

This proposed definition is also consistent with the definition that describes one of the critical data elements that brokers and other filers currently submit to FDA's OASIS via ACS when entry is made. The proposed definition refers to the country where the product that is shipped to the United States was grown or produced, depending on the kind of article. If the article is fresh produce, for example, the originating country is most likely to be the country where it is grown and harvested. If, on the other hand, the article is a processed food, e.g., canned vegetables, the originating country is likely to be the country in which the vegetables were canned. With respect to wild-caught fish or seafood that is harvested in the waters of the United States or by a U.S. flagged vessel or that is processed aboard a U.S. flagged vessel, FDA is proposing that the originating country be the United States. Otherwise, the originating country is the country under which the vessel is flagged. FDA aligned this aspect of the proposed definition of "originating country" with the principles proposed by USDA's Agricultural Marketing Service guidance published in the **Federal Register** on October 11, 2002, in response to the Farm Security and Rural Investment Act of 2002 (commonly known as the 2002 Farm Bill).

FDA recognizes that this proposed definition may not be identical in all respects to the meaning of the term "country of origin" traditionally used by U.S. Customs. However, FDA believes that using the U.S. Customs meaning would not serve the purpose of the Bioterrorism Act. The U.S. Customs term primarily serves tariff, quota, and other trade purposes; it does not provide information needed for the evaluations that Congress has directed FDA to make under the Bioterrorism Act and the act. We seek comment on this interpretation and our proposed definition of "originating country". FDA also seeks comment on whether its use of a different term will have any impact, and if so, what that impact will be.

f. *Port of entry.* For purposes of the proposed rule, FDA is defining "port of entry" as "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 food first arrives in the United States." FDA is proposing this definition because the port where the food arrives in the United States may be different than the port where the entry of the article of food is processed for U.S. Customs purposes, i.e., where the article is "entered." Under U.S. Customs statutes, products can be imported into one port

and then transported to another port under a custodial bond before a consumption entry is filed. For example, food may be imported into the United States from Canada through Buffalo, NY, but not be entered for consumption with U.S. Customs until it reaches St. Louis, MO, several days later. In this example, under FDA's proposed definition, the port of entry is Buffalo, NY. If food is imported into the United States from Mexico through Otay Mesa, CA, for transport through the United States for exportation into Canada, the port of entry under FDA's proposed definition is Otay Mesa, CA.

The prior notice authority in the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism and other food related problems. Given this purpose, "port of entry" must be defined as the port of arrival, that is, the location where the food first physically appeared in the United States. Allowing food that is presented for importation into the United States without prior notice to be shipped around the country and potentially lost to government oversight simply is not consistent with the Bioterrorism Act's stated purpose. FDA believes that its ability to protect U.S. consumers from terrorism or other food-related emergencies will be strongest if food can be examined, and if necessary, held at the point when it first arrives in the United States. FDA requests comments on the proposed definition of "port of entry."

g. *You.* The proposed definition of "you" is the description of the party responsible for submitting the prior notice in proposed § 1.285. FDA is proposing to define "you" in proposed § 1.277(f) as the "purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer" or, "if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier."

3. What Are the Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (Proposed § 1.278)

As set out in section 801(m)(1) of the act, proposed § 1.278(a) provides that, if an article of food is imported or offered for import with no prior notice or inadequate prior notice, the food shall be refused admission under section

801(m) of the act. Examples of inadequacy are untimely, inaccurate, or incomplete prior notice.

As set out in section 801(m)(2)(B)(i) of the act, proposed § 1.278(b) provides that if the food is refused admission under section 801(m), it must be held at the port of entry unless FDA directs its removal to a secure facility.

In accordance with section 801(m)(2)(B)(i), proposed § 1.278(c) provides that FDA may require that an article of food be held in a secure facility as appropriate. FDA may determine such storage is appropriate because of the condition of the product, circumstances of importation, or other information available to the government, e.g., a concern with the safety or security of the article of food or space limitations in the port of entry.

Examples of secure facilities include U.S. Customs Bonded Warehouses, Container Freight Stations, and Centralized Examinations Stations. Perishables, however, may not be stored in U.S. Customs Bonded Warehouses; thus, FDA may direct fresh produce or seafood that requires storage to another facility. FDA and U.S. Customs plan to issue guidance for their field offices that will identify locations of secure storage facilities that may be used for food required to be held for failure to provide adequate prior notice.

In order to minimize confusion about who is responsible for making arrangements if food is refused admission under section 801(m) of the act, proposed § 1.278(d) provides that if FDA requires the article of food to be held at the port of entry or in a secure facility, the carrier or the person who submitted the prior notice must arrange for the movement of the food under appropriate custodial bond and promptly notify FDA of the location. This provision also makes clear that the purchaser, owner, importer, or consignee is responsible for transportation and storage expenses. We note that when section 801(m) of the act requires that food be held, it does not appear to mandate that the government take actual physical custody of the goods; instead it limits both the movement of the goods and the potential storage locations, thereby making government oversight straightforward. As described previously, U.S. Customs has identified a well-established network of storage facilities that are secure. When these storage facilities are used, charges are borne by the private parties. We thus believe that although Congress intended strict controls over food refused admission under § 801(m), it did not intend to require FDA or U.S. Customs