

importer, owner, or consignee. Thus, FDA is proposing to require their identities so that FDA knows who they are and can take steps to ensure that food refused admission under section 801(m) is not delivered to them illegally. FDA is proposing that only one importer, owner, and consignee can be identified for each prior notice. Under most circumstances, FDA believes the importer will be the importer of record for U.S. Customs Entry Summary purposes.

o. The carrier. FDA is proposing to require the identity of each carrier or transporter firm that transports the article of food from the country from which the article was shipped into the United States. This identification includes the submission of the Standard Carrier Abbreviation Code. Identification of the carrier is necessary to enable FDA and U.S. Customs to identify the appropriate article of food for inspection or holding when the food arrives in the United States. FDA notes that a carrier typically is a different firm than the shipper. The filer currently submits carrier information to U.S. Customs' ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

5. What Changes are Allowed to a Prior Notice After it Has Been Submitted to FDA? (Proposed § 1.289)

FDA is allowing additional information to be supplied once a prior notice is submitted in two situations. FDA believes that under the standards in section 801(m)(2)(A) for establishing the timeframes for submission of prior notice, amendments are appropriate when complete product identity will not exist by the deadline for the submission of a prior notice. As described in more detail elsewhere, FDA believes that these situations largely involve fresh produce and fish harvested in countries close to the United States, e.g., Mexico and Canada. Second, FDA believes that it must have accurate arrival information in order to ensure it can inspect an article or take other appropriate action. In the event that other information in the prior notice must be changed, no amendment or update is permitted. The submitter must cancel the initial prior notice and submit a new one.

6. Under What Circumstances Must You Submit a Product Identity Amendment to Your Prior Notice After You Have Submitted It to FDA? (Proposed § 1.290)

FDA is proposing that the prior notice must be amended if all information about the identity of the food required by proposed § 1.288(e)(1) does not exist

by noon of the calendar day before the day of arrival. The submitter must indicate his or her intention to amend the information at the time the initial prior notice is submitted. FDA is proposing that the prior notice may be amended only once. FDA is limiting the number of times a prior notice may be amended because FDA believes that it would be an inefficient use of its review and planning resources to address intermediate, still incomplete submissions. FDA wants to encourage submissions that are as complete as possible to allow FDA to deploy its resources effectively. FDA requests comment on our proposal to restrict the number of amendments to one.

FDA is proposing that only the information required by proposed § 1.288(e)(1) and indicated in the initial prior notice as being subject to amendment may thereafter be amended. FDA is proposing to limit the information that may be amended in a prior notice to the product identification information required in proposed § 1.288(e)(1). As we explain elsewhere in this preamble, we believe that in most situations, complete product identity will exist by noon of the calendar day before the day of arrival. However, we recognize that in certain limited circumstances, such as wild-caught fresh fish and fresh produce with many varieties that are caught or harvested close to the time of shipment in locations close to the U.S. border, this specificity may not be known by noon of the calendar day before the day of arrival. FDA is proposing that the last two digits of the FDA product code and other product identity information that provides the specific identity of the article may be amended when this information does not exist by the prior notice deadline.

For example, there may be occasions when an entry of lettuce is ordered and prior notice is submitted by noon the calendar day prior to arrival, but the specific variety of lettuce that will be shipped does not exist because the growers that supply the shippers have not yet harvested their crops. At or before the time when the article is placed in the carrier for shipment, however, the complete identity of the article exists and the prior notice must be amended to identify the specific type of lettuce (e.g., romaine or leaf).

A prior notice may not be amended to change completely the identity of the article, e.g., a prior notice identifying the food as lettuce may not be amended to identify the food as pears.

If an article of food is not covered by a specific FDA product code, e.g., a root vegetable not more specifically

described by numerical code in the FDA product code builder, then the last two numbers of the product code may be provided as "99" which means root vegetables, not elsewhere classified. However, this prior notice cannot be amended later to identify the product as carrots because, even though carrots are root vegetables, there is an FDA product code that is specific to carrots and thus it should have been used in the initial notice. We plan to design the prior notice system so that it will not acknowledge that a prior notice submission is completely filled out if it does not contain a seven-digit product code. The system will be designed to provide, where appropriate, a reminder about the need for amendment with the electronic message acknowledging receipt of the initial submission.

The information that may be amended also includes the common or usual or trade name, brand name, lot or code or identification numbers, and quantity.

FDA is proposing that, if the identity of the grower was not provided at the time the prior notice was submitted because it was not known at that time but the identity is known at the time of the amendment, the amendment must include information that identifies all known growers.

7. What is the Deadline for Product Identity Amendments Under § 1.290? (Proposed § 1.291)

FDA is proposing a 2 hour minimum deadline for amendments submitted under proposed § 1.291, or updates submitted under proposed § 1.294.

FDA believes that the deadline will allow submitters to provide FDA the information it needs in order to effectively assess whether a particular shipment of food needs to be investigated and if so, to ensure FDA personnel are present to do so when the food arrives at the port of entry, while allowing submitters to amend and/or update information that may not be known with exact certainty by noon of the prior calendar day. FDA considered the type of food in proposing the deadline for amendment to the product identity and updates to the anticipated arrival information.

FDA believes that product identity amendments are most likely to be needed to accommodate articles imported by land or air rather than water arrivals. FDA also recognizes that this limitation on amendments may also affect the practice of "topping off a container" by filling unused space in the container or truck bed with last-minute shipments of other food products not covered by prior notice.