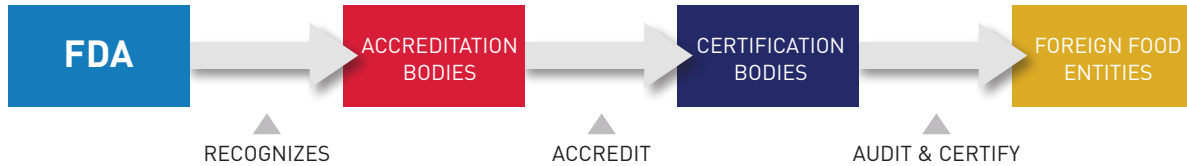




Key Facts about the Accredited Third-Party Certification Program



HOW DOES THE ACCREDITED THIRD-PARTY CERTIFICATION PROGRAM WORK?

FDA's Accredited Third-Party Certification Program was established under the FDA Food Safety Modernization Act (FSMA). It is a voluntary program that allows "accreditation bodies" to apply for recognition by FDA. Recognized accreditation bodies will have the authority to accredit third-party "certification bodies," otherwise known as third-party auditors. In turn, the certification bodies (1) conduct consultative and/or regulatory food safety audits and (2) issue certifications to eligible entities that produce food for humans and animals.

- **Consultative Audits** are conducted to help foreign eligible entities prepare for a regulatory audit. The audit is used to determine if the entity is in compliance with applicable U.S. food safety requirements as well as with industry standards and practices.

Consultative audit reports do not have to be submitted to FDA, but certification bodies must maintain records of the audit. The records must be made available to FDA in accordance with section 414 of the Federal Food Drug & Cosmetic (FD&C) Act.

- **Regulatory Audits** are conducted to determine if facilities are complying with applicable food safety requirements under the FD&C Act and FDA regulations.

Only the results of a regulatory audit can determine if a facility may receive certification.

What is a food safety audit?

Under the Accredited Third-Party Certification Program, certification bodies examine entities to determine if they are complying with applicable FDA food safety requirements and / or some industry standards. Audits can be **Consultative** or **Regulatory**.

In either type of food safety audit, FDA must be notified immediately if the audit reveals conditions that could cause or contribute to a serious risk to public health.

REGULATORY AUDITS AND CERTIFICATION: WHY ARE THEY IMPORTANT?

Only the results of a regulatory audit can determine if a facility may receive certification under this program. FSMA states two purposes for certifications obtained through the Accredited Third-Party Certification Program:

- (1) Importers can use a certification to establish their eligibility to participate in the **Voluntary Qualified Importer Program (VQIP)**.
- (2) FDA can require certification as a condition of entry for imported food products in limited circumstances when specific, risk-based criteria are met.

Voluntary Qualified Importer Program (VQIP)

Importers who participate in VQIP receive faster review and entry of food imports. Certification through FDA's Accredited Third-Party Certification Program is one of the eligibility criteria for participation in VQIP.

FDA anticipates that the agency will begin to accept applications from importers who wish to participate in VQIP in 2018.

TELL ME MORE ABOUT ACCREDITATION BODIES. WHAT WILL THEIR ROLE BE?

Accreditation bodies under the Accredited Third-Party Certification Program must:

- Assess third-party certification bodies to determine if they can be accredited. This includes observing a representative sample of the applicant's work;
- Monitor the performance of the certification bodies it accredits. Accreditation bodies must notify FDA of any change in, or withdrawal of, accreditations it has granted;
- Assess and correct any problems in the accreditation body's own performance;
- Submit monitoring and self-assessment reports and other notifications to FDA;
- Maintain and provide FDA with access to the records that the program requires.

Accreditation bodies may begin to accredit certification bodies to issue certifications under this program once they receive recognition from FDA.

WHAT WILL BE THE CERTIFICATION BODIES' ROLE?

Accredited third-party certification bodies will be accredited to (1) conduct unannounced food safety audits and (2) certify that foreign food entities and the foods they produce meet applicable FDA food safety standards.

The Accredited Third Party Certification Program requires certification bodies to:

- Make sure their audit agents are competent and objective;
- Verify that an entity's corrective actions effectively address deficiencies that are identified;
- Assess and correct any problems in the certification body's own performance;
- Maintain and provide FDA with access to records that the program requires.

WHO CAN APPLY TO BECOME RECOGNIZED AS AN ACCREDITATION BODY?

Foreign governments and agencies, or private third-parties may apply to become accreditation bodies.

How to Become a FDA-Recognized Accreditation Body

- Web-based application
- User fee

WHAT IS THE ACCREDITATION BODY APPLICATION PROCESS?

To submit your application or learn more about the application process, go to: www.access.fda.gov.

Potential accreditation bodies must submit a user fee with their application. The user fee reimburses FDA for the work the agency does to establish and administer the Accredited Third-Party Certification Program. Specifically, the user fee will, in part, reimburse FDA for evaluating applications, which includes on-site reviews of foreign facilities.

User Fee

The user fee rates are calculated each Fiscal Year and published before the start of a new Fiscal Year. In Fiscal Year 2017, FDA will only collect the initial application fee for potential accreditation bodies. There are other user fees associated with the program. To learn more about current user fee rates, estimated fees under this program and what activities the fees fund, please review the Federal Register Notice: Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2017. Find it here:

<https://www.federalregister.gov/documents/2016/12/14/2016-30034/food-safety-modernization-act-third-party-certification-program-user-fee-rate-for-fiscal-year-2017>

WHAT DO I NEED TO SHOW IN ORDER TO PARTICIPATE IN THE PROGRAM? EITHER AS AN ACCREDITATION BODY OR AS A CERTIFICATION BODY?

Organizations that wish to become an accreditation body or a certification body must meet the eligibility requirements for the program, including:

- Possessing and demonstrating **authority**:
 - **Accreditation body**: Authority to assess a third-party certification body for accreditation;
 - **Certification body**: Authority to conduct site audits and review records;
- Possessing and demonstrating **capacity & competency**: have adequate (1) finances for operation, (2) staff with the knowledge, skills, and experience to perform effectively, and (3) resources and equipment necessary for audits and testing;
- Having a written program to monitor **quality assurance**;
- Having written measures to protect against **conflicts of interest**;
- Having written procedures to establish, control, and retain **records**.

Organizations of any size can apply to become recognized as an accreditation body or accredited as a certification body.

FDA will post a notification on the Accredited Third-Party Certification Program webpage for each accreditation body it recognizes. FDA will also provide information about each certification body that is accredited. Information on certification bodies will be available on the Accredited Third-Party Certification Program webpage directly or there will be a link from the page to information about the certification body that is hosted on the accreditation body's website.

WHO CAN BECOME ACCREDITED AS A CERTIFICATION BODY? HOW DO I BECOME ONE?

Foreign governments and agencies, or private third-parties are eligible for accreditation as third-party certification bodies.

Interested organizations will work with an FDA recognized accreditation body to become accredited. Organizations can use this guidance to learn more about the standards FDA recommends accreditation bodies use to accredit certification bodies:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm455328.htm>

I WANT TO BE ACCREDITED AS A CERTIFICATION BODY, CAN FDA DIRECTLY ACCREDIT ME?

In limited circumstances, the FDA may directly accredit third-party certification bodies. If FDA does not identify and recognize an accreditation body to meet the requirements of the program within two years after establishing the Accredited Third-Party Certification Program, the Agency will determine if there is a need for direct accreditation. ■