

WORLD TRADE ORGANIZATION

G/TBT/N/USA/32
13 February 2003

(03-0933)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (32) Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Food Facilities (ICS 67)
5.	Title, number of pages and language(s) of the notified document: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (50 pages, in English)
6.	Description of content: 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 12 December 2003. The proposed regulation would implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires domestic and foreign facilities to register with FDA by 12 December 2003, even in the absence of final regulations. 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.
7.	Objective and rationale, including the nature of urgent problems where applicable: To 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.
8.	Relevant documents: 68 Federal Register (FR) 5378, 3 February 2003; Title 21 Code of Federal Regulations (CFR) Part 1. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption: } Proposed date of entry into force: } 12 December 2003

10. Final date for comments: 4 April 2003

Written comments on the document should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 U.S.A. Electronic comments may be submitted at <http://www.fda.gov/dockets/ecomments> under DOCKET Number 02N-0276 and Title of Document, *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

<http://www.access.gpo.gov/nara/index.html>

Complete text can be also be found on the Internet at:

<http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm> looking under DOCKET NO. 02N-0276

and at <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-2443.pdf>