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FDA Extends the Compliance Date for Removal of Partially Hydrogenated Oils From Food

May 18, 2018

Food, Beverage, and Dietary Supplements

Today, FDA [announced](#) that it has [extended the June 18, 2018 compliance date](#) for removal of industrially-produced partially hydrogenated oils (PHOs) from food.¹ Simultaneously, FDA announced that it had [denied approval](#) a 2015 food additive petition (FAP) on limited uses of PHOs.

The compliance dates are summarized in the table below, which FDA provided in its public announcement. FDA provides two sets of compliance dates. A set of compliance dates for uses of PHOs that were not included in the FAP (“non-petitioned uses”) and a set of compliance dates for PHOs that were included in the FAP (“petitioned uses”). Each set of compliance dates includes a manufacturing stop-date and a date when all product manufactured before the stop-date must be out of the supply chain.

For non-petitioned uses, all such manufacturing must stop before June 18, 2018, and the products must be out of the supply chain by January 1, 2020. For petitioned uses, all such manufacturing must stop before June 18, 2019, and the products must be out of the supply chain by January 1, 2021.

Non-Petitioned Uses		
Product Uses	Original Compliance Date	Extended Compliance Date
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*		
Product Uses	Original Compliance Date	Extended Compliance Date
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

¹ See [“FDA Tentatively Determines that Partially Hydrogenated Oils are not GRAS,”](#) Covington Alert (Nov. 7, 2013); [“FDA Issues Final Determination withdrawing the GRAS status of PHO’s,”](#) Covington Alert (June 17, 2015).

* 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.

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The attorneys in Covington & Burling's food law practice have extensive expertise in all aspects of human and animal food law and advise companies and trade associations on compliance with FDA, FTC, USDA, and state regulatory requirements and on strategies for mitigating and responding to consumer and competitor litigation and regulatory actions. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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