

(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.)

Editorial Notes

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.

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.

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 Department of Commerce), State, or locality with a demonstrated capability to conduct 1

or more sampling and analytical testing methodologies for food.

(3) Increasing the number of qualified laboratories

The Secretary shall work with the laboratory accreditation bodies recognized under paragraph (1), as appropriate, to increase the number of qualified laboratories that are eligible to perform testing under subparagraph¹ (b) beyond the number so qualified on January 4, 2011.

(4) Limited distribution

In the interest of national security, the Secretary, in coordination with the Secretary of Homeland Security, may determine the time, manner, and form in which the registry established under paragraph (1)(B) is made publicly available.

(5) Foreign laboratories

Accreditation bodies recognized by the Secretary under paragraph (1) may accredit laboratories that operate outside the United States, so long as such laboratories meet the accreditation standards applicable to domestic laboratories accredited under this section.

(6) Model laboratory standards

The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and included in the registry provided for under paragraph (1). In developing the model standards, the Secretary shall consult existing standards for guidance. The model standards shall include—

(A) methods to ensure that—

(i) appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate;

(ii) internal quality systems are established and maintained;

(iii) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited; and

(iv) individuals who conduct the sampling and analyses are qualified by training and experience to do so; and

(B) any other criteria determined appropriate by the Secretary.

(7) Review of recognition

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

(A) shall periodically, and in no case less than once every 5 years, reevaluate accreditation bodies recognized under paragraph (1) and may accompany auditors from an accreditation body to assess whether the accreditation body meets the criteria for recognition; and

(B) shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this

¹ So in original. Probably should be “subsection”.

section, specifying, as appropriate, any terms and conditions necessary for laboratories accredited by such body to continue to perform testing as described in this section.

(b) Testing procedures

(1) In general

Not later than 30 months after January 4, 2011, food testing shall be conducted by Federal laboratories or non-Federal laboratories that have been accredited for the appropriate sampling or analytical testing methodology or methodologies by a recognized accreditation body on the registry established by the Secretary under subsection (a)(1)(B) whenever such testing is conducted—

(A) by or on behalf of an owner or consignee—

(i) in response to a specific testing requirement under this chapter or implementing regulations, when applied to address an identified or suspected food safety problem; and

(ii) as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem; or

(B) on behalf of an owner or consignee—

(i) in support of admission of an article of food under section 381(a) of this title; and

(ii) under an Import Alert that requires successful consecutive tests.

(2) Results of testing

The results of any such testing shall be sent directly to the Food and Drug Administration, except the Secretary may by regulation exempt test results from such submission requirement if the Secretary determines that such results do not contribute to the protection of public health. Test results required to be submitted may be submitted to the Food and Drug Administration through electronic means.

(3) Exception

The Secretary may waive requirements under this subsection if—

(A) a new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform such methodology or methodologies; and

(B) the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

(c) Review by Secretary

If food sampling and testing performed by a laboratory run and operated by a State or locality that is accredited by a recognized accreditation body on the registry established by the Secretary under subsection (a) result in a State recalling a food, the Secretary shall review the sampling and testing results for the purpose of determining the need for a national recall or other compliance and enforcement activities.

(d) No limit on Secretarial authority

Nothing in this section shall be construed to limit the ability of the Secretary to review and

act upon information from food testing, including determining the sufficiency of such information and testing.

(June 25, 1938, ch. 675, §422, as added Pub. L. 111-353, title II, §202(a), Jan. 4, 2011, 124 Stat. 3926.)

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.

§ 350f. Mandatory recall authority

(a) Voluntary procedures

If the Secretary determines, based on information gathered through the reportable food registry under section 350f of this title or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 342 of this title or misbranded under section 343(w) of this title and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 350f of this title) with an opportunity to cease distribution and recall such article.

(b) Prehearing order to cease distribution and give notice

(1) In general

If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to—

(A) immediately cease distribution of such article; and

(B) as applicable, immediately notify all persons—

(i) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and

(ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article.¹

(2) Required additional information

(A) In general

If an article of food covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order that is in its possession, the notice provided by the responsible party subject to the order issued under paragraph (1)(B) shall include

¹ So in original. The words “to immediately cease distribution of such article.” probably should follow cl. (ii).