

6. "What Must You Do if the Anticipated Arrival Information (Required Under Proposed § 1.288(k)(1)) Submitted in Your Prior Notice Changes?" (Proposed as § 1.294)

FDA proposed to require the submitter to update anticipated arrival information submitted in a prior notice, if the anticipated information changes after the submission. FDA proposed that if the time of arrival is expected to be more than 1 hour earlier or more than 3 hours later than the anticipated time of arrival, the time of arrival must be updated. FDA proposed that updates to the arrival information must be submitted 2 hours before arrival (proposed § 1.294).

a. *General.* (Comments) Many comments indicate that the window of time for arrival updates is too small. Several comments suggest changing the requirements for submitting updates for arrival information. Suggested changes included expanding the window for arrival to 2 hours and 6 hours before the anticipated arrival time and 6, 7, 8, and 18 hours after the anticipated arrival time. A few comments state that notification of the day of arrival, not the time, should be sufficient. Some comments state that updates to arrival information should be allowed upon arrival at the border. One comment objects to allowing only one update to arrival information. The comment complains that this is very restrictive and that submitters must be allowed to keep updating the "prior notice of arrival" without worrying about the form being rejected.

Some comments point out that the owner, importer, and U.S. agent often do not know the actual port of entry for a ship or airplane, the time of entry, or changes in this information. For example, an air shipment of seafood may be switched to a different plane, which arrives at the U.S. port outside the anticipated arrival window. This may occur during nonbusiness hours, before notification of the change can be provided.

One comment suggests that exporters who choose to report to specific border crossings identified by FDA, should not be required to provide updates due to lateness in the time of arrival at the border.

One comment states that ambiguity on when updates can be submitted might lead to confusion and inconsistent application of these provisions. The comment expresses concern that some ports may take the position that the update must be provided within the 4-hour window so FDA will be informed that the shipment will not be arriving

when originally anticipated. Yet other ports may take the position that the update requirements are satisfied as long as the update is received at least 2 hours before arrival, regardless of how many hours or days it arrives after the originally identified arrival time.

Some question how notifications that need to be amended and subsequent amendments for numerous entries could assist FDA in scheduling of inspections.

Some point out that carriers should continue to be able to change ports of arrival, as necessary, to find a more expeditious route, based on weather and/or traffic conditions. One comment states that exporters/importers should be able to declare up to three possible ports of entry that all fall under the jurisdiction of a single FDA regional office for administrative and inspection purposes.

One comment suggests that a requirement to update the port of entry could be viewed as limiting the port of entry, which is prohibited by the statute.

One comment points out that the proposed rule is silent on changes to border crossings, unlike changes in arrival time and suggested that FDA clarify whether it needs to be notified of a change to the anticipated border crossing or if any border crossing is acceptable.

b. *Water.* (Comments) One comment asks for a wider margin of variability for the arrival of ocean-going vessels. Some comments state that for ocean-going shipments, an update should not be required if the actual arrival at the port of entry is not more than 24 hours before or after the anticipated time of arrival specified in the prior notice. One comment notes that because of the logistics and unpredictability of ocean transport, it is not possible to accurately predict arrival time of a carrier within the 4-hour window provided. One comment notes that such tight time frames would increase the cost of the prior notice process because the submitter will be forced to continuously check on the status of the shipment to ensure that the arrival time is correct all the way up to 2 hours before delivery. For ocean imports, vessel arrival times may vary widely depending upon weather conditions, scheduling, and loading changes. Vessels can be held or delayed at various ports en route and importers are unlikely to be informed of these changes. Some comments state that it is unrealistic for a sea vessel to have to individually update hundreds or thousands of notices when the vessel is delayed. Comments ask that FDA allow a single update from a carrier to automatically update each prior notice

associated with food products on that vessel.

c. *Air.* (Comments) One comment states that the 2 hours for updates is not practical for air shipments because air carriers often do not inform importers of changes in arrival time until the cargo is close to its destination. One comment notes that because of current air and travel security procedures, arrivals are rarely at their scheduled times.

d. *Land/road.* (Comments) A few comments indicate that with respect to trucks, there will be circumstances where a driver cannot contact a dispatcher to submit an arrival update, e.g., 2 a.m. The comments note that a large amount of border truck traffic flows in the early morning/mid-to-late evening to avoid rush-hour traffic in major centers. However, shippers do not have a mechanism for submitting updates at these times when there are unforeseen delays that prevent arrival outside of the anticipated window. Comments state that FDA should provide flexibility in the rule for these and similar circumstances where, for legitimate reasons, it is not possible to provide an update.

Some comments express concern about current delays for trucks at ports of entry, which may vary from a few minutes to 12 hours. The comments note that, because it is necessary to submit updates when a truck is outside the proposed time range for arrival, many trucks might be forced to sit idly on the side of the road waiting for their proper window when FDA will allow entry. Comments express concern that if a shipment were to miss the original arrival time, they would be forced to file an update and wait 2 hours to rejoin the line.

e. *Land/rail.* (Comments) For rail cargo, arrival times may vary depending on scheduling and loading changes. Often, multiple rail cars on one entry can be located at multiple locations across the rail yard. Actual crossing times for those cars can vary widely depending on that location and the ability of the rail to load and cross them. In these cases, linking prior notice into the manifest could also allow the carrier to provide electronic updates.

(Response) FDA agrees that there may be factors such as business practices, weather, and traffic congestion that may impact the accurate representation of the port, date, and time of arrival. Although the interim final rule will continue to require submission of the anticipated place, date, and time of arrival that is known to the submitter, the interim final rule does not require an update to that information, and prior notice will not be deemed inadequate if