

the prior notice refers to the owner of the article of food at the time it arrives at the port of arrival.

(Response) FDA believes that the persons affected by this interim final rule will know, in most situations, what entities are referred to by the terms "importer" and "owner" since these terms are commonly used in importation, including the CBP entry process. If experience with this interim final rule indicates confusion regarding these terms, then FDA will issue guidance on them.

Regarding the term, "importer," FDA agrees with the comment. The agency believes this term should be interpreted the same as "importer of record" as that term is used by CBP in regard to the entry of merchandise.

Regarding the term, "owner," FDA agrees that this is the owner of the article of food at the time of arrival. However, if a prior notice is given after the article is refused under section 801(m)(1) of the FD&C Act, then the owner is the owner or the article of food at the time the prior notice is submitted.

(Comments) Comments ask FDA to limit the information required to identify the importer, owner, and consignee to the registration number, which FDA could use to obtain the other identity information elements from its databases. In this way, comments seek to decrease the burden of prior notice submission by avoiding manual entry of addresses. Other comments seek to decrease the burden by asking FDA to require information regarding the entity submitting the prior notice, which could be the importer, owner, or consignee, but not regarding all three.

(Response) The interim final rule does not require the registration number of the importer, owner, or ultimate consignee. However, if a registration number is provided, city and country may be provided instead of the full address.

(Comments) A comment states that the identification of the importer, owner, and consignee could be obtained from AMS.

(Response) Although AMS may contain information concerning the consignee, that information is located in the AMS module of ACS and is not available to FDA, as required under section 801(m) of the FD&C Act, which provides that the information must be submitted to FDA. CBP and FDA have concluded that it is not practical, at this time, to attempt to modify AMS and the ACS/OASIS interface to provide this information to FDA.

(Interim final rule) Section 1.281(a)(12), (a)(13), and (a)(14) of the

interim final rule require submission of information that identifies the importer, owner, and ultimate consignee.

However, the identification of the importer, owner, and ultimate consignee are not required if the article of food is imported or offered for import for transshipment through the United States under a T&E bond.

17. Mode of Transportation (§ 1.281(a)(15))

In the proposed rule, the timeframe for prior notice was the same for all imports, regardless of mode of transportation. Thus, FDA did not propose submission of the identification of the mode of transportation.

(Comments) No comments were received on identification of the mode of transportation. However, as discussed earlier, many comments recommend that FDA should set the timeframes for prior notice by mode of transport. FDA agrees and has revised the timeframes accordingly.

(Response) In the interim final rule, the timeframes are tied to mode of transportation. Thus, mode of transportation is necessary to calculate when prior notice is timely. In addition, FDA has determined that, for submitting prior notice, identification of the mode of transportation is necessary for identification of the article of food at the time of arrival for the purposes of planning examinations and communicating with CBP for enforcement and examination. This information currently is provided to FDA by customs brokers or self-filers through ACS.

(Interim final rule) Section 1.281(a)(15) requires submission of information concerning the mode of transportation, except for those prior notice submissions covering articles of food arriving by international mail. For submissions through ABI/ACS, this information will take the form of the current ABI requirements for declaration of mode of transportation. For submissions through the FDA PN System Interface, selection of the mode of transportation will be accommodated by a drop-down menu.

18. Carrier (§ 1.281(a)(16) Proposed as § 1.288(q))

FDA proposed 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, including the submission of the SCAC. 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 broker or self-filer currently submits carrier information to ABI/ACS when entry is made, and it later is transmitted to OASIS.

(Comments) Comments agree that this information is helpful and necessary for locating cargo. Comments note that carrier information is currently submitted to CBP via ABI/ACS to OASIS. Other comments state that accurate carrier information cannot be provided by 12 noon the day before arrival.

(Response) FDA believes that identification of the carrier is necessary for the purpose of response to prior notice, both for examination purposes and communication with CBP. The shortened timeframes resolve the concern that the carrier may not be known by noon the day before arrival, to the extent possible, given the mandate from Congress to require prior notice.

(Comments) Comments ask that FDA eliminate the requirement to identify multiple carriers, suggesting that the only pertinent carrier is the one arriving at the U.S. port.

(Response) FDA agrees and has eliminated the requirement to identify each and every carrier that transported the article of food from the country of production to the United States, *i.e.*, multiple carriers. The interim final rule requires submission of the identity of the carrier that is or will be carrying the article of the food from the country from which the article is shipped to the United States.

(Interim final rule) Section 1.281(a)(16) requires submission of the carrier's SCAC or IATA code. If these codes are not applicable, the carrier's name and country must be submitted.

19. Planned Shipment Information (§ 1.281(a)(17))

The proposed rule did not require submission of planned shipment information beyond identification of the carrier.

(Comments) Some comments suggest that, in addition to carrier information, FDA should require vessel name, voyage/flight numbers, and bill of lading information.

(Response) FDA agrees. FDA has determined that additional planned shipment information is necessary for identification of the article of food for examination and communication with CPB. The requirement is to provide planned shipment information as it exists when the prior notice is submitted. FDA recognizes that some of this information may change after the