

- The definition of farm now includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership;

- The definition of food for purposes of the Bioterrorism Act excludes food contact substances as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) and pesticides as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136(u);

- Packaging (when used as a verb) has been defined and means “placing food into the container that directly contacts the food and that the consumer receives;”

- The definition of “retail food establishment” has been revised to

an establishment that sells food products directly to consumers as its primary function. A retail establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food that it manufactures/processes, packs, or holds directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to the consumers exceeds the annual monetary value of sales of food products to all other buyers. The term ‘consumers’ does not include businesses. A ‘retail food establishment’ includes grocery stores, convenience stores, and vending machine locations.

- FDA has added a definition for “trade name” as “the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product;”

- FDA has determined that it will contact the foreign facility's U.S. agent when an emergency occurs, unless the registration specifies another emergency contact under § 1.233(b);

- FDA is clarifying that having a single U.S. agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of registration;

- FDA is allowing registrants to submit their registrations by fax or CD-ROM, which FDA will enter into its registration system, along with the mailed submissions, as soon as practicable, in the order received;

- FDA has changed the timeframe in which registrants must update their registrations from 30 days to within 60

days of any change in the required information;

- FDA has deleted the requirement to update optional information previously submitted, but encourages facilities to do so voluntarily; and

- FDA has clarified that if a facility has a new owner, the former owner must submit a cancellation within 60 calendar days of the change and the new owner must re-register the facility.

- FDA now provides that the failure of an owner, operator, or agent in charge of a facility governed by this interim final rule to register such facility, update required elements of its registration, or cancel its registration, is a prohibited act under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)).

III. Comments on the Proposed Rule

FDA received approximately 350 submissions in response to the proposed rule, which raised almost 200 major issues. To make it easier to identify comments and FDA's responses to the comments, the word “Comment” will appear in parentheses before the description of the comment, and the word “Response” will appear in parentheses before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

(Comment 1) Most commenters state that they generally support protection of the U.S. food supply under the Bioterrorism Act. Although some commenters assert that the proposed rule should be amended to reflect more accurately industry practices, other commenters believe the regulation should be strengthened to ensure that FDA has all the information required to identify foods that may pose a health or security threat. Other commenters question how the interim final rule would enhance FDA's ability to improve food safety and whether the benefits outweigh the costs.

Some commenters argue that the proposed regulation should either be repropose or not implemented at all. These commenters claim that the proposed rule is seriously flawed, unduly burdensome, and will unnecessarily interfere with trade. Some of these commenters also argue that FDA already has complete information to allow for identification of, and quick communication with, affected facilities before a shipment is introduced into U.S. commerce.

(Response) In response to the comments regarding repropose or not implementing the rule, these options are not available to FDA under the Bioterrorism Act, because that act requires FDA to “promulgate proposed and final regulations for the requirement of registration” by December 12, 2003. The Bioterrorism Act further states that the registration requirement takes effect on December 12, 2003, even if FDA does not have a final regulation in effect by the deadline. FDA believes that both the proposed rule and this interim final rule properly implement section 305 of the Bioterrorism Act, and thus, there is no need to repropose the regulation. Further, based on the many comments supporting the proposed regulation as well as those comments suggesting limited changes to the rule as proposed, FDA disagrees that the proposed regulation is so flawed that reproposal is required.

FDA is aware that the registration regulation may alter industry practices to some extent. In enacting the Bioterrorism Act, Congress determined that registration with FDA was necessary to respond to bioterrorism and other food-related emergencies. Registration will give FDA information it does not currently have about facilities that manufacture/process, pack, or hold food for consumption in the United States, and current contact information for all of these facilities. FDA will be able to use this information to target its contacts to both domestic and foreign facilities in the event of a bioterrorist threat or other food-related emergency. Information about food product categories will permit FDA to screen food imports more carefully because the agency will be able to match a registrant's food product category with the product code and common or usual or market name submitted as part of a prior notice (21 CFR part 1, subpart I). Registration will also give FDA information that we can use to focus and better utilize the agency's limited inspection resources.

Registering with FDA creates an information trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the registrant. By creating this paper trail, persons in the food supply chain who might intentionally contaminate food may be deterred by the creation of additional evidence that might be used against them. Persons who might intentionally contaminate the food supply but refuse to register would be subject to criminal and civil sanctions and would risk having their product, if imported, held at the port.