WORLD TRADE ORGANIZATION

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3 October 2014

(14-5589)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 30 September 2014, is being circulated at the request of the Delegation of the United States of America.

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Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Proposed rule; Supplemental Notice of Proposed Rulemaking

The Food and Drug Administration (FDA) is proposing to amend its 2013 proposed rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Human Food. In that 2013 proposed rule, we proposed to amend the CGMP requirements to modernize them and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. We also proposed to revise certain definitions in our current regulation for Registration of Food Facilities to clarify the scope of an exemption from registration requirements for ''farms'' and, in so doing, to clarify which domestic and foreign facilities would be subject to the proposed requirements for hazard analysis and risk-based preventive controls for human food. We are taking this action because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions of these proposed rules. We are reopening the comment period only with respect to specific issues identified in this proposed rule.

http://members.wto.org/crnattachments/2014/sps/USA/14_4337_00_e.pdf

This addendum concerns a:

[ ] Modification of final date for comments
[ ] Notification of adoption, publication or entry into force of regulation
[**X**] Modification of content and/or scope of previously notified draft regulation
[ ] Withdrawal of proposed regulation
[ ] Change in proposed date of adoption, publication or date of entry into force
[ ] Other:

Comment period: ***(If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)***

[ ] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: 15 December 2014

Agency or authority designated to handle comments: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions
Submit electronic comments in the following way:
Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions
Submit written submissions in the following ways:
Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions:
All submissions received must include the Docket No. FDA-2011-N-0920 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the SUPPLEMENTARY INFORMATION section of this document.

Text(s) available from: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: us.spsenquirypoint@fas.usda.gov

Text available in the Federal Register at Vol. 79, No. 188, Page 58524 or at:
http://www.gpo.gov/fdsys/pkg/FR-2014-09-29/pdf/2014-22446.pdf

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