



27 March 2024

(24-2620)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 26 March 2024, is being circulated at the request of the Delegation of the United States of America.

Food Additives: Food Contact Substance Notification That Is No Longer Effective; Final Rule

The Food and Drug Administration (FDA or we) is amending its regulations relating to the procedures for determining that a premarket notification for a food contact substance (FCN) is no longer effective. The final rule provides additional reasons that could form the basis for FDA to determine that an FCN is no longer effective. The final rule also ensures that manufacturers or suppliers have the opportunity to provide input before we determine that an FCN is no longer effective. We are making these changes to allow FDA to respond better to new information on the safety and use of food contact substances (FCSs), as well as manufacturers' business decisions, and also improve the efficiency of the premarket notification program.

This rule is effective 21 May 2024.

<https://www.govinfo.gov/content/pkg/FR-2024-03-22/pdf/2024-05802.pdf>
https://members.wto.org/crnattachments/2024/SPS/USA/24_02270_00_e.pdf

This addendum concerns a:

- Modification of final date for comments
- 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 access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this

final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, +(240) 402 7500.

For further information contact: Sharon Koh-Fallet, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(301) 796 7732; or Carrol Bascus, Center for Food Safety and Applied Nutrition (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 2378.

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. 89, No. 57, Page 20306 or on the internet at: <https://www.govinfo.gov/content/pkg/FR-2024-03-22/pdf/2024-05802.pdf>.
