

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act; and

“(ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415.

“(B) CLARIFICATION.—The rulemaking described under subparagraph (A) shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term ‘facility’ under such section 415. Nothing in this Act [see Short Title note set out under section 2201 of this title] authorizes the Secretary to modify the definition of the term ‘facility’ under such section.

“(C) SCIENCE-BASED RISK ANALYSIS.—In promulgating regulations under subparagraph (A), the Secretary shall conduct a science-based risk analysis of—

“(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and

“(ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.

“(D) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

“(i) IN GENERAL.—In promulgating the regulations under subparagraph (A), the Secretary shall consider the results of the science-based risk analysis conducted under subparagraph (C), and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350g] (as added by this section), including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act [21 U.S.C. 350j] (as added by section 201), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.

“(ii) LIMITATION.—The exemptions or modifications under clause (i) shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added under subsection (a)).

“(2) FINAL REGULATIONS.—Not later than 9 months after the close of the comment period for the proposed rulemaking under paragraph (1), the Secretary shall adopt final rules with respect to—

“(A) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act;

“(B) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415; and

“(C) the requirements under sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350g, 350j], as added by this Act, from which the Secretary may issue exemptions or modifications of the requirements for certain types of facilities.”

Pub. L. 107-188, title III, §305(e), June 12, 2002, 116 Stat. 669, provided that: “Not later than 18 months after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services shall promulgate proposed and final regulations for the re-

quirement of registration under section 415 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350d] (as added by subsection (a) of this section). Such requirement of registration takes effect—

“(1) upon the effective date of such final regulations; or

“(2) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.”

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendments by Pub. L. 111-353 to be construed 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 2251 and 2252 of this title.

SMALL ENTITY COMPLIANCE POLICY GUIDE

Pub. L. 111-353, title I, §102(b)(2), Jan. 4, 2011, 124 Stat. 3888, provided that: “Not later than 180 days after the issuance of the regulations promulgated under section 415(b)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350d(b)(5)] (as added by this section), the Secretary shall issue a small entity compliance policy guide setting forth in plain language the requirements of such regulations to assist small entities in complying with registration requirements and other activities required under such section.”

ELECTRONIC FILING

Pub. L. 107-188, title III, §305(d), June 12, 2002, 116 Stat. 668, provided that: “For the purpose of reducing paperwork and reporting burdens, the Secretary of Health and Human Services may provide for, and encourage the use of, electronic methods of submitting to the Secretary registrations required pursuant to this section [enacting this section, amending sections 331 and 381 of this title, and enacting provisions set out as a note under this section]. In providing for the electronic submission of such registrations, the Secretary shall ensure adequate authentication protocols are used to enable identification of the registrant and validation of the data as appropriate.”

§ 350e. Sanitary transportation practices

(a) Definitions

In this section:

(1) Bulk vehicle

The term “bulk vehicle” includes a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, and any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

(2) Transportation

The term “transportation” means any movement in commerce by motor vehicle or rail vehicle.

(b) Regulations

The Secretary shall by regulation require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.

(c) Contents

The regulations under subsection (b) of this section shall—

(1) prescribe such practices as the Secretary determines to be appropriate relating to—

- (A) sanitation;
- (B) packaging, isolation, and other protective measures;
- (C) limitations on the use of vehicles;
- (D) information to be disclosed—
 - (i) to a carrier by a person arranging for the transport of food; and
 - (ii) to a manufacturer or other person that—
 - (I) arranges for the transportation of food by a carrier; or
 - (II) furnishes a tank vehicle or bulk vehicle for the transportation of food; and
- (E) recordkeeping; and

(2) include—

(A) a list of nonfood products that the Secretary determines may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle; and

(B) a list of nonfood products that the Secretary determines may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle.

(d) Waivers**(1) In general**

The Secretary may waive any requirement under this section, with respect to any class of persons, vehicles, food, or nonfood products, if the Secretary determines that the waiver—

(A) will not result in the transportation of food under conditions that would be unsafe for human or animal health; and

(B) will not be contrary to the public interest.

(2) Publication

The Secretary shall publish in the Federal Register any waiver and the reasons for the waiver.

(e) Preemption**(1) In general**

A requirement of a State or political subdivision of a State that concerns the transportation of food is preempted if—

(A) complying with a requirement of the State or political subdivision and a requirement of this section, or a regulation prescribed under this section, is not possible; or

(B) the requirement of the State or political subdivision as applied or enforced is an obstacle to accomplishing and carrying out this section or a regulation prescribed under this section.

(2) Applicability

This subsection applies to transportation that occurs on or after the effective date of the regulations promulgated under subsection (b) of this section.

(f) Assistance of other agencies

The Secretary of Transportation, the Secretary of Agriculture, the Administrator of the Environmental Protection Agency, and the heads of other Federal agencies, as appropriate, shall provide assistance on request, to the ex-

tent resources are available, to the Secretary for the purposes of carrying out this section.

(June 25, 1938, ch. 675, §416, as added Pub. L. 109-59, title VII, §7202(b), Aug. 10, 2005, 119 Stat. 1911.)

EFFECTIVE DATE

Section effective Oct. 1, 2005, see section 7204 of Pub. L. 109-59, set out as an Effective Date of 2005 Amendment note under section 331 of this title.

REGULATIONS

Pub. L. 111-353, title I, §111(a), Jan. 4, 2011, 124 Stat. 3916, provided that: “Not later than 18 months after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall promulgate regulations described in section 416(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).”

§ 350f. Reportable food registry**(a) Definitions**

In this section:

(1) Responsible party

The term “responsible party”, with respect to an article of food, means a person that submits the registration under section 350d(a) of this title for a food facility that is required to register under section 350d(a) of this title, at which such article of food is manufactured, processed, packed, or held.

(2) Reportable food

The term “reportable food” means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

(b) Establishment**(1) In general**

Not later than 1 year after September 27, 2007, the Secretary shall establish within the Food and Drug Administration a Reportable Food Registry to which instances of reportable food may be submitted by the Food and Drug Administration after receipt of reports under subsection (d), via an electronic portal, from—

(A) Federal, State, and local public health officials; or

(B) responsible parties.

(2) Review by Secretary

The Secretary shall promptly review and assess the information submitted under paragraph (1) for the purposes of identifying reportable food, submitting entries to the Reportable Food Registry, acting under subsection (c), and exercising other existing food safety authorities under this chapter to protect the public health.

(c) Issuance of an alert by the Secretary**(1) In general**

The Secretary shall issue, or cause to be issued, an alert or a notification with respect to a reportable food using information from the Reportable Food Registry as the Secretary deems necessary to protect the public health.