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.

(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.

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

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

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.

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 risk-based inspections in accordance with the schedule established in section 360(h)(3) 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 conduction 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.

(June 25, 1938, ch. 675, § 809, as added Pub. L. 112–144, title VII, § 712, July 9, 2012, 126 Stat. 1072.)

SUBCHAPTER IX—TOBACCO PRODUCTS

PRIOR PROVISIONS

A prior subchapter IX of this chapter, consisting of sections 391 to 399a of this title, was redesignated sub-