



5 September 2025

(25-5564)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 5 September 2025, is being circulated at the request of the Delegation of the United States of America.

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D3 in Yogurt and Other Cultured Dairy Products Fermented With *Lactobacillus delbrueckii*, Subspecies *bulgaricus*, and *Streptococcus thermophilus*; Final Amendment; Order

The Food and Drug Administration (FDA or we) is amending the food additive regulations to provide for the safe use of vitamin D3 as a nutrient supplement in yogurt and other cultured dairy products fermented with *Lactobacillus delbrueckii*, subspecies *bulgaricus* (*L. delbrueckii*, subsp. *bulgaricus*), and *Streptococcus thermophilus* (*S. thermophilus*) at a level higher than is currently permitted. We are taking this action in response to a food additive petition filed by General Mills, Inc. (General Mills or petitioner). We are also updating the reference for the vitamin D3 specifications.

This order is effective 4 September 2025. The incorporation by reference of certain material listed in the order is approved by the Director of the Federal Register as of 4 September 2025.

<https://www.federalregister.gov/d/2025-16946>

https://members.wto.org/crnattachments/2025/SPS/USA/25_05863_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): Submit either electronic or written objections and requests for a hearing by 11:59 p.m. Eastern Time on 6 October 2025.

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 objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The <https://www.regulations.gov> electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of 6 October 2025. Objections received by mail/hand delivery/courier (for written/ paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

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. 90, No. 169, page 42699 or on the Internet at: <https://www.federalregister.gov/d/2025-16946>
