

products not covered by prior notice. FDA solicited comments on how common "topping off" is and the quantities of food involved.

(Comments) Comments state that it is common practice to fill extra space in a shipment with additional product after an order has been filled. A comment suggests that there should be an allowance for last minute changes in a load. A comment suggests that more flexibility is needed to avoid the extraordinary cost of importing a partial shipment. A comment states that a prohibition on the practice of topping off would make some shipments, particularly of smaller items, less cost competitive and may reduce the overall availability of some products. Another states that late offers to add additional quantities or even additional products to a shipment at a discount make for more efficient commerce for importers and can provide economy and value to American consumers. Another comment suggests that FDA reconsider and adopt in the final rule circumstances under which shippers could amend notices to include foods from the same manufacturer or grower. The comment further states that this would allow the full utilization of transport space even when that space is filled with additional items not explicitly declared in the original prior notice.

(Response) The requirements of the statute are to provide FDA with notification of each article of food in advance of importation, not advance notice of some of the articles of food and post-arrival notification of others. The complete identity of each article of food is necessary for FDA to receive, review, and respond to the notice. FDA has significantly reduced the time required for submission of the prior notice before arrival. FDA has also revised the way information on quantity may be presented. The interim final rule requires the estimated quantity of the article of food. FDA believes that both of these revisions will allow for timely submission of accurate information and should limit, as much as is permissible under the statute, the effect of prior notice on the practice of "topping-off."

3. "What Is the Deadline for Product Identity Amendments Under Proposed § 1.290?" (Proposed as § 1.291)

FDA proposed a 2-hour minimum deadline for product identity amendments submitted under proposed § 1.291. FDA noted that product identity amendments are most likely to be needed for articles imported by land or air rather than water arrivals.

(Comments) Some comments are supportive of a deadline for

amendments of up to two hours before arrival, but only if that gave FDA sufficient time to receive, review, and respond to the information. Some comments state that allowing amendments to be submitted up to 2 hours before arrival would not be problematic, while others contend that limiting amendments to two hours before arrival was too restrictive and would result in higher costs and compromised product integrity. Comments suggest changing the deadline to allow amendments up to 1 hour before arrival; until just before or at the time of arrival; after arrival (with a 3 hour limit, 24 hour limit, or no limit at all); or at any time before or after arrival. Several comments note that some information, such as the Customs entry number or quantity, cannot be verified by the proposed submitter until the shipment arrives. Several comments state that the carriers should be permitted to amend product identity information. A few commenters point out that the proposed 2-hour period for amendments before arrival is particularly problematic for multiple commodity exports. Comments indicate that the need for amendments might be identified at the time of loading, which may be less than one-half hour before arrival at the border.

(Response) FDA has chosen timeframes that provide it with very little leeway in the time it has to "receive, review and respond" to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. In addition, as noted earlier, ACS cannot accommodate changes in submissions that have been confirmed by FDA for review. Therefore, the interim final rule does not provide for amendments.

4. "How Do You Submit a Product Identity Amendment or an Arrival Update to a Prior Notice?" (Proposed § 1.292)

The proposed rule required that a product identity amendment or an arrival update to a prior notice may be submitted only in the same manner as an initial prior notice; that is, electronically to FDA through the FDA PN System Interface.

(Comments) A comment asks that the agency examine means by which communication to the agency of any unexpected change in this information can be provided by the entity that is actually knowledgeable about a change in the date of arrival, for example, by the ocean or air carrier. Several comments suggest that the carrier that is the party with the most accurate

information on arrival time and can therefore provide the most efficient communication to FDA. Other comments raise concerns about providing unlimited discretion to carriers to make substantive changes to submissions, but note that the need for carriers to make "updates" is essential. One comment indicates that alternative mechanisms for the carrier to submit updates, such as touch-tone telephones, should be explored.

(Response) Although requirements for amendments to product identity information and arrival updates have been deleted from the interim final rule, FDA recognized that several entities might have critical information concerning required prior notice information. Therefore, the interim final rule does not limit who can submit prior notice information. The interim final rule continues to require electronic submission of prior notice to FDA.

5. "What Are the Consequences if You Do Not Submit a Product Identity Amendment to Your Prior Notice?" (Proposed § 1.293)

FDA proposed that if a U.S. importer or U.S. purchaser, or their U.S. agent, informed FDA in a prior notice that the submission would be amended, but subsequently did not amend it appropriately and within the applicable timeframe, then the prior notice would be inadequate for the purposes of proposed § 1.278(a). FDA clarified that the consequences of inadequate prior notice are the same as the consequences for failing to provide prior notice, *e.g.*, the food is subject to refusal if admission. FDA explained that the indication that a prior notice would be amended tells us that the prior notice is incomplete. FDA noted that without complete product identity, the agency could not adequately determine whether to inspect or take other action when the food arrives in the United States.

(Comments) Some comments object to the proposed provision that, if the submitter of a prior notice indicates that an amendment to the product identity will be submitted, but subsequently fails to do so, the original prior notice will be deemed inadequate and the product would not be allowed to enter. Some point out that FDA should not penalize a submitter for anticipating an amendment and then not amending the prior notice.

(Response) For the reasons set forth previously, FDA has eliminated the requirement to provide product identity amendments.