

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 1

[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:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing a regulation that would require 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 proposed regulation would implement 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 final regulations. 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 all facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne 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 impacted by the outbreak.

**DATES:** Submit written or electronic comments by April 4, 2003. Written comments on the information collection provisions should be submitted by March 5, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, the Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

### FOR FURTHER INFORMATION CONTACT:

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### SUPPLEMENTARY INFORMATION:

#### Table of Contents

- I. Background and Legal Authority
- II. Preliminary Stakeholder Comments
- III. The Proposed Regulation
  - A. Highlights of Proposed Rule
  - B. General Provisions
    - 1. Who Must Register Under This Subpart? (Proposed § 1.225)
    - 2. Who Is Exempt From This Subpart? (Proposed § 1.226)
    - 3. What Definitions Apply to This Subpart? (Proposed § 1.227)
  - C. Procedures for Registration of Food Facilities
    - 1. When Must You Register? (Proposed § 1.230)
    - 2. How and Where Do You Register? (Proposed § 1.231)
    - 3. What Information is Required in the Registration? (Proposed § 1.232)
    - 4. What Optional Items are Included in the Registration Form? (Proposed § 1.233)
    - 5. How and When Do You Update Your Registration Information? (Proposed § 1.234)
  - D. Additional Provisions
    - 1. What Other Registration Requirements Apply? (Proposed § 1.240)
    - 2. What Happens if You Fail to Register? (Proposed § 1.241)
    - 3. What Does Assignment of a Registration Number Mean? (Proposed § 1.242)
    - 4. Is Food Registration Information Available to the Public? (Proposed § 1.243)
- IV. Analysis of Economic Impacts
  - A. Benefit-Cost Analysis
  - B. Need for the Regulation
  - C. Reason for the Regulation
  - D. Options
- V. Initial Regulatory Flexibility Act
- VI. Unfunded Mandates
- VII. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule
- VIII. Paperwork Reduction Act of 1995
- IX. Analysis of Environmental Impact
- X. Federalism
- XI. Comments
- XII. References

#### I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

("the Bioterrorism Act") (Public Law 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 regulations mandating 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 provision creates section 415 and amends sections 301 and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*).

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 submitting the registration form to FDA;
- The registration form must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. Foreign facilities also must include the name of the U.S. agent for the facility;
- FDA also may require each facility to submit 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 this submission necessary through guidance. FDA plans to issue such guidance;
- Foreign facilities exporting food to the United States are required to register unless the food undergoes further processing or packaging by another facility outside the United States;
- Other facilities excluded from the registration requirement are: farms, restaurants and other retail facilities, nonprofit food establishments in which food is prepared for or served directly to the consumer, 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 and assign a unique registration number to each registered facility. This number is not subject to public disclosure under section 552 of title 5, United States Code (the Freedom of Information Act);
- FDA may encourage electronic registration; and
- Registered facilities must notify FDA in a timely manner of changes to their registration information.

In addition to section 305 of the Bioterrorism Act, 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