

such other facility as the U.S. Customs port director might require) and held pending the filing of an entry or other action.

Accordingly, under current laws and regulations, there are times when FDA does not receive complete information about the food imports it regulates until days after the food has arrived in the U.S. and been moved from the port it arrived in.

FDA receives information about imported food through its Operational and Administrative System for Import Support (OASIS). Entry information is usually provided electronically to OASIS by U.S. Customs via its Automated Broker Interface (ABI) of the Automated Commercial System (ACS). The information that is currently supplied to FDA through this system includes: the entry type, the entry number (both ACS line number and FDA line identifier); the mode of transportation; the carrier code; the name and address of the manufacturer, shipper, importer, and ultimate consignee; the country of origin; the FDA product code; a written description of the product in common business terms; and the quantity. If neither FDA nor U.S. Customs wishes to examine or detain the entry, the product is allowed to proceed.

By adding section 801(m) to the act, Congress changed when information about FDA-regulated food imports must be provided to FDA. The major components of new section 801(m) of the act are:

- Requires prior notice of imported food shipments beginning on December 12, 2003;
- Provides that, if adequate notice is not provided, the food shall be refused admission and held until adequate notice is given;
- Amends section 301 of the act to make it a prohibited act to import or offer for import an article of food in violation of any requirements under section 801(m) of the act; and
- Mandates that prior notice be submitted no less than 8 hours and not more than 5 days before it is imported or offered for import, if final rules are not in effect on December 12, 2003, and until such rules become effective.

In addition to section 307 of the Bioterrorism Act, which establishes the requirement for prior notice for food imported or offered for import into the U.S., FDA is relying on sections 701(a) and 701(b) of the act (21 U.S.C. 371(a) and (b)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and the

Department of Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to the members of the public interested in food issues outlining the four provisions in Title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see <http://www.cfsan.fda.gov/~dms/sec-ltr.html>). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, to solicit stakeholder comments. In response to these solicitations, FDA received 37 comments regarding section 307 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we have received so far with the comments we receive during the public comment period on this proposed rule in developing the final rule. Several broad themes emerged from the comments FDA received on or before August 30, 2002, including:

- Maintaining flexibility when setting the minimum time required for prior notice and taking into account different modes of transportation, the nature of perishable food, and the needs of businesses which operate close to the U.S. border;
- Permitting the prior notice to be amended;
- Integrating with U.S. Customs and other agencies to avoid duplication of notification requirements;
- Allowing a qualified agent to submit prior notices for authorized submitters;
- Providing immediate acknowledgement of the submission, if prior notice is submitted electronically;
- Defining "food" consistent with the act's definition;
- Extending FDA's hours of operation;
- Complying with international trade obligations; and
- Including a model of the Prior Notice screen.

III. The Proposed Regulation

This rule would enhance FDA's ability to inspect imported food when it arrives in the U.S. This in turn would result in a significant improvement in FDA's ability to deter, prepare for, and respond effectively to bioterrorism and other public health emergencies that

might result from imported food. Additionally, should an outbreak or a bioterrorism event occur, prior notice would enhance FDA's ability to respond to the event by enhancing FDA's ability to prevent entry of shipments that appear related and to facilitate product tracking for containment. This proposed rule would facilitate product tracking because we would know, at the time of receipt of prior notice, the name and address of the actual importer and consignee in the United States. We could then use the U.S. importer and consignee information to follow-up and trace the location of the goods. FDA thus would be better able to ensure that consumers in the United States do not eat food that is contaminated (whether intentionally or otherwise). This information would also assist FDA and other authorities in determining the source and cause of problems and in communicating with affected firms. Finally, we believe that the information provided by prior notice would help us use our foreign inspection resources more effectively.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement ("NAFTA"). For example, we believe this proposed rule is not more trade restrictive than necessary to meet the objectives of the Bioterrorism Act.

A. Highlights of This Rule

The key features of this proposed rule are:

- The purchaser or importer of an article of food (or their agent) who resides or maintains a place of business in the United States generally is responsible for submitting the notice.
- The notice must be submitted by noon of the calendar day before the day of arrival.
 - Amendments relating to product identity information are allowed under specified circumstances.
 - Updates about arrival information are required if plans change.
- The notice must be submitted electronically through the Prior Notice System unless the FDA system is not functioning. The FDA Prior Notice System will be designed to provide an automatic electronic acknowledgment of receipt of a complete prior notice submission, with a time and date "stamp." The notice must contain information that identifies:
 - The individual and firm submitting the prior notice;
 - The entry type and U.S. Customs