

that will be shipped by the deadline for prior notice because the field has not been harvested or the supplier has not yet received the day's harvest by the time prior notice of the planned shipment is due. In these instances, the importer knows generally what kind of product has been ordered, but not the exact type (species for fish and variety for lettuce). The proposed amendment process would allow submitters who cannot report complete product identity information to FDA by the prior notice deadline because it does not yet exist to maintain current business practices. However, it would provide FDA some of the information that it needs to begin the assessment of whether a particular shipment of food should be investigated and if so, to ensure that FDA personnel can be available when the food arrives at the port. FDA does not intend this amendment process to apply when a shipper "tops off a container" by filling unused space in the container or truck bed with additional different food products.

FDA also recognizes that information concerning the anticipated arrival may change after the article is ordered due to unforeseen traffic or weather issues and has accommodated those potential changes by requiring updates of that information.

"Noon" means 12:00 p.m. in the time zone in which the FDA office with responsibility over the anticipated port of entry resides. For example, if the anticipated port of entry is the Peace Bridge in the Buffalo, NY, and the anticipated date of entry is January 9, 2004, the prior notice must be submitted to the FDA Prior Notice System before noon Eastern Standard Time (EST) on January 8, 2004.

FDA is proposing that prior notice may not be submitted until all of the information required by § 1.288 exists except as provided in § 1.288(e)(2) and § 1.290, both of which relate to product identity amendments. FDA is also proposing that the prior notice may not be submitted more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry. For example, if the anticipated date of arrival is January 12, 2004, the prior notice may not be submitted before January 7, 2004. This 5 day limitation is consistent with the limitation set by Congress in section 307(a)(2)(A) of the Bioterrorism Act. Such limitations are necessary to ensure that FDA's Prior Notice System is not overburdened with premature information or submissions that may need to be cancelled and resubmitted.

3. How Must You Submit the Prior Notice? (Proposed § 1.287)

FDA is proposing that the prior notice, amendments, and updates must be submitted electronically to FDA through FDA's Prior Notice System. The web-based FDA Prior Notice System is under development with an anticipated completion date of no later than October 12, 2003. A "mock-up" of the Prior Notice Screen a submitter would see once he or she accessed this system is part of this proposed rule.

FDA has consulted with the U.S. Customs Service of the Department of the Treasury about this proposed rule. FDA and U.S. Customs considered modifying ACS to accommodate the new prior notice requirement. However, during these consultations, U.S. Customs determined that ACS could not be modified to accommodate the data requirements of the prior notice regulation by the December 12, 2003, statutory deadline. Currently, U.S. Customs is focusing its resources on developing the Automated Commercial Environment (ACE) as a replacement for ACS, and integrating its other electronic systems, such as the Automated Manifest System (AMS). FDA is participating in the development of ACE through the International Trade Data System (ITDS) Board and directly through integration of FDA and U.S. Customs business practices, policies, and border cooperation. FDA intends to allow prior notice to be submitted through ACE when it is fully operational. However, implementation of ACE is not expected before 2005. Given these circumstances, FDA and U.S. Customs agreed that to meet the statutory deadline, an FDA stand-alone, web-based electronic system to execute receipt of prior notice would be necessary until ACE is fully operational.

FDA seeks to minimize the submission of duplicative information. The Bioterrorism Act requires certain prior notice information to be submitted to FDA. FDA seeks comments on the extent to which these proposed prior notice requirements would result in persons submitting duplicative prior notice information to more than one federal agency. FDA also seeks comments on whether there is any way, consistent with the requirements and purpose of the Bioterrorism Act, to minimize the duplication of information required to be submitted to the federal government under these prior notice requirements. As discussed previously, FDA and U.S. Customs are working together on their systems to allow prior notice to be submitted to FDA through U.S. Customs System when ACE is fully operational.

FDA is proposing to require electronic submission of prior notice because we

believe an electronic system will be the least burdensome and most efficient way to implement and enforce the requirement of section 801(m) of the act. Nationwide, in FY 2001 FDA received over 4.7 million food entry lines; therefore, we believe a paper system would be unmanageable for FDA, require a longer deadline, and could slow down imports for some food products. Moreover, we currently receive the majority of information we base admissibility decisions on electronically from U.S. Customs. Thus, we already have the electronic capability to process and screen the information. We also believe that an electronic system will mean fewer errors than a paper system. Another important benefit of electronic submission will be immediate and accurate communication between FDA offices and between FDA offices and U.S. Customs about arrivals and adequacy of the prior notice.

An electronic prior notice system will have several key features that will benefit firms that export to the United States, U.S. importers, and FDA. First, the volume of submissions on a daily basis is expected to be such that electronic submission and processing are the only practical way for FDA to manage prior notice—FDA expects, upon average, 20,000 submissions per day. Second, an electronic system will be able to provide instantaneous confirmation of receipt of the prior notice. Third, an electronic system will be able to ensure that the form is filled out completely (though not accurately) by being set to reject submissions until all of the mandatory fields are completed. Finally, an electronic system will make it more likely that information in the submissions is "legible" to FDA.

In contrast, prior notice by mail, fax, or e-mail would have several significant downsides for firms that export to the United States, U.S. importers, and FDA. All three of these methods would require FDA to input the data manually to process it, which means that FDA would need to set a longer deadline for submission or devote resources on data entry that are better spent on tasks like inspections. Those whose paper submissions were not legible or complete would not know until their shipments arrived at the port and were refused admission.

Moreover, FDA believes that almost all proposed submitters have access to the Internet, either within their companies or through public libraries, copy centers, schools, or Internet cafes, as well as through agents or brokers. FDA requests comments on this assumption. Because most of the