

required: The first prior notice would cover 30 cartons of tomatoes and must identify grower A; the second prior notice would cover the remaining 60 cartons, and the submitter may opt to identify consolidator X.

When bulk grains are commingled, they lose their association with each grower and the identity of grain would then be associated with the facility that commingled, *i.e.*, consolidated, the grain in a silo or truck or rail car before shipment. The submitter may opt to provide the identity of this consolidator in the prior notice.

(Comments) Comments suggest that FDA define "if known" and provide guidance as to the extent of effort that should be applied to find grower information and what will satisfy "if known."

(Response) Section 801(m)(1) of the FD&C Act requires that grower information be submitted (or provided to the transmitter for submission) if it is known. Thus, this information is not optional: If it is known by the submitter, it must be submitted. For purposes of this rule, FDA considers the information to be known if the submitter is aware of or learns the grower name and growing location due to business relationships. FDA is not requiring the submitter to seek out information of which the submitter is not aware. However, if the identity of the grower is in the possession of the submitter (*e.g.*, on documents), we believe the submitter is aware of the identity of the grower.

(Comments) Comments state that if knowing the grower is such crucial information, then it should be made mandatory.

(Response) Because the statute provides the identification of the grower "if known," FDA does not have the authority under section 801(m) of the FD&C Act to require the identification of the grower in cases where that identity is not known to the submitter.

(Interim final rule) Section 1.281(a)(7) requires that a prior notice identify the grower, if known to the submitter for an article of food that is in its natural state. If a food comes from more than one grower, a prior notice must provide for an article of food associated with each grower, if their identity of that grower is known. As stated previously under discussion of product identity, an "article" refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower. FDA has determined that identification of the grower and the growing location address is a more appropriate identifier than the address of the grower. Therefore, FDA has revised the interim

final rule to require the grower name and growing location. We have eliminated the grower's address. The interim final rule also allows that if the submitter does not know the identity of the grower or, if the article of food has been consolidated, the identity of any of the growers, the submitter may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations.

As stated previously under discussion of "manufacturer," the FDA system will recognize (by FDA product code) which products should be associated with a grower and will recognize (by FDA product code) which products should be associated with a manufacturer. Thus, if the manufacturer field is completed for a food that is in its natural state (as identified by FDA product code), the system will not accept the transmission. Guidance, which FDA intends to issue before implementation of this rule, regarding FDA product codes that require prior notice will identify which product codes should be associated with a grower. Submission of prior notice via the FDA PN System Interface will allow for association of "header information" with an article of food so that the transmitter would only have to identify list each grower and growing location. Each would be identified with a separate PN Confirmation Number associated with an entry identified. (See description under discussion of lot/code identifier in the previous paragraph in section III.H.7.f of this document.) A similar capability may be possible for submission through the ABI/ACS interface, but that is dependent upon the ABI software used by the broker or self-filer.

10. FDA Country of Production (§ 1.281(a)(8) Proposed as § 1.288(h)—Originating Country)

As provided for in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the originating country of the article of food (proposed § 1.288(h)). This term was defined in proposed § 1.277(c)(2) as the country where the article of food was grown and harvested or if manufactured/processed, where the article of food was produced. It is proposed, that if the article of food is wild fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the FDA Country of Production is the United States.

(Comments) Comments ask that FDA clarify which country should be identified when the major component of

the final processed food may have come from a number of countries. Comments point to blended or decaffeinated coffee or apple juice produced from fresh apples and apple concentrates from more than one country as examples of such foods. Comments also ask that FDA clarify the definition of "originating country" to mean the country in which the product was last processed.

(Response) For a food that is no longer in its natural state, the FDA Country of Production is the country where the article of food was made. Therefore, for a food such as decaffeinated coffee or apple juice, the FDA Country of Production is the country in which the facility that made the food is located. For example, if the decaffeinated coffee is produced in Country C by decaffeinating a blend of coffees from Country A and Country B, the FDA Country of Production is Country C.

(Interim final rule) The interim final rule in § 1.281(a)(8), requires that a prior notice contain the FDA Country of Production of the article of food being imported or offered for import into the United States. As set out in its definition at § 1.276(b)(4), the FDA Country of Production is, for an article of food is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If, however, an article of food is wild fish, including seafood, that was caught or harvested outside the waters of the United States or by a that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. For a food that is no longer in its natural state, the FDA Country of Production is the country where the article of food was made. However, if an article of food is wild fish including seafood, that was made aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. The interim final rule also provides that the FDA Country of Production of food grown and harvested or collected or made in a U.S. Territory is the United States.

11. Shipper (§ 1.281(a)(9) Proposed as § 1.288(i))

As provided for in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the shipper of the article of food (proposed § 1.288(i)). The shipper is typically not the carrier.

(Comments) A comment states that this information could be obtained from Customs' AMS.

(Response) Although CBP's AMS contains information concerning the