

To alleviate some of the burden registration may impose on industry, FDA has modified some of the elements of registration, including emergency contact information; the definitions for "farm," "facility," and "retail food establishment," and the timing for submitting updates to FDA when required elements in a registration change. These changes will be discussed in the appropriate sections later in this document.

FDA also believes that its electronic registration system will make registration an efficient and straightforward process. FDA has received positive comments from stakeholders who attended FDA's preliminary demonstrations of the electronic prototype registration system.

(Comment 2) Some commenters request that FDA include a provision in the interim final rule that permits the agency to amend the system quickly to respond to flaws in the rule discovered through practice. Some of these commenters state that this arrangement would be especially helpful for countries that are able to reach a more efficient or effective registration arrangement with FDA that reflects actual reductions in risks through such arrangements.

(Response) FDA always has the option to amend its regulations if the agency believes that improvements would serve the public interest, and interested persons may request such modification by following the procedures in 21 CFR 10.30, regarding citizen petitions. The process for any amendment to an existing FDA regulation must conform to the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 551–559). Notably, section 553 of the APA provides a process for issuing a final rule in an expedited timeframe if certain conditions are met. Importantly, however, FDA can only amend the interim final registration rule consistent with the requirements in the Bioterrorism Act.

(Comment 3) FDA received several comments about the need for outreach efforts regarding the registration requirement. Some commenters encourage FDA to facilitate education regarding the new rule and to provide foreign facilities with information necessary to maintain the flow of trade to the United States. Other commenters encourage FDA to develop clear, definitive statements that outline registration requirements in a simple manner. Some commenters ask about the role of States in the outreach strategy. One commenter recommends that FDA reach out to State agencies and the relevant media to ensure that all

affected industries are aware of the registration requirement. Finally, some commenters request that FDA establish consultation services staffed with both English and foreign language speakers to answer questions about the registration system and requirements and to give technical assistance to help foreign facilities meet the requirements of the regulation.

(Response) FDA conducted extensive outreach on the proposed registration 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 registration requirement. On January 29, 2003, FDA held a public meeting (via satellite downlink) to discuss the registration and prior notice proposed rules. (See 68 FR 1568, January 13, 2003, or <http://www.accessdata.fda.gov/scripts/oc/ohrms/advsdisplay.cfm>.) Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later rebroadcast to Europe, Asia, Africa, and the Pacific (areas in different time zones). FDA has also provided transcripts of the broadcast in English, French, and Spanish (the three official WTO languages) on the agency's Web site. In addition to this outreach to the affected industry, FDA has conducted outreach on the proposed rule to States.

FDA plans similar outreach directed to both domestic and international stakeholders following publication of the interim final rules implementing the registration and prior notice provisions of the Bioterrorism Act. Our outreach will include:

- Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement the registration and prior notice requirements of the Bioterrorism Act;
- A satellite downlink video broadcast and a series of videoconferences to various regions of the world;
- Materials and events for the media;
- Domestic outreach meetings to States and industry;
- International outreach to U.S. trading partners;
- Online assistance to registrants;
- 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 regulations and their requirements; and
- Cooperative arrangements with Customs and Border Protection (CBP) and other Federal agencies to ensure that information on the final regulations

and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included on FDA's Web site at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

FDA will notify the WTO of these regulations. In addition, shortly after publication of this interim final rule, FDA will begin disseminating at the U.S. ports of entry flyers and posters summarizing the new requirements and informing representatives of affected facilities how to register and provide prior notice to FDA.

(Comment 4) One commenter suggests that FDA should utilize State resources to cross-reference with its registration database. This commenter suggests that FDA supply States with copies of registration forms that the State inspectors can give to local facilities during routine inspections, but cautions that FDA should supply the forms so as not to deplete State funds.

(Response) FDA agrees with the commenter's suggestion that FDA should use State resources to cross-reference registrations, and will work with States to do so. FDA believes working in cooperation with our State partners will enhance our collective ability to protect the safety of the U.S. food supply, and our ability to work with facilities in the event of an actual or potential threat against a facility or food product. FDA acknowledges the suggestion that the agency should supply States with copies of the FDA registration form for distribution to potential registrants. However, because FDA is trying to encourage as many registrants as possible to register electronically, FDA intends to make paper forms available only through the methods described in this rule. FDA intends to work with States to disseminate information about the Federal registration requirements.

B. Foreign Trade Issues

(Comment 5) Some commenters questioned the consistency of the proposed regulation with U.S. obligations under the NAFTA and various WTO 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. As noted below, FDA believes that these regulations are consistent with these international trade obligations.

(Comment 6) Some commenters asserted that the proposed regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade.