

to greater compliance. Less confusion will also mean that fewer imports will be delayed for lack of prior notice.

FDA chose the U.S. entities in proposed § 1.285(a) for several reasons. First, we do not believe that there is importation of food to the United States that does not involve one of the U.S. entities identified, except in those instances where the food is imported with the intention of in-bond movement through the United States for export (where the proposed rule authorizes submission by the arriving carrier or, if known, the in-bond carrier). We also believe that it is the U.S. importer or U.S. purchaser who orders or buys the article of food, thereby initiating its importation into the United States. These persons thus should possess, or have the ability to obtain, the information required to be submitted in the prior notice within the time period in proposed § 1.286. As U.S. businesses, these persons are also more likely to already have web access than some foreign businesses, which reduces potential costs and impacts on trade. Finally, placing responsibility on these U.S. entities will facilitate FDA's ability to conduct audits, investigations, and inspections, which will facilitate efficient enforcement of section 801(m).

FDA notes that the submitter is the entity responsible for ensuring the adequacy and accuracy of the prior notice. For the reasons described above, FDA believes that these entities are in the best position to do so.

FDA seeks comment on whether others should be authorized to provide prior notice and, if so, why.

2. When Must the Prior Notice be Submitted to FDA? (Proposed § 1.286)

Based on consideration of the factors set out in the statute, FDA is proposing that the prior notice must be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

Section 801(m)(1) of the act makes clear that a primary purpose of prior notice is to enable inspections or other FDA action upon arrival of food in the United States to protect consumers in the United States from food imports that may be at risk of intentional adulteration or that may pose other risks. Section 801(m)(2)(A) of the act states that the deadline for prior notice "shall be no less than the minimum amount of time necessary for [FDA] to receive, review, and appropriately respond to such notification." In addition, section 801(m)(2)(A) provides that FDA may take other factors into consideration when deciding on the

deadline for prior notice, specifically: its effect on commerce; the locations of various ports; various modes of transportation; types of food; and any other consideration. However, although the statute gives FDA some latitude in setting the deadline for prior notice, it nonetheless makes clear that we must establish a timeframe for prior notice that allows FDA to receive, review, and appropriately respond to all prior notices. Finally, section 801(m)(1) states, "Nothing in this section may be construed as a limitation on the port of entry for an article of food."

Reading section 801(m) as a whole and in conjunction with other provisions in the Bioterrorism Act, FDA believes that Congress intended that FDA assess the information in the prior notice to determine if inspection upon arrival or other action is appropriate. For FDA to inspect, upon arrival, food imports that may be at risk of intentional adulteration or that may pose other risks to U.S. consumers, FDA must be able to effectively deploy its staff. Although FDA inspectors are located throughout the United States, FDA does not have staff located at or near all of the 250 ports where over 4.7 million entry lines of food were entered in fiscal year (FY) 2001. Port locations are established by U.S. Customs and, under the statute, FDA cannot limit ports at which food may be imported or offered for import. Thus, FDA must have enough time, on a daily basis, to process the information in the approximately 20,000 prior notices we expect to receive and to send inspectors to any port in the United States if necessary. FDA believes that the minimum amount of time necessary to ensure it can plan and that its staff can travel to the arrival point is noon of the calendar day before the day the article arrives at the border crossing. FDA believes that this timeframe will give it the minimum time it needs to conduct its assessments and provide the information to its field offices so they can allocate their inspectional resources on a daily basis and plan any necessary travel.

Before proposing this deadline FDA also considered its potential effects on imported food. FDA believes that in most circumstances information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States. FDA has examined a selection of imported food documents and compared dates of these documents with the dates of arrival in the United States and U.S. Customs entry. FDA asked several field offices to send entry documents with invoices covering

imported foods. Sixty-four packages of entry documents were received in response to this request. The dates of the invoices were compared to the dates of arrival and receipt in OASIS. In 48 cases (75 percent), the invoice date or date of sale preceded the arrival date by at least 1 day. In 31 cases (48 percent), the invoice or sale date preceded the arrival date by 2 or more days. In 16 cases (25 percent), the invoice date was the same as the arrival date. FDA invites comment on the representativeness of this sampling. Based on this examination, we believe that orders are normally placed a day or more prior to shipment. See the compilation of imported food documents that FDA has placed in the administrative record and the docket (Ref. 1). FDA believes that the information required for prior notice therefore generally does exist by noon of the calendar day before the day of arrival. FDA recognizes, however, that currently one person may not possess all of the information and that some practices regarding the flow of information about food imports will have to change to ensure that the submitter has all of the information needed to submit a prior notice for the food shipment by the deadline.

FDA believes that this proposed deadline will have the most impact on those who import food by truck and rail over the land borders, with less effect at airports, and almost no effect at water ports. However, even on the land borders, FDA believes that the information required by prior notice will be, in most cases, sufficiently fixed by noon of the calendar day before arrival to allow the U.S. importer or U.S. purchaser, or their U.S. agents, to submit prior notice to FDA that meets the proposed requirements without slowing down the shipment.

FDA is proposing to allow submitters to amend prior notices for that portion of the product identity information that cannot be completed, because it does not yet exist by noon of the calendar day prior to arrival. We believe this may be the case with product identity for fresh products imported from countries close to the United States (e.g., Canada or Mexico). For example, fresh seafood may be ordered as "catch-of-the-day" from Canada or Mexico; the importer intends to import the fish the day after the order is placed, but cannot find out what exact species and quantity will arrive by the deadline for prior notice because the boat is not due back until late afternoon on the day prior notice is due. Another example is an importer who orders fresh lettuce for import the day after the order but cannot find out the exact variety and quantity of lettuce