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FDA Decision On Trans Fats Could Have Major Impact

Law360, New York (November 15, 2013, 5:24 PM ET) -- On Nov. 15, 2013, the U.S. Food and Drug Administration issued a prepublication notice in the Federal Register[1] 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 the FDA before being added to food. The 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 on Nov. 8, 2013.

Basis for the FDA's Tentative Determination

The 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 trans fat consumption, (2) findings from the Center for Disease Control and Prevention 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.[2]

Impact of the FDA's Determination that Added PHOs are not GRAS

During the live teleconference, Michael Landa, Director of the Center for Food Safety and Applied Nutrition ("CFSAN"), stated that it was the FDA's obligation to take action with respect to ingredients it concludes are no longer deemed GRAS. Although 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. Landa acknowledged that for certain foods, such as frosting, it might be difficult to replace the PHOs with alternative ingredients. He requested that stakeholders submit comments to the FDA on whether the agency could take a different approach other than completely banning 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, 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 the FDA for PHOs, Landa 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, the FDA confirmed that the rounding rules for trans fat in its nutrition labeling regulations[3] 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 the FDA finalizes its tentative determination, we believe it would be the first time the agency 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 have been driving forces behind the campaign against trans fat — have petitioned the FDA to withdraw GRAS status from salt due to concerns about its effect of increasing the risk for cardiovascular disease.

FDA Requests the Information From Stakeholders

In addition to its specific comments, the FDA requested from stakeholders during the live teleconference, the public notice requests comments on the following:[4]

- Should the FDA finalize its tentative determination that PHOs are no longer GRAS?
- Is 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?
- If the FDA makes a final determination that PHOs are not GRAS and does not otherwise authorize their use in food, does the FDA intend to provide a compliance date that would be adequate for producers to reformulate any products as necessary that would minimize market disruption? (We 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 the 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?

Timing of the FDA's Proposed Actions Regarding Added PHOs

The 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 the 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.

Next Steps

Affected stakeholders should consider submitting individual or joint comments to the FDA and developing strategies to address the many implications that are posed by this agency action.

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[1] 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).

[2] 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.

[3] 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).

[4] See FDA prepub notice, supra, note 1.

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