the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Sikorsky S–76 Helicopter Alert Service Bulletin ASB 76–73–8, Revision A, dated December 4, 2015.

(ii) Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–07, dated August 17, 2016.

(iii) Sikorsky Maintenance Manual, SA 4047–76C–2, Temporary Revision No. 73–08, dated September 20, 2017.

(3) For Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-Winged-S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on May 9, 2018.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–10581 Filed 5–18–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2013–N–1317]

Final Determination Regarding Partially Hydrogenated Oils

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; declaratory order; extension of compliance date.

SUMMARY: Based on the available scientific evidence and the findings of expert scientific panels, the Food and Drug Administration (FDA or we) made a final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially produced *trans* fatty acids (IP–TFA), are generally recognized as safe (GRAS) for any use in human food. In a declaratory order announcing our final determination, we set a compliance date of June 18, 2018. We are now extending the compliance date for certain uses of PHOs.

DATES: *Compliance dates:* See sections II and III of this document.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1309, email: *ellen.anderson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 17, 2015 (80 FR 34650), we issued a final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food. Because PHOs are the primary dietary source of IP–TFA, FDA's evaluation of the GRAS status of PHOs centered on the *trans* fatty acid component of these fats and oils. We based our determination on available scientific evidence and the findings of expert scientific panels establishing the health risks associated with the consumption of *trans* fat. FDA's determination identified significant human health risks, namely an increased risk of coronary heart disease, associated with the consumption of *trans* fat (78 FR 67169 at 67172; 80 FR 34650 at 34659).

The order established a 3-year compliance date, to June 18, 2018, to allow time for food manufacturers using PHOs to identify suitable replacement ingredients for PHOs and to reformulate and modify labeling of affected products. The 3-year compliance date was also intended to allow time for submission and review and, if applicable requirements were met, approval of food additive petitions for uses of PHOs for which industry or other interested individuals believe that safe conditions of use may be prescribed. Finally, this compliance date was also intended to give manufacturers time to exhaust existing inventories and give distributors and retailers time to distribute products with PHOs (80 FR 34650 at 34669). We based the compliance date on the information available, including comments on the proposed order (80 FR 34650 at 34668 to 34669).

In the 2015 final order, we stated that food that is adulterated may be subject to seizure and distributors, manufacturers, and other parties responsible for such food may be subject to injunction. We also reminded distributors and other members of the food industry that they have an obligation to ensure that the food they manufacture, distribute, sell, or otherwise market complies with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (80 FR 34650 at 34655).

In the **Federal Register** of October 28, 2015 (80 FR 65978), we published a document announcing that we had filed a food additive petition submitted by the Grocery Manufacturers Association (GMA) seeking approval for certain uses of PHOs in or on select foods. We initially filed the food additive petition on October 1, 2015. GMA subsequently amended their food additive petition, and it was re-filed on March 7, 2017. The amended food additive petition requested that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. Elsewhere in this issue of the **Federal Register**, we have published a document announcing our denial of this food additive petition.

For purposes of this document extending the compliance date for certain uses of PHOs, we refer to the specified uses of PHOs in GMA's food additive petition as the ''petitioned uses'' and all other uses of PHOs not authorized by FDA as ''non-petitioned uses.'' We refer to ''manufacturing'' in this document as making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. See 21 CFR 1.227.

On March 23, 2018, the Consolidated Appropriations Act, 2018, (Pub. L. 115–141) was enacted into law. Section 738 of the Consolidated Appropriations Act, 2018, provided that no PHOs, as defined in our declaratory order, shall be deemed unsafe within the meaning of section 409(a) of the FD&C Act (21 U.S.C. 348(a)) and no food that is introduced or delivered for introduction into interstate commerce that bears or contains a partially hydrogenated oil shall be deemed adulterated under sections 402(a)(1) or (a)(2)(C)(i) of the FD&C Act (21 U.S.C. 342(a)(1) or (a)(2)(C)(i)) by virtue of bearing or containing a partially hydrogenated oil, until June 18, 2018.

II. Extension of the Compliance Date for Certain Uses

We have been informed by a number of trade associations representing many segments of the food industry that they have replaced the PHO uses that are not covered by the food additive petition (the non-petitioned uses) and thus will be able to stop using PHOs by the June 18, 2018, compliance date (Ref. 1). However, the trade associations also

have informed us that, due to shelf lives ranging from 3 to 24 months, a variety of products containing non-petitioned uses of PHOs will be in distribution on, and for some time after, the compliance date in the final order (Ref. 1). In addition, the trade associations have informed us that, if we deny the food additive petition, they will need additional time beyond June 18, 2018, to remove and replace the petitioned uses and deplete the product in distribution (Refs. 1 and 2). FDA has considered these requests as well as the health benefits of removing the uses of PHOs in food manufacturing and is revising the compliance date for certain uses.

A. Non-Petitioned Uses

Foods manufactured after June 18, 2018 with non-petitioned uses of PHOs may be subject to enforcement action by FDA. Based on the recent industry information, FDA understands additional time is needed for products manufactured (domestically and internationally) before June 18, 2018, to work their way through distribution. Therefore, we are extending the compliance date of food products that were manufactured before June 18, 2018, with non-petitioned uses of PHO. The new compliance date for these products is January 1, 2020. After January 1, 2020, such foods may be subject to enforcement action by FDA. FDA believes an 18-month extension is appropriate given the range of shelf lives brought to our attention and the 3-year original compliance date.

B. Petitioned Uses

In light of our denial of GMA's food additive petition, we acknowledge that the food industry needs additional time to identify suitable replacement substances for the petitioned uses of PHOs and that the food industry may not have done so for the petitioned uses while the petition was under our review. Industry has indicated that 12 months could be a reasonable timeframe for reformulation activities (Ref 1). Therefore, we are extending the compliance date to June 18, 2019, for the manufacturing of food with the petitioned uses of PHOs. Food manufactured with the petitioned uses after June 18, 2019, may be subject to enforcement action by FDA.

The petitioned uses are as follows:

- PHO, or a blend of PHOs, used as a solvent or carrier, or a component thereof, for flavoring agents, flavor enhancers, and coloring agents intended for food use, provided the PHOs in the solvent or carrier contribute no more than 150 parts per million (ppm) (150 milligrams per kilogram (mg/kg)) IP–TFA to the finished food as consumed;
- PHO, or a blend of PHOs, used as a processing aid, or a component thereof, provided the PHOs in the processing aid contribute no more than 50 ppm (50 mg/kg) IP–TFA to the finished food as consumed;
- PHO, or a blend of PHOs, used as a pan release agent for baked goods at levels up to 0.2 grams/100 grams (0.2 g/100 g) in pan release spray oils, provided the PHO contributes no more than 0.14 g IP–TFA/100 g spray oil.

The petitioned uses excluded dietary supplements. The physical and technical effects of the petitioned uses of PHOs were specified as: Release agents, either alone or in combination with other components (§ 170.3(o)(18) (21 CFR 170.3(o)(18))); processing aids or components thereof (§ 170.3(o)(24)); and as solvents, carriers, and vehicles for fat soluble coloring agents, flavoring agents, and flavor enhancers (§ 170.3(o)(27)).

In addition, for food manufactured with the petitioned uses before June 18, 2019, we are extending the compliance date to January 1, 2021. This time frame will allow manufacturers, distributors, and retailers to exhaust product inventory of foods made with the petitioned uses before the manufacturing compliance date. All foods containing unauthorized uses of PHOs after January 1, 2021, may be subject to FDA enforcement action.

III. Compliance Dates

For convenience, we are summarizing the extended compliance dates as follows:

Product uses	Original compliance date	Extended compliance date
Non-Petitioned Uses		
Manufacturing of food with non-petitioned uses of PHOs	June 18, 2018	Not Extended.
Foods manufactured with non-petitioned uses of PHOs before June 18, 2018	June 18, 2018	January 1, 2020.
Petitioned Uses *		
Manufacturing of food with the petitioned uses of PHOs	June 18, 2018	June 18, 2019.
Foods manufactured with the petitioned uses of PHOs before June 18, 2019	June 18, 2018	January 1, 2021.

* Petitioned uses exclude use in dietary supplements and are limited to:

- PHO, or a blend of PHOs, used as a pan release agent for baked goods at levels up to 0.2 grams/100 grams (0.2 g/100 g) in pan release spray oils, provided the PHO contributes no more than 0.14 g IP–TFA/100 g spray oil;
- PHO, or a blend of PHOs, used as a solvent or carrier, or a component thereof, as defined in § 170.3(o)(27), for flavoring agents, flavor enhancers, and coloring agents intended for food use, provided the PHOs in the solvent or carrier contribute no more than 150 parts per million (ppm) (150 milligrams per kilogram (mg/kg)) IP–TFA to the finished food as consumed; and
- PHO, or a blend of PHOs, used as a processing aid, or a component thereof, as defined in § 170.3(o)(24) and 21 CFR 101.100(a)(3)(ii), provided the PHOs in the processing aid contribute no more than 50 ppm (50 mg/kg) IP–TFA to the finished food as consumed.

IV. References

The following references are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from the American Bakers Association, et al., to Dr. Scott Gottlieb, Commissioner, Food and Drug Administration (April 30, 2018) (sent by electronic mail).
2. Letter from Leon H. Bruner, DVM, Ph.D., Senior Vice President, Science and Regulatory Affairs and Chief Science Officer, Grocery Manufacturers Association, to Dr. Scott Gottlieb, Commissioner, Food and Drug Administration (April 27, 2018).

Dated: May 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10714 Filed 5–18–18; 8:45 am]

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