

ALERTS

Food, Drug & Device Law Alert, "FDA Begins Process To Ban Adding Trans Fats To Food"

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Late last week, the FDA issued a notice and request for comments on its tentative determination that partially hydrogenated oils (PHOs) are not generally recognized as safe (GRAS) for use in any food because of the adverse health effects of the trans fatty acids (or trans fat) that PHOs contain. If the tentative determination becomes final, the consequence will be that food manufacturers must obtain prior FDA approval before adding PHOs to any food. As stated in the summary section of the notice:

Based on new scientific evidence and the findings of expert scientific panels, the Food and Drug Administration (FDA) has tentatively determined that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced trans fatty acids, or trans fat, are not generally recognized as safe (GRAS) for any use in food based on current scientific evidence establishing the health risks associated with the consumption of trans fat, and therefore that PHOs are food additives (emphasis added).

The primary health issue associated with the consumption of trans fat is coronary heart disease because trans fat tends to lower good cholesterol levels and raise bad cholesterol levels in the blood. The notice cites other adverse health effects also, such as contribution to diabetes.

The food industry has reduced the use of trans fat based on health concerns over the last 10 years or more. Several foods still use PHOs, however, and can include significant amounts of trans fat, including cookies, baked goods, microwave popcorn, frozen pizza, frozen pies, shortening, ready-to-use frostings and stick margarine. The FDA's action seeks to eliminate PHOs from these remaining categories of foods.

Interested parties have 60 days from Nov. 8, 2013, or to and including Jan. 7, 2014 to submit comments on the notice. The FDA has specifically invited comments on the following questions:

- Should FDA finalize its tentative determination that PHOs are no longer GRAS?
- Are there data to support other possible approaches to addressing the use of PHOs in food, such as by setting a specification for trans fat levels in food?
- How long would it take producers to reformulate food products to eliminate PHOs from the food supply? Are there likely to be differences in reformulation time for certain foods or for certain types of businesses?

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- If FDA makes a final determination that PHOs are not GRAS and does not otherwise authorize their use in food, FDA intends to provide for a compliance date that would be adequate for producers to reformulate any products as necessary and that would minimize market disruption. FDA states that it would welcome comments on what would be an adequate time period for compliance.
- Are there any special considerations that could be made to reduce the burden on small businesses that would result from removal of PHOs from foods, such as additional time for reformulation? Would those considerations be consistent with a final determination that PHOs are not GRAS?
- Are there other challenges regarding the removal of PHOs from foods? Are there products that may not be able to be reformulated? If so, what sorts of products and what challenges are faced?
- Is there any knowledge of an applicable prior sanction for the use of PHOs in food?

A copy of the notice can be found [here](#).

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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