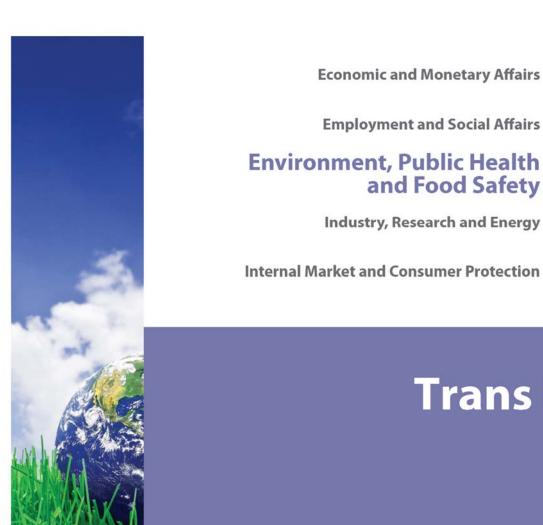




DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT **ECONOMIC AND SCIENTIFIC POLICY**



Trans Fats

WORKSHOP

2014 EN



DIRECTORATE GENERAL FOR INTERNAL POLICIES POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Trans Fats

Brussels, 5 November 2013

PROCEEDINGS

Abstract

This report summarises the presentations and discussions at the Workshop on 'Trans Fats', held at the European Parliament in Brussels, on Tuesday, 5 November, 2013. The aim of the workshop was to discuss the risks posed by trans fats in human health and to exchange views on the existing solutions to this issue. The workshop was hosted by MEP Ms Glenis WILLMOTT (S&D, UK), Co-chair of the Health Working Group within the ENVI Committee.

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LIST OF ABBREVIATIONS

CHD Coronary heart disease

DG SANCO Directorate General for Health and Consumers

EC European Commission

EFSA European Food Safety Authority

ENVI Environment, Public Health and Food Safety

EP European Parliament

EU European Union

EUR Euro

HDL High-density lipoprotein

HLG High level Group

IHCP Institute for Health and Consumer Protection

IP-TFAs Industrially produced trans fatty acids

LDL Low-density lipoprotein

MEP Member of the European Parliament

SFAs Saturated fats

TFAs Trans fatty acids

EXECUTIVE SUMMARY

On 5 November 2013, the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament held a workshop on 'Trans Fats'. The workshop was hosted by Ms Glenis WILLMOTT, Member of the European Parliament (MEP), Co-chair of the Health Working Group within the ENVI Committee.

In her opening statement, Ms WILLMOTT highlighted the importance of discussing the topic of trans fats in the context of the on-going Cardiovascular Health Week organised by the Heart Group at the European Parliament. Introducing the aims of the workshop, Ms WILLMOTT stated that the focus of the discussion would be on the adverse health effects of trans fats as well as on the need to regulate the presence of trans fats in food.

Ms Stephanie BODENBACH, from the Unit of Nutrition & Nutrition Related Aspects of Labelling at DG Health and Consumers (DG SANCO), gave an overview of the work carried out by the European Commission (EC) in promoting healthier dietary options that help to improve the quality of citizens' health. She presented the EU Platform for Action on Diet, Physical Activity and Health, as being a forum of European-level organisations and industries committed to carrying out different types of activities to help tackle current trends in diet and physical activity. In particular, she described some specific initiatives undertaken to deal with trans fats. Ms BODENBACH acknowledged that, despite the progress made so far, the EU approach towards the reduction of trans fats in food needs to be further strengthened. For this reason, the EC is preparing a report that aims to assess the presence of trans fats in foods and in diets across the EU. If appropriate, the EC will accompany this report with a legislative proposal on trans fats.

The first part of the workshop gave an overview of the adverse health effects of trans fats. Dr Valeriu CURTUI, Head of the Nutrition Unit at the European Food Safety Authority (EFSA), started his presentation by outlining the findings of two scientific opinions prepared by EFSA on trans fatty acids (TFAs). The 2004 opinion looked at the presence of TFAs in food and concluded that TFAs, like saturated fatty acids, raise low-density lipoprotein (LDL), or 'bad' cholesterol levels in the blood, thereby increasing the risk of coronary heart disease (CHD). Dr CURTUI further explained that opinion from 2009 demonstrated that the intake of TFAs had decreased considerably over the years. Moreover, the opinion highlighted that TFAs are provided by several fats and oils that are also important sources of essential fatty acids and other nutrients. Thus, there is a limit to which the intake of TFAs can be lowered without compromising the adequate intake of essential nutrients.

Prof. Steen STENDER, Chief physician and Lab Director at the Department of Clinical Biochemistry, Copenhagen County Hospital in Gentofte, stressed that, although the detrimental effects of industrially produced trans fatty acids (IP-TFAs) on cardiovascular health are beyond dispute amongst the scientific community, IP-TFAs are still contained in certain food products. While a few European countries have put in place legislative limits on the content of IP-TFAs in food, most countries still rely on the industry's voluntary commitment to reduce the IP-TFAs content in food. A market investigation carried out by Prof. STENDER in 20 European countries, observed that, in 2013, the contents of IP-TFAs in popular foods in Western Europe are lower than it was in 2009. However, in spite of some reduction, high levels are still registered in some Eastern European and Balkan countries.

Dr Søren LANGKILDE, from the Ministry of Food, Agriculture and Fisheries, Denmark, started the second part of the workshop by presenting the Danish legislation on trans fats – which has been in force since 2004. The laws set a maximum level on the content of IP-TFAs in processed foods.

The legislation is based on scientific studies that have indicated that the intake of trans fats, compared with saturated fats, implies a 4-5-fold higher risk increment for the development of heart disease. Dr LANGKILDE then underlined that the ban had not caused a significant rise in the price of the food products involved, nor had it impacted their availability. Explaining the positive results brought by the Danish legislation, Dr LANGKILDE emphasised that a survey conducted before and after the ban had demonstrated a gradual decline of IP-TFAs in food products in Denmark. In his final remarks, he stressed that the legislation in Denmark had been an adequate response to the health risks associated with trans fats and argued that the EU should follow the same legislative approach.

The presentations stimulated an intense debate on whether or not the 'ban approach' would be preferable to the mandatory 'labelling approach'. Ms WILLMOTT ultimately concluded that appropriate solutions should be implemented as soon as the European Commission's report is published in 2014.

1. LEGAL AND POLICY BACKGROUND

Trans fats are unsaturated fats which occur naturally in animal fats, can be produced through industrial processes, i.e. hydrogenation of unsaturated vegetable oils, or cooking processes, e.g. frying unsaturated oils. The majority of trans fats in our diets can be found in industrial food products, such as ready meals, biscuits, potato chips, ready-made sauces or margarines. Scientists associate the consumption of trans fats with the increase of obesity, diabetes and cardiovascular diseases.

To date, EU legislation does not regulate the content of trans fats in food stuffs, neither does it require specific labelling of food stuffs containing trans fats. General labelling requirements were first provided by Directive 90/496/EEC on nutrition labelling rules of foodstuffs¹. Nutrition labelling is optional, but becomes compulsory if a nutrition claim is made on the label, in a presentation or in advertising. The only nutrition claims allowed are those which relate to the energy values, the nutrients, e.g. proteins, carbohydrates, fats, dietary fibres, sodium, vitamins and minerals, substances which belong to one of these categories of nutrients or are components of them. Afterwards, Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs², repealed by Regulation (EC) No. 1169/2011³, required the listing of food product ingredients on the labels. It did not, however, require the types of fats to be specified to give consumers information on the levels of trans fats in the products.

Denmark did not consider the EU level requirements strict enough to protect human health – given the scientific evidence associating consumption of trans fats with health hazards. In 2003, the Danish Parliament adopted a law stipulating that the content of trans fats in oils and fats that are intended for human consumption either alone, or as part of processed foods, must not exceed 2 grams per 100 grams of oil or fat⁴.

In response to the regulatory action by Denmark and to undertake a review of the scientific evidence concerning trans fats, the EC decided in 2004 to seek the opinion of the European Food Safety Authority (EFSA). It concluded⁵ that the intake of trans fats had increased in some Member States and had potentially damaging health effects.

In the following years, both the EU and its Member States and several countries worldwide, made progress in regulating the presence of trans fats in food. To minimise the intake of industrial trans fats, some countries have implemented measures to reduce the presence of trans fats in foods: legislative limits on industrially produced trans fats in Denmark and Austria; mandatory trans fats labelling throughout most of the American continent; voluntary agreements with the private sector to reduce trans fats in foods, e.g. in Germany and The Netherlands.

¹ Directive 90/496/EEC on nutrition labelling, available at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1990:276:0040:0044:EN:PDF.

Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, available at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:109:0029:0042:EN:PDF.

Regulation (EC) No. 1169/2011 on the provision of food information to consumers, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2011R1169:20111212:EN:PDF.

⁴ Executive Order No. 160 of 11 March 2003 on the Content of Trans Fatty Acids in Oils and Fats.

⁵ EFSA (2004), Opinion of the Scientific Panel on Dietetic products, nutrition and allergies related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids, available at: http://www.efsa.europa.eu/en/efsajournal/pub/81.htm.

In 2006, the EU adopted Regulation (EC) No. 1924/2006⁶ on Nutrition and Health Claims Made on Foods. It sets specific rules on how food manufacturers can inform consumers about the beneficial nutritional or health properties of food. Pressure for action to regulate trans fats at the EU level has come from both the Members of the European Parliament and the European public. In April 2007, four Members of the European Parliament presented a declaration calling for more restrictive regulation of trans fats in the EU. The declaration stated that diseases of the heart and circulatory system account for 1.9 million deaths in the EU per year. It highlighted the link between the consumption of trans fats and coronary heart disease and suggested the replacement of trans fats with alternatives. The declaration applauded Denmark's initiative to reduce the amount of trans fats in food products and encouraged the EC and the Council to introduce a mandatory labelling system and public awareness campaigns⁷.

Following an evaluation of the legislation on food labelling by DG SANCO, the European Commission issued in 2008, a proposal with the aim of combining the two major Directives – Directive 2000/13/EC and Directive 90/496/EEC, into one Framework Regulation. Regulation (EC) No. 1169/2011 establishes a legal framework in the European Union regulating the type of foodstuff related information to be provided to consumers by food business operators at all stages of the food chain. With regard to trans fats, the Regulation has called on the EC to prepare a report, by 13 December 2014, on the presence of trans fats in foods and in the overall diet of the population. The report will assess the impact of 'appropriate means that could enable consumers to make healthier food and overall dietary choices or that could promote the provision of healthier food options to consumers'⁸. If appropriate, the EC will accompany this report with a legislative proposal.

Notwithstanding the progress made so far, there is still limited information on the consumption of trans fats in many EU Member States. Moreover, recent evidence⁹ suggests that in the absence of measures targeting trans fats, specific population groups may be at risk.

Regulation (EC) No 1924/2006 on nutrition and health claims made on food, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0009:0025:EN:PD.

European Parliament (2007), Trans Fatty Acids and Health: A Review of Health Hazards and Existing Legislation. Study requested by the European Parliament's Committee on the Environment, Public Health and Food Safety, available at:

 $[\]label{lem:http://www.europarl.europa.eu/RegData/etudes/etudes/join/2008/408584/IPOLJOIN ET(2008)408584 EN.pdf.$

⁸ Article 30(7) of Regulation (EC) No. 1169/2011.

The most important studies have been presented by the speakers during the workshop.

2. PROCEEDINGS OF THE WORKSHOP

2.1 Introduction

2.1.1 Welcome and opening – Ms Glenis WILLMOTT (MEP)

Ms Glenis Willmott, Member of the Environment, Public Health and Food Safety Committee (ENVI) and Co-chair of the Health Working Group, welcomed the attendees and speakers to the workshop. In her introduction, she highlighted the importance of discussing the topic of trans fats in the context of the on-going Cardiovascular Health Week organised by the Heart Group¹⁰, at the European Parliament. She also emphasised that the effects of trans fats on health have become subject to considerable public attention – with several EU Member States taking steps to reduce the consumption.

She then reminded the audience about the aims of the workshop, by stating that the focus of the discussion would be on the adverse health effects of trans fats as well as on the need to regulate the presence of trans fats in food. She finally said that the voluntary labelling schemes adopted by the food industry have not shown particular progress and expressed her preference for more restrictive means, such as, a mandatory labelling system or a legislative ban.

2.1.2 Presentation of the EU Platform for Action on Diet, Physical Activity and Health

Ms Stephanie BODENBACH, Unit of Nutrition & Nutrition Related Aspects of Labelling, DG SANCO, EC

Ms Bodenbach's presentation provided an overview of the work done by the EC in promoting healthier dietary options that help improve the quality of citizens' health. In particular, she described the EU Platform for Action on Diet, Physical Activity and Health¹¹ (Platform) and placed it into the wider context of the EU Nutrition Strategy¹².

The Platform was set up in 2005 with the aims of showing examples of the complex problem of unhealthy diet and lack of physical activity and also providing examples of actions undertaken by different parts of society. The 33 members are required to undertake concrete actions (commitments) to tackle the current trends in diets and physical activities. Ms Bodenbach explained that the Platform's members commit themselves to carrying out different types of activities, varying from the provision of consumer information to education activities. Of the six activity types, composition of foods (reformulation), availability of health food options, and portion sizes', are specifically implemented to deal with problems linked to trans fats.

¹⁰ The Members of the European Parliament (MEP) Heart Group is a forum which provides MEPs with an opportunity to generate dialogue, outreach and activities at EU and Member State level. MEP Health Groups website available at: http://www.mepheartgroup.eu/.

¹¹ EU Diet Platform website available at:

http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm.

European Commission (2007), White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues, COM(2007) 279 final, available at:

http://ec.europa.eu/health/archive/ph determinants/life style/nutrition/documents/nutrition wp en.pdf.

Out of the 19 commitments focussing on 'reformulation', some were implemented in the whole EU, whilst others covered only one or certain Member States. Ms Bodenbach mentioned the examples of Ferrero, Nestlé and Unilever that have committed - and succeeded - to remove all trans fats from products containing partially hydrogenated fats. The Mars company reduced trans fats to less than 0.5 %, while McDonald's reduced trans fats in their cooking oil to a maximum of 2% of the total fat level. Ms Bodenbach emphasised that these activities have covered the whole EU, making a huge impact on the consumption of trans fats. She also cited examples from members that operate at a more limited geographical coverage, for instance, the UK British Retail Consortium, Spain EROSKI and France Casino – all succeeded in reducing partially hydrogenated vegetable oils from their own brand products.

With regard to the wider context in which the Platform operates, Ms Bodenbach presented the main features of the EU Strategy on Nutrition, Overweight and Obesity-related Health issues¹³ (Strategy), which was launched in 2007. The Strategy builds mainly on the activities of the Platform, further strengthening its role. In particular, it describes a partnership approach between different types of actors and defines the platform activities as a key tool for implementing the Strategy.

Another important forum established within the context of the Strategy is the High Level Group (HLG) which focuses on nutrition and physical activity related health issues. The HLG is comprised of government representatives from all Member States that cooperate to identify areas where progress is being made with good practices aiming to share this information and enable other Member States to learn and develop similar initiatives.

Ms Bodenbach then presented the current activities of the EC and, in particular, its obligation deriving from Regulation (EC) No. 1169/2011, to prepare a report on trans fats. The report will be prepared with the support of the Joint Research Centre - Institute for Health and Consumer Protection¹⁴ (IHCP) and EFSA. The EC with this report aims to assess in a detailed manner, the presence of trans fats in foods and in overall diets. Another purpose of the report is to look at the impact of applying appropriate means enabling consumers to make healthier food and diet choices, or that could promote the provision of healthier food options to consumers. Amongst the potentially appropriate means, the Regulation refers to the provision of information to consumers on trans fats and to the restriction of the use of trans fats. If appropriate, the EC will accompany this document with a legislative proposal.

With regard to labelling, Ms Bodenbach mentioned that the EC is really keen to know whether or not consumers would be able to understand the nutritional information given on the label – in case new legislation will make it mandatory to indicate the type of fats present in the product ingredients list. For this reason, the EC is funding a study on food information and its provision to consumers, including information on trans fats. The study will cover eight countries and will investigate the level of consumer's awareness of different types of fats, including trans fats.

Ms Bodenbach ended the presentation by stressing that the report is due by the end of 2014 and that the EC is still at the data collection phase. Therefore it would be premature to give more information on the report's content.

¹⁴ IHCP website available at: http://ihcp.jrc.ec.europa.eu/.

¹³ European Commission (2007), White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues, COM(2007) 279 final, available at:

http://ec.europa.eu/health/archive/ph_determinants/life_style/nutrition/documents/nutrition_wp_en.pdf

2.2 Trans Fats effects on health

2.2.1 Overview of EFSA opinion on trans fatty acids

Dr Valeriu CURTUI, Head of Nutrition Unit, EFSA

Dr Valeriu Curtui began by explaining that currently there are no on-going activities at EFSA on the topic of trans fats, also known as trans fatty acids (TFAs), in the scientific community. Thus his presentation focused on previously published EFSA opinions on TFAs. He started with the first opinion of 2004¹⁵ and then moved chronologically to more recent EFSA work on TFAs.

The first opinion of TFAs, prepared by the Scientific Panel on Dietetic Products, Nutrition and Allergies, was published in 2004. The purposes of this opinion were to investigate the presence of TFAs in food products and to assess the effects of TFAs consumption on human health.

The panel acknowledged that there are three main dietary sources of TFAs. Firstly, TFAs are produced via bacterial transformation of unsaturated fatty acids in the rumen of ruminant animals. This type of TFAs can be found in ruminant-derived milk products or meat. Secondly, industrially produced TFAs are formed during industrial hydrogenation and deodorisation of unsaturated vegetable oils. Finally, TFAs can also be originated from heating and frying oils at high temperatures.

With regard to the dietary intake of TFAs, the TRANSFAIR study¹⁶ conducted in the 1990s, demonstrated that the mean intake of TFAs in the EU ranged from 1.2 to 6.7 grammes per day, corresponding to 0.5-2.1 % of the total daily energy. Comparing the mean intake of saturated fatty acids (SFAs) with the TFAs, it was observed that the intake of saturated fats was much higher, accounting for 10.5 to 18 % of the total energy intake. The panel also noted that the isomer of oleic acid contributed 54-82 % of the total TFAs, whilst TFAs from ruminant fats ranged only from 30 to 80 % of the total TFAs.

Dietary surveys, carried out throughout the years, indicated that the intake of TFAs had decreased in some European countries, mainly due to the reformulation of food products, such as fat spreads, to reduce TFAs content. With regard to health effects, the panel observed a clear link between elevated LDL Cholesterol – the so called 'bad cholesterol', and coronary heart disease and therefore concluded that a higher intake of TFAs may increase the risk of coronary heart disease (CHD). However, at that time, the available evidence did not provide a definitive answer to the question as to whether or not TFAs, compared to a mixture of SFAs, had different effects on LDL cholesterol on a gram for gram basis. In addition to this, the panel did not find enough evidence on possible relationships of TFAs intake with other adverse health effects, such as cancer, type 2 diabetes or allergies.

¹⁵ EFSA (2004), Opinion of the Scientific Panel on Dietetic products, nutrition and allergies related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids, EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), available at:

http://www.efsa.europa.eu/en/efsajournal/pub/81.htm.

Hulshof K.F. et al (1999), Intake of fatty acids in Western Europe with emphasis on trans fatty acids: the TRANSFAIR Study. European Journal of Clinical Nutrition, February 1999, 53(2):143-57, available at: http://www.ncbi.nlm.nih.gov/pubmed/10099948.

Dr Curtui then presented the results of the EFSA opinion issued in 2009¹⁷ in the context of Dietary Reference Values. The opinion assessed the Dietary Reference Values¹⁸ for different types of fats including TFAs. In its conclusion, the panel highlighted that TFAs are not synthesised in the human body and are therefore not required in the diet. With regard to health effects, the panel went beyond the conclusions of the 2004 opinion by stating that consumption of trans-monosaturated fatty acids also results in reduced blood HDL cholesterol concentrations – the so called 'good cholesterol', and increases the HDL cholesterol to the total cholesterol ratio. The panel also concluded that TFAs from ruminant sources had similar adverse effects on blood lipids and lipoproteins as those caused by industrial TFAs, if consumed in equal quantities. Due to insufficient levels of evidence, the Panel could not reach similar conclusions concerning links between consumption of the same amounts of ruminant TFAs or industrial TFAs and the risks of coronary heart diseases.

The 2009 opinion was accompanied by some dietary recommendations. The panel clarified that dietary TFAs are provided by several fats and oils that are also important sources of essential fatty acids and other nutrients. Therefore, there is a limit to which the intake of TFAs can be lowered without compromising the adequacy of essential nutrient intake. Notwithstanding this discovery, the panel also recommended that the intake of TFAs should be as low as possible within the context of nutritionally adequate diets.

Dr Curtui then focused on the more recent work of EFSA, in the area of health claims, by describing an opinion issued as a result of an application in 2011. The applicant claimed that replacing SFAs and TFAs with unsaturated fatty acids decreases blood LDL cholesterol concentration. In the scientific substantiation of the claim, the panel agreed that TFAs have a role in increasing blood LDL cholesterol concentration. The panel further pointed out that food containing TFAs typically contained high amounts of SFAs as well, which are likely to have similar effects to TFAs on LDL cholesterol concentrations when they are consumed on gram for gram basis. Hence, the panel questioned if it would be better to replace only marginal amounts of TFAs, or better to replace significant amounts of SFAs, in order to gain greater success in decreasing cardiovascular disease.

Dr Curtui concluded that given the evidence of decreased TFAs intake, the panel has stressed the importance of reducing SFAs for preventing the development of coronary heart disease.

2.2.2 Adverse effect of trans fats in the cardiovascular system

Prof. Steen STENDER, Chief physician and Lab Director at the Department of Clinical Biochemistry, Copenhagen County Hospital in Gentofte, University of Copenhagen, Denmark

Prof. Stender explained that the most common heart disease is atherosclerosis and that it is the major cause of mortality in the Western Hemisphere. He explained how an atherosclerotic plaque, which consists of LDL cholesterol, develops and grows in the artery.

EFSA (2010), Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol, EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), available at: http://www.efsa.europa.eu/en/efsaiournal/doc/1461.pdf.

Dietary Reference Values (DRVs) are the complete set of nutrient recommendations and reference values, such as population reference intakes, the average requirement, adequate intake level and the lower threshold intake'. Source: http://www.efsa.europa.eu/en/topics/topic/drv.htm.

Atherosclerotic plaques may suddenly burst and cause strokes – if the plaque is in the artery leading to the brain –, or myocardial infarction – if the plaque is in the arteries that provide blood for the heart muscles –, as well as a gangrene of the foot - if it is in the lower abdominal artery. An important step in the development of the plaque is the penetration of cholesterol from blood into the plaque. The more the cholesterol is in the blood the more enters the plaque. Prof. Stender presented the results of a study¹⁹ carried out in the 1990s, which demonstrated that it is especially the penetration of 'bad' LDL-cholesterol that makes the plaque grow, whereas 'good' HDL-cholesterol has the opposite effect. Prof. Stender also specified that saturated fats increase 'bad' cholesterol, but also increase healthy 'good' cholesterol. Whereas, unsaturated fats decrease LDL in blood and, to a certain extent, they also decrease HDL. Trans fats mix the characteristics of saturated and unsaturated fats, thereby increasing LDL and decreasing HDL levels in the blood, taking only the bad characteristic from the saturated fat and only the bad one from the unsaturated fat.

Following this discovery in the 1980-90s, several large-scale studies on females and males in the US and in Europe have been carried out that demonstrated an association between the intake of trans fats and the increase of coronary heart disease. Most recently, in 2013, an important US study²⁰ demonstrated that higher intake of trans fats is associated with an increased risk of 'all-causes' mortality. The scientific evidence proving the harmful effect of trans fat was reviewed in 2013 in another paper²¹ which stated that the detrimental effects of IP-TFAs on heart health are beyond dispute.

Prof. Stender went on to present how different Member States across Europe have dealt with the trans fats issue. He has personally contributed to the work done in Denmark. As the chairman of the Danish Nutrition Council working group on trans fats, he contributed to the production of reports in 1994, 2001 and 2003. The 2003 report²² laid down the basis for the legislative ban put forward by Denmark. The report concluded that, given the adverse effect that IP-TFAs have on heart disease, they should not be used in foods for humans. The report also emphasised that trans fats have no beneficial effects on human health.

When providing an overview of the regulation to minimise the intake of IP-TFAs in various countries, he highlighted that some States in the US have introduced labelling, while others in the EU have put in place legislative limits regulating the IP-TFAs content in food, e.g. in Denmark and Austria with Hungary and Sweden on the way. However, most countries in Europe still rely on food producers to voluntarily reduce the IP-TFAs content in food.

To assess the efficiency of these strategies, several market based investigations have been conducted. Prof. Stender, who was involved in these investigations, collected in 2005-2006 high trans fats menus in many countries. The menus consisted of a standard meal from McDonalds and Kentucky Fried Chicken, 100 gram of pre-packaged biscuits/cakes/wafers

Mensink RP, Katan MB (1990), Effect of dietary trans fatty acids on high-density and low-density lipoprotein cholesterol levels in healthy subjects. The New England Journal of Medicine, August 1990, 323(7):439-45, available at: http://www.ncbi.nlm.nih.gov/pubmed/2374566.

Kiage JN. et al. (2013), Intake of trans fat and all-cause mortality in the Reasons for Geographical and Racial Differences in Stroke (REGARDS) cohort, The American Journal of Clinical Nutrition, April 2013, 97(5):1121-8, available at: http://www.ncbi.nlm.nih.gov/pubmed/23553155.

²¹ Brouwer IA. et al. (2013), Trans fatty acids and cardiovascular health: research completed?, The American Journal of Clinical Nutrition, May 2013, 67(5):541-7, available at: http://www.ncbi.nlm.nih.gov/pubmed/23531781.

Stender S. and Dyerberg J. (2003), The influence of trans fatty acids on health. Fourth edition. A report from the Danish Nutrition Council, available at: http://www.sst.dk/publ/mer/2003/The influence of trans fatty acids on health-fourth edition2003.pdf.

and microwave popcorn. The results demonstrated that high levels of trans fat in a menu provided rather high IP-TFAs – above 30g, in five EU countries in Eastern Europe and just little lower amounts - 20-30 g, in eight EU countries in Western Europe. While the menu provided 37 gram of IP-TFAs in Denmark in 2001 before the legislation was adopted, the same products contained together less than 1 gram IP-TFAs in 2005, one year after the adoption of the Danish legislation, which demonstrates the efficiency of introducing legislative limit. In the most recent market investigation in 2013, contents of IP-TFAs in pre-packaged biscuit/cakes/wafers in Western Europe appeared lower but, in spite of some reduction, were still high in the Eastern and Balkan European countries. For instance, values in Hungary and the Czech Republic registered a clear decline, whereas values remained high in Bulgaria, Poland and Romania. Products with high amounts of IP-TFAs from some Balkan countries appeared to be exported to many other countries in Europe. These findings suggest that millions of people in the EU still, in 2013, consume IP-TFAs in amounts that substantially increase the risk of coronary heart disease.

Drawing to conclusion, Prof. Stender stressed that most European countries rely on their own producers to voluntarily reduce the amounts of IP-TFAs in food – which has variable results and does not take export/import from countries inside and outside EU into account. Prof. Stender highlighted, once again, that the well-known detrimental effects of IP-TFAs make the case for a legislative ban that would contribute to the future prevention of premature heart disease in subgroups still at high risk all over Europe.

2.2.3 First round of questions and answers

With the participation of Christel SCHALDEMOSE, MEP

Before opening the floor for questions, Ms WILLMOTT welcomed her colleague MEP Christel SCHALDEMOSE (S&D, DK).

The first question was addressed by Prof. STENDER to the EFSA representative. He expressed his concern about the fact that saturated fats are often used to replace trans fats in food products. He mentioned a publication of the New England Journal of Medicine²³ which investigated food products in different countries before and after trans fats have been replaced. Its conclusion indicated that the trans fats in these food products can be replaced with a mixture of saturated, monounsaturated, and polyunsaturated fats. The nutritional benefit of this shift is even greater than the benefit of a one-to-one substitution of trans fats with saturated fats.

In his response, Dr CURTUI explained that the EFSA approach for trans fats substitution follows the same assumption. Moreover, EFSA acknowledges that the use of unsaturated over saturated fats is preferable.

Afterwards, Ms SCHALDEMOSE took the floor in order to thank the panel and the Working Group for their interesting presentations. She then asked the EC whether or not this well-known scientific evidence on the adverse effect of trans fats would already be a strong basis for putting forward a proposal on the mandatory banning of IP-TFAs.

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²³ Stender S. et al., (2009), What Went In When Trans Went Out?, New England Journal of Medicine, July 16, 2009, 361:314-316, available at: http://www.nejm.org/doi/full/10.1056/NEJMc0903380.

Answering this question, Ms BODENBACH clarified that the report, which will be issued in 2014, will try to gather and process all types of available information on the intake levels of trans fats. They will also be looking for alternative measures – including labelling and legislative limit options. With regard to labelling, the EC is preparing a study that looks at how consumers understand labelling information and to what extent the use of mandatory labelling would change their behaviour towards the selection of healthy food products. She emphasised that it is a very complex issue and many different factors have to be taken into account before putting forward a legislative proposal. For example, she explained that the EFSA opinions do not provide clear evidence on the different effects that trans fats, produced from both natural and industrial sources, have on health if they are consumed in equal amounts. She also added that the EC is not limiting the analysis to trans fats, but will take into consideration the overall healthiness of the mixed fats options.

Raising her concerns over the capacity of consumers to understand the labelling information, Ms SCHALDEMOSE expressed her preference for a ban proposal. She then addressed the question to Prof. STENDER – asking his point of view on the need to consider the effect of both natural trans fats and IP-TFAs.

Prof. STENDER replied by explaining that the hydrogenation process of industrial fats can contribute to 60% of trans fats within the total fats, whereas in ruminant fats the trans fats level is no more than 5 or 6% trans fat. In light of this very important difference, he argued that the limit should only be on IP-TFAs. He continued by saying that the adverse effects on the cardiovascular system have so far only been demonstrated for IP-TFAs and not for ruminant trans fats.

Ms Susanne LOGSTRUP, Director of the European Heart Network, took the floor. She asked the EC whether or not the fact that two EU Member States, namely Hungary and Sweden, will soon introduce a legislative ban similar to what is already in place in Denmark and Austria, would have an impact on the report's conclusions.

Ms BODENBACH replied with a positive answer to this question, by remarking that the report will look into the impact of any appropriate means that could enable consumers to make healthier food and dietary choices including, amongst others, restrictions on the use of trans fats. She also added that, to the extent possible, the EC will compare the impact of legislative limit to the impacts of mandatory labelling, with the voluntary schemes adopted by different Member States.

Ms WILLMOTT concluded the open discussion session by introducing the work done by Denmark. She stressed that Denmark has led the way on trans fats regulation and she hopes that the EC will take its example into consideration when drafting its report and putting forward the legislative proposal next year. She also expressed agreement with her colleague Ms SCHALDEMOSE in stating that whilst labelling is a good measure, it may not be the best option, bearing in mind that it would be complicated for consumers to understand label information and the difference between the types of fats.

2.3 How to proceed?

2.3.1 Regulation of Trans fats in Denmark

Dr Søren LANGKILDE, Ministry of Food, Agriculture and Fisheries, Denmark

Dr Søren Langkilde began his presentation by outlining the main features of the Danish Order on TFAs, oils and fats²⁴. It has been applied since January 2004 and has set the maximum level of IP-TFAs in foodstuffs to 2 grams per 100 grams of fat. The ban concerns IP-TFAs produced in Denmark as well as in imported products.

He gave an overview of other countries that have the same or a similar regulation. It is already in place or on its ways in countries like Austria, Hungary, Norway, Switzerland, Iceland and Sweden. Outside the EU, the example of New York is considered as a positive one, as it has recently restricted IP-TFAs in restaurants. The state of California has introduced similar rules.

Dr Langkilde explained that the legislation is based on scientific studies carried out from the mid 1990's onward. As already indicated by the previous speakers, he re-iterated that there is a well-established link between TFAs intake and the risk of cardiovascular disease. Scientific studies indicated that the TFAs intake compared with SFAs intake is associated with a 4-5-fold higher risk increment for the development of heart disease. More specifically, an increased intake of TFAs, i.e. to 2% of dietary energy, has been estimated to increase the risk for developing cardiovascular disease by 25 %. In addition to this, some data also highlighted the relation between the intake of TFAs and insulin resistance.

While underlying the key facts that formed the basis for the Danish ban, Dr Langkilde also explained that the Danish Nutrition Council found that there are no real beneficial effects related to the intake of TFAs and that their removal would be a substantial health gain for the population. He also added that it is easy to remove and replace IP-TFAs with already available technologies. The Danish experience has also showed the importance of giving the industry enough/appropriate time to adapt their production.

When analysing the impacts that the ban had in Denmark, Dr Langkilde emphasised that surveys conducted before and after the ban has demonstrated a gradual decline of IP-TFAs in food products and thus, the desired effect of the Danish regulation was obtained. More specifically, before the ban, approximately 26 % of the analysed products – the fast food products, cakes, chocolates, sweets, biscuits, French fries, frying oils and shortenings, contained more than 2% TFAs – with many of these products containing high level of TFAs up to 30-40%. In the early years after the ban, these numbers were already significantly reduced. The most recent survey carried out in 2013 found that only 6 % of products had high TFAs content.

From a health perspective, it was estimated that the ban saved the lives of 4-500 citizens each year, from a population of around 5 million. In addition to this, the ban did not cause a significant rise in product price, nor has it modified the availability of those food products. Since the introduction of the Danish law, it is worth noting that a number of new methods of production have been developed producing such foodstuffs as solid and semisolid specialty fats, and there is still potential for further innovation if necessary.

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²⁴ Executive Order No. 160 of 11 March, 2003, on the Content of Trans Fatty Acids in Oils and Fats.

Dr Langkilde moved on to more general considerations on how to deal with the regulation of IP-TFAs in food. He explained why the Danish Government believes that a ban regulation is preferable to the labelling approach. Whilst labelling requirements may empower consumers, they would also leave vulnerable groups still at risk of high intake of TFAs. In addition to this, the Danish Government also considered that labelling would require massive raising of public awareness and there would still be problems in relation to unpacked foods. A regulation approach, on the contrary, would protect all the consumers – regardless of their sex, age, social status, in a simple and efficient way. It is easily enforceable, controllable and technologically feasible.

In his final remarks Dr Langkilde emphasised that the legislation in Denmark was an adequate response to the health risks associated with TFAs and suggested that the EU should follow the same approach.

2.3.2 Open discussion

Before opening the floor to questions, Ms WILLMOTT commented on the session. As a legislator, she understood the importance of regulating trans fats. She explained that one of the reasons why the ban proposal was not taken into consideration few years before was due to the lack of technological solutions for fat substitution. After hearing that this problem was not experienced in Denmark, where the ban proved to be successful, she asked for the EFSA and the EC views on reformulation options.

Dr CURTUI clarified that EFSA can only provide scientific advice and recommendations on risk management issues. From EFSA's opinions it is clear that, when reducing the intake of trans fats, the adequacy of a diet should also be taken into account. It is not clear whether or not the ban would be a good measure, because trans fats are provided by several fats and oils that are also important sources of essential fatty acids and other nutrient. He finally said that it is the responsibility of the EC to assess the possible ways of lowering trans fats in food.

In replying to Ms WILLMOTT's question, Ms BODENBACH reiterated her answers to previous questions, by saying that it would be premature to anticipate the results of the report as the European Commission is still at the data collection phase. The EC is aware of the fact that in a number of countries trans fats intake levels have been significantly reduced. However, the EC should avoid generalisation on such complex issues. She hopes that the EC will gather all of the available information from each Member State in order to put forward evidence-base specific recommendations.

Ms LOGSTRUP then asked the EC to explain the main drawbacks of introducing legislation in the EU and the main differences between voluntary and regulatory approaches.

Ms BODENBACH explained that, in order to propose a legislative ban, this has to be subject to an impact assessment and several different factors will have to be taken into account from a broad angle. Scientific evidence demonstrating the adverse effects of trans fats on human health is a good justification for regulation. However, it has also been demonstrated that in a number of countries there has been an elimination or quasi-elimination of trans fats on the market without the legislation. Costs and benefits for the industry as well as the consumers, brought by selected measures, would also have to be looked at.

Ms WILLMOTT intervened at this point stressing that, even if there are some costs for the industry, the costs that trans fats bring to human health are much more important and would constitute a strong argument in favour of regulation- although, costs are expected to be minimal as demonstrated by the Danish experience.

Ms LOGSTRUP made some observations on the Commission's report – she suggested using some of the data and figures already collected by the Danish Government on the results of the ban, whilst carrying out the impact assessment.

2.3.3 Conclusions

At the end of the workshop, Ms Willmott emphasised the importance of regulating trans fats in the light of the evidence reviewed during the discussion, as well as the successful example of Denmark. She also concluded that appropriate solutions should be implemented as soon as the EC report is published in 2014.

Ms Willmott ultimately expressed her gratitude to all speakers for their very interesting contributions and fruitful debate.

ANNEX 1: PROGRAMME

WORKSHOP Trans Fats

Tuesday, 5 November 2013 from 15.30 to 17.30 European Parliament, A-1E2, Brussels

Organised by the Policy Department A-Economy & Science for the Committee on the Environment, Public Health and Food Safety (ENVI)

AGENDA

15.30 - 15.35

Welcome and opening by Co-chairs of the Health Working Group, Glenis WILLMOTT and Alojz PETERLE, MEPs

15.35 - 15.45

Presentation of the EU Platform for Action on Diet, Physical Activity and Health Ms Stephanie BODENBACH, Unit of Nutrition & Nutrition Related Aspects of Labelling, DG SANCO, European Commission

Part 1 Trans fats effects on health

15.45 - 15.55

Overview of EFSA opinion on trans fatty acids

Dr Valeriu CURTUI, Head of Nutrition Unit, EFSA

15.55 - 16.05

Adverse effect of trans fats in the cardiovascular system

Prof Steen STENDER, Chief physician and Lab Director at the Department of Clinical Biochemistry, Copenhagen County Hospital in Gentofte, University of Copenhagen

16.05 - 16.25 **Q&A**

Part 2 How to proceed?

16.25 - 16.35

Regulation of trans fats in Denmark

Dr Søren LANGKILDE, Ministry of Food, Agriculture and Fisheries, Denmark

16.35 - 17.25

Open Discussion

17.25 - 17.30

Conclusions

17.30 Closing

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Ms Stephanie Bodenbach

Ms Stephanie Bodenbach joined the European Commission in 2006 as a policy officer, where she is dealing with nutrition labelling and related nutrition issues. She is also responsible for the implementation of the White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related Health Issues, specifically focusing on reformulation.

Previously, she held positions as a researcher and scientific coordinator in the coordination office of the Public Health Association of Saxony and as a technical and scientific consultant in the European sales branch of a Japanese pharmaceutical and fine chemicals company.

Stephanie Bodenbach holds Master degrees in Nutritional Science from Bonn University and Public Health from the University of North Carolina at Chapel Hill.

Dr Valeriu Curtui

Dr Valeriu Curtui is Head of the Nutrition Unit at the European Food Safety Authority (EFSA), which provides scientific and administrative support to the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies. Prior to his appointment in February 2013, he worked, from 2008 onwards, as a scientific officer in EFSA's Dietary and Chemical Monitoring Unit on subjects such as, chemical occurrence in food and dietary exposure assessments.

From 2001 to 2008, Dr Curtui was an Assistant Professor at the Institute of Veterinary Food Science of the Justus Liebig University, Giessen, Germany, and from 1991 to 2001 he was an academic member of staff in the field of toxicology and medicinal plants at the University of Agricultural Sciences and Veterinary Medicine of Timisoara, Romania. His research activity was focused on chemical food safety.

Dr Curtui was awarded a degree in Veterinary Medicine from the University of Agricultural Sciences and Veterinary Medicine of Timisoara, Romania, in 1991, and received a PhD in Toxicology from the same University in 1998. His scientific formation included scholarships at Universities in France, Germany and the UK.

Prof. Steen Stender

Prof. Steen Stender currently works as Chief physician and Lab Director at Department of Clinical Biochemistry, Copenhagen University Hospital, Gentofte. He previously covered the position of Professor in Preventive Cardiology at the Odense University, Denmark. Between 1993 and 2005, Prof. Steen Stender was vice-president of the Danish Nutrition Council and chairman of several subgroups – amonst others, the subgroup dealing with trans fatty acids and health.

During the last 40 years, Prof Stender's research interest has focused on the biochemistry of atherosclerosis. He has published over 200 papers in scientific journals. A major achievement has been the development of a method for measuring the *in vivo* transfer of various types of lipoproteins from the blood into the arterial wall of humans. In recent years, he dedicated his scientific research on the biological effect of trans fats in the human diet and as a consequence, of the presence of trans fats in various types of popular foods in many countries around the world.

He recently analysed the amount of trans fats in fast food servings from the same international chains and demonstrated differences among countries.

He holds a degree of Medical Doctor, with a dissertation on 'Cholesterol metabolism in the arterial wall' from the University of Copenhagen and a postdoc degree at the Department of Nutritional Sciences, Cornell University in Ithaca, NY, US.

Dr Søren Langkilde

Dr Søren Langkilde works as a scientific adviser at the Ministry of Food, Agriculture and Fisheries of Denmark since 2007. His work involves legal and scientific matters related to various areas such as trans fatty acids in foods, food supplements, fortified foods, nutrition and health claims and dietetic foods (PARNUTS), at national and EU levels. The key objective of his work is to facilitate proper conditions for food business operators in Denmark and to ensure safe and high quality foods on the market, thus promoting safety, health and quality from farm to table. Dr Langkilde finished his Masters degree in Biology at the University of Copenhagen in 2003 and his PhD in Food Toxicology and Risk Benefit Analysis at the Danish Technical University in 2007.

ANNEX 3: PRESENTATIONS

Presentation by Ms Stephanie Bodenbach



The EU Platform for Action on Diet, Physical Activity and Health

Stephanie Bodenbach European Commission, Directorate General Health and Consumers Nutrition, food composition and labelling

Workshop on "TRANS FATS" Tuesday, 5 November 2013 European Parliament, A-1-E-2, Brussels





The EU Platform for Action on Diet, Physical Activity and Health

EU Platform on Diet, Physical Activity and Health

- 2005
- A forum for EU-level organisations (33 members)
- Commitment to tackle current trends in diet & physical activity
- Led by Commission
- Provide example of action by different parts of society and encourage initiatives across Europe
- Member organisations monitor their own performance, evaluation reports are examined by outside evaluators



The EU Platform for Action on Diet, Physical Activity and Health

- 256 commitments (123 active, 133 non-active)
- 6 activity types
 - 1. Consumer information, including labelling
 - 2. Education, including lifestyle modification
 - 3. Physical activity promotion
 - 4. Marketing & advertising
 - Composition of foods (reformulation), availability of health food options, portion sizes
 - 6. Advocacy & information exchange





White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues

- 2007
- Builds on initiatives undertaken (EU Platform)
- Partnership approach for developing action at European level
- Platform activities: key tool to implement strategy
- Commission will set up High Level Group,
 focus: nutrition & physical activity related health issues
 - liaison with governments
 - effective exchange of policy ideas, best practice
 - liaison with EU Platform







Trans Fat: EU Platform Commitments

Reformulation commitments: 19 active Examples, EU wide:

- remove all TFA from partially hydrogenated fats (Nestlé by end 2012, Unilever by 2012, Ferrero by 2006)
- reduce trans fats to <0.5% by end 2009 (Mars)
- reduce trans fats in cooking oil to max. 2% (McDonald's by 2008)

Examples, limited geographical coverage

remove partially hydrogenated vegetable oils from own brand products

(UK British Retail Consortium (8 members) by end 2007, Spain EROSKI by end 2009 (affected 229 products), France Casino (37 products) by end 2007)

> Health and Consumers



Strategy: Reformulation

- Interest in composition of foods
 - > reformulation to make diets healthier
- Commission to facilitate roll out of salt reformulation campaigns + campaigns aimed at improving nutrient content of manufactured foods in the EU more generally
- → EU Framework for National Salt Initiatives mid 2008
- → EU Framework for National Initiatives on Selected Nutrients 2/2011 (energy, fat, saturated fat, trans fat, added sugars, portion sizes, consumption frequency)

Annex I: saturated fat 2/2012





Report on Trans Fat

Regulation (EU) No 1169/2011, Article 30 7.:

"By 13 December 2014, the Commission, taking into account scientific evidence and experience acquired in Member States, shall submit a report on the presence of trans fats in foods and in the overall diet of the Union population.

The aim of the report shall be to assess the impact of appropriate means that could enable consumers to make healthier food and overall dietary choices or that could promote the provision of healthier food options to consumers, including, among others, the provision of information on trans fats to consumers or restrictions on their use; The Commission shall accompany this report with a legislative proposal, if appropriate."

Health and Consumers 8



Presentation by Dr Valeriu Curtui



OVERVIEW OF EFSA'S WORK ON trans FATTY ACIDS

Valeriu CURTUI Head of Nutrition Unit

Workshop on *trans* fatty acids, ENVI Committee, 5 November 2013



Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the presence of *trans* fatty acids in foods and the effect on human health of the consumption of *trans* fatty acids (Request N° EFSA-Q-2003-022) (adopted on 8 July 2004)

Dietary sources of trans fats:

- bacterial transformation of unsaturated fatty acids in the rumen of ruminant animals;
- industrial hydrogenation (used to produce semi-solid and solid fats that can be used for the production of foods such as margarines, shortenings and biscuits) and deodorisation of unsaturated vegetable oils (or occasionally fish oils) high in polyunsaturated fatty acids;
- during heating and frying of oils at high temperatures.

2

DIETARY INTAKES



- > TRANSFAIR study (1995-1999):
 - ✓ Mean intakes of trans fatty acids (TFA) In the EU: from 1.2 to 6.7 g/d and 1.7 to 4.1 g/d among men and women, corresponding to 0.5-2.1 % and 0.8-1.9 % of total energy intake, respectively;
 - ✓ Mean intakes of saturated fatty acids (SFA) ranged from 10.5 to 18% of total energy intake;
 - ✓ Isomers of 18:1 (oleic acid) contributed 54-82% of the total TFA, and TFA from ruminant fat ranged from about 30 to 80% of total TFA, corresponding to 0.3-0.8% of total energy intake.
- More recent dietary surveys indicate that the intakes of TFA have decreased in a number of EU countries, mainly due to reformulation of food products, e.g. fat spreads, to reduce the TFA content.

3

HEALTH EFFECTS



- Consumption of diets containing TFA, like diets containing mixtures of SFA, consistently increases serum LDL cholesterol (LDL-C), compared to consumption of diets containing cis-monounsaturated or cispolyunsaturated fatty acids.
- The effect shows a linear dose response with serum LDL-C indicating that effects are proportional to amounts of TFA consumed.
- ➤ Elevated LDL-C has been causally linked to coronary heart disease; thus, higher intakes of TFA may increase risk for coronary heart disease (CHD).
- ➤ The available evidence does not provide a definitive answer to the question of whether TFA have an effect on LDL-C different to a mixture of SFA on a gram-for-gram basis.
- Evidence for a possible relationship of TFA intake with other adverse health effects (e.g. cancer, type 2 diabetes or allergy) is weak or inconsistent.

4



Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol (Request N° EFSA-Q-2008-466) (adopted on 4 December 2009)

TFA are not synthesised by the human body and are not required in the diet. Therefore, no Population Reference Intake, Average Requirement, or Adequate Intake is set.

5

DIETARY INTAKES



- ➤ Intake of TFA in the EU has decreased considerably over recent years, owing to reformulation of food products.
- UK: average intake of TFA has been halved to < 1% of total energy intake.
- France: intakes have decreased by 40 % and are, on average, 1 % of total energy intake in adults (0.6 % from ruminant sources and 0.4 % from other sources).
- ➤ Average intakes of TFA in Denmark, Finland, Norway and Sweden have decreased to around 0.5 to 0.6 % of total energy intake.

6

HEALTH EFFECTS



- > Same for LDL-C as in the 2004 Opinion.
- Consumption of diets containing trans-monounsaturated fatty acids also results in reduced blood HDL cholesterol concentrations and increases the total cholesterol to HDL cholesterol ratio.
- ➤ TFA from ruminant sources have adverse effects on blood lipids and lipoproteins similar to those from industrial sources when consumed in equal amounts.
- Evidence is insufficient to establish whether there is a difference between ruminant and industrial TFA consumed in equivalent amounts on the risk of coronary heart disease.

7

DIETARY RECOMMENDATION



- Dietary TFA are provided by several fats and oils that are also important sources of essential fatty acids and other nutrients, thus:
 - ✓ there is a limit to which the intake of TFA can be lowered without compromising adequacy of intake of essential nutrients;
 - ✓ intake of TFA should be as low as possible within the context of a nutritionally adequate diet.
- Limiting the intake of TFA should be considered when establishing nutrient goals and recommendations.

8



Scientific Opinion on the substantiation of a health claim related to "low fat and low trans spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC)

No 1924/2006

(Request N° EFSA-Q- 2009-00458) (adopted on 13 May 2011)

Request:

➤ Replacing SFA and TFA by *cis*-monounsaturated fatty acids (cis-MUFA) and *cis*-polyunsaturated fatty acids (*cis*-PUFA) decreases blood LDL-cholesterol concentration.

9

SCIENTIFIC SUBSTANTIATION



- ➤ The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is consensus on the role of *trans-MUFA* in increasing total and blood LDL-cholesterol concentrations compared to *cis-MUFA* or *cis-PUFA*.
- Foods containing TFA typically contain high amounts of SFA, which are likely to have similar effects to TFA on LDL-cholesterol concentrations on a gram-for-gram basis.
- ➤ The effects of replacing marginal amounts of TFA in foods high in SFA may be small as compared to the effects of replacing SFA in those foods.

10

CONCLUSION



- ➤ A cause and effect relationship has been established between the consumption of mixtures of dietary SFA and an increase in LDL-cholesterol concentrations.
- ➤ Replacement of significant amounts of mixed SFA by *cis*-MUFA and/or *cis*-PUFA in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations.
- > The claim applies to the replacement of SFA.

11

OVERALL CONCLUSIONS



- Consumption of diets containing TFA consistently increases serum LDL cholesterol.
- ☐ Consumption of diets containing trans-MUFA also results in reduced blood HDL cholesterol concentrations and increases the total cholesterol to HDL cholesterol ratio.
- ☐ Intake of TFA should be as low as possible in the context of a nutritionally adequate diet.
- ☐ The intake of TFA should be lowered without compromising the adequacy of intake of essential nutrients.

12



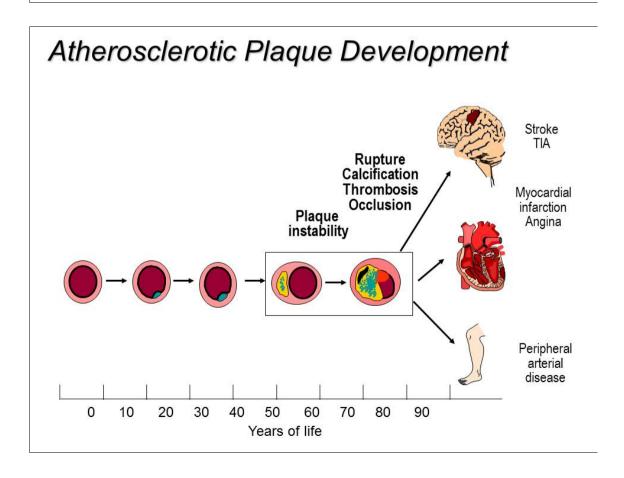
Presentation by Prof. Steen Stender

Adverse effect of trans fats in the cardiovascular systema health issue in Europe

by

Steen Stender
Professor, MD, Lab Director
Department of Clinical Biochemistry
Copenhagen University Hospital, Gentofte
Denmark

5th of November 2013, European Parliament, Brussels Belgium



Fatty acids in the diet and cholesterol in the blood

Cholesterol in blood

LDL (Lousy) (Healthy)

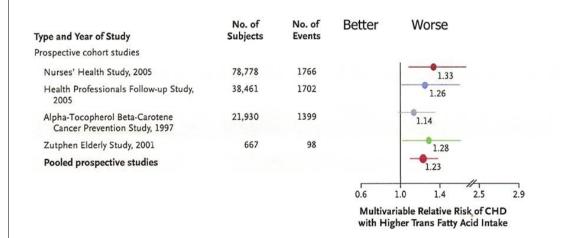
Saturated fatty acids in diet

Unsaturated fatty acids in diet

Trans fatty acids in diet

Trans fatty acids in diet

Isocaloric substitution of 2E% carbohydrates with trans fat ~ 5 gram/day



Mozaffarian et al. NEJM 2006;354(15):1601-13

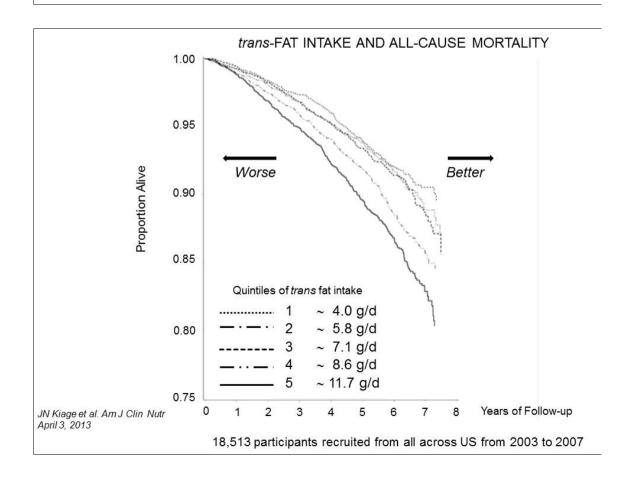


WHO recommends global phasing out of trans fats

By Anthony Fletcher

29/09/2006 - The World Health Organization (WHO) has recommended that governments around the world phase out partially hydrogenated oils if trans-fat labeling alone doesn't spur significant reductions.

http://www.foodproductiondaily.com/news



The Dutch statement

REVIEW

Trans fatty acids and cardiovascular health: research completed?

IA Brouwer¹, AJ Wanders² and MB Katan¹

This review asks the question if further research on *trans* fatty acids and cardiovascular health is needed. We therefore review the evidence from human studies on *trans* fatty acids and cardiovascular health, and provide a quantitative review of effects of *trans* fatty acid intake on lipoproteins. The results show that the effect of industrially produced *trans* fatty acids on heart health seen in observational studies is larger than predicted from changes in lipoprotein concentrations. There is debate on the effect of ruminant *trans* fatty acids and cardiovascular disease. Of special interest is conjugated linoleic acid (CLA), which is produced industrially for sale as supplements. Observational studies do not show higher risks of cardiovascular disease with higher intakes of ruminant *trans* fatty acids. However, CLA, industrial and ruminant *trans* fatty acids all raise plasma low-density lipoprotein and the total to high-density lipoprotein ratio. Gram for gram, all *trans* fatty acids have largely the same effect on blood lipoproteins. In conclusion, the detrimental effects of industrial *trans* fatty acids on heart health are beyond dispute. The exact size of effect will remain hard to determine. Further research is warranted on the effects of ruminant *trans* fatty acids and CLA on cardiovascular disease and its risk factors.

European Journal of Clinical Nutrition advance online publication, 27 March 2013; doi:10.1038/ejcn.2013.43

"In conclusion, the detrimental effects of industrial trans fatty acids on heart health are beyond dispute."

The use of industrial trans fat has been favoured by industry- and removal resisted-because:

- They are cheap
- They are semisolid at room temperatures which makes them easier to use in baked products
- They have a long shelf life
- · They can withstand repeated heating



An intake of 5 grams per day is associated with 23 % increase in risk of heart disease

There is no beneficial effect of trans fatty acids on health

In light of the Danish Nutrition Council's reports on trans fatty acids from 1994, 2001, 2003, and the present update, the Danish Nutrition Council recommends the following:

That industrially produced trans fatty acids should not be used in food.

Danmark 2001 0 10 20 30 40 Grams of industrially produced trans fatty acids □ A large serving of nuggets and French fries □ 100 grams biscuits/cakes/wafers □ 100 grams popcorn

"A high trans fat menu"

A large fast food serving

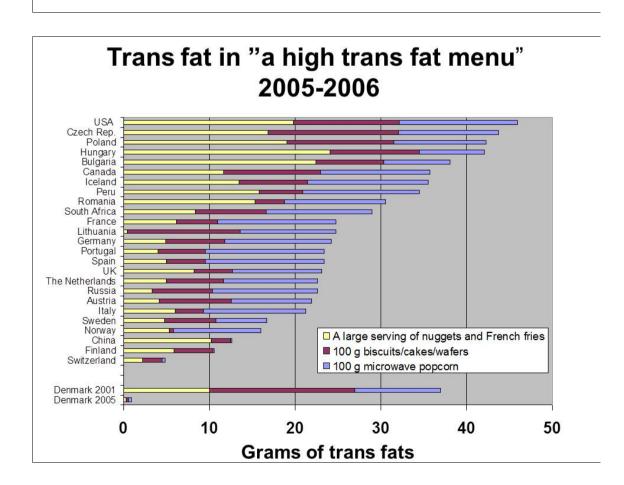
French fries and fried chicken meat from McDonalds and from KFC

Biscuits/cakes/wafers and microwave popcorn

More than 15% fat in the product

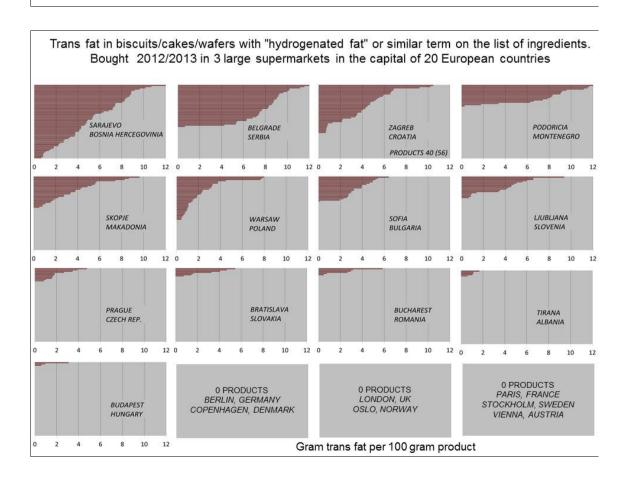
Partially hydrogenated fat or similar term high on the list of ingredients

3 large supermarkets in the capital chosen by the local Turist Information Office were visited



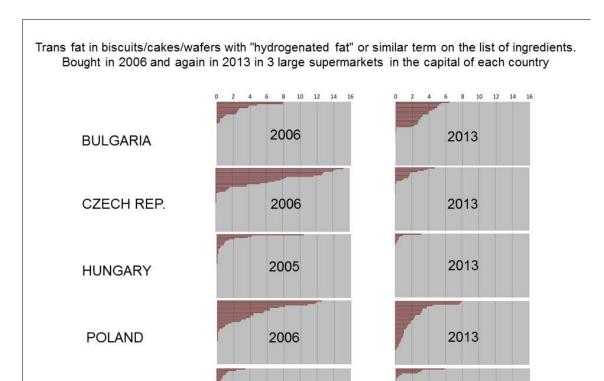
Regulation in various countries concerning industrial trans fat (I-TF) in food





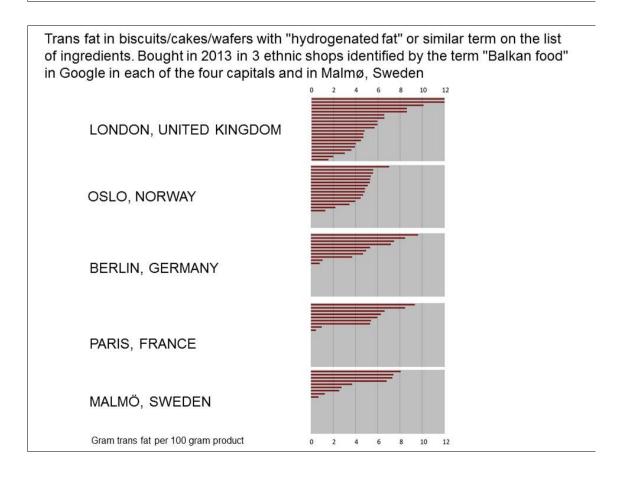
ROMANIA

Gram trans fat per 100 gram product



2006

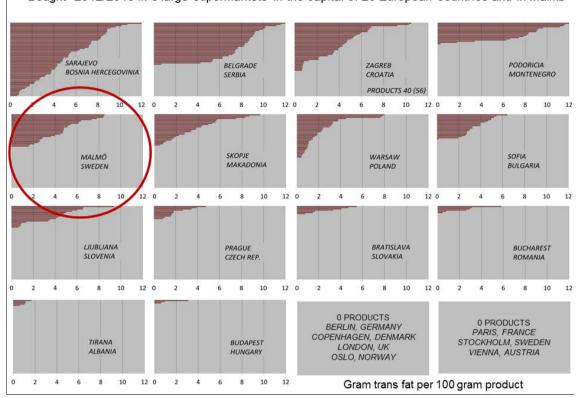
0 2 4 6 8 10 12 14 16



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0 2 4 6 8 10 12 14 16



Trans fat in biscuits/cakes/wafers with "hydrogenated fat" or similar term on the list of ingredients. Bought 2012/2013 in 3 large supermarkets in the capital of 20 European countries and in Malmø

Summary I

- "The detrimental effects of industrial trans fat on heart health are beyond dispute."
- Industrial trans fat in popular foods in Western Europe has declined considerably since 2005 probably due to societal pressure on food producers.
- In some countries in Eastern and South East Europe industrial trans fat in some popular foods is still high in 2013.
- Most European countries rely on their own food producers to voluntarily reduce the amounts of industrial trans fats in foods with variable results. And hope for no import.
- But import/export occurs exemplified by the present abundance of foods high in trans fat in large supermarkets in Southern Sweden.

SUMMARY II

- A low average intake of industrial trans fat at the population level will not preclude a high intake among subgroups as long as foods with high amounts of trans fats are available.
- A legislative trans fat limit has so far been used only by a few European countries. It appears to be a low hanging fruit in the future prevention of premature heart disease in subgroups at high risk all over Europe.

Order No. 160 of 11 March 2003

Courtesy translation

Order on the content of trans fatty acids in oils and fats etc.

The following is laid down pursuant to Section 13, Section 55, subsection 2 and Section 78 subsection 3 of Act No 471 of 1 July 1998 on foodstuffs etc. (Foodstuffs Act):

Chapter 1
Scope
Section 1. This Order applies to oils and fats, including emulsions with fat as the continuous phase which, either alone or as part of processed foodstuffs, are intended, or are likely, to be consumed by humans.
Subsection 2. The Order does not apply to the naturally occurring content of trans fatty acids in animal fats or products governed under other legislation.
Subsection 3. The Order only applies to products sold to the final consumer.
Section 2. It is prohibited to sell the oils and fats covered by the Order to consumers if they contain a higher level of the trans fatty acids defined in the Annex than that stated in Section 3.

Section 3. As from 1 June 2003, the content of trans fatty acids in the oils and fats covered by this Order must not exceed 2 grams per 100 grams of oil or fat, cf. however subsection 2.

Subsection 2. From 1 June 2003 until 31 December 2003 the oils and fats covered by this

Order and included in processed foodstuffs which also contain ingredients other than oils and fats and which are produced by the foodstuffs industry, in retail outlets, catering establishments, restaurants, institutions, bakeries etc. may, however, contain up to 5 grams of trans fatty acids per 100 grams of oil or fat.

Section 4. In products which are claimed to be "free from trans fatty acids", the content of

trans fatty acids in the finished product shall be less than 1 gram per 100 grams of the individual oil or fat.

Penally provisions etc.
Section 5. A fine shall be imposed on anyone who contravenes Section 2 or Section 4 of this

Order.

Subsection 2. The penalty may increase to imprisonment for up to two years if the contravention was committed wilfully or through gross negligence, and the

caused damage to health or led to the risk thereof, or

1) caused damage to health or led to the risk thereof, or
2) resulted in, or was intended to result in, financial gain for the perpetrator themselves or for others, including as a result of savings made.

Subsection 3. Criminal liability may be incurred by companies etc. (legal entities) in accordance with the rules of Chapter 5 of the Penal Code.

Section 6. This Order shall enter into force on 31 March 2003.

Subsection 2. Products manufactured before this Order has entered into force, as well as products manufactured within the periods stated in Section 3(2), may be sold until expiry of the best before date. Annex 1

Definition of trans fature.

expiry of the dest decire date. Annex 1

Definition of trans fatty acids

For the purposes of this Order, trans fatty acids are defined as the sum of all fatty acid isomers with 14, 16, 18, 20 or 22 carbon atoms and one or more trans double bonds, i.e. Cl4:1, Cl6:1, Cl8:1, Cl8:2, Cl8:3, C20:1, C20:2, C22:1, C22:2 fatty acid trans isomers, but only polyunsaturated fatty acids with methylene interrupted double bonds.

Section 3. As from 1 June 2003, the content of trans fatty acids in the oils and fats covered by this Order must not exceed 2 grams per 100 grams of oil or fat, cf. however subsection 2.

Section 5.

Subsection 2. The penalty may increase to imprisonment for up to two years if the contravention was committed willfully or through gross negligence...

11 March 2003

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Trans Fat Consumption and Aggression

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Conclusion: This study of 1000 subjects provides the first evidence linking dietary trans fatty acids with behavioral irritability and aggression. Although confounding is a concern, several relationships add weight to the prospect of a causal connection.

The results may have relevance to public policy determinations regarding dietary trans fats.

March 5, 2012

Presentation by Dr Søren Langkilde



Trans Fatty Acids – a case for legislation? Søren Langkilde Ministry of Food, Agriculture and Fisheries

5. November 2013 Work shop trans fatty acids

Overview of presentation

- 1. The Danish ban on trans fatty acids.
- 2. Scientific background.
- 3. Results of the ban.
- 4. Labeling or legislation?
- 5. Conclusions.

Ministry of Food, Agriculture and Fisheries of Denmark

5. November 2013

The Danish ban on trans fatty acids

The Danish order on trans fatty acids (TFA) in oils and fats:

- · Applied from in January 2004.
- Trans fatty acids maximum level: 2 % of fat content.
- Only industrially processed trans fatty acids (IP-TFA).
- Same or similar regulation applied or on its way in Hungary, Norway and Iceland.
- New York City restricting artificial trans fatty acids in restaurants (max. 0.5 grams per serving).

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Scientific background (1)

Recommendations from scientific bodies:

- WHO 2004 and 2009: " ... Towards the elimination of TFA".
- Institute of Medicine 2002 (US): "Keep intake as low as possible while consuming a nutritionally adequate diet".
- AFSSA 2005: "Intake >2 E% increases risk of CVD." Maximum of 1% of dietary energy, which corresponds to about 2.2 grams/day for someone with a daily energy need of 2000 kcal.

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Scientific background (2)

Well-established link between trans fatty acids and cardiovascular disease:

- Increase intake of TFA (2% of dietary energy) = increase of 25% in risk for developing cardiovascular disease.
- TFA may worsen insulin resistance.
- Risk related to TFA 4-5 times higher than risk related to saturated fats.
- US estimate (1997): 30-40% of deaths related to cardiovascular disease due to TFA (>30.000 deaths a year); average TFA-intake 5 g/day.
- It has been estimated that the Danish ban will save the life of 4-500 citizens each year out of a population of around 5 million.

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Scientific background (3)

Key premises behind the Danish ban on trans fatty acids:

- The problem to be addressed is industrial trans fatty acids.
- Fats added in the production process.
- Level potentially high.
- Reduction technologically possible and distinction by analysis possible.
- Well-established link between trans fatty acids and cardiovascular disease and no safe upper level.
- High risk product groups.
- No benefits for the consumers. However, removal would be a substantial health gain for the population.
- Easy to remove and replace for the industry when given proper time to adapt.

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Results of the ban (1)

Danish surveys on target products 2002 to 2013:

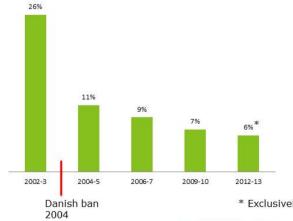
- Significant decrease in products >2 % TFA.
- Substitution: both monounsaturated and saturated fats. Vegetable oils and tropical oils.
- New methods of production developed solid and semi-solid 'specialty fats'.
- No increase in prices and same product availability.

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Results of the ban (2)

Danish surveys (2002 – 2013) showed significant reduction of foods containing IP-TFA > 2 g/100 g fat.



Fast food, cakes, chocolate, sweets, biscuits, French fries, frying oils and shortenings.

* Exclusively imported products

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Results of the ban (3)

Case: Fat content in foods at McDonalds in Denmark

Pre-regulation

- 56 % Monounsaturated
- 11 % Polyunsaturated
- 21 % Saturated
- 12 % Trans fatty acids.

Post regulation

- 70 % Monounsaturated
- 15 % Polyunsaturated
- 15 % Saturated
- NO Trans fatty acids!

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Labeling or regulation

Labeling

- Empowering citizens leaving vulnerable groups at risk.
- Reduces intake doesn't eliminate risk.
- · Unpacked food products.
- Massive public information required.

Regulation

- Protection of citizens.
- Simple and efficient way of reducing intake and to eliminate risk.
- Enforceable, controllable and technologically feasible.

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Conclusions

- Scientific evidence is there trans fatty acids are harmful.
- Legislation is an adequate response to the health risks associated with trans fatty acids.
- Legislation shown to be technologically feasible and costs for the industry not significant. No increase in prices and same product availability.
- Labeling is not an adequate response.

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