

(June 25, 1938, ch. 675, §420, as added Pub. L. 111-353, title I, §106(a), Jan. 4, 2011, 124 Stat. 3905.)

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.

GUIDANCE DOCUMENTS

Pub. L. 111-353, title I, §106(b), Jan. 4, 2011, 124 Stat. 3906, provided that:

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Jan. 4, 2011], the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adulteration as required under section 420 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 450i], as added by subsection (a).

“(2) CONTENT.—The guidance documents issued under paragraph (1) shall—

“(A) include a model assessment for a person to use under subsection (b)(1) of section 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

“(B) include examples of mitigation strategies or measures described in subsection (b)(2) of such section; and

“(C) specify situations in which the examples of mitigation strategies or measures described in subsection (b)(2) of such section are appropriate.

“(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which the guidance documents issued under paragraph (1) are made public, including by releasing such documents to targeted audiences.”

PERIODIC REVIEW

Pub. L. 111-353, title I, §106(c), Jan. 4, 2011, 124 Stat. 3906, provided that: “The Secretary of Health and Human Services shall periodically review and, as appropriate, update the regulations under section 420(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 450i(b)], as added by subsection (a), and the guidance documents under subsection (b) [section 106(b) of Pub. L. 111-353, set out above].”

§ 350j. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report

(a) Identification and inspection of facilities

(1) Identification

The Secretary shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors:

(A) The known safety risks of the food manufactured, processed, packed, or held at the facility.

(B) The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.

(C) The rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls.

(D) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 381(h)(1) of this title.

(E) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 381(q) or 384b of this title, as appropriate.

(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(2) Inspections

(A) In general

Beginning on January 4, 2011, the Secretary shall increase the frequency of inspection of all facilities.

(B) Domestic high-risk facilities

The Secretary shall increase the frequency of inspection of domestic facilities identified under paragraph (1) as high-risk facilities such that each such facility is inspected—

(i) not less often than once in the 5-year period following January 4, 2011; and

(ii) not less often than once every 3 years thereafter.

(C) Domestic non-high-risk facilities

The Secretary shall ensure that each domestic facility that is not identified under paragraph (1) as a high-risk facility is inspected—

(i) not less often than once in the 7-year period following January 4, 2011; and

(ii) not less often than once every 5 years thereafter.

(D) Foreign facilities

(i) Year 1

In the 1-year period following January 4, 2011, the Secretary shall inspect not fewer than 600 foreign facilities.

(ii) Subsequent years

In each of the 5 years following the 1-year period described in clause (i), the Secretary shall inspect not fewer than twice the number of foreign facilities inspected by the Secretary during the previous year.

(E) Reliance on Federal, State, or local inspections

In meeting the inspection requirements under this subsection for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation.

(b) Identification and inspection at ports of entry

The Secretary, in consultation with the Secretary of Homeland Security, shall allocate resources to inspect any article of food imported into the United States according to the known safety risks of the article of food, which shall be based on the following factors:

(1) The known safety risks of the food imported.

(2) The known safety risks of the countries or regions of origin and countries through which such article of food is transported.

(3) The compliance history of the importer, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.

(4) The rigor and effectiveness of the activities conducted by the importer of such article of food to satisfy the requirements of the foreign supplier verification program under section 384a of this title.

(5) Whether the food importer participates in the voluntary qualified importer program under section 384b of this title.

(6) Whether the food meets the criteria for priority under section 381(h)(1) of this title.

(7) Whether the food or the facility that manufactured, processed, packed, or held such food received a certification as described in section 381(q) or 384b of this title.

(8) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(c) Interagency agreements with respect to seafood

(1) In general

The Secretary of Health and Human Services, the Secretary of Commerce, the Secretary of Homeland Security, the Chairman of the Federal Trade Commission, and the heads of other appropriate agencies may enter into such agreements as may be necessary or appropriate to improve seafood safety.

(2) Scope of agreements

The agreements under paragraph (1) may include—

(A) cooperative arrangements for examining and testing seafood imports that leverage the resources, capabilities, and authorities of each party to the agreement;

(B) coordination of inspections of foreign facilities to increase the percentage of imported seafood and seafood facilities inspected;

(C) standardization of data on seafood names, inspection records, and laboratory testing to improve interagency coordination;

(D) coordination to detect and investigate violations under applicable Federal law;

(E) a process, including the use or modification of existing processes, by which officers and employees of the National Oceanic and Atmospheric Administration may be duly designated by the Secretary to carry out seafood examinations and investigations under section 381 of this title or section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004;

(F) the sharing of information concerning observed non-compliance with United States food requirements domestically and in foreign nations and new regulatory decisions and policies that may affect the safety of food imported into the United States;

(G) conducting joint training on subjects that affect and strengthen seafood inspection effectiveness by Federal authorities; and

(H) outreach on Federal efforts to enhance seafood safety and compliance with Federal food safety requirements.

(d) Coordination

The Secretary shall improve coordination and cooperation with the Secretary of Agriculture and the Secretary of Homeland Security to target food inspection resources.

(e) Facility

For purposes of this section, the term “facility” means a domestic facility or a foreign facility that is required to register under section 350d of this title.

(June 25, 1938, ch. 675, §421, as added Pub. L. 111-353, title II, §201(a), Jan. 4, 2011, 124 Stat. 3923.)

REFERENCES IN TEXT

Section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004, referred to in subsec. (c)(2)(E), is section 203 of Pub. L. 108-282, Aug. 2, 2004, 118 Stat. 906, which amended sections 321, 343, and 343-1 of this title and enacted provisions set out as notes under sections 321 and 343 of this title.

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.

ADVISORY COMMITTEE CONSULTATION

Pub. L. 111-353, title II, §201(c), Jan. 4, 2011, 124 Stat. 3926, provided that: “In allocating inspection resources as described in section 421 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 450j] (as added by subsection (a)), the Secretary may, as appropriate, consult with any relevant advisory committee within the Department of Health and Human Services.”

§ 350k. Laboratory accreditation for analyses of foods

(a) Recognition of laboratory accreditation

(1) In general

Not later than 2 years after January 4, 2011, the Secretary shall—

(A) establish a program for the testing of food by accredited laboratories;

(B) establish a publicly available registry of accreditation bodies recognized by the Secretary and laboratories accredited by a recognized accreditation body, including the name of, contact information for, and other information deemed appropriate by the Secretary about such bodies and laboratories; and

(C) require, as a condition of recognition or accreditation, as appropriate, that recognized accreditation bodies and accredited laboratories report to the Secretary any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory.

(2) Program requirements

The program established under paragraph (1)(A) shall provide for the recognition of laboratory accreditation bodies that meet criteria established by the Secretary for accreditation of laboratories, including independent private laboratories and laboratories run and operated by a Federal agency (including the