Revocation of Uses of Partially Hydrogenated Oils in Foods: Guidance for Industry Small Entity Compliance Guide

Additional copies are available from:
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-1200
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2024-D-1669 listed in the notice of availability that publishes in the *Federal Register.*

For questions regarding this document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1450.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

April 2024

Table of Contents

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

Small Entity Compliance Guide[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

In the *Federal Register* of August 9, 2023 (88 FR 53764), FDA (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).[2] We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document restates in plain language the revisions made in the final rule and is intended to help small entities comply with the requirements established in 21 CFR parts 161, 164, 184, and 186.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be

[1] This guidance has been prepared by the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] In June 2015, we issued a final declaratory order that PHOs are no longer generally recognized as safe (GRAS) under any condition for use in human food (80 FR 34650 (June 17, 2015)). We made this determination based on evidence, including results from controlled feeding studies on trans fatty acid consumption in humans, findings from long-term prospective epidemiological studies, and expert panel opinions. By finding that PHOs are not GRAS, parties who wanted to use PHOs as a food additive would have to seek approval of those PHOs as food additives under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) for one or more specific uses. We established a compliance date of June 18, 2018, for such petitions and to allow time for food manufacturers to identify suitable replacement ingredients for PHOs and to reformulate and modify labeling for affected products (see 80 FR 34650 at 34653). We later extended the compliance date to January 1, 2020, for foods manufactured with non-petitioned uses of PHOs and to June 18, 2019, for petitioned uses of PHOs (83 FR 23358 (May 21, 2018)).

viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

In the remainder of this guidance, "you" refers to food manufacturers that are subject to the rule. Many answers in this guidance are followed by citations to show where a specific requirement can be found in either the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Title 21 of the *Code of Federal Regulations*.

II. Who Is Subject to the Rule?

You are subject to the rule if you:

- Manufacture canned tuna meeting the food standard for canned tuna at 21 CFR 161.190;
- Manufacture peanut butter meeting the food standard for peanut butter at 21 CFR 164.150;
- Use partially hydrogenated menhaden oil as a direct food substance under 21 CFR 184.1472;
- Use partially hydrogenated low erucic acid rapeseed oil (LEAR oil) as a direct food substance under 21 CFR 184.1555;
- Used partially hydrogenated fish oil as a constituent of cotton and cotton fabrics used for dry food packaging under then-existing 21 CFR 186.1551; or
- Use partially hydrogenated oils in making margarine, shortening, and bread, rolls and buns.

III. How Do You Comply with the Rule?

The final rule:

- Removes PHOs as an optional ingredient in the standards of identity for canned tuna and for peanut butter;
- Revises our regulations affirming food substances as GRAS pertaining to menhaden oil and LEAR oil 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 used as a constituent of cotton and cotton fabrics used for dry food packaging; and

- Revokes prior sanctions[3] for the use of PHOs in margarine, shortening, and bread, rolls, and buns.

Thus, to comply with the rule, you should no longer use:

- PHOs as an optional ingredient in canned tuna under the standard of identity for canned tuna at 21 CFR 161.190;
- PHOs as an optional ingredient in peanut butter under the standard of identity for peanut butter at 21 CFR 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; or
- PHOs as an ingredient in margarine, shortening, bread, rolls, and buns.

[3] 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 FD&C 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).