

WORLD TRADE ORGANIZATION

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(04-1712)

Committee on Sanitary and Phytosanitary Measures

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NOTIFICATION

Addendum

The following communication, dated 14 April 2004 is being circulated at the request of the Delegation of the United States.

Interim Final Rule; Regulation Implementing Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Section 305: Registration of Food Facilities (Docket. No. 2002N-0276)

The US Food and Drug Administration (FDA) is reopening for 30 days, on a limited range of issues, the comment period for FDA's interim final rule (IFR), "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" that was published in the **Federal Register** of 10 October 2003 (68 FR 58894). The IFR required 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.

FDA is taking this action consistent with its statement in the preamble of the registration IFR that it would re-open the comment period for an additional 30 days to ensure that those commenting on the IFR have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration program. Accordingly, we are seeking comments on the following issues in order to improve FDA's economic analysis:

1. The cost to foreign facilities of hiring and retaining a US agent. Specifically, FDA invites comment, and the submission of data or other information, on the following:
 - (a) The costs to a foreign facility of hiring a US agent;
 - (b) The number of foreign facilities that have hired a US agent or negotiated additional duties from someone with whom they have an existing relationship in response to the IFR, instead of relying on an existing relationship with a person who qualifies as a US agent;
 - (c) The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a US agent for registration purposes.
 - (d) The distribution of costs between submitting registrations and other services offered by the US agent; and retaining a US agent.
 - (e) The assumptions underlying FDA's estimates of the costs of hiring and retaining a US agent.
2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

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- (a) The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and
- (b) The costs incurred by these domestic small businesses due to the loss of these trading partners.

Submit written or electronic comments on the above issues by 14 May 2004. Submit written comments on the document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, U.S.A. It is possible to submit electronic comments to: <http://www.fda.gov/dockets/ecomments>. Submit comments by indicating DOCKET Number 2002N-0276 and title of document "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002".

The complete text of the Notice contained in the Federal Register (FR), 69 FR 19766 (available in English) can be found in the Internet at:
<http://www.fda.gov/OHRMS/DOCKETS/98fr/04-8516.htm>
<http://www.fda.gov/OHRMS/DOCKETS/98fr/04-8516.pdf>

In addition, the document can be obtained from Ms. Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, Tel. 301-436-2378.

Further information can be found on the FDA web site at
<http://www.fda.gov/oc/bioterrorism/bioact.html>
