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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

regarding trans fats in foods and in the overall diet of the Union population

{SWD(2015) 268 final}

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

regarding trans fats in foods and in the overall diet of the Union population

1. INTRODUCTION

Article 30(7) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers[1], requires the Commission to submit a report to the European Parliament and the Council on "*the presence of trans fats in foods and in the overall diet of the Union population. The aim of the report shall be to assess the impact of appropriate means that could enable consumers to make healthier food and overall dietary choices or that could promote the provision of healthier food options to consumers, including, among others, the provision of information on trans fats to consumers or restrictions on their use. The Commission shall accompany this report with a legislative proposal, if appropriate.*"[1]

The present report is submitted in this context; it

- reports on the presence of trans fatty acids (TFA) in foods and in the overall diet of the Union population;
- presents the current approaches to limit TFA consumption worldwide and their effectiveness, with a focus on legal TFA limits, mandatory TFA labelling, and voluntary reformulation; and
- outlines some of the possible consequences of introducing such approaches in the European Union.

This report builds upon literature reviews and data gathered analysed and summarised by the Joint Research Centre on the subject and extensive consultation with national competent authorities and relevant stakeholders. It is accompanied by a Commission Staff Working Document which provides detailed information underpinning some of the conclusions set out herein.[2]

2. TFA – A BRIEF OVERVIEW

TFA are a particular type of unsaturated fatty acids. In Regulation (EU) No 1169/2011 they are defined as "fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration."[3] Some TFA is produced industrially (industrial TFA). The primary dietary source of industrial TFA is partially hydrogenated oils. Partially hydrogenated oils generally contain saturated and unsaturated fats, among them TFA in variable proportions (with TFA ranging from a few up to more than 50%), according to the production technology used. TFA can also be naturally present in food products

[1] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ L 304,22.11.2011, p.18
[2] Commission Staff Working Document " Results of the Commission's consultations on 'TFA in foodstuffs in Europe"
[3] Point 4 of Annex I to Regulation (EU) No 1169/2011.

derived from ruminant animals such as dairy products or meat from cattle, sheep or goat (ruminant TFA). Reductions of TFA are targeted to industrially produced TFA because the proportion of TFA in those fats can be modified whereas the proportion of TFA in ruminant fats is relatively stable. Ruminant TFA sources contribute between 0.3 and 0.8% of the daily energy intake depending on dietary habits across Europe[4].

Societal implications of TFA consumption and recommendations for maximum TFA consumption levels

The consumption of TFA increases the risk of heart disease more than any other macronutrient compared on a per-calorie basis[5]. The risk of dying from heart disease is higher when 2% of the daily energy intake is consumed as TFA instead of an exchange of carbohydrates, saturated fatty acids, cis monounsaturated fatty acids and cis polyunsaturated or other types of fatty acids, respectively if the exchanged amounts of calories remain the same (evidence available quantifies the increase in risk between 20-32%).[5] Despite limited availability of EU-wide data, a recent study compiled data from only 9 EU countries and reports that population average daily TFA intakes are below 1% of daily energy but higher intakes exist for specific sub-populations of some of those Member States.[13]

High TFA intake is one among a number of risk factors for developing coronary heart disease. Coronary heart disease is conservatively estimated to account for some 660 thousand deaths annually in the EU or some 14% of overall mortality. A wide variability is observed in the EU, with coronary heart disease representing between 6% and 36% of total mortality, respectively for France and Lithuania[6]. Costs associated with coronary heart disease are estimated to amount to 0.5% of Gross Domestic Product (GDP), with healthcare related costs running up to 2.9% of total healthcare costs. The work-up of these estimates and underpinning references is shown in below tables.

Table 1 – Cost and total healthcare cost of coronary heart disease in the EU-25 in Euro and as % of GDP[7]

EU-25		
	Million EUR (2003)	% GDP (2003)
Overall cost to the economy of coronary heart disease	45.564	0,5%
Total healthcare cost of coronary heart disease	28.250	0,3%

[4] Hulshof KF *et al*. Eur J Clin Nutr. 1999;53(2):143-57

[5] Mozaffarian D *et al*. Eur J Clin Nutr, 2009;63(S2):S5-S21: if 2% of the daily energy intake is consumed as TFA instead of carbohydrates, the risk of dying of heart disease is 24% higher, if 2% as TFA replace saturated fatty acids, the risk is 20% higher, if 2% as TFA replace cis monounsaturated fatty acids, the risk is 27% higher and if 2% as TFA replace cis polyunsaturated fatty acids, the risk is 32% higher.

[6] ESTAT 2011, causes of death data

[7] Leal et al 2006 Eur Heart J. 2006 Jul;27(13):1610-9 Economic burden of cardiovascular diseases in the enlarged European Union, ESTAT GDP data

Table 2 – Cost and total healthcare cost of coronary heart disease in the EU-28 in euro, as % of GDP and as % of the total healthcare cost[8]

EU-28			
	Million EUR (2012)	% GDP (2012)	% Total Healthcare Cost (2012)
Cost of coronary heart disease	58.755	0,5%	Not applicable
Total healthcare cost of coronary heart disease	36.428	0,3%	2,9%

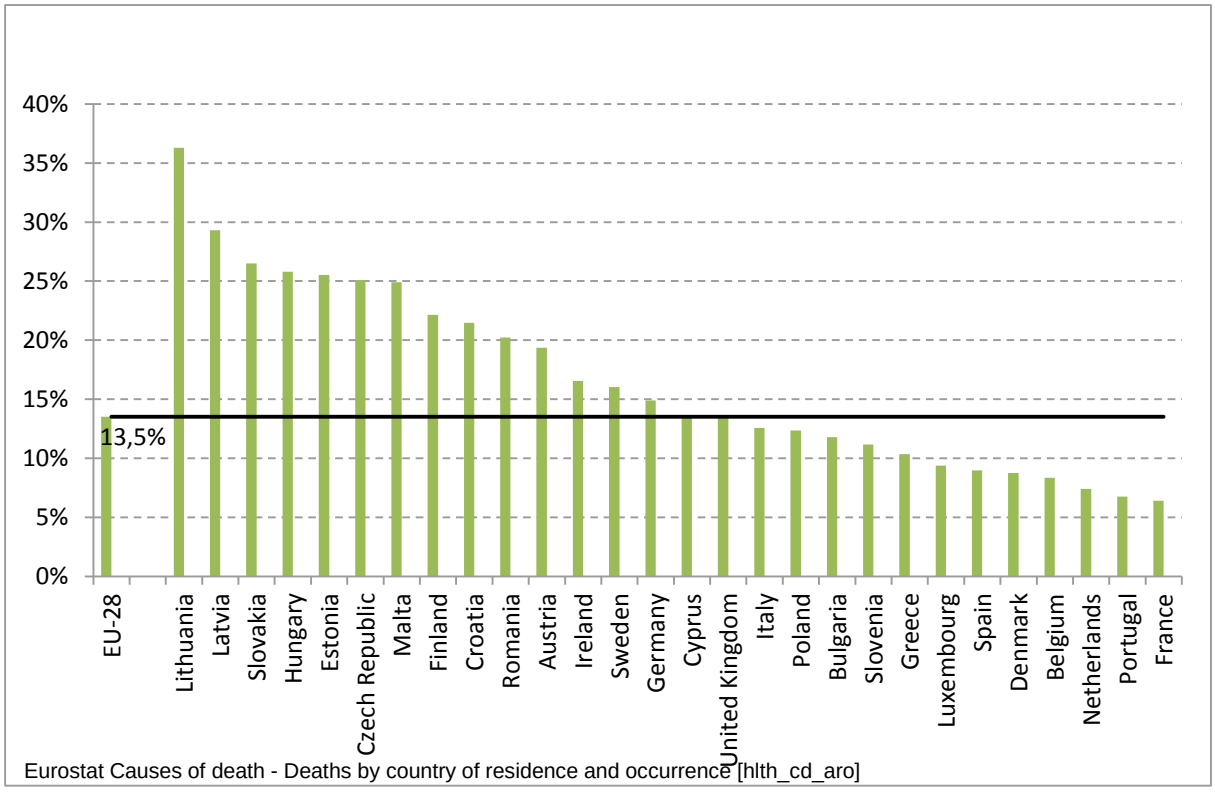

Figure 1 – Share of coronary heart disease[9] among total mortality (%, 2011)

High intakes of TFA contribute to the risk of developing coronary heart disease, however, the precise contribution to the overall health and economic problem is difficult to assess for the entire EU due to limited data available for TFA intakes in the entire EU. There is evidence that Denmark's introduction of legal limits for industrial TFA, which nearly eliminated those TFA from the Danish food supply, reduced deaths caused by cardiovascular disease.[10] In the 3 years after the legal limit

[8] Extrapolation assuming constant %GDP to EU-28 in 2012 from EU-25 in 2003 based on 1) Leal et al 2006 Eur Heart J. 2006 Jul;27(13):1610-9 Economic burden of cardiovascular diseases in the enlarged European Union, 2) ESTAT GDP data. Healthcare cost share based on WHO estimated for 2012

[9] ischaemic ICD-10 codes I20-I25

[10] Brandon J. *et al.* Denmark's policy on artificial trans fat and cardiovascular disease, Am J Prev Med 2015 (in print)

was implemented, mortality attributable to cardiovascular disease decreased on average by about 14.2 deaths per 100,000 people per year relative to a synthetic control group.
Industrial and ruminant TFA essentially contain the same compounds, yet in different proportions. TFA from both sources appear to have the same effects on blood lipids. According to the European Food Safety Authority, the available evidence indicates that TFA from ruminant sources have adverse effects on blood lipids and lipoproteins similar to those from industrial sources when consumed in equal amounts. At the same time, there is insufficient evidence to establish whether there is any difference between ruminant and industrial TFA consumed in equivalent amounts on the risk of heart disease.[11]

The European Food Safety Authority concluded that *"TFA intakes should be as low as is possible within the context of a nutritionally adequate diet"*[11,12], while the World Health Organization recommends to consume not more than 1% or others not more than 2% of daily energy as TFA (see[13]for an overview).

3. TFA REDUCTION MEASURES WORLDWIDE

Possible approaches to limiting TFA levels in food and population intakes can broadly be divided into legislative actions on the one hand and voluntary measures on the other. Legislative measures may be TFA limits in foodstuffs (either at the ingredient level or in the final product) or the mandatory TFA content information in the nutrition declaration. Voluntary reformulation or – where allowed – the voluntary inclusion of TFA content in the nutrition declaration, which is currently legally not possible in the EU,[14] leave it to the food business operators to decide whether or not to reformulate products or inform consumers about TFA. Furthermore, governments may issue dietary recommendations on maximum TFA intakes and relevant food sources of TFA. Tables 4 and 5 summarise which of these policies or measures are currently in place in Europe and beyond. For a specific category of foods (infant formulae and follow-on formulae), the maximum TFA content is currently regulated at the European level.[15]

[11] EFSA Journal. 2010;8(3):1461
[12] Dietary TFA are provided by several fats and oils that are also important sources of essential fatty acids and other nutrients. Thus, there is a limit to which the intake of TFA can be lowered without compromising adequacy of intake of essential nutrients. Therefore, the EFSA Panel concluded that TFA intake should be as low as is possible within the context of a nutritionally adequate diet.
[13] Mouratidou *et al.* Trans Fatty acids in Europe: where do we stand? JRC Science and Policy Reports 2014 doi:10.2788/1070
[14] Regulation 1169/2011 has harmonised the content of the nutrition declaration: (i) mandatory (Article 30(1) and ii) voluntary (Article 30(2)). TFA are neither among the nutrients listed in Article 30(1) nor Article 30(2). Therefore, it is legally not possible to indicate TFA content.
[15] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1.

Table 4 –TFA reduction measures applied throughout the EU countries. Adapted from [2,13].

Policy/measure	**Country (two letter country code)**
Voluntary – self-regulation	BE, DE, NL, PL, UK, EL
Voluntary – dietary recommendation	BG, MT, SK, UK, FI
Voluntary – composition criteria for specific traditional products	EE
Legislation –limiting TFA content of foodstuffs*	AT, DK, LV[16]HU
- limiting TFA content of foodstuffs which voluntarily bear a specific nutrition claim (keyhole)	SE
Other legislation**	ES, EL, FI

* all legal acts apply to products sold to the final consumer (as defined in[17]) . Ruminant TFA is exempt in all acts.
** *e.g.* TFA limits only for specific product categories

Table 5 - TFA regulation outside Europe. Compiled from[13] and WHO Europe[18].

Policy/measure	**Country**
Voluntary – self regulation	Costa Rica
Voluntary – nutrition labelling (mandatory in combination with	Australia/New Zealand, Colombia,
Combined approach (legislation – mandatory nutrition labelling	Canada (territorial legal limit in British Columbia)
Legislation -mandatory nutrition labelling	China, Ecuador, Hong Kong, Israel, Jamaica (under certain conditions), Malaysia, Mexico (under certain conditions),
Legislation - limiting TFA content of foodstuffs and mandatory nutrition labelling	Argentina, Brazil (mandatory label in food service proposed), Chile, Gulf Cooperation Council States (draft), India, Peru (legal limit in social programs providing food to certain parts of the population), Puerto Rico (legal limit in food service), Singapore, South Africa, USA (partially hydrogenated oils not "generally recognized as safe")

A noteworthy recent development is the decision of the US Food and Drug Administration (FDA) of 16 June 2015 which concluded, based on a thorough review of the scientific evidence, that partially hydrogenated oils, the primary dietary source of industrial TFA in processed foods, are not "generally recognized as safe" for use in human food. Food manufacturers will have three years to remove partially hydrogenated oils from products unless they are otherwise approved by the FDA.[19]

[16] Latvia notified its national measure on 02 September 2015; this measure is currently examined by the Commission.
[17] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.
[18] Communication from WHO Regional Office for Europe, 6 March 2015
[19] Department of Health and Human Services Fed Regist 2015;148832013: 34650-70

4. HOW WIDESPREAD ARE TFA IN EUROPE?

4.1 TFA content of foods in Europe

The majority of food products contain less than 2 g TFA/100 g fat (the lowest limit set in EU countries with limiting legislation). Seventy-seven per cent of these are below 0.5 g TFA/100 g fat according to an analysis of the most recent available data on the presence of TFA in food in European food markets.[13] However, the data also show that there are still products in the European food market with high levels of TFA (*e.g.* biscuits or popcorn with values in the order of 40-50 g TFA/100 g fat). These also include non-pre-packed foods such as bakery products that contain TFA (> 2 g of TFA per 100 g fat)[13].

Another recent study[20] with products sampled in 2012-2013 confirms this analysis. In supermarkets in seven cities (London, Paris, Berlin, Vienna, Copenhagen, Oslo and Stockholm) popular foods such as pre-packed biscuits, cakes or wafers did not contain partially hydrogenated oils whereas products with high industrial TFA content were found in nine countries (EU countries: Sweden, Croatia, Poland, Bulgaria and Slovenia as well as candidate countries - Serbia, Montenegro and the former Yugoslav Republic of Macedonia and the potential candidate country Bosnia-Hercegovina).. The study suggests that industrial TFA levels have been decreasing in selected food groups in some but not in all European countries between 2006 and 2013. In some Eastern and South-Eastern European countries, industrial TFA levels in pre-packaged biscuits, cakes and wafers have not dropped meaningfully since the mid-2000s. This suggests that in certain parts of the EU little progress has been made. The results of a consultation with Member States and stakeholders[2], albeit with limited participation, confirm the overall conclusions of these studies. Examples of products found to contain TFA in considerable amounts in Member States are mostly food containing industrial TFA: frying fat also for industrial use, stick margarines, margarine used to produce pastry products, bakery products, biscuits, wafers, confectionary products including those with cocoa coatings such as covered puffed rice, soups and sauces.

4.2 TFA intake in Europe

European data from the mid-1990s showed that average intakes of TFA from all sources per country ranged between 0.5-2.1% of daily energy in men and 0.8-1.8% of daily energy in women.[21] More recent reports indicate that the TFA intake has been decreasing in many European countries.[11,20, ,22] Despite limited availability of EU-wide data, a recent study compiled data from 9 EU countries and reports that population average daily TFA intakes are below 1% of daily energy but that some population groups exceed or are at risk of exceeding levels recommended by the World Health Organization, 1% of the energy intake.[13] Examples of such sub-populations are low

[20] Stender *et al*. BMJ Open. 2014;20;4(5):e005218
[21] EFSA Journal. 2004;81:1-49
[22] Krettek A *et al*. Trans Fatty Acids and Health: A Review of Health Hazards and Existing Legislation, 2008, European Parliament - Policy Department, Economic and Scientific Policy

income citizens (British participants of a low income diet and nutrition survey), university students aged 18 to 30 years or generally citizens of this age range (data from Croatia or Spain, respectively)[13]. Products with high (industrial) TFA content contribute to such high intakes, although due to the variety of consumption patterns, these data cannot directly be extrapolated to the entire EU for general conclusions. The consultation with Member States[2] confirms these findings. It also points to fat containing bakery products, cakes and biscuits, convenience food, and deep-fried products as the main TFA sources, and dairy products and ruminant meat as important sources of natural TFA.

5. CONSUMER UNDERSTANDING OF TFA

Consumers are only able to make informed food choices if they are aware of the health effects of a high TFA intake. In relation to the current EU rules, consumers need to understand the difference between partially hydrogenated oils (containing among others TFA) and fully hydrogenated oils (containing no TFA but saturated fatty acids only) as Regulation (EU) No 1169/2011 requires this information to be given in the ingredients list of pre-packed foods[23]. Currently, checking the ingredient list of pre-packed foods for partially hydrogenated oils is the only possibility for consumers to identify products that may contain TFA, although this is not giving any indication about the actual TFA content.

There is limited information on European consumer knowledge of TFA and even less on whether such knowledge affects consumers' food choice.[2] The little information available suggests that the majority of Europeans do not know about TFA, industrial TFA or ruminant TFA and partially hydrogenated or fully hydrogenated oils. Also, only a small fraction of people seems to be concerned about TFA intake.[2]

A recent study reports that only about 1 in 3 consumers stated to have heard about TFA and considered them unhealthy.[24] The same figures were obtained when consumers were asked about partially and fully hydrogenated oils but no difference in the health ratings between those two terms were seen. When choosing between otherwise identical products differing in industrial TFA content, providing TFA information in the nutrition declaration table improves participants' ability to identify the healthier choice compared to identifying it based on the information provided in the ingredients list only (partially hydrogenated oils indicate that TFA is present in a product). However, more complex but also more realistic choice situations posed a challenge, e.g. comparing two alternative products that differed in TFA content as well as different contents of saturated fatty acids, salt and sugars. Providing TFA information was impacting little on the respondents' ability to identify the healthier alternative in such complex situations. Participants seemed to ignore the TFA information and focus on the other, more familiar nutrients instead. These complex situations reflect real-life food choices where trade-offs between the content of TFA and other nutrients are difficult

[23] Article 18 read in conjunction with Annex VII to Regulation (EU) No 1169/2011.
[24] Study on the impact of food information to consumers decision making', unpublished, TNS commissioned by DG SANTE

to make. Consumer surveys from the US and Canada[25,26], where TFA content is labelled on pre-packed foods, indicate more widespread self-reported familiarity with the term TFA but little is known about how this affects food choices. Without appropriate consumer education programmes, the addition of TFA information to the nutrition declaration may have limited or even detrimental effects[27] if consumers are not able to link nutrition information to a nutritionally balanced diet.

6. POSSIBLE MEANS TO ADDRESS TFA CONSUMPTION IN THE EU

The key possible means to reduce TFA consumption in the EU could be the introduction of a EU mandatory TFA content declaration[28], a EU legal limit on the TFA content of food[29], voluntary agreements towards reducing TFA in foods and diets at EU level, or EU guidance for national legal limits on the TFA content of food. Alternatively, action could be left at the national level and/or to voluntary reduction efforts.[30]

Under current legal provisions, consumers can infer from the ingredient labelling whether partially hydrogenated oils are contained in a product and that therefore, the product could contain industrial TFA. This however does not allow a precise estimation of the actual TFA content and is only valid for pre-packed foods. Also, the impact on consumer behaviour ultimately depends on the (currently low) consumer understanding of the dangers posed by TFA and of the difference between partially and fully hydrogenated oils.

Individual action by Member States may, of course, lead to a reduction in the intake of TFA but risks creating a patchwork of regulations hampering the smooth functioning of the single market.

6.1 General considerations

Before looking at possible means to address TFA consumption in the EU, it is worth noting that the available evidence indicates that all existing TFA reduction strategies appear to be associated with significant reductions in food TFA levels.[31] It has been noted in particular that "*national and local bans were most effective at eliminating TFAs from the food supply, whereas mandatory TFA labelling and voluntary TFA limits had a varying degree of success, which largely depended on food category*." [31]

Austria and Denmark have monitored compliance with their national legislation **limiting TFA content** in foodstuff. Austria reported that in 2011 or 2013 no products were found to exceed the

[25] Eckel R *et al*. Circulation. 2007;115:2231-46
[26] Ellis S. Consumer use and interpretation of trans fat information on food labels. MSc Thesis, 2007
[27] Howlett *et al*. Journal of Public Policy & Marketing. 2008;27(1):83-97
[28] By adding the TFA to the nutrients referred to in Article 30(1)(b) of Regulation (EU) No 1169/2011 for which the declaration would be mandatory.
[29] Assuming that, the limit applies to industrial TFA in raw materials used for food production and/or final products
[30] Assuming that there is no TFA-related EU level action; measures are limited to self-regulation and measures at national or regional level, incl. reformulation agreements with food business operators
[31] Downs S *et al*. Bull World Health Organ. 2013;91:262-9

legal limit set in 2009. Denmark reported that good compliance with the regulation was seen shortly after its introduction and that only occasional transgressions are observed, with the majority of those in foods produced outside Denmark. The average industrial TFA intake in Denmark is very low; it has been estimated at 0.01-0.03 g/day[2] after introduction of the legislation.

However, there is, at this point, little empirical evidence on how the strategies employed worldwide to reduce TFA levels in food have impacted on health outcomes. Some North American studies have drawn parallels between the introduction of mandatory TFA labelling and lower levels of plasma TFA (as well as lower levels of low-density lipoprotein cholesterol and other blood markers) or TFA in breast milk[32,33] . Modelling studies estimated the effects of dietary TFA reduction on heart disease morbidity and mortality, regardless of the measures taken. A UK study estimated that reductions in population TFA intakes of 0.5 and 0.8% of daily energy could result in approximately 3,500 and 4,700 fewer heart disease-related deaths per year in the UK.[34] In the US, an estimate of costs and potential health effects of reducing 0.64% of daily energy intake of TFA would in two alternative scenarios avoid an average of 15,000 and 58,000 heart disease events, representing approximately 1.2% and 4.5% of all heart disease events in the US, and 5,000 and 15,000 heart disease-related deaths, representing approximately 1.5% and 4.4% of all heart disease-related deaths in the US, annually.[35]

It should also be understood that ultimate impacts in terms of TFA intake (and health outcome) also depend on certain underlying factors, most notably:

- Nutrition literacy of the population;
- Dietary habits of different groups of the population across Europe (different traditions, different sensitivities to differences in prices, etc.);
- The consumption levels of ruminant TFA (dairy and other ruminant-derived products which are part of a balanced diet);
- The way in which foods could and would be reformulated to reduce industrial TFA content. The full profile of the reformulated product has to be considered to ensure healthier food options are provided after reformulation. For example, there are concerns that reformulation to reduce TFA may lead to increased saturated fatty acids content. Although it is preferable, from a public health perspective, to replace TFA with cis-unsaturated fats (leading to a 21 to 24% risk reduction for heart disease for a replacement of 2% of daily energy from TFA with unsaturated or polyunsaturated fatty acids), even the most unfavourable replacement with saturated fatty acids still entails significant public health benefits (leading to a 17% risk reduction for heart disease; risk reductions were estimated).[5] Several studies monitoring results from EU countries show that while in some products TFA has indeed been replaced by saturated fatty acids, in the majority of cases there have been no major differences in the saturated fatty acids content, that

[32] Vesper *et al*. JAMA. 2012;307(6):562-3
[33] Ratnayake *et al.* Am J Clin Nutr. 2014;100(4):1036-40
[34] O'Flaherty *et al*. Bull World Health Organ. 2012;90:522-31
[35] Bruns R. Estimate of Cost and Benefits Partially Hydrogenated Oils Memorandum November 5 2013

the sum of TFA and saturated fatty acids content was reduced in most cases, and that reformulated products have increased the content of cis-unsaturated fats and have an overall healthier profile[36].

Keeping the above in consideration, the following offers a preliminary analysis of the key possible EU level measures.

6.2 Mandatory TFA content declaration

Mandatory TFA labelling would serve two purposes: i) to provide incentives to the industry towards reducing TFA from food products and ii) to enable consumers to make informed food choices. If consumer awareness is low, mandatory TFA labelling may have a limited impact. Manufacturers may also feel little pressure to reformulate products. In addition, consumer understanding of TFA labelling has been shown to be low whereas mandatory TFA labelling would increase the complexity of a decision making process that includes a number of nutritional elements. This might lead to a reduced ability of consumers to identify the healthier food choice[24].

Moreover, mandatory TFA labelling would also most likely not apply to non-pre-packed foods, food sold loose and food consumed outside of the home, all of which may contain high levels of industrial TFA and thus (depending on dietary patterns) be important contributors to overall TFA intake.

TFA labelling would likely not distinguish between ruminant TFA and industrial TFA, given the European Food Safety Authority's evaluation that there is insufficient evidence to establish whether there is any difference between ruminant and industrial TFA consumed in equivalent amounts on the risk of heart disease.[37] However, before a final decision on the matter would be taken, the European Food Safety Authority should be asked to review and if necessary update its opinion, in order to reflect the latest science. Depending on how TFA labelling could be designed on the basis of the advice obtained, it could also affect consumption of dairy and other ruminant-derived products.

It should also be noted that labelling would allow the marketing of products with different TFA content on the same market. Consumers' choices would be affected not only by the information provided by the label but also by the possible price differences between reformulated products and cheaper alternatives. Low income populations would be more likely to consume the cheaper products (with high TFA contents); this could widen health inequalities (but not worsen health effects for the most vulnerable compared to a no policy change scenario).

Finally, should Member States still be allowed and interested to set national legal limits, the risk of increasing single market fragmentation would remain.

[36] Mozaffarian *et al*. N Engl J Med. 2010;362:2037-9 (and references therein)
[37] EFSA Journal. 2010;8(3):1461

6.3 EU legal limit on the industrial TFA content of food

Introducing a legal limit would be expected to achieve the biggest reductions in industrial TFA intake as the phasing out of products containing high levels of industrial TFA- from the market would be potentially complete, applying to all products, pre-packaged and non-packaged. Technically, ruminant TFA cannot be covered by this measure as TFA are formed naturally in relatively stable proportions in ruminant fats, and cannot be avoided in ruminant products, that contribute essential nutrients in the EU diet. When combined with adequate dietary habits, this approach could thus be the most effective in achieving full respect of the European Food Safety Authority recommendation for a TFA intake 'as low as is possible within the context of a nutritionally adequate diet', witness the Danish average population intake of 0.01 to 0.03 g industrial TFA per day.

Consumers would be systematically provided with healthier food options without needing to distinguish products with lower TFA levels. Potential public health benefits would be the highest for this option as all products would be covered and all population groups would benefit from TFA reductions, including the more vulnerable groups.

By setting an EU wide harmonised legal limit, the approach would also minimise, or even abolish, the risk of national regulatory choices (further) fragmenting the single market.

The approach taken with the US decision regarding the safety of partially hydrogenated oils is not *a priori* incompatible with an EU legal limit for TFA, since it pursues an equivalent objective within an overall different regulatory framework. Depending upon how a legal limit would be designed for the EU, any prospective divergence with US regulatory standards could also be addressed, thus avoiding the emergence of unnecessary regulatory barriers in bilateral trade.

It should however be noted that a full appreciation of the effectiveness of such a measure would also need to assess its overall proportionality in view of the existing evidence on the magnitude (and evolution) of the problem caused by TFA and the need to consider the possible costs that such a measure could imply for consumers, the producers and suppliers of different type of foods,. Although there is a wide availability of alternatives to partially hydrogenated oils, possible unintended effects in terms of the technological function of TFA in different types of food would also need to be carefully verified. Finally, the available methods for monitoring and enforcing a limit for specific products should also be taken into due account, particularly regarding the analysis of industrial versus ruminant TFA in a given product.

6.4 Voluntary agreements towards reducing industrial TFA in foods and diets at EU level

There are several examples of effective voluntary reformulation by food business operators accompanied or not by public-private partnerships. The case of the Netherlands is often cited as a

success in voluntary and self-regulated TFA reduction by food business operators.[13] The success of this approach appears to depend on the country and the degree of public engagement and corporate social responsibility of food business operators.[2,20] However, there may be limited incentives for food business operators to comply with national policies to reduce TFA, if they have to compete in other parts of the EU market with food business operators that offer slightly cheaper products with high TFA contents.

From a more general point of view, consequences would be similar to the ones of a mandatory limit but their magnitude (in terms of all types of benefits and costs) would clearly depend on the scope of industry participation and the coverage of food products on the market.

6.5 Development of EU guidance for national legal limits on the TFA content of food

Consequences can be expected to be similar as in the case of no further action at EU level, with the exception that the risk of an increasingly fragmented internal market would be possibly mitigated.

7. CONCLUSIONS

Heart disease is the leading cause of death in the Union and a high intake of TFA seriously increases the risk for heart disease - more than any other nutrient on a per calorie basis. Although average intake in the EU has been reported below nationally and internationally recommended levels, this is not true for all groups of population. Food products with high industrial TFA content are available on the market and there are public health gains to be reaped by reducing intake. In addition, four Member States have already introduced national legal limits and several others have signalled their preference for an EU level decision, while highlighting their readiness to go ahead with national TFA-related measures to reduce population exposure in the absence of a decision at EU level. As a result further market fragmentation could be expected. Should no action be taken at EU level, difficulties might also arise for EU producers who are interested in access to the US market.

This report has carried out a preliminary analysis of the potential effectiveness of the measures that could be adopted at EU level, each resulting in different potential health benefits but also different potential burden on producers. In the specific case of labelling, effectiveness would seem to depend on three key factors: the contribution to the average TFA intake from the products for which a label would be required , consumers' capacity to appropriately use the information provided by a label, and their readiness to pay more for healthier food. A preliminary assessment of these factors points to important limitations. The assessment also suggests that a legal limit for industrial TFA content would be the most effective measure in terms of public health, consumer protection and compatibility with the internal market. The way in which it could be technically put into practice would require further investigation. Any such limit would also most likely need to be designed so as to minimize the risks of unintended consequences and impacts on specific producers and products.

All of the above clearly indicates the need to continue and expedite work in this area by collecting more information and by developing a fuller analysis of the magnitude of the problem to be addressed and the different possible solutions, in particular the option of legal limits for industrial TFA. Accordingly, in accordance with its Better Regulation principles, the Commission intends to rapidly launch a public consultation and carry out a fully-fledged impact assessment. This will allow the Commission to take an informed policy decision in the near future.