

providing notice in accordance with section 801(m)" by December 12, 2003, but also provides that an 8 hour prior notice requirement takes effect on this date even if FDA has not promulgated regulations that are in effect by this deadline. However, we are publishing this rule as an interim final rule and are, accordingly, soliciting comment on its provisions.

(Comments) Most comments generally support the protections of the food supply provided under the Bioterrorism Act. Although comments recommend that the final rule be amended to reflect more accurately industry practices, other comments suggest the regulation should be strengthened to ensure that FDA has all of the information required to identify foods that may pose a health or security threat. Some comments argue that FDA already has access to information currently submitted to CBP to allow for identification and quick interdiction of foods that may pose a health or security threat. Other comments question how the final rule would enhance FDA's ability to improve food safety and whether the benefits outweigh the costs.

(Response) Through section 307 of the Bioterrorism Act, Congress amended the FD&C Act to require the submission to FDA of a notice providing information regarding food before its importation into the United States. Congress also required FDA to issue implementing regulations to be effective not later than December 12, 2003. Thus, a postponement of the rule is not an option. Although FDA is aware that the prior notice regulation will affect industry, Congress determined the need for prior notice by passing the Bioterrorism Act. Prior notice of imported food will give FDA better information about the food earlier, enabling FDA to review and respond to the information before the arrival of the food at the border. Prior notice also will give FDA information with which it will be able to better focus its inspection resources. Section V of this preamble, Analysis of Economic Impacts, discusses the benefits of this interim final rule in detail. To address many of the concerns raised by the comments, FDA has made significant modifications in the interim final rule. However, we are publishing this rule as an interim final rule and are, accordingly, soliciting comment on its provisions.

(Comments) Some comments ask that FDA provide clear guidance and training to industry and agency field personnel about the procedures for implementing the regulation.

(Response) FDA conducted extensive outreach on the proposed prior notice

rule, including having relevant FDA staff attend 6 international meetings and over 100 domestic meetings to ensure that affected parties were aware of the Bioterrorism Act prior notice requirements. On January 29, 2003, FDA held a public meeting (via satellite downlink) to discuss both the registration and prior notice proposed rules (*see* 68 FR 1568, January 13, 2003) or <http://www.accessdata.fda.gov/scripts/oc/ohrms/advisdisplay.cfm>. Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later re-broadcast to Europe, Asia, Africa, and the Pacific. FDA has also posted transcripts of the broadcast in English, French, and Spanish on the agency's Web site.

FDA plans similar outreach efforts directed to both domestic and international stakeholders after publication of the interim final rule implementing the registration and prior notice provisions of the Bioterrorism Act. Outreach will include many methods of communication:

- Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement the registration and prior notice requirements;
- Domestic outreach meetings to State regulators and industry;
- A satellite downlink video broadcast and a series of videoconferences to various regions of the world;
- Materials and events for the media;
- International outreach to food trading partners;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and state and local government representatives of the new requirements; and
- Cooperative arrangements with CBP and other Federal agencies to ensure that information on the interim final regulations and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included in FDA's Web site at <http://www.fda.gov>. In addition, FDA also plans training in new or revised procedures for its field personnel, as well as CBP field personnel. FDA will also provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds

under section 801(l). As described in greater detail later, FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. Guidance documents are available to the public, and FDA will shortly publish a notice of availability in the **Federal Register**.

FDA will notify the World Trade Organization (WTO) of this interim final rule. Shortly after publication of this interim final rule, FDA will begin disseminating at U.S. ports flyers and posters summarizing the new requirements and informing representatives of affected entities how to provide prior notice to FDA. Online assistance and a help desk will be available when the interim final rule becomes effective.

B. Foreign Trade Issues

(Comments) Some comments questioned the consistency of the proposed regulation with U.S. obligations under various WTO agreements, NAFTA, and other international agreements.

(Response) FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation and the interim final regulation is consistent with these international obligations.

(Comments) Some comments asserted that the proposed regulation is burdensome, confusing, costly, disproportionate, discriminatory, and will have a negative impact on foreign trade.

(Response) In drafting the proposed rule, FDA considered how best to structure the proposed rule consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. As discussed in more detail in the following paragraphs, FDA has carefully considered comments received regarding the burden imposed by the proposed rule, including its effects on international trade. Furthermore, based on the comments received on the proposed requirements, FDA has made a number of significant changes that minimize the impact of prior notice requirements on the food industry. These changes include removing restrictions on who can submit prior notice; allowing submission to be made either through ABI/ACS (the existing mechanism for filing entry information with CBP) or the FDA PN System Interface (the FDA PN Web system described in the proposed rule); reducing the timeframes for submission of prior notice and tying them to mode