

## E-ALERT | Food & Drug

November 7, 2013

### FDA TENTATIVELY DETERMINES THAT PARTIALLY HYDROGENATED OILS ARE NOT GRAS

Today FDA issued a pre-publication notice in the Federal Register<sup>1</sup> and held a public teleconference announcing its tentative determination that partially-hydrogenated oils (PHOs) are no longer generally recognized as safe (GRAS) and are therefore food additives requiring prior approval by FDA before being added to food. FDA is requesting comments and will keep the docket open for 60 days after it posts the official notice in the Federal Register (which it anticipates doing tomorrow, November 8, 2013).

#### I. Basis for FDA's Tentative Determination

FDA based its tentative determination that added PHOs are not GRAS due to the cardiovascular health risks associated with the consumption of trans fat, an unavoidable component in PHOs, on: (1) a 2005 Institute of Medicine (IOM) report that concluded there was no safe level of consumption of trans fat, (2) findings from the Center for Disease Control and Prevention (CDC) that elimination of PHOs from food could prevent heart disease and coronary deaths, and (3) its conclusion that there is no longer a consensus among qualified experts that PHOs (the primary dietary source of trans fat) are safe ingredients, even though daily per capita consumption of trans fat in the U.S. has declined from 4.6 grams in 2003 to 1 gram in 2012.<sup>2</sup>

#### II. The Impact of FDA's Determination that Added PHOs Are Not GRAS

During the live teleconference, Michael Landa, Director, Center for Food Safety and Applied Nutrition (CFSAN), stated that it was FDA's obligation to take action with respect to ingredients it concludes are no longer deemed GRAS. Although Mr. Landa recognized the significant reductions of added trans fat in food, he listed several foods—certain microwave popcorns, frozen pizzas, refrigerated doughs, cookies, coffee creamers, and frosting—that still contain trans fat from PHOs. Mr. Landa acknowledged that for certain foods—e.g., frosting—it might be difficult to replace the PHOs with alternative ingredients, and requested that stakeholders submit comments to FDA on whether the Agency could take a different approach other than to completely ban PHOs such as setting an added trans fat limit, while taking into account the current public health risks.

During the question and answer session of the live teleconference, Mr. Landa confirmed that the safety standard is the same for GRAS ingredients and food additives—i.e., a reasonable certainty of no harm. Consequently, if a food additive petition were to be submitted to FDA for PHOs, Mr. Landa

---

<sup>1</sup> See FDA, Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, Docket No. FDA-2013-N-1317, Federal Register Prepub Notice, <https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-26854.pdf> (FDA prepub notice).

<sup>2</sup> See FDA prepub notice, *supra* note 1; IOM, Dietary Reference Intakes for Energy Carbohydrate, Fat, Fatty Acids, Cholesterol, and Amino Acids, chapters 8 and 11, National Academies Press, Washington DC, 2002/2005; Dietz, W. H. and Scanlon, K. S., Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation, *Journal of the American Medical Association* 108:143-144, 2012.

indicated the petitioner would face a “heavy burden” because the currently available scientific safety data for trans fat set a “very high” safety hurdle a PHO food additive petition would have to overcome.

In response to a question on the safety profile of saturated fats, an FDA representative stated that the scientific data reflect a notable difference in the health risks associated with trans fat as compared to saturated fats, and the Agency accordingly does not intend to take similar action against saturated fats.

In addition, FDA confirmed that the rounding rules for trans fat in FDA’s nutrition labeling regulations<sup>3</sup> would remain the same, but would eventually become obsolete for added trans fat if the Agency’s final determination for banning PHOs is identical to its tentative determination and no other alternative way of permitting added PHOs is agreed upon.

Finally, if FDA finalizes its tentative determination, we believe it would be the first time FDA will have withdrawn GRAS status of an ingredient based on concerns about long-term disease risk. Hence, the Agency’s tentative determination regarding PHOs under this paradigm could have implications for other ingredients such as salt. The American Medical Association and the Center for Science in the Public Interest (which has been a driving force behind the campaign against trans fat) have petitioned FDA to withdraw the GRAS status of salt due to concerns about its effect on cardiovascular disease risk.

### III. FDA Requests the Information From Stakeholders

In addition to the specific comments FDA requested from stakeholders during the live teleconference, the public notice requests comments on the following:<sup>4</sup>

1. Should FDA finalize its tentative determination that PHOs are no longer GRAS?
2. 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?
3. 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?
4. 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. We welcome comments on what would be an adequate time period for compliance.
5. 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?
6. 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?
7. Is there any knowledge of an applicable prior sanction for the use of PHOs in food?

---

<sup>3</sup>See 21 C.F.R. 101.9(c)(2)(ii) (stating that if a food contains less than 0.5 grams trans fat per serving, the amount in the Nutrition Facts is to be listed as zero).

<sup>4</sup> See FDA prepub notice, *supra*, note 1.

#### IV. Timing of FDA's Proposed Actions Regarding Added PHOs

FDA confirmed during the live teleconference that, if the tentative determination that added PHOs are not GRAS is finalized, there will be a transition period for phasing out added PHOs from food that takes into consideration FDA's current understanding of the obstacles facing industry in implementing the determination, the feasibility of alternatives based on comments submitted by stakeholders, and the existing public health risks.

#### V. Next Steps

Affected stakeholders should consider submitting individual or joint comments to FDA and developing strategies to address the many implications that are posed by this Agency action. Covington & Burling LLP combines unparalleled expertise in food regulatory law, risk management and defense against products liability and class action litigation. We are available to assist in the development of comments and contingency planning regarding these important developments.

---

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

<b>Miriam Guggenheim</b>	+1.202.662.5235	<a href="mailto:mguggenheim@cov.com">mguggenheim@cov.com</a>
<b>Jeannie Perron</b>	+1.202.662.5687	<a href="mailto:jperron@cov.com">jperron@cov.com</a>
<b>Clausen Ely</b>	+1.202.662.5152	<a href="mailto:cely@cov.com">cely@cov.com</a>
<b>Theodore Voorhees</b>	+1.202.662.5236	<a href="mailto:tvoorhees@cov.com">tvoorhees@cov.com</a>
<b>MaryJoy Ballantyne</b>	+1.202.662.5933	<a href="mailto:mballantyne@cov.com">mballantyne@cov.com</a>

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to [unsubscribe@cov.com](mailto:unsubscribe@cov.com) if you do not wish to receive future emails or electronic alerts.

© 2013 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.