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November 7, 2013

### Policing Your Donuts: FDA Tentatively Determines That *Trans* Fats from Partially Hydrogenated Oils Are Not Generally Recognized as Safe

*This article was also published in Gourmet News on November 7, 2013.*

Today the U.S. Food and Drug Administration (FDA) issued a notice, due to publish in tomorrow's Federal Register, tentatively determining that partially hydrogenated oils (PHOs) are not generally recognized as safe (GRAS) for use in food. If this determination is finalized, PHOs would effectively be banned from use in foods unless they are first approved by the FDA as "food additives," which would likely be difficult. This would have a major impact on the food industry. In particular, products such as donuts, cookies, margarine, microwave popcorn, frozen pizzas, baked goods, frostings, and many other foods would need to be reformulated.

The FDA's concern focuses on *trans* fats, which are deliberately produced in the manufacturing process for PHOs to help increase the melting point, shelf life, and flavor stability of the oil. Although *trans* fats exist elsewhere in the diet to some extent, PHOs are the major source. According to the FDA, *trans* fats may have adverse effects on blood cholesterol parameters that affect the risk of coronary heart disease, and may have other health implications that, as the FDA acknowledges, are unconfirmed. This tentative determination that PHOs are not GRAS follows a 2003 rule requiring labeling of *trans* fat content in nutrition labeling, as well as various state and local initiatives that have restricted the use of PHOs.

The FDA has established a 60-day public comment period from publication of the notice. Given the complexity and economic significance of the tentative finding, it is likely that this period could be extended if requested by stakeholders noting a need for more time to prepare fulsome comments. Besides requesting comments on whether the FDA should finalize its tentative determination, the Agency also requests comments on:

- Other possible approaches to addressing PHOs in food, such as setting *trans* fat specification levels.
- How long reformulation would take.
- What would be a reasonable compliance date to allow adequate time for reformulation while minimizing market disruption? (The notice hints that a "multi-year compliance period" may be allowed.)
- How can the burden on small businesses be reduced?
- What other challenges may exist, such as products that cannot be reformulated?
- Whether there is a "prior sanction" for the use of PHO in food of which the FDA is unaware.

To view the pre-publication version of the notice, [click here](#).

For additional information on the FDA's tentative determination or assistance in preparation of comments, please contact [John G. Moore](#) or your usual contact on Venable's [Food and Drug team](#).