

### Summary of the Interim Final Rule

Section 1.277(a) provides that the interim final rule applies to food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, including food for gifts, trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. FTZ. Section 1.277(b) sets out the exclusions from prior notice. It excludes food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (*i.e.*, consumption by the individual or his or her family or friends, not for sale or other distribution); food that was made by an individual in his or her personal residence and sent by that individual as a personal gift (*i.e.*, for nonbusiness reasons); food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg products subject to the exclusive jurisdiction of USDA 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.*).

### E. "Who Is Authorized To Submit Prior Notice?" (Section 1.278 Proposed as § 1.285)

The proposed rule (§ 1.285) provided that a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof was authorized to submit prior notice. FDA noted that a broker/filer would be authorized to be a submitter if it was the U.S. agent of the U.S. importer or U.S. purchaser.

FDA further proposed that if the article of food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the carrier making the in-bond entry.

(Comments) Many comments object to the limitation that only a person who resides or maintains a place of business in the United States can submit the prior notice. Some comments state that foreign-based companies that sell food directly to U.S. individuals for their own use, including companies that sell via the Internet, cannot expect their individual customers to submit prior notice. In addition, comments point out that, under some circumstances, the U.S. importer or purchaser or carrier

would not have all the information required by prior notice, but that other entities, *e.g.*, the foreign manufacturer/processor, shipper, or exporter, would have the required information. Many comments state that entities other than U.S. firms or carriers should be allowed to submit prior notice.

(Response) FDA agrees and has removed this restriction on who can submit prior notice. Accordingly, § 1.278 of the interim final rule provides that any person with knowledge of the required information may submit prior notice to FDA. Thus, any person may now take responsibility for submitting prior notice for a particular article of food, as long as that person can provide all the required information. This person is referred to as the submitter in the interim final rule. The interim final rule also states that the submitter may use another person to transmit the required information to FDA. For ease of reference, the person who transmits the prior notice is referred to as the transmitter in the interim final rule. If the submitter submits and transmits the prior notice, he or she is both the submitter and the transmitter. FDA notes that all reply messages sent by the FDA PN System Interface will be sent to the transmitter. If prior notice is submitted via ABI/ACS, all reply messaging goes to the customs broker or self-filer. FDA has also revised the definition of "you" accordingly.

(Comments) Comments from customs brokers noted that, although they are responsible for timely submission of all documentation required for import entry, they are not responsible for verifying the accuracy of information provided to them from their customer. Comments ask FDA to clarify in the final rule that the customs broker is merely an agent for the filing of information obtained from the importer and is not responsible for either the adequacy or accuracy of the data submitted. Comments assert that the responsibility of the customs broker is to accurately submit the information provided by his or her client in correct form and in a timely manner.

(Response) The submitter of prior notice information, regardless of the method of or person transmitting the information, is responsible for the accuracy of that information. If the transmitter is not the submitter, we expect the transmitter, whether he or she is a licensed customs broker or other kind of agent, to exercise diligence and care to transmit the information provided by the submitter accurately.

(Interim final rule) Proposed § 1.285 has been changed in the interim final rule to § 1.278, "Who is authorized to

submit prior notice?" The interim final rule states that any person with knowledge of the required information may submit prior notice. This person is the submitter. The submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information to FDA is the transmitter. The submitter and the transmitter may be the same person. The interim final rule also defines "you" to mean the submitter or transmitter (§ 1.276(b)(12)).

### F. "When Must Prior Notice Be Submitted to FDA?" (Section 1.279 Proposed as § 1.286)

FDA proposed that the prior notice must be submitted to FDA no later than 12 noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry. As described in the proposal, this was based on FDA's assessment of what time was needed to meet its statutory mandate of receiving, reviewing, and responding to prior notice.

(Comments) Generally, the comments recommend that FDA adopt a shorter, rolling prior notice submission timeframe to reduce the burden of the prior notice requirement on the smooth flow of commerce. Many comments recommend a specific timeframe for submission of prior notice. These recommendations ranged from submission of an annual report for repetitive shipments, to submission of the notice at the time of distribution of the food after it arrives in the United States.

Many comments recommend that the prior notice submission timeframe be linked to a mode of transportation or type of port of entry, and others recommend that it be linked to the type of food. Many comments recommend a specific timeframe and associated that timeframe with either a mode of transportation/type of port or with a type of food or both. Comments recommend that prior notice be submitted 8 hours before arrival; some associate the 8 hours timeframe with a water mode of arrival only, while others associate the 8 hours timeframe with nonperishable foods. Many comments recommend that prior notice be submitted 4 hours before arrival; some associating the 4 hours timeframe with land and air modes of arrival only and some associating the 4 hours timeframe with perishable foods (produce and seafood) and live animals only.

(Response) FDA agrees that the time for submission of prior notice should be a rolling timeframe. FDA has determined that the time can be shortened to reduce the effect on the