

smooth flow of trade while still providing FDA with sufficient time to receive, review, and respond to the information. FDA also agrees that timeframes should be different for different modes of transport. As such, FDA has revised the rule to require that the timing of submission will be no more than 5 days (except in the case of international mail) and that the prior notice submission be confirmed by FDA for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water.

When food carried by or otherwise accompanying an individual is subject to this rule, the timeframe associated with the manner of the individual's arrival applies. If the individual and article of food are arriving by land via road, the prior notice must be submitted and confirmed at least 2 hours before arrival. If the individual and article of food are arriving by air or by land via rail, the prior notice must be submitted and confirmed at least 4 hours before arrival. If the individual and article of food are arriving by water, the prior notice must be submitted and confirmed at least 8 hours before arrival.

Two major agreements between CBP and FDA allow FDA to reduce significantly the time necessary to receive, review, and respond to prior notice information. First, FDA and CBP have agreed to commission or use CBP staff to perform examinations for FDA when FDA is not present at the port of arrival. Since CBP staff generally will be available where FDA is not, this means that FDA no longer needs lead-time to travel significant distances to conduct inspections. In addition, CBP agreed to modify ABI/ACS to receive, transmit, and communicate prior notice information electronically between CBP and FDA for most entries of imported foods by the statutory deadline in the Bioterrorism Act of December 12, 2003. CBP's assistance with prior notice means that FDA needs far less time to respond to prior notices.

In considering how to modify the timeframes, FDA concluded that setting them by mode of transportation would be the best approach. Mode of transportation is clear and easy to apply and administer, so there is likely to be little confusion about what timeframes apply. If we were to set timeframes based on type of food, *e.g.*, perishable versus nonperishable, we would have to develop and implement a system for determining which articles of food were which. In addition, different articles of

food in the same conveyance would be subject to different prior notice timeframes, which would subject all items in the conveyance to the longest timeframe and add an additional layer of complexity that could cause confusion and delays at the border. Moreover, many comments recommended mode of transportation, which suggests that many stakeholders, including industry, believe such a system is workable.

In determining the actual timeframes for submission of prior notice for each mode of transportation, FDA considered the need to provide sufficient time for the agency to review and respond to the information submitted, as well as the current ability of the food industry to provide the information required within the stated timeframe given the differences in lead time before arrival among different modes of transportation. We determined that information for shipments whose transport time is measured in days or weeks (*e.g.*, ocean shipments) is available further in advance of arrival than shipments whose transport time is measured in hours (*e.g.*, land and air shipments.) Staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with short transport times and to defer review of shipments with longer transport times. Based on these considerations, FDA established the prior notice timeframes in the interim final rule to associate with the mode of transportation.

FDA is committed to exploring ways to increase integration and reduce the prior notice timeframes further. Accordingly, FDA and CBP will continue working together to determine what is needed to achieve this goal. No later than March 12, 2004, the Commissioners of FDA and CBP will publish a plan, which will include an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize the rule entitled "Required Advance Electronic Presentation of Cargo Information," published in the **Federal Register** on July 23, 2003 (68 FR 43574).

For imported food arriving via international mail, the interim final rule requires that prior notice be submitted before the food has been sent. This timeframe allows the FDA PN Confirmation Number to accompany the package, which is necessary to establish that prior notice has been submitted and

to match the prior notice submission to the package upon arrival.

(Comments) Some comments recommend that the prior notice submission timeframe be waived for foods exported from U.S.-owned foreign companies. Other comments recommend that a different timeframe be established for foods associated with a program of assessment of low risk, such as the C-TPAT.

(Response) The interim final rule does not provide for a waiver of the timeframe for foods imported by U.S.-owned firms. Nor does the rule provide for a different timeframe for foods or firms covered by programs of other agencies, such as C-TPAT. The interim final rule provides for greatly reduced timeframes for foods based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to "receive, review, and respond" to prior notices. However, FDA is also interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C-TPAT, or imported by other agencies.

(Interim final rule) Section 1.279(a) in the interim final rule has been revised to require submission of the prior notice to FDA and the submission must be confirmed by FDA for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water. Under § 1.279(b), prior notice may not be submitted more than 5 calendar days before arrival, except in the case of food imported or offered for import by international mail.

Under § 1.279(c), if the article of food is arriving by international mail, the prior notice must be submitted before the food is sent to the United States.

Section 1.279(d) provides that the time of submission is fixed and the prior notice time will start for purposes of determining if prior notice is timely when the prior notice submission is confirmed by FDA for review. FDA will confirm a prior notice once all required information has been submitted and confirmed as facially complete. For example, if the information submitted were to include a registration number, name, city, and country for the manufacture of an article of food, and the system review were to reveal that the registration number does not exist or does not match the name, city, and country of the facility, the FDA PN