

- The term “country from which the article originates” was added and defined as “FDA Country of Production.”

- The term “country from which the article of food was shipped” was revised to “country from which the article is shipped.”

- The term “FDA Country of Production” replaces the term “originating country.” For an article of food that is in its natural state, the FDA Country of Production is 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 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. For an article of food that is no longer in its natural state, the FDA Country of Production is the country where the article was made; except that, if an article of food is made from wild fish 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.

- The term “food” has been redefined. The new definition excludes “food contact substances” as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) and “pesticides” as defined in 7 U.S.C. 136(u).

- The term “grower” has been added to the interim final rule. It means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

- The term “international mail” has been added to the interim final rule. The term “international mail” means foreign national mail services, but not express carriers, express consignment operators, or other private delivery services.

- The term “no longer in its natural state” has been added to the interim final rule. The term 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. However, crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of the prior notice interim final rule. Likewise, whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of the prior notice interim final rule.

- The term “port of entry” has been defined, as having the meaning given in 19 CFR 101.1.

- The term “port of arrival” has been added to the interim final rule. The interim final rule defines “port of arrival” to mean “the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States.”

- The term “registration number” has been added to the interim final rule. Registration number refers to the registration number assigned by FDA under section 415 of the FD&C Act, 21 U.S.C. 350d, and 21 CFR part 1, subpart H.

- The term “shipper” has been added to the interim final rule. The interim final rule defines “shipper” as “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 to the United States.”

- The term “United States” has been added to the interim final rule. It defines “United States” as the Customs territory of the United States, i.e., “the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.”

- The term “you” has been revised to reflect the removal of limitations on who is authorized to submit prior notice.

B. “What is the Scope of This Subpart?” (Section 1.277 Proposed as § 1.276)

This provision has been revised. Section 1.277(a) clarifies that the interim final rule applies to all food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, and includes food for gifts, 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. FTZ. Section 1.277(b) sets out the exclusions from prior notice. It excludes food for an individual’s personal use when it is carried by or otherwise accompanies the individual

when arriving in the United States (i.e., for consumption by themselves, family and friends, not for sale or other distribution); 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; food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg 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.*), 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.*).

C. “Who Is Authorized to Submit Prior Notice?” (Section 1.278 Proposed as § 1.285)

This provision has been revised. The interim final rule has been revised to remove the restriction that the submitter be the U.S. importer or purchaser. The interim final rule provides that any person with knowledge of the required information may submit prior notice or have it transmitted on their behalf.

D. “When Must Prior Notice Be Submitted to FDA?” (Section 1.279 Proposed as § 1.286)

This provision has been revised. FDA had proposed that all information required in the prior notice be submitted to FDA no later than 12 noon of the calendar day before the day the article of food arrived at the border crossing in the port of entry. Under the interim final rule, prior notice must be submitted to FDA and confirmed for FDA review no less than 2 hours before arrival by land via road, no less than 4 hours before arrival by air and land via rail, and no less than 8 hours before arrival by water. If the article of food is arriving by international mail, the prior notice must be submitted before the food has been sent to the United States and the parcel must be accompanied by confirmation of FDA receipt of prior notice. With the exception of prior notice for international mail, prior notice may not be submitted more than 5 calendar days before the anticipated date of arrival at the anticipated port of entry. When an article of food that is carried by or otherwise accompanies an individual is subject to prior notice, the prior notice must be submitted within the timeframe established for the mode of transportation, and the food must be accompanied by a copy of the FDA confirmation including the PN Confirmation Number. Because we