Proposed FDA Rule To Ban Partially Hydrogenated (PHO) Oils

Johari Minal
johari.usa@gmail.com
Outline

• Chronology of events
• The harmful effects of trans fats
• The alternatives
Background

- 1957 – Fred Kummerow published paper against trans fats
- 1968 – Asked AHA and ISEO to reduce trans fats
- November 17, 1999 FDA proposed rule on “Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims
- July 11, 2003 FDA issued a final rule on nutrition labeling regulations to require declaration of the trans fatty acid content, effective Jan 1, 2006
- 2004 - CSPI requested FDA to revoke the GRAS status of PHOs
- August 28, 2009 Fred Kummerow filed a petition to FDA to ban trans fat
- November 7, 2013, the US Food and Drug Administration (FDA) announced it is now considering removing partially hydrogenated oils (PHO)—the primary source of trans fats—from the list of "generally recognized as safe" (GRAS) ingredients.
  - Became globals news
  - If finalized, this would mean that food manufacturers would no longer be permitted to sell PHOs, either directly or as ingredients in another food product, without prior FDA approval for use as a food additive.
# Adverse Effects of Trans Fatty Acids

<table>
<thead>
<tr>
<th>PHOs could be harmful (i.e., increased risk for CHD) under any condition of use in food</th>
<th>there is no threshold intake level for industrially-produced trans fat that would not increase an individual's risk of CHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>risk factors for CHD - increased LDL-C levels and an increased risk of CHD</td>
<td>stronger effect on the risk of CHD than saturated fatty acids</td>
</tr>
<tr>
<td>mediated changes in lipid metabolism</td>
<td>pro-inflammatory</td>
</tr>
<tr>
<td>endothelial dysfunction</td>
<td>worsen insulin resistance - trans fat may also increase diabetes risk</td>
</tr>
<tr>
<td>fetuses and breastfeeding infants of mothers who regularly consume trans fat may be at higher risk for impaired growth</td>
<td>lowers serum high-density lipoprotein cholesterol (HDL-C)</td>
</tr>
<tr>
<td>cancer, bone problems, hormonal imbalance and skin disease; infertility</td>
<td>difficulties in pregnancy and problems with lactation; low birth weight, growth problems, and learning disabilities in children</td>
</tr>
</tbody>
</table>
Adverse Effects of Trans Fats

- Cancer: They interfere with enzymes your body uses to fight cancer
- Diabetes: They interfere with the insulin receptors in your cell membranes
- Decreased immune function: They reduce your immune response
- Problems with reproduction: They interfere with enzymes needed to produce sex hormones
- Trans fats interfere with your body’s use of beneficial omega-3 fats
- Heart disease: Trans fats can cause major clogging of your arteries. (Among women with underlying coronary heart disease, eating trans fats increased the risk of sudden cardiac arrest three-fold)
- Obesity
- Asthma
- Alzheimer’s disease
- Aggressive and violent behavior
Countries and regions mandating trans fatty acid labelling
Nutrition labelling other than trans fatty acids (e.g., saturated fatty acids) is also mandatory.

Countries mandating nutrition labelling
Israel, India, Australia, Cuba, China, New Zealand, Malaysia
Trans fatty acid labelling is voluntary (may have standards for Nutrition and Health Claims).

Japan: Nutrition labelling is voluntary, and standards for trans fatty acid labelling are not established.

[Note] Countries regulating content of trans fatty acids in oils and fats
Current status of trans fats consumption

- The partial hydrogenation process was developed in the 1930s and has been in widespread commercial use since the 1940s.

- The Centers for Disease Control and Prevention estimates that eliminating intake of trans fat from partially hydrogenated oils could prevent up to 20,000 cases of coronary heart disease (CHD) and up to 7,000 deaths annually.

- The state of California, New York City, the City of Baltimore, and Montgomery County, Maryland, have imposed restrictions on the use of trans fat ingredients in food service establishments.
The updated cumulative eaters-only dietary exposure to trans fat from the use of PHOs was estimated to be 1.0 g/p/d at the mean and 2.0 g/p/d at the 90th percentile for the U.S. population aged 2 years or more.

The updated worst-case cumulative eaters-only dietary exposure to trans fat from the use of PHOs was estimated to be 2.1 g/p/d at the mean and 4.2 g/p/d at the 90th percentile for the U.S. population aged 2 years or more.

The updated dietary exposure to trans fat from the use of PHOs has decreased slightly from the 2010 estimate for all age groups considered.

As food products are reformulated to either remove PHOs or lower the trans fat content, the dietary exposure to trans fat from the use of PHOs would be expected to decrease.

Individuals with certain dietary habits may still consume relatively high levels of trans fat if certain brands or types of food products are frequently consumed.

Savory snacks, frozen pizza, cake, cookies, margarine and spreads, coffee creamer, and pies are still the major contributors to the overall exposure to trans fat from the use of PHOs.
Intakes of Trans Fats

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2010</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4.6 g/d</td>
<td>1.3 g/p/d (mean)</td>
<td>1.0 g/p/d (mean)</td>
</tr>
<tr>
<td></td>
<td>2.6 g/p/d (90th percentile)</td>
<td>2.0 g/p/d (90th percentile)</td>
<td></td>
</tr>
</tbody>
</table>

The independent Institute of Medicine (IOM) has concluded that trans fat provides no known health benefit and that there is no safe level of consumption of artificial trans fat.

**Reformulated Foods**

Many foods (e.g., frozen potato products, most frozen breaded products)

**Foods with PHO**

Foods for which consumers have alternatives containing lower levels of *trans* fat (e.g., cookies, baked goods, microwave popcorn, frozen pizza, frozen pies, shortening)

Foods for which consumers have limited or no choice of an alternative containing a lower level of *trans* fat (e.g., ready-to-use frostings, stick margarine).
Facts about trans fat in U.S.

- Currently, the FDA allows products with 0.5 grams or less of trans fat to be labeled as 0 grams of trans fat.
- Trans fats are commonly found in food products such as margarine, shortening, cake mixes, fried foods and microwave popcorn.
- The phrase “partially hydrogenated,” found in a product’s “Nutrition Facts,” means it contains trans fats.
- More than 500,000 people die every year from heart disease.
- The FDA recommends a diet low in trans fat, saturated fat and cholesterol to prevent heart disease.

Sources: [FDA.gov](https://www.fda.gov) and “Cholesterol Won’t Kill You But Trans Fat Could” by Fred Kummerow
Trans Fats’ Replacement May Also Be Harmful

It's worth noting that many processed food manufacturers are swapping out trans fats for what's known as interesterified fats. The interesterification process hardens fat, similar to the hydrogenation process, but without producing oils that contain trans fats. The end product, like trans fat, is less likely to go rancid and is stable enough to use to fry foods. However, while the highly industrialized process of interesterification may result in a product that is trans fat-free, that product will still contain chemical residues, hexanes (crude oil derivatives), and other hazardous waste products full of free radicals that cause cell damage. Studies show that interesterified fat raises your blood glucose and depresses insulin production. These conditions are common precursors to diabetes, and can present an even more immediate danger if you already have the disease. Interesterified fats are in virtually all the foods that trans fats are, so by avoiding trans fat, and processed foods in general, you will also avoid interesterified fats. If a processed food product is labeled "0 grams trans-fats" or "no trans-fats" but is made from vegetable oils, you can be certain it probably contains either interesterified fats or fully hydrogenated vegetable oils, both of which you'll want to avoid in addition to the partially hydrogenated oils that contain trans fats.
Solution to eliminate or reduce TFA

- USE PALM OIL
- Economical
- Natural
- A Balanced Oil
- Versatile Functional Properties
FAC of Selected Oils and Fats
Olive Oil and Palm Olein Have Similar Effects on Plasma Cholesterol in Humans

Palm Olein and Olive Oil have similar effect on Plasma Cholesterol in Humans

Monounsaturated fatty acid at SN2 position

Type of fatty acids in sn-2 position

- Saturated
- Monounsaturated
- Polyunsaturated

Content of Fatty Acid (%)

<table>
<thead>
<tr>
<th>Type of Fatty Acid</th>
<th>Palm Olein</th>
<th>Olive Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturated</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Monounsaturated</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Polyunsaturated</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>
Saturated fatty acids are better absorbed in the form of 2-MAG than as FFA.
Fats and fatty acids in human nutrition
Report of an expert consultation

CHAPTER 10 OF WHO REPORT:
FAT AND FATTY ACID INTAKE AND METABOLIC EFFECTS IN THE HUMAN BODY

TC and LDL-C raising effects of palmitic acid are lower for vegetable than animal sources because it is present predominantly in the sn-1 and sn-3 position as opposed to sn-2 position as in animal fats such as lard

(Ng et al.; 1992; Choudhury et al., 1995; Zhang et al., 1997).
Sat fats have nothing to do with CHD?

This meta-analysis of prospective epidemiologic studies showed there is NO significant evidence for concluding that dietary saturated fat is associated with increased risk of CVD or CHD. More data are needed to elucidate whether CVD risks are likely to be influenced by the specific nutrients used to replace saturated fat. (Am J Clin Nutr. doi: 10.3945/ajcn.2009.27725)

No association between intakes of SFA and CVD. There is insufficient evidence to judge the effect on CVD risk on replacing SFA with MUFA.
<table>
<thead>
<tr>
<th>Melanson <em>et al.</em> (2009)</th>
<th>There is insufficient evidence to substantiate the association between diabetes risk and intake of SFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanders (2009)</td>
<td>There is insufficient evidence to support association of SFA and cluster of metabolic risk factors (endothelial function, insulin sensitivity, arterial stiffness and inflammation)</td>
</tr>
<tr>
<td>Reference</td>
<td>Summary</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Siri Tarino et al (2010)</td>
<td>The relative effect of dietary saturated fatty acids on CVD risk factors needs to be evaluated, taking consideration of the changing paradigms associated with CVD risk factors.</td>
</tr>
<tr>
<td>Mozaffarian (2011)</td>
<td>Current scientific evidence do not support the traditional diet-heart paradigm which relates the consumption of saturated fats and coronary heart disease (CHD). Taking into isolation a single nutrient in relation to one or two biomarkers without considering dietary consumptions can lead to misleading conclusions</td>
</tr>
</tbody>
</table>
Numerous clinical studies have shown that saturated fatty acid intake does not increase cardiovascular heart disease event and death.
Current intakes are close to guidance levels (< 10-11%), but achieving lower levels of intake would pose challenges requiring major changes in dietary patterns, with only minor impact on CVD risks.

Sanders (2013)
Dietary Fats and Health: Dietary Recommendations in the Context of Scientific Evidence

Glen D. Lawrence*
Department of Chemistry and Biochemistry, Long Island University, Brooklyn, NY

ABSTRACT

Although early studies showed that saturated fat diets with very low levels of PUFAs increase serum cholesterol, whereas other studies showed high serum cholesterol increased the risk of coronary artery disease (CAD), the evidence of dietary saturated fats increasing CAD or causing premature death was weak. Over the years, data revealed that dietary saturated fatty acids (SFAs) are not associated with CAD and other adverse health effects or at worst are weakly associated in some analyses when other contributing factors may be overlooked. Several recent analyses indicate that SFAs, particularly in dairy products and coconut oil, can improve health. The evidence of \( \omega 6 \) polyunsaturated fatty acids (PUFAs) promoting inflammation and augmenting many diseases continues to grow, whereas \( \omega 3 \) PUFAs seem to counter these adverse effects. The replacement of saturated fats in the diet with carbohydrates, especially sugars, has resulted in increased obesity and its associated health complications. Well-established mechanisms have been proposed for the adverse health effects of some alternative or replacement nutrients, such as simple carbohydrates and PUFAs. The focus on dietary manipulation of serum cholesterol may be moot in view of numerous other factors that increase the risk of heart disease. The adverse health effects that have been associated with saturated fats in the past are most likely due to factors other than SFAs, which are discussed here. This review calls for a rational reevaluation of existing dietary recommendations that focus on minimizing dietary SFAs, for which mechanisms for adverse health effects are lacking. Adv. Nutr. 4: 294–302, 2013.
Various aldehydes produced in the oxidation of PUFAs, as well as sugars, are known to initiate or augment several diseases, such as cancer, inflammation, asthma, type 2 diabetes, atherosclerosis, and endothelial dysfunction. Saturated fats per se may not be responsible for many of the adverse health effects with which they have been associated; instead, oxidation of PUFAs in those foods may be the cause of any associations that have been found.

Fats and fatty acids in human nutrition

Based on experimental studies, risk of lipid peroxidation may increase with high (>11% E) PUFA consumption, particularly when tocopherol intake is low. Therefore, the resulting acceptable range for total PUFA (n-6 and n-3 fatty acids) can range between 6 and 11% E. The adequate intake to prevent deficiency is 2.5–3.5% E.

Vitamin E (Tocotrienols, tocopherols) 600-1000 ppm

- Squalene 250-540 ppm
- Lecithin 20-100 ppm
- Polyphenols 40-70 ppm
- Co-Q10 10-80 ppm
- Carotenoids 500-700 ppm
- Phytosterols 300-620 ppm

Choo et al. 2008
- Cancer (breast, prostate, pancreatic, colon, gastric)
- Neuroprotection
- Immune-response
- Anti-inflammation
- Anti-angiogenic effects
- Arthritis
- Cholesterol and Atherosclerosis
- Cancer vaccine
- Wound healing
- Radioprotection
CAROTENOIDs
. Antioxidant
- Anti microbial
- Anti atherogenic
- Anti cancer
- Anti hypertensive
- Anti inflammatory
- Memory enhancing
- Anti obesity
- Anti spasmodic
- Anti thrombotic
- Anti allergenic
- Anti ulcer
ADVANTAGES OF USING PO

• At 20°C, it has 22-25% solids which is the desired constituent in shortening formulations.

• PO stabilizes the shortening in the beta prime form. This is also desired for optimum performance of the shortening.

• PO requires no hydrogenation and has no negative connotations associated with trans fatty acids.

• Can be tailor-made to suit most applications.

• Stable and has a long shelf-life. Desirable amounts of natural vitamin E which acts as an antioxidant.
Conclusions

• To maintain the functional properties of trans fatty acids-containing fat products trans fatty acids have to be replaced by saturated fatty acids
• Trans fatty acids, but not saturated fatty acids increase risk of developing CHD
• Palmitic acid in the form of palm oil would be the most convenient replacement.
• Palm oil is the natural substitute for trans fats