

Trans Fatty Acids - An Update on its Regulatory Status

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INTRODUCTION

Trans fatty acids are unsaturated fatty acids containing at least one double bond in the *trans* configuration, formed when edible oils are partially hydrogenated. This process is normally done to increase the melting points of the fatty acids to enable liquid oils to be used in solid fats formulations such as margarines, shortenings, vanaspati and bakery fats. The conformation of the double bond(s) impacts the physical properties of the fatty acids. Those fatty acids containing a *trans* double bond have the potential for closer packing or alignment of their acyl chains, resulting in decreased mobility and reduced fluidity compared to natural fatty acids containing a *cis* double bond. Partial hydrogenation of edible oils causes isomerization of some of the remaining double bonds, resulting in an increase in the *trans* fatty acids content and hardening of the fat.

A major *trans* fatty acid is elaidic acid (9 *trans* 18:1), but during hydrogenation of unsaturated fatty acids, small amounts of other *trans* fatty acids (9 *trans*, 12 *cis* 18:2; 9 *cis* and 12 *trans* 18:2) are also produced. In addition to these isomers, dairy fat and meat contain 9 *trans* 16:1 and conjugated dienes (9 *cis*, 11 *trans* 18:2). Conjugated linoleic acid (CLA) is a term used to describe group of geometric and positional isomers of linoleic acid in which the *trans/cis* double bonds are conjugated. CLA is present naturally in dairy products and ruminant meats as a consequence of biohydrogenation of linoleic acid in the rumen.

Foods containing hydrogenated oils tend to contribute to *trans* fatty acids in our diets (Emken, 1995). *Trans* fatty acids are present in foods containing traditional stick margarine and vegetable shortenings that have been subjected to hydrogenation as well as in milk, butter and meats. Foods that contribute to *trans* fatty acids include

pastries, fried foods such as doughnuts and French fries, dairy products and meats.

Prior to 1980, there was generally little concern about the increasing consumption of *trans* fatty acids, particularly as the use of hydrogenated fats was seen as the safe preferred alternative to solid fats formulations, especially margarines, targeted to replace saturated fats which have been associated with increased risk of cardiovascular disease (CVD). However, recent studies have shown that *trans* fatty acids are not as innocent as they appear to be. The nutritional implications and adverse health effects of *trans* fatty acids have currently become more obvious.

The study by Mensink and Katan (1990) suggested that *trans* increased the total and atherogenic low-density lipoprotein cholesterol (LDL-C) concentrations and decreased the beneficial high-density lipoprotein (HDL-C) concentration, resulting in a less desirable total/HDL-C ratio. A number of other studies have also found that *trans* fatty acids increase the atherogenic LDL-C and decreases

the beneficial HDL-C following diets rich in *trans* fatty acids (Institute of Medicine, 2002). Recent data have demonstrated a dose-dependent relationship between *trans* fatty acids intake and the LDL/HDL ratio and, combining a number of studies, the magnitude of the effect is greater for *trans* fatty acids compared to saturated fats (Ascherio *et al.*, 1999).

Lipoprotein(a) or Lp(a) concentration in human plasma has been associated with increased risk for CVD. Lp(a) concentration has been reported to be increased after the consumption of diets rich in *trans* fatty acids. Sundram *et al.* (1997) subsequently demonstrated that when palm oil replaced a *trans* enriched diet, Lp(a) was significantly reduced by the palm oil diet, even in a low fat environment.

Recent studies have implicated *trans* fatty acids not only with coronary heart disease but also with increased risk and incidence of diabetes. A 2% increase in *trans* fatty acids consumption relative to carbohydrate intake resulted in a relative risk score of 1.93 for CHD and 1.39 for type II diabetes (Hu *et al.*, 1997).

REGULATORY STATUS OF TRANS FATTY ACIDS

In view of the increasing concerns over the health implications of *trans* fatty acids, some countries have now developed standards to limit the amount of *trans* fatty acids in their foods. Denmark is the first country in the European Union, and the first in the world to set maxi-

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mum limits on the level of *trans* fatty acids in foods. The Danish Executive Order, which came into force on 31 March 2003, requires that effective from June 2003, the *trans* fatty acids content in oils and fats should not exceed 2%. From 31 December 2003, the level of *trans* fatty acids should not exceed 5% in oils and fats as ingredients in processed foods (Danish Ministry of Food, Agriculture and Fisheries, 2003). The Order, however, does not cover naturally occurring *trans* fatty acids from animal fats and does not apply to products for exports. The Order, however, does not cover naturally occurring *trans* fatty acids from animal fats and does not apply to products for exports.

The United States Food and Drug Administration (USFDA) is now amending its regulations on nutrition labelling to require *trans* fatty acids to be declared in the Nutrition Facts panel. This was partly in response to petitions made by consumer organizations in the United States. The declaration of *trans* fatty acid content in the United States has however been a slow progress. In January 1993, the final rule implementing the 1990 amendments of the Nutrition Labelling and Education Act 1990 was made. In that Act, total fats and saturated fats were required to be labelled, with a declaration for monounsaturated fat and polyunsaturated fat defined as the *cis* isomers only (Food and Drug Administration, 2003). *Trans* fatty acids was not included as the agency felt that it was premature to label *trans* fats given the limited scientific knowledge on *trans* fatty acids then. However, this issue was revisited in November 1999. In the Federal Register of 17 November, the USFDA proposed to amend its nutrition labelling regulations to require the amount of *trans* fatty acids in foods including dietary supplements to be included in the amount and percent daily value (%DV) declared for saturated fats. A footnote indicates the amount of *trans* fatty acids in a serving of the

product when the product contains 0.5 g or more *trans* fatty acids per serving. In the proposal, USFDA concluded that dietary *trans* fatty acids have adverse effects on the blood cholesterol and CHD risk.

Even though this development to include *trans* fatty acids was appreciated, consumers will only know the amount of *trans* fatty acids by deducting saturated, monounsaturated and polyunsaturated fatty acids from the total fats declared on the label. During period prescribed for public comments by the USFDA, the Malaysian palm oil industry advocated that *trans* fatty acids should be declared separately from saturated fatty acids. Subsequent to the USFDA's November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) (2002) reported a positive linear trend between *trans* fatty acids intake and total and LDL-C concentrations, and, therefore, an increased risk of heart disease. This suggests a tolerable upper intake level (UL) of zero for *trans* fatty acids. Though no UL was proposed, the report recommended that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.

In response to recommendations in new scientific reports to limit the intake of *trans* fats and to provide consumers with label information to assist them understand the quantitative declaration of *trans* fats in the context of their total daily diet, USFDA reopened the comment period for the November 1999 proposal in November 2002. In a new proposal, the agency proposed an asterisked footnote for *trans* fats at the bottom of the Nutrition Facts box with the statement "Intake of *trans* fat should be as low as practically possible". USFDA, however, cautioned manufacturers that the final rule for *trans* fats may differ from that proposed in November 2002.

The Final Rule of the USFDA's regulations on nutrition labelling now requires mandatory declaration of the amount of *trans* fatty acids

in foods, including those from dietary supplements. The declaration must be on a separate line immediately under the declaration for saturated fatty acids but without the %DV. With this final ruling, the agency withdrew the proposed footnote "Intake of *trans* fat should be as low as practically possible". This Final Rule will be effective 1 January 2006. In addition, USFDA is also soliciting comments on establishing new nutrient content and health claims on *trans* fatty acids as well as a footnote or disclosure statements on food labels that would enhance consumer understanding about saturated fats, *trans* fats and cholesterol.

In international standards development, Codex Alimentarius is discussing the labelling and maximum levels of *trans* fatty acids primarily in the Codex Committee on Food Labelling (CCFL) and the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). The labelling of *trans* fatty acids was discussed during elaboration of the Draft Amendments to the Guidelines on Nutrition Labelling by the CCFL. The Guidelines on Nutrition Labelling is applicable when a nutrition or health claim is made. The declaration on the amount of *trans* fatty acids was included in the Draft Amendments, proposed by Malaysia (through MPOB) during the 29th Session of the CCFL in Ottawa, Canada in 2001 (Codex Committee on Food Labelling, 2001). However, at the 31st Session of the CCFL in May 2003, the Committee decided that the declaration of *trans* fatty acids should be left to national legislation as the meeting could not agree on the different types of *trans* fatty acids, *i.e.*, *trans* fatty acids from hydrogenation and natural *trans* fatty acids (Codex Committee on Food Labelling, 2003). In view of this, the CCFL requested the CCNFSDU to define *trans* fatty acids for the Guidelines and agreed to consider this matter further only when such advice from the CCNFSDU became available. It is however to be noted

that the amount of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids are to be declared when a claim on the amount and/or types of fatty acids or the amount of cholesterol is made.

In adopting the Draft Amendments to the Guidelines on Nutrition Labelling at Step 8 at the 26th Session of the Codex Alimentarius Commission (CAC), in Rome (July 2003), Malaysia proposed that the amount of *trans* fatty acids be declared along with saturated, monounsaturated and polyunsaturated fatty acids when such claims on the amount and/or types of fatty acids are made. This is because consumers need to be informed regarding the different types of fatty acids in foods, which should also include *trans* fatty acids. The 26th Session of the CAC, however, adopted the Draft Amendment as proposed by the CCFL. The CAC, however, requested the CCFL to continue its work on *trans* fatty acids in cooperation with the CCFNSDU and also asked FAO and WHO to advise on the scientific data to facilitate resolution of this issue (Codex Committee on Alimentarius Commission, 2003). Malaysia and some other countries expressed reservation on the adoption of the Draft Amendments.

The definition of *trans* fatty acids was discussed during the 25th Session of the CCFNSDU in Bonn, Germany in November 2003 (Codex Committee on Nutrition and Foods for special Dietary Uses, 2003). Malaysia has been given the mandate by the CCFNSDU to work with Denmark to produce a discussion paper on the matter for deliberation at the next 26th Session of the CCFNSDU in November 2004. MPOB is currently working on drafting a definition of *trans* fatty acids in collaboration with Denmark.

In addition to the Codex Guidelines on Nutrition Labelling, *trans* fatty acids have also been included in the Table of Conditions for Nutrient Contents in the Draft

Guidelines for Use of Health and Nutrition Claims. In this context, *trans* fatty acids are referred in the footnote of the Table with the statement "In the case of the claim for low in saturated fat, *trans* fatty acids should be taken into account where applicable". This provision consequentially applies to foods claimed to be *low in cholesterol* and *cholesterol free*. This Table of Conditions was adopted by the 22nd Session of the CAC in 1997.

Apart from labelling requirements, maximum levels for *trans* fatty acids are required in some Codex standards, for example, in the Proposed Draft Revised Standard for Infant Formula. During elaboration of the proposed draft standard, the CCFNSDU agreed to prohibit the use of commercially hydrogenated oils and fats in infant formulae. The discussion on the maximum levels for *trans* fatty acids as well as the prohibition on the use of commercially hydrogenated oils and fats is still ongoing.

The Ministry of Health, Malaysia, the authority for food quality control in the country, in their new law on nutrition labelling gazetted on 31 March 2003, requires the mandatory declaration on the amount of *trans* fatty acids together with the amount of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids on nutrition labels, when a claim is made regarding the amount and/or types of fatty acids (Ministry of Health, 2003). In addition, the Malaysian Food Act 1983 Food (Amendment) Regulation 2003 has also made provisions for nutrient content claims on *low* and *free trans* fatty acids in foods.

IMPLICATION REGARDING REGULATIONS ON TRANS FATS

Increased awareness on the levels of *trans* fatty acids in foods through labelling is indeed welcome since consumers would be better informed on the presence of *trans* fats in the foods they consume to

enable them to make the right food choices. Consumers may be misguided if the declaration on the fatty acids does not include *trans* fatty acids. Limiting the level of *trans* fatty acids in foods would provide an opportunity to reformulate those products normally containing high *trans* fatty acids such as in margarine, vanaspati, bakery fats and other solid fats to make them *trans*-free. Palm oil and its fractions with their functionality and versatility are able to provide the solids needed while maintaining the functionality of these products. Furthermore, palm oil has been shown to be neutral with respect to CHD risk.

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ERRATA

Please note that in *Palm Oil Developments No. 38 (June 2003)*:

a. Page 6 column 2 line 24, should read as:

.....(between 20 and 48 hr)and not as
(between 20 and 38 hr).....

b. Page 9, the caption for *Figure 6* should read as:

Figure 6. Free fatty acid (FFA) changes during final frying of French fries in sunflower oil (mid samples).

The error is regretted.