



14 November 2024

(24-8049)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 13 November 2024, is being circulated at the request of the Delegation of the United States of America.

Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers; Final Rule; Response to Objection; Confirmation of Effective Date

The Food and Drug Administration (FDA or we) is responding to the objection that we received from the Environmental Defense Fund, Breast Cancer Prevention Partners, Environmental Protection Network, Environmental Working Group, and Healthy Babies Bright Futures on the final rule that amended the food additive regulations to no longer provide for the use of 25 plasticizers that the petition identified as ortho-phthalates because these food additive uses have been permanently abandoned. After reviewing the objection, FDA has concluded that the objection does not provide a basis for modifying FDA's final rule amending the food additive regulations.

DATES: The effective date of 20 May 2022, for the final rule published on 20 May 2022 (87 FR 31080), is confirmed.

<https://www.govinfo.gov/content/pkg/FR-2024-10-30/pdf/2024-25122.pdf>

<https://www.federalregister.gov/d/2024-25122>

https://members.wto.org/crnattachments/2024/SPS/USA/24_07742_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: Stephen DiFranco, Office of Food Chemical Safety, Dietary Supplements, and Innovation (HFS-275), Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, +(240) 402 2710; or Lauren Kleinman, Human Foods Program, Office of Policy, Regulations and Information (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. 210, Page 86239 or on the internet at: <https://www.federalregister.gov/d/2024-25122>.
