

- ACS entry number or other U.S. Customs identification number associated with the import;
- If the article of food is under hold under proposed § 1.278, the location where it is being held;
 - The identity of the article of food being imported or offered for import;
 - The complete FDA product code;
 - The common or usual name or market name;
 - The trade or brand name, if different from the common or usual name or market name;
 - The quantity described from smallest package size to largest container; and
 - The lot or code numbers or other identifier of the food if applicable;
 - The manufacturer;
 - All growers, if known;
 - The country from which the article originates;
 - The shipper;
 - The country from which the article of food was shipped;
 - The anticipated arrival information;
 - Information related to U.S. Customs entry process;
 - The importer, owner, and consignee; and
 - The carrier.
 - Amendments relating to product identity are allowed if complete information about product identity does not exist by the deadline for prior notice for the planned shipment:
 - Information regarding identity of the article may be amended once;
 - Amendments may not be used to change the nature of the article of food;
 - Quantity may be amended; and
 - Any amendments must be submitted no later than 2 hours prior to arrival.
 - If a change occurs in the anticipated port of entry or anticipated time of arrival stated in the prior notice, the information must be updated.
 - The proposed rule does not apply to:
 - Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use; or
 - 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).

B. General Provisions

1. What Imported Food is Subject to This Subpart? (Proposed § 1.276)

Under new section 801(m)(1) of the act, prior notice is required for all food

“being imported or offered for import into the United States.” Accordingly, prior notice requirements apply to all food that is brought across the U.S. border (with the following four exceptions) regardless of whether the food is intended for consumption in the United States. In other words, FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is “imported or offered for import” and thus must comply with the prior notice requirements.

The proposed rule establishes four categories of imported food that are not subject to the prior notice requirements. In each of these cases, FDA believes that the statutory language requires this result.

The first category is food that individual travelers carry in their personal baggage for their own personal enjoyment. Although we believe that this food is imported into the United States, the information that section 801(m)(1) of the act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (i.e., consumption by themselves, family or friends, not for sale to anyone). In particular, under section 801(m)(1) of the act, a prior notice must contain the identity of the shipper of the food. When travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended for us to characterize such travelers as “shippers” for purposes of section 801(m) of the act. We seek comment on this reasoning. However, when travelers bring food into the United States in their personal baggage to sell or otherwise distribute in a broader fashion, the travelers would seem to be acting for or on behalf of other entities. Under these circumstances, these travelers would seem to be shippers and subject to the provisions of this proposed rule.

The remaining three categories of imported food not subject to the prior notice requirement are those foods within the exclusive jurisdiction of USDA. In accordance with section 801(m)(3)(B) of the act, FDA is proposing to exempt from the requirements of this regulation imported foods that, at the time of importation, are subject to USDA's exclusive jurisdiction 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.*).

2. What Definitions Apply to This Subpart? (Proposed § 1.277)

The following definitions are used throughout the proposed rule:

a. *The act.* The proposed rule defines “the act” as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act to such terms as used in the proposed rule.

b. *Calendar day.* The proposed rule defines “calendar day” as “every day shown on the calendar.”

c. *Country from which the article of food was shipped.* The proposed rule defines “country from which the article of food was shipped” as the country in which the article of food was loaded onto the conveyance that brings it to the United States. A conveyance is the means of transportation, e.g., ship, truck, car, van, plane, railcar, etc., not the shipping container that could be moved from a ship to a truck to a train bed.

FDA is requesting comment on whether this term should include the countries of intermediate destination.

d. *Food.* FDA is proposing to refer to the definition of “food” in section 201(f) of the act (21 U.S.C. 321(f)), which is: “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” FDA also is proposing to include examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. FDA already receives entry information on all these articles of food as defined in section 201(f) of the Act.

With respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required if the article is being imported for use as food.

e. *Originating country.* The proposed rule defines “originating country” as “the country from which the article of food originates.” FDA is proposing this definition to be consistent with the language used in the Bioterrorism Act.