#### FSA 07/12/07

#### TRANS FATTY ACIDS

#### Executive Summary

- 1. Increasing trans fatty acids *(*trans fats) intakes are associated with raised serum cholesterol levels and coronary heart disease (CHD) risk.
- 2. The Board is asked to agree advice to UK Health Ministers on the health impacts of trans fats, and need for action to restrict trans fats in food, following the regulatory actions already taken in Denmark and New York.
- 3. The paper sets out the current position in the UK; independent advice from the Scientific Advisory Committee on Nutrition (SACN); an overview of voluntary and regulatory action internationally on trans fats, practical and legal issues which need to be taken into account, stakeholder views, and a re-estimate of average dietary intakes of trans fats from foods.
- 4. It analyses 2 options:
  - maintain current voluntary approach (Option 1);
  - introduce mandatory restrictions on trans fats in foods (Option 2).
- 5. In response to the specific questions posed by the Secretary of State, the evidence and analysis presented in the paper indicates:
  - 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 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 Treaty;

- we are 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.
- 6. The Board is asked to:
  - note the advice of SACN on the health effects of trans fats ;
  - **<u>note</u>** the action taken internationally on trans fats levels in foods;
  - **<u>consider</u>** the options for action in light of existing voluntary initiatives by the food industry; and
  - <u>agree</u> the Agency's advice to UK Health Ministers set out in paragraphs 48-53.

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#### TRANS FATTY ACIDS

#### lssue

1. To agree advice to UK Health Ministers on the health impacts of trans fats, and consider appropriate risk management action.

#### Strategic Aims

2. To reduce diet related chronic disease, in particular coronary heart disease.

#### **Background**

- 3. 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. 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) (Further details at Annex 1).</p>
- 4. Average trans fats intakes, 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 well 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). The Agency's priority, agreed with UK Health Departments in 2003, has therefore been to reduce consumers' saturated fat intakes. This objective is a key strategic target, and the subject of the Agency's draft Saturated Fat and Energy Intake Programme, which was the subject of a recent public consultation.

#### Current FSA policy on trans fats

- 5. The Agency's policy on trans fats (Annex 2) has three strands:
  - dietary advice on reducing trans fats intakes, and the type of foods in which they occur;
  - promotion of voluntary industry action to reduce trans fats without increasing saturated fat levels; and

• enabling consumer choice through labelling of trans fats. The FSA is lobbying the Commission to allow trans fats labelling on foods as part of new nutrition labelling proposals expected early next year.

## The Secretary of State (SoS) for England's request and Agency actions

- 6. In October 2007 the SoS requested that the Agency undertake a review of the evidence of health impacts of trans fats and advise whether unilateral action would be appropriate, considering action taken in New York and Denmark. (Request at Annex 3). The Agency has therefore:
  - commissioned a review of health evidence, that has been considered by SACN;
  - held a stakeholder meeting to gather views and information on industry initiatives to reduce trans fats; and
  - re-estimated average intakes of trans fats using current levels in certain foods, including key contributors.

# Evidence of health effects of trans fats

7. The primary health concerns relating to trans fats are an association between increasing trans fat intakes, coronary heart disease (CHD) risk, and raised serum cholesterol levels. The health implications of trans fats have been the subject of several reviews internationally and by SACN since the Committee on Medical Aspects of Food Policy<sup>1</sup> (COMA) recommended that average intakes of trans fats should not exceed 2.0% of food energy in 1994. These reviews show an increasing body of evidence in relation to trans fat increasing CHD risk. (See Annex 4)

#### Existing voluntary initiatives to reduce trans fat levels in foods

8. Consultation with the food industry has shown that key trade associations spanning the retailer, food manufacturing and catering sectors all have policies in place to remove HVO from their products (see Annex 5). As a result virtually all British Retail Consortium (BRC) Members<sup>2</sup> own brand products will be free from HVO by the end of this year. Other retailers including Budgen, Londis, Lidl, Netto and Spar have also committed to remove HVOs from their own brand products. Food manufacturers within the Food and Drink Federation are working to reduce trans fats levels without increasing saturates, where technically feasible, and businesses within the food service sector are also reformulating their products to reduce trans fats levels.

<sup>&</sup>lt;sup>1</sup> COMA is the predecessor of SACN

<sup>&</sup>lt;sup>2</sup> Members of the BRC account for 85% of the retail market.

9. The impact of these policies and the achievements of UK fats and oils suppliers in meeting demands for lower trans fats oils is more clearly illustrated by changes in trans fats levels in oil supplies. Table 1 Annex 6 shows that trans fat levels in virtually all oils sold as bottled oils or food ingredients in the UK have reduced from up to 55% to <2%. It is not possible to remove all trans fats, as standard oil refining processes e.g. de-odorisation result in trans fats formation at low levels. Action by the oils and fats suppliers has therefore already reduced trans fats to a minimum.</p>

#### Impacts of alternatives to PHVOs

- 10. 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. 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-flavoured 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.
- 11. The information available 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 minimise the impact of reformulation on saturated fat levels.

#### International perspective

- 12. Trans fats are a global concern and different countries have adopted a wide range of responses. These initiatives are detailed in Tables 1 & 2 of Annex 7 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.
- 13. Overall dietary intakes in the UK are moderate compared to data for other European member states, and much lower than the US and Canada (Table 1 Annex 7). 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.

#### USA and New York City

- 14. 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%<sup>3</sup> 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%<sup>4</sup> of energy) while consuming a nutritionally adequate diet"<sup>5</sup>.
- 15. Action on trans fats has encompassed voluntary and mandatory activities. The US Food and Drug Administration (FDA) introduced mandatory trans fat labelling 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 labelled as 0g trans fat.
- 16. 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<sup>6</sup> was prohibited in foodservice 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.
- 17. 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.
- 18. 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

<sup>&</sup>lt;sup>3</sup> National Health and Nutrition Examination Survey – US Department of Health and Human Services Centers for Disease Control and Prevention National Center for Health Statistics. Intake of Calories and Selected Nutrients for the United States Population 1999-2000.

<sup>&</sup>lt;sup>4</sup> American Heart Association Nutrition Committee. Lichtenstein, A. et al. Diet and lifestyle recommendations revision 2006: a scientific statement from the American Heart Association Nutrition Committee. Circulation. 2006 July 4:114(1)e27.

<sup>&</sup>lt;sup>5</sup> Institute of Medicine of the National Academy of Sciences (IOM/NAS) report "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids. 2005. No dietary reference value is recommended.

<sup>&</sup>lt;sup>6</sup> The legislation provided an additional 1year transition period for fry oils used to deep fry cake batter and yeast dough. A per serving approach is possible in the US because serving sizes are laid down in legislation.

York, and this legislation is expected to save around 500 lives per year<sup>7</sup>. Although the impact<sup>8</sup> on dietary intakes is as yet unknown, around 95% of businesses are now compliant with the legislation.

19. Further details about US action on trans fats are presented in Annex 8.

## Denmark

- 20. 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.
- 21. 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<sup>9</sup> 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 organoleptic quality of foods, and with no/minimal cost implications for the food industry.
- 22. Details of the Danish activities are at Annex 9.

#### UK situation and evidence of health impacts of trans fats

23. The review of health evidence commissioned by the Agency considered:

- the evidence regarding health effects of trans fats on CHD since the EFSA (2004) and WHO (2003) reports, plus effects on cancer, obesity and diabetes;
- whether it is possible to distinguish the health effects of trans fats from vegetable oil versus animal origin; and
- whether there is sufficient data to warrant a revision of the current recommendations that intakes of trans fats should not exceed 2% of food energy for the population average.

<sup>&</sup>lt;sup>7</sup> Total mortality rate of 19,000/yr from CHD.

<sup>&</sup>lt;sup>8</sup> It may not be possible to determine the impact of catering controls from those effected by reformulation by retailers.

<sup>&</sup>lt;sup>9</sup> Take-away foods, wafer biscuits, popcorn.

- 24. SACN considered the review and made the following observations and recommendations<sup>10</sup>:
- There is consistent evidence to support a moderate effect of trans fatty acids on increasing the risk of CHD. The primary mechanism for this effect appears to be via changes in the serum lipoprotein profile, although inflammatory responses and endothelial function may also be negatively affected by dietary trans fatty acids.
- The evidence relating trans fatty acid intakes to risk of diseases other than CHD is limited, and no reliable risk assessments can be made. However, future reports on these associations should be monitored, particularly the effect of trans fatty acids on insulin sensitivity and diabetes, and the trans fatty acid -genotype interaction with risk of prostate cancer.
- The current data provides insufficient evidence to justify the differentiation of trans fatty acids from vegetable oil and animal sources based on the isomeric forms of the trans fatty acids. There is also inadequate data to demonstrate that trans fatty acids from different dietary sources have differential effects on CHD risk or lipoprotein profiles.
- The impact of reformulations of fats within the diet should be monitored to ensure there are no unintended adverse consequences for dietary lipid profiles and related CHD risk factors.
- SACN endorsed the current recommendation set by COMA (1994), that the average trans fatty acid intake should not exceed 2% of food energy, as there is currently no firm scientific basis for its revision.
- The conclusions and recommendations from SACN's report are provided in full at Annex 10.

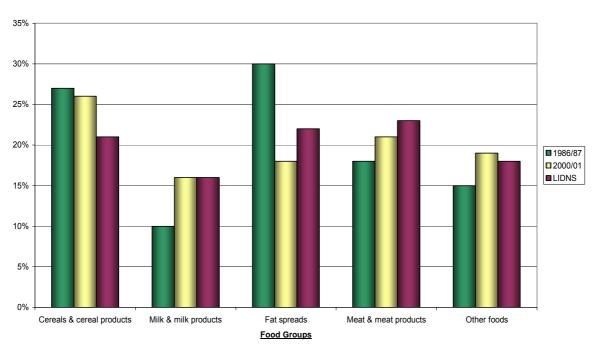
#### Trans fats intakes

25. The main contributors to trans fats intakes from the National Diet and Nutrition Survey<sup>11</sup> and Low Income Diet and Nutrition Survey are shown below in Figure 1. Cereal and cereal products includes biscuits, buns, cakes, pastries, and the 'other food' category includes, among others, chips, potato products, savoury snacks, and confectionery. An estimate of the sources of trans fats in foods suggests that around 55-65% is derived from PHVO with the remainder from the natural sources of meat and dairy products from ruminant animals.

<sup>&</sup>lt;sup>10</sup> Update on trans fatty acids and health – Position statement by the Scientific Advisory Committee on Nutrition, 2007. Available at : www.sacn.gov.uk

<sup>&</sup>lt;sup>11</sup> Data from 2000/01

26. Overall dietary intakes of total fat, saturated fat and trans fats fell between 1986/7 - 2000/01 (see Annex 11 for full details). Reduction in trans fats has been most significant, with average population intakes reducing by almost half from 2.2% to just 1.2% of food energy, with no significant differences as a proportion of energy evident on either regional or socio-economic<sup>12</sup> bases. Intakes were within 2% of energy for 97% of the population in 2000/1.



#### Figure 1: Percentage contribution of food types to trans fatty acid intakes: adults<sup>a</sup>

- 27. For adults in the general population, food eaten outside the home provides a higher proportion of food energy from fat, saturated fat and trans fat than does food eaten at home. However for trans fats the difference is small –food eaten out providing 1.3% of food energy compared to 1.1% for food eaten at home. In low income adults this is even less marked.
- 28. Estimates of average population trans fats intakes for NDNS (2000/01) and LIDNS (2003-5) represent an overestimate because the compositional data for products used to make the assessment have not kept pace with industry reformulation initiatives. Using current data supplied by the food industry for a limited range of food groups that include key contributors to intakes<sup>13</sup> from PHVO, a revised estimate of average intakes has been made. Assuming no changes in consumption patterns, product reformulation of these foods has reduced average population intakes to 1%<sup>14</sup> of food energy. This is likely to be an over estimate of intake as it does not take into account changes in the trans fats levels in all food groups, and particularly those making up the 'other foods' category, which contribute around 18 -19% to intakes.

<sup>&</sup>lt;sup>12</sup> Benefit households were compared with non-benefit households.

<sup>&</sup>lt;sup>13</sup> Biscuits, cakes, pastries reduced and low fat spreads and soft margarine, ice cream.

<sup>&</sup>lt;sup>14</sup> Re-estimation of average dietary intakes published on FSA website www.food.gov.uk

#### Summary of stakeholder views and consumer awareness research results

- 29. FSA research into consumer attitudes to foods shows that concern about key nutrients such as salt, fat, and saturated fat far outweighs that for trans fat [see Annex 12]. At a stakeholder meeting consumer and public health groups (Which?, Sustain, Nutrition Society, British Heart Foundation, Heart UK, National Consumer Council, TfX (a lobby group on trans fats), the Fat Panel) were generally supportive of the elimination of PHVOs from food, and favour a mandatory approach which they feel would offer greater clarity for consumers, and provide a level playing field for businesses. As many foods, particularly those eaten outside the home are not labelled, TfX felt this lent support for controls, similar to those implemented by Denmark, which focus on oils and fats rather than final foods. The National Consumer Council expressed concern about cost implications of a mandatory approach if these were passed onto the consumer. In contrast the Fat Panel expressed concern that saturated fat intake is a much bigger risk to public health and the Agency should avoid being side tracked by trans fats, intakes of which are well within dietary recommendations.
- 30. Industry stakeholders considered that legislation would have little or no effect on most businesses, as comprehensive action on trans fats had already been taken.

#### **Discussion - Policy Options For Action**

31. The policy options available, taking into account the views of stakeholders, advice from SACN and information from other countries are:

**Option 1** – continue with a voluntary approach;

**Option 2** – recommend mandatory restrictions on trans fats levels in oils used as foods or food ingredients.

#### **Option 1**

- 32. Voluntary action by the food industry has been highly successful in reducing trans fats in oils for food use to a minimum. There may be scope to develop advice on reformulation for those small and medium size enterprises with limited technical expertise that are still reformulating products. This could be achieved as part of the Agency's developing Saturated Fat and Energy Intake Programme, in collaboration with oil suppliers, and take the form of Agency advice to encourage both trans and saturated fats reductions in foods and their substitution for healthier oils.
- 33. The Agency would continue to press for trans fat labelling, and promote appropriate dietary advice to consumers.

# **Option 2**

- 34. Introduction of legislation similar to Denmark would have no impact for the majority of businesses, since oil supplies in the UK contain trans fats at levels at, or below 2%, but would introduce additional requirements on enforcement bodies. The effect of the New York model would be similar, and require introduction of additional UK legislation on portion size.
- 35. Legislation would give consumers the same level of protection from trans fats in imported products as they currently have through voluntary measures in relation to domestic products. In the light of SACN's advice and current dietary intakes, such an approach would be unlikely to deliver a significant public health benefit.

#### Practical considerations

36. A wide range of practical considerations would need to be considered, and consulted upon, if a legislative route were adopted. This would need to include consideration of whether restrictions on PHVOs, or trans fat levels in final foods or food ingredients was preferable, thresholds for trans fat levels (natural/ artificial/total), the scope of legislation across food industry sectors, the potential impact on small and medium size businesses and relevant transition periods, plus effective enforcement measures, as currently there is no method of analysis which can accurately distinguish between artificial and natural trans fats.

#### Legal implications

- 37. Any legislation would have to be compatible with EU law and should not create barriers to Community trade, unless justified, for example on health grounds. The relevant EU legal framework is briefly summarised in Annex 13. The legislation would have to go through a notification procedure, so that it could be assessed by the Community. It is noted that infraction proceedings were commenced by the Commission against Denmark, but were closed earlier this year. Existing voluntary action poses little or no risk under EU law.
- 38. Health is a devolved matter in the UK; therefore introduction of national legislation across UK would require the agreement of Health Ministers across the four countries if the intention was to ensure unified action. Disparate measures within the UK could create trade problems for UK businesses.

#### Impact

39. Sustainability issues including food waste implications, product sourcing and environmental issues, particularly in relation to palm oil have been raised in relation to reformulation. However the BRC has advised us that product shelf-life reductions are minimal and unlikely to increase levels of food waste. Additionally, all the major UK oil suppliers are members of the Roundtable on Sustainable Palm Oil (RSPO).

#### Impact on the Agency

- 40. If the Board recommends advice to SoS that action should extend beyond current initiatives this would slow progress on saturated fat reductions, which is the public health priority. Any proposals would need to be subject to a full 12-week public consultation, and give due consideration to the principles of Better Regulation which requires the administrative burden imposed on businesses to be minimised. The wider costs and benefits in relation to businesses and public health, including enforcement costs, would need to be assessed through an Impact Assessment process.
- 41. Additional funding to generate food composition data that reflects recent reformulation activities, for those foods which contribute significantly to industrial trans fats intakes, would be valuable in helping to develop a more accurate estimate of trans fats intakes as part of the 2008/9 and subsequent NDNS surveys.

#### Activities In SWANI

- 42. It has not been possible for the Food Advisory Committees (FACs) to discuss this issue. Some FAC members have however submitted their views to the relevant FAC Chair's for consideration as part of the Board discussions.
- 43. The Scottish Government has made a commitment to "place an upper limit on artificially produced fats (trans fats) both in food and in oils and fats used in the preparation of food."

# **Board Action Required**

- 44. The information presented in this paper illustrates just how successful the food and oils industry have been in recognising and responding through voluntary initiatives to their customers' and consumer groups' concerns, and encouragement from the FSA to reduce trans fats in foods
- 45. The impact of PHVO removal from foods has dramatically reduced artificial trans fat levels in foods. The levels of trans fats in oils used in UK food production are generally as low as possible which is <1%. This is now lower than the most restrictive legislative controls introduced by Denmark.
- 46. Industry action has been directly responsible for the drop in average consumer intakes of trans fats by more than half, to 1% of food energy. Assessment of the data supplied by industry and estimated dietary intakes do not indicate significant

variations in intakes by region, sub-population or socio-economic groups, or the contribution to energy of trans fats from foods eaten outside the home.

- 47. Taking into account the evidence provided above on the scientific advice, the impact of voluntary industry initiatives on trans fats, practical and technical issues, the findings of consumer research, and stakeholder views, it is recommended that the Board agree to advise UK Health Ministers as follows.
- 48. A review of the available evidence on the health impacts of trans fats shows that while there is consistent evidence to support a moderate impact of dietary trans fats on increasing the risk of CHD, the evidence for an association between trans fats and cancer, obesity and diabetes is insufficient and contradictory.
- 49. SACN's advice based on the available evidence of the adverse effects of trans fats on the risk of CHD is that average intakes of trans fats should not exceed a maximum of 2% of food energy. Current average dietary intakes of trans fats for UK consumers are not therefore a cause for concern, as they are half the maximum recommended level at 1% of food energy. This is an upper estimate and actual intakes are likely to be lower.
- 50. Data provided by the food, and oils industries shows that comprehensive action has been taken to reduce trans fats levels in vegetable oils used in UK food production to a minimum which is <1%. This is lower than the most restrictive legislative controls introduced by Denmark. There is no scope for further reductions in UK oil supplies. Unilateral action to introduce mandatory restrictions would formalise existing practices among the UK producers, but would be unlikely to offer an additional public health benefit.
- 51. Action in New York, where heart disease is the leading cause of death, stemmed from public health concerns about high trans fats intakes, which at around 2.6% of energy are more than 2.5 times those in the UK.
- 52. Danish average trans fats intakes are comparable to the UK. Legislative action in 2003 was triggered by advice the Danish authorities received on the adverse effects of trans fats, coupled with the high levels found in some foods in 2000/01 which were popular in Denmark. The UK situation is different as our recommendation, based on SACN's further advice that average intakes should not exceed 2% of food energy, is that current intakes do not give cause for concern. In addition industry data shows that levels of artificial trans fats in UK food production have declined dramatically in recent years as levels in ingredient oils have been reduced to the minimum.
- 53. The primary concern relating to removal of PHVO from foods is the potential for increases in saturated fat levels, since dietary intakes of saturated fats (13.3%) currently exceed maximum recommended intakes of 11% of food energy. Early progress with the food industry to reduce saturated fat levels in foods, without increasing trans fat levels, should therefore be the priority.

#### Annexes

1	Fats – Background information
2	FSA policy on trans fats
3	SoS request for advice
4	Evidence of health effects of trans fats
5	Industry Initiatives
6	Table of compositional changes in industrially-processed oils
7	Intakes of trans fats in selected countries and international activities on trans fats
8	Background to activity in US
9	Background to activity in Denmark
10	SACN Report : Update on trans fatty acids and health Overall summary, conclusions and recommendations
11	Intakes of total fats, saturated fats and trans fats and levels in foods
12	Consumer awareness and concerns about trans fats
13	Controls on trans fatty acids – the legal framework

## FATS – Background information

#### Hydrogenated vegetable oils

- <u>Hydrogenation</u> is one of the processes that can be used to turn a liquid unsaturated oil into a solid saturated fat. The process of hydrogenation can be controlled to produce different oils with increasing solidity and melting point. Partial hydrogenation of an oil results in the formation of trans fats as a byproduct of the process. Levels of trans fats in partially hydrogenated oils up to around 60% are possible. These trans fats are eliminated if the hydrogenation process is allowed to continue to produce fully hydrogenated oils. Hydrogenation was first introduced in 1909 when it was applied to fish and whale oil, as hydrogenation increased so it was increasingly applied to vegetable oils.
- 2. Partially hydrogenated vegetable oils (PHVOs) have been used in the manufacture of a wide range of foods including biscuits, pastries, cakes, margarines and other processed foods. The characteristics and benefits of hydrogenation and PHVOs for manufacturers and consumers include:
  - cost, and availability;
  - flavour;
  - the ability to produce fats with a wide range of melting points from single oils melting point affects mouth feel, and stability of products at different temperatures (room temperatures, fry temperature etc)
  - stability to oxidation, which may be perceived as off-flavours or rancidity, and will have implications for safety and product shelf-life;
  - appearance gloss retention is important for some confectionery products; and
  - PHVOs provide structure to products (e.g. enabling solid fat spreads that maintains spreadability), and other functional characteristics e.g. crystallisation rates which determine how air is held within the food structure.
- 3. Although PHVO is the main source of trans fats in the diet, small amounts also occur in nature in dairy produce and the flesh of ruminants e.g. beef, lamb, mutton. These are formed as a result of hydrogenation of polyunsaturated fats in the rumen of animals by microbes. The levels of naturally occurring TFA in meat and dairy produce ranges between around 3-8% (of the total fat content), and demonstrates a degree of seasonal variation.

#### General Information on Fats

4. **Fats** present in foods consist of a mixture of saturated and unsaturated fats which differ according to their chemical structure. The combination of the different saturated and unsaturated fats present within a food play a part in its technological characteristics and their levels within the diet impact on health.

- 5. **Saturated fats** form the basis of the more stable hard fats, such as those found in butter, cheese, the fat on meat and lard. Healthy eating advice discourages over-consumption of foods high in saturated fats because of the ability of saturated fat to raise blood cholesterol levels. There is a direct association between blood (low-density lipoprotein) cholesterol and coronary heart disease risk.
- 6. **Unsaturated fats** are found in plant and fish oils and are associated with some health benefits. Having unsaturated fat instead of saturated fat can help lower blood cholesterol. The consumption of mono- and poly-unsaturated fats can help decrease the risk of developing cardiovascular disease because:
  - Mono-unsaturated fats (for example found in olive oil) are thought to lower LDL ("bad") cholesterol, they have a neutral effect on HDL ("good") cholesterol (although at high intakes they may raise HDL);
  - ω-6 polyunsaturated fats (found in Sunflower oil) also lower LDL cholesterol, they have a neutral effect on HDL cholesterol (at high intakes they may raise HDL);
  - ω-3 polyunsaturated fats (found in oily fish) raise HDL cholesterol levels (at practical levels of consumption they have little effect on LDL.

## Current Agency policy on trans fats and EU activities

#### Consumer advice

 The Agency's healthy eating advice recommends that consumption of foods that are high in saturated fat or trans fats should be reduced or that such foods should be replaced by foods that are high in unsaturated fats. The advice identifies biscuits and cakes, fast food, pastry and some margarines as foods that often contain trans fats (as well as saturated fats, sugar and salt) and recommends that consumption of these types of foods should be kept to a minimum.

#### Product labelling

2. Consumers can identify the presence of hydrogenated vegetable oils that contain trans fats using the ingredients list of prepacked foods. The use of HVO as an ingredient is required by law to be declared as part of the ingredients list (i.e. 'hydrogenated fat/oil' or 'partially hydrogenated fat/oil'). However consumers have no way of knowing the actual amount of trans fats present in that ingredient or in the product as a whole. Current EC legislation controlling the label declaration of the nutrient content of a food (the 'nutrition label') prohibits a voluntary indication of the trans fats level unless a claim about trans fats is made, such as 'reduced trans fats'.

#### Agency work with the food industry

#### Trans fat

3. The Agency has welcomed the voluntary initiatives undertaken by manufacturers, retailers, food service organisations and their suppliers to reduce the levels of trans fats in their products.

#### Saturated fat

4. In line with the Agency's public health objectives, our Strategic Plan includes a commitment to work with stakeholders to reduce the population average intake of saturated fat to as current intake levels exceed public health recommendations. This is a priority for the Agency and we are developing a programme of initiatives to address this issue.

#### **European Commission Activities**

5. The European Commission's White Paper on Nutrition, Overweight and Obesity proposes EU-wide action on product reformulation to reduce trans fats and other

nutrients<sup>15</sup> in foods, and advocates the development of non-regulatory publicprivate partnerships as the delivery vehicle for such work. The Commission will undertake a study in 2008 to explore the potential for reformulation, and further action, which will take into account progress already achieved through legislative and voluntary action.

6. The European Commission is also currently reviewing the rules for food and nutrition labelling to bring them more into line with the needs and expectations of consumers. A formal Commission proposal is expected before the end of this year, and will be the subject of a full public consultation. The Agency considers that it is unhelpful that businesses cannot give customers information on trans fat levels unless they make a claim and are pressing for the labelling of trans fats to be included in the European Commission's new nutritional labelling proposals. Currently there are no criteria laid down for nutrient claims that products are free from trans fats.

<sup>&</sup>lt;sup>15</sup> Total fat, saturated fat, and salt are also included.

DH CONT

From the Rt Hon Alan Johnson MP Secretary of State for Health **DH** Department of Health **Richmond House** Food Standards Agency SofS47352 79 Whitehall London SW1A 2NS Received Dame Deidre Hutton Chair Tel: 020 7210 3000 19 OCT 2007 Food Standards Agency **Aviation House** 125 Kingsway Private Office London EC2B 6NH 1 8 OCT 2007 me Deidre

#### **REVIEW OF TRANS-FATS**

I am writing to you to formally ask the Food Standards Agency to undertake a review of the evidence on trans-fatty acids (TFAs).

I am keen that the Agency treat this as a priority to determine whether or not we should be seeking to act to restrict the use of TFAs, in particular in light of the work underway in New York City and Denmark.

I should be grateful if this would cover the following areas:

- Review of all available evidence on the health impacts of TFAs, and an assessment of the relative threat to health.
- International comparison both in terms of TFA intakes and action taken.
- Options for unilateral action (promoting further voluntary restrictions, partial/total ban), the legal position and risks for each course (e.g. judicial review, EU infraction).
- Other relevant considerations, e.g. risk of an alternative to TFAs being developed which proves to be worse in terms of health impacts.

I should also be grateful if the Food Standards Agency could submit this review to me by 29 November.

AGer Church

ALAN JOHNSON

DG1710

#### ANNEX 4

#### Evidence of health effects of trans fats

- 1. The primary health concerns relating to trans fats are an association between increasing trans fat intakes, coronary heart disease (CHD) risk, and raised serum cholesterol levels. Increasing trans fats intakes result in an increase in levels of low density lipoprotein (LDL) or "bad" cholesterol, whilst also lowering the levels of high density lipo-protein (HDL) or "good" cholesterol.
- 2. Since 1994, when 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.
- 3. The evidence of health effects of trans fats were:
  - reviewed 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 Organisation (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 up national dietary guidelines." The WHO's report of the 57<sup>th</sup> 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."

#### **Industry Initiatives**

- 1. The Agency held a stakeholder meeting on 29<sup>th</sup> October 2007, to discuss issues relating to trans fats. The information below outlines the policies and commitments provided by the trade associations covering foods which contribute significantly to intakes of industrial trans fats in the diet. British Retail Consortium (BRC) members have been working with their suppliers towards the removal of HVOs as an ingredient in their own-brand ranges. BRC estimates that to date nearly 7000 products have been reformulated to remove HVOs with only 26 products remaining. These final products will be reformulated by the end of this year.
- 2. Members of the Food and Drink Federation (FDF), which represents food and drink manufacturing companies and trade associations supporting specific food and drink sectors, are committed to reducing trans fat levels, where this is technically feasible, without raising saturated fat levels. In 2006, an FDF survey of its members found that hundreds of brands with sales worth £1.5 billion had been reformulated to remove trans fats.
- 3. The Margarine and Spreads Association, an FDF member, reports that reformulation of fat spreads to remove HVOs has resulted in reductions of trans fat levels to below 1% of the final product.
- 4. Other key food sectors that contributor to industrial-trans fats in the diet include biscuits, cakes, savoury snacks, confectionery and potato products. The Biscuit Cake Chocolate & Confectionery Association (BCCCA) and the Snacks, Nuts and Crisps Manufacturers Association (SNACMA) have reported on progress made by their members to reformulate their products to reduce trans fats. In December 2006, BCCCA reported that since its members committed to a trans fat reduction programme in 2003, many popular biscuits now contained only trace levels of trans fats and that, in most cases, this had been achieved without an increase in saturated fat levels. SNACMA has also reported that since its members moved away from using hydrogenated oils the trans fat levels in the savoury snacks range had dropped to trace levels. Similarly, processed potato products are now produced using non-HVOs. The Potato Processors' Association (PPA) has stated that its members have been tackling trans fats over the past few years and have reduced levels in the final processed product to within 2%.
- 5. Members of the British Hospitality Association (BHA), the trade body that represents foodservice providers are also reformulating their products to reduce trans fats levels. HVOs are no longer used as ingredients in foods provided to institutions, such as schools and care homes.

Table 1: Compositional changes in industrially-processed oils supplied for use in food groups that are key contributors to artificially-sourced trans fats. The data covers the majority of such oil ingredients used in food production.

Note that the following data takes no account of the different fat levels of the final foods in which the oils are used as ingredients. Actual levels of trans fats
and saturated fat may be much lower when expressed per 100 g of the finished food product.

Foodstuff	Ingredient	Action on HVO	Combination of oils used (may include one or more of the following in varying quantities)	TFA level	Saturated fat level (% of the total oil ingredient)
Biscuits	Shortening (100% fat)	Pre	Hydrogenated rape, Hydrogenated palm, Hydrogenated palm kernel, Palm, Rape	5-10%	30%-50%
		Post	Palm, Rape	<1%	26-51%
	Cream fillings	Pre	Hydrogenated palm kernel, Palm kernel, Hydrogenated rape, Hydrogenated palm	2-50%	15-90%
		Post	Palm, palm kernel	<1%	50-85%
Buns, Cakes,	Cake margarine (80- 82% fat)	Pre	Hydrogenated rape, Hydrogenated palm, Palm, Rape	10%	25-40%
Pastries Meat pies Meat pastries		Post	Palm, Rape, Some palm kernel	<1%	28-42%
	Shortening (100% fat)	Pre	Hydrogenated rape, Hydrogenated palm, Palm, Rape	12%	30-50%
		Post	Palm, Rape, Some palm kernel	<1%	35-50%
	Puff Pastry margarine (80-82% fat)	Pre	Palm, Rapeseed, Some hydrogenated palm & rape	8%	39%
	· · · ·	Post	Palm, Rapeseed	<1%	40-45%
Industrial and foodservice frying oils	Frying oils (100% fat)	Pre	Hydrogenated Rapeseed, Palm, Palm kernel	<1-25%	16-50%
		Post	High oleic sunflower & rapeseed, Palm	<1%	10-50%
Chocolate confectionery <sup>ii</sup>	Cocoa butter alternatives for use in chocolate-flavoured coatings	Pre	Hydrogenated palm kernel, Hydrogenated palm, Hydrogenated soy, Hydrogenated cottonseed, Hydrogenated rape	<1-55%	35-99%
	C C	Post	Palm Kernel, Palm	<1%	60-99%

	Filling fats, toffee fats	Pre	Hydrogenated palm, Hydrogenated Rape, Hydrogenated palm kernel	25-30%	25-90%
		Post	Palm, Palm kernel, Coconut	<1%	45-90%
Margarines, fat spreads	Oil blend (for the most popular spreads of 39- 59% fat)	Pre	Palm, Rape, Palm kernel, Hydrogenated rape, Hydrogenated palm, Sunflower, Hydrogenated sunflower, Olive	<1-5%	25-30%
	_	Post	Palm, Rape, Palm kernel, Sunflower, Olive	<1%	25-30%

# Table 1 Intake of trans fats in selected countries - European data reported derived from the TRANSFAIR study.

Country	Trans intake		Year collected
	men	women	
Belgium <sup>16</sup>	1.4	1.5	1991 / 92
Denmark	1.0	1.0	1995
Finland	0.8	0.9	1992
France	1.1	1.2	1993 / 94
Germany	0.8	0.9	1991
Greece	0.5	0.8	1995
Iceland	2.1	1.9	1990
Italy	0.5		1980 / 84
Netherlands	1.5	1.6	1992
Norway	1.5	1.4	1993 / 94
Portugal	0.6	-	1988 / 89
Spain	0.7		1991
Sweden	1.1	1.1	1989
United Kingdom	1.3		1996
United States <sup>17</sup>	2.6		1994 / 96
Canada <sup>18</sup>	1.8 – 2.4	1.7 – 2.2	1997 / 99
Australia & New Zeal'd <sup>19</sup>	0.6 (Aus); 0.	7 (NZ)	2007

Mean intakes of trans fat as percentage of energy intake

#### Background to the TRANSFAIR Study

The TRANSFAIR study brings together data from pre-existing national surveys from 14 Western European countries. The individual studies are diverse in the methodology applied (i.e., they include food supply, household consumption and individual consumption studies) and the year of data collection (ranging from 1980/84 – 1996). There are also differences in the method of data collection and the time period for which data was recorded.

<sup>17</sup> Food and Drink Administration, 2005

<sup>&</sup>lt;sup>16</sup> Information for European countries is taken from the TRANSFAIR study (Intake of fatty acids in Western Europe with emphasis on trans fatty acids, Hulshof et al, EJCN (1999) 53, 143-157)

<sup>&</sup>lt;sup>18</sup> Report of the Trans Fat Task Force, June 2006

<sup>&</sup>lt;sup>19</sup> Australia and New Zealand Food Safety Authority, 2007

The data contained in the report in respect of UK trans fat intakes are based on household purchase data from the National Food Survey collected in 1995 combined with analytical data on the trans fat content of about a hundred foods representative of total fat intake. The discrepancy between TRANSFAIR's estimate of average UK trans fat intake, and that from the 2001 NDNS (and the latest estimates contained in this paper) are therefore due to the different methodologies employed in these studies (most significantly that EFS is based on household purchases, while NDNS is based on individual food diaries).

#### Table 2: International Activities on trans fats

Australia & New Zealand	Voluntary Government-led national collaboration on trans fats established in October 2006. Intention to review progress in 2009	Population mean intakes of trans fat as % of energy intake: • Australia 0.6%, • New Zealand 0.7%, (2007)	Pan industry Quick service restaurants identified as a priority -roundtable established March 2007 No compositional targets	Trans fats from all sources. (A&NZ Food Code)	Trans fat labelling required <b>if claims are</b> <b>made</b> in relation to cholesterol or specific fatty acids. Voluntary labelling of trans fat content permitted.
France	Voluntary French Food Safety Authority (AFSSA) recommendations to industry to reduce trans fat use in ingredients.	<ul> <li>AFSSA report (2005):</li> <li>Average population intakes are 1.3% of energy intake.</li> <li>Recommends 2% energy as upper limit.</li> <li>Proposes recommended upper limit for trans fat content in domestic oils and spreads; fats and oils ingredients.</li> </ul>	Ingredients of bakery products, biscuits and pastry; and margarines and spreads identified as priorities.	Trans fats from all sources (AFSSA).	EU Nutrition Labelling Directive applies – therefore no requirement to label trans fat content. AFSSA propose mandatory labelling of trans fats
Netherlands	Voluntary programmes in place (both industry and government led) to improve fatty acid profile of foods	Food and Consumer Products Safety Authority (VWA) estimates average population intakes at ~2% and aims to reduce this to 1% by 2010 The Nutrition Centre's (Voedingscentrum) 'Hidden Fat' project	<ul> <li>'Hidden Fat' prioritises fats &amp; oils, baked goods, snack foods.</li> <li>Significant reductions in potato, meat and bakery products reported.</li> <li>Task Force - partnership between fats and oils industry and restaurant sector –</li> </ul>	Artificial trans fats.	EU Nutrition Labelling Directive applies – therefore no requirement to label trans fat content.

		seeks to engage with industry to drive reformulation. Greater emphasis on saturated fat. Task Force for Responsible Fatty Acid Composition – industry led partnership. Targeting both trans fats and saturated fats.	promoting use of liquid oils instead of solids partially hydrogenated vegetable oils. Supplemented by consumer awareness campaign. Voluntary action highly successful - >50% fast food outlets using a low trans fat oil. Evidence of reduction in intakes from 1.9% in 1998 to 1.1% in 2003. No compositional targets		
Canada	Voluntary adoption of recommendations from Trans Fat Task Force. Legislation unnecessary, as voluntary approach is succeeding. Survey of trans fats levels in food to be published shortly.	Trans Fat Task Force report that Canadians had one of the highest intakes of trans fats in the world. Average population intakes of trans fats at between 1.8 and 2.4% (men) and 1.7 and 2.2% (women) of energy intake. (dietary surveys from 1997-1999. <sup>20</sup> ) Task Force report (June 2006) recommends legislation limiting trans fats in products to bring population intakes to	Voluntary action targets domestic and imported products; and sales in all sectors, including retail and foodservice. Limits applied to final products: trans fat content of vegetable oils and soft margarines to be no more than 2% of total fat content. All other foods; trans fats not to exceed 5% of total fat	Exemption for food products containing trans fats <i>exclusively</i> from ruminant meat or dairy sources.	<b>Mandatory</b> labelling of trans fats on pre- packed foods required since December 2005.

<sup>&</sup>lt;sup>20</sup> http://www.hc-sc.gc.ca/fn-an/nutrition/gras-trans-fats/tf-ge/tf-gt\_app11\_e.html

		below WHO recommendation of <1%.			
United States	No active Federal Government-led initiative to reduce trans fat levels in foods. Focus instead on labelling. Small number of State Govt initiatives to prohibit or reduce use of trans fats in foodservice outlets.	US Institute of Medicine report 2002 recommends trans fat consumption be as low as possible while consuming a nutritionally adequate diet. FDA estimate average population intake of trans fats as 2.6% energy. (1994-96)	n/a	Labelling requirements exclude trans fats having conjugated bonds – i.e., CLAs	Mandatory labelling on pre-packed since January 2006. Foods containing less than <0.5g per serving may be labelled as 0g. FDA estimates that in 3 years trans fat labelling would prevent from 600 to 1,200 cases of CHD and 250-500 deaths each year.
New York City	Regulatory Storage or service of foods (including ingredients) containing partially hydrogenated vegetable oils trans fats at >0.5g/serving prohibited in foodservice outlets	Estimated one third of trans fat intake from foodservice outlets; estimate that 80% of trans fat intake is from PHVO. Regulation follows Trans Fat Education Campaign launched June 2005; calls for voluntary removal of PHVO accompanied by consumer education campaign. Later research indicated that this had not been effective in substantially reducing use of PHVO containing ingredients.	Applies to all foods served or used in preparation of foods served in foodservice outlets, apart from food served in manufacturers' sealed packaging.	A food is deemed to contain artificial trans fats if the food is labelled as or lists as an ingredient "vegetable shortening, margarine or any kind of partially hydrogenated vegetable oil", except where the labelling declares that the product contains less than 0.5g trans fat per serving.	Mandatory labelling pre-packed foods as per US Federal requirements described above. No trans fat labelling requirements for foodservice outlets as targeted by the NYC Health Code.

Denmark	Regulatory Legislation prohibiting use of fats and oils containing trans fats in food products.	Average population intakes 1% of food energy in 1995 (TRANSFAIR)	Measures apply in both retail and foodservice outlets. Trans fat content in oils and fats must not exceed 2%	Trans fats from ruminant sources exempted	EU Nutrition Labelling Directive applies – therefore no requirement to label trans fat content. Products may claim "free from trans fatty acids" where the trans fat content is less than 1% of the oil or fat content.
Switzerland	Draft Regulatory <b>Proposal notified</b> Similar to Danish Model		Edible oils and fats of vegetable origin. Maximum permitted trans fat 2g/100g from March 2008		

#### Background to activity in US

#### Nutrition Labelling Rules

- The US Food and Drug Administration introduced legislation requiring nutrition labelling of most food packages, with certain exceptions<sup>21</sup>, from May 1994. Mandatory trans fat labelling was introduced from January 2006, which allows products containing less than 0.5g per serving to declare 0g trans fats.
- 2. The FDA has defined trans fats for labelling purposes as unsaturated fatty acid that contain 1 or more isolated (non-conjugated) double bond in the trans configuration. Consequently conjugated linoleic acid, found in ruminant sources of meat and dairy would be excluded from the definition.

#### New York City's Health Code Amendment on Trans Fat

- New York City's (NYCs) Health Code amendment phases out the use of artificial trans fat in all food service establishments (FSEs) required to hold a New York City Health Department permit, including restaurants, caterers and mobile foodvending units.
- 4. From 1<sup>st</sup> July 2007 FSEs were prohibited from using partially hydrogenated vegetable oils, shortenings, or margarines for frying, pan-frying sautéing), grilling, or as a spread unless they hold product labels or other documents from the manufacturer showing that these ingredients contain less than 0.5g of trans fats per serving.
- 5. Trans fat-containing oils and shortenings for deep frying cake batter and yeast dough may continue to be used until 1<sup>st</sup> July 2008. However from this date no food containing partially hydrogenated vegetable oils, shortenings, or margarines with 0.5g or more trans fat per serving may be stored, used, or served by FSEs.
- 6. The regulation does not however apply to food served in the manufacturer's original, sealed packaging, such as a package of crackers, bag of crisps etc.
- 7. The penalty for breaking the Regulations may amount to a fine between \$200 and \$2,000, increasing for repeated violations, although to assist businesses in the transition to the new requirements a 3 month grace period was provided when the legislation came into effect. A separate category of violations was also

<sup>&</sup>lt;sup>21</sup> Exceptions to nutrition labelling include: foods manufactured by small businesses; food served in restaurants, or, delivered to the home for immediate consumption; delicatessen type food and bakery products sold directly to the consumer and prepared on the premises; and foods that provide no significant nutrition (eg instant coffee). Other exceptions tend to relate to areas of specific regulation eg medical foods and foods for infants and young children.

introduced which would be posted onto the web but would not determine pass/fail of routine sanitary inspections.

- 8. In support of the Regulations the NYC Department of Health and Mental Hygiene has made available free of charge and in multiple languages:
  - consumer advice through its own Health Bulletin<sup>22</sup>. This covers: 'good' and 'bad' fats, the foods in which they occur, and their effect on health; dietary advice on how to cut trans fats in home cooked meals, and when eating out; and information about how to use food labels, and to choose foods with 0g trans fat;
  - a summary of the Regulation and guidance to FSEs including a wide-range of Questions & Answers. This extends to advice on the scope and application of the legislation, alternative frying oils, and how to identify products that meet the regulations using food labels and supplier data; and
  - technical support for restaurants and bakeries
    - > a helpline staffed by recognised culinary science experts
    - training for restaurant personnel
    - resource website and printed materials including brochures, practical tips and information about alternatives to PHVO.
    - technical assistance programme supporting food service to make the transition away from trans fat and supporting replacement with heart healthiest alternatives.
- 9. The Department is also instituting a broad range of monitoring and evaluation measures which will enable it to evaluate the impact of this legislation on trans fat usage in food service and levels in baked goods.

<sup>&</sup>lt;sup>22</sup> NYC Health – Health Bulletin - Volume 5 No 9. Available at www.nyc.gov/health

#### ANNEX 9

#### Background to activity in Denmark

- The independent Danish Nutrition Council began its risk assessment work on the subject of trans fats in the early 1990's. Following the publication of an initial risk assessment in 1993, the Danish authorities (FVST) issued proposals in 1996 for an Executive Order to limit trans fats content of fats and oils. These proposals were met with opposition from stakeholder groups, but did lead to a programme of voluntary reductions and significant progress from the industry.
- 2. Emerging consumer, media and political concerns led to a reconsideration of the issue at the end of the 1990's, with the decision to take legislative action influenced by three key drivers:
  - increasing evidence of the adverse health impacts of trans fats;
  - a consensus (including from industry) that removal of artificial trans fats from products was technically straightforward, and would incur little or no cost to industry.
  - the need to ensure the application of the rules to imported as well as domestic products. Denmark's relatively small size (population c.5m) means that imported products have a considerable share of the market share in Denmark.
- 3. FVST considered that legislation represented a straightforward cost / benefit balance; the minimal costs of reformulation being set against a health benefit to all consumers. FVST considered mandatory labelling of trans fats as an alternative approach, but doubted its effectiveness in reducing intakes because of a low consumer understanding of the different types of fats and their relative health effects, and their view that labelling is of little interest in the population groups that are most likely to have a diet high in trans fats, for example young consumers.
- 4. The legislative approach for trans fats differs from the Danish policy in relation to Saturated Fats (which remains a specific priority, with intakes above the recommended intake of 10% of energy). Saturated fats occur naturally in dairy and meat products, which also contribute to intakes of protein, calcium and some vitamins. There is also some evidence that points to a much higher risk connected with trans fats. There are therefore no actual plans for legislation in this area; FVST is instead pursuing a partnership-based approach to voluntary reductions from industry.

#### The Executive Order

5. In June 2002, the Danish Government notified a draft Executive Order to the Commission under the Technical Standards Directive. The Order applies to oil and fat ingredients delivered direct to the consumer and to be used in food production and placed a limit of 1% on trans fat levels. This threshold was raised

to 2% in the final Executive Order. The legislation included a short transitional period during which higher limits would apply, and allows "free from trans fats" claims where the content is less than 1% of the oil or fat.

- 6. The Executive Order restricts the trans fats to which it applies to those from industrial sources. This distinction reflects the Danish view that it is not practicable to reduce levels of naturally occurring trans fats in dairy and meat products, and that legislation should therefore focus on those trans fats for which reductions are easily achievable. It was also documented that it is not possible to have a very high daily intake of trans fats if the intake is of animal origin, only.
- 7. The legislation was contested by the European Commission and some Member States on a range of grounds including that: alternative actions (e.g., consumer education and labelling) could achieve the desired protection with less disruption to the internal market; that the differential approach between artificial and natural trans fats was not justified on the evidence of health effects; and that no method of analysis is available to accurately distinguish between trans fats produced naturally and artificially. Despite the outcome of the Notification process, the Danish Government decided to proceed with the Executive Order, which entered into force in March 2003.
- 8. The Commission initiated infraction proceedings which were eventually dropped in February 2007.
- 9. Activity by FVST to measure the impact of the legislation has so far been limited to food composition surveys; although data on intakes will be published in 2008. Although the Danish authorities recommend that HVOs are substituted with healthier (mono-unsaturated) oils, they recognise that this may not always be the case, and consequently saturated fat may have been used to some extent as a substitute for industrially produced trans fats.

#### SACN Report: Update on trans fatty acids and health

#### Position statement by the Scientific Advisory Committee on Nutrition 2007

Please note the following abbreviations are specific to this text

- *trans* FA Trans fatty acid (s)
- RCT Randomised Control Trial
- HDL-C High density lipoprotein cholesterol
- LDL-C Low density lipoprotein cholesterol
- SFA Saturated fatty acids
- MUFA Monounsaturated fatty acid
- PUFA Polyunsaturated fatty acid

# 5. Overall summary and conclusions

- 237. Following a request from the Secretary of State for Health, this report considered: UK intake of *trans* FA; the evidence regarding effects of *trans* FA on CHD since the reports of EFSA (2004) and WHO (2003) on this issue; the evidence relating to other health effects of *trans* FA, particularly cancer, obesity and diabetes; whether, on the basis of present evidence, it is possible to distinguish the health effects of *trans* FA from vegetable oil versus those of animal origin; and whether present advice that *trans* FA intakes should not exceed on average, 2% of food energy (COMA, 1994) should be revised.
- 238. *Trans* FA naturally occur at low levels in dairy products and meats from ruminant animals. They are also produced by the industrial hydrogenation of vegetable oils, a process that has been used to produce the semi-solid and solid fats that are now widely used in food manufacture (e.g. margarines, biscuits) and catering outlets. *Trans* FA are also formed during high temperature treatment of oils and during deodorisation of unsaturated oils to remove unstable by-products of oxidation.
- 239. The SACN *Framework for the Evaluation of Evidence* (SACN 2002) was used as the basis to identify and assess evidence published on CHD since the EFSA (2004) and WHO (2003) reports, and to review published evidence for the other main diseases considered here (cancer, obesity, diabetes). The evidence base for this report was mainly restricted to retrospective and prospective epidemiology and RCTs in humans. In the epidemiology, measures of exposure included both direct measures of dietary *trans* FA intakes, as well as levels of *trans* FA in blood and tissues, which are taken to provide surrogate biomarkers of *trans* FA intakes.
- 240. The average adult (19-64 years) intake of *trans* FA in the UK was reported as being 2.2% food energy in 1986/87 (NDNS 1986/87), but had declined to 1.2%

food energy by 2000/2001 (NDNS 2000/01). Recent estimation of intake based on the reported consumption data from 2000/01, but using new composition data provided by industry, has given an estimated value of 1.00% food energy for the mean intake of *trans* FA in the UK adult population (FSA 2007). This figure is likely to be an overestimate of actual current intake as it was not possible in the time available to take account of all the reductions in *trans* FA levels in the model.

- 241. There is consistent evidence from prospective epidemiology to support a moderate impact of dietary *trans* FA on risk of CHD for ranges of intakes similar to, or slightly higher than, *trans* FA levels observed in the UK diet. Adverse effects of *trans* FA on LDL-C, HDL-C and total:HDL-C ratio have been consistently demonstrated in a number of well-controlled randomised trials. There is therefore a plausible biochemical mechanism to explain the pathophysiology underlying the prospective epidemiological findings.
- 242. Data obtained from a number of RCTs and meal studies using varying *trans* FA contents have not consistently demonstrated adverse effects of these FA on CHD biomarkers other than serum lipoproteins. These include classical biomarkers such as blood pressure and CRP, as well as emerging risk markers such as postprandial lipemia, lipid oxidation, markers of haemostasis, endothelial function and vascular inflammation. While the number of studies is limited for many biomarkers, their findings largely support the conclusion that the adverse effects of *trans* FA on CHD risk is primarily mediated via their actions in increasing circulating concentrations of pro-atherogenic LDL-C, whilst also decreasing concentrations of protective HDL-C.
- 243. The ability to quantify the increased risk of CHD attributable to that percentage of the general population currently consuming > 1% dietary energy as *trans* FA is limited by: i) estimates of risk from epidemiology for quintiles of intake in the region 1-2% dietary energy do not differ significantly from 1.0; ii) a lack of evidence for a linear relationship between *trans* FA intake and CHD risk over the range of 1-2% dietary energy (Figure 2); and iii) RCTs that have evaluated the impact of varying doses of *trans* FA on lipoproteins have not compared levels of intake between 1-2% dietary energy.
- 244. It should be noted that of the 10 published outputs from prospective studies which have reported on the association between *trans* FA intakes or biomarker levels and CHD risk, 6 have been obtained from the same study population (the Nurses' Health Study). There are potential limitations in estimating risks based on a preponderance of evidence from the Nurses' Health Study, since the study cohort includes only women and the dietary data are derived from an FFQ which shows relatively poor correlation with fat intakes estimated using more reliable measures. Extrapolation of risk estimates from a 20 year follow up of this study cohort (Oh *et al*, 2005), suggests that a decrease of 1% energy from *trans* FA would decrease risk of CHD by up to 15-16%. Similar extrapolation using the pooled variance-weighted risk from a meta-analysis of studies that included both

men and women (6-14 y follow up) suggests that a 1% decrease in energy from *trans* FA would be associated with a 12.5% decrease in risk of CHD (Oomen *et al,* 2001).

- 245. Based on an average UK intake of 1.2% food energy (NDNS 2000/2001), it is estimated that to reduce *trans* FA intakes of the population so that every individual had a *trans* FA intake of < 1% food energy would require the average intake to be reduced by 0.6% of food energy as *trans* FA. Extrapolation from the meta-analysis of prospective studies (Oomen et al, 2001) would indicate that this decrease in trans FA intake would result in a 7.5% reduction in risk of CHD. Prospective studies assess total mortality or morbidity, and therefore consider the total effect of all contributors to disease pathology. Estimates for CHD risk based solely on the impact of trans FA on LDL-C and HDL-C and on the total: HDL-C ratio, rather than total disease incidence, suggest that the reduction in CHD risk arising from an average reduction in *trans* FA of 0.6% energy would be in the region of 4.0%. This figure is lower than the risk reduction calculated from the epidemiological data, suggesting that either the CHD risk that can be specifically attributed to changes in lipoprotein profiles does not include the contribution of other pathophysiological pathways, or that the epidemiological risk estimate has been inflated by some unmeasured confounding.
- 246. Applying this same approach, but using the more recent estimates of UK *trans* FA intakes based on updates food composition data (FSA 2007), the estimated reductions in CHD risk based on an average UK intake of 1.00% food energy would be 5% and 2.8% for extrapolations from epidemiological and lipoprotein data, respectively.
- 247. Care must be taken when considering all of these estimates of risk reduction as they are based, in the case of some studies, on intake ranges higher than the current UK levels which assume a linear dose-response between *trans* FA intake and CHD risk. The latter assumption may not be valid given the distribution of the risk estimates at intake levels relevant to the UK population (Figure 2). The lack of linearity at the lower end of the range of *trans* FA intakes, suggest the actual reduction in risk is likely to be lower than the values estimated above.
- 248. There is some evidence from dietary data to suggest a more significant association between risk of CHD and *trans* FA of vegetable oil compared with that of animal origin. It should be noted that these conclusions were drawn from early prospective studies, including that of Willett *et al* (1993). Later outputs from the Nurses' Health Study have not reported separate associations for the dietary *trans* FA from vegetable or animal origin (Oh *et al*, 2005), although they have reported RRs for specific *trans* FA isomers in erythrocytes (Sun *et al*, 2007a; Sun *et al*, 2007b). It has been proposed that biomarker measurements of *trans* 18:2 and *trans* 16:1 in tissues and blood may provide surrogate markers for habitual intakes of *trans* FA of vegetable oil and animal origin, respectively. However, the evidence for this does not appear to have been subjected to systematic scrutiny.

Until the validity of the use of these tissue biomarkers has been sufficiently well established, it may be misleading to use them to distinguish between *trans* FA of vegetable oil and animal origin.

- 249. There is weak and inconsistent evidence for a relationship between *trans* FA and breast or colorectal cancer. Evidence for an association between *trans* FA and prostate cancer is limited, but a recent large case-control study has shown a strong interaction between risk and *trans* FA intake for a particular genotype that make up ~35% of the population. This potential association requires further investigation. The strong association between non-Hodgkin's lymphoma and *trans* FA intakes reported in a single study require further verification by means of intake data based on more recent estimates of *trans* FA intake.
- 250. There are limited data available upon which to assess the risk of obesity or increased weight gain associated with increased intakes of dietary *trans* FA. The reports from 3 prospective cohorts show a small positive relationship between *trans* FA intake and increased weight or waist circumference. However, in the studies that reported positive associations, the effect size was small (a weight increase over 8 years of approximately 0.5-1.0 kg for a 1% increase in dietary *trans* FA) when considered in the context of the extended time periods investigated. Although relatively large effects on weight gain were reported by a long-term study involving primates, the level of *trans* FA used in this study (8% dietary energy) was much higher than the average UK intake (1.0-1.2% food energy).
- 251. The evidence for an association between *trans* FA intakes and incidence of diabetes is limited. Prospective cohort studies have reported inconsistent results, with two showing a positive association of moderate effect size, but the association lost significance after adjustment in one study. One of the studies, which did show a positive association, did not adjust for the effects of other fatty acids. No effect on insulin sensitivity or glucose tolerance was found in 4 RCTs or meal studies of healthy individuals. However, postprandial hyperinsulinaemia was observed in obese subjects with type 2 diabetes fed very high *trans* FA diets (20% dietary energy). An acute meal study reported a significantly higher insulin response following meals high in *trans* FA (10% dietary energy), with other adverse effects of *trans* FA appearing to be genotype dependent. Data from isolated islet studies suggest that there is a differential effect of *trans* FA potentiating glucose-stimulated insulin secretion more than *cis*-isomers of identical chain length.
- 252. The assessment of the possible relationship between *trans* FA and early development is hindered by a lack of studies that are of suitable size and rigorous design which include adequate adjustment for potential confounding factors. Amongst the limited data available, the level of *trans* FA in plasma and tissue lipids is reported to be inversely proportional to the levels of long-chain  $\omega$ -6

PUFA, with the conclusion that, indirectly, *trans* FA may interfere with the metabolism of essential fatty acids. This may be important as long-chain PUFA have been shown to be important in fetal growth and development, and may have longer-term effects on physical health and behaviour. The data require cautious interpretation because the use of FA compositional data from observational studies to indicate the effects of *trans* FA on long-chain  $\omega$ -6 PUFA metabolism lacks rigour. This area requires further investigation by well-designed studies.

- 253. The potential association between *trans* FA intake and a number of health issues has been investigated in prospective epidemiological and population studies. Although a significant positive association was reported for gallstone formation, this has only been examined in one study. Trends towards positive associations were reported for Alzheimer's disease, cognitive decline and ovulatory infertility, but these failed to reach statistical significance.
- 254. Although this report has not been able to distinguish differences in risks attributable to *trans* FA of vegetable and animal origin, foods of animal origin that contain *trans* FA (dairy products, beef, lamb) are valuable sources of other nutrients such as protein, calcium and iron. These products currently account for roughly 40-50% of total *trans* FA intakes, although that proportionate figure is increasing as the *trans* FA levels in manufactured foods fall due to action taken by food manufacturers to reduce *trans* FA levels to the minimum required to maintain the quality of the product. Any recommendation for further reductions in *trans* FA intake levels should take account of the overall contribution these animal products make to the intake of key nutrients by the UK population.
- 255. At a horizon scanning meeting in 2003, SACN considered the need for an updated risk assessment on the health effects of *trans* FA. The Committee agreed that the original risk assessments made by COMA in 1994 remained appropriate and that the recommendation that *trans* FA intakes should not, on average exceed 2% food energy, should continue. The Committee considered that, although reductions in SFA intakes in the UK diet had been achieved since 1994, they remained above the target set by COMA (1994) and were considered to pose a greater risk to health than *trans* FA.
- 256. In considering the impact of changes in *trans* FA on targets for SFA, this review has also briefly considered the current intake levels of SFA (13.3% food energy) compared with the target intake of 11% food energy, and the dietary changes that would be required to achieve these intake levels by the UK population as a whole. There are already some indications that efforts by industry to reduce *trans* FA levels may have compromised efforts to achieve the dietary target for SFA, with reports that the reformulation of fats to remove *trans* FA may have resulted in increased SFA levels. This is of concern given the priority for reducing SFA as a population measure for reducing CHD risk. It is therefore important to monitor and assess changes in the overall lipid profile of the diet

(*trans* FA, SFA, MUFA and PUFA) and their impacts on lipoprotein profiles of the population (LDL-C and HDL-C), so that adverse consequences can be identified.

# Conclusions

- 257. The previous recommendation made by COMA that, on average, *trans* FA should contribute no more than 2% food energy, was based on epidemiological evidence of adverse effects of these fatty acids on risk of CHD. Since that report, epidemiological evidence based on up to 20 years of follow-up in prospective studies has remained consistent for an adverse effect of *trans* FA on CHD risk, although estimates of the size of the effect are smaller now than in 1994. Much of this evidence is based on a single large cohort of women in the USA. Evidence from RCTs that has emerged since 1994 has provided strong support for adverse effects of *trans* FA on LDL-C (increases) and HDL-C (decreases). In addition, the evidence for cardioprotective effects of HDL-C has strengthened over the same time period, resulting in greater recognition of the potential hazards of *trans* FA due to their unique properties in reducing HDL-C compared with other FA classes.
- 258. In most cases, the data that are available are for ranges of intakes slightly higher than those of current UK intakes. It is concluded that there is sufficient evidence upon which to base a risk estimate for CHD, but not for other diseases. The reduction in risk of CHD that would be obtained if all the population were to reduce *trans* FA intake to < 1% energy is estimated to be in the region of 7.5%. However, the overall impact may be less than this since this estimate is based on mean intake levels of 1.2% food energy (NDNS 2000/01), whereas current intake levels (FSA 2007) may be closer to 1.0% food energy due to continuing efforts by the food industry to reduce levels of *trans* FA in manufactured foods. In the latter case, the reduction in risk is estimated to be in the region of 5%.
- 259. There is insufficient evidence to make reliable risk assessments for adverse effects of *trans* FA on risk of diseases other than CHD. Recent epidemiological data on the potential impact of *trans* FA on some types of cancers (colon, prostate, non- Hodgkin's lymphoma) and diabetes is inconsistent, and further research is required. There is some, but very limited, data to suggest adverse effects of *trans* FA on body weight and body fat accumulation. However, the data are sparse and the impact cannot presently be quantified with any accuracy. There is currently no putative mechanism that could explain differential effects of *trans* FA on energy balance and adipose tissue deposition. On the basis of this evidence, this review has concluded that a specific recommendation for further reduction in *trans* FA based on potential adverse effects on body weight and obesity cannot be made.
- 260. Taking into account the totality of the evidence reviewed in this report the Committee endorse the recommendation made by COMA in 1994 that average *trans* FA intakes should be no more than 2% of food energy intake. The

Committee agreed that there is currently no firm scientific basis for revising the recommendations.

261. Steps taken since the COMA report (1994) to reduce levels of *trans* FA in manufactured foods are likely to have contributed to a reduction in risk of CHD for the UK population as a whole. A recommendation that no individual in the UK population should have a *trans* FA intake > 1% food energy may have adverse consequences for the overall lipid profile of the diet, including increasing SFA intake, and may also impact adversely on the consumption of animal products.

# Recommendations

- 262. There is consistent evidence to support a moderate effect of *trans* FA on risk of CHD. The primary mechanism for this effect appears to be via changes in the serum lipoprotein profile, although inflammatory responses and endothelial function may also be negatively affected by dietary *trans* FA.
- 263. The evidence relating *trans* FA intakes to risk of diseases other than CHD is limited, and no reliable risk assessments can be made. However, future reports on these associations should be monitored, particularly the effect of *trans* FA on insulin sensitivity and diabetes, and the *trans* FA-genotype interaction with risk of prostate cancer.
- 264. This review endorses the current recommendation set by COMA (1994), that the average *trans* FA intake should not exceed 2% of food energy, as there is currently no firm scientific basis for its revision.
- 265. The current data provides insufficient evidence to justify the differentiation of *trans* FA from vegetable oil and animal sources based on the isomeric forms of the *trans* FA. There are also inadequate data to demonstrate that *trans* FA from different dietary sources have differential effects on CHD risk or lipoprotein profiles.
- 266. The impact of reformulations of fats within the diet should be monitored to ensure there are no unintended adverse consequences for dietary lipid profiles and related CHD risk factors.

# **Recommendations for further research**

267. Outputs from the Nurses' Health Study provide 6 of the 10 prospective epidemiological reports on the association between *trans* FA and risk of CHD, as well as much of the data for associations between *trans* FA and diabetes (the largest of 3 studies) and weight gain (the largest of 2 studies). Reliance on outputs from a single large US study cohort as the basis for formulating public

health recommendations within the UK is unsatisfactory. Further research is required using large cohorts which include both genders and which consider other biological variables such as high-risk genotypes. There may be a particular advantage in studying UK/European cohorts, in whom there may also be greater possibility of estimating risk of CHD at the lower end of the *trans* FA intake range.

- 268. There is a gap in the literature that would be filled by well-designed RCTs assessing the impact of *trans* FA on CHD and other disease risk factors at intake levels relevant to the current UK population (0.5-3% food energy).
- 269. Further research is required to distinguish the metabolic and health effects of different *trans* FA isomers. There is also a need for evidence to support the use of tissue and blood levels of specific *trans* FA isomers as markers of dietary origin, i.e. animal verses vegetable oil origin.

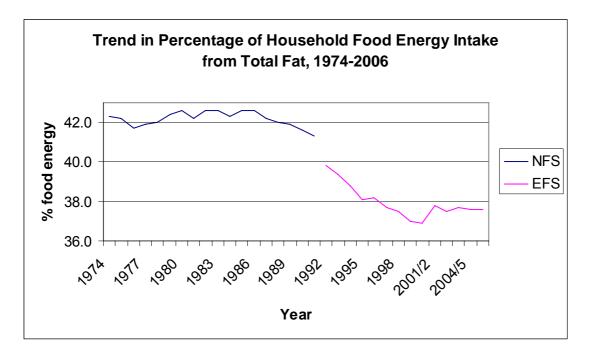
#### Intakes of total fats, saturated fats and trans fats and levels in foods

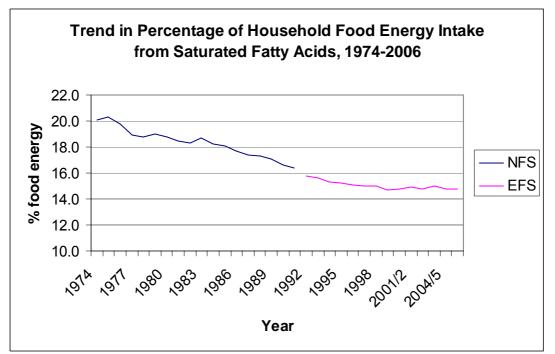
#### Sources of data on trans fat intakes

1 The National Diet and Nutrition Surveys (NDNS) and the Low Income Diet and Nutrition Survey (LIDNS) provide data on total trans fat intakes at the level of the individual. There is no data available from NDNS or LIDNS on intakes of individual trans fats nor any differentiation between naturally occurring trans fats and those present as a result of hydrogenation processes. The Expenditure and Food Survey (EFS) provides time trends in intakes of total fat and saturated fat, based on household purchase data, but no data are available on trans fats.

#### Time trends in fat/fatty acids intake

*Based on household purchase data* there is a long term downward trend in intakes of total fat and saturated fat since the mid 1970s, based on household food purchase data.





Source: MAFF National Food Survey 1974-2000; Defra Expenditure and Food Survey 2001/02 – 2005/06

#### Sources of composition data used to estimate trans fat intakes in NDNS and LIDNS

2 Trans fat composition values used to estimate intakes in the NDNS and LIDNS are based on analysis of composite samples carried out mainly in the 1990s. Table 1 shows the age of trans fat composition data for the main contributors to intakes.

Table 1:	Age of trans	fat composition	data
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Food group	Date of most recent fatty acid analysis
Biscuits, cakes and pastries	1992
Pasteurised milk	1995
Other milks and cream	1998
Cheese	1999
Chilled and frozen desserts	1997/98
Carcase meat	1992-1995
Meat products	1991-1995
Ethnic takeaway foods	1997
Crisps and savoury snacks	1989/91
Confectionery	1992
Chips	1980s
Potato products	1990s

3 For products for which no analytical data are available the fatty acid profile was estimated based on manufacturers'/retailers' data for total fat and saturated fat (usually from the product label) and the fatty acid profile of similar foods. Any claims on the label about trans or hydrogenated fat levels was taken into account when estimating the fatty acid profile. Fatty acid profiles for reduced and low fat spreads were updated using manufacturer's data collected prior to the 2000/01 NDNS. Products that claimed to be low in trans fat were coded separately from other products.

4 The trans fat composition data used for LIDNS (2003/05) was largely the same as that used for the 2000/01 adult NDNS.

Time trends in intakes of total fat, saturated fat and trans fat

5 The NDNS provides comparable data on intakes of total fat, saturated fat and trans fat for adults in 1986/87 and 2000/01. Table 2 shows that the proportion of food energy derived from total fat was markedly lower in 2000/01 (35% for women; 36% for men) compared with 1986/87 (40% for men and women). A similar pattern was seen for saturated fat (13% of food energy in 2000/01 compared with 17% in 1986/87) and for trans fat (1.2% of food energy in 2000/01 compared with 2.2% in 1986/87). The mean proportion of food energy from trans fat for adults in 2000/01, at 1.2% of food energy, was well below the UK Dietary Reference Value (DRV) of 2%.

Table 2. Total lat, Saturated lat and trans lat intakes in 1900/07 and 2000/01			
Men	1986/87 <sup>a</sup>	2000/01 <sup>b</sup>	
	% food energy	% food energy	
	Mean	Mean	
Total fat	40.4	35.8	
Saturated fat	16.5	13.4	
Trans fat	2.19	1.2	
Women	1986/87 <sup>a</sup>	2000/01 <sup>b</sup>	
	Mean	Mean	
Total fat	40.3	34.9	
Saturated fat	17.0	13.2	
Trans fat	2.16	1.2	

Table 2: Total fat, saturated fat and trans fat intakes in 1986/87 and 2000/01

<sup>a</sup> Aged 16-64 years. Dietary and Nutritional Survey of British Adults 1986/87

<sup>b</sup> Aged 19-64 years National Diet and Nutrition Survey adults 19-64 years 2000/01

6 The fall in trans fat intake between the two surveys is due to a number of factors:

- Reformulation work by manufacturers in the late 1990s onwards to remove partially hydrogenated vegetable oils reduced the levels of trans fats in many margarines and reduced and low fat spreads.
- There was a fall in consumption of some of the main contributors to trans fats in the diet – mean consumption of biscuits, buns, cakes, pastries and fruit pies was 29% lower in 2000/01 than in 1986/87, mainly due to a fall in consumption of cakes and pastries, and mean consumption of fat spreads was a third lower due to a 50% drop in butter consumption.
- Composition values for trans fat used in the 2000/01 survey, based mainly on analysis in the mid 1990s (see Table 1), differed from and tended to be lower than the values used in the 1986/87 survey, a higher proportion of which were estimated values. In particular the values used for meat, milk and dairy

products were generally (though not universally) higher in the 1986/87 survey. In the case of meat this is partly due to higher total fat values in the older dataset. It is not clear to what extent these differences reflect real changes in the trans fat content of these foods but it is likely that at least some of the apparent changes are due to the replacement of estimated values used in 1986/87 with analytical values for the 2000/01 survey.

- 7 It should be noted that the 2000/01 intakes do not reflect any manufacturer reformulations of biscuits, buns, cakes and pastries or crisps and savoury snacks to reduce trans fat levels that may have taken place since the last comprehensive analysis of these product groups in the early 1990s.
- 8 NDNS data can be analysed separately for participants living in benefit households<sup>23</sup> as an indicator of lower socio-economic status. Table 3 shows total fat, saturated fat and trans fat intakes as a percentage of food energy for adults in 1986/87 and 2000/01 living in benefit households and also for adults in the 2003/05 LIDNS. Adults from NDNS benefit households are not necessarily equivalent to adults in LIDNS in terms of socio-economic group, so caution should be used in drawing conclusions about trends over time.

Men	1986/87 <sup>a</sup>	2000/01 <sup>b</sup>	2003/5 <sup>c</sup>
	% food energy	% food energy	% food energy
	Mean	Mean	Mean
Total fat	39.2	35.8	35.9
Saturated	15.9	13.3	13.4
fat			
Trans fat	2.26	1.2	1.3
Women	1986/87 <sup>a</sup>	2000/01 <sup>b</sup>	2003/5 <sup>c</sup>
	Mean	Mean	Mean
Total fat	39.9	34.4	35.1
Saturated	16.8	13.0	13.4
fat			
Trans fat	2.18	1.1	1.2

Table 3: Total fat, saturated fat and trans fat intakes by adults (19-64 years)
from low income/materially deprived households or from households in
receipt of benefits

<sup>a</sup> Aged 16-64 years; The Dietary and Nutritional Survey of British Adults 1986/87

<sup>b</sup> Aged 19-64 years; National Diet & Nutrition Survey adults 2000/01

<sup>c</sup> Aged 19-64 years; Low Income Diet and Nutrition Survey 2003/05

9 The fall in intake of total, saturated and trans fat between 1986/87 and 2000/01 in adults in benefit households is similar to that seen in Table 2 for the general adult population. There is little or no difference in intakes between the NDNS benefit households in 2000/01 and the LIDNS group in 2003/05.

<sup>&</sup>lt;sup>23</sup> Benefit households are those households where one or more members were receiving Working Families Tax Credit at the time of the survey or had drawn Income Support or (income related) job seekers allowance in the previous 14 days.

#### Current data on mean intakes of saturated and trans fatty acids

- 10 Tables 4 shows the latest available data on saturated and trans fat intakes for the general population split into age/gender groups. Mean intakes of trans fats as a % of food energy for all groups met the DRV while mean intakes of saturated fat exceeded the DRV in all groups with the exception of young women aged 19-24.
- 11 Data on intakes in the 1½-4½ year age group are not shown in these tables because the composition data used for this survey pre-dated the analytical surveys of meat and dairy products carried out in the 1990s and the values were generally higher than the more recent analytical values. Reported intakes for this age group are therefore likely to be higher than current intakes.

Age, yrs	Gender	% food ei	nergy from
		Saturated fat	Trans fat
		Mean	Mean
4 – 6	Boys	14.8	1.3
	Girls	15.3	1.3
7 – 10	Boys	14.3	1.4
	Girls	14.5	1.4
11 – 14	Boys	13.8	1.3
	Girls	14.0	1.3
15 – 18	Boys	13.9	1.4
	Girls	13.8	1.3
19 – 24	Men	13.5	1.2
	Women	12.9	1.1
25 – 34	Men	13.2	1.2
	Women	13.2	1.1
35 – 49	Men	13.5	1.2
	Women	13.2	1.2
50 – 64	Men	13.4	1.2
	Women	13.3	1.2

Table 4: Saturated fat intakes by age & gender: general population<sup>a</sup>

<sup>a</sup> Source: NDNS young people 4 – 18 yrs 1997; NDNS adults 19 – 64 yrs 2000/01

12 Table 5 show the latest available data on saturated and trans fat intakes for the low income/materially deprived population split into age/gender groups. Mean intakes of trans fat as a % of food energy met the DRV for all groups while mean intakes of saturated fat exceeded the DRV in all groups.

		% food energy from	
		Saturated fat	Trans fat
Age, yrs	Gender	Mean	Mean
2 – 10	Boys	14.6	1.2
	Girls	14.4	1.1
11 – 18	Boys	13.7	1.2
	Girls	13.5	1.2
19 – 34	Men	13.4	1.2
	Women	13.0	1.2
35 – 49	Men	13.4	1.4
	Women	13.6	1.2
50 – 64	Men	13.3	1.3
	Women	13.6	1.2
65+	Men	14.4	1.3
	Women	14.5	1.4

## Table 5: Saturated fat intakes by age and gender: low income population<sup>a</sup>

<sup>a</sup> Source: Low Income Diet and Nutrition Survey 2003/05

#### Regional differences

13 The NDNS has found no evidence of regional differences in intakes of trans fat when expressed as a proportion of energy intake. Data for Wales cannot be reliably reported due to the small sample size and no NDNS data has ever been collected in Northern Ireland. LIDNS also showed no regional differences in trans fat intakes.

#### Socio-economic differences

14 The NDNS has found no evidence of differences in the proportion of energy from total, saturated and trans fat between people from benefit households and people in non-benefit households. LIDNS showed intakes of trans fats, when expressed as a percentage of energy intake, broadly similar to NDNS.

#### Main contributors to trans fatty acids intakes

15 Figure 1 shows the main contributors to trans fat intakes in adults in 2000/01 compared with 1986/87. In 1986/87 fat spreads (including butter) was the leading contributor providing 30% of intake on average while in 2000/01 the contribution of this group had fallen to 18% of intake. This is due to reformulation of many fat spreads in the late 1990s to reduce/eliminate hydrogenated fat and also to an overall decrease in consumption of this food group. The contribution of cereals and cereal products was unchanged at just over a quarter of total intake in both surveys, mainly from biscuits, buns, cakes and pastries. While mean consumption of biscuits, buns, cakes, and pastries fell between 1986/87 and 2000/01 (see para. 5) their relative contribution to trans fat intakes remained stable as it was offset by the decline in fat spreads. The relative contributions of milk and milk products and meat and meat products both increased slightly.

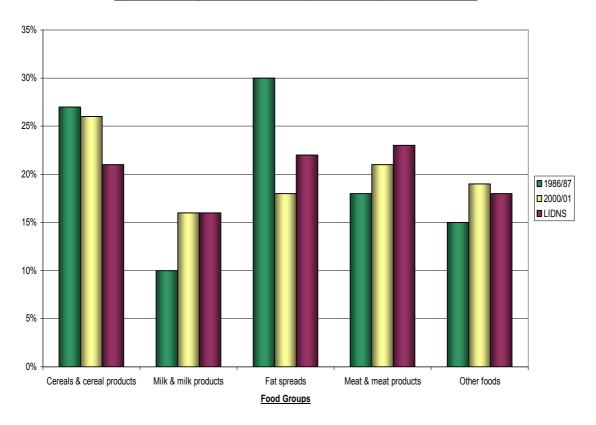


Figure 1: Percentage contribution of food types to trans fatty acid intakes: adults<sup>a</sup>

Source: Dietary and Nutritional Survey of British adults 1986/87; NDNS adults 19-64 years 2000/01; LIDNS 19 years and above 2003/05 Note: 'Other foods' includes chips, potato products and savoury snacks, confectionery, fish products, eggs and egg dishes.

#### Contribution of natural and artificial sources to trans fat intake

- 17 At present there are no methods of analysis applicable to a wide range of foods that can distinguish between trans fats which are naturally present in foods (e.g.. in ruminant products) and those formed during the processing of fats and oils. This is because of the overlap in trans fat profiles of ruminant fats and hydrogenated oils and the varying proportions of trans fat isomers among different hydrogenated fats.
- 18 An estimate of the contribution of natural and artificial sources to total trans fat intake has been made by identifying the main source of trans fat in each NDNS food group. This estimate, based on the 2000/01 NDNS, suggests that around 55-65% of trans fat intake is derived from processing, with the remainder from natural sources.

# Contribution of eating out to trans fatty acid intakes

19 Table 7 shows that, for adults in the general population, food eaten outside the home provides a higher proportion of food energy from fat, saturated fat and

trans fat than does food eaten at home. The difference in low income adults is in the same direction but less marked (Table 8).

Table 7: Variation in % food energy d	lerived from fat and fatty acids, from food
eaten at home and outside the home (	(adults 19-64 years)

	% food energy from		
	Total Fat Saturated fat Trans fat		
Food eaten at home	33.9	12.9	1.1
Food eaten out of the home	37.2	13.8	1.3

Source: NDNS adults 19-64 years 2000/01

# Table 8: Variation in % food energy derived from fat and fatty acids, from food eaten at home and outside the home (low income adults 19-64 years)

	% food energy from		
	Total Fat Saturated fat Trans Fat		
Food eaten at home	35.0	13.4	1.2
Food eaten out of home	37.2	13.7	1.3

Source: LIDNS 2003/05

# Modelling of trans fat intakes using current industry data

- 20. Estimates of average trans fat intakes are made by comparing the amounts of foods consumed with the average trans fat content of foods of that type. Recent estimates of trans fats intakes from NDNS and LIDNS represent an overestimate because the compositional data for products used to make the assessment have not kept pace with industry reformulation initiatives. Recognising that the food industry had carried out significant reformulation work to reduce trans fat content in recent years, in October 2007 the Agency sought information from various key food sector trade associations to help it prepare a more up to date estimate of trans fat intake.
- 21. The data provided were used to amend the existing compositional data in the following way:
  - Where a new **average** trans fat level was provided, the previous trans fat data for foods in that food group were replaced with the new average value. This was applied to ice-cream.
  - Where a **maximum** trans fat level was provided that was lower than the majority of the existing values, the existing values were replaced with this maximum. The true average level for such a product group cannot be identified, but will be no higher than this, so the contribution of this group to trans fat intake will be over-estimated. This was applied to margarine, fat spreads, biscuits, and buns, cakes, pastries and fruit pies.
  - Where a **maximum** trans fat level was provided that was higher than the previously used range of values the existing values were retained. The rationale for this approach (rather than replacing the existing values with the new maximum value) is that the existing values were generally based on analysis and it is consistent with specific information provided by industry that trans fat levels have been reduced in products over time. This approach was applied to confectionery, savoury snacks and processed potato products.

• Data for some individual products were also supplied, but these could not be applied to entire food groups and so no changes were made.

Current trans fat levels in food categories used in the updated estimate of average dietary intake were as follows:

Food categories	g trans FA/100g product
Biscuits	1
Buns, cakes, pastries and fruit pies	1
Reduced and low fat spreads and soft margarine	1
Ice cream	0.2

22. Assuming no change in food consumption patterns, product reformulation of the foods identified above has reduced the contribution of trans fat to 1% of average population food energy intake. This reflects an upper estimate of intake as it does not take into account changes in the trans fats levels in all food groups, and particularly those making up the 'other foods' category, which contribute around 18 -19% to intakes.

#### Consumer awareness and concerns about trans fats

- 1. Although there has been considerable media interest about trans fats and retailers have widely publicised their policies of HVO removal, consumer concerns remain relatively low in comparison to other nutrients, and food safety However, for those consumers that are aware of trans fats and issues. hydrogenated vegetable oils, these food components have a clear negative association.
- 2. The Agency's annual Consumer Attitudes to Food Standards Survey, which researches consumer attitudes, knowledge and claimed behaviour over time on food safety and standards issues, shows a clear prioritisation of concern in relation to food issues. The most recent Survey results for 2007<sup>24</sup> estimate that 20% of consumers were concerned about trans fats - a slight increase from 2006 (18%) - when consumers were prompted to choose from a list of key issues of concern. However, other food ingredients (salt (50%), fat (40%), sugar (39%) and saturated fat (37%), safety related issues (food poisoning (36%), food additives (35%), pesticides( 32%), antibiotics in meat (23%), and animal welfare issues all ranked as greater concern to the consumer than trans fats.
- 3. This prioritisation, specifically in relation to other types of fat, is mirrored in recent quantitative research<sup>25</sup> commissioned by the Agency to assess consumer awareness of saturated fat in the diet. The research, which was carried out on a representative group of consumers, between August and September of this year, was commissioned to identify consumer understanding and awareness of the need to reduce saturated fat intakes. When asked to choose from a list what types of fats it was most important for them to cut down on, just 15% of respondents selected trans fats and hydrogenated vegetable oils. In contrast 45% named saturated fats as the key fat of concern. A further 19% of respondents suggested trans fats and hydrogenated vegetable oils as the second most important fat to cut down on.
- 4. Qualitative research on consumer awareness and understanding of saturated fats published<sup>26</sup> by the Agency in May this year found a lower awareness of trans fats and hydrogenated vegetable oils than saturated fats but a predictable negative association about their presence in foods.

<sup>&</sup>lt;sup>24</sup> The Agency's Consumer Attitudes to Food Standards Survey 2007 will be published in February 2008. <sup>25</sup> Unpublished research, will be published in 2008.

<sup>&</sup>lt;sup>26</sup> Available at http://www.food.gov.uk/multimedia/pdfs/satfats0705.pdf.

## Controls on trans fatty acids – the legal framework

1. Food safety is an occupied field, i.e. it is covered by Community legislation. Within that field there are areas that are not totally harmonised, i.e. Community provisions do not cover every aspect and there is room for some discretion by Member States.

2. In relation to trans fats, two pieces of Community legislation have been identified which regulate the presence of trans fats in a particular context, namely legislation relating to novel foods and to infant and follow-on formulae.

3. The Infant Formula and Follow-on formula Regulations 1995 (as amended) which implement EC Directive 91/321/EC stipulate that the trans fat content for both infant formula and follow-on formula will not exceed 4% of the total content. The new infant formula and follow-on formula Directive (2006/141/EC) will change this to a maximum of 3% of the total fat content, and this provision of the Regulations will apply from 1st January 2010.

4. Four novel food ingredients have been authorised with associated compositional restrictions on their trans fat content, these are shown below. For each product the trans fat content is limited to not more than 1%.

Brand name	Description	Authorised	Commission Decision
Cardiabeat	Phytosterol-enriched oil	May 2007	2007/343/EC
Enova	Diacylglycerol oil of plant origin	Oct 2006	2006/720/EC
BENEFAT	Salatrims (short and long chain acyl triglycerides)	Dec 2003	2003/867/EC
DHA Gold	Algal oil rich in decosahexanoic acid	Jun 2003	2003/427/EC

5. In contexts outside of those mentioned in paragraphs 2-4, the situation is governed, as regards controls which only affect products from other Member States, by Articles 28 and 30 of the Treaty establishing the European Community ("the Treaty"), and as regards controls which affect imported and domestic product indiscriminately, by case law on the free movement of goods developed from those Articles.

4. Article 28 prohibits Member States from imposing quantitative restrictions, or any measures having equivalent effect, on imports from elsewhere in the Community.

5. Article 30 provides for a qualified derogation from Article 28 and allows prohibitions or restrictions if they can be justified on certain grounds, including the

protection of human health. The Article adds a rider that such prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

6. Case law of the European Court of Justice indicates that for prohibitions or restrictions under Article 30 to be upheld, the threat to health must be genuine, there must be no effective alternative to the restrictions, and the restrictions must be the least disruptive to inter-Community trade consistent with achieving the objective of protecting public health.

7. Any restrictive measures which a Member State is minded to impose must, except in cases of genuine emergency, be notified to the Commission and other Member States in advance of any action being taken. The procedure for notification is in most case governed by the technical standards Directive, which allows for a stand-still period of up to 6 months while the proposed measures are assessed at Community level. During this period the notifying Member State may not put the measures into effect. If the proposed measures are not eventually approved, a Member State risks infraction proceedings against it if it nonetheless goes ahead and imposes the restrictions. It would then have to defend its position before the ECJ, arguing for justification under Article 30 of the Treaty.

<sup>&</sup>lt;sup>i</sup> Note that the data contained in this table reflects the composition of industrially-produced oil blends. It does not take account of the use of dairy ingredients, such as butter and cream, for which TFA levels will not have changed.

<sup>&</sup>lt;sup>ii</sup> In accordance with EU legislation, 'chocolate' is not permitted to contain hydrogenated oil.