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## ***TRANS FATS AND THEIR REGULATION IN MEXICO***

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### **ABSTRACT**

*Introduction:* Many investigations have consistent evidence of industrially-produced *trans* fatty acids (TFA) adverse effects on human health, particularly concerning coronary heart disease, blood lipoprotein profiles, inflammation, insulin resistance, and diabetes. Moreover, in Mexico heart diseases and type 2 diabetes are the principal causes of mortality, with the mean intake of TFA in 30% of school-age children and adolescents, and 20% of adults, exceeding international recommendations. Due to this, TFA labeling and regulation in Mexico are highly important.

*Objective:* The goal of this paper is to gather and describe the information about *trans* fats and their regulation in Mexico in over the last ten years.

*Method:* In June 2005, professors and politicians met as a working group to carry out an action plan for the regulation and usage of TFA in the Mexican food industry, which concluded in a proposed bill. Those involved analyzed: 1) the definition, characteristics, and effects of TFA; 2) the current legislation; and 3) an action plan to be elaborated. Based on the Mexican General Health Law and the Health Secretary's Sanitary Control of activities, establishments, products and services; the working group concluded that there was no regulation in relation to the usage and labeling of TFA. The Mexican Official Standard, NOM-051-SCFI-1994: "General specifications for the labeling of pre-packed foods and non-alcoholic drinks," established in the section 4.2.8.1, stated that providing nutritional information on the labels of the pre-packed products was voluntary.

*Results:* Before the Senate of the Republic, an agreement made by the groups was presented in October, 2005, in which the Ministries of Economy, Agriculture, Livestock, Rural Development, Fishing, Food and Health were urged to give information from their field for specific regulations of TFA labeling of Mexican products.

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Later in June 2009, the bill was submitted before the Permanent Commission of the Union Congress, and it was decided to modify Paragraph II of Article 212 of the Mexican General Health Law, thereby stating that labels of foods and non-alcoholic drinks should mandatorily include the content of TFA and comparative elements recommended by health authorities.

The following year, via the Federal Official Gazette, it was published in the Mexican Official Standard NOM-051-SCFI/SSA1-2010: "General specifications for the labeling of pre-packed foods and non-alcoholic drinks," thus establishing that the amount or type of TFA, should be stated. However, in section 4.2.9: "Nutritional Frontal Labeling," it was established as obligatory that *only* the nutritional information of saturated fats, *other fats*, total sugars, sodium and energy be provided on the packaging, therefore *not* specifically mentioning TFA.

*Conclusion:* Partially hydrogenated oils are food additives with clear adverse effects and their regulation is a public health priority. Developed countries, such as England and Denmark have implemented TFA elimination policies, which have been followed by a decrease in CVD mortality rates.

There is still much need for improvement in terms of the TFA content in Mexican food. There is an evident need to help consumers with interpreting food labels, particularly regarding *TFA*.

**Keywords:** *trans* fatty acids, hydrogenated fat, regulation, labeling, Mexico

## INTRODUCTION

Many investigations have consistent evidence of industrially-produced *trans* fatty acids (TFA) adverse effects on human health, particularly concerning coronary heart disease, blood lipoprotein profiles, inflammation, insulin resistance, and diabetes. Moreover, in Mexico heart diseases and type 2 diabetes are the principal causes of mortality, with the mean intake of TFA in 30% of school-age children and adolescents, and 20% of adults, exceeding international recommendations [1].

However, extreme positions range from calling for the elimination of TFA from people's diets by avoiding specific foods; to removing TFA from processed foods and/or including their amounts on food labels; to denying any adverse effects or the need to modify food processing and production, food labels, health claims, or consumption. As a result of this, it is highly important that TFA are reported on food labels and considered in legislation used in Mexico.

### Definition

*Trans* fatty acids are unsaturated fatty acids with at least one carbon–carbon double bond in the *trans* configuration [2]. This means that in a *trans* double bond in an unsaturated fatty acid the two hydrogen atoms are bound to the carbon atoms that form the double bond which is located on opposite sides of the carbon chain. In contrast to the more typical *cis* isomeric configuration, the double bond angle of the TFA is smaller and the acyl chains are more linear, resulting in a more rigid molecule with a higher melting point [3]. *Trans* fats, unsaturated fatty acids with at least one double bond in the *trans* configuration, are formed during the partial hydrogenation of vegetable oils – a process that converts vegetable oils into

semisolid fats for use in margarines, commercial cooking, and manufacturing processes [4]. During the hydrogenation process, variable amounts of the unsaturated fatty acids that are not hydrogenated are converted from the *cis* to *trans* configuration. In mammals, endogenously synthesized unsaturated fatty acids have double bonds in the *cis* configuration. The main exception is ruminants such as cows, sheep, and goats, in which small amounts of TFA are produced enzymatically by the action of bacteria in the ruminant stomach. Because TFA comprise of a minority (typically <5%) of ruminant fatty acids, consumption of naturally occurring ruminant TFA typically contributes to <0.5% of total energy intake [2].

Most fats and oils consumed on a regular basis are a combination of several fatty acids. No fat or oil contains only one type of fatty acid. Saturated fatty acids are more stable than polyunsaturated and monounsaturated fatty acids. This stability is important in terms of the shelf life of packaged foods and the retardation of the rancidity of frying oils. The major fatty acids found in food are palmitic, stearic, oleic, linoleic, and linolenic acids [5].

Partial hydrogenation increases the shelf life and flavor stability of foods containing fats, and gives the fat a higher melting point. Compared with fatty acids with *cis* bonds, TFA tend to be more stable in storage and during frying. Partially hydrogenated fats tend to be more solid than unsaturated fats, but less solid than saturated fats.

## Food Sources

The major dietary sources of TFA are traditional vegetable shortenings and solid margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods. French fries and fried meat from fast-food outlets contain high amounts of TFA [6]. *Trans* fats are fats in margarines, spreads, and frying oils, produced by the industrial hardening of vegetable or marine oils, to make the product more stable and robust for handling and storage [7]. Although most dietary sources of TFA are produced by the food industry, which is usually of transnational origin, in Mexico small businesses, such as bakeries, are source of a high percentage of the TFA consumed by the population.

TFA occur naturally at relatively low levels in meat and dairy products as a result of the fermentation process in the animal's rumens. TFA are found in the body fat of ruminants such as cattle and sheep, with concentration ranging from 4-11% (similar to butter fat). The major TFA in milk, butter, and beef fat is vaccenic acid. TFA are also found in goats, deer, and marsupials. Researchers reported that in six species of plants, including pomegranates with 70% of their fatty acids being punicic acid (9c, 11t, 13c-18:3) [3].

The predominant *trans*-isomer in ruminants is vaccenic acid; from which conjugated linolenic acid (another TFA) can be formed [6]. It is possible to change the TFA content of ruminant products to some degree by altering the animals feed, although levels of *trans* fat in milk and meats are already relatively low (1-8% of total fats).

In fact, most efforts have focused on increasing, rather than decreasing, the levels of conjugated linolenic acid in ruminant products, owing to its hypothesized health benefits for humans. However, the evidence of such benefits is inconclusive. For example, dietary trials indicate that consumption of conjugated linolenic acid reduces insulin sensitivity, increases lipid peroxidation, and has mixed effects on markers of inflammation and immune function [4].

## **TFA in Health**

### ***TFA in Healthy Subjects***

There are some published studies, that investigate the effects of TFA on insulin sensitivity. In one study, a randomized controlled cross-over study using a TFA high diet that was compared with monounsaturated fatty acids (MUFA) high diet over 4 weeks. There were no differences between the TFA and MUFA diets in relation to their effects on insulin sensitivity, although fasting insulin concentrations tended to be higher after the TFA diet. There were also no significant differences between diets with reference to their acute insulin response to intravenous glucose [8].

### ***Possible Adverse Health Effects of TFA Early in Life***

There is a suspicion that pregnant women's intake of TFA may have adverse effects on fetal growth and development. Several studies have shown that TFA are transferred from the mother to the fetus. These studies show that the concentration of TFA in newborns is inversely proportional to the concentration of the longer-chain, more unsaturated derivatives of essential fatty acids, and long chain polyunsaturated fatty acids (LCPUFA). The issue is, however, that the available studies do not provide sufficient evidence for the claim that TFA have adverse effects on fetal growth and development [9].

### ***TFA and Diabetes***

Epidemiological data indicate that TFA increase the risk of developing type 2 diabetes [10]. Alternatively, the intake of *trans* fat may not be an important risk factor for new-onset diabetes; however additional studies are needed. Molecular mechanisms that might account for the effects of TFA on the incidence of diabetes are not well established, but evidence of the effects of TFA on metabolism in adipocytes and on systemic inflammation suggests plausible pathways.

### ***TFA in Cardiovascular Disease***

Strong observational and experimental evidence also exists for the increasing risk of coronary heart disease (CHD) associated with TFA. Multiple prospective studies and case-control studies have reported a positive association between TFA intake and the risk of developing CHD. A less mature data set suggests a positive association between TFA intake, type 2 diabetes, and elevated inflammatory markers [5].

On a per-calorie basis, *trans* fats appear to increase the risk of CHD more than any other macronutrient, creating a substantially increased risk at low levels of consumption (1-3% of total energy intake).

For several decades, there have been some studies in which the dietary total fat and saturated fat have been related, by means of their effects on serum total cholesterol and low-density lipoprotein cholesterol (LDL-C) concentrations. These were considered the major dietary causes of CHD. Also, there have been experimental studies conducted to examine the effects of diet on a wide range of both lipid and non-lipid-pathways. These studies examined how dietary factors relate to clinical events among individuals. *Trans* fatty acids have a wide range of physiological effects, including both lipid and non-lipid effects.



### ***TFA in Lipid Effects***

Dietary fat profiles have a significant impact on health. Many studies have shown that TFA can adversely affect LDL and HDL cholesterol levels, and some data suggests that TFA adversely affect other outcomes [2].

A meta-analysis of 60 controlled trials of dietary fats and blood lipids shows that as carbohydrates are replaced with polyunsaturated or monounsaturated fats, the ratios of total HDL and LDL cholesterol decrease. However, when carbohydrates are replaced with TFA, the ratio of total HDL cholesterol increases, as does LDL cholesterol. TFA also are the only type of fats that do not raise HDL cholesterol [2].

### ***TFA Non-Lipid Effects***

*Trans* fats have been implicated in systemic inflammation, endothelial dysfunction, adiposity, and insulin resistance.

### **Systemic Inflammation**

Inflammation is an independent risk factor for atherosclerosis, sudden death, diabetes, and heart failure. TFA have pro-inflammatory effects, seen in both observational studies and randomized control trials. In observational studies, higher TFA intake has been associated with increased activity of the tumor necrosis factor (TNF) system for healthy women, and higher levels of interleukin-6 (IL-6) and C-reactive protein (CRP) among overweight women.

### **Endothelial Function**

There are reports, some observational studies, and randomized trials that indicate that TFA consumption produces endothelial dysfunction. Among overweight women, greater TFA intake was associated with higher levels of circulating markers of endothelial dysfunction, including soluble cell adhesion molecules and E-selectin, after adjusting for other risk factors [2].

### **Adiposity**

Emerging evidence suggests that TFA consumption may increase weight gain and fat accumulation, particularly of visceral fat. In two prospective cohort studies, increases in TFA intake were associated with increases in abdominal circumference in men and increases in body weight gain [2].

### **Insulin Resistance**

Both duration of TFA exposure and underlying predisposition to insulin resistance appear to play important roles in the effects of TFA on glucose–insulin homeostasis. Short-term feeding trials in humans that compared TFA with oleic acid in lean healthy individuals found little effect on insulin sensitivity [2].

### ***Optimal Levels***

To determine the optimal level of intake for a nutrient, both the risks and benefits should be considered. The evidence and the magnitude of adverse health effects of TFA are in fact far stronger on average than those of food contaminants or pesticide residues, which have in some cases received considerable attention. Furthermore, *trans* fats from partially hydrogenated oils have no intrinsic health value above their caloric value. Thus, from a

nutritional standpoint, the consumption of TFA results in considerable potential harm, with no apparent benefit. In addition, adverse effects are seen even at low levels of intake: 1-3% of total energy intake, or approximately 20-60 calories (2-7g) for a person consuming 2000 calories per day. Thus, complete or near-complete avoidance of industrially produced *trans* fats, consumption of less than 0.5% of the total energy intake, may be necessary to avoid adverse effects and would be prudent to minimize health risks [4]. In January 2006, the US Food and Drug Administration (FDA) ruled that nutritional facts panels of all packaged food labels must indicate the quantity of TFA in a serving of the food product [5].

### ***Food Science to Reduce TFA in Food***

Advances in food technology can reduce the TFA content of foods. Improvements in the hydrogenation process (temperature, pressure, time, catalyst, methods, starting oils) should decrease the formation of TFA. Genetic engineering of oil seed plants is ongoing to modify the fatty acid composition of oils, and thus the need for hydrogenation. Collectively, these new food technologies could result in a significant decrease in the TAF content of the diet [3].

## **OBJECTIVE**

The goal of this paper is to gather and describe the information about *trans* fats and their regulation in Mexico in over the last ten years.

## **METHOD**

One of the Mexican working groups interested in TFA was comprised of health professionals, academics and researchers from the Universidad Veracruzana. From 2004, they started to plan working sessions about TFA and their regulation in Mexico. In June 2005, they conducted a workshop with international guest professors from Harvard School of Public Health, Institute of Nutrition for Central America and Panama (INCAP), Universidad de San Carlos Guatemala, Universidad de Costa Rica, Universidad Autónoma de Nuevo León, Asociación Mexicana de Miembros de Escuelas y Facultades de Nutrición (AMMFEN), Universidad Veracruzana, and a representative from the Mexican Senate. The group met to carry out an action plan for the regulation and usage of TFA in the Mexican food industry [11, 12]. An analysis was conducted of: 1) the definition, characteristics, and effects of TFA; 2) the current legislation; and 3) an action plan to be elaborated. The Mexican Official Standard, NOM-051-SCFI-1994: "General specifications for the labeling of pre-packed foods and non-alcoholic drinks" [13] established in the section 4.2.8,1 stated that nutritional information on the labels of the pre-packed products was voluntary. Nowhere was it required to specifically state the permitted fat type, the maximum amount, and the production process required. Furthermore, it did not require any specific labeling, neither of product information to guide the population about health benefits, nor information about the potential harm from its consumption. Therefore, based on the Mexican General Health Law and the Health Secretary's Sanitary Control of activities, establishments, products and services; the working group concluded that there was no regulation in relation to the usage of labeling of TFA.

They finally elaborated a proposed bill, including in it the current legislation, and rules around the use of TFA present in industrially-produced foods.

To achieve the legislation and regulation of the food industry's TFA, the following points needed to be considered [11, 12]:

1. Maximum permissible content of TFA:

- To review current legislation concerned with processing and commercialization of food products.
- To set a maximum limit for the content of TFA in food.
- To quantify the content of TFA in industrially-produced foods in accordance with the methodology laid out in the Mexican Official Standard in force.
- To include in labeling requirements about the origin, type of oils and fats, mix percentage, and TFA percentage. The label should include a legend about the health risks involved.
- To implement a systematic and permanent educational program for the general public focused on TFA and their health effects.

2. Allowable development processing and statement about the labeling of TFA:

- To implement in the field of education, study programs that include information about healthy eating and specifically about harmful substances like TFA.
- To promote research in Mexico about TFA use in the food industry and their health effects.
- To develop clear and simple content for the formal education system, including the promotion and distribution of concepts related to TFA and their health effects.
- To develop epidemiological research in the Mexican population to determine TFA health effects, and to help decision-makers in the food industry, as well as those involved in the reorientation of public policies.
- To publish the epidemiological research findings through different communication media.
- To standardize the TFA analytical methodology of industrially-produced food in highly specialized laboratories.

3. Clear legend warning about the harmful effects on health:

- To summon all the actors involved in educational programs for health and consumer.
- To implement the most appropriate strategies to spread orientation and educational programs which reject the consumption of food that contains TFA.
- To allow for a monitoring and evaluation plan that will be developed in orientation and educational programs for TFA consumption.

## RESULTS

The agreement adopted by the working group was presented before the Mexican Senate in October 2005, and the Ministries of Health, Economy, Agriculture, Livestock, Rural Development, Fisheries and Food, were urged give information from their field about the type of regulation that should be implemented for TFA labeling of Mexican products [11, 12].

In June, 2006, from the Health Ministry, Federal Commission for Protection against Sanitary Risks responded to Congress that there was not any applicable regulation for these kinds of fats. However, as part of the 2006 National Standardization Program, there was a planned revision of the Mexican Official Standard, NOM-086-SSA1-1994: "Goods and services, foods and non-alcoholic drinks with changes in their composition" [14], published in the Federal Official Gazette on 28 October 1995; and in this, the Standard would be analyzed in detail, with respect to TFA, and would include provisions that were seen necessary [11, 12].

In July 2006, the Planning, Communication and Liaison Technical Secretariat of the Economy Ministry, responded to the Senate that it would use the Mexican Official Standard NOM-051-SCFI-1994 [13] to regulate and enforce the reporting of all the ingredients to be listed on the label of pre-packed products with an individual legend. Apart from this, the Secretariat expressed that when TFA were part of a product, they should be declared as ingredients, and if they were nutrients, they should be declared in the nutritional information of foods.

Later in June 2009, the bill was submitted before the Permanent Commission of the Union Congress, and it was decided to modify Paragraph II of Article 212 of the Mexican General Health Law, thereby stating that labels of foods and non-alcoholic drinks should mandatorily include the content of TFA and comparative elements recommended by health authorities [15].

The following year, via Federal Official Gazette, it was published in the Mexican Official Standard NOM-051-SCFI/SSA1-2010: "General specifications for the labeling of pre-packed foods and non-alcoholic drinks" [16], thus establishing that the amount of TFA should be stated. However, in Paragraph 4.2.9 "Nutritional Frontal Labeling," it was established as obligatory that *only* the nutritional information of saturated fats, *other fats*, total sugars, sodium and energy should be provided on the front of packaging – *not* TFA specifically.

The work against TFA started in Latin American countries a few years earlier. Since 2004, Argentina has implemented several policies to reduce artificial TFA and surveillance systems to monitor their content in foods. Given the estimated 84 000 annual CHD events held there, the current policy of near elimination of industrially-produced TFA might avert between 1.3-6.3% of CHD events each year. The decrease would save between US\$17 million and US\$87 million in management of CHD complications and follow-up [17].

Some middle-income countries such as Brazil, Costa Rica and India have started to follow the Argentinian example [17].

In Costa Rica, a Multi-sectorial Committee on Fats and Oils proposed the reduction of TFA consumed in the Dominican Republic and Central American countries, and recommended the inclusion of data about *trans* fat content on labels.

In 2005, the *United Nations University* (UNU) created a project to evaluate the impact of the implemented interventions in Argentina, as well as similar efforts conducted in Latin

American countries. Uruguay, Chile, México and Central American countries were integrated by the INCAP [18].

In January 2006, Chile adopted the same approach, accompanied in August of the same year by the Southern Common Market (MERCOSUR) countries including Argentina, Brazil, Paraguay and Uruguay.

In 2006, as a part of the UNU project, the first course entitled “Fats and oils nutrition: human health and food industry implications,” took place in Cuernavaca, Mexico. One of the aims of the course was to strengthen local strategies and knowledge to control TFA consumption. Among those attending the course, were consumer organizations and representatives of the food industry [18].

In 2007, the Pan-American Health Organization/World Health Organization (PAHO / WHO) convened a trans-fat-free task force composed of expert scientists and public health figures from 11 countries in Latin America and the Caribbean (Argentina, Brazil, Costa Rica, Chile Guatemala, Jamaica, Mexico, Peru, Puerto Rico, Uruguay y Venezuela), the United States of America (*Centers for Disease Control and Prevention*, Harvard University, *National Institutes of Health* and Department of Agriculture), and Canada (Health Canada and Public Health Agency of Canada) with the goal of eliminating TFA in foods [18].

As part of this Trans-Fat-Free Americas initiative, in September 2007, Legislature of Puerto Rico adopted the Law 120, prohibiting the use of TFA in every prepared and/or sold food in restaurants, fast-food services, economic restaurants, food delivery services and all types of mobile food units. In June 2008, the trans-fat-free task force with 12 representatives from food industries in Latin America and the Caribbean signed a declaration in Rio de Janeiro stating their intention to voluntarily eliminate industrially-produced TFA from the Americas. Each declarant was asked to detail all changes and reductions in the TFA contained in their products. After ignoring the voluntary agreement, only three declarants provided such information in detail, and three others offered an overall summary of their reforms. Additionally, three declarants reported on the barriers that limit this process: availability of oil substitutes, cost, and consumers’ sensory acceptance [19]. Uruguay also created a working group with the task of preparing a plan to eradicate TFA by 2009. On the contrary, in Chile the public body with responsibility for implementing food regulations, was able to ensure the inclusion of nutritional elements on the labels to avoid attention focused on TFA, which may actually increase the intake of saturated fat [18].

## CONCLUSION

Partially hydrogenated oils are food additives with clear adverse effects, and their regulation is a public health priority [20].

TFA that are added to food there are *not* indispensable food components. They could be replaced by polyunsaturated fat without affecting the cost or quality of the food.

Legislative strategies to ban artificial TFA from foods have been more successful than labeling or education as shown in developed countries such as Austria, Denmark, Iceland, Sweden, Switzerland and USA, where CHD mortality rates have been decreasing [21-25]. Specifically, there is the case of England, where a regulatory policy to eliminate TFA was the most effective and equitable policy option, while simply continuing to rely on industry to voluntary reformulate products could have negative health and economic outcomes [26].

The removal of food with adverse health effects demands an appropriate strategy with cooperation from all parts of the productive chain. In other words, production, distribution and consumption, are modifiable steps with the intervention of various regulatory authorities, or by economic phenomena [24].

In Mexico, there is still much need for improvement in terms of the TFA food content. There is an evident need to help consumers with interpreting food labels, particularly regarding TFA. However, consumer education is not enough to modify the patterns of consumption. Regulatory measures are the most effective option. There are several challenges that could improve TFA regulation, for example:

- Establishing a network for surveillance and monitoring of TFA and saturated fat.
- Harmonizing and standardizing criteria for regulation and nutritional labeling.
- Establishing of a network of standardized laboratories.
- Creating a network for surveillance and monitoring of frying oils.

Since the elaboration of the action plan for the TFA regulation, there has been a positive response from academic and political institutions to work in conjunction to protect and improve people's health.

The Mexican Senate supported the process and invited the involved committees to address the revision of legislation and the regulation of new provisions for TFA use. However, unfortunately there is still no clear and specific law for the use and labeling of TFA in the current legislation. Nonetheless, measures taken by international and national health authorities, along with the food industry should not reduce their goal of eradicating TFA from the national diet [1].

It is very important to highlight the role of the universities in coordinating the implementation of public policies to improve the health of the population, and decrease health care costs which involve some chronic and degenerative health disorders, such as those associated with TFA intake.

The ban of TFA in industrially-produced food is highly complex, which underlines the importance for interdisciplinary work. Although this is basically a medical issue, the control of TFA requires participation of many disciplines.

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