

FDA Targets *Trans* Fat in Processed Foods

More than decade ago, a sea change began in the American diet, with consumers starting to avoid foods with *trans* fat and companies responding by reducing the amount of *trans* fat in their products.

This evolution began when FDA first proposed in 1999 that manufacturers be required to declare the amount of *trans* fat on Nutrition Facts labels because of public health concerns. That requirement became effective in 2006.

However, there are still many processed foods made with partially hydrogenated oils (PHOs), the major dietary source of artificial *trans* fat in processed food. *Trans* fat has been linked to an increased risk of coronary heart disease, in which plaque builds up inside the arteries and may cause a heart attack.

The Centers for Disease Control and Prevention estimates that a further reduction of *trans* fat in the food supply can prevent an additional 7,000 deaths from heart disease each year and up to 20,000 heart attacks each year.

Part of the FDA's responsibility to the public is to ensure that food in the American food supply is safe. Therefore, due to the risks associated with consuming PHOs, FDA has issued a Federal Register notice with its preliminary determination that PHOs are no longer "generally recognized as safe," or GRAS, for short.



INGREDIENTS: WHOLE GRAIN POPCORN, PARTIALLY HYDROGENATED SOYBEAN OIL, SALT, NATURAL AND ARTIFICIAL FLAVOR (MILK), COLOR ADDED, FRESHNESS PRESERVED BY PROPYL GALLATE. CONTAINS MILK.

A variety of processed foods—including frozen, canned and baked goods—contain *trans* fat. The amount per serving is listed on the Nutrition Facts label. The inclusion of partially hydrogenated oil in the list of ingredients is also an indication that *trans* fat is present.

If this preliminary determination is finalized, then PHOs would become food additives subject to premarket approval by FDA. Foods containing unapproved food additives are considered adulterated under U.S. law, meaning they cannot legally be sold.

If FDA determines that PHOs are not GRAS, it could, in effect, mean

Nutrition Facts			
Serving Size 1 Tbsp (14g)			
Servings Per Container about 32			
Amount Per Serving			
Calories 100		Calories from Fat 100	
		% Daily Value*	
Total Fat	11g		17%
Saturated Fat	2.5g		12%
Trans Fat	2.5g		
Cholesterol	0mg		0%
Sodium	105mg		4%
Total Carbohydrate	0g		0%
Dietary Fiber	0g		0%
Sugars	0g		
Protein	0g		
Vitamin A 10% • Vitamin C 0%			
Calcium 0% • Iron 0%			
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate	Less than	300g	375g
Dietary Fiber		25g	30g

Selecting foods with even small amounts of trans fat can add up to a significant intake.

the end of artificial, industrially-produced *trans* fat in foods, says Dennis M. Keefe, Ph.D., director of FDA's Office of Food Additive Safety. FDA is soliciting comments on how such an action would impact small businesses and how to ensure a smooth *trans* transition if a final determination is issued.

Trans fat wouldn't be completely gone, Keefe notes, because it also occurs naturally in small amounts in meat and dairy products. It is also present at very low levels in other edible oils, such as fully hydrogenated oils, where it is unavoidably produced during the manufacturing process.

About *Trans* Fat and PHOs

PHOs are found in many popular processed foods, like baked goods and frozen foods that time-crunched Americans use to feed their families. They have been widely used as ingredients since the 1950s to increase the shelf-life and flavor stability of foods.

But over time, various studies have linked *trans* fat—produced when hydrogen is added to vegetable oil to make it more solid—to heart disease. A 2002 report by the National Academy of Science's Institute of Medicine found a direct correlation between intake of *trans* fat and increased levels of low density lipoprotein (LDL) cholesterol, commonly referred to as "bad" cholesterol, and, therefore, increased risk of heart disease.

Keefe says that even though the FDA requirement that *trans* fat be listed on the Nutrition Facts label took effect in January 2006, consumers took the health warnings to heart early. They started turning away from foods with *trans* fat soon after publication of FDA's final rule in 2003. Taking the lead from consumers, many processed food manufacturers followed suit and voluntarily changed their food formu-

lations to reduce or eliminate *trans* fat.

However, Mical E. Honigfort, a consumer safety officer at FDA, says that *trans* fat can still be found in such processed foods as:

- crackers, cookies, cakes, frozen pies and other baked goods
- snack foods (such as microwave popcorn)
- frozen pizza
- vegetable shortenings and stick margarines
- coffee creamers
- refrigerated dough products (such as biscuits and cinnamon rolls)
- ready-to-use frostings

About GRAS

Under section 409 of the Federal Food, Drug, and Cosmetic Act, any substance intentionally added to food is a food additive subject to premarket approval and review by FDA, with some exceptions. The exceptions include substances "generally recognized as safe," or GRAS, because they are generally recognized by qualified experts as safe under the conditions of intended use.

The most widely used PHOs have long been considered GRAS ingredients by the food industry. Keefe explains that companies may voluntarily notify FDA that they have determined that the use of an ingredient is GRAS, but there is no legal requirement for food manufacturers to submit a GRAS notification before going to market. If FDA ultimately determines that PHOs are not GRAS, food manufacturers would have to obtain premarket approval by FDA before adding PHOs to food.


FDA can act when it believes an ingredient is, in fact, not GRAS. And that's what the agency's preliminary determination is doing now with partially hydrogenated oils. A Fed-

eral Register notice was published on Nov. 7 2013 announcing the preliminary determination that PHOs are not GRAS, which includes the opening of a 60-day public comment period.


If FDA makes a final determination that PHOs are not GRAS, the agency and food industry would have to figure out a way to phase out the use of PHOs over time. To help address this concern in an appropriate manner, the Federal Register notice calls for comment on how long it would take the food industry to phase out its use of PHOs.

What Should the Consumer Do?

In the meantime, what should the average consumer do if he or she picks up a favorite food and sees that it has *trans* fat on the Nutrition Facts label? The best thing to do is to consider the amounts of saturated fat, cholesterol and *trans* fat. Choose the product that has the lowest combined amount of these nutrients, Keefe says.

Even if a food claims on its packaging to have "0 grams *trans* fat," it's a good idea to look at the ingredients, says Honigfort. Under current regulations, companies can make that claim if the food contains less than 0.5 grams of *trans* fat per serving. But if there is partially hydrogenated oil listed with the ingredients, there might be a small amount of *trans* fat. Selecting foods with even small amounts of *trans* fat can add up to a significant intake. 

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