whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

(3) Application

The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

(b) Regulations concerning recordkeeping

The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

(c) Protection of sensitive information

The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

(d) Limitations

This section shall not be construed—

(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this chapter;

(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

(3) to have any legal effect on section 552 of title 5 or section 1905 of title 18; or

(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

(June 25, 1938, ch. 675, § 414, as added Pub. L. 107–188, title III, § 306(a), June 12, 2002, 116 Stat. 669; amended Pub. L. 111–353, title I, § 101(a), Jan. 4, 2011, 124 Stat. 3886.)

REFERENCES IN TEXT

The Federal Meat Inspection Act, referred to in subsec. (d)(2), is titles I to V of act Mar. 4, 1907, ch. 2907, as added Pub. L. 90–201, Dec. 15, 1967, 81 Stat. 584, and Pub. L. 110–246, title XI, § 11015(a), June 18, 2008, 122 Stat. 2124, which are classified generally to subchapters I to IV–A (§ 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

The Poultry Products Inspection Act, referred to in subsec. (d)(2), is Pub. L. 85–172, Aug. 28, 1957, 71 Stat. 441, which is classified generally to chapter 10 (§ 451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Egg Products Inspection Act, referred to in subsec. (d)(2), is Pub. L. 91–597, Dec. 29, 1970, 84 Stat. 1620, which is classified principally to chapter 15 (§ 1031 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables.

AMENDMENTS

2011—Subsec. (a). Pub. L. 111–353 reenacted heading without change, designated existing provisions as par. (1) and inserted heading, substituted ''If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is'' for ''If the Secretary has a reasonable belief that an article of food is'', inserted '', and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner,'' after ''relating to such article'', struck out at end ''The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.'', and added pars. (2) and (3).

EXPEDITED RULEMAKING

Pub. L. 107–188, title III, § 306(d), June 12, 2002, 116 Stat. 670, provided that: ''Not later than 18 months after the date of the enactment of this Act [June 12, 2002], the Secretary shall promulgate proposed and final regulations establishing recordkeeping requirements under subsection 414(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350c(b)] (as added by subsection (a)).''

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111–353 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.

§ 350d. Registration of food facilities

(a) Registration

(1) In general

The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered—

(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

(2) Registration

An entity (referred to in this section as the ''registrant'') shall submit a registration

under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business, the e-mail address for the contact person of the facility or, in the case of a foreign facility, the United States agent for the facility, and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations, or any other food categories as determined appropriate by the Secretary, including by guidance) of any food manufactured, processed, packed, or held at such facility. The registration shall contain an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this chapter. The registrant shall notify the Secretary in a timely manner of changes to such information.

(3) Biennial registration renewal

During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration under paragraph (1) shall submit to the Secretary a renewal registration containing the information described in paragraph (2). The Secretary shall provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since the registrant submitted the preceding registration or registration renewal for the facility involved.

(4) Procedure

Upon receipt of a completed registration described in paragraph (1), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered facility.

(5) List

The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5 to the extent that it discloses the identity or location of a specific registered person.

(b) Suspension of registration

(1) In general

If the Secretary determines that food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of a facility—

(A) that created, caused, or was otherwise responsible for such reasonable probability; or

(B)(i) that knew of, or had reason to know of, such reasonable probability; and

(ii) packed, received, or held such food.

(2) Hearing on suspension

The Secretary shall provide the registrant subject to an order under paragraph (1) with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of the order or such other time period, as agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

(3) Post-hearing corrective action plan; vacating of order

(A) Corrective action plan

If, after providing opportunity for an informal hearing under paragraph (2), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan not later than 14 days after the submission of the corrective action plan or such other time period as determined by the Secretary.

(B) Vacating of order

Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions required by the order, or that such actions should be modified, the Secretary shall promptly vacate the order and reinstate the registration of the facility subject to the order or modify the order, as appropriate.

(4) Effect of suspension

If the registration of a facility is suspended under this subsection, no person shall import or export food into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food from such facility into interstate or intrastate commerce in the United States.

(5) Regulations

(A) In general

The Secretary shall promulgate regulations to implement this subsection. The Secretary may promulgate such regulations on an interim final basis.

(B) Registration requirement

The Secretary may require that registration under this section be submitted in an electronic format. Such requirement may not take effect before the date that is 5 years after January 4, 2011.

(6) Application date

Facilities shall be subject to the requirements of this subsection beginning on the earlier of—

(A) the date on which the Secretary issues regulations under paragraph (5); or

(B) 180 days after January 4, 2011.

(7) No delegation

The authority conferred by this subsection to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

(c) Facility

For purposes of this section:

(1) The term ''facility'' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

(2) The term ''domestic facility'' means a facility located in any of the States or Territories.

(3)(A) The term ''foreign facility'' means a facility that manufacturers, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.

(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

(d) Rule of construction

Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (b).

(June 25, 1938, ch. 675, § 415, as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667; amended Pub. L. 111–353, title I, § 102(a)–(b)(1), (d)(2), Jan. 4, 2011, 124 Stat. 3887, 3889.)

AMENDMENTS

2011—Subsec. (a)(2). Pub. L. 111–353, § 102(a)(1), (b)(1)(A), substituted ''conducts business, the e-mail address for the contact person of the facility or, in the case of a foreign facility, the United States agent for the facility, and'' for ''conducts business and'', inserted '', or any other food categories as determined appropriate by the Secretary, including by guidance'' after ''Code of Federal Regulations'', and inserted after first sentence ''The registration shall contain an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this chapter.''

Subsec. (a)(3) to (5). Pub. L. 111–353, § 102(a)(2), (3), added par. (3) and redesignated former pars. (3) and (4) as (4) and (5), respectively.

Subsecs. (b), (c). Pub. L. 111–353, § 102(b)(1)(B), (C), added subsec. (b) and redesignated former subsec. (b) as (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 111–353, § 102(b)(1)(B), (d)(2), redesignated subsec. (c) as (d) and inserted ''for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (b)'' before period at end.

REGULATIONS

Pub. L. 111–353, title I, § 102(c), Jan. 4, 2011, 124 Stat. 3889, provided that:

''(1) RETAIL FOOD ESTABLISHMENT.—The Secretary shall amend the definition of the term 'retail food establishment' in section in [sic] 1.227(b)(11) of title 21, Code of Federal Regulations[,] to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include—

''(A) the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;

''(B) the sale and distribution of such food through a community supported agriculture program; and

''(C) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

''(2) DEFINITIONS.—For purposes of paragraph (1)—

''(A) the term 'community supported agriculture program' has the same meaning given the term 'community supported agriculture (CSA) program' in section 249.2 of title 7, Code of Federal Regulations (or any successor regulation); and

''(B) the term 'consumer' does not include a business.''

Pub. L. 111–353, title I, § 103(c), Jan. 4, 2011, 124 Stat. 3896, provided that:

''(1) PROPOSED RULEMAKING.—

''(A) IN GENERAL.—Not later than 9 months after the date of enactment of this Act [Jan. 4, 2011], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to—

''(i) 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; 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 requirement 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) 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