

System Interface will not provide a confirmation for that prior notice. The transmitter will have an opportunity to correct the rejected information. When the information is corrected, transmitted, and determined to be facially valid, the system will then notify the transmitter and provide the PN Confirmation Number. As set out in § 1.279(d), FDA will notify the transmitter that the prior notice has been confirmed for review with a confirmation that contains a PN Confirmation Number. The prior notice will be considered submitted and the prior notice time will start when FDA has confirmed the prior notice for review.

Under § 1.279(e), the PN Confirmation Number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the PN Confirmation Number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277(b)(1)), and be provided to CBP or FDA upon arrival.

Additionally, under § 1.279(g) the PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA PN System Interface when arriving in the United States and must be provided to CBP and FDA upon arrival.

*G. "How Must You Submit Prior Notice?" (§ 1.280 Proposed as § 1.287)*

FDA proposed that prior notice and any amendments and updates must be submitted electronically to FDA through a new Web interface. The proposed rule also required submission of hard-copy prior notice, in person or by e-mail or fax, if the FDA system was not operating. Before issuing the proposed rule, FDA consulted with CBP, which was then the U.S. Customs Service of the Department of the Treasury, about the proposed rule and the feasibility of modifying ABI/ACS to accommodate the new prior notice requirement. During these consultations, CBP advised that ABI/ACS could not be modified to accommodate the data requirements of the prior notice regulation by the December 12, 2003, statutory deadline.

(Comments) Many comments focus on the proposed method of submission of prior notice. These comments fall into four broad categories. The first category, which includes the largest number of comments, suggests that FDA work more closely with other agencies, and in some cases other countries, to eliminate redundancies or conflicts in the method of submission. The majority of these comments urge the FDA to work more closely with CBP. A second group of

comments addresses the viability of the proposed Web-based system for submission of prior notice. The third category includes suggestions about the prior notice form that was included in the proposed rule. The final category of comments asserts that existing systems and procedures provide adequate defense against a bioterrorism threat and that the proposed regulation is unnecessary.

*1a. Work With Other Agencies To Eliminate Redundancies*

(Comments) Most comments recommend that FDA and CBP work together to reduce the adverse impact of submission of information in both prior notice and CBP entries. Most of these comments suggest that the existing ACS-OASIS interface between CBP and FDA be used to accept prior notice information. Other comments suggest that much of the information required for prior notice was available in CBP's Automated Manifest System (AMS). Although many comments suggest that the existing systems contained sufficient information to meet the statutory requirements, others recognize that modifications were needed to meet the Bioterrorism Act's requirements.

(Response) FDA and CBP agree with many of the comments made about inter-agency cooperation as well as with the recommendation that we provide a single point of data entry for CBP and FDA for as many kinds of entries as possible. FDA and CBP are committed to the joint implementation of an automated approach to prior notice that will meet the following objectives: (1) Reduce submission of redundant data to the extent possible; (2) build on current operational procedures; and (3) implement the law with minimal disruption to current entry practices.

The interim final rule requires prior notice to be submitted electronically to FDA through CBP's ABI/ACS or the FDA PN System Interface. Prior notice may be submitted through ABI/ACS for all food imports subject to this interim final rule except food imported by international mail or other transactions that cannot be submitted through ABI/ACS and food that has been refused under section 801(m) of the FD&C Act. The proposed rule was based on an initial review by both FDA and CBP of the feasibility of implementing new operational procedures and enhancing existing systems. After further review of the potential technical, legal, and operational impacts, FDA and CBP have determined that the prior notice information required for most types of CBP entries of foods can be submitted through the existing ABI/ACS and

provided to FDA. The existing ABI/ACS-OASIS interface allows for communication both between FDA and the customs broker or self-filer (necessary for the submission of prior notice to FDA as required by section 801(m)(1) of the FD&C Act), and between FDA and CBP (necessary for followup at the border). However, although much of the information required for prior notice currently existed in some automated form in ABI/ACS, not all the necessary data were available in the right sequence or at the right time to meet prior notice requirements. Thus, FDA and CBP have been working closely together and enhancing, ABI, ACS, and OASIS to craft operational procedures and systems that meet the requirements of the Bioterrorism Act with minimal impact on existing processes.

Since prior notice is required for some of imported food for which electronic transmission of information to CBP is not available via ABI/ACS and since submission of information through ABI/ACS is not mandatory, an alternative means to submit prior notice will still be needed. Although a CBP entry is not normally submitted in ABI/ACS for T&E entries and IT entries and FTZ admissions, a new transaction format, similar to the existing ABI transactions, will be available for submitting prior notice for these imports through ABI/ACS. The FDA PN System Interface will also be available for international mail, food refused under section 801(m) of the FD&C Act, and those who choose not to submit prior notice through ABI/ACS.

*1b. CBP AMS*

(Comments) Several comments note that some of the information FDA required for prior notice was already being submitted to AMS and suggested that FDA could retrieve data from AMS rather than ask for a separate submission for prior notice.

(Response) AMS is a module of ACS through which carriers, port authorities, or service bureaus transmit electronically the cargo declaration portion of the inward foreign manifest to CBP. The information submitted to AMS is not sufficient to satisfy section 801(m)(1) of the FD&C Act's requirements. For example, the identities of the manufacturer, grower, FDA product code, and quantity of each article are not submitted to AMS. FDA and CBP have consulted about interfacing with AMS for manifest data and determined that the general cargo data in AMS were simply not suitable to accommodate the detailed information requirements of section 801(m) of the FD&C Act. In addition, no