agreements to which the United States is a party, see sections 2251 and 2252 of this title.

§ 384c. Inspection of foreign food facilities

(a) Inspection

The Secretary—

(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 350d of this title; and

(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

(b) Effect of inability to inspect

Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.

(June 25, 1938, ch. 675, § 807, as added Pub. L. 111–353, title III, § 306(a), Jan. 4, 2011, 124 Stat. 3958.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 384d. Accreditation of third-party auditors

(a) Definitions

In this section:

(1) Audit agent

The term ''audit agent'' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor.

(2) Accreditation body

The term ''accreditation body'' means an authority that performs accreditation of third-party auditors.

(3) Third-party auditor

The term ''third-party auditor'' means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements of this section. A third-party auditor may be a single individual. A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

(4) Accredited third-party auditor

The term ''accredited third-party auditor'' means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section. An accredited third-party auditor may be an individual who conducts food safety audits to certify that eligible entities meet the applicable requirements of this section.

(5) Consultative audit

The term ''consultative audit'' means an audit of an eligible entity—

(A) to determine whether such entity is in compliance with the provisions of this chapter and with applicable industry standards and practices; and

(B) the results of which are for internal purposes only.

(6) Eligible entity

The term ''eligible entity'' means a foreign entity, including a foreign facility registered under section 350d of this title, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

(7) Regulatory audit

The term ''regulatory audit'' means an audit of an eligible entity—

(A) to determine whether such entity is in compliance with the provisions of this chapter; and

(B) the results of which determine—

(i) whether an article of food manufactured, processed, packed, or held by such entity is eligible to receive a food certification under section 381(q) of this title; or

(ii) whether a facility is eligible to receive a facility certification under section 384b(a) of this title for purposes of participating in the program under section 384b of this title.

(b) Accreditation system

(1) Accreditation bodies

(A) Recognition of accreditation bodies

(i) In general

Not later than 2 years after January 4, 2011, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable requirements of this section.

(ii) Direct accreditation

If, by the date that is 2 years after the date of establishment of the system de-

scribed in clause (i), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

(B) Notification

Each accreditation body recognized by the Secretary shall submit to the Secretary a list of all accredited third-party auditors accredited by such body and the audit agents of such auditors.

(C) Revocation of recognition as an accreditation body

The Secretary shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

(D) Reinstatement

The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

(2) Model accreditation standards

Not later than 18 months after January 4, 2011, the Secretary shall develop model standards, including requirements for regulatory audit reports, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section. In developing the model standards, the Secretary shall look to standards in place on January 4, 2011, for guidance, to avoid unnecessary duplication of efforts and costs.

(c) Third-party auditors

(1) Requirements for accreditation as a third-party auditor

(A) Foreign governments

Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of food safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or foods certified by such government or agency meet the requirements of this chapter with respect to food manufactured, processed, packed, or held for import into the United States.

(B) Foreign cooperatives and other third parties

Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that cooperative or party and conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that such entity or food meets the requirements of this chapter.

(2) Requirement to issue certification of eligible entities or foods

(A) In general

An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic food certification, described in section 381(q) of this title, or facility certification under section 384b(a) of this title, as appropriate, to accompany each food shipment for import into the United States from an eligible entity, subject to requirements set forth by the Secretary. Such written or electronic certification may be included with other documentation regarding such food shipment. The Secretary shall consider certifications under section 381(q) of this title and participation in the voluntary qualified importer program described in section 384b of this title when targeting inspection resources under section 350j of this title.

(B) Purpose of certification

The Secretary shall use certification provided by accredited third-party auditors to—

(i) determine, in conjunction with any other assurances the Secretary may require under section 381(q) of this title, whether a food satisfies the requirements of such section; and

(ii) determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program under section 384b of this title.

(C) Requirements for issuing certification

(i) In general

An accredited third-party auditor shall issue a food certification under section 381(q) of this title or a facility certification described under subparagraph (B) only after conducting a regulatory audit and such other activities that may be necessary to establish compliance with the requirements of such sections.

(ii) Provision of certification

Only an accredited third-party auditor or the Secretary may provide a facility certification under section 384b(a) of this

title. Only those parties described in[1] 381(q)(3) of this title or the Secretary may provide a food certification under[1] 381(q)[2] of this title.

(3) Audit report submission requirements

(A) Requirements in general

As a condition of accreditation, not later than 45 days after conducting an audit, an accredited third-party auditor or audit agent of such auditor shall prepare, and, in the case of a regulatory audit, submit, the audit report for each audit conducted, in a form and manner designated by the Secretary, which shall include—

(i) the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements;

(ii) the dates of the audit;

(iii) the scope of the audit; and

(iv) any other information required by the Secretary that relates to or may influence an assessment of compliance with this chapter.

(B) Records

Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an onsite audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of such auditor. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.

(C) Limitation

The requirement under subparagraph (B) shall not include any report or other documents resulting from a consultative audit by the accredited third-party auditor, except that the Secretary may access the results of a consultative audit in accordance with section 350c of this title.

(4) Requirements of accredited third-party auditors and audit agents of such auditors

(A) Risks to public health

If, at any time during an audit, an accredited third-party auditor or audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—

(i) the identification of the eligible entity subject to the audit; and

(ii) such condition.

(B) Types of audits

An accredited third-party auditor or audit agent of such auditor may perform consultative and regulatory audits of eligible entities.

(C) Limitations

(i) In general

An accredited third party auditor may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period.

(ii) Waiver

The Secretary may waive the application of clause (i) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region.

(5) Conflicts of interest

(A) Third-party auditors

An accredited third-party auditor shall—

(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

(ii) in carrying out audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

(B) Audit agents

An audit agent shall—

(i) not own or operate an eligible entity to be audited by such agent;

(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

(C) Regulations

The Secretary shall promulgate regulations not later than 18 months after January 4, 2011, to implement this section and to ensure that there are protections against conflicts of interest between an accredited third-party auditor and the eligible entity to be certified by such auditor or audited by such audit agent. Such regulations shall include—

(i) requiring that audits performed under this section be unannounced;

(ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be certified by such auditor, as described in subparagraphs (A) and (B).

[1] So in original. Probably should be followed by ''section''.

[2] See References in Text note below.

(6) Withdrawal of accreditation

(A) In general

The Secretary shall withdraw accreditation from an accredited third-party auditor—

(i) if food certified under section 381(q) of this title or from a facility certified under paragraph (2)(B) by such third-party auditor is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

(ii) following an evaluation and finding by the Secretary that the third-party auditor no longer meets the requirements for accreditation; or

(iii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

(B) Additional basis for withdrawal of accreditation

The Secretary may withdraw accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked, if the Secretary determines that there is good cause for the withdrawal.

(C) Exception

The Secretary may waive the application of subparagraph (A)(i) if the Secretary—

(i) conducts an investigation of the material facts related to the outbreak of human or animal illness; and

(ii) reviews the steps or actions taken by the third party auditor to justify the certification and determines that the accredited third-party auditor satisfied the requirements under section 381(q) of this title of certifying the food, or the requirements under paragraph (2)(B) of certifying the entity.

(7) Reaccreditation

The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been withdrawn under paragraph (6)—

(A) if the Secretary determines, based on evidence presented, that the third-party auditor satisfies the requirements of this section and adequate grounds for revocation no longer exist; and

(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked—

(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (6)(A), through direct accreditation under subsection (b)(1)(A)(ii) or by an accreditation body in good standing; or

(ii) under such conditions as the Secretary may require for a third-party auditor under paragraph (6)(B).

(8) Neutralizing costs

The Secretary shall establish by regulation a reimbursement (user fee) program, similar to the method described in section 1622(h) of title 7,[2] by which the Secretary assesses fees and requires accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to establish and administer the accreditation system under this section. The Secretary shall make operating this program revenue-neutral and shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

(d) Recertification of eligible entities

An eligible entity shall apply for annual recertification by an accredited third-party auditor if such entity—

(1) intends to participate in[3] voluntary qualified importer program under section 384b of this title; or

(2) is required to provide to the Secretary a certification under section 381(q) of this title for any food from such entity.

(e) False statements

Any statement or representation made—

(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

(2) by an accredited third-party auditor to the Secretary,

shall be subject to section 1001 of title 18.

(f) Monitoring

To ensure compliance with the requirements of this section, the Secretary shall—

(1) periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

(2) periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

(3) at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

(4) take any other measures deemed necessary by the Secretary.

(g) Publicly available registry

The Secretary shall establish a publicly available registry of accreditation bodies and of accredited third-party auditors, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies and auditors.

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[3] So in original. Probably should be followed by ''the''.

(h) Limitations

(1) No effect on section 374 inspections

The audits performed under this section shall not be considered inspections under section 374 of this title.

(2) No effect on inspection authority

Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this chapter.

(June 25, 1938, ch. 675, § 808, as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.)

Editorial Notes

REFERENCES IN TEXT

Section 381(q) of this title, referred to in subsec. (c)(2)(C)(ii), was in the original ''301(g)'', and was translated as reading ''801(q)'', meaning section 801(q) of act June 25, 1938, ch. 675, which is classified to section 381(q) of this title, to reflect the probable intent of Congress, because section 381(q) of this title relates to food certification, whereas section 301(g) of act June 25, 1938, ch. 675, which is classified to section 331(g) of this title, does not relate to food certification.

Section 1622(h) of title 7, referred to in subsec. (c)(8), was in the original ''section 203(h) of the Agriculture Marketing Act of 1946'', and was translated as reading ''section 203(h) of the Agricultural Marketing Act of 1946'', meaning section 203(h) of act Aug. 14, 1946, ch. 966, which is classified to section 1622(h) of Title 7, Agriculture, to reflect the probable intent of Congress.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 384e. Recognition of foreign government inspections

(a) Inspection

The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 360(i) of this title in order to facilitate preapproval or risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 360(h) of this title;

(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this chapter; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this chapter.

(b) Results of inspection

The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

(1) evidence of compliance with section 351(a)(2)(B) of this title or section 381(r) of this title; and

(2) for any other purposes as determined appropriate by the Secretary.

(c) Periodic review

(1) In general

Beginning not later than 1 year after December 29, 2022, the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

(2) Reports to Congress

Beginning not later than 4 years after December 29, 2022, and every 4 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the findings and conclusions of each review conducted under paragraph (1).

(June 25, 1938, ch. 675, § 809, as added Pub. L. 112–144, title VII, § 712, July 9, 2012, 126 Stat. 1072; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(X), Dec. 13, 2016, 130 Stat. 1156; Pub. L. 115–52, title VII, § 701(b), Aug. 18, 2017, 131 Stat. 1055; Pub. L. 117–328, div. FF, title III, § 3613(c), Dec. 29, 2022, 136 Stat. 5872.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328, § 3613(c)(1), inserted ''preapproval or'' before ''risk-based inspections''.

Subsec. (c). Pub. L. 117–328, § 3613(c)(2), added subsec. (c).

2017—Subsec. (a)(1). Pub. L. 115–52 substituted ''paragraph (2) or (3) of section 360(h)'' for ''section 360(h)(3)''.

2016—Subsec. (a)(2). Pub. L. 114–255 substituted ''conducting'' for ''conduction''.

§ 384f. Strengthening FDA and CBP coordination and capacity

(a) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall coordinate with the Secretary of Homeland Security to carry out activities related to customs and border protection and in response to illegal controlled substances and drug imports, including at sites of import (such as international mail facilities), that will provide improvements to such facilities, technologies, and inspection capacity. Such Secretaries may carry out such activities through a memorandum of understanding between the Food and Drug Administration and the U.S. Customs and Border Protection.

(b) FDA import facilities and inspection capacity

(1) In general

In carrying out this section, the Secretary shall, in collaboration with the Secretary of