



19 May 2015

(15-2607)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	<b>Notifying Member:</b> <u>UNITED STATES OF AMERICA</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Food and Drug Administration (FDA), Health and Human Services (HHS) [1009] <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> Please submit comments to: USA WTO TBT Enquiry Point, Email: <a href="mailto:ncsci@nist.gov">ncsci@nist.gov</a>
3.	<b>Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b> For the purposes of transparency, we are notifying this measure as 'other' because it amends a previously notified measure. We note that this amendment does not appear to qualify for notification under Articles 2.9.2, 2.10.1, 5.6.2, or 5.7.1
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Food facilities. Processes in the food industry (ICS: 67.020), Plants and equipment for the food industry (ICS: 67.260)
5.	<b>Title, number of pages and language(s) of the notified document:</b> Amendments to Registration of Food Facilities (30 pages, in English).
6.	<b>Description of content:</b> The Food and Drug Administration (FDA or we) is proposing to amend its regulation for registration of food facilities 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. This proposed rule would amend and update FDA's registration regulations and is part of our implementation of the FDA Food Safety Modernization Act (FSMA), which added new provisions for the registration of food facilities. Moreover, a number of provisions in FSMA apply only to facilities required to register, including hazard analysis and risk-based preventive controls and mandatory recall authority. The proposed amendments will further enhance FDA's capabilities with respect to responding to food safety issues, and in addition, provide FDA with information that we can use to focus and better utilize our limited inspection resources.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human health or Safety
8.	<b>Relevant documents:</b> 80 Federal Register (FR) 19159, 9 April 2015; Title 21 Code of Federal Regulations (CFR) Part 1. Will appear in the Federal Register when adopted.  G/TBT/N/USA/32 (13 February 2003) Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 – <a href="http://www.gpo.gov/fdsys/pkg/FR-2003-02-03/html/03-2443.htm">http://www.gpo.gov/fdsys/pkg/FR-2003-02-03/html/03-2443.htm</a> and all related addenda/corrigenda.

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<b>9.</b>	<b>Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> To be determined
<b>10.</b>	<b>Final date for comments:</b> 8 June 2015
<b>11.</b>	<b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b> <a href="https://members.wto.org/cnattachments/2015/TBT/USA/15_2011_00_e.pdf">https://members.wto.org/cnattachments/2015/TBT/USA/15_2011_00_e.pdf</a>