

(June 25, 1938, ch. 675, §414, as added Pub. L. 107-188, title III, §306(a), June 12, 2002, 116 Stat. 669.)

REFERENCES IN TEXT

The Federal Meat Inspection Act, referred to in subsec. (d)(2), is titles I to IV of act Mar. 4, 1907, ch. 2907, as added Pub. L. 90-201, Dec. 15, 1967, 81 Stat. 584, and amended, which are classified generally to subchapters I to IV (§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, as amended, 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, as amended, which is classified generally 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.

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))."

§ 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 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) of any food manufactured, processed, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information.

(3) 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.

(4) 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) 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.

(c) Rule of construction

Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process.

(June 25, 1938, ch. 675, §415, as added Pub. L. 107-188, title III, §305(a), June 12, 2002, 116 Stat. 667.)

REGULATIONS

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."

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 extent 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.

§ 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.