

clarification on the definition of time of arrival. For arrival by water, comments suggest defining arrival as the time the vessel reaches the entrance to the seaport where the importer will be taking delivery, the time the vessel reaches the port, or the time the vessel is unloaded. For arrival by land and air, comments suggest defining arrival as the time the vehicle reaches the border crossing, the time the vehicle reaches traffic backed up at the border crossing, or the time CBP begins processing the vehicle.

(Response) The interim final rule requires submission of anticipated time and date of arrival to provide FDA with information needed for planning resources for examinations of food at the border. From FDA's standpoint, "time of arrival" relates to when the food will first become available for examination at the border. For vessels, this would be when the vessel docks in the port. For planes, this would be when the plane lands. For land vehicles, such as trucks, buses, and trains, this would be when they cross at the border.

(Comments) Some comments ask for clarification regarding which time zone to use. Comments are concerned that, due to time zones, food may appear to arrive in the United States before it leaves the country from which it is shipped. Some comments suggest FDA use the time zone of the port of arrival.

(Response) The anticipated time and date of arrival relates to the time zone of the anticipated port of arrival. The time of prior notice submission, anticipated arrival, and actual arrival are all based on local time at the port of actual arrival.

(Comments) Several comments state that it was impossible for importers to know the exact time of arrival until the food arrives 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. Other comments state that shippers and even carriers do not know when the truck will arrive. However, some comments note that exporters would be likely to know what flight the shipment was on.

(Response) The interim final rule requires the anticipated time and date of arrival. This is the time and date the submitter anticipates that the food will arrive at the port of arrival at the time the prior notice is submitted and confirmed for FDA review.

(Comments) Comments also suggest that FDA obtain the arrival information from AMS.

(Response) Although AMS contains some of this information, the information is located in the AMS

module of ACS and is not 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.

(Comments) Several comments state that the 4-hour window for updates of arrival time is too small and would cause delay in the arrival of food and create extra work in the form of amendments. Thus, the comments conclude the 4-hour window is unreasonable and should be removed. Comments note that even the best-intentioned carrier could fail to make the appointment because of waits of at least 5 hours at the borders. Others state additional delays occur on the Mexican border because the loads must change carriers. Some comments state that it was nearly impossible to predict an arrival time for a vessel within a 4-hour window because ships may arrive in port several days ahead or behind schedule and may sit in a harbor for hours or days before being granted permission to dock. Thus, these comments conclude the window for updates is not realistic for sea transportation. Others state the window for updates is impractical for rail transportation. Importers of live animals comment that the window for updates would be impossible to meet. Several comments suggest that FDA seek alternatives. One comment suggests a 6-hour window for updates. Another suggests importers be permitted to provide prior notice to FDA 2 hours before the carrier reaches the border. One comment suggests that prior notices identifying certain FDA-selected border crossings not be held to the arrival time and not be required to update the prior notice at the time of arrival.

(Response) The interim final rule requires submission of anticipated arrival information to provide FDA with information necessary for planning examinations and communicating with CBP for enforcement and examination purposes. FDA believes that the requirement for submitting anticipated arrival information serves these purposes. FDA has decided to delete the requirements for updating anticipated arrival information because of the reduction of the time requirements for submission. FDA recognizes that some of the anticipated information may change after submission due to unforeseen circumstances, such as business practices of carriers, weather conditions, and traffic conditions.

(Interim final rule) The interim final rule (§ 1.281(a)(11)) requires the submission of the anticipated port of arrival, including crossing location, if applicable, and the anticipated date and anticipated time when the article of food will arrive at that port. The interim final rule does not require that this information be updated if it changes after prior notice had been confirmed by FDA for review. The interim final rule does not require that a prior notice be cancelled and resubmitted if any of the anticipated arrival information changes after confirmation.

14. Port Where Entry Will Be Made for Customs Purposes (Proposed § 1.288(l))

FDA proposed to require the submission of the identification of the port where entry will be made for Customs purposes (§ 1.288(l)). Often, this port is different from the port where the article of food arrived in the United States. FDA proposed that this information is necessary to facilitate communication with CBP and FDA field offices concerning the adequacy of the prior notice and to enable FDA to coordinate resources for inspections, examinations, or sampling.

(Comments) A comment questions the usefulness of the information and asks that FDA delete the requirement because the Customs and FDA ports of entry can be different ports. Another comment states that providing the information would cost additional resources and time for investigation.

(Response) FDA agrees. Due to interfacing with ABI/ACS and development of various means of communication with CBP, this information is no longer necessary in the prior notice submission. Accordingly, FDA has eliminated this information requirement in the interim final rule.

(Interim final rule) The interim final rule does not require submission of the port where entry will be made for Customs purposes.

15. Anticipated Date of Customs Entry (Proposed § 1.288(m))

FDA proposed to require the submission of the anticipated date of entry for U.S. Customs purposes (proposed § 1.288(m)). FDA proposed that this information is critical to enable it to allocate resources for inspecting imported food shipments and efficient communication with and between CBP and FDA field offices.

(Comments) Several comments ask that FDA eliminate this requirement. Comments note that the Customs date of entry is not required by the Bioterrorism Act. Comments state that since the