Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Martin J. Hahn
Veronica Colas
Leigh G. Barcham

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Re: **FDA Issues Final Determination That Partially Hydrogenated Oils Are Not GRAS Due to Trans Fat Content**

Today the Food and Drug Administration (FDA) published a Declaratory Order finalizing its determination that partially hydrogenated oils (PHOs) are not generally recognized as safe (GRAS) for any use in food. 1/ FDA rejected the legal and scientific arguments submitted by the industry challenging the tentative determination and concluded there no longer is consensus among qualified individuals that PHOs are GRAS. Using a novel procedural approach under the Administrative Procedure Act, the agency issued the final determination as a "declaratory order," and thus avoided many of the procedural safeguards that are mandated by notice and comment rulemaking. The agency established a three-year "compliance date" of June 18, 2018. FDA noted the time frame should be sufficient for the agency to complete its review of any food additive petition that is submitted and for industry to reformulate foods.

FDA's determination is limited to PHOs because they are viewed as the primary dietary source of "industrially-produced *trans* fat" and does not extend to other foods or ingredients that contain *trans* fat such as meat and dairy, refined oils, fully hydrogenated oils, or ingredients derived from PHOs. In this memorandum, we explain the scientific and legal bases for FDA's determination, the procedures FDA used to revoke the GRAS status of PHOs, and implications for industry.

Background

Under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), a substance that may become a component of a food is a "food additive" for which FDA premarket approval is required *unless* the substance is GRAS for its intended use or qualifies for another statutory exemption. 2/ GRAS status may be established by common use in foods prior to 1958 or on the basis of scientific procedures. The term "safe" is defined as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use," and general recognition of safety must be based on the views of qualified experts. 3/

In November 2013, FDA issued a notice of its preliminary determination that there is no longer scientific consensus that PHOs are GRAS. In the notice and Declaratory Order, FDA avoids recognizing that PHOs are GRAS on the basis of common use in foods. Such a recognition

1/ 80 Fed. Reg. 34650 (June 17, 2015).
2/ FFDCA § 201(s); 21 U.S.C. § 321(s).
3/ 21 C.F.R. §§ 170.3(i); 170.30(a).

presumably would have been appropriate given the agency inclusion of PHOs in standards of identity, ingredient labeling, GRAS affirmation regulations, and other regulations. FDA instead asserts PHOs "have been considered GRAS by the food industry based on a history of use prior to 1958."

Scope of the Order

FDA defines PHOs as "fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4 as determined by a method that is suitable for this analysis (e.g., ISO 3961 or equivalent)." FDA expressly excludes fully hydrogenated oils (FHOs) from the definition of PHOs and defines FHOs as "fats and oils that have been hydrogenated to complete or near complete saturation, and with an IV of 4 or less, as determined by a method that is suitable for this analysis (e.g., ISO 3961 or equivalent)."

The notice also makes clear that the order applies only to PHOs used in human food, not animal feed, and applies to PHOs used as a food ingredient, which includes those uses sometimes considered processing aids or food contact substances (e.g., pan-release agents).

Though FDA recognizes that other foods such as meat and dairy contain *trans* fats, FDA's determination is limited to PHOs because they are the most significant source of "industrially-produced *trans* fats." FDA responded to industry's comments questioning the agency's distinction between naturally occurring *trans* fat and industrial sources of *trans* fat by stating that it "may determine that the use of an artificial substance is not GRAS without necessarily making the same determination about naturally-occurring versions of the substance" and that there is precedent for doing so.

The use of PHOs as raw materials used to synthesize other ingredients also is outside the scope of the order. 4/ In addition, the order does not apply to:

- Ingredients that contain only naturally occurring *trans* fat, such as those derived from ruminant sources;
- Refined oils or fully hydrogenated fats that may contain *trans* fat;
- The use of conjugated linoleic acid as a food ingredient; nor
- The use of partially hydrogenated methyl ester of rosin.

GRAS Standard

FDA rejected the industry comments regarding the appropriate standard that should be used for ingredients that are GRAS on the basis of common use in foods. According to FDA, the fact that the GRAS status of a substance may evolve over time "is the underlying basis for FDA's regulation at § 170.38," which authorizes FDA to propose to determine that a substance is not GRAS. FDA explains that "the GRAS status of a specific use of a particular substance in food may change as knowledge changes." Industry argued FDA should bear the burden of proof in demonstrating PHOs are not safe given the plain language of the statute that deems them GRAS on the basis of common use in foods prior to 1958. FDA rejected the argument that the agency must demonstrate PHOs are unsafe at current levels of use. FDA states that "there is a lack of consensus among qualified experts" and that the agency "need not determine that there is a consensus that low levels uses are unsafe to find that PHOs are not GRAS at low levels; we need only determine that based on

4/ However, when ingredients are synthetized using PHOs and the ingredient is being used on the basis of a GRAS self-determination, FDA states that reevaluation of the GRAS determination "may be appropriate in light of the health effects from the intake of *trans* fat that underlie" its determination that PHOs do not meet the GRAS standard.

available scientific evidence there is not a consensus among qualified experts that such uses are safe, as we do here." According to FDA, a history of use prior to 1958 is not sufficient to support continued GRAS status if new evidence demonstrates there is no longer a consensus that an ingredient is safe.

FDA also rejected the industry comments that the agency must demonstrate a "severe conflict" among experts about the safety of PHOs to determine they are not GRAS. FDA summarily concludes this is not the relevant standard. FDA maintains that a general recognition of safety does not exist if there is a lack of consensus among qualified experts that the use of a substance is safe. FDA asserts that, because there is disagreement among qualified experts about the safety of PHOs for human consumption, there is a "genuine dispute regarding safety" that "precludes a finding of GRAS." FDA also found unpersuasive the industry position that the FFDCA directs FDA to address concerns with multifactorial chronic diseases such as heart disease through labeling. FDA responded it may use its food additive authorities to address health risks.

Seemingly unencumbered by the plain language of the FFDCA, the agency refused to address the issues raised by the existence of prior sanctions. The food additive definition specifically excludes "any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph [September 6, 1958]." FFDCA § 201(f)(4). FDA dismissed the issue by acknowledging it received various comments on this topic and "is not making a determination regarding the existence of any prior sanctions for use of PHOs in this order" and that FDA intends "to address any claims of prior sanctions in a future action."

Scientific Basis for Determination

FDA based its tentative determination that PHOs are no longer GRAS on scientific evidence documenting significant health risks, including an increased risk of coronary heart disease (CHD), caused by the consumption of *trans* fat. FDA relied on the following scientific evidence in reaching its preliminary determination:

- A 2002 Institute of Medicine Report (IOM), which found a positive correlation between *trans* fat intake, low-density lipoprotein cholesterol levels, and heart disease, and recommended that "*trans* fatty acid consumption be kept as low as possible while consuming a nutritionally adequate diet";

- Controlled trials and observational human studies that have consistently confirmed the adverse effects of *trans* fatty acid consumption on intermediary risk factors and the increased risk of CHD; and

- Expert review panels, which all concluded there is no threshold intake level for industrially produced *trans* fat that would not increase an individual's risk of CHD, or adverse effects on risk factors for CHD. 5/

Since its tentative determination, FDA conducted a further review of key literature and expert panel reports on the relationship between *trans* fat consumption and CHD risk and found that the scientific evidence supports "a progressive linear cause and effect relationship between *trans* fatty acid intake and adverse effects" on CHD risk, with no evidence of a threshold at which effects would not be expected to occur. In light of the evidence, FDA declined to convene another expert panel to

5/ The expert review panels were conducted by IOM/National Academy of Sciences (NAS), the American Heart Association, the American Dietetic Association, the World Health Organization, the Dietary Guidelines Advisory Committee, and the FDA Food Advisory Committee Nutrition Subcommittee.

address whether evidence exists to indicate the effect of *trans* fatty acids is linear at low levels. FDA concluded, "the available data show that even at low intake levels (e.g., below 3 percent energy) there is no identifiable threshold, rather the available data support a conclusion that [industrially produced *trans* fatty acid] causes a linear increase in blood levels of [low-density lipoprotein cholesterol], a validated surrogate biomarker of CHD risk, and a linear decrease in blood levels of [high-density lipoprotein cholesterol], a major risk biomarker for CHD." FDA acknowledged the existence of an unpublished meta-regression analysis suggesting low levels of *trans* fat may fit a dose-response curve that is non-linear. FDA rejected the data stating, "this analysis is neither published (generally available) nor does it demonstrate a consensus of expert opinion that the use of PHOs at low levels in food is safe as required for general recognition of safety."

FDA developed four different methods to predict change in CHD risk with the elimination of *trans* fat from PHOs based on the current use levels of 0.5 percent of energy and replacement with mono- and poly-unsaturated fatty acids and saturated fats. FDA estimated the removal of *trans* fatty acids from PHOs would decrease the incidence of CHD by as much as 0.1 to 6.0 percent. FDA predicted three of the methods would prevent on an annual basis between 1,180 to 54,900 cases of CHD and from 490 to 22,770 deaths (FDA did not provide estimated reductions in CHD or deaths from the fourth method but reported it had the greatest reduction estimates of 4.2 to 6.0 percent). In a second set of scenarios, FDA used the four methods to calculate predicted CHD risk reduction if the 0.5 percent of energy from *trans* fatty acids from PHOs is replaced with eight alternative fats and oils, including fats with higher levels of saturated fat such as palm oil, lard, and butter. FDA reports this scenario reduced the risk of CHD by 0.4 to 1.5 percent across the respective fats. FDA concludes, "our quantitative estimates demonstrate that large numbers of CHD events and deaths may be prevented with the elimination of PHOs." It is unclear, however, if FDA's projections can be reconciled with recent trends in PHO consumption and CHD incidence. Since 2003, industry has reduced consumer exposure to *trans* fats by nearly 80 percent, and the agency's modeling would suggest such decreases would result in meaningful reductions in the prevalence of CHD. It is unclear whether the 80 percent reduction in *trans* fatty acids from PHOs has had any impact on CHD rates. It could be prudent for the industry to evaluate the rates of CHD since 2003, as the data could be useful in rebutting the modeling used by FDA.

Several comments objected to flaws in the agency's intake assessment. FDA rejected these comments, stating that "our determination that PHOs are not GRAS for use in human foods does not rely on the intake assessment." 6/

FDA conducted a quantitative estimate of the potential health benefits expected to result from the removal of industrially produced *trans* fats from PHOs. FDA estimated the 20 year costs would range from $2.8 to $11 billion while the benefits would range from $11 to $440 billion. FDA calculated the benefits by monetizing the expected health gains from the removal of PHOs and the expected medical expenditure savings. FDA calculated the net benefits of the action as ranging from $5 to $430 billion with a mean savings of $130 billion.

Procedural Issues

Contrary to industry comments that FDA is required to make its determination via notice-and-comment rulemaking, FDA states that it is authorized by regulation (§ 170.38(c)) to use a declaratory order and notes that this is not the first time it has done so. FDA also claims that the use of a

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6/ FDA conducted the intake assessment for four reasons: (1) to determine the impact of the 2003 labeling rule and subsequent reformulations; (2) to assist the agency's review of the citizen petitions it received; (3) to consider strategies for further *trans* fat reduction, if warranted; and (4) to better understand the current uses of PHOs and identify products that still contain high levels of *trans* fat.

declaratory order is appropriate because FDA is removing uncertainty regarding the GRAS status of PHOs. 7/ The agency clarifies that the Declaratory Order is not a statement of policy and will have the full force and effect of law.

However, FDA agrees that it must conduct rulemaking to revise existing regulations. In particular, two less commonly used PHOs—low erucic acid rapeseed (LEAR) oil and menhaden oil— are affirmed by regulation as GRAS for use in food. 8/ According to FDA, these oils are not widely used by the food industry, and it plans to make conforming changes to the regulations in a future rulemaking. FDA also indicates that it will consider taking further action to revise regulations regarding the standards of identity for peanut butter (§ 164.150(c)) and canned tuna (§ 151.190(a)(6)(viii)), the regulation regarding ingredient designations for PHOs (§ 101.4(b)(14)), and nutrition labeling regulations regarding *trans* fats (§§ 101.9(c)(2)(ii) and 101.36(b)(2)(i)).

FDA declined to set a threshold, as suggested by some comments, below which PHOs may safely be used in the food supply. According to FDA, no such threshold has been identified based on the available science, and even if one could be identified, this alone would not meet the requirement of "general recognition" for uses below the threshold without there also being consensus among experts that uses below the threshold are safe. FDA also declined to issue an interim food additive regulation, stating such regulations:

> are appropriate only when there is a reasonable certainty that a substance is not harmful. See 21 CFR 180.1(a). As discussed throughout this section, the available scientific evidence raises substantial concerns about the safety of PHOs. Based on the currently available data and information, FDA cannot conclude that there is reasonable certainty that PHOs are not harmful, nor did any comments provide information that would allow FDA to establish conditions of safe use at this time.

With respect to FDA's obligations under the National Environmental Policy Act (NEPA), FDA states that it has determined its order is subject to a categorical exclusion from NEPA requirements and that no extraordinary circumstances exist that would warrant further analysis. 9/

FDA also commented on whether the Declaratory Order would have preemptive effect. FDA states there is no statutory provision in the FFDCA providing for express preemption of any state or local law prohibiting or limiting PHOs in food. While FDA first declined to take a position regarding the potential for implied preemption, the agency then states it believes "state or local laws that prohibit or limit use of PHOs in food are not likely to be in conflict with federal law, or to frustrate federal objectives."

Compliance and Enforcement

Industry must comply with the order by June 18, 2018. FDA explains that the three-year compliance period should allow adequate time for industry members to identify suitable alternative ingredients and to reformulate their products. Presumably, on June 18, 2018, the order will become effective for products introduced into commerce. FDA, however, does not address the issue in the Declaratory Order, and it is possible the agency or third parties could assert the order applies to products already in commerce as of June 18, 2018.

7/ The Administrative Procedure Act permits an agency to "issue a declaratory order to terminate a controversy or remove uncertainty." 5 U.S.C. § 554(e).

8/ 21 C.F.R. § 184.1555(c)(2) (LEAR oil); 21 C.F.R. § 184.1472(b) (menhaden oil).

9/ FDA discusses its analysis of potential extraordinary circumstances in a separate review memorandum.

In response to comments that FDA should hold the manufacturer that initially introduces the food or ingredient into commerce responsible for compliance with FDA's determination, and not the product's distributors, FDA states that it recognizes the decision will most directly affect manufacturers and that it plans to "focus [its] outreach and enforcement resources accordingly." However, FDA cautions distributors and other food industry members that they have an obligation to ensure that they comply with the FFDCA.

Notably absent from the order is any response to industry requests for comment on the continued legality of PHOs during the three-year compliance period.

Food Additive Petitions

Once the compliance date takes effect, industry members must have either removed PHOs from their products or secured FDA approval of specific uses of PHOs through a food additive petition. Though FDA chose not to prescribe any safe uses of PHOs in its order, the agency invited industry to submit scientific evidence as part of a food additive petition for one or more specific uses of PHOs for which industry believes that safe conditions of use may be prescribed through regulation.

FDA set a compliance date of June 18, 2018, in part, to allow adequate time for industry to submit and FDA to review any potential food additive petitions. FDA neither confirmed nor denied that it had received a food additive petition. In a call with industry members yesterday, Deputy Commissioner for the Office of Foods and Veterinary Affairs Mike Taylor explained that the three-year compliance period would allow time for FDA to consider any food additive petitions that are submitted with respect to uses of PHOs that industry believes can meet the reasonable certainty of no harm standard.

Outlook

We continue to have concerns regarding the scientific basis and legal standards FDA applied in reaching its determination. The comments submitted by industry provided a detailed assessment of the legal and scientific standard that we believe should have applied. FDA did not provide the detailed response to many of the issues that we would have expected. In many instances FDA summarily rejected the arguments by simply stating there no longer is general a consensus among scientific experts that PHOs are GRAS. A more thorough review of the final determination would be needed before we could provide an assessment of whether the agency's action would withstand judicial scrutiny.

We would encourage companies that are continuing to use PHOs as ingredients that are declared in the ingredient statement or used as processing aids to review carefully the Declaratory Order. It also will be important to pay close attention to any progress that is made with regard to the agency review of any food additive petitions that are filed. The three-year compliance period in the Declaratory Order should provide FDA with sufficient time to complete its review of a food additive petition and identify those uses of PHOs that will be approved as food additives. It is difficult to predict at this time the uses of PHOs that will be covered by the food additive regulation. It similarly is difficult to assess what impact, if any, the agency's modeling and predicted increases in CHD with 0.5 percent of *trans* fatty acid from PHOs will have on the agency's assessment of the food additive petition. Given the uncertainty on the uses of PHOs that will be covered by the food additive regulation, it could be prudent to continue with efforts to find alternatives to PHOs.

In anticipation of the likelihood that FDA would issue the final determination before completing its review of a food additive petition, the industry asked FDA to offer several statements that should deter the filing of lawsuits. The agency recognition that a three-year compliance date is appropriate should be helpful. FDA did not, as requested by industry, make a clear statement that PHOs can

continue to be used and are lawful during this transition. By delaying the compliance date for three years, companies presumably can take the view FDA recognizes that PHOs can be used and are in compliance with federal requirements during this period.

We, nonetheless, remain concerned with the potential class action liability with past and continued uses of PHOs. We suspect creative class action lawyers will use the modeling in the final determination to argue the low levels of *trans* fat contributed by PHOs have contributed to heart attacks and deaths and that companies should be responsible for health care costs. The agency recognition that there is no express preemption and likely no implied preemption could further incentivize the class action lawyers to bring challenges against the industry. While we recognize it could be challenging for class action lawyers to demonstrate causality and liability, a critical review of the Declaratory Order reveals numerous statements establishing the agency's view that even low levels exposures to *trans* fatty acids from PHOs, including the 0.5 percent of energy in today's diet, can increase the risk of heart attack and deaths.

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We will continue to monitor FDA's activities on PHOs and *trans* fat. Should you have any questions or wish to discuss the underlying legal and policy issues, please contact us.