WORLD TRADE ORGANIZATION

G/SPS/N/USA/2502/Add.10

2 November 2022

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Committee on Sanitary and Phytosanitary Measures Original: English

NOTIFICATION

Addendum

The following communication, received on 2 November 2022, is being circulated at the request of the Delegation of the United States of America.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Supply-Chain Programs and Onsite Audits; Announcement of Effective Date

The Food and Drug Administration (FDA or we) is announcing the effective date for requirements related to establishing and implementing supply-chain programs, records documenting supply-chain programs, and onsite audits in two final rules, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, that appeared in the Federal Register of 17 September 2015.

The effective date for the amendments to 21 CFR 117.405(a)(2), 117.435(d), and 117.475(c)(2), which published in the Federal Register of 17 September 2015 (80 FR 55908), is 31 October 2022.

The effective date for the amendments to 21 CFR 507.105(a)(2), 507.135(d), and 507.175(c)(2), which published in the Federal Register of 17 September 2015 (80 FR 56170), is 31 October 2022.

https://www.govinfo.gov/content/pkg/FR-2022-10-31/pdf/2022-23534.pdf
https://members.wto.org/crnattachments/2022/SPS/USA/22_7403_00_e.pdf

This addendum concerns a:

[ ] Modification of final date for comments
[**X**] Notification of adoption, publication or entry into force of regulation
[ ] 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)*: Not applicable

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:

For questions relating to Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 2166.

For questions relating to Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Jennifer Erickson, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, +(240) 402 7382.

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

Text can be found in the Federal Register, Vol. 87, No. 209, Page 65527 or on the internet at: https://www.govinfo.gov/content/pkg/FR-2022-10-31/pdf/2022-23534.pdf.