COVINGTON

FDA Issues Final Determination withdrawing the GRAS status of PHO's

June 17, 2015

Food & Drug

Yesterday morning, June 16, 2015, FDA issued its long-anticipated final determination--in the form of a declaratory order[1] and under the provisions of 21 C.F.R. § 170.38--concluding that there is no longer a consensus among qualified experts that industrially produced (IP) partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS).[2] The agency based its conclusion on studies that it believes show that consumption of trans fat from IP PHOs raises the risk of cardiovascular disease (CVD) and other adverse health conditions.

This client alert summarizes FDA's order. The order includes, along with the references appended thereto, a full discussion of the scientific data FDA relied on to withdraw the GRAS status of PHOs. Although this client alert does not summarize the scientific data on which FDA relied, because we have reviewed FDA's conclusions based on those data and are generally familiar with the literature in this area, we are available to comment further if desired.

Major Provisions of FDA's Order

As FDA's order states, the major highlights of FDA's final determination are:

- PHOs are no longer GRAS for any use in human food.
- Any interested party may seek FDA's approval of a food additive petition (FAP) for one or more specific uses of PHOs if they are able to provide data that demonstrate the proposed use(s) pose a reasonable certainty of no harm.
- For the purposes of the order, PHOs are defined as those fats and oils that have been hydrogenated, although not to complete or near complete saturation, and that have an iodine value (IV) greater than 4. (This adopts the general industry standard that fully

[1] Under 5 U.S.C. § 554(e), an agency "in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty."

[2] *See* FDA, Final Determination Regarding Partially Hydrogenated Oils, Docket No. FDA-2013-N-1317 (June 16, 2016) (prepublication draft) [hereinafter Final Determination].

hydrogenated oils (FHOs) are those with an IV of 4 or less. FDA explained that "FHO's are outside the scope of this order."[3])

- FDA is providing a three year compliance period that ends June 18, 2018.

Substances That are Outside the Scope of FDA's Order

FDA clarified that its order:

- Does NOT apply to PHOs that are used as raw materials to synthesize other ingredients. Rather, the order applies only to PHOs used as "food ingredients," including processing aids and food contact substances (e.g., pan-release agents). (FDA notes, however, that "when ingredients are synthesized using PHOs, and the ingredient is being used on the basis of a GRAS self-determination, reevaluation of such a determination may be appropriate in light of the health effects from the intake of trans fat that underlie our determination that PHOs do not meet the GRAS standard.")[4]
- Does NOT apply to FHOs (oils with an IV of 4 or less).[5] Because FDA's initial determination did not define either PHO or FHO, the definition of PHO and the express exclusion of FHO's from the order may provide reassurance to those companies relying on FHOs and FHO-containing oil blends as alternatives to PHOs.
- Does NOT apply to PHOs used in animal feed. FDA's order is limited to PHOs used in human food.[6]

Current Safety Status of PHOs and Submission of FAPs

Importantly, FDA's determination withdrawing the GRAS status of PHOs is not a finding that any particular current uses of PHOs are *unsafe*. As FDA explains, "We need not determine that there is a consensus that low level uses are unsafe to find that PHOs are not GRAS at low levels; we need only determine that based on available scientific evidence there is not a consensus among qualified experts that such uses are safe, as we do here."[7] Based on the

---

[3] *Id.* at 71

[4] *See id.* at 8 (The full context of FDA's finding is as follows: "[T]he use of PHOs as raw materials used to synthesize other ingredients is outside the scope of this order. We do not have specific information on the intake of industrially-produced trans fat from this source. There is no requirement that materials used to make food ingredients be GRAS themselves; rather, the resultant food ingredient must be safe for the intended conditions of use. The use of PHOs as raw materials to make other food ingredients may result in the incorporation of industrially-produced trans fats into those ingredients. When ingredients are synthesized using PHOs, and the ingredient is being used on the basis of a GRAS self-determination, reevaluation of such a determination may be appropriate in light of the health effects from the intake of trans fat that underlie our determination that PHOs do not meet the GRAS standard.").

[5] *Id.* at 71.

[6] *Id.* at 8.

[7] *Id.* at 14.

available scientific data, FDA concluded that it was withdrawing the GRAS status of PHOs because a "genuine dispute regarding safety precludes a finding of GRAS."[8]

FDA specified that sponsors can submit PHO uses for FDA preapproval using the food additive petition (FAP) process, stating, "We encourage submission of scientific evidence as part of food additive petitions . . . for one or more specific uses of PHOs for which industry or other interested individuals believe that safe conditions of use may be prescribed."[9]

The Grocery Manufacturers Association (GMA) announced yesterday on its website that it has submitted a food additive petition: "GMA's food additive petition to FDA will show that the presence of trans fat from the proposed low-level uses of partially hydrogenated oils (PHOs) is as safe as the naturally occurring trans fat present in the normal diet. Food and beverage companies have already voluntarily lowered the amount of trans fat added to food products by more than 86 percent and will continue lowering PHO use in foods."[10]

Given that FDA has "encouraged" submission of appropriately supported FAPs, affected stakeholders with PHO uses appropriate for an FAP should consider whether to submit an FAP for uses that might not be covered by existing PHO FAPs. Other options for companies who use PHOs include determining whether those PHO uses might be appropriate for food contact substance notifications or are permissible because such uses contribute IP trans fat at levels below the threshold of regulation.

The Legal Status of PHOs During the Transition Period

In conjunction with issuing its order, FDA held a public meeting via teleconference yesterday morning in which Michael Taylor (Deputy Commissioner for Foods), Dr. Susan Mayne (Director, FDA Center for Food Safety and Nutrition (CFSAN)), Dr. Dennis Keefe (Deputy Director, Office of Food Additive Safety, CFSAN), and other FDA subject matter experts provided comments and answered questions. In response to a question on what the legal status of PHOs would be during the three-year transition period (given FDA's finding that PHOs are no longer GRAS and no uses of PHOs have yet been approved through the FAP process), Mr. Taylor referred stakeholders to the legal "reasonable certainty of no harm" safety standard for lawful food ingredients and made it clear that FDA would not provide comment on the legal status of PHOs during the transition period. Mr. Taylor recommended that interested stakeholders needing information on the legal status of PHOs contact their legal counsel.

[8] *Id.* at 13.

[9] *Id.* at 14.

[10] *See* http://www.gmaonline.org/news-events/newsroom/gma-statement-fda-action-on-phos-provides-needed-transition-time-for-food-m/#sthash.ZU9q4H5V.dpuf.

FDA Hints That It Might Include a Revision to the Trans Fat Declaration in the Final NFP Rule

In its order, FDA states that it "may address trans fat through labeling requirements in the future"[11] and that it is "consider[ing] taking further action to revise regulations regarding . . . nutrition labeling regulations regarding trans fat."[12] During yesterday's public teleconference, Dr. Mayne explained in response to a question on the declaration of trans fat in the nutrition facts panel (NFP) that FDA had requested comments on the mandatory trans fat declaration when it issued its 2014 proposed rule revising nutrition information and is currently reviewing the comments it received and considering next steps.

FDA may therefore issue its final NFP rule to include a change to the mandatory trans fat declaration, but has given no indication as to what the revision might be. Any revised trans fat declaration included in the final NFP rule will be final and not open for comment because FDA requested public comment on whether and how to revise the trans fat declaration during the comment period for the NFP proposed rule.

FDA Will Direct Enforcement Efforts at Manufacturers, but Cautions Other Industry Stakeholders

In response to comments and concerns voiced by distributors and retailers that they are not responsible for finished products or formulations and merely transport, handle, and/or re-sell pre-packaged and labeled finished products, FDA stated that it "intend[s] to focus [its] outreach and enforcement resources" on manufacturers, but reminded distributors and other food industry members of their obligation to ensure their food products are not adulterated.[13]

FDA Will Address Prior Sanctions and Amend PHO Regulations in Future Actions

FDA also made it clear that prior sanctions and amendments to existing PHO regulations were outside the scope of its order. Regarding prior sanctions, FDA declared, "we are not making a determination regarding the existence of any prior sanctions for uses of PHO in this order."[14] FDA will address prior sanctions in a future action.

Similarly, FDA plans to amend the regulations for partially hydrogenated LEAR[15] and menhaden[16] oils in future rulemaking and does not believe these oils are currently widely used by the food industry.[17]

---

[11] Final Determination at 18.
[12] *Id.* at 25.
[13] *Id.* at 21.
[14] *Id.* at 22.
[15] *See* 21 C.F.R. § 184.1555(c)(2).
[16] *See* 21 C.F.R. § 184.1472(b).
[17] *See* Final Determination at 4.

FDA Asserts that Its Order Will Not Impact Current State and Local Restrictions on PHOs

FDA asserts that its order is likely to have no impact on existing local and state laws directed at limiting trans fats and PHOs: "FDA believes [ ] that 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."[18]

FDA is Providing a Three Year Compliance Period That Ends June 18, 2018

FDA is providing a three year compliance period, with a compliance date of June 18, 2018, in order to:

- provide time for submission and review of FAPs for uses of PHOs;
- minimize market disruptions by providing industry sufficient time to identify suitable replacement ingredients for PHOs;
- provide time to exhaust existing product inventories;
- provide time to reformulate and modify the labels and labeling of affected products;
- provide time for the growing, harvesting, and processing of new varieties of edible oilseeds to meet the expected demands for alternative oil products; and
- address the supply chain issues associated with transition to new oils (particularly for smaller business).[19]

The Impact of FDA's Order on PHO Citizen Petitions

FDA's order states that the order is "a response, in part, to [two] citizen petitions" submitted to FDA contesting the safety of PHOs, including the 2004 Center for Science in the Public Interest (CSPI) citizen petition and the 2009 petition submitted by Dr. Fred Kummerow.[20]

Dr. Kummerow filed suit in August of 2013, claiming FDA unreasonably delayed responding to his citizen petition.[21] The Kummerow litigation likely provided some impetus for FDA issuing its tentative determination shortly thereafter on November 7, 2013 (which was submitted to the Kummerow docket that same day), and FDA has repeatedly referenced its actions related to the PHO determination in motions submitted to the Kummerow docket. FDA's order likely provides sufficient grounds for FDA to move to dismiss or settle the Kummerow case.

[18] *Id.* at 22.
[19] *Id.* at 70.
[20] *Id.* at 66.
[21] *See* Kummerow v. FDA, No. 2:13-cv-02180 (C.D. Ill. filed Aug. 9, 2013) (complaint).

How Covington Can Help

Covington has a deep understanding of FDA's actions related to PHOs and has been involved with other industry leaders in discussions with FDA, with OMB, and with members of Congress on the issue. Covington has extensive expertise in the full scope of food and beverage regulatory matters (including submission of FAPs and food contact substance notifications), food and beverage consumer litigation (including assessing, mitigating, and managing potential litigation risks), and food and beverage Congressional lobbying. If companies have questions or concerns about or need assistance complying FDA's final PHO determination order or any other PHO related matter, please feel free to contact any of the lawyers identified below:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jeannie Perron	+1 202 662 5687	jperron@cov.com
Theodore Voorhees	+1 202 662 5236	tvoorhees@cov.com
Jessica O'Connell	+1 202 662 5180	JPOConnell@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com