

has been moved from the port of arrival, and has been delivered to the ultimate consignee. While FDA may ultimately receive electronic entry notification of IT entries when the consumption entry is later filed, FDA does not receive electronic notification with information about food entered for transshipment for export or when the food is admitted to an FTZ.

The admissibility standard in section 801(a) of the FD&C Act largely focuses on whether the article of food appears to have been safely produced, contains no contaminants or illegal additives or residues, and is properly labeled. Section 801(a) provides that an article of food is subject to refusal of admission if it "appears, from physical examination or otherwise": (1) To have been manufactured, processed, or packed under insanitary conditions; (2) to be forbidden or restricted in sale in the country in which it was produced or from which it was exported; or (3) to be adulterated or misbranded. The food adulteration and misbranding provisions (sections 402 and 403 of the FD&C Act) set out most of the FD&C Act's safety and labeling standards for foods.

B. Process After December 12, 2003—Prior Notice Determination Followed by Admissibility Determination

Section 801(m) provides that an article of food is subject to refusal of admission if adequate prior notice has not been provided to FDA. Thus, the refusal standard in section 801(m) focuses in the first instance on whether the requisite information has been provided in a timely fashion, while the refusal standard in section 801(a) focuses on whether the article was safely produced, contains no contaminants or illegal additives or residues, and is properly labeled.

By adding the prior notice requirement to the FD&C Act, Congress, in the Bioterrorism Act, changed when information about FDA-regulated food imports must be provided to FDA and what happens if the information is not provided. The prior notice provisions require that notice must be provided on imported food shipments to FDA before arrival. If adequate notice is not provided, section 801(m) of the FD&C Act provides that the food is subject to refusal, and that refused food must be held until adequate notice is given and may not be delivered to the importer, owner, or consignee. The stated purpose of requiring notice of imported food shipments before arrival in the United States is to enable FDA to conduct inspections of imported food at U.S. ports (see section 801(m)(1) of the FD&C

Act). Thus, FDA intends to use prior notice information to make decisions about which inspections to conduct at the time of arrival. Currently, we intend to focus on conducting these inspections when our information suggests the potential for a significant risk to public health.

As explained in greater detail in the following paragraphs, FDA and CBP are coordinating FDA's new prior notice requirements with CBP's and FDA's existing entry requirements to the greatest extent possible. Thus, the interim final rule allows prior notice to be submitted electronically to FDA through either ABI/ACS or the FDA Prior Notice (PN) System Interface. The HTS codes will be flagged within ABI/ACS to indicate which HTS codes contain foods subject to prior notice requirements. In addition, the ABI/ACS interface will provide a new transaction for transmission of prior notice information on IT and T&E entries, and FTZ admissions, e.g., the types of entries of which FDA was not aware or did not know about until many days after arrival in the United States. This will allow for FDA electronic screening and FDA staff evaluation of the information so that FDA can assess, before the food arrives, whether to inspect and to be prepared to conduct that inspection upon arrival.

FDA expects approximately 90 percent of prior notice submissions for all importations of foods to be transmitted by a customs broker or self-filer through the ABI/ACS interface to FDA. FDA estimates that only 10 percent (or less) of the total importations cannot be accommodated by the ABI/ACS interface and, therefore, will be submitted via the FDA PN System Interface.

In addition to requiring submission of the information currently sent to FDA for admissibility determinations, information identifying the grower (if known), the country from which the article is shipped, and anticipated arrival information is also required for prior notice. If all of the prior notice information is transmitted through the ABI/ACS interface, no additional transmission of information for admissibility determinations under section 801(a) of the FD&C Act will be necessary. If prior notice is submitted through the FDA PN System Interface, additional transmission through ABI/ACS may be necessary for CBP purposes and FDA's admissibility evaluation.

Regardless of the mode of transmission, the prior notice information will undergo both a validation process and screening in OASIS for food safety and security

criteria. After the validation step is complete, the prior notice will be confirmed by FDA for review and a reply message sent to the transmitter indicating the prior notice has been received and confirmed for FDA review. The form of this reply messaging depends upon the mode of initial transmission: ABI/ACS or FDA PN System Interface. The clock starts for determining if prior notice was timely when this prior notice confirmation message is sent by FDA.

If the FDA system does not indicate that further evaluation of or action on the notice or article of food is necessary for prior notice purposes, the system will transmit a message back through the OASIS to ABI/ACS interface for CBP that the article of food "may be conditionally released under section 801(b) of the act." However, if additional evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review and assess the information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site.

In addition, the OASIS system review will determine if further staff evaluation of the article of food is necessary for admissibility determinations under section 801(a) of the FD&C Act (e.g., subject to the guidance in an import alert). If so, FDA staff in the appropriate district office will take action, which, in addition to the review and evaluation of the submitted information or other documentation, could include an examination of the article of food for admissibility purposes. This admissibility examination may take place at the border but may also take place at an examination site, a public warehouse, or other appropriate locations. If FDA determines that refusal under section 801(a) of the FD&C Act is appropriate, it will follow appropriate procedures.

II. Overview of the Interim Final Rule and Significant Changes Made to the Proposed Rule

The highlights of this interim final rule are described briefly in the following paragraphs and are discussed in more detail later in the preamble.

A. "What Definitions Apply to This Subpart?" (Section 1.276 Proposed as § 1.277)

- The term "the act" was not changed.
- The term "calendar day" was not changed.