a foreign facility, you are encouraged to be proactive and obtain accredited foreign facility certification from LRQA.

What if my facility is already certified to HACCP or a GFSI recognized standard, including FSSC 22000 or BRCGS?

If your facility is already certified to HACCP or a GFSI-recognized food safety standard, your FDA-recognized accredited Foreign Supplier Facility Certification can be added to your existing certification assessment.

Why Choose LRQA for accredited Foreign Supplier Facility Certification under FSMA?

LRQA offers extensive global food supply chain and food safety experience, and we are ready to help your organization and your supply chain with FSMA.

Trusted food safety and supply chain experience

LRQA has been at the forefront of food safety standards development and is a market leader in ISO 22000, FSSC 22000, BRCGS and HACCP certification and training. This is why many of the world's leading food, beverage, packaging and animal feed manufacturers choose LRQA to certify their organizations and their supply chains.

Technical expertise

LRQA food safety technical experts contributed toward the development of HACCP, ISO 22000, PRPs and FSSC 22000, giving your organization and your supply chain the confidence that you're working with experts in food safety management systems.

Our food safety assessors and technical specialists have some of the most extensive food safety and food supply chain experience in the world. Many are hand-selected to provide input into the work of the ISO technical committees as well as the Global Food Safety Initiative and are able to provide first-hand insight into requirements of the standard and its logic.

Accreditation

Globally, LRQA has been independently accredited by UKAS for ISO 22000 and FSSC 22000 certification. For FSMA, LRQA is pursuing accreditation under the FDA FSMA Accredited Third-Party Certification program.

Proven client satisfaction

Year after year, LRQA clients continue to report high satisfaction ratings of our service and technical support, and many recommend LRQA to their colleagues and industry peers.

Assessment methodology

LRQA helps you manage your systems and risks to improve and protect the current and future performance of your organization. Our approach is built on three pillars and extends the focus beyond the certificate to an assessment approach designed to help organizations meet their strategic objectives. We're confident that LRQA further helps our food and beverage clients minimize and better manage their food safety risks.

FSMA and Food Safety Training

LRQA offers an extensive range of FSMA Training Courses (including PCQI Human Food, PCQI Animal Food, FSVP), ISO 22000 training and FSSC 22000 training courses that are recognized by the Foundation for Food Safety Certification and/or IRCA.

Browse FSMA and Food Safety Training

Have questions or ready to discuss if FSMA Accredited Foreign Supplier Facility Certification is right for your organization?

Contact the LRQA Food Safety team today

Get in touch

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