

Food and Drug Administration, HHS

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address a copy of the cancellation(s) as entered and confirmation of the cancellation.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(11) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

[68 FR 58960, Oct. 10, 2003 as amended at 73 FR 15883, Mar. 26, 2008]

ADDITIONAL PROVISIONS

§ 1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§ 1.241 What are the consequences of failing to register, update, or cancel your registration?

(a) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the act.

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, op-

erator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(c) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

Subpart I—Prior Notice of Imported Food

SOURCE: 73 FR 66402, November 7, 2008, unless otherwise noted.

GENERAL PROVISIONS

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

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(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined in this section.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mailed.

(4) *FDA Country of Production* means: (i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act, except as provided in paragraph (b)(5)(i) of this section.

(i) For purposes of this subpart, food does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural

commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(6) *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.

(7) *Grower* means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(8) *International mail* means foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.

(9) *Manufacturer* means the last facility, as that word is defined in § 1.227(b)(2), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

(10) *No longer in its natural state* means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished are still in their natural state for purposes of this

subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.

(11) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

(12) *Port of entry*, in section 801(m) and (1) of the act (21 U.S.C. 381(m) and (1)), means the port of entry as defined in 19 CFR 101.1.

(13) *Registration number* means the registration number assigned to a facility by FDA under section 415 of the act (21 U.S.C. 350d) and subpart H of this part.

(14) *Shipper* means the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail or express consignment operators or carriers or other private delivery service to the United States.

(15) *United States* means the Customs territory of the United States (i.e., the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(16) *You* means the person submitting the prior notice, i.e., the submitter or the transmitter, if any.

§ 1.277 What is the scope of this subpart?

(a) This subpart applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

(b) Notwithstanding paragraph (a) of this section, this subpart does not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*);

(6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); and

(7) Articles of food subject to Article 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD

§ 1.278 Who is authorized to submit prior notice?

A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person.

§ 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the