



FDA Issues Ban on Artificial Trans Fat in Processed Foods

William H. Kitchen, Alan G. Minsk and Cathy Fortney

On June 15, 2015, the U.S. Food and Drug Administration announced a final determination order regarding the use of partially hydrogenated oils (PHOs) in foods manufactured for human consumption, concluding that PHOs are not generally recognized as safe (GRAS) and, therefore, are “food additives” that require prior FDA approval.

PHOs are the primary dietary source of trans fats found in processed foods (e.g., microwave popcorn, some stick margarines, ready-to-use frostings), and have been shown to be a major cause of increased LDL cholesterol levels in humans. They may also be a contributor to other diseases, such as diabetes, insulin resistance, and cause adverse effects on fetuses and breastfeeding infants. FDA is concerned that the trans fat content of PHOs is far greater than the amount found in other edible oils, and these oils are contributing to cardiovascular disease in humans. The agency said the move is expected to reduce the number of cardiovascular events in the U.S. by “thousands” each year.

FDA has implemented a three-year compliance deadline and has ordered that PHOs be removed from foods unless their use is pursuant to an approved food additive petition. Failure to comply with the deadline can lead to FDA enforcement.

Here are the highlights of FDA’s decision:

- PHOs are no longer considered GRAS.
- FDA is defining PHOs as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value greater than four.
- During the three-year period, any interested party may petition FDA to seek “food additive approval” for one or more specific uses of PHOs, with data demonstrating a reasonable certainty of no harm of the proposed use, or may reformulate the products.
- FDA’s enforcement will focus on manufacturers that add PHO to food, rather than other parties, such as distributors, who merely receive and sell finished goods.
- The order does not apply to ingredients that contain naturally-occurring trans fats, such as those derived from ruminant sources (animal meat), fully-hydrogenated oils, or oils that contain trans fatty acids as an impurity (or that which occurs to a minimal degree as a result of the manufacturing process). It also does not apply to animal feed.

The declaratory order is available [here](#)¹.

¹ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-14883.pdf>

Authors and Contributors

William H. Kitchens

Partner, Atlanta Office
404.873.8644
william.kitchens@agg.com

Alan G. Minsk

Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Cathy Fortney

Legislative Assistant, DC Office
202.677.4956
cathy.fortney@agg.com

not *if*, but *how*.[®]

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a “business sensibility” approach, developing a deep understanding of each client’s industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal’s prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief “not if, but how.” Visit www.agg.com.

Atlanta Office

171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office

1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: <http://www.agg.com/subscribe/>

©2015. Arnall Golden Gregory LLP. This legal insight provides a general summary of recent legal developments. It is not intended to be, and should not be relied upon as, legal advice. Under professional rules, this communication may be considered advertising material.