email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 1, 2023.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 161, 164, 184, and 186

[Docket No. FDA–2019–N–4750]

RIN 0910–AI15

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend 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). We are proposing to remove PHOs as an optional ingredient in the standards of identity for peanut butter and canned tuna. We are also proposing to revise 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 delete the regulation affirming hydrogenated fish oil as GRAS as an indirect food substance. We are also proposing to revoke 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.

DATES: Either electronic or written comments on the proposed rule or its companion direct final rule must be submitted by October 23, 2023. If FDA receives any timely significant adverse comments on the direct final rule with which this proposed rule is associated, we will publish a document withdrawing the direct final rule within 30 days after the comment period ends and we will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: 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 October 23, 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: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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 *http://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 *http://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 *http://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.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

The purpose of this action is to propose amendments to amend our regulations and revoke prior-sanctioned uses of PHOs to conform with the current state of scientific knowledge regarding the public health risks of PHOs. In June 2015, FDA published a declaratory order (Order) setting forth our final determination, based on the available scientific evidence and the findings of expert scientific panels, that there is no longer a consensus among qualified experts that PHOs, which are the primary dietary source of industrially produced *trans* fatty acids, are GRAS for any use in human food. The Order stated that we determined that this body of evidence established the health risks associated with the consumption of *trans* fat. In the Order, we recognized that there were some uses of PHOs in foods that are expressly authorized by GRAS affirmation regulations, acknowledged that there could be some uses recognized by ''prior sanction'' (and thus could not be regulated as a food additive), and stated that we would address such uses separate from the final determination. We also stated that we would consider taking further action, including revising certain standards of identity that list PHOs as optional ingredients.

As explained in the Order, there is a lack of convincing evidence that PHOs are GRAS. FDA has not approved a food additive petition for PHOs. Accordingly, we are proposing to remove PHOs from our food regulations in light of our determination that PHOs are no longer GRAS.

Furthermore, based on our current review of scientific data and information, as well as previous safety reviews performed to support various FDA actions regarding *trans* fat, we are proposing to prohibit all prior-sanctioned uses of PHOs. 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 (FD&C Act) if the use was sanctioned or approved prior to September 6, 1958. In accordance with FDA's 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. We have tentatively determined that the prior-sanctioned uses of PHOs may render food injurious to health. Consequently, we are proposing to revoke the prior-sanctioned uses of PHOs.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule if finalized, would remove PHOs as an optional ingredient in the standards of identity for peanut butter and canned tuna, revise the regulations affirming the use of menhaden oil and rapeseed oil as GRAS to delete language regarding partially hydrogenated forms of these oils, and revoke the regulation affirming hydrogenated fish oil as GRAS as an indirect food substance. We are also proposing to revoke prior sanctions (*i.e.,* pre-1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls, and buns.

C. Legal Authority

We are proposing this rule consistent with our authority in sections 201, 401, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 341, 342, 348, and 371). We discuss our legal authority in greater detail in section V of this document.

D. Costs and Benefits

We estimated the costs of removing PHO-containing foods from the market including those of product reformulation, relabeling products, changing food recipes, finding substitute ingredients, and changes in functional and sensory product properties, such as taste, texture, and shelf life. The benefits of the rule accrue from reduction of coronary heart diseases. Discounted at 7 percent over a 20-year period, the annualized primary cost estimate of the rule is $24.5 million with a lower bound estimate of $20.8 million and an upper bound estimate of $29.7 million. The annualized benefits of this rule discounted at 7 percent over 20-year period is $61.5 million for the primary estimate with a lower bound of $20.1 million and an upper bound of $120.7 million.

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event the direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received in response to this companion proposed rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because we believe the rule contains noncontroversial changes and there is little likelihood that there will be significant adverse comments opposing the rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the direct final rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to a part of the direct final rule and that part can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of the significant adverse comment.

If any significant adverse comments to the direct final rule are received during the comment period, FDA will publish,

within 30 days after the comment period ends, a notice of significant adverse comment and withdraw the direct final rule. If we withdraw the direct final rule, any comments received will be considered comments on the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedure.

If no significant adverse comment is received in response to the direct final rule during the comment period, no further action will be taken related to this proposed rule. Instead, we will publish a document confirming the effective date within 30 days after the comment period ends. Additional information about direct final rulemaking procedures is set forth in the document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures,'' announced and provided in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance may be accessed at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.*

III. Table of Abbreviations/Acronyms Used in This Document

Abbreviation/ acronym	What it means
CFR	Code of Federal Regulations.
CHD	Coronary heart disease.
CVD	Cardiovascular disease.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FR	Federal Register.
GRAS	Generally Recognized as Safe.
IP–TFA	Industrially Produced *Trans* Fatty Acid.
LEAR oil	Low Erucic Acid Rapeseed Oil.
%en	Percentage of Total Energy Intake per Day.
PHOs	Partially Hydrogenated Oils.
USC	United States Code.
USDA	United States Department of Agriculture.

IV. Background

In the **Federal Register** of November 8, 2013 (78 FR 67169), we announced our tentative determination that, based on currently available scientific information, PHOs are no longer GRAS under any condition of use in human food and, therefore, are food additives. Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) defines a food additive, in part, as a substance that is not GRAS, and section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)) establishes that food bearing or containing a food additive that is unsafe within the meaning of section 409 of the FD&C Act (21 U.S.C. 348) is adulterated. Section 409 of the FD&C Act establishes that a food additive is unsafe for the purposes of section 402(a)(2)(C) of the FD&C Act unless certain criteria are met, such as conformance with a regulation prescribing the conditions under which the additive may be safely used. In the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order (the Order) announcing our final determination that there is no longer a consensus among qualified experts that PHOs, the primary dietary source of industrially produced *trans* fatty acids (IP–TFA), are GRAS for any use in human food. For a discussion of the science regarding PHOs, we refer readers to the Order and to our tentative determination that PHOs are no longer GRAS for any use in food (see 78 FR 67169 at 67171).

The Order acknowledged (see 80 FR 34650 at 34651) that the regulations at 21 CFR part 184, ''Direct Food Substances Affirmed as Generally Recognized as Safe,'' (GRAS affirmation regulations) include partially hydrogenated versions of two oils: (1) menhaden oil (§ 184.1472(b) (21 CFR 184.1472(b))); and (2) low erucic acid rapeseed (LEAR) oil (§ 184.1555(c)(2) (21 CFR 184.1555(c)(2))). Partially hydrogenated menhaden oil was affirmed as GRAS for use in food (54 FR 38219, September 15, 1989) on the basis that the oil is chemically and biologically comparable to commonly used partially hydrogenated vegetable oils such as corn and soybean oils. Partially hydrogenated LEAR oil was affirmed as GRAS for use in food (50 FR 3745, January 28, 1985) based on published safety studies (*i.e.,* scientific procedures) (21 CFR 170.30). In the Order, we stated that we would amend the GRAS affirmation regulations for menhaden oil and LEAR oil (§§ 184.1472 and 184.1555) in a future rulemaking (see 80 FR 34650 at 34651, 34655, and 34667).

In addition, our GRAS affirmation regulation for hydrogenated fish oil at § 186.1551 (21 CFR 186.1551) (44 FR 28323, May 15, 1979), provides for partial hydrogenation of oils expressed from fish, primarily menhaden, and secondarily herring or tuna, used as a constituent of cotton and cotton fabrics used for dry food packaging.

Certain standard of identity regulations include PHOs as an optional ingredient. Since 1990, the standard of identity for canned tuna at § 161.190 (21 CFR 161.190) has provided for the use of PHOs as an optional seasoning or flavoring ingredient in canned tuna in water (55 FR 45795, October 31, 1990). Since 1968, the standard of identity for peanut butter at § 164.150 (21 CFR 164.150) has provided for the use of PHOs as an optional stabilizing ingredient (33 FR 10506, July 24, 1968).

In addition, based on a review of our regulations and on comments submitted in response to our tentative determination, ''prior sanctions'' exist for the use of PHOs in margarine, shortening, and bread, rolls, and buns. As discussed in more detail in section VI of this document, a prior sanction exempts a specific use of a substance in food if the use was sanctioned or approved prior to September 6, 1958, from the definition of a food additive under section 201(s)(4) of the FD&C Act and from all related food additive provisions of the FD&C Act.

V. Legal Authority

We are issuing this proposed rule under the legal authority of sections 201, 401, 402, 409, and 701 of the FD&C Act. The FD&C Act defines ''food additive,'' in relevant part, as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of food, if such substance is not generally recognized by experts as safe under the conditions of its intended use (section 201(s) of the FD&C Act). The definition of ''food additive'' exempts any uses that are the subject of a prior sanction (section 201(s)(4) of the FD&C Act). Food additives are deemed unsafe except to the extent that FDA approves their use (section 409(a) of the FD&C Act). Food is adulterated when it contains an unapproved food additive (section 402(a)(2)(C) of the FD&C Act). In addition, we may establish standards of identity for foods to promote honesty and fair dealing in the interest of consumers (section 401 of the FD&C Act). Section 701(a) of the FD&C Act provides the authority to issue regulations for the efficient enforcement of the FD&C Act.

With respect to prior sanctions, section 201(s)(4) of the FD&C Act exempts from the definition of a food additive any substance used in accordance with a sanction or approval granted under the FD&C Act, the Meat Inspection Act, or the Poultry Products Inspection Act before the enactment of the Food Additives Amendment of 1958 on September 6, 1958. This type of sanction or approval is referred to as a ''prior sanction.'' Our regulation, at 21 CFR 170.3(l), defines this term as an explicit approval granted with respect to use of a substance in food before September 6, 1958, under the FD&C Act, the Meat Inspection Act, or the Poultry Products Inspection Act. Another FDA

regulation (21 CFR 181.5(a)) states that a prior sanction exists only for a specific use(s) of a substance in food, *i.e.,* the level(s), condition(s), product(s), etc., for which there was explicit approval by FDA or the U.S. Department of Agriculture (USDA) before September 6, 1958. The ''explicit approval'' needed to establish a prior sanction may be either formal or informal. If a formal approval, such as a food standard regulation issued under the FD&C Act before 1958, does not exist, correspondence issued by authorized FDA officials can constitute an informal prior sanction.

In accordance with FDA's general regulations regarding prior sanctions found at 21 CFR 181.1(b) and 181.5(c), 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 and, thus, adulterates the food under section 402 of the FD&C Act.

VI. Description of the Proposed Rule

The proposed rule, if finalized, would:

- Amend the food standard for canned tuna at § 161.190 to no longer include partially hydrogenated vegetable oil as an optional ingredient for seasoning in canned tuna packed in water;
- Amend the food standard for peanut butter at § 164.150 to no longer include partially hydrogenated vegetable oil as an optional stabilizing ingredient in peanut butter;
- Revise § 184.1472 to delete references to partially hydrogenated menhaden oil;
- Revise § 184.1555 to delete references to partially hydrogenated LEAR oil;
- Revoke § 186.1551, which permits the use of partially hydrogenated fish oil in cotton and cotton fabrics used for dry food packaging; and
- Revoke the prior sanctions for the use of PHOs in margarine, shortening, and bread, rolls, and buns.

A. Amendment of Standard of Identity Regulations

Standard of identity regulations for food are issued under section 401 of the FD&C Act and do not provide either an authorization or an exemption from regulation as a food additive under section 409 of the FD&C Act. FDA's standards of identity, among other things, establish the common or usual name for a food and define the basic nature of the food, generally in terms of the types of ingredients that it must contain (*i.e.,* mandatory ingredients) and that it may contain (*i.e.,* optional ingredients). The purpose of food standards is to promote honesty and fair dealing in the interest of consumers. Therefore, the inclusion of PHOs in certain standards of identity does not necessarily mean that their use is permissible under section 409 of the FD&C Act. As such, our proposed changes to these standard of identity regulations are merely for clarification purposes.

1. Canned Tuna—§ 161.190

Since 1990, our regulations, at § 161.190(a) have described canned tuna as processed flesh of fish of the species enumerated in § 161.190(a)(2), commonly known as tuna, in any of the forms of pack specified in § 161.190(a)(3) (55 FR 45795). The standard of identity for canned tuna includes, as an optional ingredient, edible vegetable oil or partially hydrogenated vegetable oil, excluding olive oil, to be used alone or in combination, as seasoning in canned tuna packed in water (§ 161.190(a)(6)(viii)).

The proposed rule would delete the words ''or partially hydrogenated vegetable oil'' and ''alone or in combination'' from the list of optional ingredients in canned tuna (§ 161.190(a)(6)(viii)). The remaining term ''edible vegetable oil'' would not include the use of any partially hydrogenated oils in canned tuna. (See Ref. 1.)

2. Peanut Butter—§ 164.150

Since 1968, our regulations, at § 164.150 have described standardized peanut butter as a product prepared by grinding one of the shelled and roasted peanut ingredients provided for by § 164.150(b), to which may be added safe and suitable seasoning and stabilizing ingredients provided for by § 164.150(c), if such seasoning and stabilizing ingredients do not, in the aggregate, exceed 10 percent of the weight of the finished food (33 FR 10506).

The standard of identity for peanut butter, at § 164.150(c), includes oil products as optional stabilizing ingredients, which must be hydrogenated vegetable oils; for purposes of § 164.150(c), hydrogenated vegetable oil is considered to include partially hydrogenated vegetable oil.

The proposed rule would revise the standard of identity for peanut butter by deleting the reference to partially hydrogenated vegetable oil in § 164.150(c). The proposed rule also would make a minor editorial change by replacing ''shall'' with ''must.''

B. Amendment/Revocation of GRAS Affirmation Regulations

1. Menhaden Oil—§ 184.1472

Since 1997, our GRAS affirmation regulations for menhaden oil at § 184.1472(a) have described menhaden oil as being prepared from fish of the genus *Brevoortia,* commonly known as menhaden, by cooking and pressing (62 FR 30756, June 5, 1997). The resulting crude oil is then refined using the following steps: storage (winterization), degumming (optional), neutralization, bleaching, and deodorization.

Our regulations, at § 184.1472(b), address the preparation of partially hydrogenated and hydrogenated menhaden oils (§ 184.1472(b)(1)), the specifications for partially hydrogenated and hydrogenated menhaden oils (§ 184.1472(b)(2)), the uses of partially hydrogenated and hydrogenated menhaden oils (§ 184.1472(b)(3)), and the name to be used on the product's label (§ 184.1472(b)(4)).

The proposed rule would amend the GRAS affirmation regulation for menhaden oil at § 184.1472 to delete references to partially hydrogenated menhaden oil from § 184.1472(b), (b)(1), (b)(2), (b)(2)(iv), (b)(3), and (b)(4). The proposed rule also would change the iodine value specification for hydrogenated menhaden oil from the current specification of ''not more than 10,'' to ''not more than 4.'' This is consistent with our definition of PHOs in the Order. For the purposes of the Order, we defined PHOs as fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value greater than 4 (80 FR 34650 at 34651). The proposed rule also would make minor editorial changes, such as referring to hydrogenated menhaden oil (singular) rather than to hydrogenated menhaden oils (plural) and substituting ''is'' for ''are'' to reflect that the rule would refer to only hydrogenated menhaden oil.

2. Low Erucic Acid Rapeseed Oil—§ 184.1555

Since 1985, our GRAS affirmation regulations for LEAR oil, at § 184.1555(c) have described LEAR oil, also known as canola oil, as the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica napus* or *B. campestris* of the family *Cruciferae* (50 FR 3745 at 3755). The plant varieties are those producing oil-bearing seeds with a low erucic acid content. Chemically, low erucic acid rapeseed oil is a mixture of triglycerides, composed of both saturated and unsaturated fatty acids, with an erucic acid content of no more

than 2 percent of the component fatty acids. The regulation provides for the partial hydrogenation of LEAR oil (§ 184.1555(c)(2)) and discusses the oil's purity (§ 184.1555(c)(3)) and uses in food (§ 184.1555(c)(4)).

The proposed rule would delete § 184.1555(c)(2) entirely, delete all mention of partially hydrogenated LEAR oil from § 184.1555(c)(3) and (4), and redesignate current § 184.1555(c)(3) and (4) as § 184.1555(c)(2) and (3), respectively.

3. Hydrogenated Fish Oil—§ 186.1551

Since 1979, our GRAS affirmation regulations for hydrogenated fish oil at § 186.1551 have described hydrogenated fish oil as a class of oils produced by the partial hydrogenation of oils expressed from fish, primarily menhaden and secondarily herring or tuna (44 FR 28323). The regulation allows the use of this oil as a constituent of cotton and cotton fabrics used for dry food packaging. It was noted in the final rule entitled ''Substances Generally Recognized as Safe and Indirect Food Substances Affirmed as Generally Recognized as Safe; Hydrogenated Fish Oil'' that no reports of a prior-sanctioned use for hydrogenated fish oil were submitted in response to the proposed rule, and therefore, in accordance with that proposal, any right to assert a prior sanction for a use of hydrogenated fish oil under conditions different from those set forth in this regulation had been waived (44 FR 28323). Prior sanctions for hydrogenated fish oil that differ from the use set forth in the GRAS affirmation regulations do not exist or have been waived (§ 186.1551(e)).

The proposed rule would delete the GRAS affirmation regulations for hydrogenated fish oil at § 186.1551 entirely. Our earlier determination that there are no prior sanctions for this ingredient different from the use provided for in § 186.1551 or that any other prior sanctions have been waived remains in effect.

C. Comments on Prior-Sanctioned Uses of PHOs

We stated in our tentative determination that we were not aware that FDA or USDA had granted any explicit approval for any use of PHOs in food before the 1958 Food Additives Amendment to the FD&C Act (78 FR 67169 at 67171) and requested comments on whether there was knowledge of an applicable prior sanction for the use of PHOs in food (78 FR 67169 at 67174). We discuss the comments in this section. In addition, we tentatively conclude that any prior sanctions for other uses of PHOs in food different from the uses discussed in sections VI.C.1, 2, and 3 of this proposed rule do not exist or have been waived.

1. GRAS Affirmation Regulations for Menhaden Oil, LEAR Oil, and Hydrogenated Fish Oil

As noted in the Order we acknowledged that we had, in our regulations, previously affirmed as GRAS the use of PHOs in certain foods or food contact substances (80 FR 34650 at 34651). We describe these regulations and our proposed revocation elsewhere in this proposed rule. Although some comments on our tentative determination suggested that these uses are prior-sanctioned, in each case the regulation affirming the status of the use as GRAS post-dates 1958. We have no evidence that the uses affirmed for menhaden oil (§ 184.1472) or LEAR oil (§ 184.1555) are prior-sanctioned. In the case of hydrogenated fish oil (§ 186.1551), any prior sanctions for this ingredient different from the use in the GRAS affirmation regulation do not exist or have been waived (§ 186.1551(e)).

2. Canned Tuna and Peanut Butter Standards of Identity

Some comments identified the standards of identity for canned tuna (§ 161.190) and peanut butter (§ 164.150) as providing proof of prior sanction of PHOs because ''partially hydrogenated vegetable oil'' is explicitly listed as an optional ingredient in each of those regulations. As discussed in section VI.A of this document, the standards of identity for canned tuna and peanut butter both post-date 1958. We have no evidence of any prior sanctions for the use of PHOs as described in the standards of identity for canned tuna and peanut butter.

3. Mayonnaise, French Dressing, and Salad Dressing Standards of Identity

Some comments identified the pre-September 6, 1958, standards of identity for mayonnaise (21 CFR 169.140), salad dressing (21 CFR 169.150), and French dressing (21 CFR 169.115 (revoked effective February 14, 2022 (87 FR 2038))) and claimed that they constituted prior sanctions for PHOs. The comments acknowledged that these standards did not explicitly list PHOs but argued that because the standards allow use of ''edible vegetable oil'' in the standardized products, they were understood by both FDA and industry to include PHOs because vegetable oil can be hydrogenated.

We issued the standards of identity for mayonnaise, French dressing, and salad dressing in 1950 (15 FR 5227, August 12, 1950). They permit use of ''edible vegetable oil'' in the standardized products. No comments to our tentative determination identified any reference to hydrogenation of oils in the rulemaking issuing these standards. No comments suggested that industry used PHOs in these products at the time or that industry is currently using PHOs in these products. We understand that, since at least 1940, hydrogenation changes the physical properties of an oil and therefore, changes a product's identity (see Ref. 1, discussing labeling for, among other things, ''vegetable oils which have not had their identity changed through hydrogenation . . .''). Thus, the references to ''edible vegetable oil'' in these standards, without mention of hydrogenation or hardening, do not include PHOs or fully hydrogenated oils. Therefore, the evidence does not provide an adequate basis on which to establish a prior sanction.

4. Margarine, and Bread, Rolls, and Buns Standards of Identity, and Shortening

Some comments identified the pre-September 6, 1958, standards of identity for bread, rolls, and buns (§ 136.110 (21 CFR 136.110)), and margarine (§ 166.110 (21 CFR 166.110)), and claimed that they constituted prior sanctions for PHOs. The comments acknowledged that these standards did not explicitly list PHOs but argued that because the standards allow use of ''shortening'' (bread, rolls, and buns), and ''oil'' (margarine) in the standardized products, they were understood by both FDA and industry to include PHOs because shortening and oil can be hydrogenated. Moreover, the comments acknowledged that, while there is no standard of identity for shortening that mentions PHOs specifically, historical evidence shows that shortening was generally understood to contain PHOs before 1958.

We issued the standard of identity for margarine in 1941 (6 FR 2761, June 7, 1941). At that time, the standard of identity stated that oleomargarine is prepared with one or more of several optional fat ingredients, including the rendered fat, or oil, or stearin derived therefrom (any or all of which may be hydrogenated), of cattle, sheep, swine, or goats or any vegetable food fat or oil, or oil or stearin derived therefrom (any or all of which may be hydrogenated) (6 FR 2761 at 2762). The standard of identity, as it existed in 1941, contained no specific limitations on these ingredients. The current standard of

identity (now codified at § 166.110) states, in relevant part, that margarine may include edible fats and/or oils from animals, vegetables, or fish, or mixtures of these, which may have been subjected to an accepted process of physico-chemical modification (§ 166.110(a)(1)). The standard of identity for margarine also states that margarine ''may contain small amounts of other lipids, such as phosphatides or unsaponifiable constituents, and of free fatty acids naturally present in the fat or oil'' (id.).

We issued the standard of identity for bread, rolls, and buns in 1952 (17 FR 4453, May 15, 1952). The standard of identity, which is now codified at § 136.110, identifies ''shortening'' as an optional ingredient. We initially proposed a more detailed description of the term ''shortening'' in 1941 that was very similar to the term used in the margarine standard issued that same year; that description indicated that shortening is composed of fat or oil from animals, vegetables, or fish, any or all of which may be hydrogenated, or of butter, or any combination of two or more such articles (6 FR 2771, June 7, 1941). However, the final rule that we issued in 1952 simply referred to ''shortening'' and did not prescribe the contents of or otherwise define ''shortening'' (17 FR 4453). Similarly, the current standard of identity mentions ''shortening,'' but does not prescribe the contents of or otherwise define ''shortening'' (see § 136.110(c)(5)). Additionally, the standard of identity, as it existed in 1952, contained no specific limitations on these ingredients.

In addition to identifying these standards of identity, some comments to our tentative determination stated that the reference to hydrogenation in the pre-September 6, 1958, standard of identity for margarine was likely to have meant partially hydrogenated oils as a practical matter, based on the inherent difference in the functional characteristics of partially and fully hydrogenated oils and the history of use of PHOs in margarine products.

Other comments submitted historical evidence relating to widespread use of PHOs in margarine and shortening before 1958. This evidence included a 1945 USDA publication, ''Foods—Enriched, Restored, Fortified'' (Ref. 2), that described margarine by saying: ''As it is made by 41 manufacturing plants in the United States, margarine contains a mixture of animal fats and vegetable oils or one or the other—fats that have been used as food for centuries. These are partially hydrogenated and blended to give the right spreading consistency.'' The comments also submitted two patents, one from 1915 for ''[a] homogeneous lard-like food product consisting of an incompletely hydrogenized vegetable oil,'' (Ref. 3) and one from 1957 for ''fluid shortening,'' stating ''[s]hortenings heretofore available for baking have included . . . compounded or blended shortenings, made from mixtures of naturally hard fats or hydrogenated vegetable oils with liquid, soft, or partially hydrogenated vegetable oils'' (Ref. 4). One comment cited a Supreme Court decision regarding the patentability of the product of partial hydrogenation of vegetable oil for use as shortening (*Berlin Mills Co.* v. *Procter & Gamble Co.,* 254 U.S. 156 (1920)). In finding the 1915 patent invalid, the Court held that ''it was known before [the patentee] took up the subject that a vegetable oil could be changed into a semi-solid, homogeneous, substance by a process of hydrogenation arrested before completion and that it might be edible'' (*Berlin Mills,* 254 U.S. at 165).

Some comments said that we intended to include PHOs in the terms ''shortening'' and ''oil . . . (any or all of which may be hydrogenated)'' used in these pre-1958 standards of identity. One comment said that we have, in other contexts, used the term ''hydrogenated oils'' when we intended to refer to PHOs (see, *e.g.,* 68 FR 41434 at 41443, July 11, 2003 (''*trans* fatty acids (provided by food sources of hydrogenated oil)'') and that the term ''partially hydrogenated'' did not appear in our regulations until 1978 (43 FR 12856, March 28, 1978 (amending the food labeling regulations by substituting ''hydrogenated'' and ''partially hydrogenated'' for ''saturated'' and ''partially saturated'' when describing a fat or oil ingredient)). Additionally, in trade correspondence in 1940, we described three general types of shortening in response to a question about ingredient labeling; we said that the types of shortening were: ''(1) vegetable shortenings composed wholly of mixtures of edible vegetable oils, which have been subjected to a chemical hardening process known as hydrogenation; (2) mixtures of vegetable oils with or without varying proportions of hardened vegetable oils and with edible animal fats; and (3) hydrogenated mixtures of vegetable oils and marine animal oils (Ref. 1).'' In addition, during a rulemaking regarding oils and fats, we used the phrase ''oil . . . (any or all of which may be hydrogenated)'' and acknowledged that this category included PHOs (36 FR 11521, June 15, 1971). We proposed that, if the vegetable fats or oils present are hydrogenated, the ingredient declaration should include the term ''hydrogenated,'' ''partially hydrogenated,'' or ''hardened,'' and gave an example of ''partially hydrogenated cottonseed oil'' (36 FR 11521).

Thus, a prior sanction, as provided for in section 201(s)(4) of the FD&C Act, exists for the uses of PHOs in margarine, shortening, and bread, rolls, and buns. However, as discussed in the next section, we are proposing to revoke the prior sanction for these uses.

VII. Revocation of Prior-Sanctioned Uses of PHOs

We have tentatively concluded that there are prior-sanctioned uses of PHOs in margarine, shortening, and bread, rolls, and buns, and that these uses may be injurious to health and may adulterate food under section 402 of the FD&C Act. Therefore, we are proposing to revoke the prior sanction for the uses of PHOs in margarine, shortening, and bread, rolls, and buns. Our tentative conclusion is based on our current review of scientific data and information, as well as previous safety reviews performed in support of various FDA actions regarding *trans* fat and PHOs spanning 1999 to 2018 (see 64 FR 62746, November 17, 1999; 68 FR 41434, July 11, 2003; 78 FR 67169, November 8, 2013; 80 FR 34650, June 17, 2015; 83 FR 23382, May 21, 2018). In our review for this proposed rule, we estimated the dietary exposure for IP–TFA from the prior-sanctioned uses of PHOs in margarine, shortening, and bread, rolls, and buns (Ref. 5) and conducted a quantitative risk assessment for the coronary heart disease (CHD) and cardiovascular disease (CVD) risks associated with this estimated exposure to IP–TFA (Ref. 6). We also conducted an updated scientific review of published studies and evaluations by expert panels on the safety of *trans* fat (Ref. 7).

As for the standards of identity for margarine and bread, rolls, and buns, no corresponding revision to these regulations would be necessary. Each standard, as currently written, is limited so that only ''safe and suitable'' ingredients may be used, and neither current standard expressly refers to hydrogenation or partial hydrogenation (see §§ 136.110(b) and 166.110(a)). Moreover, our regulations provide that no provision of any regulation prescribing a definition and standard of identity is to be construed as affecting the concurrent applicability of the general provisions of the FD&C Act and our regulations (see § 130.3(c) (21 CFR 130.3(c))). For example, all standard of

identity regulations contemplate that the food and all articles used as components or ingredients must not be poisonous or deleterious (see § 130.3(c); see also § 130.3(d) (further defining ''safe and suitable'')). As for shortening, our standards of identity do not describe the contents of or otherwise define ''shortening,'' so no amendment is necessary.

VIII. Trans Fat Consumption Health Effects

A. Updated Scientific Literature and Expert Opinion Review

Our Order references three safety memoranda prepared by FDA that document our review of the available scientific evidence regarding human health effects of *trans* fat, focusing on the adverse effects of *trans* fat on risk of CHD (Refs. 8 to 10). In addition, we previously reviewed the health effects of IP–TFA and PHOs in 2013 in support of our tentative determination regarding the GRAS status of PHOs (78 FR 67169, Docket No. FDA–2013–N–1317). Our Order announced our final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food (80 FR 34650). The safety reviews for the Order, together with the previous safety reviews of IP–TFA and PHOs, provided important scientific background information for our review and denial of a food additive petition for certain uses of PHOs in 2018 (83 FR 23382).

We based our Order on the available scientific evidence that included results from controlled feeding studies on *trans* fatty acid consumption in humans, findings from long-term prospective epidemiological studies, and the opinions of expert panels that there is no threshold intake level for IP–TFA that would not increase an individual's risk of CHD. We also published a safety review for specific uses of PHOs in a notice denying a food additive petition for certain uses of PHOs in food (83 FR 23382, Docket No. FDA–2015–F–3663)). This safety review reinforced our 2015 scientific review supporting the final determination that PHOs are not GRAS for use in human food. We denied the food additive petition because we determined that the petition did not contain convincing evidence to support the conclusion that the proposed uses of PHOs were safe (83 FR 23382 at 23391). All the previously mentioned safety reviews of IP–TFA and PHOs provide important scientific background information for review of the health effects of the prior-sanctioned uses of PHOs.

We are not aware of any new, scientific literature on the safety of IP–TFA and PHOs that would cause us to reconsider our previous safety conclusions. International and U.S. expert panels, using additional scientific evidence available since 2015, have continued to recognize the positive linear relationship between increased *trans* fat intake and increased low density lipoprotein cholesterol blood levels associated with increased CHD risk, have concluded that *trans* fats are not essential nutrients in the diet, and have recommended that *trans* fat consumption be kept as low as possible.

B. Estimated Exposure to Trans Fat From Prior-Sanctioned Uses of PHOs

For this proposed rule, in order to estimate the risks to CHD and CVD associated with consumption of IP–TFA from prior-sanctioned uses of PHOs, we first had to estimate dietary exposure to IP–TFA from these uses of PHOs. We used two non-consecutive days of 24-hour dietary recall data from the 2011–2014 National Health and Nutrition Examination Survey (NHANES) to estimate dietary exposure to IP–TFA from the use of PHOs in margarine and shortening (which includes the prior-sanctioned uses in bread, rolls, and buns due to the use of margarine and/or shortening in the food). We included all foods reported in NHANES that contained margarine or shortening as an ingredient in our analysis. We applied levels of *trans* fat commonly used in margarine and shortening manufactured before the publication of the tentative determination in 2013. These use levels reflect our conservative assumption that manufacturers may revert back to using PHOs at these higher use levels in margarine and shortening if prior sanctions are not revoked. For the U.S. population aged 2 years and older, we estimated a cumulative mean dietary IP–TFA exposure of 0.3 grams per person per day for typical *trans* fat levels, for both margarine and shortening, based on 53 percent of the population consuming margarine or shortening (Ref. 5). The mean IP–TFA exposure for the total population (*i.e.,* per capita intake) was also determined (Ref. 7). Expressed as a percentage of total energy intake per day (%en) based on a 2000 calorie diet, the mean per-capita IP–TFA exposure for typical IP–TFA levels in foods was estimated to be 0.07%en (Ref. 7).

C. Risk Estimates Associated With Prior-Sanctioned Uses of PHOs

We used four risk methods to estimate change in CHD and CVD risk associated with 0.07%en IP–TFA exposure from prior-sanctioned uses of PHOs (Ref. 6). Our assessment methodology is documented in our memorandum (Ref. 6).

Our quantitative risk assessments demonstrate that there is a substantial health risk associated with 0.07%en from IP–TFA from prior-sanctioned uses of PHOs (Ref. 6). Along with our Order, our denial of the food additive petition for certain uses of PHOs in food, and our recent updated scientific literature review on the safety of PHOs and *trans* fat (Ref. 7), these analyses provide further support for the revocation of the prior-sanctioned uses of PHOs. The scientific consensus is that there is no threshold intake level of IP–TFA that would not increase an individual's risk of CHD (Ref. 7). Thus, based on the available data, we tentatively conclude that PHOs used in food may cause the food to be injurious to health and that the use of PHOs as ingredients in margarine, shortening, and bread, rolls, and buns would adulterate these foods under section 402(a)(1) of the FD&C Act.

IX. Economic Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all costs, benefits, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule may require some

small business entities to undertake costly reformulations, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The benefits of this proposed rule are expected to accrue from the number of coronary heart diseases averted from discontinued use of foods made with PHOs. The removal of PHO containing foods from the marketplace will limit their access by most consumers. Such action will protect the public by reducing the health risk of developing CHDs and improving population health among those who would otherwise consume products containing PHOs. Continual use of PHOs is associated with increased CHD and CVDs. Per capita higher intake of PHOs can lead to elevated risk of CHD and CVDs among the U.S. population. Therefore, FDA notes that the benefit of this rule relative to baseline market conditions are expected to decrease over time as PHO containing products exit the marketplace. The annualized benefits of this rule at a 7 percent discount rate over a 20-year period is $61.5 million for the primary estimate with a lower bound of $20.1 million and an upper bound of $120.7 million.

The quantified costs of the rule are from reformulating manufactured products currently produced with PHOs, relabeling products that contain PHOs, changing recipes for some PHO containing breads by retail bakeries, finding substitute ingredients as well as costs arising from functional and sensory product properties such as taste and texture. The annualized cost of the rule at a 7 percent discount rate over a 20-year period has a primary estimate of $24.5 million with a lower bound estimate of $20.8 million and an upper bound estimate of $29.7 million.

Table 1 presents a summary of costs and benefits of the proposed rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE, IN 2020 MILLION DOLLARS

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$61.5	$20.1	$120.7	2020	7	20	
	58.3	19.1	114.3	2020	3	20	
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized millions/year	24.5	20.8	29.7	2020	7	20	
	20.2	17.1	33.2	2020	3	20	
AnnualizedQuantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized millions/year					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.
Small Business: Potential impact on small business entities that are currently continuing to use or produce PHOs and PHO containing ingredients in their products.
Wages: None.
Growth: None.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 11) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

X. Analysis of Environmental Impacts

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set

forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. We invite comments from tribal officials or other interested parties, on any potential impact on Indian tribes from this proposed action.

XIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIV. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, Trade Correspondence TC–62 (Feb. 15, 1940), reprinted in Kleinfeld, Vincent A. and Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act Judicial and Administrative Record 1938–1949.*
2. U.S. Bureau of Human Nutrition and Home Economics (1945). *Foods—Enriched, Restored, Fortified.* USDA, page 11. available at *https://naldc.nal.usda.gov/download/5804422/PDF.*
3. Serial No. 591,726, Record No. 1,135,351, U.S. Patent Office, Official Gazette of the U.S. Patent Office, April 13, 1915, at 492; available at: *https://www.uspto.gov/learning-and-resources/official-gazette/official-gazette-patents.*
4. Serial No. 639,222, Record No. 2,909,432, U.S. Patent Office, Official Gazette of the U.S. Patent Office, October 20, 1959, at 697; available at: *https://www.uspto.gov/learning-and-resources/official-gazette/official-gazette-patents.*
5. FDA, Memorandum from D. Doell to E. Anderson, Exposure to *Trans* Fat from the Prior-Sanctioned Uses of Partially Hydrogenated Oils (PHOs), October 23, 2019.
6. FDA, Memorandum from J. Park to E. Anderson, Toxicology Prior Sanction PHO Review Memo One: Agency-initiated Quantitative Coronary Heart and Cardiovascular Disease Risk Assessment of Industrially-Produced *Trans* Fatty Acids (IP–TFA) Exposure from Prior- Sanctioned Uses of Partially Hydrogenated Vegetable Oils (PHOs), October 22, 2019.
7. FDA, Memorandum from J. Park to E. Anderson, Toxicology Prior Sanction PHO Review Memo Two: Scientific Literature Review of Safety Information Regarding Prior-Sanctioned Uses of Partially Hydrogenated Oils (PHOs) in Margarine and Shortenings, October 22, 2019.
8. FDA, Memorandum from J. Park to M. Honigfort, Scientific Update on Experimental and Observational Studies of *Trans* Fat Intake and Coronary Heart Disease Risk, June 11, 2015.
9. FDA Memorandum from J. Park to M. Honigfort, Literature Review, June 11, 2015.
10. FDA, Memorandum from J. Park to M. Honigfort, Quantitative Estimate of Industrial *Trans* Fat Intake and Coronary Heart Disease Risk, June 11, 2015.
11. FDA, ''Revocation of Uses of Partially Hydrogenated Oils in Foods'' Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Analysis. Also available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

21 CFR Part 164

Food grades and standards, Nuts, Peanuts.

21 CFR Part 184

Food additives.

21 CFR Part 186

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose to amend 21 CFR parts 161, 164, 184, and 186 as follows:

PART 161—FISH AND SHELLFISH

■ 1. The authority citation for part 161 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

■ 2. In § 161.190, revise paragraph (a)(6)(viii) to read as follows:

§ 161.190 Canned tuna.

(a) * * *

(6) * * *

(viii) Edible vegetable oil, excluding olive oil, used in an amount not to exceed 5 percent of the volume capacity of the container, with or without any suitable form of emulsifying and suspending ingredients that has been affirmed as GRAS or approved as a food additive to aid in dispersion of the oil, as seasoning in canned tuna packed in water.

* * * * *

PART 164—TREE NUT AND PEANUT PRODUCTS

■ 3. The authority citation for part 164 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

■ 4. In § 164.150, revise paragraph (c) to read as follows:

§ 164.150 Peanut butter.

* * * * *

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, and color additives are not suitable ingredients in peanut butter. Oil products used as optional stabilizing ingredients must be hydrogenated vegetable oils.

* * * * *

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 5. The authority citation for part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 6. In § 184.1472, revise paragraph (b) to read as follows:

§ 184.1472 Menhaden oil.

* * * * *

(b) *Hydrogenated menhaden oil.* (1) Hydrogenated menhaden oil is prepared by feeding hydrogen gas under pressure to a converter containing crude menhaden oil and a nickel catalyst. The reaction is begun at 150 to 160 °C and after 1 hour the temperature is raised to

180 °C until the menhaden oil is fully hydrogenated.

(2) Hydrogenated menhaden oil meets the following specifications:

(i) *Color.* Opaque white solid.

(ii) *Odor.* Odorless.

(iii) *Saponification value.* Between 180 and 200.

(iv) *Iodine number.* Not more than 4.

(v) *Unsaponifiable matter.* Not more than 1.5 percent.

(vi) *Free fatty acids.* Not more than 0.1 percent.

(vii) *Peroxide value.* Not more than 5 milliequivalents per kilogram of oil.

(viii) *Nickel.* Not more than 0.5 part per million.

(ix) *Mercury.* Not more than 0.5 part per million.

(x) *Arsenic (as As).* Not more than 0.1 part per million.

(xi) *Lead.* Not more than 0.1 part per million.

(3) Hydrogenated menhaden oil is used as edible fat or oil, as defined in § 170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) The name to be used on the label of a product containing hydrogenated menhaden oil must include the term ''hydrogenated,'' in accordance with § 101.4(b)(14) of this chapter.

■ 7. In § 184.1555, revise paragraphs (c)(2) and (3) and remove (c)(4) to read as follows:

§ 184.1555 Rapeseed oil.

* * * * *

(c) * * *

(2) In addition to limiting the content of erucic acid to a level not exceeding 2 percent of the component fatty acids, low erucic acid rapeseed oil must be of a purity suitable for its intended use.

(3) Low erucic acid rapeseed oil is used as an edible fat and oil in food, except in infant formula, at levels not to exceed current good manufacturing practice.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 8. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 186.1551 [Removed]

■ 9. Remove § 186.1551.

Dated: July 28, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–16724 Filed 8–8–23; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 262, 264, 265, 266, 270, 271 and 441

[EPA–HQ–OLEM–2023–0081]; FRL 8687–01–OLEM

RIN 2050–AH23

Hazardous Waste Generator Improvements Rule, the Hazardous Waste Pharmaceuticals Rule, and the Definition of Solid Waste Rule; Technical Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to make technical corrections that correct or clarify several parts of the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. These technical corrections correct or clarify specific provisions in the existing hazardous waste regulations that were promulgated in the Hazardous Waste Generator Improvements rule, the Hazardous Waste Pharmaceuticals rule, and the Definition of Solid Waste rule. This rule also makes other minor corrections that fall within the same sections of the hazardous waste regulations but are independent of these three rules. Examples of the types of corrections being made in this rule include, but are not limited to, correcting typographical errors, correcting incorrect or outdated citations, making minor clarifications, and updating addresses. In the ''Rules and Regulations'' section of this **Federal Register**, we are making these technical corrections as a direct final rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. In the preamble to the direct final rule, we have explained our reasons for taking this action without a prior proposed rule. If we receive no adverse comment, we will not take further action on this proposed rule.

DATES: Written comments must be received by October 10, 2023.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2023–0081, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Resource Conservation and Recovery Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Brian Knieser, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304T), 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–0516, (*knieser.brian@epa.gov*) or Kathy Lett, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304T), 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–0517, (*lett.kathy@epa.gov*).

SUPPLEMENTARY INFORMATION:

I. Why is the EPA issuing this proposed rule?

This document proposes to make technical corrections that correct or clarify several parts of the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. These technical corrections correct or clarify specific provisions in the existing hazardous waste regulations that were promulgated in the Hazardous Waste Generator Improvements rule, the Hazardous Waste Pharmaceuticals rule, and the Definition of Solid Waste rule. This rule also makes other minor corrections that fall within the same sections of the hazardous waste regulations but are independent of these three rules. We have published a direct final rule to codify these technical corrections and clarifications in the ''Rules and Regulations'' section of this **Federal Register** because we view this as a noncontroversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse