

(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, 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 (l) of the act (21 U.S.C. 381(m) and (l)), 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.

[73 FR 66402, Nov. 7, 2008, as amended at 80 FR 56143, Sept. 17, 2015]

§ 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;

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(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 prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

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(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import by international mail:

(1) If prior notice is submitted via the Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS), you may not submit prior notice more than 30-calendar days before the anticipated date of arrival.

(2) If prior notice is submitted via the FDA Prior Notice System Interface (FDA PNSI), you may not submit prior notice more than 15-calendar days before the anticipated date of arrival.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration (e.g., CN22 or CN23 or U.S. equivalent) that accompanies the package.

(f) A copy of the confirmation, including the PN Confirmation Number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to U.S. Customs and Border Protection (CBP) or FDA upon arrival.

(g) The PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

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