

## **NICE PDG: The prevention of cardiovascular disease at a population level**

### **Expert testimony on the public health harm caused by industrially produced Trans Fatty Acids and actions to reduce and eliminate them from the food system in the UK**

#### **What are Trans-Fatty Acids?**

Trans fats or trans fatty acids (TFAs) are chemically altered vegetable oils, used to give processed foods a longer shelf life. They are produced artificially by a process called hydrogenation which turns liquid oil into solid fat. They can be used for frying and baking or put into processed foods and readymade mixes for cakes and drinks like hot chocolate. Trans fats are used because they are cheap and add bulk to products, have a neutral flavor and give products a long shelf life.

More specifically trans fat is the term given to a form of unsaturated fat produced when liquid vegetable oils are turned into solid fats through the process of hydrogenation.

Levels of trans fats in hydrogenated vegetable oils (HVOs) vary depending upon the degree of hydrogenation, and can range from <1% for fully hydrogenated oils, to as much as 60% in their partially hydrogenated versions. Partially hydrogenated vegetable oils (PHVOs) have been used in the manufacture of foods such as biscuits, cakes, fast food, and some margarines.

TFAs produced in food manufacturing processes are known as industrially produced TFAs (IPTFAs). This is to distinguish them from trans fats also occur naturally in the meat and dairy products of ruminant animals, as a result of microbial action in the rumen. Levels of these naturally occurring trans fats vary between 3-8% (of total fat).

In the UK average trans fats intakes for adults, of which 35-45% was from natural sources, was estimated at 1.2% of food energy by the National Diet and Nutrition Survey (NDNS) in 2000/1 – this is within the maximum recommended average intake of 2%, whereas saturated fat intakes, at 13.3% of food energy, far exceed maximum recommended intakes (11% of food energy).

#### **How do trans fats affect health and what are the recommendations about consumption?**

Trans fats are toxic. As with cigarettes there is no safe level of consumption. The primary health concerns relating to trans fats are an association between increasing trans fatty acids (trans fats) intakes, coronary heart disease (CHD) risk, and raised serum cholesterol levels. Increasing trans fats intake results in an increase in levels of low density lipoprotein (LDL) or “bad” cholesterol, whilst also lowering the levels of high density lipoprotein (HDL) or “good” cholesterol.

According to the New England journal of Medicine review (2006) and Mozafarian (2008) A one per cent increase in energy intake from TFA's is increases CHD deaths by 12% (pooled relative risk, 1.12; 95 percent confidence interval, 1.06 to 1.18:P < 0.001) and on a per calorie basis, TFAs appear to increase the risk of CHD more than any other nutrient, conferring a substantially increased risk at low levels of consumption (1-3 percent of total energy intake)

However the Scientific Advisory Council on Nutrition (SACN) (2007) has been conservative in its estimates. They talk about a "moderate effect" of TFAs on the risk of CHD and claim that there is insufficient data to make any risk estimates for other diseases. However, links have been postulated based on observational studies on cancer, diabetes, prostate and breast cancer and neuron development. A reduction of 1 per cent in TFA's as calculated by SACN would result in a mortality reduction of 5,000-7,000 deaths annually.

## **Recommended maximum population consumption levels of TFA's**

### **1. International**

The evidence of health effects of trans fats were reviewed internationally by:

- the independent European Food Safety Authority (EFSA) in 2004, whose opinion was then revised in January 2007. EFSA concluded that in relation to CHD, diets containing trans fats, like diets containing mixtures of saturated fatty acids consistently result in increased serum LDL-C and that elevated LDL-C has been causally linked to CHD therefore higher intakes of trans fats may increase risk of CHD; and considered as part of the 2003 World Health Organization (WHO) Technical Report on Diet, Nutrition and the Prevention of Chronic Diseases. This report recommended ranges for population nutrient intake goals for key macronutrients, including trans fat. WHO recommended a population goal of <1% of energy. It was however noted that "In translating these goals into dietary guidelines, due consideration should be given to the process for setting national dietary guidelines." The WHO's report of the 57th World Health Assembly in 2004 on a Global Strategy on Diet, Physical Activity and Health, also included a more general recommendation about a "a need to shift fat consumption from saturated to unsaturated fats and towards the elimination of trans fats."

### **2. Current DH/FSA/National policy/guidance/advice on TFA's**

In 1994, the Committee on Medical Aspects of Food Policy (COMA) reviewed the evidence on the adverse effects of trans fats on coronary heart disease risk, and recommended that average intakes of trans fats should not exceed 2.0% of food energy, the implications for health of trans fats have been

the subject of several reviews internationally and by SACN. Additionally, in 2003 SACN endorsed COMA's original advice and concluded that a further assessment of trans fats was not warranted.

It is important to note that the evidence on which risk assessment are made is based on studies of adults only.

The FSA Board reviewed the position in England by commissioning a SACN TFA update (2007), following some specific questions posed by the Secretary of State of Health about measures taken in Denmark and the US. The FSA considered whether to maintain the current voluntary approach or introduce mandatory restrictions on trans fats in foods

The FSA concluded from the SACN report that there was a moderate effect of trans fats on CHD risk, but insufficient evidence regarding an association with other diseases (diabetes, obesity and cancer). Estimated UK intakes are 1% of food energy, just half SACN's maximum recommended average intake of 2% of food energy which is based on CHD risk.

The FSA review relies on the available evidence but the National Heart Forum and Heart of Mersey in correspondence to the DH considers that it has taken insufficient account of:

- Gaps in the available research – such as the effects of TFAs on children;
- Distortions arising from published food composition data that is incomplete and often out-of-date;
- Under-reporting in food consumption surveys;
- The likely masking of high TFA intakes among particular population groups by focusing on average intakes across the population.

This is discussed further in the section on scope for further UK action below.

In reaching their conclusions the FSA alleged that “the situations in New York and Denmark where legislative approaches have been applied differ to that currently in the UK. US average intakes of trans fats are more than 2.5 times the UK, and therefore US consumers are at increased risk of CHD from trans fats. Unlike Denmark which identified in 2000/01 very high levels of trans fats in popular foods on the Danish market, voluntary industry action has reduced artificial trans fat levels in food and UK average dietary intakes dramatically. Trans fat levels in vegetable oils used as ingredients are at a minimum, and legislation would be unlikely to deliver a public health benefit. Existing voluntary action poses little or no risk under EU law. Any restrictive measures would have to be notified to the Commission and justified under Article 30 of the EU Treaty”. Further the FSA was concerned that reformulation to reduce trans fats, should not increase saturated fat levels in food, which are also associated with CHD

risk. “Reducing average intakes of saturated fat from the current 13.3% to 11% of food energy is our priority for cardiovascular public health benefits”

The Food Standards Agency’s priority agreed with UK Health Departments in 2003 is to reduce consumers’ saturated fat intakes.

## **Natural experiments to reduce population TFA levels**

### **International perspective**

Trans fats are a global concern and different countries have adopted a wide range of responses. These initiatives are detailed in Annex 1 together with relevant dietary intakes and recommendations where available.

Most initiatives are voluntary with regulatory action limited to Denmark, New York City and now Switzerland. Unfortunately there is insufficient data available to evaluate the impact of the different approaches on dietary intakes. Overall average dietary intakes in the UK are moderate compared to data for other European member states, and much lower than the US and Canada (Annex 2). The lowest trans fats intakes have been reported among Mediterranean countries, while the highest intake was reported for Iceland. These data must however be interpreted with caution because they are both historic and calculated using different methodologies.

### **Denmark**

In March 2003, Denmark became the first country to introduce legislation to set an upper limit (2%) on the industrially produced trans fat content of fats and oils delivered direct to the consumer or to be used in food production. At the time dietary intakes of trans fats for the Danish population were around 1% of energy, and saturated fat intakes for men and women estimated as 15.8 and 15.5% of energy respectively.

The Danish authorities were acting on advice from the Danish Nutrition Council about the evidence on the adverse health effects of trans fats, and concerns about the presence of high trans fat levels in a range of popular foods which may be eaten frequently and result in consumers exceeding recommended intakes. The Danish authorities considered that artificial trans fats were unnecessary from a nutritional point of view and could easily be removed from the food supply without impacting upon product availability or the quality of foods, and with no/minimal cost implications for the food industry.

### **USA and New York City**

The average dietary intakes of trans fats in the US were estimated in 1994-6 to be around 2.6% of energy, (more than double UK levels) with artificial trans fats

accounting for around 80% of this. In contrast US intakes of saturated fats were around 11% of energy – only marginally above maximum recommended US intakes of 10%. Dietary advice to US consumers is that “trans fat consumption be as low as possible (below 1% of energy) while consuming a nutritionally adequate diet”

Action on trans fats has encompassed voluntary and mandatory activities. The US Food and Drug Administration (FDA) introduced mandatory trans fat labeling in January 2006, which prompted industry to reformulate products, consequently most retail products in the US are now free from PHVO. Products that contain less than 0.5g trans fat per serving may be labeled as 0g trans fat.

In New York City the use of PHVOs, shortenings, or margarines that are used for frying or as a spread and contain 0.5g or more of trans fat per serving was prohibited in foodservices from July 2007. This action followed an education campaign in 2005, targeted at caterers and consumers which proved ineffective. From July 2008 food establishments can no longer store, use or serve any product that contains these fats and spreads and has 0.5g or more of trans fat per serving. The legislation does not however apply to pre-packed foods served in the manufacturer’s original sealed packaging.

There is a regulatory framework in New York – the New York City Health Code – which requires that all food service establishments including restaurants, caterers and mobile food-vending units must be licensed to operate. The New York City Department of Health and Mental Hygiene is responsible for the issue of permits. The situation in the UK is different as we have no legislation that provides for this type of prior approval system for food businesses.

The catering sector was considered to be of particular importance because food eaten outside the home is both unlabelled and represents around a third of energy consumption for New Yorkers. CHD is the leading cause of death in New York and this legislation is expected to save around 500 lives per year. Although the impact on dietary intakes is as yet unknown, around 95% of businesses are now compliant with the legislation.

### **Trans Fat Free Americas June 2008**

PAHO, as a consequence of the WHO global strategy on Diet and Physical activity and Health , convened a meeting between the public health authorities and representatives from the food industry and cooking oil companies has agreed the Rio de Janeiro declaration for a Trans Fat Free Americas. The primary goal being to replace industrially produced TFA’s so that they are not greater than 2% of total fat in oils and margarines and not greater than 5% in processed foods. The measures include mandatory labelling, substitution of oils,

tax incentives for substitutes including crop production and processed foods etc, public education especially for children and young people.

### **Key issues for consideration**

The key issue is what scope is there for further improvement within the UK?

### **Scope for further reductions of IPTFA's in the UK**

The scope for further action within the UK is dependent upon the extent to which it is desirable or possible to completely reduce the UK consumption of IPTFA's without raising saturated fat levels. This would mean reducing TFA levels from around 1-1.3% to 0.4- 0.5 % of total fat content.

There also needs to be better quality information about TFA consumption levels within population subgroups. Especially children who consume large quantities of fast foods, confectionery, cakes, biscuits and pastries etc. Based on this analysis the scope for reducing inequalities between population groups can be established.

The UK also needs to assess the situation with imported pre packaged processed foods and with small and medium sized enterprise food companies who do not have the technology or resources to reformulate.

It should be noted that The US regulation is that products can declare zero trans fats if they contain 0.5g or less per serving. Serving sizes are standardized in the US. Therefore a regular Krispy Kreme donut (52g) containing 12g of fat (according to the KK website) and which declares 0 trans fats, could contain as much as 4% trans fat.

We need to know how TFA levels vary according to social class. The National Diet and Nutrition Study data shows that approximately 3 per cent of the adult population (around 1.3million people) are consuming above the maximum recommended amount of TFAs (2 per cent of food energy). LIDNS data shows that among lower income adults, an estimated 12 per cent are eating more than the maximum recommended amounts. Such differences will compound the continuing problems of social inequalities in disease rates.

The likely contribution to IP-TFA intake from foods has not been fully accounted for in the dietary survey data as it does not include foods eaten outside the home especially snacks and fast foods eaten out (which are higher risk foods for TFA content)

Both the National Diet and Nutrition Survey (NDNS) and the Low-Income Diet and Nutrition Survey (LIDNS) make assumptions about the amount of TFAs in the various foods listed in the survey respondent's food diaries. The listed foods

may not include all foods, especially snacks and fast foods eaten out (which are higher risk foods for TFA content).

The FSA's own dietary analyses acknowledge that typically, around 20 per cent of food is not reported in food diaries and therefore not included in the estimates of intake.

In the UK there is limited information on TFA levels in food eaten outside the home. There needs to be assessments of TFA levels from food establishments and the consumption patterns of population subgroups. According to unpublished recent research by Martin Caraher in Newham showed that eating out three times a week meant that some individuals were consuming between 6-12% of dietary energy from TFA's.

Furthermore, the SACN report (2007) does not appear to refer to consumption of IP-TFAs from fast food sources. Evidence from Stender (2007) suggests that a single fast food meal of nuggets and fries can contain well in excess of an adult's maximum recommended daily intake. In McDonalds in the UK, 170g of fries and 160g of nuggets contain 6 to 8g of TFAs. This one meal would greatly exceed the current recommended maximum of 4.5g (which would equate to 2 per cent of dietary energy, 2000 kcal).

IP- TFAs have been removed from the food supply in Denmark and New York and individual companies such as Marks and Spencer across all food categories.

### **Impacts of alternatives to partially hydrogenated vegetable oils (PHVOs)**

The use of non-hydrogenated oils has the potential to increase saturated fat levels. The effects of reformulation vary according to the application of the oil.

According to the FSA the saturated fat content of the oil used for biscuits and other baked products has increased by around 10%, although manufacturers allied to the Biscuit Cake Chocolate & Confectionery Association report that in most cases reformulation has been achieved without an increase in saturated fat levels of the final products. The rise in saturated fat content of oils used in chocolate-flavored coatings for confectionery may be higher, but for other applications saturated fat levels have not increased, for example in margarines, and may even have reduced, for example in frying oils. The use of high oleic sunflower oils in the snack sector in particular, has delivered significant reductions in saturated fat levels in these foods, and has ongoing cost implications.

According to the FSA the information from industry does not allow an assessment of what impact reformulation may have had on dietary saturated fat intakes. Many manufacturers and retailers however report that they are working with oil suppliers to minimize the impact of reformulation on saturated fat levels.

## **Suggestions for population level TFA research and monitoring and intervention**

Taking a precautionary approach, where there is no safe level of consumption of TFA's; the public health goal as suggested by WHO should be the elimination of IPTFAs.

On the basis of the national epidemiology, current national and international policy and the recent reviews set out above the following suggestions are proposed for discussion by the NICE PDG:

### **A. Interventions:**

- Ban the use of industrial TFAs in food sold within the UK, as successfully done in Denmark in processed foods and throughout the food service sector
- Consider the need to adopt a license (which would include public health requirements) to operate as a food establishment in the UK.
- Label IPTFA's (or TFA's) in food takeaways and restaurants
- Push for IPTFA (TFA) nutritional labeling at EU level
- Mandate use of oils and industrial processes that do not increase IPTFA levels
- Explore use of taxation/subsidies in relation to discouraging consumption of industrially produced TFA's and saturated fats.
- Standardize international measurements of IPTFA's (per 100g or per total fat content) for labeling purposes and to assess intervention impact. Do not use the misleading portion sized or less than 0.5g zero rating measures as adopted in the USA.

### **B. Research and monitoring**

- Monitor IPTFA levels in food eaten outside the home and intakes in children and young people.
- Check on IPTFA levels in imported food
- Undertake independent studies to validate industry claims on reductions in industrially produced TFA's within the UK
- Seek independent expert food technology advice on the measures being adopted across the main TFA food categories in the UK and what scope there is for a total reduction of industrially produced TFA's without increasing saturated fat levels.
- Analyze further published studies since the SACN trans fatty acids (2007) position statement that take account of new studies on the disease impacts and population risk

- Monitor and assess changes to the overall lipid profile of the diet and their impacts on lipoprotein profiles of the population so that adverse consequences can be identified (SACN 2007)
- Ascertain the absolute and relative CVD risk of industrially produced TFA's with saturated fats and if risk/toxicity varies with dosage, age and population groups
- Monitor context and progress and health outcomes of the natural experiments on IPTFA reduction in the US, Denmark and more recently in Canada and South Korea

### **Key references**

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SACN update on trans fatty acids and health – position statement by the Scientific Advisory Committee on Nutrition (2007)

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**Paul Lincoln**