

party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

§ 1.601 Who is subject to this subpart?

(a) *Accreditation bodies.* Any accreditation body seeking recognition from FDA to accredit third-party certification bodies to conduct food safety audits and to issue food and facility certifications under this subpart.

(b) *Third-party certification bodies.* Any third-party certification body seeking accreditation from a recognized accreditation body or direct accreditation by FDA for:

- (1) Conducting food safety audits; and
- (2) Issuing certifications that may be used in satisfying a condition of admissibility of an article of food under section 801(q) of the FD&C Act; or issuing a facility certification for meeting the eligibility requirements for the Voluntary Qualified Importer Program under section 806 of the FD&C Act.

(c) *Eligible entities.* Any eligible entity seeking a food safety audit or a food or

facility certification from an accredited third-party certification body under this subpart.

(d) *Limited exemptions from section 801(q) of the FD&C Act—*(1) *Alcoholic beverages.* (i) Any certification required under section 801(q) of the FD&C Act does not apply with respect to alcoholic beverages from an eligible entity that is a facility that meets the following two conditions:

(A) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(B) Under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(ii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to food that is not an alcoholic beverage that is received and distributed by a facility described in paragraph (d)(1)(i) of this section, provided such food:

(A) Is received and distributed in pre-packaged form that prevents any direct human contact with such food; and

(B) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(iii) Any certification required under section 801(q) of the FD&C Act does not apply with respect to raw materials or other ingredients that are imported for use in alcoholic beverages provided that:

(A) The imported raw materials or other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(B) Such manufacturing/processing, packing, or holding is performed by the importer;

(C) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

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(D) The importer is exempt from the regulations in part 117 of this chapter in accordance with §117.5(i).

(2) *Certain meat, poultry, and egg products.* Any certification required under section 801(q) of the FD&C Act does not apply with respect to:

(i) Meat food products that at the time of importation are subject to the requirements of the United States Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(ii) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(iii) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

RECOGNITION OF ACCREDITATION BODIES UNDER THIS SUBPART

§ 1.610 Who is eligible to seek recognition?

An accreditation body is eligible to seek recognition by FDA if it can demonstrate that it meets the requirements of §§1.611 through 1.615. The accreditation body may use documentation of conformance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17011:2004, supplemented as necessary, in meeting the applicable requirements of this subpart.

§ 1.611 What legal authority must an accreditation body have to qualify for recognition?

(a) An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

(1) Review any relevant records;

(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of

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a third-party certification body that is an individual, such individual) conducting a representative sample of audits;

(3) Perform any reassessments or surveillance necessary to monitor compliance of accredited third-party certification bodies; and

(4) Suspend, withdraw, or reduce the scope of accreditation for failure to comply with the requirements of accreditation.

(b) An accreditation body seeking recognition must demonstrate that it is capable of exerting the authority (as a governmental entity or as a legal entity with contractual rights) necessary to meet the applicable requirements of this subpart, if recognized.

§ 1.612 What competency and capacity must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) The resources required to adequately implement its accreditation program, including:

(1) Adequate numbers of employees and other agents with relevant knowledge, skills, and experience to effectively evaluate the qualifications of third-party certification bodies seeking accreditation and to effectively monitor the performance of accredited third-party certification bodies; and

(2) Adequate financial resources for its operations; and

(b) The capability to meet the applicable assessment and monitoring requirements, the reporting and notification requirements, and the procedures of this subpart, if recognized.

§ 1.613 What protections against conflicts of interest must an accreditation body have to qualify for recognition?

An accreditation body must demonstrate that it has:

(a) Implemented written measures to protect against conflicts of interest between the accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation