Food and Drug Administration, HHS § 1.279

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.

§ 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.

§ 1.278 Who is authorized to submit prior notice of imported food?

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
§ 1.280 How must you submit prior notice?

You must submit the prior notice electronically to FDA. You must submit all prior notice information in the English language, except that an individual’s name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including the items listed in the previous sentence, must be submitted using the Latin (Roman) alphabet. Unless paragraph (c) of this section applies, you must submit prior notice through:

(a) The U.S. Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS); or

(b) The FDA Prior Notice System Interface (FDA PNSI) at http://www.access.fda.gov. You must submit prior notice through the FDA Prior Notice System Interface (FDA PNSI) for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACS. Prior notice for articles that have been refused under section 801(m)(1) of the act and under this subpart must be submitted through the FDA PNSI until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions.

(c) If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (OASIS) is not working, FDA will post prominent notification and instructions at http://www.fda.gov. FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.