

shipper, that information is located in the AMS module of ACS and is not currently 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) § 1.281(a)(9) requires that the shipper be included in a prior notice. The interim final rule defines shipper (§ 1.277(b)(12)) as the owner or exporter who consigns and ships the article of food from a foreign country or the person who sends an article of food in international mail to the United States.

#### 12. Country From Which the Article Is Shipped (§ 1.281(a)(10) Proposed as § 1.288(j))

As provided in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the country from which the article of food was shipped (proposed § 1.288(j)). This term is defined in proposed § 1.277(c)(3) as the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(Comments) Several comments state that this provision would require submission of information that FDA could obtain from Customs' AMS.

(Response) Although AMS contains information concerning the country from which the article of food is shipped, that information is located in the AMS module of ACS and is not currently 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)(10) requires that the country from which the article is shipped be included a prior notice. The interim final rule defines the country from which the article is shipped (§ 1.277(b)(3)) as the country in which the article of food is loaded onto the conveyance that brings it to the United States.

#### 13. Anticipated Arrival Information (§ 1.281(a)(11) Proposed as § 1.288(k))—Anticipated Port of Entry, Anticipated Date of Arrival, Anticipated Time of Arrival)

FDA proposed to require the submission of the anticipated port of

entry (defined as port of arrival), the anticipated date and anticipated time when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)) to coordinate resources for inspections, examinations, or sampling. FDA also proposed to require the prior notice to be updated if any of the anticipated arrival information changes after the submission of the prior notice (proposed § 1.288(k)(2)). Updates were deemed necessary so FDA could change its plan for coordinating resources when anticipated arrival information changes.

a. *General comments.* (Comments) Comments state that the proposed rule is more restrictive than the Bioterrorism Act. Others suggest that importers would have to work 24 hours a day, 7 days a week and that the proposed rule would eliminate their current methods of doing business. Several commenters ask FDA to recognize commercial realities of weather and traffic problems that result in port and arrival time changes and to provide more flexibility on the information requirements or elimination of the requirements altogether. Comments state that a lack of flexibility would amount to a limitation of the port that is prohibited by the Bioterrorism Act and could impede trade. Other comments state flexible arrival requirements are what Congress envisioned and ask that FDA not refuse food at the border based on inadequacy of anticipated arrival information, changes in border crossing, and other problems beyond the control of the importer.

(Response) The interim final rule requires that the prior notice identify the anticipated port of arrival. This information is necessary to ensure FDA can plan for inspections and communicate with CBP. FDA believes that the reduction of the timeframe for providing prior notice will reduce the number of changes that occur to the arrival information after submission. However, FDA also recognizes the realities of weather and traffic changes and has written the interim final rule to accommodate these variances.

As section 801(m)(1) of the FD&C Act prohibits any limitation on ports, a prior notice will not be inadequate if the anticipated port of arrival, the anticipated date of arrival, or the anticipated time of arrival changes between the time of confirmation of prior notice and the time of arrival. This is reflected in § 1.282(a) of the interim final rule that specifies what changes in information require resubmission of a prior notice. However, if FDA has determined that the article of food must be examined upon arrival and the

anticipated arrival information has changed since timely submission of the prior notice, the article may be held by CBP at the port of arrival until the examination can be performed.

#### b. *Anticipated port of arrival.*

(Comments) Comments state it was unclear whether the prior notice was to specify a particular bridge crossing or the port itself.

(Response) The anticipated arrival information must specify the anticipated port of arrival and, if there is more than one crossing location within that port, the anticipated crossing. For the most part, this applies to ports along the northern and southern borders of the United States where there are several crossings over many miles, but all are included in the same port. For example, a food arriving at the port of Buffalo-Niagara Falls may cross at the Peace Bridge or the Lewiston Bridge. For the purpose of this rule, to facilitate inspection, the identification of the bridge is required. However, the prior notice will not be inadequate if the anticipated crossing changes between the time of confirmation of prior notice and the time of arrival.

(Comments) Several comments ask that FDA allow importers to choose alternate border crossings or ports because of possible traffic delays and adverse weather conditions for air and land modes of arrival, or changing flight destinations for air modes of arrival. Comments state importers and even shippers and carriers do not know which border crossing will be used until the food arrives. Some comments note that portions of food may be discharged at different ports of arrival at the discretion of the carrier due to cargo space and weight limitations.

(Response) As noted previously, FDA agrees that arrival locations and times may change due to business practices, inclement weather, and traffic conditions. The interim final rule requires the submission of anticipated arrival information. This means that what must be submitted are the port, crossing location, date, and time that are known to the submitter at the time that prior notice is submitted to FDA. The interim final rule does not require that prior notice be cancelled and resubmitted if this information changes after FDA has confirmed the prior notice for review. A prior notice will not be inadequate if the anticipated port of arrival (including crossing location), the anticipated date of arrival, or the anticipated time of arrival changes between the confirmation of prior notice and the time of arrival.

#### c. *Anticipated date/time of arrival.*

(Comments) Several comments ask for