WORLD TRADE ORGANIZATION

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23 August 2023

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Committee on Sanitary and Phytosanitary Measures Original: English

NOTIFICATION

Addendum

The following communication, received on 22 August 2023, is being circulated at the request of the Delegation of the United States of America.

Revocation of Uses of Partially Hydrogenated Oils in Foods; Direct Final Rule

The Food and Drug Administration (FDA or we) is amending our regulations that provide for the use of partially hydrogenated oils (PHOs) in food in light of our determination that PHOs are no longer generally recognized as safe (GRAS). The rule removes PHOs as an optional ingredient in the standards of identity for peanut butter and canned tuna. It revises FDA's regulations affirming food substances as GRAS pertaining to menhaden oil and rapeseed oil to no longer include partially hydrogenated forms of these oils, and deletes the regulation affirming hydrogenated fish oil as GRAS as an indirect food substance. We are also revoking prior sanctions (*i.e.,* pre-1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls, and buns based on our conclusion that these uses of PHOs may be injurious to health. We are issuing these amendments directly as a final rule because they are noncontroversial given the public health risks associated with PHOs and the increasing use of PHO alternatives, and we anticipate no significant adverse comments because PHOs were declared no longer GRAS for any use in human food in 2015.

This rule is effective 22 December 2023. Either electronic or written comments on the direct final rule or its companion proposed rule must be submitted by 23 October 2023. If FDA receives no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, FDA will publish a document in the **Federal Register** withdrawing this direct final rule within 30 days after the comment period on this direct final rule ends and we will then proceed to respond to comments under the companion proposed rule using the usual notice and comment procedures.

Direct Final Rule: https://www.govinfo.gov/content/pkg/FR-2023-08-09/pdf/2023-16725.pdf
Companion Proposed Rule: https://www.govinfo.gov/content/pkg/FR-2023-08-09/pdf/2023-16724.pdf

https://members.wto.org/crnattachments/2023/SPS/USA/23_11951_00_e.pdf
https://members.wto.org/crnattachments/2023/SPS/USA/23_11951_01_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)*: 23 October 2023

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 as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of 23 October 2023. Comments 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 comments in the following way:

- *Federal eRulemaking Portal:* https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions".

Instructions: All submissions received must include the Docket No. FDA–2019–N–4750 for "Revocation of Uses of Partially Hydrogenated Oils in Foods". Received comments, those filed in a timely manner (see **ADDRESSES**) will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, +(240) 402 7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential". Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or

access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, 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:

Ellen Anderson, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 1309; or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (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. 88, No. 152, page 53764 or on the internet at: https://www.govinfo.gov/content/pkg/FR-2023-08-09/pdf/2023-16725.pdf