



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 161, 164, 184, and 186

[Docket No. FDA-2024-D-1669]

Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry;

Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry; Small Entity Compliance Guide.” The small entity compliance guide (SECG) is intended to help small entities comply with our regulations after we revoked specific requirements pertaining to the use of partially hydrogenated oils in certain foods or as a direct or indirect food substance.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

#### *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-2024-D-1669 for "Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry; Small Entity Compliance Guide." Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the SECG to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

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 Philip Chao, 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.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry; Small Entity Compliance Guide.” We are issuing this SECG consistent with our good guidance practices regulation (21 CFR 10.115). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the *Federal Register* of August 9, 2023 (88 FR 53764), we published a direct final rule entitled “Revocation of Uses of Partially Hydrogenated Oils in Foods” (“the final rule”). The final rule amends 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 final rule:

- Removes PHOs as an optional ingredient in the standards of identity for canned tuna and for peanut butter at §§ 161.190 (21 CFR 161.190) and 164.150 (21 CFR 164.150), respectively;
- Revises our regulations affirming food substances as GRAS pertaining to menhaden oil (21 CFR 184.1472) and to low erucic acid rapeseed oil (LEAR oil) (21 CFR 184.1555) to no longer include partially hydrogenated forms of these oils;
- Deletes the regulation affirming partially hydrogenated fish oil as GRAS as an indirect food substance (21 CFR 186.1551); and
- Revokes prior sanctions for the use of PHOs in margarine, shortening, and bread, rolls, and buns. (A “prior sanction” exempts a specific use of a substance in food from the

definition of food additive and from all related food additive provisions of the Federal Food, Drug, and Cosmetic Act if the use was sanctioned or approved before September 6, 1958. In accordance with our general regulations regarding prior sanctions, we may revoke a prior sanctioned use of a food ingredient where scientific data or information demonstrate that prior-sanctioned use of the food ingredient may be injurious to health (see 21 CFR 181.1.)

The final rule became effective on December 22, 2023 (88 FR 86580, December 14, 2023).

Because we revised, removed, or revoked the regulations mentioned above, the SECG informs small entities that they should no longer use:

- PHOs as an optional ingredient in canned tuna under the standard of identity for canned tuna at § 161.190;
- PHOs as an optional ingredient in peanut butter under the standard of identity for peanut butter at § 164.150;
- Partially hydrogenated versions of menhaden oil or LEAR oil as a direct food substance;
- Partially hydrogenated fish oil as an indirect food substance used as a constituent of cotton and cotton fabrics used for dry food packaging; and
- PHOs as an ingredient in margarine, shortening, bread, rolls, and buns.

## II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this guidance contains no collection of information.

Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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