Partially Hydrogenated Oils and *Trans* Fat

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What is Trans Fat?

- Unsaturated fat with a *trans* isomer

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- *Trans* fatty isomers in oil are created during the hydrogenation process

- 2 sources found in food:
  - Naturally occurring in meat from ruminant animals
  - Industrially-produced, or artificial, formed during hydrogenation of oils (most commonly soybean and cottonseed oils)
Partially Hydrogenated Oils (PHOs)

- Primary dietary source of industrially-produced trans fat
- Trans fat content of PHOs controlled by temperature, pressure, reaction time, catalyst, fat source
- Typical trans fat content is 25-45% of the oil, with higher levels possible
- These oils are used to improve the flavor, shelf-life, and flavor stability of foods
- Historically, they were used to replace butter and lard (high in saturated fat)
- No formal regulatory definition
Other Sources of *Trans* Fat

- Non-hydrogenated refined oils and fully hydrogenated oils may contain some *trans* fatty acid isomers as a byproduct of processing
  - Not intentionally produced
  - Levels low compared to PHOs
- *Trans* isomers can also occur naturally in products of ruminant animals
Public Health Issues- CHD Risk

• Industrially-produced *trans* fat added to food increases serum low-density lipoprotein cholesterol (LDL-C)

• Increases risk of coronary heart disease (CHD)

• Lowers high-density lipoprotein cholesterol (HDL-C)
Other Adverse Effects

• In addition to increased CHD risk, *trans* fat consumption has been linked to other adverse health effects:
  – Worsens insulin resistance
  – May increase diabetes risk
  – Effects on breastfeeding infants
Public Health- Expert Panel Reviews

• 2005, Institute of Medicine (IOM): Trans fat consumption should be kept as low as possible while consuming a nutritionally adequate diet

• 2010, Dietary Guidelines for Americans recommends trans fat intake be as low as possible

• 2013, American Heart Association/American College of Cardiology recommends reducing calories from trans fat
Regulatory Status of Partially Hydrogenated Oils

- Long history of use in food

- Used in food based on industry’s independent determination that these oils are generally recognized as safe (GRAS)

- PHOs affirmed as GRAS: low erucic acid rapeseed (canola) oil (21 CFR 184.1555(c)(2)) and menhaden oil (21 CFR 184.1472(b))
Take the Poll!

Do you read food labels and avoid products containing partially hydrogenated oils?
Food Additives

“---any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food ---”

- Require pre-market approval by FDA
- Petition requirements are in 21 CFR 171.1
- FDA reviews data and makes a safety determination
- Results in a food additive regulation in 21 CFR
GRAS Substances

• Food, Drug, and Cosmetic Act exempts GRAS substances from the definition of “food additive”

• To be GRAS, the use of a substance must:
  – be generally recognized by experts to be safe through scientific procedures OR
  – be based on common use in food prior to 1958

• Safety determinations are based on the best available information. When new evidence becomes available the safety standard may not be met and the use of the substance may no longer meet the GRAS standard.
GRAS Substances vs. Food Additives

“Safe” means a reasonable certainty of no harm under the intended conditions of use
FDA Actions on *Trans* Fat Labeling

- July 11, 2003 – Final Rule published requiring *trans* fat content be declared on the nutrition label ([68 FR 41470](http://www.fda.gov))

- Final Rule took effect on January 1, 2006

- Many manufacturers voluntarily reformulated products to reduce or eliminate *trans* fat as a result of this rule

- Intake for artificial *trans* fat was estimated to be **4.6 grams per person per day** for adults in 2003 rule
  - Intake of naturally-occurring *trans* fat estimated to be **1.2 g/p/d**
Quiz

Where would you look on the product label to find out if a product contains a partially hydrogenated oil (PHO)?

a. Front of package
b. Ingredient statement
c. Nutrition facts panel
d. Inside the package
Label Declaration of *Trans* Fat

- *Trans* fat content expressed to nearest 0.5 g per serving < 5 g and to nearest 1 g > 5 g
- For products containing < 0.5 g *trans* fat, the content declared on the label is 0 g
- For products that contain < 0.5 g of total fat, “Not a significant source of *trans* fat” may be used instead of a declaration of *trans* fat content if no claims are made about fat, fatty acid, or cholesterol content
- Foods sold at deli and bakery service cases are exempt from labeling unless the food bears a claim or other nutrition information
Citizen Petitions

• CFSAN’s Office of Food Additive Safety has received two citizen petitions requesting that the GRAS status of PHOs be revoked.
  – Center for Science in the Public Interest (CSPI, 2004)
  – Dr. Fred Kummerow (2009)
FDA Priority: *Trans* Fat Reduction

- One of FDA’s goals in the 2012-2015 Foods and Veterinary Medicine Strategic Plan is to reduce industrially-produced *trans* fat in the food supply.

- Reduction of *trans* fat consumption is an integral part of DHHS Million Hearts™ Initiative.
Trans Fat Intake Estimate

FDA calculated updated intake of trans fat in 2010 and 2012:

- To determine the impact of the labeling rule and subsequent reformulations
- To assist in our review of the citizen petitions and strategies for further trans fat reduction
- To better understand the current uses of PHOs and identify products that still contain high levels of trans fat
Intake Summary

• Individuals may still consume relatively high levels of *trans* fat if certain brands or types of food products are frequently consumed
  – Microwave popcorn and frozen pizza were the biggest contributors to intake

• A reduction in *trans* fat intake is continuing:
  – State and municipality restrictions for food service facilities
  – Walmart’s initiative: plan to eliminate all artificial *trans* fats in the products it sells by 2015
  – Industry continues to make efforts in certain product categories

• Consumers can monitor *trans* fat intake by reading both the *trans* fat content on the Nutrition Facts panel, as well as the ingredient list
FDA’s Tentative Determination Regarding PHOs


- FDA has tentatively determined that PHOs are not GRAS based on the health risks associated with consumption of *trans* fat from these oils.

- Elimination of PHOs from the food supply could prevent 10,000-20,000 coronary events and 3,000-7,000 coronary deaths annually (source: CDC)
FDA’s Tentative Determination

• Determination based on review of scientific evidence and findings of expert panels (i.e., IOM recommends intake of trans fat be as low as possible)

• While intake has decreased as a result of voluntary reformulations, there are many processed foods still formulated with PHOs, some at high levels

• Determination applies to the use of PHOs in processed food, regardless of whether it is sold in a grocery store, bakery, or restaurant

• [FDA Consumer Update](#)
FDA’s Tentative Determination: Authority

• FDA’s core regulatory function is to ensure safe food

• If a substance added to food is not safe, we are obligated to take action

• GRAS substances do not require premarket approval by FDA, however there must be “general recognition” of their safety

• Interested parties can submit a food additive petition to establish safe conditions of use for PHOs as a food additive
Comments and Data Requested

• Comment period closed March 8, 2014 (received over 1500 comments)

• FDA requested comments on the following:
  – Should we finalize our tentative determination?
  – Are there data to support other approaches (e.g., a specification level for trans fats in food)?
  – How long would it take to eliminate PHOs from the food supply?
  – Are there special considerations for small businesses?
  – Are there other challenges to the removal of PHOs, or products that may not be able to be reformulated?
  – Is there a prior sanction for the PHOs in food for which FDA is unaware?
Economic Impact

- Initial costs of removing PHOs estimated to be $8 billion
- 20 year net present value of costs to be between $12 and $14 billion
- 20 year net benefits estimated between $117 and $244 billion
- About 12% of packaged foods contain a PHO
- Reformulation and labeling costs estimated between $60,000 and $140,000 per product
Next Steps

• The comments are currently under review by FDA

• FDA will conduct a fair evaluation of all comments and determine our next steps.

More information on FDA’s website