Food and Drug Administration’s Ban on Partially Hydrogenated Oils

Introduction
On June 17, 2015, the FDA made the final determination to ban the use of partially hydrogenated oils (PHOs) in our food by declaring them no longer generally recognized as safe (GRAS) in human food. This is an important step in improving the country’s health because PHOs are the major source of dietary trans fats. Trans fats cause several negative health effects and have been linked to:

- decreased good (HDL) cholesterol and increased bad (LDL) cholesterol;
- higher risk of developing heart disease and stroke;
- higher risk of developing type 2 diabetes; and
- memory loss

PHOs can be found in a wide variety of processed foods including certain coffee creamers, crackers, cookies, frozen pizza, ready-to-use frostings, microwave popcor
- inns, and vegetable shortenings. By removing PHOs from the food supply, the FDA believes that 10,000 to 20,000 coronary events could be prevented each year and 3,000 to 7,000 lives could be saved. In addition, the FDA estimates that the ban will produce $140 billion in benefits over the 20 years, while only costing industry $6.2 billion during that time period. The benefits include the monetized health gains and projected healthcare savings in the United States during this time period.

What does it mean to lose general recognized as safe (GRAS) status?
If a substance is GRAS, it can be used in food without the review and approval of the FDA. For a substance to be deemed GRAS it must meet one of two standards. It must be:

1. Generally recognized among experts, qualified by scientific training and experience to evaluate its safety, to be safe under conditions of its intended use or
2. In the case of substances used in food prior to January 1, 1958, it can be deemed safe through scientific procedure or based on experience from common use in food.
The two common PHOs used by food industry are partially hydrogenated soybean oil and partially hydrogenated cottonseed oil. Originally, these PHOs achieved GRAS status based on a history of use prior to 1958. However, a history of prior use is not sufficient to maintain GRAS status if new information arises revealing that there is no longer a consensus on the safety of the substance. The FDA has the authority to reevaluate the GRAS status of a substance. This reevaluation can be through agency initiative or in response to a petition from the public. The FDA released a tentative determination that PHOs were no longer GRAS in 2013 based on the growing body of scientific evidence linking PHOs, based on their trans fat content, to an array health problems. After receiving over 6,000 comments in response to the tentative determination, the FDA revoked PHOs GRAS status.

With the loss of GRAS status, PHOs are now food additives and subject to FDA review and approval before they can be used in food. Any food manufacturer that would like to use PHOs in a food product must petition the FDA for a regulation outlining the conditions under which PHOs can be used in food. This petition must contain specific information including:

1. the chemical and composition of the additive;
2. the conditions of the proposed use of the additive;
3. all relevant data bearing on the physical and technical effects of the additive, and the quantities required to produce these effects;
4. description of methods used to measure the amount of the additive in or on food; and
5. safety data regarding the use of the additive.

Once the petition has been filed, the FDA has 30 days to publish a notice of the proposed regulation for the additive in the federal register. The FDA has 90 days from the filing of the petition to evaluate the food additive for safety and to determine if the use of the additive would promote deception of consumers. If the additive fails either of these reviews the FDA will issue an order denying the petition.

Unless a successful petition is filed, the food industry can no longer sell PHO directly or as an ingredient in another food.

**What products does the ban affect?**

This ban only affects partially hydrogenated oils (PHOs). PHOs are the major source of trans fat in our food system. They are created when hydrogen is added to vegetable oils to alter the physical and chemical properties. They have become a staple in the food industry because they provide a desirable taste and texture to products, extend the shelf life of processed food, and are relatively inexpensive when compared to animal-based fats, e.g., butter or lard. PHOs can be found in a wide variety of processed foods, e.g., crackers, cookies, and frozen pizza. However, PHOs contain on average 20 to 45 percent trans fatty acids, the fat linked to the health problems discussed above.

Trans fats occur naturally in dairy products and the meat of ruminant animals, e.g., cows. Trans fats are also created in the processing of other oils. However, these products contain minute traces of trans fats. For example, fully hydrogenated oils contain less than two percent trans fatty acids. These products are not subject to the FDA’s ban.

**When will this ban take affect?**

The FDA established June 18, 2018, as the compliance date for the ban on PHOs. This gives the food industry three years to reformulate recipes; exhaust existing product inventory; modify product labels; identify and develop alternative edible oil sources; and address supply chain issues. This transition period will also allow industry to petition for the use of PHO as a food additive.
How can consumers avoid trans fat prior to the effective date of the PHO ban?

If consumers would like to reduce their exposure to trans fats, they need to review food labels. In 2003, the FDA issued a regulation requiring food and dietary supplements to indicate the amount of trans fat in the product. However, a food label that lists 0 grams of trans fat doesn't mean that the food is trans fat free. The regulations allow food producers to label their product as containing 0 grams of trans fat, if it contains less than .5 grams per serving. As a result, concerned consumers should also check ingredient lists for PHOs.

What does the FDA’s determination mean for state and local governments that have already taken actions to regulate PHOs?

Prior to the FDA's final determination banning PHOs, several local jurisdictions had taken action to regulate trans fats. For example, Baltimore City passed a trans fat ban in 2008 that prohibited the use of PHOs in foods served at food service facilities, e.g., restaurants, coffee shops, or cafeterias. In addition, one state, California, regulated PHOs by banning them in restaurants.

However, when the federal government regulates the same topic as state and local government there can be issues of preemption. The concept of preemption is derived from the Supremacy Clause of the United States Constitution that states:

“This Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding.

Based on this Constitutional provision, when the laws of the federal government conflict with state and local laws, the federal law prevails. Preemption can be explicit, meaning that Congress has stated in a federal statute that states are prohibited from legislating on the same issue. Preemption can also be implied, meaning Congress has not included language that prohibits states from regulating a specific issue yet circumstances reveal Congressional intention to preempt. Implied preemption can occur in two circumstances. First, it can occur when federal government has so extensively regulated a topic that it is deemed to “occupy the legislative field.” Second, it can occur when a conflict arises between a federal and a state regulation and this conflict makes it impossible to comply with both standards. Jurisdictions that have already taken action should not have any preemption problems based on the FDA’s final determination. There is no provision in the Food Drug and Cosmetic Act (the law which defines the FDA’s scope of authority and establishes the federal food safety system) that explicitly preempts state and local governments from banning PHOs. Also, a court is unlikely to find a conflict between the local and state bans and the FDA’s actions. State and local laws generally ban PHOs in restaurants, while the FDA will ban their use in all foods. Based on this dynamic one can comply with both without creating a conflict. As a result, state and local trans fat laws are unlikely to be preempted by the FDA’s action. To support this view, the FDA made a guarded statement in its final determination.

We decline to take a position regarding the potential for implied preemptive effect of this order on any specific state or local law; as such matters must be analyzed with respect to the specific relationship between the state or local law and the federal law. FDA believes, however, that state or local laws that prohibit or limit use of PHOs in food are not likely to be in conflict with federal law, or to frustrate federal objectives. (italics and bold for emphasis)
SUPPORTERS

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8 Id.

9 Id.

10 21 U.S.C.A § 321(s) (defining generally regarded as safe in the definition for food additives).


12 Id.

13 21 C.F.R. § 170.30(l).

14 21 C.F.R. § 170.38.

15 Id.


18 See 21 U.S.C.A. § 321 (s) (defining food additive); See also 21 U.S.C.A. § 348 (outlining the petition and review process for food additives); See also 21 U.S.C.A. § 342(a)(2)(C) (stating that a food is adulterated if it contains unsafe food additives).

19 See 21 U.S.C.A. § 348 (outlining the petition and review process for food additives).


22 21 U.S.C.A.§ 348(c) (2,3).

23 Id.


27 M.T. Tarrago-Trani ET AL., New and Existing Oils and Fats Used in Products with Reduced Trans-Fatty Acid Content, 106 J. Am. Dietetic Ass’n 867-880 (May 20, 2006).


29 Id. at 34651.


Id. at 34651.

Id. at 34669.


Id. at 41466.

21 C.F.R. 101.9 (c)(ii).

BALTIMORE CITY HEALTH CODE § 6-507; see also BALTIMORE CITY HEALTH CODE § 6-101(d) (defining food services facilities by adopting the definition provided by Md. CODE REGS. 10.15.03.02(B)); see also Md. CODE REGS. 10.15.03.02(B) (defining a food service facility as "(i) A place where food or drink is prepared for sale or service on the premises or elsewhere; or (ii) An operation where food is served to or provided for the public with or without charge").

CALIFORNIA HEALTH & SAFETY CODE § 114377.

U.S. CONST. art. 6, cl. 2.


Altria Group, Inc. v. Good, 555 U.S. 70, 76-78 (Dec 15, 2008)(discussing explicit and implied preemption)

Id.

Id.

Id.