THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

March 8, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA Notice; Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, Docket No. FDA-2013-N-1317

Dear Sir or Madam:

On November 8, 2013, the Food and Drug Administration (FDA) published in the *Federal Register* a tentative determination on the generally recognized as safe (GRAS) status of partially hydrogenated oils (PHOs). 1/ Finalizing this notice would effectively prohibit the use of PHOs in food.

FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

History of *Trans* Fat Labeling

The FDA required that *trans* Fat be added to the Nutrition Facts Panel starting January 2006. 2/ This regulation had two results, it gave the food industry an incentive to remove *trans* fat from products in which the formulation allowed for the substitution of an alternate fat source, and it provided consumers with information about the type of fat in the products they were purchasing and consuming. Since that time, the average consumption of *trans* fat of American consumers has declined from 4.6 grams per day in 2003 to about one gram per day in 2012. That is a significant decrease and the efforts of the food industry to remove *trans* fat from the food supply should be recognized. FDA should investigatie the source of the remaining gram in the diet as

1/ 78 Fed. Reg. 67169 (Nov. 8, 2013).
2/ 68 Fed. Reg. 41434 (July 11, 2003)

well as the physiological effect. Can the intake of *trans* fat go much lower than one gram per day and at what cost and what benefit?

Generally Recognized as Safe (GRAS) Status

FDA defines GRAS substances as those which are not harmful under their intended conditions of use. PHOs have been in the food supply for decades and while we agree that consumption should be reduced to minimum levels. The current intake of all *trans* fat in the diet is one gram per day. How much of that one gram is from PHOs? Is that one gram physiological harmful? What will that one gram be replaced with if PHOs become food additives and disappear from the US food supply?

Is revoking the GRAS status of a widely used labeled ingredient for public health reasons the proper use of FDA's authority of tentative determination of GRAS status? Does FDA have evidence that PHOs are no longer safe? PHOs have been in the food supply for the better part of a century. The health profile can be questioned, but the safety?

Need to Consider Alternative Regulatory Approaches

FDA reached its tentative conclusion that PHOs are no longer GRAS without considering other regulatory alternatives. We are concerned that such an approach does not comply with the agency's procedural obligations. Under Executive Order 12866, a cost-benefit analysis, including evaluation of regulatory alternatives (with one alternative being the option of not regulating), is required for significant regulatory actions that may have an annual effect on the economy of $100 million or more. FDA has estimated the costs of removing PHOs from the food supply as $8 billion in the first year, with several hundred million in costs recurring thereafter. Therefore, even under FDA's initial cost estimate, which is admittedly based on "very limited data," FDA is required to consider alternative approaches to revoking the GRAS status of PHOs that would similarly accomplish the agency's stated goal of achieving further reductions in *trans* fat.

Based on the success of FDA's 2006 requirement to include *trans* fat on the nutrition label in reducing *trans* fat from PHOs, there are a number of alternative regulatory approaches that could result in further reductions in *trans* fat. We ask the agency to consider the costs and benefits of these alternative approaches compared to the proposed option before finalizing the tentative determination. FDA could also consider whether it would be possible to achieve further reductions in *trans* fat on a voluntary basis, such as by engaging in consumer education, setting a voluntary timeline for reformulation, or exploring hydrogenation technologies that result in a lower *trans* fat content. We urge FDA to evaluate these and other measures beyond effectively banning PHOs before finalizing the tentative determination.

Need to Consider What Will Replace PHOs in the Food Supply

In reviewing the information and comments received in response to the agency's tentative determination, we urge FDA to carefully consider the net public health impact of revoking the GRAS status of PHOs. Specifically, the agency should obtain a thorough understanding of the alternative fats and oils likely to be used if PHOs are no longer considered GRAS. FDA does not currently have this information, as reflected by its assumption in the cost estimate that PHOs would be replaced with an equal mixture of all available substitutes. Nor did the agency request this information in the *Federal Register* notice. 3/

We encourage FDA to obtain information on the fats and oils likely to replace PHOs in the food supply and evaluate the public health impact of those compounds. In addition, FDA should consider the available supply, cost and environmental impact of the substitution of alternate fats and oils for PHOs. For example, a common replacement for *trans* fat is palm oil. FDA's cost-benefit memorandum does not account for the potential increase in saturated fat intake resulting from alternative oils and fats. In order to accurately estimate the costs and benefits of the proposed action, the agency must consider the public health outcome of PHOs and alternatives. The unintended consequences could be devastating to the food industry and to consumers if the public health effects of this decision are not well evaluated.

The other concern is that PHOs have been removed from many products. The products that still contain PHOs are the ones that are challenging to reformulate. Research and development is needed to create the next generations of fats and oils and that takes time.

Environmental Consequences of Decision

Sustainability is of key importance to many FMI member companies and concerns have been expressed about the impact of the decision in regards to the environment. As stated above, palm oil is one of the primary substitutes for PHOs and a sudden jump in demand for palm oil would almost certainly lead to accelerated deforestation causing increased greenhouse gas emissions and loss of habitat for critically endangered species. Many food industry firms have established policies on sourcing palm oil from sustainable producers. FDA's decision to revoke the GRAS status of PHOs would lead to supply chain demands that would pose significant challenges to firms with sustainable sourcing policies.

Need to Consider Scientific Data at Current Consumption Levels

Any final determination by FDA should be based on current scientific evidence evaluating the levels of PHOs in today's diet. In its Tentative Determination, FDA recognizes that the levels of *trans* fats and PHOs in the food supply have significantly decreased in the past decade. While acknowledging the meaningful reductions in PHOs from 2% of caloric intake in 2003 to 0.5% in

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33/ *Id. at* 67174.

2012, FDA has not adjusted its review of the scientific data accordingly. The scientific data referenced by FDA does not address these lower levels of PHOs, but assumes that a linear relationship exists between *trans* fats and LDL-cholesterol that extends to these low levels.

Before determining that PHOs are no longer GRAS, FDA should conduct a thorough review of scientific data that evaluate the effect of PHOs at current consumption levels. Absent such data, we do not believe the agency could reach a conclusion that there is a health or safety issue that would justify effectively banning PHOs and revoking the GRAS status of an ingredient long viewed by both FDA and the industry as safe.

The agency referenced the 2002 IOM Report 4/ in the *Federal Register* notice and in the recently published Revision of the Nutrition and Supplement Facts Labels Proposed Rule which noted "that any increase in *trans* fat intake increases CHD risk but because trans fats are unavoidable in ordinary diets, consuming zero percent of calories would require significant changes in dietary intake patterns that may introduce undesirable effects and unknown and unquantifiable health risks."5/

Need for Flexibility in Timeline for Reformulation

If, after a thorough review of the science, food industry use and public health impact on alternative oils, FDA determines to finalize its tentative determination on PHOs, we request a flexible timeline of at least five years to reformulate products. Our members are concerned that appropriate substitutes are not readily available for use in baked goods. In order to remove PHOs from foods, retailers must depend on suppliers of oils and fats to develop alternatives in commercially available quantities. We are at least several years away from having such alternatives at our disposal and will need time to phase in the required changes. The costs of alternatives must be considered since some natural oils will have limited supply as demand increases.

Once an alternative is identified, it must be tested in each specific product application to ensure product reformulations provide suitable performance, including texture, shelf stability, taste, and other factors. The alternative must be tested not only in the manufacturing of the product, but must also be tested with customers and consumers to ensure it meets expectations. This entire process would likely take five years at the minimum, with longer timeframes required for applications where substitutes do not provide the necessary product stability that solid fats offer. We therefore request that the agency provide a flexible timeline for reformulating products of at least five years.

4/ Institute of Medicine (IOM) of the National Academies. Washington, DC: National Academies Press; 2002

5/ 79 Fed. Reg. 11897 (March 3, 2014)

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Request for Comments by FDA

1. Should FDA finalize its tentative determination that PHOs are no longer GRAS?

   No, FDA should not finalize the tentative determination. The food industry has made significant reductions in *trans* fat since the FDA mandated *trans* fat labeling. There are other ways to work with the food industry to shift to healthier alternative oils in order to continue to reduce the use of PHOs that contribute to the *trans* fat content of food.

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?

   Look at models in other countries, such as Canada, and look at how American consumers respond to nutrition messages in the US. We do not think a specification will work, but recommendations to choose healthier foods and healthy lifestyles have broad appeal.

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?

   The retail industry estimates that five years will be necessary to implement any changes. We think other options will work better than revoking the GRAS status of PHOs but a very long implementation time period would be essential.

   Certain foods will pose a challenge because previous reformulation attempts have failed. The supply of alternative fats and oils will also be an issue that must be factored into the time required for successful product reformulation.

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.

   For compliance, we recommend 10 years. The sheer number of products in our industry that would need to be reformulated and the challenges associated with reformulating such products demand such a timetable.

Our members have made and continue to make significant efforts to further reduce the *trans* fat content of their foods in their stores and from their suppliers. While we are supportive of the public health goal of reducing *trans* fat in the food supply, we respectfully urge the agency to

consider the impact of removing PHOs from the food supply. Further, should FDA determine to move forward with the tentative determination, it is critical that the agency allows flexibility for reformulation and a generous compliance timeline to avoid market disruptions.

Please do not hesitate to contact us if further information would be helpful.

Sincerely,

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