

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

[Docket No. 02N-0276]

RIN 0910-AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final regulation that requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of a final regulation. Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be affected by the outbreak.

DATES: This interim final rule is effective December 12, 2003. Submit written or electronic comments by December 24, 2003.

FOR FURTHER INFORMATION CONTACT: Leslye M. Fraser, Center for Food Safety and Applied Nutrition (HFS-4), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background and Legal Authority
- II. Highlights of the Interim Final Rule and Summary of the Significant Changes Made to the Proposed Rule
- III. Comments on the Proposed Rule
 - A. General Comments
 - B. Foreign Trade Issues
 - C. Comments on "Who Must Register Under This Subpart?" (Proposed § 1.225)
 - D. Comments on "Who is Exempt from This Subpart?" (Proposed § 1.226)
 - E. Comments on "What Definitions Apply to This Subpart?" (Proposed § 1.227)
 - F. Comments on "When Must You Register?" (Proposed § 1.230)
 - G. Comments on "How and Where Do You Register?" (Proposed § 1.231)
 - H. Comments on "What Information is Required in the Registration?" (Proposed § 1.232)
 - I. Comments on "What Optional Items are Included in the Registration Form?" (Proposed § 1.233)
 - J. Comments on "How and When Do You Update Your Registration Information?" (Proposed § 1.234)
 - K. Comments on "What Other Registration Requirements Apply?" (Proposed § 1.240)
 - L. Comments on "What Happens if You Fail to Register?" (Proposed § 1.241)
 - M. Comments on "What Does Assignment of a Registration Number Mean?" (Proposed § 1.242)
 - N. Comments on "Is Food Registration Information Available to the Public?" (Proposed § 1.243)
- IV. Analysis of Economic Impacts
 - A. Final Regulatory Impact Analysis
 - V. Final Regulatory Flexibility Analysis
 - VI. Unfunded Mandates
 - VII. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule
 - VIII. Paperwork Reduction Act of 1995
 - IX. Request for Comments
 - X. Analysis of Environmental Impact
 - XI. Federalism
 - XII. References

I. Background and Legal Authority

On February 3, 2003 (68 FR 5378), FDA and the Department of the Treasury jointly issued a proposed rule requiring certain food facilities to register with FDA. The events of September 11, 2001, had highlighted the need to enhance the security of the infrastructure of the United States, including the food supply. Congress had responded by enacting the Bioterrorism Act (Pub. L. 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 305, which requires the Secretary of Health and Human Services (the Secretary) to develop a regulation to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to

register with FDA by December 12, 2003. The provision creates section 415 and amends sections 301 and 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331 and 381). The Bioterrorism Act also requires FDA to issue regulations mandating prior notice of imported food shipments (section 307), directs FDA to issue regulations regarding the maintenance of certain records (section 306), and grants FDA the authority to administratively detain food (section 303). FDA and the Department of the Treasury have jointly published proposed rules implementing section 307 (68 FR 5428, February 3, 2003), and FDA has published proposed rules implementing section 303 (68 FR 25242, May 9, 2003), and section 306 (68 FR 25188, May 9, 2003). The prior notice interim final rule appears elsewhere in this issue of the **Federal Register**.

The major components of section 305 of the Bioterrorism Act are as follows:

- The owner, operator, or agent in charge of a facility is responsible for the submission of a registration to FDA;
- Each facility must be separately registered and the registration must include the name and address of the facility, and all trade names under which the registrant conducts business from that facility. The registration for foreign facilities also must include the name of the U.S. agent for the facility;
- FDA also may require each registration to include the general food category (as identified under § 170.3 (21 CFR 170.3)) of the food manufactured, processed, packed, or held at the facility, if FDA determines through guidance that this submission is necessary. FDA issued guidance on July 17, 2003 (68 FR 42415), available at <http://www.fda.gov/oc/bioterrorism/bioact.html>, that concluded that information about food product categories is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency;
- Foreign facilities that manufacture/process, pack, or hold food that is exported for consumption in the United States are required to register unless the food undergoes further processing or packaging at another facility outside the United States;
- Establishments excluded from the registration requirement are farms, restaurants and other retail food establishments, nonprofit food establishments, and fishing vessels (except those engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k));
- FDA shall notify the registrant when it has received the registration