



Brussels, 24.4.2019
SWD(2019) 162 final

PART 1/6

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Commission Regulation (EU)

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in animal fat, in foods intended for the final consumer

{C(2019) 2902 final} - {SEC(2019) 187 final} - {SWD(2019) 161 final}

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List of abbreviations

CAOBISCO	Association of Chocolate, Biscuit and Confectionery Industries of the European Union
CI	Confidence Interval
EFSA	European Food Safety Authority
FEDIOL	EU vegetable oil and protein meal industry association
HOTREC	Association of hotels, restaurants and cafés in Europe
IA	Impact Assessment
IIA	Inception IA
IMACE	European Margarine Association
ISG	Inter-services Steering Group
JRC	the Joint Research Centre of the European Commission
NGO	Non-governmental Organisation
OPC	(On-line) Open Public Consultation (carried out for this IA)
RR	Relative Risk
RSPO	Roundtable on Sustainable Palm Oil
SKU	Stock Keeping Unit
SMEs	Micro, Small and Medium-sized Enterprises
SWD	Commission Staff Working Document
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organisation

Glossary

<i>Term or acronym</i>	<i>Meaning or definition</i>
Cardio vascular disease	a class of diseases affecting the heart or blood vessels. It includes coronary artery disease as well as stroke, heart failure, arrhythmia, aortic aneurysms, among others
Coronary artery disease	a group of diseases that includes: stable angina, unstable angina, myocardial infarction, and sudden cardiac death. It is within the group of cardio vascular diseases of which it is the most common type
Coronary heart disease	a health condition that reduces blood flow through the coronary arteries to the heart and typically results in chest pain or heart damage. It is the outcome of coronary artery disease
Deforestation	the action or process of clearing of forests
Disability adjusted life years	one disability adjusted life year can be thought of as one lost year of "healthy" life. The sum of disability adjusted life years across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability. Disability-adjusted life years measure overall disease burden. It expresses that burden as the number of years lost due to ill health, disability or early death
Food business operator	the natural or legal person responsible for ensuring that the requirements of food law are met within the food business under their control
Isocaloric	having similar caloric values
Labour cost	the total expenditure borne by employers in order to employ workers, including social security contributions and other non-wage labour costs

Markov model	a state-transition model used to model randomly changing systems where it is assumed that future states depend only on the current state not on the events that occurred before it
Mortality rate	a measure of the number of deaths in a given population per unit of time
Non-prepacked food	foods sold without packaging
Partially hydrogenated oil:	a liquid oil which has only been processed through partial hydrogenation and is semi-solid
Pre-packed food	any food that is put into packaging before being put on sale and that cannot be altered without opening or changing the packaging (as defined article 2 (2) (e) of Regulation (EU) No 1169/2011)
Trans fats	<p>also called Trans fatty acids and sometimes abbreviated as TFAs, are a particular type of unsaturated fatty acids that are present in foods .'Trans' describes the specific and rather unusual configuration of the unsaturated bond in a fatty acid, while generally fats in foods contain unsaturated fatty acids in 'cis' configuration</p> <p>Annex I point 4 of Regulation (EU) No 1169/2011 on the provision of food information to consumers defines: ' " trans fat" means fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration'</p> <p>There are two sources of trans fats: those produced industrially (so called industrial trans fats) and those naturally produced by ruminant animals (ruminant trans fats), which are present in derived food products, such as dairy products or meat from cattle, sheep or goats</p>

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Trans fats (also called 'trans fatty acids' and sometimes abbreviated as TFAs) are a particular type of unsaturated fatty acids that are present in some foods¹ as natural trans fats in ruminant (dairy and meat) products² or as industrially manufactured trans fats. Industrial trans fats, in the form of partial hydrogenated oils, are added to improve stability or texture or for other technological reasons, in a variety of products including pastries and chocolates. One of the common substitution fats with similar technological and cost advantages is palm oil. Trans fats are not synthesised by the human body and are not required in the human diet.

There is scientific consensus that trans fats intake has a negative effect on human health: more specifically, consumption of trans fats has a negative impact on blood cholesterol levels and increases the risk of coronary heart disease³ more than any other macronutrient compared on a per-calorie basis; the risk of dying from heart disease is 20-32 % higher when consuming 2 % of the daily energy intake from trans fats instead of consuming the same energy amount from carbohydrates, saturated fatty acids, cis monounsaturated fatty acids and cis polyunsaturated fatty acids.⁴

The European Food Safety Authority recommends that trans fats intakes should be 'as low as is possible within the context of a nutritionally adequate diet'.⁵ The World Health Organisation recommends that less than 1 % of dietary energy intake should come from consuming trans fats⁶ (which equates to maximum 2,2 g of trans fats per day for a person requiring 2000 kilocalories).⁷ Currently, in total 7 Member States have introduced legislation regarding intakes of industrial trans fats. In particular, 6 Member States (Denmark, Austria, Hungary, Latvia, Lithuania and Slovenia) have set legal limits and one (Romania) has recently notified a draft legal measure. The legal limit of maximum 2 % of industrially produced trans fats in foods introduced in several Member States is in line both with the intake recommendations of the European Food Safety Authority and of WHO: typical intakes of total fat in European countries are reported to be at a maximum of 48 % of the daily energy intake (95th percentile).⁸ Provided that all foods contain trans fats at 2 % in a very unlikely, extreme scenario, intake levels would be at 0.96 % of energy intake, below the WHO recommendation. Assuming a 2000 kilocalorie diet, 0.96

¹ Annex 5 provides the legal definition in the EU and chemical and scientific background information

² Ruminant trans fats sources typically contribute between 0.3 and 0.8 % of the daily energy intake Hulshof KF et al. *Eur J Clin Nutr.* 1999;53(2):143-57

³ Different health indicators such as coronary heart disease, cardio vascular disease and coronary artery disease are used throughout this report, Annex 6 explains those different terminologies and the background of their use

⁴ Mozaffarian D et al., 2009, Health effects of trans-fatty acids: experimental and observational evidence, *European Journal of Clinical Nutrition* 63(S2): p. S5-S21

⁵ European Food Safety Authority, 2010, Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol, *EFSA Journal* 2010; 8(3):1461

⁶ WHO/FAO, 2003, Expert Report: Diet, nutrition and prevention of chronic diseases. Report of a Joint WHO/FAO Expert Consultation, WHO Technical Report Series 916

⁷ On 15 May 2018, WHO has in addition called for the elimination of trans fats from the food supply chain by 2023

⁸ European Food Safety Authority, 2010, Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol, *EFSA Journal* 2010; 8(3):1461

% of daily energy intake equates to a maximum of 2.1 g of industrial trans fats intake per day. Empirical evidence from Denmark, where a 2 % legal limit per 100 g fat content applies, suggests that (in 2014) the average industrial trans fats intake was 0.009 % of energy intake.⁹ This very low level could be considered to be in line with the recommendation of the European Food Safety Authority ('as low as possible'). In this context it is noteworthy that some small amounts of trans fats are generated during the normal processing and production of foods. Ruminant trans fats sources typically contribute between 0.3 and 0.8 % of the daily energy intake depending on dietary habits across Europe.¹⁰ Thus, even the combination of ruminant and industrial trans fats typically amount to 0.309 to 0.809 % of daily energy intake.

The issue of trans fats was intensively debated during the negotiations that preceded the adoption of Regulation (EU) No 1169/2011 on food information to consumers¹¹. This Regulation does not include trans fats in the list of mandatory nutrition declaration since the co-legislator was not convinced that the introduction of trans fats amounts on food labels would consistently enable consumers to identify the healthier choice. In addition, the efficiency of such measure was questioned since it would not apply to non-pre-packed foods, all of which may contain high levels of industrial trans fats. Finally, trans fats labelling would not distinguish between ruminant and industrial trans fats. Regulation (EU) No 1169/2011 also prohibits operators from declaring the trans fats content of foods on nutrition labels on a voluntary basis. It was considered that this possibility would be used as a marketing tool by some operators only and could lead to consumers' confusion. Therefore, the co-legislator agreed that instead of looking only into the labelling aspect, the Commission should assess the impacts of all means to enable consumers to make healthier choices, including restrictions on the use of trans fats. A report was requested by Article 30(7) of Regulation (EU) No 1169/2011 of the European Parliament and the Council on the provision of food information to consumers.

In its 2015 report¹², the Commission noted that average trans fats intake in the EU is below nationally and internationally recommended levels, however, this conclusion is not valid for all population groups. Food products with high industrial trans fats content remain available on the EU market, thus, reducing industrial trans fats intakes entails public health gains. The report concluded that a legal limit for industrial trans fats would be the most effective measure in terms of public health, consumer protection and compatibility with the Internal Market but that further investigation is required.

Numerous calls for a reduction of trans fats intakes in the EU have emerged from the agenda of the European Parliament and the Council, individual Member States, and stakeholders. Member States' concerns on industrial trans fats had been voiced in the

⁹ Martin-Saborido CM et al. (2016) Public health economic evaluation of different European Union-level policy options aimed at reducing population dietary trans fat intake. *American Journal of Clinical Nutrition*, 104: 1218-26

¹⁰ Hulshof KF et al. *Eur J Clin Nutr*. 1999;53(2):143-57

¹¹ 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

¹² 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. COM(2015) 619 final of 3 December 2015

context of the High Level Group on nutrition and physical activity¹³ where 22 Member States indicated industrial trans fats as one of the priorities with respect to reformulation or nutrient policy.¹⁴ Health EU Ministers exchanged views on trans fats at two informal Council meetings: in April 2015 in Riga, a large majority of intervening delegations expressed support to the necessity of reducing industrial trans fats levels in food products.¹⁵ In September 2015 in Luxembourg, Member States discussed possible solutions to reduce industrial trans fats levels in foods. Some delegations called for legal limits to industrial trans fats presence in foods at EU level, while others favoured self-regulatory approaches based on product reformulation.¹⁶

Council Conclusions of 2014 and of 2016 noted with concern¹⁷ 'the high intake of ...trans fatty acids...' and¹⁸ 'The prevalence of overweight, obesity and other diet-related non-communicable diseases in the European population is too high and is still rising. This has a negative impact on life expectancy, reducing Union citizens' quality of life and affecting society, for example by threatening the availability of a healthy and sustainable workforce and inducing high healthcare costs which may affect the sustainability of the healthcare systems. It thus also imposes an economic burden on the Union and its Member States. (...) Nutrition plays an important role in this context, alongside other lifestyle-related matters: (...). In some Member States, people are still exposed to high amounts of trans fatty acids'.¹⁹

The European Parliament adopted on 26 October 2016 a resolution calling on the Commission to propose legislation setting a limit on industrial trans fats within two years and to carry out an impact assessment evaluating impacts on operators and consumers.²⁰

Following the adoption of the Commission report, a considerable number of external stakeholders, such as associations representing producers and consumer representatives have expressed a keen interest in this issue.^{21 22} All stakeholders that intervened in the debate on trans fats so far have welcomed the Commission's report and/or supported an

¹³ The High Level Group is composed of European government representatives and constitutes a platform for information sharing on policy ideas and practices in the area of nutrition and physical activity (http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/index_en.htm)

¹⁴ http://ec.europa.eu/health/nutrition_physical_activity/docs/overview_nationalinitiatives_selectednutrients_en.pdf

¹⁵ <https://eu2015.lv/news/media-releases/1353-health-ministers-in-riga-agree-on-the-need-for-common-eu-nutrition-and-alcohol-policies>

¹⁶ <http://www.eu2015lu.eu/en/actualites/articles-actualite/2015/09/25-info-sante/>

¹⁷ 2014/C 213/01

¹⁸ 9484/16 DENLEG 56 AGRI 295 SAN 219

¹⁹ Further Council Conclusions call for action on trans fats, such as the 2017 Council Conclusions to contribute towards halting the rise in Childhood Overweight and Obesity, where Member States and the Commission are invited to take measures to reduce the exposure of children and adolescents to marketing of foods high in trans-fatty acids

²⁰ 2016/2637(RSP) Resolution on trans fats (TFAs)

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2016-0417+0+DOC+XML+V0/EN>

²¹ http://www.beuc.eu/documents/files/Open%20Letter_industrially_produced%20TFAs_freeEU.pdf

²² http://www.fooddrinkEurope.eu/uploads/statements_documents/FoodDrinkEurope_statement_on_TFA_%28November_2015%29.pdf

EU initiative to set legal limits to industrial trans fats in foods, both on the consumers' side²³ and on the industry's side.²⁴

In this context, of particular note is the joint letter²¹ addressed on 15 October 2015 to the European Commission by four major food manufacturers, together with leading consumers' and health NGOs and the Standing Committee of European Doctors. Also of note are the number of reformulation commitments to lower the content of industrial trans fats in foods made in the past years by food manufacturers in the EU Platform for Diet, Physical Activity and Health.²⁵ The positions of industry stakeholders (also well summarised in a statement by Food Drink Europe of 19 November 2015)²⁶ indicate that the industrial trans fats content of foods can effectively be lowered without disproportionate cost²⁷, that an EU initiative would benefit consumers and the industry by setting a level playing field in the Internal Market, and that particular support might be needed for SMEs.

Stakeholders^{28 29} also broadly supported national initiatives that set limits to the presence of industrial trans fats in foods.

At the global level, calls for reduction of trans fats intakes led to the REPLACE initiative ('trans fat free by 2023') of WHO in May 2018.³⁰ WHO recommends to 'legislate or enact regulatory actions to eliminate industrially-produced trans fats'.

The objective of this impact assessment is to enable an informed decision on how to deal with trans fats, taking into account the potential economic, social and environmental impacts of different policy options, including implementing the option of a legal limit for

²³ For the views of the European Consumers' Organisation (BEUC) see http://www.beuc.eu/publications/beuc-x-2014-010_the_consumer_case_for_eu_legal_restrictions_on_the_use_of_artificial_trans.pdf; for the views of the European Heart Network see <http://www.ehnheart.org/component/downloads/downloads/2212>; for the views of the European Public Health Alliance see <http://www.epha.org/a/6458>

²⁴ For the views of the European Margarine Association (IMACE) see <http://imace.org/wp-content/uploads/2015/12/Trans-fatty-acids-Commission-report-IMACE-Press-release1.pdf>; for the views of the European Vegetable Oil and Proteinmeal Industry Federation (FEDIOL) see: <http://www.fediol.be/data/FEDIOL%20press%20communiqu%20on%20TFA%20report%20-%20December%202015%20-%20final.pdf>

²⁵ The Platform brings together European-level organisations ranging from the food industry to consumer protection NGOs that are ready to take concrete commitments to tackling current trends in diet and physical activity. (http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm). Commitments can be consulted online: http://ec.europa.eu/health/ph_determinants/life_style/nutrition/platform/database/dsp_search.cfm?CFID=221283&CFTOKEN=24033781&jsessionid=090cc3d272167d16db18227f4573197e292bTR

²⁶ <http://www.fooddrinkeurope.eu/S=0/news/statement/fooddrinkeurope-statement-on-trans-fats/>

²⁷ This was confirmed in Denmark, the first Member State introducing a legal limit for industrial trans fats in foods (Ministry of Food, Agriculture and Fisheries of Denmark and the Danish Technical University, National Food Institute, 2014, Danish data on trans fatty acids in foods, <https://www.foedevarestyrelsen.dk/Publikationer/Alle%20publikationer/2014004.pdf>)

²⁸ <https://epha.org/wp-content/uploads/2017/09/Declaration-of-support-trans-fats-bill-Romania-EHN-EPHA-12.9.2017.pdf>
http://doc.cpme.eu:591/adopted/2018/CPME_AD_Board_14042018_017_FINAL_EN_CPME.Policy.o.n.Trans.Fats.pdf

²⁹ <https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf>

³⁰ <http://www.who.int/nutrition/topics/replace-transfat/>

industrial trans fats. In this context, the factual situation, as regards the issue of excessive trans fats intakes in the EU and its underlying causes and the policy implications of available alternative approaches to setting a legal limit, i.e. mandatory labelling of trans fats and voluntary approaches to food reformulation, are examined. Besides the public health dimension and ensuring a sound basis for consumer choice, the impact assessment also examines the consequences of the policy options available for the businesses, including SMEs and the Single Market.

In addition to the report adopted by the Commission in 2015 on trans fats³¹, the impact assessment takes into account various studies on trans fats at the European level^{32 33 34} and internationally³⁵, investigating the impacts of trans fats and the potential effects of alternative policy options to limit their use. These build on analyses by the Joint Research Centre of the Commission (JRC)³⁶, scientific opinions of the European Food Safety Authority^{5 37}, international reports by the World Health Organization^{6 38} and academic studies. In 2017, the European Commission commissioned an external study by the contractor ICF to support this IA.³⁹

2. PROBLEM DEFINITION

2.1. What is the problem?

Trans fats are an important risk factor for the development of coronary heart disease^{5 37}, the single leading cause of mortality in the EU.⁴⁰ Cardiovascular disease comprises a range of diseases that affect the heart, including heart failure (which can be caused by coronary heart disease, among other factors), arrhythmia (abnormal heart beat) and heart valve problems, and imposes substantial health burdens in the EU. It is estimated that 49 million people live with cardiovascular disease and that the condition imposes costs of

³¹ 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. COM(2015) 619 final of 3 December 2015

³² Saborido C M et al, 2016, Public health economic evaluation of different European Union–level policy options aimed at reducing population dietary trans fat intake, *American Journal of Clinical Nutrition*, 2016;104:1218–26
<http://ajcn.nutrition.org/content/early/2016/09/28/ajcn.116.136911.full.pdf>

³³ Mouratidou T et al. (2013) Trans Fatty Acides in Diets: Health and Legislative Implications. A workshop report. JRC Scientific and Policy Report.

³⁴ WHO (2015) Eliminating trans fats in Europe. A policy brief. World Health Organisation, Europe Office

³⁵ Legal measures limiting the content of industrial trans fats in foods exist also outside the EU, details are provided in Annex 8

³⁶ Mouratidou T et al., 2014, Trans Fatty acids in Europe: where do we stand? JRC Science and Policy Reports <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC91353/lbna26795enn.pdf>

³⁷ European Food Safety Authority, 2004, Opinion related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids. *The EFSA Journal*, 81, 1-49

³⁸ http://www.euro.who.int/_data/assets/pdf_file/0010/288442/Eliminating-trans-fats-in-Europe-A-policy-brief.pdf?ua=1

³⁹ ICF: Study to support the impact assessment of the initiative to limit industrial trans fats in the EU Final report, document prepared for the European Commission. February 2018

⁴⁰ Eurostat, Causes of death data, 2012

more than €200 billion each year in the EU.⁴¹ The European Food Safety Authority and the World Health Organization recommend that their consumption is limited or minimised.^{5 6 42} Industrial trans fats intakes are particularly high among consumers with lower income, who are also the most at risk of coronary heart disease⁴³ and intakes continue to contribute to the absolute health and economic disease burdens of cardiovascular disease.

The precise contribution of trans fats intake to health risks and associated economic problems are difficult to assess for the entire EU due to limited data available for trans fats intakes in the entire EU. There is empirical evidence that the introduction of a legal limit for industrial trans fats reduced deaths caused by cardiovascular disease.^{44 45} Over 3 years following the introduction of the legal limit, 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, meaning that the Danish limit on industrial trans fats saves around 700 people a year in Denmark.⁴⁶ Further evidence of the effectiveness of legal measures is available from outside the EU: in Argentina, near elimination of industrially produced trans fats from food is estimated to be associated with an annual 1,3 to 6,3 % reduction in coronary heart disease events⁴⁷. In New York, people living in counties in New York State with restrictions on industrial trans fats in food had a 7,8 % greater decrease in hospital admissions for heart attacks between 2007 and 2013 than people in counties without restrictions⁴⁸.

How widespread are trans fats in the EU?

There is limited availability of comparable/EU-level data on the intakes of trans fats in the different population groups or on the presence of trans fats in foods in the different Member States. Evidence from a number of countries indicates that the intake of trans fats in the EU has decreased considerably over recent years⁴⁹ but that the situation is not homogeneous for all products consumed by all population groups in all EU Member States. Studies summarised by the JRC in its 2014 report concluded that⁵⁰:

⁴¹ European Heart Network CVD statistics 2017

⁴² Details are provided in Annex 6

⁴³ Psaltopoulou T et al., 2017, *Socioeconomic status and risk factors for cardiovascular disease: Impact of dietary mediators*, Hellenic Society of Cardiology (2017) 58, 32e42

⁴⁴ Restrepo B.J. et al. Denmark's policy on artificial trans fat and cardiovascular disease *Am J Prev Med* 2016;50(1):69–76

⁴⁵ More empirical evidence about the effectiveness of legally restricting trans fats from the US: Brandt EJ, et al. Hospital Admissions for Myocardial Infarction and Stroke Before and After the Trans-Fatty Acid Restrictions in New York. *JAMA Cardiol*. Published online April 12, 2017.

<https://jamanetwork.com/journals/jamacardiology/article-abstract/2618359/>

⁴⁶ <http://videnskab.dk/krop-sundhed/dansk-forbud-mod-transfedt-redder-liv-om-dagen>

⁴⁷ Rubinstein, Adolfo, et al. "Eliminating artificial trans fatty acids in Argentina: estimated effects on the burden of coronary heart disease and costs." *Bulletin of the World Health Organization* 93 (2015): 614-622.

⁴⁸ Brandt, EJ, Myerson, R, Perrailon, MC, and Polonsky, TS. Hospital admissions for myocardial infarction and stroke before and after the trans-fatty acid restrictions in New York. *JAMA Cardiol*. 2017; 2: 627–634

⁴⁹ EFSA (2010), Mouratidou T et al (2014)

⁵⁰ Mouratidou T et al. (2014) and COM (2015) 619

- Average daily trans fats intakes for the overall EU population are below 1 % of daily energy intake⁵¹. Yet some population groups have (or are at risk of having) higher intakes.

Examples of such sub-populations are low-income citizens (British male and female participants of the Low Income Diet and Nutrition Survey⁵² where all age groups had intake levels above 1 % of energy intake, ranging from 1.2 to 1.4 % of energy intake) or male or female university students aged 18 to 30 years (data from Croatia, intake levels ranging from 1.1 to 1.2 % of energy intake⁵³). Also, according to surveys collected by the JRC, Swedish boys aged 8 and 11 years exceeded the WHO recommendation (1 % of energy intake), as well as Spanish males and females aged 18 to 30 years (1.05 % of energy intake) and French females over 55 years of age (1 % of energy intake) and between 3 to 10 years (1.02 % of energy intake).⁵⁴ As calculated by the JRC, up to 25 % of surveyed individuals aged 20-30 years have trans fats intakes above 1 % of daily energy intake. Annex 9 provides more details. Latest information collected during the OPC confirm this assessment.⁵⁵

- Most of the analysed food products contain trans fats at amounts below 2 % of the total fat content of the food and 77 % of these contain trans fats at amounts below 0.5 % of the total fat content of the food. However, there are still products in the European food market with high levels of industrial trans fats (e.g. biscuits or popcorn with industrial trans fats values in the order of 40-50 % of the total fat content of the food). While most of the analysed products are pre-packed products, there are also several reported cases of non pre-packed foods with trans fats levels above 2% of the total fat content in food. Examples of products found to contain trans fats in considerable amounts in Member States, generally of industrial origin, are 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.⁵⁶ Further recent studies about trans fats content in food in the EU were published after the finalisation of the JRC³⁶ work:
 - A study⁵⁷ focused on the market for pastries, confectionery, and potato products in Poland in the period 2009-2010 and reported a great diversity

⁵¹ 1 % of daily energy intake is the maximum intake level recommended by WHO

⁵² Nelson M et al., 2007, Low income diet and nutrition survey, National Centre for Social Research (NatCen), Nutritional Sciences Research Division at King's College London, Department of Epidemiology and Public Health at the Royal Free and University College London Medical School

⁵³ Satalic Z et al., 2007, Diet quality in Croatian university students: Energy, macronutrient and micronutrient intakes according to gender, *Int J of Food Sciences and Nutrition*, 58(5): p. 398-410

⁵⁴ Intake recommendations for substances that provide energy are frequently expressed in relation to the total energy consumed as this enables to adjust amounts for different energy intakes in a population.

⁵⁵ The German consumer association Verbraucherzentrale Bundesverband informed during the OPC that while in Germany a self-regulatory approach is followed, According to a statement by the Federal Institute for Risk Assessment (from 2013), the mean intake is currently 0.66 energy percent. But: 10 percent of consumers eat in a way so that they are above the recommendation

⁵⁶ Commission Staff Working Document "Results of the Commission's consultations on 'TFA in foodstuffs in Europe'"

⁵⁷ Zbikowska A et al., 2015, *Consumption Safety of Pastries, Confectioneries, and Potato Products as Related to Fat Content*, *Journal of the American College of Nutrition*, 2015;34(6):507-14

of trans fats content (0.1 % to 24.8 % of total fat content). Wafers were characterized by the highest average content of trans fats in the group of pastries (1.94 % of total fat content);

- A research in Germany⁵⁸ in 2017 quoting data from the Federal Office for Consumer Protection and Food Safety noted that in the period 2014 to 2017 the mean trans fats content in certain sampled fried bakery products was higher than 10 % of total fat content, sometimes even more than 30 %;
- Tests carried out by the Czech consumer association^{59 60} found that more than half of the tested margarines, 60% of wafers and 20 % of chocolate waffles tested were above the 2 % limit.
- Quantitative comprehensive data of industrial trans fats use for particular food sectors, or particular regions or sorted by company size in the EU is not available. However, available data⁶¹ has shown significant presence of trans fats in different food categories, such as convenience products, cereal products, confectionary, crisps, savoury, biscuits, fast food products, fats and oils, without however a distinction between prepacked and non-prepacked, locally produced produce or not. Given that larger companies were more likely to participate in reformulation campaigns than SMEs, the residual share of products still high in trans fats is considered to be higher among SMEs.

Consultation with Member States⁶² confirmed the findings in the JRC report⁶³. In some Member States high intake levels prompted activities to reduce intake levels of trans fats, contributing to enhanced reformulation activities and reduced levels.

A study⁶⁴ noted that, in different Member States, industrial trans fats levels in some foods were still above 2 % of their total fat content and that, in some EU countries, industrial trans fats levels in pre-packed biscuits, cakes and wafers have not dropped meaningfully since the mid-2000s. The authors of this study continued analysing the evolution of the market in six countries in South East Europe covered by the previous study (including two EU Member States) and noted that availability of popular foods with high amounts of industrial trans fats increased from a high level in 2012 to an even higher level in 2014.⁶⁵ Another study⁶⁶ specifically focused on the Portuguese market showed that, in

⁵⁸ <http://www.foodwatch.org/de/informieren/zucker-fett-co/aktuelle-nachrichten/schaedliche-transfette-in-donuts-berliner-co/>

⁵⁹ Jedlé nejedlé tuky, D Test, November 2013 <www.dtest.cz>

⁶⁰ Test hořických trubiček a plněných oplatek, D Test, January 2014 <www.dtest.cz>

⁶¹ Further details are provided in Annex 9

⁶² Commission staff working document: Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'. 3.12.2015, SWD(2015) 268

⁶³ Mouratidou T et al. (2014) and COM (2015) 619

⁶⁴ Stender S et al., 2014, Tracing artificial trans fat in popular foods in Europe: a market basket investigation, *BMJ Open*. 2014;4:e005218

⁶⁵ Stender S et al., 2016 Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries, *BMJ Open* 2016;6:e010673

⁶⁶ Costa N et al., 2016, Trans fatty acids in the Portuguese food market, *Food Control* 64, 128-134

2013, total trans fats content in different foods ranged from 0.06 % to 30.2 % of the total fat content of the food (average 1.9 %), with the highest average values in the 'biscuits, wafers and cookies' group (3.4 % of the total fat content of the food). 50 samples out of 268 (19 %) contained trans fats at amounts higher than 2 % of the total fat content of the food. Replies during the OPC revealed that 78 % and 77 %, respectively, of respondents agreed with the problem description above with regard to intake levels and content in foods, while 9 % and 8 disagreed, all but one disagreeing respondent stated that intake level and contents in food were actually higher than described above.⁶⁷ An unpublished study in Hungary⁶⁸ confirmed a steadily increasing trend of trans fats content in foods from 2009/2010 until 2012, which was reverted only in 2013 when the decision on a national legal limit of trans fats was notified to the Commission (further details are provided in section 5.1).

Sources of trans fats

Ruminant trans fats in dairy products or meat from cattle, sheep or goat⁶⁹ are present in relatively constant, low proportions of the fat part of those foods, at levels most commonly around 3 % (ranging from 2 to 9 %) of the total fat content.⁷⁰

The primary dietary source of industrial trans fats is partly hydrogenated oils which contain various amounts of trans fats (up to more than 50 % of the total fat content). The partial hydrogenation process turns oils into semi-solid and solid fats. Industrial trans fats in the form of partly hydrogenated oils have been used or introduced into manufacturing processes of foods in order to achieve at comparative low prices a particular technological function, such as a solid fat texture at room temperature (e.g. in vegetable fat cocoa coatings).⁷¹ Other than partly hydrogenated oils, industrial trans fats can also be the result of refining of unsaturated oils or of heating and frying of oils at too high temperatures (> 220°C).⁷²

Reduction of intake levels of industrial trans fats is technologically feasible. However, the fat composition of ruminant fats with regard to their trans fats content is not modifiable to a significant degree, therefore their intake cannot totally be avoided when consuming ruminant derived foods that are important in the EU diet of the EU population as they contribute essential nutrients. Also, ruminant trans fats sources generally contribute in a limited way to high total trans fats intake.⁷³ National public health policies generally address the problem of intake of ruminant trans fat intake already by initiatives

⁶⁷ Details are provided in Annex 2

⁶⁸ Unpublished, Technical Report, Budapest, November 2017, National Institute of Pharmacy and Nutrition, Department of Nutrition Epidemiology: Assessment of the impact of the TFA Regulation on the availability and population intake of industrial TFA in Hungary. This work was done in the framework of the Biannual Collaborative Agreement between the World Health Organization Regional Office for Europe and the Ministry of Human Capacities

⁶⁹ Annex 5 provides further technical details

⁷⁰ Mouratidou T et al., (2014); Stender S., 2015, Editorial, American Journal of Clinical Nutrition 2015;102:1301–2; Kuhnt K. et al, 2011, Trans fatty acid isomers and the trans-9/trans-11 index in fat containing foods, European Journal of Lipid Science and Technology, 113, 1281–1292

⁷¹ Previous to the introduction of trans fat rich oils, more expensive alternative semi-solid fats such as animal fats, butter or cocoa butter were used

⁷² European Food Safety Authority (2010)

⁷³ Annex 7 provides further details

to reduce saturated fat intake.⁷⁴ Although different actions were taken in several Member States and intakes have decreased over the past years, industrial trans fats are still present at levels of concern in certain foods and intakes are still excessive in certain cases. The evidence collected by ICF also suggests that gains obtained in recent years through voluntary industry initiatives may have reached their limits. The issue is of particular relevance in certain Member States and for particular population groups. This results in the following problems:

- **Protection of consumers' health**

Different levels of protection of consumers' health currently exist in the EU, depending on the presence of foods with high industrial trans fats content in the Member State's market (presence influenced by the existence or not of national regulatory or non-regulatory initiatives) and on consumers' consumption patterns. Consumption patterns are influenced by socio-economic factors (e.g. consumers with lower income are more likely to consume products with high industrial trans fats content that are generally sold at a lower price⁷⁵ so that this situation contributes to the perpetuation of health inequalities in the EU.⁷⁶ In light of the global trend to reduce intakes of trans fats and the WHO's recent REPLACE initiative ('trans fat free by 2023') recommending to 'legislate or enact regulatory actions to eliminate industrially-produced trans fats', a number of countries worldwide have acted and others are expected to act. Therefore, not taking any action at EU level could entail a reputational risk for the EU of not adequately addressing a serious health concern of global dimension.

- **Functioning of the Internal Market and international trade**

Only some Member States have taken action on industrial trans fats, which is problematic for the effective functioning of the Internal Market: food business operators active in countries where no limit on industrial trans fats exists have no related reformulation costs and are therefore at a competitive advantage vis-à-vis operators active in countries where legal limits exist or operators abide by self-regulatory commitments. The current lack of a consistent approach at EU level means that there is not a level playing field between operators that have reformulated their products in order to reduce or fully remove ingredients containing industrial trans fats, due to self-regulation, voluntary agreements with national governments or legal measures, and those that have not. Generally, manufacturers face higher cost if they produce different varieties of a food with different ingredients to meet diverging national legal limits, rather than benefitting from economies of scale regarding one recipe for a food product. Producers that have not taken any steps to reduce industrial trans fats may save costs as

⁷⁴ Ruminant fats contain approximately 3 % trans fats and between 40 to 60 % of saturated fats, generally the proportions of those fats are fixed. Both types of fats increase the risk of dying from heart disease. The risk associated with trans fats is higher as compared to saturated fats. However, in order to address excessive intakes of saturated fats national nutrition policies aim to reduce the population intake of ruminant fats in the diet (for example with recommendation to prefer low fat versions of dairy products) and address then automatically also the problem of ruminant trans fats

⁷⁵ European Commission inception impact assessment 2016. Initiative to limit industrial trans fats intakes in the EU. 11/10/2016

⁷⁶ Allen K et al., 2015, Potential of trans fats policies to reduce socioeconomic inequalities in mortality from coronary heart disease in England: cost effectiveness modelling study, *BMJ* 2015;351:h4583

they do not invest in reformulation and through use of lower priced ingredients. This may provide a competitive advantage in the market.

This is particularly relevant for operators active in different Member States. At the same time, operators active in countries where no limit on industrial trans fats exists are negatively affected by the legal uncertainty over whether new initiatives to reduce industrial trans fats intakes will be adopted at national level and might have difficulties in planning R&D investments. The above described situation also hampers international trade: operators from third countries exporting their foods to the EU are subject to different conditions depending on where their foods are marketed. Similar considerations also apply to EU exporters to third countries. In countries without legal measures but with industry complying with voluntary agreements, industry may face unfair competition with producers in third countries. This issue in relation to external trade stems from import of products with high industrial trans fats contents into the EU. Eastern European countries may be at heightened risk for such imports due to their geographical position and the price sensitivity of consumers. Empirical evidence supports this description⁷⁷. Of note, all national legal measures apply to all foods sold in the country, including both foods produced nationally and foods imported from other Member States or from third countries.

Types of stakeholders affected

1. EU consumers are directly exposed to trans in foods and would be affected by any EU initiative on the matter through reductions in their trans fats intakes. Consumers will benefit from reduced risk of contracting coronary artery disease when industrial trans fats intakes are reduced, but they may experience an increase in the price and potentially a change in the quality and attributes of certain food products. Consumers in Member States where foods containing high levels of industrial trans fats are still on the market and consumers with high trans fats intakes are particularly affected.
2. Healthcare providers and healthcare systems are affected by the impact the presence of industrial trans fats has on the incidence of coronary heart disease and associated costs of healthcare.
3. Food businesses, including SMEs, would be impacted by action to limit industrial trans fats in food and additional costs. More specifically:
 - Manufacturers of pre-packed foods placed on the market in the EU or exported outside the EU operating chiefly in the following sectors: manufacture of margarine and similar edible fats, bread, fresh pastry goods and cakes, rusk and biscuits, preserved pastry goods and cakes, cocoa, chocolate and sugar confectionery, condiments and seasonings, preserving of potatoes;

⁷⁷ Unpublished letter of the European Margarine Association from October 2017 to the Commission about imports of products with high industrial trans fats content (up to 20-30%) from Eastern neighbouring countries.

- Mass caterers providing non pre-packed foods to consumers (e.g. fries) which (might) contain industrial trans fats, restaurants and businesses offering mobile food service (different sizes of business: multinational, national, SMEs);
- Manufacturers of ingredients placed on the market in the EU or exported outside the EU which contain industrial trans fats or are trans fats-free and can, in the latter case, be used as replacement of industrial trans fats-containing ingredients (e.g. frying oils) (mainly large operators);
- Retailers distributing foods which (might) contain industrial trans fats: they will be indirectly affected (different sizes of business).
- Third-country-based food business operators exporting into the EU would be affected by any EU initiative on the matter.

All food business operators have a role in determining the level of industrial trans fats in their products. Many of the large players have reduced industrial trans fats levels through reformulation. In this context, major producers and associations of the food industry have supported the implementation of a recommendation of a legal limit of industrial trans fats.^{78 79}

Manufacturers of oils and fats have a critical role to play as suppliers of ingredients that may contain industrial trans fats to food manufacturers, particularly to SMEs. A number of manufacturers have already acted on this issue, while others have not (in particular smaller and less organised businesses).

4. Public authorities of EU Member States are directly affected by the problem and by EU action as they will be responsible for implementing, publicising, administering and enforcing the new rules, incurring costs as a result.
5. Populations around the globe are affected, especially given concern about the potential impact on palm oil consumption and its effects on climate change and biodiversity.

2.2. What are the problem drivers?

The drivers of industrial trans fats intake are partly a matter of efficiency of industrial recipe and process and related lower costs, partly one of different national approaches and partly related to consumer behaviour.

Industrial recipe and process

High trans fats intake results from consumption of food products containing high levels of industrial trans fats. **Industrial trans fats are used in the manufacturing process and in the recipe of certain foods for technological reasons.** Especially, partly

⁷⁸ http://www.beuc.eu/documents/files/Open%20Letter_industrially_produced%20TFAs_freeEU.pdf

⁷⁹ http://www.fooddrinkEurope.eu/uploads/statements_documents/FoodDrinkEurope_statement_on_TFA_%28November_2015%29.pdf

hydrogenated oils are solid at room temperature and relative stable, either to rancidity over storage time or when heated repeatedly as frying oils.⁸⁰

In addition, they may be chosen due to their **competitive price**. Alternative ingredients need to be found when replacing ingredients with high trans fats levels, and sometimes developed, so that the product presents similar characteristics of texture, taste, etc. after reformulation.

Reformulation can entail substitution or development of a new product, and sometimes changes to the manufacturing equipment to accommodate new ingredients. This poses various challenges to industry, and chiefly to smaller businesses, which may be dependent on suppliers to provide alternative ingredients.

In order to overcome cost-related barriers to replace ingredients with a high industrial trans fats content with alternatives, a stimulus to change by the market or regulators, may be needed, such as market pressure, legal obligations or other action by public authorities. The level of corporate social responsibility as well as responsiveness of food business operators vary depending on the Member State.

Different national approaches

National authorities have the power to limit industrial trans fats levels in foods through initiatives at national level if they find it necessary to protect public health. However, evidence⁸¹ shows that national authorities have different approaches to industrial trans fats, with some acting and others not.

Among the Member States that have introduced legislation, a limit of 2 % of industrial trans fats of fat was the preferred choice. However, additionally, 4 Member States have complemented this with different limits established for lower fat products⁸². Due to those differences, all foods that contain between 3 and 20 % of fat with industrial trans fats levels between 2 and 4 % of fat would comply in 4 Member States but not comply in 3 Member States and all foods that contain less than 3 % of fat with industrial trans fats levels between 4 and 10 % of fat would comply in 2 Member States but not in 5 Member States. Those differences are in practice significant, as the majority of food products are below 20 % of fat and many are below 3 % of fat per 100 g of food. Tall existing Member States measures have in common the general 2 % limit for all foods with more than 20 % of fat content, while this food category represents generally a minor share of the total food offer. In Member States where voluntary measures have been taken, reductions were achieved, however, not always in line with legal limits mentioned above.

There is evidence collected by ICF about the effectiveness of both legal as well as voluntary measures in Europe. For example, in Denmark, a legal limit led to virtually eliminating industrial trans fats from the Danish food supply⁸³. Data collected in Austria

⁸⁰ Partial hydrogenation of oils is largely in use only since the middle of the 20th century

⁸¹ Please see Annex 8

⁸² Different limits established for lower fat products in Member States are described in Annex 9

⁸³ Ministry of Food, Agriculture and Fisheries of Denmark: Danish data on trans fatty acids in foods. ISBN 978-87-93147-02-7. 2014

before and after the introduction of the legal measure indicate that from bakery products controlled over time, once before the introduction of the legal measure and twice afterwards, 18 out of 30 samples were not compliant while 3 years after the measure came into force 1 out of 68 samples was not compliant and two years later all samples were compliant⁸⁴. Data collected in Hungary before and after the introduction of the legal limit point to a reduction of industrial trans fats intakes per person foods in the order of 40 % to 75 %⁸⁵.

While it could be assumed that more Member States would take action in the absence of EU intervention, there are no precise indications for all Member States, taking into account that incentives for food business operators to act can vary significantly and national authorities have different approaches to industrial trans fats. If parallel action is not undertaken at national level in all EU Member States, operators would remain subject to different conditions for the manufacturing and placing on the market of foods that could contain industrial trans fats and obstacles to the functioning of the Internal Market would persist. At the same time, products with high industrial trans fats levels would remain on the market in some parts of the EU and intakes of trans fats would remain excessive for certain consumer groups. This would negatively affect the protection of consumers' health and would contribute to the perpetuation of health inequalities in the EU.

Even if action was undertaken at national level in all EU Member States, it is very likely that differences would exist in the timing of the interventions (i.e. not all national actions would be launched at the same time) and in their content (i.e. it is possible that different measures would set different legal limits or cover different products). This explains the clear added value of an EU-based, EU-wide action: the possibility to ensure a level playing field in the Internal Market and the same high level of protection of consumers' health by the means of an initiative that would apply simultaneously in the entire EU and would minimise the risk of national regulatory interventions (further) fragmenting the Internal Market.

Consumer behaviour

Low consumer awareness of the risks associated with the consumption of trans fats may also contribute to industrial trans fats intake. The evidence in the EU points to low levels of consumer information and consumer awareness on trans fats⁸⁶, including which ingredient that is declared on the label or which non prepacked foods may contain trans

⁸⁴ Bundesministerium fuer Gesundheit, AGES: Lebensmittelsicherheitsbericht 2013, Zahlen, Daten, Fakten aus Österreich https://www.verbrauchergesundheit.gv.at/lebensmittel/lebensmittelkontrolle/LMSB2013_VersionWR_23_06_2014.pdf?6fdfsbi

⁸⁵ Unpublished, Technical Report, Budapest, November 2017, National Institute of Pharmacy and Nutrition, Department of Nutrition Epidemiology: Assessment of the impact of the TFA Regulation on the availability and population intake of industrial TFA in Hungary. This work was done in the framework of the Biannual Collaborative Agreement between the World Health Organization Regional Office for Europe and the Ministry of Human Capacities

⁸⁶ Please see Annex 8 for more details

fats. Many foods are potential sources that are difficult to avoid totally as this would lead to very restricted dietary choices.

Not all consumers can relate the information on the use of partly hydrogenated oils required by Regulation (EU) No 1169/2011 to the presence of industrial trans fats in foods and not all consumers can use that information to effectively compare different products taking into account their overall nutritional composition.⁸⁷

Finally, other considerations may influence consumer behaviour (e.g. cost, taste, habits) stronger than the intention to reduce trans fats intake.

2.3. How would the problem evolve

Whether the decline in industrial trans fats levels in food product and industrial trans fats intake observed in the past years will continue at the same speed and achieve a near elimination of industrial trans fats in the EU is not certain. Contrary, there is some evidence of new products that contain high levels of industrial trans fats being introduced to the market in recent years.⁸⁸ Consumer health would continue to be at risk in a number of Member States, particularly in the Eastern and Southern part of the EU. The perspectives provided by stakeholders in the consultation conducted by ICF in the context of the study to support this IA suggested that the problem would remain in the absence of EU action but also that many Member States would act unilaterally in the absence of EU action. Based on previous experiences, national legal measures introduced for public health protection, would likely differ to a certain degree in scope and content and could contribute to fragmenting further the Single Market for food products.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

EU action could be taken within the framework of Article 114 TFEU, in order to ensure the functioning of the Internal Market, whilst ensuring a high level of protection for health and consumers. The adoption of a legal measure to set limits to trans fats presence in food can be considered through the implementation of existing legislation, more specifically, on the basis of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. That Regulation aims at providing a high level of consumer protection whilst ensuring the effective functioning of the internal market. The Regulation empowers the Commission to take measures restricting the addition of certain substances to foods or the use of such substances in the manufacture of foods in view of harmful effects on health which have been identified in relation to a particular substance. For the specific case of the presence of trans fats in food, harmful effects have been identified based on scientific advice provided by EFSA, as explained under point 1.

⁸⁷ https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_legislation_study_food-info-vs-cons-decision_2014.pdf

⁸⁸ Stender et al. (2016) Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries, *BMJ Open* 2016;6:e010673

3.2. Subsidiarity: Necessity of EU action

The existing situation on industrial trans fats negatively affects the protection of consumers' health and contributes to the perpetuation of health inequalities. Excessive intakes of industrial trans fats are associated with avoidable suffering and pose burden on public health care systems.⁸⁹

Industrial trans fats are still present at levels of concern in certain foods in many Member States and particularly in Member States where no national action has been undertaken so far (voluntary or regulatory) to reduce such levels. While average daily trans fats intakes for the overall EU population are below 1 % of daily energy intake, some population groups have (or are at risk of having) higher intakes, including low-income groups and younger population groups (18 to 30 years).³⁶ As calculated by the JRC, up to 25 % of surveyed individuals aged 20-30 years have trans fats intakes above 1 % of daily energy intake.³⁶ But even if population average intake levels are around or slightly below 1 % of daily energy intake, this level can be considered as excessive, taking into account the recommendation from the European Food Safety Authority that intakes should be as low as possible. Empirical evidence supports this view, as reducing intake levels of industrial trans fats from below 1 % of daily energy intake to minimal levels in Denmark, 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.⁹⁰

According to the ICF research, levels of industrial trans fats are not necessarily declining in the coming years. While data gathered for the ICF study confirm a trend towards industrial trans fats reduction in food products, it shows also that the limits of the current approach with no action taken at EU level have been reached. Levels of industrial trans fats appear to remain high in certain countries, predominantly Eastern and Southern Europe, and certain sub-groups of food businesses, particularly SMEs. Levels were still above 2 % of their total fat content and in some Eastern and South-Eastern EU countries, industrial trans fats levels in pre-packed biscuits, cakes and wafers have not dropped meaningfully since the mid-2000s⁹¹. The authors of this study continued analysing the evolution of the market in six countries in South-East Europe covered by the previous study (including two EU Member States) and noted that availability of popular foods with high amounts of industrial trans fats increased from a high level in 2012 to an even higher level in 2014⁹². Another study⁹³ specifically focused on the Portuguese market showed that, in 2013, total trans fats content in different foods ranged from 0.06 % to 30.2 % of the total fat content of the food (average 1.9 %), with the highest average values in the “biscuits, wafers and cookies” group (3.4 % of the total fat content of the food). 50 samples out of 268 (19 %) contained trans fats at amounts higher than 2 % of the total fat content of the food. Several consultations and triangulation of data have confirmed these findings.

⁸⁹ Further details are provided in Annex 6

⁹⁰ Restrepo B.J. et al. Denmark's policy on artificial trans fat and cardiovascular disease *Am J Prev Med* 2016;50(1):69–76

⁹¹ Stender et al. *BMJ Open*. 2014;20;4(5):e005218

⁹² Stender S, Astrup A, Dyerberg J Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries *BMJ Open* 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

⁹³ Costa N et al., 2016, Trans fatty acids in the Portuguese food market, *Food Control* 64, 128-134

Even under the assumption that a decline in industrial trans fats intake would take place over time without EU level action, evidence suggests that from a society benefit/cost point of view, taking EU level legal action is a highly efficient measure⁹⁴. Therefore, opportunity cost for not acting at EU level are high, and they could be reduced the faster action is taken and measures are implemented, with resulting benefits for human health and cost to society.

3.3. Subsidiarity: Added value of EU action

The existing situation on industrial trans fats hampers the effective functioning of the Internal Market.

Whilst action has been taken by some countries⁹⁵, and others may be expected to act in the absence of an EU initiative⁹⁶, rapid and universal action on industrial trans fats by Member States is currently not envisaged. Products with high industrial trans fats content would therefore remain on the EU market and industrial trans fats would continue to contribute to health impacts and health inequalities.

In addition, legal measures and voluntary initiatives taken by Member States so far differ, as different national views in relation to acceptable levels exist.⁹⁷ Additional measures at Member State level could lead to further differences in approach, adding complexity and cost for food business operators.

Furthermore, as a basis for the Internal Market in foods, the EU has a detailed and rather comprehensive system of general and specific food laws, ensuring that products can be freely traded, but also that consumers can be confident that products offered are safe. To address potential health concerns, food safety measures ensure a high level of health protection of consumers. Excessive industrial trans fats in foods pose risks from a food safety angle. In case a food constituent is linked to serious health concerns, confirmed by an opinion by EFSA, their presence should be either prohibited or limited, both for products produced in the EU and for imported products. Recent EFSA opinions^{98 99} in relation to the presence of industrial trans fats in food ingredients recommended that the Commission considers revising the specifications for the ingredients, ‘including maximum limits for trans fatty acids’.

Added value at EU level thus derives from the possibility to ensure a level playing field in the Internal Market and the same high level of protection of consumers' health.. In this

⁹⁴ Saborido C M et al, 2016, Public health economic evaluation of different European Union–level policy options aimed at reducing population dietary trans fat intake, *American Journal of Clinical Nutrition*, 2016;104:1218–26

⁹⁵ Annex 8 provides further details

⁹⁶ WHO is calling on a global elimination of trans fats, therefore pressure on Member States to act may increase in the coming years

⁹⁷ For example, Denmark applies a legal limit of 2% trans fats of the fat content, in Lithuania the maximum permissible trans fats content is 10 % of the fat content if the total fat content is less than 3 %

⁹⁸ EFSA: Re-evaluation of mono- and di-glycerides of fatty acids (E471) as food additives. *EFSA Journal* 2017; 15 (11):5045

⁹⁹ EFSA: Re-evaluation of sodium, potassium and calcium salts of fatty acids (E470a) and magnesium salts of fatty acids (E470b) as food additives. *EFSA Journal* 2018; 16 (3):5180

context, it is of note that¹⁰⁰ in the consultation that preceded the adoption of the Commission's report, several Member States proactively signalled their preference for an EU level initiative on industrial trans fats.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

To address the problems that industrial trans fats intake is an important risk factor for the development of coronary heart disease and contributes to the perpetuation of health inequalities within the EU, the identified general objectives of EU action on industrial trans fats to be achieved are:

- To ensure a high level of health protection for EU consumers;
- This will also contribute to reducing health inequalities, one the objectives of Europe 2020¹⁰¹;

To address the problem of obstacles to the functioning of the Internal Market (unfair competition, legal uncertainty), the identified general objective is:

- To contribute to the effective functioning of the Internal Market for foods that could contain industrial trans fats.

4.2. Specific objectives

The following specific objectives of EU action on industrial trans fats to be achieved are:

- To reduce intake of industrial trans fats in the entire EU for all population groups;
- To ensure that the same rules/conditions apply in the EU to the manufacturing and placing on the market of foods that could contain industrial trans fats, so as to ensure legal certainty of EU food business operators within and outside the EU¹⁰²

Data collected during the Impact Assessment support the view, that trans fats are particularly a problem in Eastern and South-Eastern Europe, a region that generally also suffers from relatively high rated of heart disease and lower life expectancy than Western

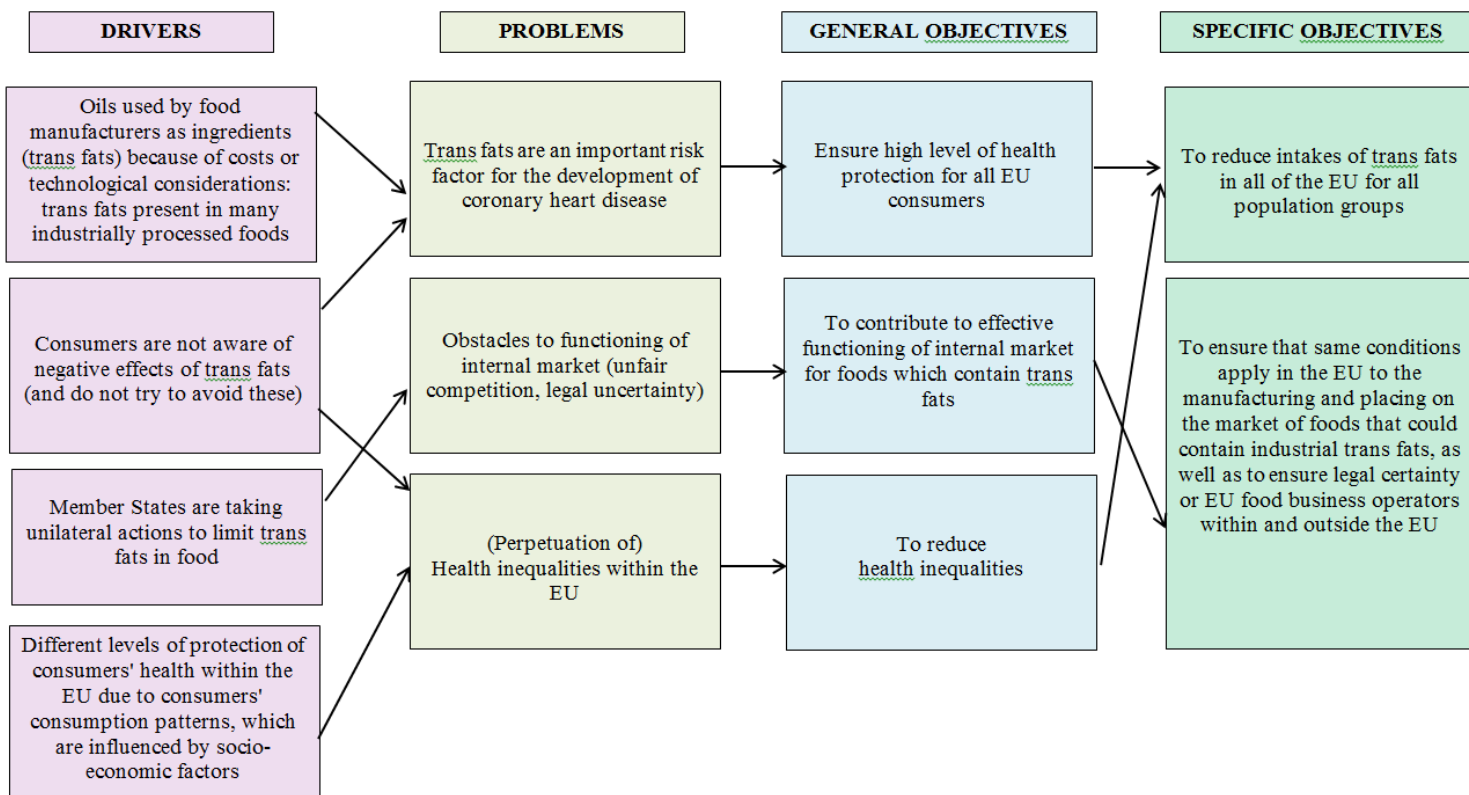
¹⁰⁰ <https://eu2015.lv/news/media-releases/1353-health-ministers-in-riga-agree-on-the-need-for-common-eu-nutrition-and-alcohol-policies>

¹⁰¹ COM (2010) 2020 final, Communication from the Commission, "EUROPE 2020 A strategy for smart, sustainable and inclusive growth"

¹⁰² This specific objective needs to be distinguished from the issue of 'dual quality' of products, which concerns situations, where a trader markets a product as being identical to the same product marketed in several other Member States, while those products, in fact, have significantly different composition and characteristics. In order to tackle the issue of 'dual quality', the Commission is currently implementing an articulated action plan (see: http://europa.eu/rapid/press-release_IP-17-3403_en.htm). Furthermore, this issue is also addressed in the Commission's New Deal for Consumers package (see Article 1(2) and recitals 39-43 of the Proposal for a Directive on better enforcement and modernisation of EU consumer protection rules (COM(2018) 185 final): http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=620435).

Europe. The results of a study¹⁰³ suggest that industrial trans fats levels in pre-packaged biscuits, cakes and wafers in some Eastern and South-Eastern European countries have not dropped meaningfully since the mid-2000s. This suggests that in certain parts of the EU little progress has been made, while in some Western EU countries reductions were achieved. The European consumer association BEUC highlighted in their position paper on trans fats in 2014¹⁰⁴, that regional inequalities between Western versus Eastern EU countries persist, citing results from product testing, which showed consumers in Eastern EU countries are more exposed to industrial trans fats than their Western neighbours. A test on margarines and wafers carried out by the Czech consumer association^{105 106} in 2013 and 2014 confirmed that reformulation efforts have not been equal in Eastern and Western EU countries. According to a published study¹⁰⁷, the same product categories would contain minimal amounts of industrial trans fats, while in Eastern Europe, substantial contents of trans fats were found. Figure 1 summarises the problems, drivers and objectives associated with industrial trans fats in the EU.

Figure 1 Illustrative summary of the problems, drivers and objectives associated with industrial trans fats in the EU



¹⁰³ Stender S, Astrup A, Dyerberg J. (2014) Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries *BMJ Open* 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

¹⁰⁴ BEUC: Position Paper, The consumer case for EU legal restrictions on the use of artificial trans-fats in food. February 2014. http://www.beuc.eu/publications/beuc-x-2014-010_the_consumer_case_for_eu_legal_restrictions_on_the_use_of_artificial_trans.pdf

¹⁰⁵ Jedlé nejdělné tuky, D Test, November 2013 <www.dtest.cz>

¹⁰⁶ Test hořických trubiček a plněných oplatek, D Test, January 2014 <www.dtest.cz>

¹⁰⁷ Stender, S., A. Astrup, and J. Dyerberg: A trans European Union difference in the decline in trans fatty acids in popular foods: a market basket investigation. *BMJ open*, 2012:

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

In the baseline scenario, option 0, no initiative would be taken on trans fats at EU level. The qualitative and quantitative analysis¹⁰⁸ was informed by the baseline scenario of a study completed by the JRC and the qualitative evidence collected in the external study by ICF.

The JRC study highlighted that the assumed baseline of 10 years in their modelling exercise was chosen as a rather conservative approach to show that measures which are cost effective under this very conservative assumption would prove even more cost effective under any further, less conservative baseline scenario¹⁰⁹.

The assessment methodology was designed to accommodate uncertainty about the future trend in industrial trans fats intake in the absence of EU action (the baseline scenario). The purpose was to reinforce the analysis by referring to three possible future trends (baselines), taking into account uncertainty rather than focusing on one scenario only.

It is suggested that industrial trans fats levels in food have been declining over time under the influence of various factors, while there is also some evidence that the decline has levelled off, according to the ICF study. In its recent public health economic evaluation³², the JRC extrapolated from available evidence and based its modelling on the assumption that industrial trans fats would be completely removed from the EU food supply chain in 10 years. While data gathered for the study by ICF confirm this trend, it shows also that most changes that could be triggered in the absence of EU policy action have already taken place, either as a result of voluntary initiatives or national legislation. Nevertheless, levels of industrial trans fats in foods appear to remain high in certain countries and certain sub-groups of food businesses, particularly SMEs.

A continuous downward trend in the years to come is not certain.¹¹⁰ Industry in some Member States has not acted voluntarily on industrial trans fats, and the evidence from certain Member States collected by ICF suggests that a voluntary approach may not deliver any progress there. Data on the industrial trans fats content of foods manufactured and sold in some Member States¹¹¹ suggests that, in spite of reductions in certain categories of products, levels of industrial trans fats in other food products remain high.

¹⁰⁸ Expected change in the industrial trans fats amounts present in the food chain, industrial trans fats consumption, and associated socio-economic impacts

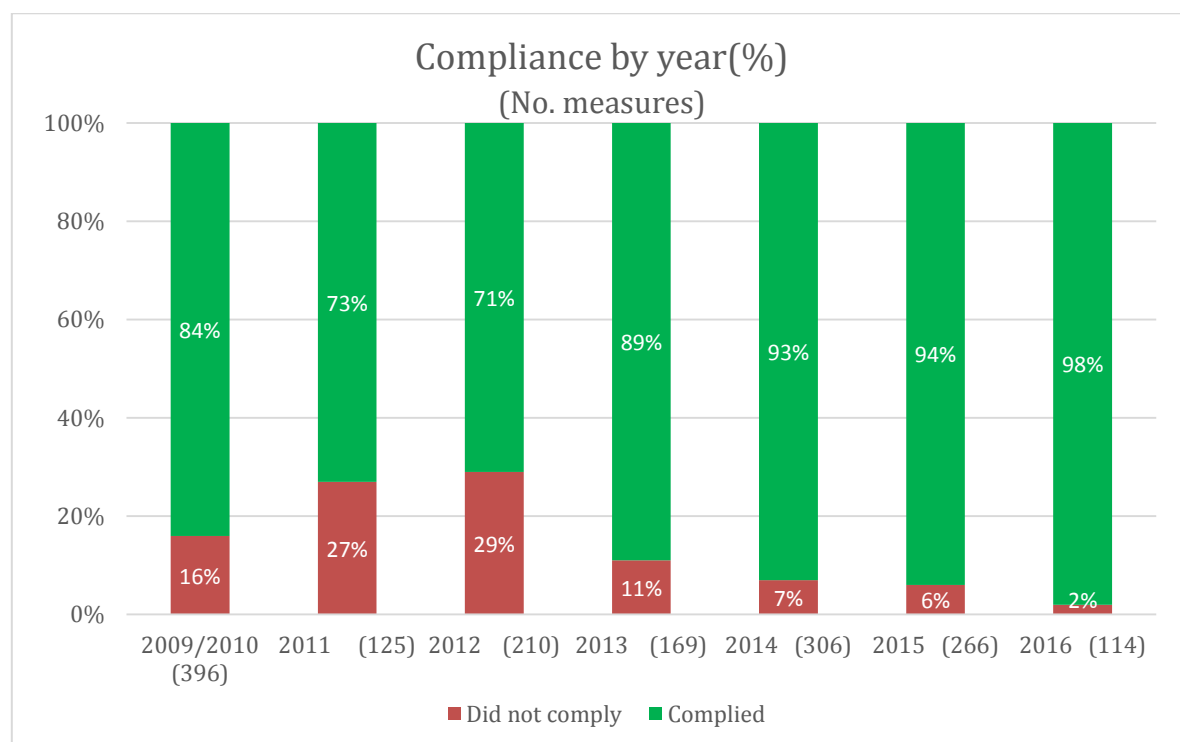
¹⁰⁹ Saborido C M et al, 2016, Public health economic evaluation of different European Union–level policy options aimed at reducing population dietary trans fat intake, *American Journal of Clinical Nutrition*, 2016;104:1218–26: 'Concerning a possible establishment of a limit on industrial trans fats: experience shows impact is limited or non-existent for the hospitality industry: industrial trans fats contained in meals prepared by hospitality businesses are only the result of the content of such trans fats in supplies bought from the processing industry. If the supplies are already below the limits, food prepared by hospitality businesses will always be below the limits. Moreover, the majority of hospitality businesses cook dishes with raw products (and do not produce industrial trans fats), meaning that they will easily comply with limits.'

¹¹⁰ Evidence is discussed in more detail in Annex 10

¹¹¹ Stender S., Astrup A., Dyerberg J. (2014) Tracing artificial trans fat in popular foods in Europe: a market basket investigation *BMJ Open* 2014;4:e005218. doi: 10.1136/bmjopen-2014-005218

The evidence on voluntary industry initiatives collected by ICF strongly suggests that potential action by those sectors willing to act and sufficiently well organised at national and EU level to carry out coordinated reductions in industrial trans fats has already been carried out. Other sectors and countries that have not acted voluntarily are highly unlikely to do so in the near future. Further evidence collected in six countries (including the EU Member States Croatia and Slovenia) has found that the number of packages of food products (considering the group of biscuits, cakes, wafers) that contained more than 2% of total fat as industrial trans fats had doubled between 2012 and 2014¹¹², indicating that food industry operators had expanded their offer of products with high industrial trans fats content, contradicting the notion of a general downward trend. Further evidence for actual increases of industrial trans fats exposure, particularly in Eastern Europe, is provided in a recent, unpublished study in Hungary, the outcome of a collaborative agreement between the World Health Organization Regional Office for Europe which supported the process and technical product, and the Ministry of Human Capacities of Hungary¹¹³. Hungary introduced its national legal limit in February 2014 with a transition period of 1 year. In the years proceeding to the enforcement of the national legislation, a steady increase in the percentage of products above the legal limit could be observed: 2009/2010 16% of products surveyed, 2011 27 %, 2012 29 %, respectively.

Figure 2: Compliance with the Hungarian national legal limit by year (%)



¹¹² Stender S, Astrup A, Dyerberg J. (2014) Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries *BMJ Open* 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

¹¹³ Unpublished, Technical Report, Budapest, November 2017, National Institute of Pharmacy and Nutrition, Department of Nutrition Epidemiology: Assessment of the impact of the TFA Regulation on the availability and population intake of industrial TFA in Hungary. This work was done in the framework of the Biannual Collaborative Agreement between the World Health Organization Regional Office for Europe and the Ministry of Human Capacities

Substantial improvements were only seen from the period where the national legal limit had been decided and notified to the EU, in 2013 with 11% of the sampled products above the legal limit, with following steady declines, 2014 7%, 2015 6 % and 2016 2%, showing the effectiveness of a legal limit to revert an increasing trend of products with high industrial trans fats levels on the market. This development is illustrated in Figure 2

Likewise, mean trans fats content in products was seen to steadily increase on the Hungarian market until a national legal limit was decided, as shown in Table 1.

Table 1: Mean trans fats content (g/100 g food) in the food samples by year in Hungary

Year	N	Mean	SD	Minimum	Maximum
2009/2010	396	0.55	1.46	0	15.36
2011	125	0.76	1.67	0	11.84
2012	210	0.70	1.41	0	10
2013	169	0.53	2.02	0	14.43
2014	306	0.26	0.42	0	3.46
2015	266	0.29	0.99	0	10.19
2016	114	0.20	0.41	0.004	3.53

Possible reasons for increased levels of industrial trans fats in foods are, for instance, availability of food ingredients with high industrial trans fats levels at low prices, a high price sensitivity of consumers, low responsiveness of food business operators to respond to calls for voluntary reformulation and a perceived low reputational risk for food business operators linked to the offer of products with high levels of industrial trans fats. For the Hungarian example described above, it was not possible to determine whether products with high industrial trans fats levels were imported as information was only available about the distributor and not about the manufacturer.

Of note, the national legal measures prohibit the sale of non-complying foods on the national territory, while non complying foods may still be legally produced for export.

A number of published evidence, including research articles, were available for citation to provide evidence, apart from data on trans fats levels collected by JRC, showing and confirming higher levels of industrial trans fats, particularly also in Eastern European countries^{114 115 116 117 118}. Despite this fact, the validity of assuming a baseline scenario of

¹¹⁴ Jedlé nejedlé tuky, D Test, November 2013 <www.dtest.cz>

¹¹⁵ Test hořických trubiček a plněných oplatek, D Test, January 2014 <www.dtest.cz>

¹¹⁶ Costa N et al., 2016, Trans fatty acids in the Portuguese food market, Food Control 64, 128-134

no change has been confirmed by ICF. ICF conducted an online consultation to maximise their ability to validate the data collected during desk research and expert interviews and triangulate the findings from the impact assessment with a wide range of stakeholders. This enabled ascertaining the validity of key elements of the analysis. The first part of the consultation posed general questions on current and predicted industrial trans fats use under different policy options. Overall the results from the ICF consultation have confirmed the appropriateness of the assumptions and estimates, while they have helped to qualify the baseline scenario. According to the ICF research, levels of industrial trans fats are not necessarily declining in the coming years. While data gathered for the ICF study confirm a trend towards industrial trans fats reduction in food products, it shows also that most changes that could be triggered in the absence of EU policy have already taken place, either as a result of voluntary initiatives or national legislation.

This suggests that obstacles stand in the way of further changes and of further diffusion of initiatives, either private or public, to that part of the EU food industry that has not yet reduced industrial trans fats levels in its products. Whether these obstacles would be removed in the absence of EU activity is not clear from the evidence that has been gathered by ICF. A continuous downward trend in the years to come is therefore not certain.

This uncertainty in the baseline is mitigated by the analytical approach; three variants of the baseline scenario have been adopted to capture that uncertainty, about how trans fat intakes may develop in the future. The policy options are compared against each variant. This approach helps to ensure that the conclusions about the absolute and relative impacts of options are robust in the context of all foreseen reference scenarios, thereby accommodating the uncertainty about future evolution of the problem in the absence of further EU action (cf Figure 2):

- A continuous decrease leading to the complete elimination of industrial trans fats from the food chain over a period of 10 years (B1 – ‘10 year elimination’);
- A continuous decrease leading to the complete elimination of industrial trans fats from the food chain over a period of 15 years (B2 – ‘15 year elimination’);
- Industrial trans fats intake remains constant at current levels (B3 – ‘no change’).

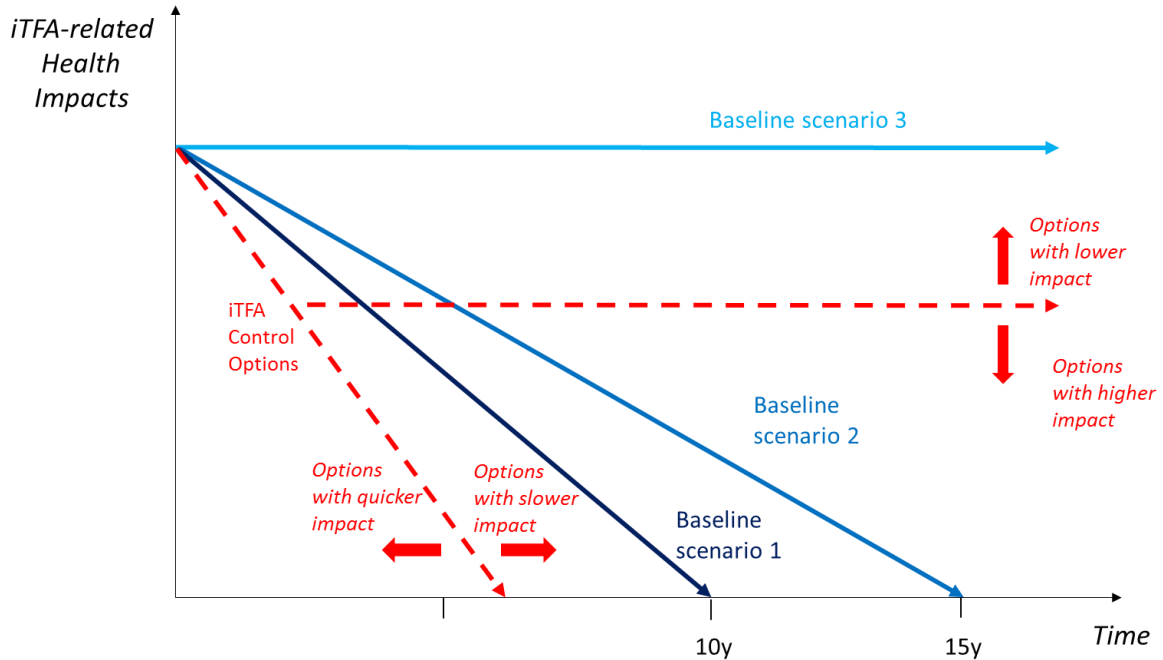
The three variants of the baseline represent the spectrum of expected possible trajectories – industrial trans fats intake remaining constant at current levels, a linear decline in industrial trans fats intake to zero over 15 years and an accelerated linear decline to zero over 10 years.

¹¹⁷ Unpublished letter of the European Margarine Association from October 2017 to the Commission about imports of products with high industrial trans fats content (up to 20-30%) from Eastern neighbouring countries.

¹¹⁸ <http://www.foodwatch.org/de/informieren/zucker-fett-co/aktuelle-nachrichten/schaedliche-transfette-in-donuts-berliner-co/>

From an impact appraisal perspective, the first variant (B1) is conservative: An option that is cost-effective under the first variant (B1) would be even more cost-effective under the other variants.

Figure 3 Dynamic baseline: illustrative representation of how benefits of industrial trans fats control arise compared to the variants of the baseline scenario¹¹⁹ (source: ICF)



iTFA : industrial trans fats

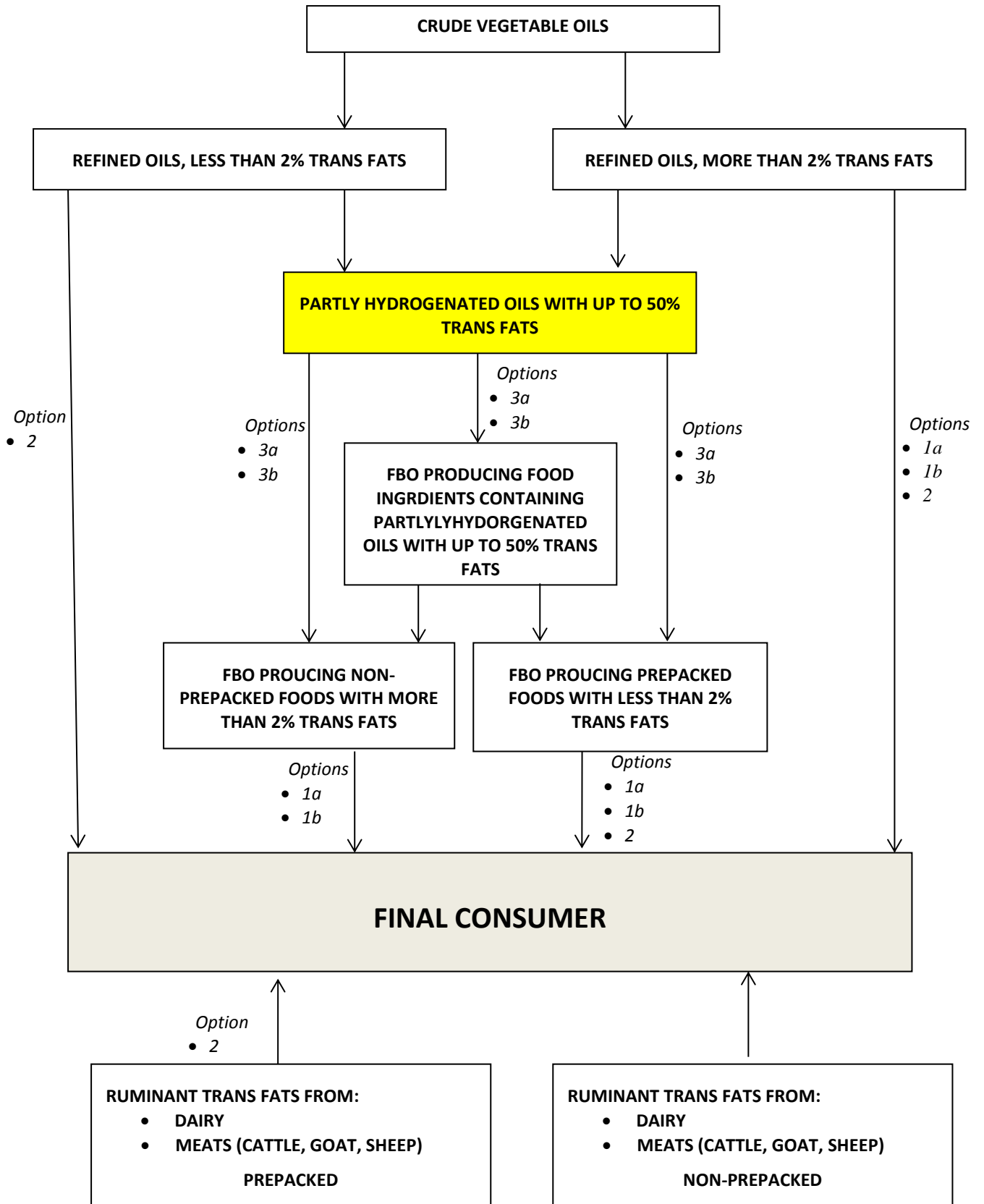
5.2. Description of the policy options

Overall, three options were considered, option 1 and 3 were subdivided into two sub options each to consider different instruments. Logic models and theories of change for each option are presented in Annex 11, Figure 4 describes potential dietary sources of trans fats and indicates where the different options affect those sources.

¹¹⁹ This illustrative chart shows a linear progression in industrial trans fats consumption in either of the three scenarios, the actual shape of the curve in both baseline and with-policy options may be non-linear

Figure 4 Overview of potential dietary sources of trans fats and where the different options affect the (% trans fats are given as % of fat content)

FBO: food business operator



Option 1 – Establishment of a limit for the industrial trans fats content in foods

In this option, the EU would establish a limit for the presence of industrial trans fats in foods, both pre-packed and non-pre-packed.

Different limits could be considered, one possibility would be to set the limit of industrial trans fats at 2% of the total fat content of the food, in line with the approach followed in seven Member States that have already taken legislative action on the matter.¹²⁰ This limit could be set through different instruments:

Option 1a: Voluntary agreement with the relevant food business operators to set a limit for industrial trans fats content in foods

In option 1a, a limit for industrial trans fats content in foods would be established by a voluntary agreement at European level between relevant food business operators. The agreement as a form of self-regulation would be under the auspices of the Commission, and involve EU-level representative organisations from the industry, themselves representing both national federations of companies and large companies operating across many countries of the EU.

Since some industry sectors are not organised and represented at EU level, this would not be fully inclusive. Voluntary agreements would primarily focus on foods sold to the consumer (and not include ingredients that are sold as inputs to final products).

The agreement is assumed to include an annual reporting requirement for participants. Industry associations would collect and report the information on behalf of their members. This information could be commercially sensitive, and business associations would need to operate as a “safe space”¹²¹, collecting and anonymizing the information from its members so that it may then be publicised. Such arrangements would build upon the examples of voluntary agreements to reduce industrial trans fats content in food which have been implemented in Germany and in the Netherlands.

It is assumed that the agreement would set a target of achieving levels of industrial trans fats in food products below 2% of fat within a period of 3 years. The evidence collected by ICF suggests that such a timespan would enable producers to factor reformulation into their regular cycle of product review and reformulation (whereas legislation might impose a shorter transition period for businesses).

Reporting obligations (and so the associated costs) would continue to apply even after the participating sectors had reduced industrial trans fats content to below the threshold. A review mechanism and ‘sunset clause’ by which reporting requirements lapsed a specified period after objectives had been met would mitigate ongoing costs incurred even after industrial trans fats had been reduced to levels below 2% of fat. There would be a credible incentive for Member States that legislation would be introduced in the absence of progress.

¹²⁰ Annex 8 provides details on the Member States

¹²¹ Etienne J (2015) Making sense of inter-organizational ‘safe spaces’ in business regulation, CARR Discussion Paper n°79, London School of Economics and Political Science.

A part of the food business operators that participated in the consultations favour a voluntary approach with regard to a legal limit, as more flexibility to act would be given. Generally, neither consumers nor NGOs favour this approach as it does not guarantee a high level of health protection. Public authorities think this option is somewhat appropriate as it could deliver some results, while most Member States support a harmonised, legal European approach (option 1b) ensuring the Internal Market and fair competition between food business operators in all EU Member States.

Option 1b: Legally-binding measure to set a limit for industrial trans fats content in foods

In Option 1b, EU legislation would set a limit industrial trans fats content of 2% of the total fat content of final food products sold to the consumer, following the example of 2% limits to final food products in some Member States' legislation.¹²² ¹²³ The 2% limit assuming it applies to all products consumed in a very conservative scenario means in practical terms an intake of between 0.6 and 0.7 % of energy intake from industrial trans fats for a large number of average consumers (between 33 and 60 %) in the EU. A 2 % limit applies to the content in the particular food or product and it would still enable minimal use of partly hydrogenated oils as raw ingredients containing industrial trans fats by the industry, e.g. for the manufacture of additives. Such additives could continue to be used, provided that the total industrial trans fats content of the final food sold to the consumer meets the 2% limit on fat basis.

In order to implement option 1b, it is assumed that the majority of food ingredients in the EU will comply with the legal limit, so that food manufacturers are sure to comply with the legal limit and that most food manufacturers that buy ingredients will ask for a industrial trans fats specification of not more than 2% of their supplier. In specific cases, ingredients with higher industrial trans fats levels could be used, as explained above. The enforcement of option 1b includes testing of final food products in the market for their industrial trans fats level. The JRC has proposed assessment methods for industrial trans fats and developed a standardised calculation method to estimate the industrial trans fats level in a food that contains industrial and ruminant trans fats.

Alternatively, a more differentiated approach could be chosen, with higher limits (above 2% of total fat) for products with low fat content, and 2% of total fat for food categories with high fat content. Such differentiated limits have been adopted in some Member States.¹²⁴ Consistently with the modelling study by the JRC, a transition period of 2 years is assumed.

A large part of the food business operators that contributed during the various consultations favour this option that is achievable and provides a level playing field and avoids any further fragmenting of the EU Internal Market. Also, most public authorities

¹²² Denmark (2003), Romania (2017) and Slovenia (2017)

¹²³ A 2% limit enables residual use of raw ingredients or additives containing industrial trans fats and take into account the unintentional generation of trans fats during processing

¹²⁴ Austrian/Hungarian legislation established a maximum content of trans fats at 10% of the total fat content where the total fat content is less than 3% of the product, and at 4% where the total fat content is between 3% and 20% of the product; further details on the levels are provided in Annex 8

and Member States, as well as consumers, and NGOs favour this approach as it guarantees a high level of health protection, is in line with certain national legal measures already in force in the EU, as it is ensuring the Internal Market and fair competition between food business operators in all EU Member States.

Limits below 2 % of fat content were not considered in detail in this IA. During the normal refining steps (deodorisation) of oils that contain high levels of polyunsaturated fats industrial trans fats can be formed, even if the oil is not undergoing partial hydrogenation. Oils with a high content of polyunsaturated fats, providing essential nutrients, are generally recommended as a part of a healthy diet. Also, in food service establishments, during normal frying processes trans fats are formed to a certain degree. It would not be proportionate to ask small food business operators active in food service to frequently control the level of trans fats produced in the frying oils to ensure that a low threshold limit is not exceeded. The 2 % limit on fat basis has been found to be in line with the need to accommodate trans fats levels generated during normal oil and food processing. However, empirical evidence shows, that with this threshold, very low average intake levels of industrial trans fats, in the order of 0.009 %, were achieved with the legal limit of 2 % per 100 g fat content. Therefore, the 2 % limit was assumed to achieve a high level of health protection while being technologically feasible for food business operators.

Option 2 – Introduction of the obligation to indicate the trans fats content of foods in the nutrition declaration

Option 2 involves the introduction of an obligation to indicate the trans fats content as part of the (mandatory) nutrition declaration for pre-packed foods. This would provide incentives to the industry to reformulate and reduce trans fats from food products and enable consumers to make informed food choices.¹²⁵

The labelling obligation would be required for all foods that carry a nutrition declaration, with resulting costs even for foods free of trans fats, while non pre-packed foods e.g. in restaurants, are out of scope. Where applicable, the nutrition declaration would describe total trans fats content, both ruminant and industrial trans fats.

A two-year transition period, would allow a majority of businesses to process label changes into their normal cycle of label updating.¹²⁶

A large part of the food business operators that contributed during the various consultations do not favour this option due to the high administrative burden and linked costs. Generally, food business operators active in the vegetable oils sector have been more favourable in principle, given that this measure also covers ruminant trans fats, while food business operators providing ruminant fat sources are not favourable to this option as they are unable to reformulate the basic fat composition of ruminant fats and

¹²⁵ EC (2015) 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 COM(2015) 619 final

¹²⁶ Longer transition periods have been allowed for implementation of the Food Information Regulation, however, that legislation involved greater changes than those implied by this Option, therefore a shorter transition period has been assumed

fear negative impacts on the overall diet of consumers as a potential consequence. Consumers often point to their desire for transparency in relation to the foods they eat and prefer to be provided with comprehensive information, so they supported this option. Public authorities generally 'do not favour' this measure or only 'favour it somewhat' according to the results of the OPC; also NGOs do not largely support this option, one of the reasons here being that labelling covers only part of the food offer, pre-packed foods, and therefore only part of the trans fats problem.

Option 3 – Prohibition of the use of partly hydrogenated oils in foods

In this option, the EU would follow a similar approach as adopted in the US and would prohibit the use of partly hydrogenated oils in foods, as primary dietary source of industrial trans fats. This could be achieved through a voluntary agreement with the relevant food business operators (sub-option 3a), or a legally-binding measure (sub-option 3b).

Option 3a – Voluntary measure to eliminate the use of partly hydrogenated oils

In Option 3a, partly hydrogenated oils would be removed from foods through a voluntary agreement negotiated and managed at European level. Food business operators would commit to the ban individually or through their representative associations.

The arrangements for the voluntary agreement would be similar to that for option 1a. There is currently no definition of partly hydrogenated oils in EU law or in the Codex Alimentarius. For the implementation of Option 3a, a definition of partly hydrogenated oils would need to be established at EU level, linked to a measurable indicator, which could then be relied on for monitoring purposes. The US Food & Drug Administration¹²⁷ defined partly hydrogenated oils in terms of their 'Iodine Value', which is measurable.

Consumers and public authorities consider this option as somewhat appropriate, while industry and NGOs generally are not supportive about what they see as less effective voluntary action.

Option 3b – Legal measure to prohibit the use of partly hydrogenated oils

This option would mirror action taken in the USA. In June 2015 the US Food and Drug Administration concluded that partly hydrogenated oils are not “generally recognized as safe” for use in human food, and introduced a prohibition on their use, with a compliance period of three years. This allows food companies to either reformulate products without partly hydrogenated oils and/or petition the FDA to permit specific uses of partly hydrogenated oils. A similar measure has been introduced in Canada.¹²⁸

¹²⁷ Food & Drug Administration's determination on partly hydrogenated oils being not Generally Recognized as Safe <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

¹²⁸ Government of Canada (2017) Notice of Proposal - Prohibiting the Use of Partially Hydrogenated Oils in Foods.

This option would introduce via EU law a prohibition on the use of partly hydrogenated oils as food ingredients. Provision could be made for limited derogations applicable to certain categories of products and for technical uses of partly hydrogenated oils in limited quantities. Partly hydrogenated oils are the primary dietary source of industrial trans fats in the diet. Although all refined edible oils and oils heated up under high temperatures during cooking processes contain some industrial trans fats as an unintentional by-product of their manufacturing- or the cooking process, industrial trans fats are an integral component of partly hydrogenated oils and are purposely produced in these oils to affect the properties of the oil and the characteristics of the food to which they are added.

As for Option 3a, the matter of the definition and a suitable test for enforcement purposes would need to be agreed. Neither at EU level, nor at international level (Codex Alimentarius) a definition of 'partly hydrogenated oil' exists so far. The definition of 'partly hydrogenated oil' would need to be decided, and a suitable test would need to be agreed for monitoring and enforcement purposes. In the US, the definition of partial hydrogenation is linked to the extent to which a fat or oil reacts with iodine, referred to as the "Iodine Value (also referred to as IV)". In this context, partially hydrogenated oils and fats are defined as those vegetable oils and fats with an Iodine Value (IV) above 4¹²⁹. The iodine value does not measure directly the level of trans fats and hence does not always imply a reliable trans fats result and can also vary depending on other technical parameters applied during the hydrogenation process, irrespective of the trans fats content. The Iodine Value can also vary depending on the refining process used or depending on the presence of other substances in some vegetable oils and fats (called "unsaponified components"). However, when comparing option 3b to option 1b it is noted, that according to the definition chosen in the US for partly hydrogenated oils, in many cases oils above levels of 2 % trans fats per fat basis would be covered.

It is expected that difficulties may arise for enforcement of option 3b and the linked Iodine Value measurement based definition in final food products, where in most relevant cases, vegetable oils/fats are only one ingredient. The US approach is based on the ban of an ingredient, which means they must not be brought into circulation, which may be controlled. End product controls using the Iodine Value as an analytical measure are not applicable to finished, multicomponent products.

For cases where suspicion about compliance with the legal ban of using partly hydrogenated oils is raised, a document check or a check of the ingredients used for manufacture of a product or checks at the manufacturing plant for the oils used is necessary. This is thought to be particularly demanding for imported products, but also for control authorities in a Member State controlling compliance of products manufactured in another Member State.

Option 3b completely bans any use of partly hydrogenated oils. It means that a production process is banned, where industrial trans fats are produced in high amounts. The definition of partly hydrogenated oils applied in the US equals roughly oils that

¹²⁹ The iodine value is used by the refining sector as a technical measurement of the level of unsaturation in vegetable oils and fats.

contain industrial trans fats levels of 2% on fat bases. Most oils that contain approximately more than 2 % trans fats would be considered by the definition applied in the US as being partly hydrogenated oils and would therefore not be allowed any more in the food chain. This is contrary to option 1b, where residual use of industrial trans fats for the manufacture of ingredients for food business operators would be permitted, as long as the legal limit of maximum 2 % of industrial trans fats per 100 g of fats in the food product sold to the final consumer is complied with.

A large part of the food business operators and NGOs that contributed during the various consultations does not favour this option that would ban a production technology rather than limiting the problematic substance itself, industrial trans fats. Furthermore, in the EU such a measure has no precedent. Public authorities perceived this option to be somewhat appropriate, while consumers are very supportive of option 3b as it ensures a high level of health protection.

Combinations of options

In addition to the above options, the following combinations of some of the options were considered:

- Combining mandatory labelling with legislation (2 + 1b or 2 + 3b)
- Combining mandatory labelling with voluntary agreements (2 + 1a or 2 + 3a)

5.3. Options discarded at an early stage

Fiscal measures, for instance introducing taxes, are proposed as effective measures for addressing nutrients of public health concern that are over consumed in a population. Examples are sugar taxes addressing sugars levels in sweetened beverages. However, industrial trans fats are seen from a food safety perspective, where fiscal measures are less appropriate. Furthermore, the Commission report of 2015 identified already the introduction of a legal limit as the most effective measure and announced the present IA to assess further its impact.

Sub-options of Option 1b with specific requirements for low fats have not been considered. Four of the seven Member States with national legal limits apply different limits for lower fat products. In view of an EU level legal limit, a legal limit of 2 % on fat basis is in line with EFSA and WHO recommendation, seems achievable in practice and is generally accepted by both consumer organisations as well as health NGOs on the one hand, and industry on the other hand. Granting additionally higher levels for low fat products, that are forming the major part of the diet in terms of quantity, could potentially lead to intake levels above 1 % of energy intake. For example, 100 g of a food with a fat content of 3 % and a maximum level of 10 % industrial trans fats of the fat content, would lead to products with 0.3g of industrial trans fats per 100 g of the final food product. For a person consuming a 2000 kcal diet per day, the standard used in EU food law and Codex Alimentarius guidelines, the WHO recommendation of less than 1 % of energy intake corresponds to less than 2.2 g TFA per day. Consuming more than 730 g of foods that are at this threshold would lead to industrial trans fats intakes exceeding the

WHO recommendation. Generally, adults consume more than 730 g of food per day. The sub-options were not in detail discussed in the IA report. However, during discussions and consultations of a draft measure well justified proposals could be considered.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Annex 12 explains how options were screened against possible relevant impacts and how relevant impacts were identified. The main impacts of the policy options described in section 5 which were identified during the screening phase and therefore analysed in detail are: social impacts (health benefits, quantified in terms of health care costs - direct and indirect - and disability adjusted life years; effects on health inequalities), economic impacts (direct costs for businesses and public authorities which consist of administrative burdens for business, compliance costs for business, including the role of innovation and technological development and administrative burdens for public authorities; consumer impacts – prices, choice and product quality; Single Market impacts; effects on international trade; impacts on SMEs) and environmental impacts, particularly in relation to deforestation and implications for climate change and biodiversity. The potential indirect effects of the above on competitiveness, growth and social cohesion were also considered in the analysis.

6.1. Social impacts

The impacts of the options on human health are quantified in terms of direct and indirect health care costs and disability adjusted life years.

These impacts are influenced by the level of industrial trans fats intake currently observed in the population, which varies as a result of the different policy options. Furthermore, dietary habits of certain population subgroups, consumption levels of ruminant trans fats and the type of fat used to replace of industrial trans fats in reformulated products will also contribute to potential health impacts. In this analysis all factors are assumed constant.¹³⁰

6.1.1. Impacts on health

The health impact assessment used a number of assumptions that, together with the underlying evidence for those assumptions, are described in detail in Annex 13.

Food policies have the potential to reduce non-communicable disease mortality and morbidity, with associated cost savings quantified in Table 1 and associated health gains expressed in disability adjusted life years averted, quantified in Table 3 for the different policy options assuming three variants of the baseline scenario.

¹³⁰ Assuming constant factors here means that in the modelling no such variables were included

Impact on health care costs (direct and indirect)

Both direct and indirect health-related cost estimates are expressed in 2016 prices (in €). The model of the contractor ICF considers two types of costs, both were based on the European Cardiovascular Disease Statistics 2012¹³¹:

- Direct healthcare costs: costs related to the use of health resources (i.e., primary care costs, outpatient costs, emergency costs, and medication used during the hospitalization).
- Indirect costs of ill health: costs related to the disease, namely loss of productivity and informal care.

In the case of no EU action (Option 0) all health-related costs for the EU over the course of a lifetime (85 y) have a present value¹³² of €10,764,979 million under the 10 year elimination variant (B1). Under the 15 year elimination variant (B2) and ‘no change’ variant (B3) the present value of total health-related costs would be €33,753 million higher and €245,009 million higher respectively.

Table 2 shows the cost savings resulting from each policy option as compared to the baseline scenario variants. The figures are calculated by subtracting the costs associated with the disease burden expected under the given policy with that of the relevant baseline variant.

Options 1b and 3b deliver the highest health-related cost savings; the implementation of legal measures (1b or 3b) would lead to savings with a present value of €58,611 million under variant B1 and €94,008 million under variant B2. In variant B3 disease-related costs savings are much greater than under the other two variants. In B3 there is no reduction of industrial trans fats intake without an action at EU level.

Table 2 Cost savings associated with lower disease burden for each policy option compared to the baseline, under each of the baseline scenario variants (M EUR)

Policy option	Savings from lower disease burden		
	B1 – 10 year elimination	B2 - 15 year elimination	B3 - No change
Option 1a	6,197	11,078	42,798
Option 1b	58,611	94,008	304,366
Option 2	10,329	15,353	141,484
Option 3a	6,197	11,078	42,798
Option 3b	58,611	94,008	304,366

¹³¹ Martin-Saborido CM et al. (2016) Public health economic evaluation of different European Union-level policy options aimed at reducing population dietary trans fat intake. *American Journal of Clinical Nutrition*, 104: 1218-26

¹³² Discounting renders benefits and costs that occur in different time periods comparable by expressing their values in present terms. In practice, it is accomplished by multiplying the future values by a discount factor

Note: Figures represent the reduction of health-related costs over 85 years, in present value terms, in million Euro

A sensitivity analysis ¹³³ has been conducted to show the impacts of alternative specifications of the starting point – i.e. the initial population industrial trans fats intake when the model starts (point 0). This shows that the results are robust, all options deliver cost savings in all cases, and options 1b and 3b provide the largest benefits.

Impact on disability-adjusted life years

The disability-adjusted life years measure overall disease burden as the number of years lost due to ill health, disability or early death. Resulting disability-adjusted life years are then calculated on the basis of the modelled number of coronary artery disease events and deaths.

In the case of no EU action (option 0) the disability adjusted life years for the entire EU population amount to 1,076 million over the course of a lifetime (85 years) under the best case scenario. Under variants B2 and B3 the total EU coronary artery disease burden in disability adjusted life years would be 1,079 million and 1,142 million respectively.

Table 3 illustrates the number of disability adjusted life years avoided thanks to the implementation each option as compared to the baseline scenario variants. They are calculated by subtracting the estimated disability adjusted life years in the baseline from the disability adjusted life years in the given policy.

Options 1b and 3b lead to the highest reduction in morbidity and mortality (as measured in terms of disability adjusted life years). The implementation of legal measures (1b or 3b) would reduce the disease burden by 4 million disability adjusted life years for the EU population under variant B1 and by 6 million disability adjusted life years for the EU population under B2. In the B3 case the reduction in disease burden is much greater. Options 1b and 3b have the greatest positive impact.

Table 3 Health gains in disability adjusted life years averted (EU28, Millions) for each policy option compared to the baseline, under each of the baseline scenario variants

Policy option	Health benefits in disability adjusted life years averted		
	B1 – 10 year elimination	B2 - 15 year elimination	B3 - No change
Option 1a	0.4	0.7	10
Option 1b	4	6	66
Option 2	0.7	1	34
Option 3a	0.4	0.7	10
Option 3b	4	6	66

¹³³ Details are provided in Annex 14

A sensitivity analysis¹³⁴ shows that results are robust, all options reduce the disease burden as compared to the baseline.

Options 1b and 3b have identical expected health benefits. The underlying assumptions explain this similarity. With regard to option 1b, evidence from Denmark suggests that the introduction of legislation limiting the industrial trans fats content of foods was very effective in reducing the population intake. Since the introduction of the measure in 2002, the average intake of industrial trans fats decreased in all age groups of the Danish population. The most recent data suggest that in 2014 the average industrial trans fats intake in Denmark was 0.009 % of the energy intake. Based on this evidence, the health model assumes that for options 1b the industrial trans fats intake decreases to 0.009 % of energy intake after two years (assumption of 2 year implementation period) and then evolves as assumed in each of the three baseline scenarios. With regard to option 3b, introduction of a ban on the use of partly hydrogenated oils as a food ingredient through EU legislation, with a transition period of 2 years, the model assumes that industrial trans fats intake will vary as in option 1b, for instance, that the removal of partly hydrogenated oils from the food supply will successfully eliminate the presence of food with high industrial trans fats content from the market and lead to trans fats intake decreases to 0.009 % of energy intake. Residual small industrial trans fats intake from deodorised oils and trans fats generated during the heating of oils during cooking will remain.

Replacement of industrial trans fats with other ingredients as fat sources could potentially have unintended consequences for health. There is a range of approaches to reformulate foods and reduce industrial trans fats content for example replacing partly hydrogenated oils with alternative oils and fats and/or mixing of various non-hydrogenated oils. The 'toolkit' of oils and fats is vast and includes for example food technological approaches to 'design' fats of desired composition and properties, in particular by applying fat interesterification and fractionation processes. Some stakeholders highlighted during the OPC the need to ascertain that the full health profile of the reformulated product has to be considered; for example there are concerns that reformulation may lead to increased saturated fat content. However, several studies have shown that for a number of food products, industrial trans fats have not simply been replaced by saturated fats, but the reformulated products have increased the content of cis-unsaturated fats, thus leading to an overall healthier profile of the product. Even if industrial trans fats were replaced completely with saturated fat, a net health benefit would result.

The recently launched REPLACE package of WHO¹³⁵ asks for encouragement of manufacturers to replace industrial trans fats with the most healthy available alternative fat. Many Member States already work on voluntary reformulation campaigns with industry to replace saturated fat intake. The EU is supporting such efforts, both via research projects or by support to exchange best practice models of reformulation.

One of the potential replacement fats for partly hydrogenated oils is palm oil and potential health implications of such a replacement need to be considered. Palm oil contains various fatty acids that could be considered in relation to their health profile. Around 49 % stem from saturated fat, 37 % from monounsaturated fat and 9 % from

¹³⁴ Details are provided in Annex 14

¹³⁵ <http://www.who.int/nutrition/topics/replace-transfat/>

polyunsaturated fat. Saturated fat intakes are increasing the risk for developing heart disease and their intake should be limited. However, even if industrial trans fats are completely replaced by saturated fat, a net health gain is achieved. Replacing trans fats with either mono- or polyunsaturated fats yield higher health gains. Palm oil is particularly rich in palmitic acid, approximately 44 % of the fat. This may be seen as problematic as palmitic acid has been reported to be linked to bigger effects on increasing the undesirable LDL blood cholesterol levels and therefore with higher risks in relation to heart disease than other saturates fatty acids. EFSA has stated with regards to individual saturated fatty acids, that the 4 major saturated fatty acids (lauric, myristic, palmitic, stearic acid) may have different effects; however, that data is not sufficient for setting intake recommendations for individual saturated fats.

6.1.2. Impacts on health inequalities

Inequalities in health remain an important issue in the EU and across the globe. While the model of the JRC does not produce quantitative estimates of the potential effects of options on health inequalities, evidence collected by ICF from the implementation of trans fats policies and other dietary policies across the world suggest that the legal limit would be the most effective in reducing health inequalities, followed by the voluntary reformulation. The labelling policy is likely to have a minimal effect upon reducing health inequalities, and could in some populations actually worsen health inequalities.

Consumers with lower income are more likely to consume products with high industrial trans fats content, products that are generally sold at a lower price. As such the current situation can contribute to health inequalities. Another population group at risk off high industrial trans fats intakes are younger population groups. Examples were young males in Germany and Austria, identified as population groups at risk if high industrial trans fats intakes as they consume a high proportion of processed foods and fried fast foods that was found to contain more likely to contain high industrial trans fats levels. For instance, in Austria, young apprentices were identified as a group at-risk population to exceed recommended intake levels of industrial trans fats due to their high consumption of fast foods. Before Austria introduced their national legal measure, in a study covering 2989 young apprentices¹³⁶, 75 % were consuming levels below the national recommended level (1 % of energy intake), 25 % were above this intake level. In Germany, a report by the Federal Institute for Risk Assessment stated in 2013¹³⁷ that young adults were found to consume approximately 2,5 times the amounts of industrial trans fats as compared to older adults. While most consumers achieve trans fats intakes below 1 % of energy intake, the average intake is 0,66 % of energy intake. However, even with this low average level, 10 % of the population is above the recommended level of % of the energy intake. Particularly voluntary reductions of ready meals, here deep frozen pizzas, have contributed to reducing high intakes of an identified at-risk population of young adult males.

Detailed considerations and expected impacts for all policy options are provided in Annex 15.

¹³⁶ Österreichischer Ernährungsbericht 2008, Herausgegeben vom Institut für Ernährungswissenschaften der Universität Wien im Auftrag des Bundesministeriums für Gesundheit

¹³⁷ Bundesinstitut für Risikobewertung: Stellungnahme 028/2013 vom 6. Juni 2013

6.2. Economic impacts

Each of the policy options considered has the potential to have a number of economic impacts, most importantly benefits and costs: administrative costs are incurred by businesses in understanding the rules, determining responses and providing information, and by the public authorities in implementing and enforcing the rules, monitoring and reporting. Compliance costs are incurred by businesses in meeting the legal obligations or voluntary commitments. These may include the costs of reformulating products, purchasing alternative ingredients, and product labelling. Further economic impacts were considered as well.

Economic impacts have been assessed by ICF with a cost model developed in MS Excel in parallel to the JRC model. The analysis provides a quantitative assessment of administrative and compliance costs for business, and administrative costs for public authorities. Quantitative estimates of the costs borne by SMEs were also made

Additional evidence collected from the consultations, informed a more qualitative assessment of related impacts on consumers, the Internal Market, competitiveness and international trade. Evidence and data on price impacts, competitiveness, the Internal Market and international trade was not available to enable a quantitative analysis. Available data and empirical evidence, while valid in specific cases in a certain context informed the evaluation, however, it was not possible to extrapolate such data for a quantitative assessment with a sufficient degree of confidence in the robustness of the results.

In order to assess costs for food business operators, the market structure needs to be analysed. For all businesses in relevant food industry subsectors that are potentially affected by the measures, Annex 16 provides an detailed analysis on the number of businesses affected and how the different measures that create costs are concerned. Based on EUROSTAT data, policy option 1a affects according to the ICF estimates 117,918 businesses, option 1b 1,019,240 businesses, option 2 260,397 businesses, option 3a 124,403 businesses and option 3b 1,081,514 businesses. With regard to the different sectors, around 85 % are in food service (such as restaurants or caterers) and 15 % in the food manufacturing sector. The food sector, in terms of number of businesses, is dominated by SMEs. In food manufacturing, approximately 99.1 % of businesses are SMEs, of food service approximately 99.9 %, respectively.

6.2.1. Impacts on direct costs for businesses and public authorities

Table 4 presents estimates of the total costs to business and the public authorities of implementing the five options, as compared to the baseline scenario. The detailed costs that are summarised in this table and the underlying assumptions and methods for

establishing them are described in Annexes 16 to 18. The figures present the sum of the present value of costs over 10 years, using a discount rate of 4%.¹³⁸

Costs are assumed to be zero after 10 years for each option. Many are one-off costs such as reformulation or relabelling costs. It is assumed that monitoring and enforcement will cease to generate costs after 10 years (by which time industrial trans fats will have disappeared from the food chain). By that time, monitoring of foods for the presence of industrial trans fats would likely become part of the routine operations carried out by National Competent Authorities regarding food composition. The development of cost-effective alternative ingredients should be followed by a decrease in costs for the substitute ingredients over time

The present values are calculated by summing the different estimated costs incurred each year over the 10 year period, and calculating the present value of these using the 4% discount rate. These costs are then summed up over the 10 year period to give a total present value.

Table 4 Present value of total costs of implementing options over 10 years (M EUR)

Policy option	Business administrative costs	Business compliance costs	Public administrative costs	Total costs
Option 1a	3.2	43.5	3.2	49.8
Option 1b	17.8	251.5	27.7	297.0
Option 2	6.7	9,568.8	250.6	9,826.2
Option 3a	3.3	51.6	3.4	58.6
Option 3b	18.7	297.4	29.9	346.0

Option 2 is estimated to be linked by far to the largest costs, especially as a result of the costs of relabelling of food products, whether or not they currently contain or are likely to contain trans fats.

Options 1b and 3b are estimated to have significantly larger costs than 1a and 3a, because a greater level of business action is anticipated in response to legislation than voluntary initiatives.

The estimated costs represent a small proportion of the annual value of EU output of the business sectors affected (Table 5).

¹³⁸ The discount rate of 4 % was chosen in line with the Better Regulation toolbox advice https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-61_en_0.pdf

Table 5 Estimated costs as a proportion of the value of output of affected food business subsectors (%)

Policy option	Business administrative costs	Business compliance costs	Public administrative costs	Total costs	Business costs
Option 1a	0.0001%	0.0011%	0.0001%	0.0012%	0.0011%
Option 1b	0.0004%	0.0062%	0.0007%	0.0073%	0.0066%
Option 2*	0.0002%	0.2349%	0.0062%	0.2412%	0.2350%
Option 3a	0.0001%	0.0013%	0.0001%	0.0014%	0.0013%
Option 3b	0.0005%	0.0073%	0.0007%	0.0085%	0.0078%

Note: Figures are expressed as a % of output of the main sub-sectors affected by action for industrial trans fats.¹³⁹ *Costs of option 2 include costs for all pre-packaged food producers.

While the cost estimates are based on broad averages and assumptions, it is likely that the costs for the majority of food businesses will be minor, but that a small proportion of businesses will face greater challenges and costs. Examples of businesses that may face greater challenges and costs are those suppliers of oils, fats and margarines that have not yet reformulated their products, as well as a number of smaller bakeries across the EU that are currently users of partly hydrogenated oils.

6.2.2. Impacts on consumers

The main impacts on consumers (besides health-related impacts discussed in section 6.1.) are expected to be:

- Possible increases in the price of food products; and
- Possible changes in the attributes of food products, including their taste and texture.

Consumer prices

Increases in costs to food businesses could (partly) be absorbed within the food chain, (resulting in lower business profits), but would be expected to be reflected, at least partly, in increases in the price of food products to the consumer.

The expected impact of each option on consumer prices is summarised in Table 6, details about the underlying assumptions to establish the expected impact on consumer prices are provided in Annex 19. Only qualitative data are available as it was not possible to quantify the increase of consumer prices.

Potential price increases on items consumed primarily by low-income citizens could lead to less available budget for food purchase (fruit and vegetables) and therefore have the unintended impact of leading to less healthy diets. However, the price increases for most

¹³⁹ Based on Eurostat data on production value in annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

food items is assumed to be moderate. Furthermore, most substantial price increases are expected to occur in foods with cocoa, vegetable fat coatings. Those foods are generally recommended to be consumed in smaller quantities and price increases could also lead to smaller consumption quantities or to less frequent consumption. The total net impact on health is uncertain.

Table 6 Expected impact of each option on consumer prices

Policy option	Expected impact	Comments
Option 1a	Very small increase	Low cost option, unlikely to impact on food prices
Option 1b	Very small increase	Overall costs expected to be very low relative to value of output. Prices of some products may increase slightly, particularly those for which reformulation and cost of ingredients present challenges
Option 2*	Small increase	Estimates suggest this will be the highest cost option. Will impact on a wider range of packaged food businesses, potentially having a small effect on price. However, food service prices will not be affected as they may potentially be under other options.
Option 3a	Very small increase	As for option 1a
Option 3b	Very small increase	As for option 1b

Product attributes

One of the challenges in reducing industrial trans fats is the difficulty of finding alternative ingredients and formulations that allow products to offer a similar experience to consumers in terms of their taste, texture, appearance and shelf-life. If these challenges cannot be adequately addressed, there is a danger that the satisfaction that consumers derive from affected food products will be adversely affected. Also, consumer choice could be affected when products would be taken from the market as reformulation is not possible.

Overall, evidence presented in the ICF study suggests that these issues do present challenges for some sectors of the food industry, but that these challenges are not insurmountable, also considering that products were produced before the wide introduction of trans fats in the middle of the 20th century. Some evidence collected by the external contractor ICF is provided in Annex 20. Options 1b and 3b – by mandating changes in product content – can be expected to have greatest potential impacts (Table 7). In a view of evidence where reformulation may prove difficult and result in the possible disappearance of some food items and/or a loss of product variety, it would be premature to conclude that product choice available for the consumer may be lost. As an example, the introduction of an industrial trans fats legislative limit in Denmark resulted in a reduction of industrial trans fats shortly after (in one year) its introduction without any obvious side effects for the population. Also in Austria and Hungary, no reduction of

product choice available for the consumer was observed. There remain some uncertainties as the proposed measures would cover the entire EU.

Table 7 Expected impact of each option on product attributes

Policy option	Expected impact	Comments
Option 1a	Negligible	Action will be voluntary – products facing technical challenges can be excluded
Option 1b	Small, negative	Some challenges in reformulating certain products to maintain same attributes. Changes will be mandatory, suggesting that some enforced changes may be required. However, no evidence of significant negative impacts from those countries that have taken action to date. Derogations to a 2% limit for products with low fat content may further contribute to limiting negative impact on product attributes
Option 2*	Negligible	As for option 1a
Option 3a	Negligible	As for option 1a
Option 3b	Small, negative	Some challenges in reformulating certain products to maintain same attributes. Changes will be mandatory, suggesting that some enforced changes may be required.

6.2.3. Internal Market impacts

Differences in product standards between Member States can distort the free movement of goods within the EU. National rules may impose higher costs on national operators, affecting competition in the market as a whole. They may also restrict access to domestic markets for producers in countries which do not adhere to the same standards.

In the absence of legal action at EU level, future national actions are likely, leading to further differences in standards across the EU. Further evidence with regard to Internal Market impacts is provided in Annex 21.

Significant differences between the options can be expected, with Options 1b and 3b having a significant harmonising effect. The voluntary options 1a and 3a would seek to raise standards across the EU, without affecting the legal framework. There is a risk that varying rates of progress and uptake of voluntary agreements could have a complicating effect and lead to further differences between countries and sub-sectors. Option 2, relating to labelling, would have no effect in harmonising product standards, but would aim to encourage consumers to make more informed choices. Options 3a and 3b, by focusing on eliminating partly hydrogenated oils rather than placing limits on industrial trans fats, would introduce differences compared to existing legislation in the mentioned seven Member States. This would potentially create confusion in the market and requiring some further action to harmonise standards at national level. Annex 21 provides a summary table and qualitative assessment of expected impact of each option on the Internal Market.

6.2.4. Competitiveness and trade impacts

A number of non-EU countries have introduced legal limits on industrial trans fats in food or banned the use of partly hydrogenated oils in food products (Canada, US). The majority of countries globally have yet to introduce legislation on industrial trans fats.

EU policy on industrial trans fats has the potential to impact on international trade in food products:

- Elimination of industrial trans fats from the EU food chain will help to position EU producers to sell to markets such as Canada and the US, as far as they are accessible, which have taken action to limit partly hydrogenated oils/ industrial trans fats;
- Limiting industrial trans fats use, by increasing costs for food businesses, could potentially hamper competitiveness in price sensitive export markets;
- Legal limits on industrial trans fats /partly hydrogenated oils applied to products sold in the EU would apply to foreign imports as well as domestic production, potentially reducing imports from countries that have not acted to reduce industrial trans fats;
- Voluntary measures could potentially increase costs for EU producers, while exposing them to competition from low cost, high foreign trans fats imports;
- Labelling measures would apply equally to imports and domestic products sold in the EU.

The net effect of these potential impacts is difficult to predict, and will vary between the different options.

Little evidence was found from the literature review of the ICF study to suggest that impacts on trade and competitiveness are likely to be significant, and in general the stakeholders interviewed by ICF did not express this as a concern. This is likely to be because:

- Extra-EU trade represents only a small proportion of the market for most of the industrial trans fats relevant food industry subsectors;
- Most companies active in international markets have already taken action to eliminate industrial trans fats from their products; and
- Any additional costs involved in eliminating industrial trans fats are a small proportion of industry output (as estimated above), such that the presence or absence of limits is unlikely to be a major factor influencing competitiveness.

Where consultees in the ICF study commented on trade issues, a general view was that action to eliminate industrial trans fats from food is taking place internationally, and that taking action on industrial trans fats will tend to enhance rather than reduce competitiveness. Pressure to reduce trans fats levels in foods and related legal measures is expected to increase worldwide in view of the plan to eliminate industrial trans fats

from global food supply published by WHO on 14 May 2018.¹⁴⁰ Overall, the expected impact of all the options is small, further details are provided in Annex 22.

6.2.5. Impacts on SMEs

The EU's food and drink industry is a highly diversified sector with many companies of different sizes. It includes more than 280,000 SMEs which generate almost 50% of the sector's turnover and value added and provide two thirds its employments.¹⁴¹ SMEs are particularly prevalent in particular subsectors – such as bakeries and food service – which face greater challenges in reducing industrial trans fats.

Little specific evidence was found in the ICF study through the literature review or stakeholder interviews or the OPC¹⁴² regarding the particular impact on SMEs resulting from action to address the industrial trans fats issue. However, interviewees expressed a general view that SMEs may be impacted by the different policy options on the grounds that:

- SMEs are in general less likely than their larger counterparts to have taken action to eliminate industrial trans fats from their products; and
- SMEs generally have less staff time and fewer resources to devote to product development, and therefore may face greater challenges to reformulate their products

On the other hand, evidence collected by ICF also suggests that many SMEs will benefit from action by their suppliers to reformulate ingredients and this will provide simple routes to compliance with limits on industrial trans fats. For example, many small bakeries will simply use alternative fats and oils developed by larger firms that supply ingredients to the baked goods sector. Substitute frying oils have been developed for use by food service businesses.¹⁴³ Micro-businesses, which are prevalent in the food service sector, are likely to make use of these supply chain solutions and may, as a result, incur smaller costs than businesses from the food manufacturing sector. It should be noted, however, that the size of business is not necessarily correlated to the nature and size of the costs borne. Also, evidence from Canada was found by ICF that SMEs were able to follow reformulation activities of large multi-national companies. There was a tendency for SMEs to copy these reformulated products rather than investing in own research and development. As a result, the measures were not as costly to SMEs as may be assumed.

With regard to a considerable part of the SME food business operators in the EU, the hospitality industry, empirical evidence collected by ICF points to the fact that a legal limit on industrial trans fats has a rather limited impact or non-existent impact. The: industrial trans fats contained in meals prepared by hospitality businesses are only the result of the content of such trans fats in supplies bought from the processing industry. If

¹⁴⁰ Eliminating trans fats is now listed as a target in WHO's strategic plan, which directs the global body's work over the next five years. <http://www.who.int/news-room/detail/14-05-2018-who-plan-to-eliminate-industrially-produced-trans-fatty-acids-from-global-food-supply>

¹⁴¹ FoodDrinkEurope (2016) Data and Trends – European Food and Drink Industry 2016.

¹⁴² Details of the results of the OPC are provided in Annex 2

¹⁴³ This is supported by the views from respondents to the validation consultation, who mentioned the experience from food service SMEs in Austria and Denmark.

the supplies are already below the limits, food prepared by hospitality businesses will always be below the limits.

Some further evidence on the potential impacts on SMEs is provided in Annex 23.

Overall, the evidence collected in the ICF study suggests that:

- SMEs will bear a significant proportion of the costs identified above, particularly because of their prevalence in the affected sub-sectors, and the tendency for SMEs to have been less active to date in reformulating their products;
- Many SMEs will be able to eliminate industrial trans fats by accepting alternative ingredients developed by their suppliers, and will therefore not face significant costs;
- Those SMEs forced to reformulate their products will face additional costs and may experience greater challenges than larger companies because of their limited resources for R&D. For many small businesses, reformulation may be relatively simple, and require a few hours' work to test an alternative recipe. The greater impacts will be on those SMEs facing more complex and costlier reformulation.
- The impact of the measures is likely to be greater for SMEs operating in the food manufacturing sector rather than SMEs operating in the food service sector.

The alternative options will have different impacts on SMEs:

- The legal options (Options 1b and 3b) will require all SMEs currently with non-compliant products to take action, potentially imposing significant costs on some;
- The mandatory labelling Option (Option 2) will place similar obligations on SMEs and larger companies. SMEs should be familiar with labelling obligations so should not face particular technical barriers. However, some SMEs may face greater difficulties in absorbing the additional costs involved;
- SMEs which face challenges in reducing industrial trans fats may choose to opt out of a voluntary agreement (Options 1a and 3a). These options are therefore likely to have least impact on SMEs;

Table 8 provides a summary table and qualitative assessment of expected impact of each option on SMEs. A specific SME test is provided in section 7.8, informing about the average cost per SME for the different options. Transition periods will help to mitigate the above mentioned costs. Empirical evidence from a Hungarian SME active in the chocolate confectionary sector demonstrates that adaptation to legal limits (Option 1b) is possible, however, sufficient transition periods, in the specific case between 1.5 to 2 years, are crucial as longer transition periods mitigate cost burden of the necessary adaptations.^{144 145} Furthermore, larger food business operators that have removed trans

¹⁴⁴ <https://eu-brusszel.mfa.gov.hu/eng/news/tfa-reduction-a-low-hanging-fruit-to-reap-for-securing-better-health>

fats from their portfolio, as well as food business associations have committed to guide companies, particularly SMEs, that have not taken action through the process of removing trans fats from all foods in order to meet a legal limit^{21 22}.

Table 8 Expected impact of each option on SMEs

Policy option	Expected impact	Comments
Option 1a	Small	SMEs facing significant costs may opt out of the voluntary agreement
Option 1b	Potentially significant, negative	All SMEs producing foods above legal limit will be forced to take action SMEs may face relatively greater costs and challenges compared to larger firms Many SMEs will adopt solutions developed by suppliers, limiting costs
Option 2*	Potentially significant, negative	SMEs will face similar costs to larger companies Costs of this option are relatively large Some SMEs may face difficulties in absorbing increased costs
Option 3a	Small	SMEs facing significant costs are likely to opt out of the voluntary agreement
Option 3b	Potentially significant, negative	All SMEs producing foods containing partly hydrogenated oils will be forced to take action SMEs may face relatively greater costs and challenges compared to larger firms Many SMEs will adopt solutions developed by suppliers, limiting costs

6.3. Environmental impacts

Measures to reduce the use of industrial trans fats have potential impacts on the environment, by altering the use of ingredients and production processes. The primary concern raised in studies to date, and mentioned by interviewees of the ICF study, relates to the substitution of palm oil, a trans fats free, semi-solid fat, for partly hydrogenated oils, and the potential of increased palm oil production to cause deforestation.

The extent of such impacts depends on:

- The degree to which palm oil – as opposed to other possible ingredients – is used as a substitute for partly hydrogenated oils, and hence the extent to which limits on industrial trans fats production result in increased demand for palm oil;

¹⁴⁵ <https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf>

- The degree to which any increase in palm oil demand results in environmental damage, which depends on the sustainability or otherwise of the production systems;
- The relative environmental impacts of palm oil compared to the oils that are partly hydrogenated (typically soy) and alternatives.

Some qualitative evidence in relation to substitutes for partly hydrogenated oils and their environmental impacts collected by the external contractor is provided in Annex 24.

Possible impacts of alternative options

Overall, the situation is complex and the resulting environmental impacts are difficult to predict. It is clear that:

- Palm oil is an attractive substitute for partly hydrogenated oils, particularly in the baked goods sector, on account of its physical properties and cost-effectiveness;
- It is therefore likely that limits on industrial trans fats will lead to increases in use of palm oil in products currently using partly hydrogenated oils. Overall consumption of palm oil in the EU will not necessarily increase, as it is forecasted to decline in the food sector as a whole, although global demand is growing;
- Increased use of palm oil is of concern since it has contributed to deforestation, with adverse impacts on biodiversity and climate;
- The EU is a leading player in the development of markets for sustainable palm oil. There is currently an excess supply of sustainably certified palm oil and any increase at EU level resulting from limits on partly hydrogenated oils could be met from sustainable sources, if consumers were willing to pay a price premium;
- As a result, action on industrial trans fats need not necessarily have an adverse environmental impact. However, there are no guarantees that any palm oil used to replace partly hydrogenated oils would be sustainably sourced; adverse impacts on biodiversity and climate are therefore a risk;
- However, the use of other vegetable oils such as soy also contributes to deforestation, and it is likely that current use of partly hydrogenated oils in food in the EU already impacts adversely on biodiversity and climate. The net effect of any change towards palm oil is difficult to assess. One advantage of palm oil is that it produces a high yield of oil per hectare compared to alternatives;
- Any potential negative impacts on the environment can be mitigated by further action by the EU food industry to ensure that palm and other oils are sustainably sourced.

It is therefore unclear whether or not any net impact on the environment as a result of action to reduce industrial trans fats will be positive or negative. However, it is clear that the magnitude of any environmental impact will be greater for those options leading to greater change in industrial trans fats. On this basis, options 1b and 3b can be expected to lead to greater environmental changes than Options 1a, 2 and 3a. Annex 24 provides a summary table and qualitative assessment¹⁴⁶ of expected impact of each option on the environment.

6.4. Impacts of combined options

Any additional benefit of adding labelling requirements to a legal limit on industrial trans fats or a ban on partly hydrogenated oils is expected to be limited as population industrial trans fats intake will already be reduced to very low levels under Options 1b and 3b.

Combining a voluntary agreement with labelling may be expected to have a higher impact in reducing the population industrial trans fats intake and will lead to greater cost savings and disability-adjusted life years reduction than adopting only one of the two options. However, according to estimates by ICF, details are provided in Annex 25, these benefits are significantly less than those delivered by Options 1b and 3b.

Because all of the combinations of options include Option 2, which has high costs of relabelling, product testing and awareness raising, each combination of options also has high costs. Therefore, even though combining voluntary agreements with mandatory labelling is estimated to lead to additional benefits (while remaining at levels significantly below Options 1b and 3b), the costs are high compared to Options 1b and 3b, as a result of the high relabelling and promotional costs of Option 2. Details are provided in Annex 25.

7. HOW DO THE OPTIONS COMPARE?

This section considers how the options compare in the expected performance against the stated general and specific objectives and how the options compare in effectiveness, efficiency, coherence and with reference to the proportionality principle.

Of note, with regard to the validity and reliability of modelling results, a number of uncertainties need to be highlighted in order to avoid a false impression of scientific accuracy. Overall, there are limitations of the ICF modelling exercise due to the assumptions needed, data scarcity linked to intakes and future projections, paucity of evidence related to other trans fats health effects, possibilities to model more complex dietary changes making strong simplification necessary. The main purpose of the model was to support with modelling the relative comparison of the viable policy options against a reference of no policy; this outcome of a legal limit performing better under this specific framing of a public health economic evaluation in terms of health benefits and

¹⁴⁶ It was not possible to gather quantitative evidence for environmental impacts due to the complexity of the issue

cost-effectiveness has been shown to be robust. Nevertheless, the relative findings are based on past experience. There is inevitably uncertainty how the future trans fats intakes might develop under the alternative policy scenarios. Annex 4 provides additional explanations about uncertainties.

7.1. General objective 1: Ensuring a high level of health protection for EU and Specific objective 1: Reduce intake of industrial trans fats in the entire EU for all population groups

7.1.1. Direct health impacts

The direct health impacts for EU citizens are positive under all options relative to all variants of the baseline scenario. The benefits of prompt action are strongly amplified if, in the baseline scenario, industrial trans fats intake does not decline. If, without further EU intervention, industrial trans fats would be phased out 10 years through industry actions then adopting options 1b or 3b could save around 4 million disability-adjusted life years that would otherwise be lost to coronary artery disease. If, however, industrial trans fats levels were to otherwise persist at current levels then legislating to remove them would conserve 66 million disability-adjusted life years.

The legal options (option 1b, 3b) deliver larger benefits than the voluntary agreements (option 1a, 3a) and labelling option (option 2). There is also a much higher degree of confidence that the legislation will deliver positive results – there is significant uncertainty about whether food business operators that are still placing products high in industrial trans fats on the market will participate in voluntary agreements, and how far consumers will respond to a modification of the nutrient declaration that adds reference to products' trans fats content. In that context, the figures for options 1a, 3a and 2 in the Table 56 and Figure 13 in Annex 26, 1. may be regarded as upper estimates of potential impact.¹⁴⁷

Health benefits are expected to follow close behind the action taken by food business operators to reduce industrial trans fats. Experience from countries that have acted suggests that signalling that action is going to be taken can result in benefits starting before the legislation comes into force as some producers take proactive action in advance of the deadline.

The health impacts of derogations providing for authorised use of industrial trans fats for technical applications in low fat products under option 1b or partly hydrogenated oils under option 3b are uncertain.

7.1.2. Direct and indirect economic impacts of changes in health status

All options deliver savings in direct and indirect economic costs of industrial trans fats-related disease. These comprise changes in:

¹⁴⁷ Annex 26 provides a slightly updated version of table 3 illustrating this concept and provides furthermore a figure for illustration

- Healthcare expenditure: This is a benefit that accrues principally to healthcare service providers and hence governments (where healthcare is publicly funded) or health insurers. Some of the benefits would accrue indirectly to citizens, whether as taxpayers or purchasers of health insurance.
- The wider economic impact of the changes to health status and coronary artery disease incidence triggered by EU industrial trans fats policies, focusing specifically on changes in productivity and in changes in demand for informal care. Productivity changes will accrue initially to employers and then to the economy as a whole. Changes in demand for informal care will impact directly on carers and may have a wider impact on economic output (e.g. where someone is able to continue in work because the incapacity of a family member due to coronary artery disease is avoided).

The analysis, using the model of the JRC, has calculated the present value of benefits over an 85 year horizon.¹⁴⁸ In baseline variants B1 and B2 industrial trans fats would be phased out after 10 and 15 years respectively so industrial trans fats would not be causing new and additional health impacts after those dates. In variant B3 industrial trans fats intake continues to cause negative health impacts in the baseline scenario in perpetuity so the options that reduce intake avoid a long stream of health impacts. The monetary benefits under B3 are therefore substantially larger than under the other two variants (Annex 26, Table 57).¹⁴⁹

The analysis shows that the uncertainty in the baseline is not grounds for inaction – the slower the phase-out of industrial trans fats in the baseline, the greater the health impacts of effective EU action increase. The model is constructed to work at EU level, with reference to the EU population and EU-level cost factors taken from third party sources.

The legal options (1b, 3b) deliver larger benefits (cost savings) than either the voluntary agreements (1a, 3a) or the labelling option (2). The assumptions in the model (whereby the residual industrial trans fats intake under a partly hydrogenated oils ban is the same as the intake under a 2% limit) mean that 1b and 3b are equivalent in the healthcare savings delivered and deliver much larger savings than the alternatives. If option 1b was applied to ingredients as well as final products it would have the effect of implementing a partly hydrogenated oils ban of the kind specified in option 3b. It seems likely that this would deliver additional health benefits, but the information required to estimate those effects are not available.

As with the human health benefits, there is a much higher level of confidence that the legal options will deliver the scale of benefits indicated – there are significant uncertainties attached to the estimate of benefits of the voluntary agreements and labelling, and the values indicated are likely to be upper limits. This assumes compliance

¹⁴⁸ The presentation here replicated the Joint Research Centre of the European Commission model outputs in combining the direct and indirect costs. ICF looked at separating the two categories of impact in future presentations of the results. Annex 4 provides details about the background of choosing a 85 year horizon

¹⁴⁹ Annex 26 provides a slightly updated version of table 2 as the direct and indirect cost savings for the combined options are added, and provides furthermore a figure for illustration

by food business operators with the legislation, which should be complemented by effective communication, by monitoring and enforcement by regulators.

Combined options are also considered:

- Combining mandatory labelling with legislation is not expected to yield significant additional health benefits over and above those delivered by Option 1b or 3b. There are theoretical direct and induced effects arising from consumers having a preference for industrial trans fats content closer to zero than the 2% legislated threshold, however the labelling option may also lead to adverse effects and heightened social inequalities.
- Combining mandatory labelling with a voluntary agreement is expected to yield additional benefits in terms of further avoided health-related costs, through synergistic effects, estimated at EUR 19,248 million for the combined option as compared to EUR 11,078 million for Option 1a and 3a and EUR 15,353 million for Option 2.

The performance of options against the specific objective 1 mirrors that for General Objective 1 described above, as well as for General Objective 3 on health inequalities. The performance of each option is summarised in Table 58 presented in Annex 26.

7.2. General objective 2: Contribute to the effective functioning of the Internal Market for foods that could contain industrial trans fats and Specific objective 2: Ensure that the same rules/conditions apply in the EU to the manufacturing and placing on the market of foods that could contain industrial trans fats, so as to ensure legal certainty of EU food business operators within and outside the EU

The legal options (Options 1b and 3b) impose a uniform approach across all entities that place food on the market across the EU.

Option 2 would provide a consistent level of visibility for consumers of industrial trans fats content in products but not provide consistent protection against the health impacts of high industrial trans fats products for those not aware of the risks. As it does not set limits for industrial trans fats content, it would also not fully address legislatively-driven cost differentials between producers in national markets where limits on trans fats content apply and producers from other countries.

With full participation and if fully effective the voluntary agreements (option 1a, 3a) approximate to the effects of legislation in their consequences for the Internal Market, but the evidence collected by ICF suggests that participation will be at best partial.

Options 3a and 3b, which aim to eliminate partly hydrogenated oils rather than place limits on industrial trans fats, would introduce differences compared to existing legislation in the seven Member States, potentially creating some confusion in the market and requiring some further action to harmonise standards at national level.

There are also potential indirect effects of non-legislative action in so far as, in the absence of EU legislation, there are some indications that certain Member States may adopt national legislation that varies in specification from those already in place and adds to the emerging legal complexity in this aspect of the market. Table 9 summarises the options' performance against this general objective.

Table 9 Appraisal of options' performance under general objective 3: Contribute to the effective functioning of the Internal Market for foods that could contain industrial trans fats

Policy option	Expected impact	Comment
Option 1a	(+)/(-)	Small impact, unclear whether positive or negative. Existing differences in legal standards will remain. Voluntary standards will be extended towards the legal limits existing in seven countries. However, variable uptake could lead to varying rates of progress and compliance in different Member States.
Option 1b	++	Significant, positive impact. Harmonisation of standards ought to remove industrial trans fats regulation as a factor contributing to differential operating conditions for firms in the Internal Market and avoid the legal complexity arising from differences in Member State law on this issue.
Option 2*	0	No change. No effect on product compositional standards, though the uniform requirement for transparency on industrial trans fats content provides information to facilitate informed consumer choice. Consumers not protected from high industrial trans fats products. Firms producing in countries that have imposed industrial trans fats limits may continue to face additional ingredient costs as compared to equivalent producers in other Member States.
Option 3a	(+)/(-)	Small impact, unclear whether positive or negative. Existing differences in legal standards will remain. Voluntary standards will aim to extend efforts to reduce industrial trans fats across the EU. However, variable uptake could lead to varying rates of progress and compliance in different Member States. In addition, focusing voluntary action on eliminating partly hydrogenated oils, when legislation in five countries places limits on industrial trans fats, could cause confusion.
Option 3b	+(+)	Significant, positive of impact via harmonisation of standards. EU legislation would differ from that in five Member States (given focus on partly hydrogenated oils ban rather than industrial trans fats limit), potentially creating some confusion and

Policy option	Expected impact	Comment
		requiring harmonisation of existing national rules.
Option 1a/3a + 2	(+)/(-)	Combining labelling with voluntary agreements is not expected to deliver Internal Market effects different to voluntary agreements.
Option 1b/3b + 2	++	No additional impact over and above the legal options is anticipated by adding a labelling requirement.

Note: scale of - - to + + indicates a range of strongly negative (- -) to strongly positive (+ +) impacts, with '0' being neutral.

The results for the specific objective 2 mirror those for General Objective 3 described in the table above. The options vary in the number of food business operators directly affected. These differences are determined by the sectors engaged (e.g. non-packaged goods are excluded from Option 2) and the level of participation expected. An important qualifying comment is that most of those subject to legislation will not need to act to reformulate products because their products do either not or not anymore contain industrial trans fats. There is uncertainty about the number of firms that will engage in the voluntary agreements.

Option 1b provides full and immediate legal certainty. Option 3b provides general legal certainty but creates challenges for those Member States that have already legislated and adopted the 2% limit model rather than a partly hydrogenated oils ban. These countries would need to adjust their domestic legislation to fit the EU model.

The other options provide less certainty in that there is the potential for unilateral Member State legislative action in countries that want to go further than Options 2 or 1a/3a provide for.¹⁵⁰

7.3. General objective 3: Contribution to reducing health inequalities, one of the objectives of Europe 2020

The legal options (1b, 3b) could potentially remove all present industrial trans fats-related health inequalities, which is not the case for the alternative options. All food consumers would benefit irrespective of social-economic, demographic status or consumption patterns. The impact of the alternatives is constrained by the limits to engagement by food business operators that have not already acted, and limits to responsiveness of consumers to trans fats-related additions to the back-of-pack nutrient declaration.

The performance of each option is summarised in Table 39 in Annex 15.

7.4. Effectiveness

Effectiveness is measured by the extent to which options are expected to achieve the target objectives, the three general objectives.

¹⁵⁰ Details are provided in Annex 27

The main findings relevant for assessing the effectiveness of each option in achieving these objectives are specified in Table 9.

In relation to the health impact, the used model considers only coronary artery disease. Other potential benefits of lowering trans fats intake, which have been referred to in the literature such as impacts on insulin sensitivity, obesity, diabetes, cancer, or early growth and development, are excluded because of inconsistent evidence¹⁵¹ and lack of data. As such the impact assessment can be considered to be conservative with respect to achievable health benefits resulting from (fast) industrial trans fats removal from the food supply.

Table 10 Effectiveness of all options and combinations of options under variant 2 of the baseline scenario

	Option 1a	Option 1b	Option2	Option3 a	Option3 b	Options 1a/3a + 2	Options 1b/3b + 2
disability-adjusted life years saved	0.7m	6m	1m	0.7m	6m	1.3m	6m
Health inequalities reduction	(+)	++	(+)	(+)	++	+	++
Internal Market	(+)/(-)	++	0	(+)/(-)	+(+)	(+)/(-)	++

Note: scale of - - to + + indicates a range of strongly negative (- -) to strongly positive (+ +) impacts, with '0' being neutral.

Options 1b and 3b would be the most effective, in that they would achieve the greatest improvement in terms of health protection, reduction of health inequalities and contribution to the functioning of the Internal Market.

Option 2 would also prove effective in improving the level of health protection for EU consumers; however the assessment does not suggest that it would be effective in addressing health inequalities nor the current imbalances and fragmentation of the Internal Market in this area.

Options 1a and 3a would be less effective than other options in achieving a high level of health protection for EU consumers, and would contribute less than Options 1b and 3b to reducing health inequalities. Since voluntary agreements would be heavily dependent on the level of organisation of the food industry, they are unlikely to achieve any significant results in terms of addressing the fragmentation of the Internal Market on the matter of industrial trans fats.

The combination of Options 1a and 3a with Option 2 offers potential to provide greater health benefits and reductions in inequalities than these options alone, but does not offer

¹⁵¹ European Food Safety Authority, 2010, Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol, EFSA Journal 2010; 8(3):1461

added benefits with respect to the Internal Market. Combining Option 2 with Options 1b and 3b does not enhance effectiveness compared to Options 1b or 3b alone.

7.5. Efficiency (balance of costs and benefits)

The analysis has provided quantitative estimates of the administrative and compliance costs for businesses and public authorities, as well as the social benefits in terms of reduced costs of healthcare. Other relevant costs and benefits, including those relating to health inequalities, the Internal Market, consumers, international trade and the environment, have been assessed qualitatively.

Because some effects have been assessed in qualitative terms only, a comprehensive cost-benefit analysis is not possible. However, it is possible to compare those costs and benefits which have been quantified in money terms. In doing so, it is helpful to consider the likely significance of those costs and benefits that have not been quantified. Furthermore, the degree of uncertainty surrounding the quantified estimates is important.

The cost analysis has attempted to estimate a wide range of administrative and compliance costs, albeit with some uncertainty and the application of a range of assumptions. There is uncertainty about the environmental impacts, which could be positive or negative. The costs of agreeing a shared definition of partly hydrogenated oils and defining a common test for detecting partly hydrogenated oils (under options 3a and 3b) are undetermined but expected to be small relative to the overall costs (and benefits) of the proposed options.

It could be argued that a greater proportion of the costs of the proposed options are likely to have been captured than the benefits since:

- The health benefits are valued only in terms of savings in healthcare expenditure, and gains in productivity. Other health benefits – particularly in relation to human welfare – have not been estimated;
- The estimated savings in healthcare costs relate only to the reduced incidence of coronary heart disease. Other adverse health effects linked to trans fats are excluded.

Monetisation of these ancillary health benefits would increase the overall scale of the benefits. The understatement of benefits is expected to be much larger than any understatement of costs.

Table 11 summarises the monetised estimates of costs and benefits of the different options. In all cases the value of estimated savings in health-related costs exceeds those of estimated administrative and compliance costs. Options 1b and 3b are estimated to deliver the largest net benefits and Option 2 the smallest net benefits.

Table 11 Comparison between the monetised costs (administrative and compliance costs) and benefits (health-related savings) for the 5 options under variant B2 of the baseline scenario (NPV, EUR)

	Option 1a	Option 1b	Option 2	Option 3a	Option 3b
Administrative and compliance costs	50m	297m	9826m	59m	346m
Health-related savings	11,078m	94,008m	15,353m	11,078m	94,008m
Ratio of monetised benefits to costs	222	317	1.6	189	272

Based on this evidence, action to limit industrial trans fats in food sold direct to consumers appears to be a very efficient use of resources. Legislation to limit industrial trans fats offers the largest potential net gains, followed by legislation to ban partly hydrogenated oils. A legal limit on industrial trans fats content avoids the need to agree a partly hydrogenated oils definition and to establish the capacity across the EU to test oils for compliance.

The finding that legislation to limit industrial trans fats or ban partly hydrogenated oils are the most efficient of all options is supported by *ex-ante* analyses in the US and Canada, both of which found large benefit: cost ratios for legal limits on trans fats/ partly hydrogenated oils, details are summarised in Annex 28.

The same result emerges when looking at cost-effectiveness as measured by the cost of the average disability-adjusted life years saved, as shown in Table 12. Option 1b delivers disability-adjusted life years at the lowest cost under all variants of the baseline scenario. The cost-effectiveness of the policies by this measure improves significantly in the transition from variant B1 to B2 to B3 (as the costs are assumed to be fixed but the health benefits increase substantially in B3 as compared to B1). The legal options emerge as a highly cost-effective mechanism for ‘purchasing’ health improvements.

Option 2 imposes significant ‘deadweight costs’ on the food manufacturing sector – it imposes additional labelling costs on food business operators for products that contain no industrial trans fats and where there is therefore no direct benefit. Firms that have already removed industrial trans fats from their products and firms whose products will never contain industrial trans fats by virtue of their composition will still need to change the nutrient declaration.

Voluntary agreements also have the potential for deadweight costs if there is substantial participation by firms that already meet the agreements’ objectives.

Of note, the period over which benefits and costs are assessed is in principle the same, but the costs of implementation are zero after 10 years irrespective of the option implemented. An important difference in the profile of costs and benefits is that costs are incurred only while the options are being implemented, while benefits extend over a longer time period as actions to eliminate industrial trans fats from the food chain now will affect the health of the population long into the future.

Benefits under the different baselines are expected to start to materialise well before 10 years. Generally, benefits are assessed against baseline impacts over a 85 year period. While the changes in intake of industrial trans fats would take place only during the 10 year period, these would have ongoing health impacts which are measured over a longer 85 year period.

Table 12 Cost-effectiveness measure of options by variant of the baseline scenario

Policy option	EUR per disability-adjusted life year saved		
	B1	B2	B3
Option 1a	>125	>71	>5
Option 1b	74	50	5
Option 2	>14,037	>9,826	>289
Option 3a	>148	>84	>6
Option 3b	87	58	5

Note: ‘>’ indicates that the figures show the lowest expected cost per disability-adjusted life year saved given the greater uncertainty about the efficacy of labelling and voluntary agreements in changing intake.

7.6. Coherence with other EU policy objectives

There were concerns from industry that the legal obligation to label the presence of partially or fully hydrogenated oils in a product might interact negatively with a legal limit on industrial trans fats. Industry stakeholders consider that consumers who have been monitoring the mention of “hydrogenated oil” on labels to avoid industrial trans fats may not understand the difference between “partial” and “fully” hydrogenated oil. Products compliant with the legal limit on industrial trans fats content but containing fully hydrogenated oil could be penalised, according to industry. However, studies on consumer awareness in the EU point to very low levels of consumer knowledge about industrial trans fats and the link to partly or fully or hydrogenated oils.¹⁵² Option 3 b would potentially be a measure in coherence with measures adopted in the US and Canada, facilitating external trade with those regions as similar product requirements are established, in line with EU policy objectives to facilitate external trade,.

7.7. Proportionality

Based on the appraisal summarised above the legal options appear to be the most proportionate solution to the problem of the health consequences of industrial trans fats consumption and the Internal Market effects of uncoordinated approaches to tackling them. The legal options are broad in scope as they in principle concern all food business operators. However, more significant costs are imposed only on those food business operators still using ingredients with industrial trans fats levels above the legal limit and

¹⁵² https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_legislation_study_food-info-vs-cons-decision_2014.pdf

that need to use alternative ingredients to comply. This is in contrast to the labelling option which in many cases will impose costs without generating a corresponding benefit. The scale of the direct health benefits on offer, and the associated reductions in burdens on healthcare services and expenditure are substantial.

7.8. Specific tests: SME test

Based on the screening appraisal, the Competition Test and the Fundamental Rights tests specified by the Better Regulation toolbox do not apply. Specific consideration is needed of the impacts on SMEs, which form a large share of the population of food business operators affected. The ICF study collected evidence to document the perspective from SMEs. This has included direct interviews with a small number of SME representatives (see Table 20 in Annex 4). Due to the challenges of reaching out to SMEs directly, the study team has aimed to clarify the SME perspective by engaging with business organisations that represent a large proportion of SMEs within the sector impacted by the policy options. The majority of members were SMEs for nine of the 16 business organisations who responded to the validation consultation in the ICF study.

The assessment of the impacts on SMEs is summarised below. Eurostat data indicate that SMEs account for:

- 99% of enterprises and 50% of value added in the food manufacturing sector; and
- 99.9% of enterprises and 75% of value added in the food service sector.

The number of SMEs falling within the scope of each option is estimated in Table 13. The number is larger for Options 1a, 1b, 3a and 3b, which cover the food service sector, than Option 2, which relates to pre-packaged foods only. In practice, many SMEs will not be affected by Options 1a and 3a as they will choose not to participate in the voluntary agreement.

Table 13 Cost-effectiveness measure of options by baseline variant

Policy option	Number of SMEs in scope	Nature of measure
Options 1a, 3a	1,079,169	Voluntary
Options 1b, 3b	1,079,169	Mandatory
Option 2	258,020	Mandatory
Combined options 1a/3a and 2	1,172,789	Mandatory & Voluntary
Combined options 1b/3b and 2	1,172,789	Mandatory

The number of SMEs in scope is largest for the combined options, as (like Option 2) they affect all pre-packed food businesses (whether or not their products are likely to contain industrial trans fats), and, like Options 1 and 3, they affect food service as well as manufacturing businesses.

The estimated costs of the options for SMEs are given in Table 14. These costs have been estimated by estimating the share of the overall business cost estimates above that are borne by SMEs. It is assumed that the share of administrative costs borne by SMEs is proportionate to the number of SMEs in the relevant sectors, and that the share of compliance costs is proportionate to the share of output accounted for by SMEs. These costs are then divided by the overall number of SMEs to estimate the average cost per business.

The estimated average cost per business (expressed in present value terms) ranges from €32 for Option 1a to €18,569 for Option 2. This includes both one-off and recurring costs.

Table 14 Present value of expected costs incurred by SMEs

Policy option	Administrative costs (M EUR)	Compliance costs (M EUR)	Total costs (M EUR)	Average cost per SME (Euro)
Option 1a	3.2	31.0	34.1	32
Option 1b	17.7	179.2	196.9	182
Option 2	6.6	4,784.4	4,791.0	18,569
Option 3a	3.3	36.9	40.2	37
Option 3b	18.7	211.9	230.6	214
Option 1a+2	17.6	4,784.4	4,802.0	4,095
Option 1b+2	18.6	4,784.4	4,803.0	4,095
Option 3a+2	6.6	4,784.4	4,791.0	4,085
Option 3b+2	6.6	4,784.4	4,791.0	4,085

The country research looked specifically for evidence of impacts on SMEs but little was identified beyond reference to:

- The opportunity provided by supply chain innovation for SMEs to achieve compliance through switching to alternative oils or fats from their ingredient suppliers;
- The challenges some producers, including some small firms, had experienced in reformulation due to particular performance requirements of fats or oils in their production.

The average cost per SME for option 1b of 182 Euro seems to be not too excessive, however, as this is an average value individual SMEs may have to bear a larger cost burden. In order to mitigate the cost and therefore the risk for SMEs of being forced out of business, sufficient transition time would need to be considered. During such period, SMEs have to search for alternative ingredients and test them. Empirical evidence from Hungary (the confectionary industry) suggests that 1.5 to 2 years transition periods

(rather than the 1 year given in Hungary) would have helped the sector significantly¹⁵³. In the same vein, Slovenia provides for 1 year, also to help small businesses such as bakeries. A transition period of up to 2 years could be considered, which should enable SMEs to factor in reformulation costs and other costs in their planning to accommodate changes when it best suits their situation.

Apart from sufficient transition time, (technical) support from associations and larger food business operators could help SMEs to adapt. Both a numbers of multinationals as well as FoodDrinkEurope have committed to provide technical support to SMEs to eliminate partial hydrogenated oils from foods. Finally, technical (and economic) solutions provided by suppliers are expected to help SMEs to comply with the new regulatory requirements. Examples from Canada and from the Netherlands (both provided in detail in Annex 17.2) show that ingredient suppliers developed formulations to allow bakeries, as well as other producers such as margarine companies, the food service sector, and virtually all food companies to provide products with no trans fats and, in most cases, lower saturated fat. Ingredients to the bakery sector such as bread and pastry mixes were developed more than 10 years ago to replace partly hydrogenated oil with high levels of industrial trans fats content to fully hydrogenated oil with a industrial trans fats content below 2 %. The initiative of suppliers responded to regulatory requirements (including the legislation in Denmark) and customer demands (demands from large customers, supermarkets and producers of bakery products).

The evidence collected by ICF indicates that SMEs are likely to incur significant costs in order to comply with the measures. The views of stakeholders are that most SMEs will address the requirements by switching ingredients, relying on suppliers of oils and fats. This applies notably to food service SMEs: in some countries such as Austria or Denmark alternative oils have been purchased for frying that effectively enable compliance with the 2% limit on industrial trans fats content. However, the evidence collected by ICF also indicates that challenges will be greater in the food manufacturing industry, where SMEs are likely to encounter difficulties when reformulating their products. According to ICF, while business associations, mainly informed by the experience of very large manufacturers, may provide supporting information to SMEs, it is not certain that SMEs will be able to profit from the solutions developed by larger players in order to achieve compliance.

8. PREFERRED OPTION

The legal policy options (1b and 3b) perform better than the alternatives in relation to health benefits (measured in disability-adjusted life years), reduction in health inequalities, improvements in the functioning of the Internal Market, efficiency and proportionality. Details are provided in Table 50 in Annex 21, Table 11 and section 7.7.

The savings in health-related costs to society are very much greater than the incremental costs for all options except the labelling. The benefit: cost ratio is largest for options 1b and 3b. Details are provided in Table 11. Furthermore, legislation imposing a maximum

¹⁵³ <https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf>

limit to industrial trans fats content of products sold direct to consumers (option 1b) performs better in terms of efficiency and coherence than a legal ban on partly hydrogenated oils (option 3b) in that:

- Equivalent social benefits are delivered at a lower cost to the industry;
- Its approach is consistent with the measures already adopted by a number of Member States (and actions planned in others);
- Compared to option 3b, option 1b avoids the need to agree a partly hydrogenated oils definition and establish the capacity across the EU to test oils for compliance with it (both for enforcement purposes and for assurance within the supply chain).

A combination of either of the two options 1b and 3b with mandatory labelling of trans fats levels on pre-packed products (option 2) would raise overall costs significantly. Such a combination is unlikely to deliver added social benefits.

The expected benefits of the voluntary options (1a or 3a), while positive, are smaller and much less certain, generating smaller overall costs, and providing much smaller expected benefits than options 1a or 3a. The members of the food business organisations that are likely to participate in EU voluntary agreements have already reformulated their products to reduce industrial trans fats levels or have eliminated industrial trans fats from their products completely. Research collected by ICF suggests that the businesses responsible for much of the residual industrial trans fats in the food chain are unlikely to participate in an EU agreement, either directly or through representative organisations. The voluntary options do not provide the assured protection that is delivered by the legal alternatives.

In summary, legal policy options (1b and 3b) are the preferred options. Legal action at EU level to reduce industrial trans fats in food would generate positive impacts on health that are substantial as compared to the costs. These measures would substantially remove industrial trans fats-related health inequalities, provide assured protection to consumers across the EU, and support the integrity of the Internal Market. They would also help to ensure a consistent standard of food quality across the EU. The results are robust across all foreseen variants of the baseline scenario. The options that perform best in the appraisal are a legal limit of 2% on industrial trans fats content on food products sold directly to consumers and a legal ban on partly hydrogenated oils. A legal limit of 2% on industrial trans fats content performs marginally better than a legal ban on partly hydrogenated oils in terms of efficiency and of coherence with existing Member State legislation. Therefore, selecting between 1b and 3b, option 1b is the preferred option.

The preferred option is 1b rather than 3b, even though both achieve the same health benefits for the following reasons:

Efficiency and coherence

Option 1b) performs better in terms of efficiency and coherence with existing Member State laws on industrial trans fats than a legal ban on partly hydrogenated oils (option 3b)

in that equivalent social benefits are delivered at a lower cost to the industry; Its approach is consistent with the measures already adopted by a number of Member States (and actions planned in others); Compared to option 3b, option 1b is not linked to enforcement challenges: for option 3b a definition of partly hydrogenated oils and a test would need to be established. However, available tools, such as the IV value would pose the following challenges: (i) there is no health or consumer benefit rationale as a basis for the use of iodine value as an enforcement tool; (ii) an iodine value cannot be directly related to TFA content; (iii) there are technological problems to assess the iodine value on a composite food product, which also is not a robust indicator for the presence of industrial trans fats.

Acceptance

Particularly industry in the EU has clearly expressed preference for option 1b as compared to option 3b. Also consumer organisations and health NGOs have expressed agreement with and support for option 1b. The European Parliament and the Council have called for legal limits; particularly the 7 Member States that have already implemented legal limits are in favour of such an EU wide measure, option 3b would need to be introduced as a new legal measure in all Member States, option 1b only in 21 Member States. The same would apply to food business operators where with option 3b they would need to adjust throughout the EU, while for option 1b only FBOs not active in the 7 Member States with existing legal measures would need to adapt, FBO active in 4 of the 7 Member States would need to slightly adapt to the harmonised legal limit of 2 % on fat basis. Choosing option 3b is expected to meet some opposition, particularly from industry side, but potentially also from the MS that already have a legal limit in place.

In relation to option 1b following the model applied in Member States already, derogations for low fat products could be considered. However, the health impact of such derogations needs to be taken into account. Four of the 7 Member States with national legal limits apply different limits for lower fat products. In view of an EU level legal limit, a legal limit of 2 % on fat basis is in line with EFSA and WHO recommendation, seems achievable in practice and is generally accepted by both consumer organisations as well as health NGOs on the one hand, and industry on the other hand.

Small and micro enterprises constitute the majority of food business operators in the EU. Furthermore, particularly those enterprises are assumed to be contributing to a high degree to still high intakes of industrial trans fats as they have not yet followed past reformulation trends. Further derogations for those SMEs, including for micro enterprises, would jeopardise the effectiveness of the measure.

In order to address the cost burden of the legal measure for SMEs, sufficient transition periods could be granted to ease the burden on them and reduce the risk that due to the measure, small and micro enterprises would be forced out of the market. Empirical evidence from Hungary (for the confectionary industry – a sector estimated to face major technical challenges) suggests that 1.5 to 2 years transition periods (rather than the 1 year given in Hungary) would have helped the sector significantly¹⁵⁴. In the same vein,

¹⁵⁴ <https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf>

Slovenia provides for 1 year, also to help small businesses such as bakeries. A transition period of up to 2 years could be considered, which should enable SMEs to factor in reformulation costs and other costs in their planning to accommodate changes when it best suits their situation.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

Present knowledge on trans fats intakes in most EU countries is not robust because it is often obtained from pragmatic dietary assessment surveys that do not rely on nutrient composition databases with complete trans fats data. Therefore, current levels in foods in the EU as well as intake levels cannot be determined with a very high degree of confidence, uncertainties remain. Collecting comprehensive data about industrial trans fats levels in foods before and after the measure enters into force is estimated to be costly. Dietary intake is measured in Member States not very frequently and collection methods may have to be considerably adjusted and refined in order to capture differences in industrial trans fats intake, which would be also linked with considerable costs.

Using assessment methods and instruments already in place could generate valuable indications and estimates about development of industrial trans fats levels in foods after the measure is implemented, and could be considered an alternative, more cost-efficient way to measure success of the initiative.

A number of instruments are available at EU level to monitoring health impacts. However, to assess whether those health impacts are linked with the proposed initiative could only be determined in a dedicated research project. Methods are already in place to collect health data in the EU with regard to cardio vascular diseases in the years following the implementation of an EU level policy measure. Such data are regularly collected, such as for a two-year initiative undertaken by the European Commission in 'The State of Health in the EU initiative'.

The evolution of levels of industrial trans fats in foods will be assessed regularly by Member States checking compliance. DG Health and Food Safety audits and related non-audit activities ensures that EU legislation on food safety is properly implemented and enforced and could integrate the issue of trans fats levels in foods in the multi-annual programme. Costs of analysis would be borne by Member States, costs for the auditing by the Commission.

With regard to enforcement issues, in 2016, the JRC of the Commission provided support in developing a reliable methodology to determine levels of industrial trans fats. The JRC delivered their final report 'Analytical approach for checking the compliance of fats and oils' that describes a way of measurement of trans fats and estimating the respective content of industrial trans fats by a proposed calculation method.

ANNEX 1: Procedural information

1. LEAD DG, DECIDE PLANNING

Lead DG: European Commission Directorate-General Health and Food Safety, DG SANTE

The Inception Impact Assessment on an Initiative to limit industrial trans fats intakes in the EU¹⁵⁵ was published on 11 October 2016 and the corresponding consultation strategy¹⁵⁶ on 23 June 2017. The inception impact assessment set out the context, scope and aim of the exercise.

The Inter-service Steering Group (ISG) on the initiative to limit industrial trans fats intakes in the EU that had been set up held its first meeting on 8 November 2016 and supported DG SANTE for this Impact Assessment. In addition to the Secretariat General and Legal Service, 6 Directorates-General were invited and designated their representatives to the ISG: MARE, AGRI, RTD, GROW, JRC-ISPRA, ENV and TRADE. The ISG was consulted on the consultation strategy, draft documents and questionnaires of the Study to support the Impact Assessment on the initiative to limit industrial trans fats intakes in the EU, the draft questionnaire of the public consultation and the drafts of this IA report. The ISG met six times to discuss preparatory documents and the draft IA report.

Political validation by Commissioner Andriukaitis, Vice President Katainen and first Vice President Timmermans was received for the Agenda Planning Fiche (2016/SANTE/143) on 6 September 2016.

¹⁵⁵ http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_143_trans_fats_en.pdf

¹⁵⁶ https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_consultation-strategy.pdf

2. ORGANISATION AND TIMING

5 December 2015	Adoption of 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 (COM(2015) 619)
6 September 2016	Political validation by CSSR Andriukaitis, VP Katainen & 1st VP Timmermans of Agenda Planning Fiche (2016/SANTE/143)
11 October 2016	Publication of the Inception Impact Assessment (IIA)
8 November 2016	1st meeting of the ISG on the trans fats initiative - Presented the IIA; Exchange of views on the Terms of Reference (ToR) for external study; agreement to carry out an OPC
13 December 2016	Final version of ToR for the external study to support the IA sent to ISG
21 December 2016	SANTE/2016/E1/055 - Call for tender for external study to support the I.A. launched [Ares(2016) 7115662]
	Two offers were received, and the evaluation Committee decided to award the contract to ICF Consulting Services Limited
17 February 2017	Feedback received on the IIA published on the relevant webpage of DG Health and Food Safety (a total of 9 contributions received)
22 March 2017	Contract signed with ICF Consulting Services
29 March 2017	2nd meeting of the ISG on the trans fats initiative - Kick-off meeting with the contractor
15 May 2017	3rd meeting of the ISG on the trans fats initiative - To discuss the Draft Inception Report on trans fats study from contractor
17 May 2017	Draft Inception Report sent to ISG for comments
15 June 2017	Email to ISG for comments and approval of 1) revised Inception Report, which was prepared by the contractor (ICF) after taking into account the different comments of the ISG; 2) draft Consultation Strategy Document for the Trans Fats initiative
16 June 2017	ISG approved revised Inception Report
21 June 2017	ISG approved the draft Consultation Strategy document for the trans fats initiative
23 June 2017	Publication of the Consultation Strategy document
11 September 2017	4th meeting of the ISG on the trans fats initiative - To discuss the Draft Interim Report on trans fats study from contractor
12 September 2017	Email to ISG for comments on 1) draft Interim Report; 2) draft validation questionnaire for ICF study
18 September 2017	Draft validation questionnaire approved by ISG
12 October 2017	Email to ISG with draft questionnaire for the OPC
27 October 2017	Final version of OPC questionnaire approved by ISG
16 November	SG approval of OPC

17 November 2017 to 9 February 2018	Public consultation open for 12 weeks 'Open public consultation on the initiative to limit industrial trans fats intakes in the EU'
6 December 2017	Email to ISG with draft Final Report
12 December 2017	5th meeting of the ISG on the trans fats initiative - To discuss the draft Final Report on trans fats study from contractor
12 December 2017	Email to ISG for comments on draft Final Report
12 January 2018	Email to ISG with revised Final Report for comments
24 January 2018	ISG approves Final Report: Study to support the impact assessment of the initiative to limit industrial trans fats in the EU
3 May 2018	6th meeting of the ISG on the trans fats initiative - To discuss the Final Report on trans fats study from contractor; the outcome of the OPC; inform on state of play on IA; agreement to discuss draft IA via exchange of emails and if ISG wish to discuss a meeting will be arranged
4 May 2018	Email to ISG for comments on draft IA
14 May 2018	ISG approves draft IA
16 May 2018	Submission of the draft IA to Regulatory Scrutiny Board (RSB)
13 June 2018	Regulatory Scrutiny Board meeting
18 June 2018	Positive opinion by the Regulatory Scrutiny Board,

3. CONSULTATION OF THE RSB

The meeting of the Regulatory Scrutiny Board (RSB) took place on 13 June 2018. The Regulatory Scrutiny Board gave its positive opinion on 18 June 2018 together with a recommendation to further improve the IA report with respect to some aspects, which are reported below. All the Board's recommendations were taken into account by adding explanations in the IA report, except for the preference of the RSB to select the most likely scenario as baseline and to include the others in the impacts section as sensitivity analysis; since there is evidence underpinning each of the baseline scenarios, a decision on the most likely scenario could face the risk of being seen as arbitrary. By taking into account the RSB's recommendation to justify the use of alternative baseline scenarios and including clear explanations with respect to the rationale for the alternative scenarios (which are included to take into account uncertainty about future developments) the various baseline scenarios are presented in clearer terms.

Indications on how the RSB's comments, including the paragraphs/pages which have been added/modified to address the RSB comments, can be found under each element of the recommendations below.

Considerations and recommendations for improvement by the Regulatory Scrutiny Board:

- (1) The report should further justify the use of alternative baseline scenarios.

This recommendation was taken into account by adding explanatory text and justification on page 28 paragraph 2 and 3 and pages 29 to 31.

The report should elaborate on the reasons for questioning the validity of the JRC projections and provide additional evidence of the levelling-off of the downward trend in TFA intake across Europe.

This recommendation was taken into account by adding explanatory text and additional evidence on pages 15/16 in the 2nd bullet point, page 17 paragraph 1, page 24 paragraph 3, page 27 paragraph 1 and pages 29 to 31.

It should also further acknowledge uncertainties surrounding this trend, and stress the reasons for increase of TFA intake in some regions.

This recommendation was taken into account by adding explanatory text on page 28 paragraph 2 to 3 and pages 29 to 31.

It could better indicate the distribution and size of population subgroups at risk of excessive TFA intake.

This recommendation was taken into account by information and detailed background data on page 15 1st bullet point, page 44 paragraph 3 and Annex 9.

The report could better explain that existing instruments (such as voluntary industry initiatives) have reached their limits.

This recommendation was taken into account by adding explanatory text on page 19 regarding the risk that imported products that would not be covered by voluntary industry initiatives in a Member State is high, particular in certain Member States, and pages 29 to 31.

The introduction could also better reflect the ongoing global trend in terms of adopting legal measures to limit TFA intakes.

This recommendation was taken into account by adding explanatory text on page 12 paragraph 4 and page 18 1st bullet point.

Building on these elements, the description of the need to act could better reflect potential reputational risks for the EU in case of inaction.

This recommendation was taken into account by adding text about the potential reputational risks on page 18 1st bullet point.

(2) The report should better explain the differences between the option to set an upper limit on TFA content and the option to ban partly hydrogenated oils.

This recommendation was taken into account by adding a figure and explanatory text on page 33, page 35, page 38, page 39 paragraph 1 to 2 and page 70.

The impacts section should more clearly explain why the two options have identical expected health benefits.

This recommendation was taken into account by adding explanatory text on page 38 paragraphs 2 and 5, page 39 paragraph 1, highlighting that both options would introduce a comparable cut-off point at 2% trans fats of the fat content, and page 43 paragraph 2.

The report could explain why a more ambitious option in terms of health benefits was not envisaged. The report should also better justify the proposed threshold and explain why it does not consider alternative options such as a limit below 2% of total fat content as feasible. It should more clearly compare them in terms of scope, approach, potential implementation issues and impacts on health as well as for businesses.

These recommendations were taken into account by adding explanatory text and justifications on pages 9/10 paragraph 3, page 35 paragraphs 2, 3 and 5, page 36 paragraphs 1 and 2, page 39 last paragraph.

(3) The report could refine its analysis of the impacts of the proposed measures on the food sector, including the costs for SMEs.

This recommendation was taken into account by adding more evidence on the impact on SMEs from Canada and the hospitality sector on page 51 paragraphs 4 to 5.

It could better describe the market structure of the relevant food sector(s) and describe how the measures might impact different actors in the food value chain. A revised intervention logic could support such an explanation by illustrating the channels through which trans fats enter the food chain and the stages at which different measures propose to intervene.

These recommendations were taken into account by adding information and adding an illustration of the channels through which trans fats may enter the food chain and the stages at which different measures would intervene therefore showing how the measures impact on different actors in the food chain on page 33 and page 45 paragraph 4.

The report could also expand on planned mitigation measures, e.g. in terms of transition periods.

This recommendation was taken into account by expanding on mitigation measures on page 67 last paragraph, page 68 paragraphs 1 to 3, page 70 last paragraph and page 71 paragraph 1.

(4) The report should better explain how future monitoring and evaluation would work.

This recommendation was taken into account by adding explanatory text on future monitoring and evaluation on page 71 paragraphs 2 to 4 and paragraph 6.

4. EVIDENCE, SOURCES AND QUALITY

The main source of evidence was the study performed by ICF. Robustness of the results of the study was ensured thanks to sensitivity analysis and comprehensive triangulation of data and evidence collected in the first phase of work via input on a validation questionnaire. Annex 4 provides a detailed explanation about the methodology used, as well as under Annex 4, 6. information about the strength and limitations of the method and under Annex 4, 7. a discussion of information gaps and uncertainties.

ANNEX 2: Stakeholder consultation

1. INTRODUCTION

Trans fats¹⁵⁷ are present in foods and increase the risk of coronary heart disease more than any other macronutrient. Industrial trans fats are still present at levels of concern in certain foods and intakes are still excessive in certain cases. This lack of homogeneity in the EU hampers the effective functioning of the Internal Market, negatively affects the protection of consumers' health and contributes to the perpetuation of health inequalities.

In this context, the European Commission is carrying out an Impact Assessment (IA) on a possible EU-based initiative to limit industrial trans fats intakes in the diet of EU consumers. The Inception Impact Assessment (IAA) on the trans fats initiative was published on 11 October 2016 for stakeholders' feedback¹⁵⁸. It included a preliminary reflection on all the key elements of the IA with a listing of the policy options considered¹⁵⁹. The Consultation Strategy¹⁶⁰ provided a more detailed outline of the consultation activities planned by the Commission in the context of its trans fats initiative.

2. STAKEHOLDER GROUPS COVERED BY THE CONSULTATION ACTIVITIES

The Consultation Strategy listed the stakeholders expected to have an interest in the trans fats initiative:

- EU consumers;
- EU food business operators, an effort was made in the consultations to try to obtain specific feedback on mass caterers providing non pre-packed foods ready for consumption and SMEs, taking into account the sometimes more limited resources at their disposal;
- Third-country-based food business operators exporting into the EU;
- Public authorities of EU Member States;
- International organisations and associations, academia and think tanks;
- Public authorities of third countries which already took action on trans fats;
- Individual citizens.

¹⁵⁷ Trans fats can be naturally present in food products derived from ruminant animals such as dairy products or meat from cattle, sheep or goat ('ruminant trans fats'). Trans fats can also be produced industrially ('industrial trans fats'), due to the food manufacturing process. The primary dietary source of industrial trans fats is partly hydrogenated oils which contain various amounts of trans fats (up to more than 50 % of the total fat content)

¹⁵⁸ http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_143_trans_fats_en.pdf

¹⁵⁹ Option 0 (baseline): No EU policy change; Option 1: Establishment of a limit for the industrial trans fats content in foods through a voluntary agreement (Option 1a) or through a legally-binding measure (Option 1b); Option 2: Introduction of the obligation to indicate the trans fats content of foods in the nutrition declaration; Option 3: Prohibition of the use of partly hydrogenated oils (PHO) in foods through a voluntary agreement (Option 3a) or through a legally-binding measure (Option 3b)

¹⁶⁰ https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_consultation-strategy.pdf

3. CONSULTATION ACTIVITIES ALREADY CARRIED OUT BEFORE THE LAUNCH OF THE IA

The Commission services had already carried out different consultations on trans fats in preparation of the Commission's report of 3 December 2015¹⁶¹, and in relation to the feedback mechanism for the IIA, which constitute an important data source for the IA and the related consultations. Two surveys (one with experts of Member States, Iceland and Norway), and one with stakeholders in the context of the Advisory Group on the Food Chain and Animal and Plant Health, that also was consulted via a written consultation, collected factual information and stakeholders' views on trans fats in foodstuffs and diets in Europe and impacts of strategies to reduce population exposure.

The feedback gathered through these surveys contributed to constitute the evidence-base for the Commission's report on trans fats and helped developing different elements of the IA.

The results of the abovementioned consultations are analysed in detail in the Staff Working Document accompanying the Commission's report¹⁶².

Nine Stakeholders provided feedback during the feedback mechanism period for the IIA. All of them except for one being an organisation representing national business interests, were EU level organisations and identified themselves as representing company/industry (3 replies) or NGOs (4 replies). Eight contributors expressed preferences for the identified policy options, the majority for legal measures, such as option legal limits on trans fats. Voluntary measures were preferred by 2 business interest contributors, a national contributor pointed to positive experiences. Mandatory labelling of trans fats, was only preferred by one business interest contributor.

Furthermore, NGOs considered that options 1a and 3a as well as the labelling options would not address the problem. Also, NGOs emphasised the urgency of the matter, calling for swift implementations and short transition periods in order to save lives and costs. Replacement fats would need to be considered as well and their impacts on environment and health.

Business interest contributors representing food categories that are sources of ruminant trans fats were satisfied with the focus on industrial trans fats, while the 2 contributors representing business interests of the vegetable oils and fats sector highlighted that scientific evidence was pointing to similar health effects of industrial versus ruminant trans fats and that measures focussing on industrial trans fats only could lead to unfair competition.

¹⁶¹ COM (2015) 619 final, http://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf

¹⁶² Commission Staff Working Document SWD (2015) 268, Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe', http://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

4. OUTLINE OF THE CONSULTATION STRATEGY FOR THE IA ON AN INITIATIVE TO LIMIT INDUSTRIAL TRANS FATS INTAKES IN THE EU

The objective of the consultations for the IA on an initiative to limit industrial trans fats intakes in the EU was three-fold:

- to fill in data/information gaps with respect to the baseline scenario and the potential impact of the different policy options retained in the IA;
- to corroborate the findings on the expected economic, social and environmental impacts of the different policy options;
- to give an additional possibility to all stakeholders and individual citizens to provide their views on key elements of the IA.

The planned consultations should also allow the Commission to identify whether anything has been left out in its assessment and to foster transparency and accountability and ensure broadest public validation for the EU initiative.

The following consultation activities were foreseen as part of the Consultation Strategy.

1. Targeted consultations: these were carried out by the contractor ICF which prepared the external study to support the IA and included:
 - a. Interviews with national competent authorities in the areas of health and food safety and relevant food business representative organisations. The interviews were aimed at collecting primary data to fill in information gaps. The interviews were carried out in the official language of each country selected or in English.
 - b. Targeted follow-up contacts with sector associations and/or individual businesses to gather additional data. Getting insights into impacts on SMEs was a key objective of these follow-ups.
 - c. An online survey of a variety of stakeholder groups based on a questionnaire that allowed the contractor to corroborate its findings on the economic, social and environmental impacts of the different policy options. The online survey was distributed to stakeholders at EU and national level in English, responses were accepted in other languages.
2. Open Public consultation (OPC).

A questionnaire translated in all EU official languages was published on the "Your Voice in Europe" website for 12 weeks with the possibility to reply in all EU official languages. The questionnaire built on the progress in the IA process and feedback received.

The methodology used to process the data of the OPC was done via counting from excel tables and clustering of open text field replies in order to qualitatively assess major themes.

5. RESULTS OF THE CONSULTATION ACTIVITIES FOR THE IA ON AN INITIATIVE TO LIMIT INDUSTRIAL TRANS FATS INTAKES IN THE EU

The results of the targeted consultations¹⁶³ fed into the IA report on an initiative to limit industrial trans fats intakes in the EU and are in detail reported there. Generally, a number of replies there were in line with replies received from stakeholders during the OPC. Legal limits received support by a number of (also industry) stakeholders, while particular views relating to the labelling of ruminant trans fats or a link with requirements to indicate hydrogenation of oils in the ingredient lists were fully in agreement with the replies received in the OPC.

Regarding the OPC¹⁶⁴, 118 replies were received, 54 % from individuals¹⁶⁵ and 46 % from stakeholders, experts or participants replying on behalf of an organisation. NGOs represented 20 % of all replies. 15 % of all replies were from business. Of those, 3 SMEs replied, as well as 11 national or EU level business associations that represent a membership with more than 30 % of SMEs. Therefore 12 % of all replies represented SMEs' views. Business was active predominantly in the following sectors: margarines and spreads; dairy products; oils and fats. 7 % of all replies were from public authorities. Two respondents identified themselves as "other", and one international organisations as well as a think tank/research institute participated. A campaign could not be identified in the replies. Not all respondents provided replies for all questions.

With regard to geographic representation, respondents from 23 Member States and 1 respondent from a non-EU country were registered. Over 10 respondents replied from Spain (22) Belgium (19), Germany (15) and the United Kingdom (11).

The first set of questions asked whether the problem description with regard to the trans fats intakes and the trans fats level in foods¹⁶⁶ and the conclusions of the 2015 Commission report on trans fats, summarised again in the IIA¹⁶⁷ were supported. With regard to the trans fats intake, among the respondents to this question, 72 % of consumers, 71 % of industry and 88 % of both public authorities and NGOs respondents agreed, 11 % of consumers and one of the public authorities replying to this question as

¹⁶³ The validation survey questionnaire is provided in Annex 31 of the IA report

¹⁶⁴ The OPC questionnaire is provided in Annex 33 of the IA report

¹⁶⁵ Individuals were asked additional questions, replies indicated that this group was well informed about the trans fats issue and very health oriented individuals

¹⁶⁶ 'There is limited availability of comparable/EU-level data, however, some evidence collected by ICF indicates that the intake of trans fats in the EU has decreased considerably over recent years, but that the situation is not homogeneous for all products consumed by all population groups in all EU Member States. While average daily trans fats intakes for the overall EU population are below 1% of daily energy intake, some population groups have, or are at risk of having higher intakes. Most of the analysed food products contain trans fats at amounts below 2% of the total fat content, however, there are still products in the European food market with high levels of industrial trans fats.'

¹⁶⁷ 'Trans fats are an important risk factor for the development of CHD [Coronary Heart Disease] and their intake should be reduced in the diet of EU consumers. Although different actions were taken in different Member States and intakes have decreased over the past years, industrial trans fats are still present at levels of concern in certain foods and intakes are still excessive in certain cases (...). The issue is of particular relevance in certain Member States and for particular population groups' The Commission concluded that this lack of homogeneity in the EU hampers the effective functioning of the Internal Market, negatively affects the protection of consumers' health and contributes to the perpetuation of health inequalities

well as one of the 21 NGOs replying to this question disagreed.¹⁶⁸ Number of responses by stakeholder category is given in Table 15. All but one (individual) respondent that disagreed indicated that actual trans fats intakes and trans fats levels in foods were higher than described in the IIA.

Table 15: Number of responses by stakeholder category in relation to trans fats intake levels and levels in foods as described in Inception Impact Assessment

	consumers	industry	public authorities	NGOs	others
Trans fats intake					
Agreement	46	12	7	21	3
Disagreement	7	0	1	1	1
I don't know	11	5	0	2	0
Trans fats levels in food					
Agreement	49	10	8	22	4
Disagreement	7	1	0	1	0
I don't know	8	6	0	1	0

Asked about their level of concern, most of respondents that answered this question were very concerned or concerned about the impacts of industrial trans fats consumption on the health of the population as a whole (46 % and 27 %, respectively), on the health of particular social groups (61 % and 29 %, respectively) and about current differences in rules and standards regarding industrial trans fats content in the EU market and impacts on consumer protection levels (48 % and 35 %, respectively).

Table 16 Number of respondents rating their level of concern of different issues related to trans fats by stakeholder category

Option	Rating				
	not at all concerned	not concerned	somewhat concerned	concerned	very concerned
The impacts of industrial trans fats consumption on the health of the population as a whole	a) 1	a) 3	a) 9	a) 19	a) 32
	b) 1	b) 3	b) 6	b) 2	b) 3
	c) 0	c) 0	c) 4	c) 3	c) 1
	d) 0	d) 0	d) 2	d) 7	d) 14
	e) 0	e) 0	e) 2	e) 0	e) 2
	total: 2	total: 6	total: 23	total: 31	total: 52
The impacts of industrial trans fats consumption on the health of particular social groups	a) 0	a) 0	a) 6	a) 18	a) 40
	b) 0	b) 2	b) 2	b) 7	b) 4
	c) 0	c) 0	c) 0	c) 5	c) 3
	d) 0	d) 0	d) 0	d) 3	d) 20
	e) 0	e) 0	e) 1	e) 0	e) 3

¹⁶⁸ Those disagreeing stated that there was no negative effect on the Internal Market or that difference between Member States with regard to the trans fats issue was hardly noticeable

	total: 0	total: 2	total: 9	total: 33	total: 70
Current differences in rules and standards regarding industrial trans fats content in the EU market and impacts on consumer protection levels	a) 0 b) 0 c) 0 d) 0 e) 0 total: 0	a) 2 b) 0 c) 0 d) 0 e) 1 total: 3	a) 9 b) 6 c) 1 d) 0 e) 1 total: 17	a) 22 b) 6 c) 4 d) 7 e) 1 total: 40	a) 31 b) 3 c) 3 d) 16 e) 2 total: 55
Current differences in rules and standards regarding industrial trans fats content in the EU market and impacts on the functioning of the Internal Market	a) 2 b) 0 c) 0 d) 0 e) 0 total: 2	a) 8 b) 1 c) 2 d) 4 e) 1 total: 16	a) 20 b) 4 c) 1 d) 1 e) 2 total: 28	a) 14 b) 3 c) 2 d) 12 e) 0 total: 31	a) 20 b) 7 c) 3 d) 6 e) 1 total: 37
Current differences in rules and standards regarding industrial trans fats content and impacts on external trade	a) 7 b) 0 c) 0 d) 0 e) 0 total: 7	a) 15 b) 3 c) 3 d) 4 e) 1 total: 26	a) 20 b) 5 c) 1 d) 4 e) 2 total: 32	a) 7 b) 4 c) 3 d) 10 e) 0 total: 24	a) 15 b) 3 c) 1 d) 5 e) 1 total: 25
Legal uncertainty on future developments on industrial trans fats and impacts on the functioning of the Internal Market	a) 4 b) 0 c) 0 d) 0 e) 0 total: 4	a) 9 b) 2 c) 1 d) 0 e) 1 total: 13	a) 14 b) 3 c) 2 d) 7 e) 2 total: 28	a) 19 b) 3 c) 1 d) 12 e) 0 total: 35	a) 18 b) 7 c) 4 d) 4 e) 1 total: 34
The effects of industrial trans fats use on the image and reputation of the food industry	a) 6 b) 0 c) 0 d) 1 e) 1 total: 8	a) 13 b) 3 c) 2 d) 6 e) 1 total: 25	a) 18 b) 3 c) 2 d) 11 e) 1 total: 35	a) 12 b) 0 c) 3 d) 1 e) 0 total: 16	a) 15 b) 9 c) 1 d) 4 e) 1 total: 30

a) consumers b) industry c) Member States d) NGOs e) others

Most respondents were very concerned or concerned about current differences in rules and standards regarding industrial trans fats content in the EU market and impacts on the functioning of the Internal Market (33 % and 27 %, respectively) and about legal uncertainty on future developments on industrial trans fats and impacts on the functioning of the Internal Market (30 % and 31 %, respectively).

Most respondents totally agreed or agreed that food business operators tend to engage into reformulation only if there is an adequate incentive, which vary depending on the Member State (67 % and 19 %, respectively), that consumers could reduce industrial trans fats intakes by reducing consumption of products that contain them while in the EU, there are different levels of nutritional literacy/consumer awareness of the negative

effects of trans fats on health so that not all consumers are actively seeking to avoid trans fats from their diet (63 % and 22 %, respectively).

Table 17 Number of respondents rating their level of agreement with different issues related to trans fats by stakeholder category

	don't agree at all	don't agree	somewhat agree	agree	totally agree
The presence of industrial trans fats in foods is primarily the consequence of the use of particular oils by food manufacturers. These oils are commonly used as ingredients because of costs or technological considerations.	a) 1 b) 1 c) 0 d) 0 e) 0 total: 2	a) 1 b) 2 c) 0 d) 0 e) 0 total: 3	a) 4 b) 3 c) 1 d) 1 e) 0 total: 9	a) 28 b) 7 c) 3 d) 3 e) 1 total: 42	a) 30 b) 2 c) 4 d) 19 e) 3 total: 58
Food business operators tend to engage into reformulation only if there is an adequate incentive (e.g. market pressure, pressure by public authorities or legal obligations, level of corporate social responsibility) and these incentives vary depending on the Member State.	a) 0 b) 1 c) 0 d) 0 e) 0 total: 1	a) 2 b) 2 c) 0 d) 0 e) 0 total: 4	a) 3 b) 3 c) 2 d) 3 e) 0 total: 11	a) 12 b) 7 c) 1 d) 1 e) 1 total: 22	a) 47 b) 2 c) 5 d) 19 e) 3 total: 76
Consumers could reduce industrial trans fats intakes by reducing consumption of products that contain them. However, in the EU, there are different levels of nutritional literacy/consumer awareness of the negative effects of trans fats on health so that not all consumers are actively seeking to avoid trans fats from their diet.	a) 0 b) 2 c) 0 d) 0 e) 0 total: 2	a) 1 b) 4 c) 0 d) 0 e) 0 total: 5	a) 5 b) 4 c) 0 d) 1 e) 0 total: 10	a) 13 b) 4 c) 3 d) 4 e) 1 total: 25	a) 45 b) 1 c) 5 d) 18 e) 3 total: 72
Other considerations may influence consumers' behaviour (e.g. cost, taste, habits) and may have a stronger impact on some consumers' final decision than the intention to reduce trans fats intake.	a) 2 b) 0 c) 0 d) 0 e) 0 total: 2	a) 0 b) 2 c) 0 d) 0 e) 0 total: 2	a) 9 b) 5 c) 1 d) 1 e) 0 total: 16	a) 24 b) 5 c) 4 d) 6 e) 1 total: 40	a) 29 b) 3 c) 3 d) 16 e) 3 total: 54
Not all consumers can relate the information present on labels to the presence of industrial trans fats in foods and not all consumers can use that information to effectively compare different products taking into account their overall nutritional composition.	a) 1 b) 0 c) 0 d) 0 e) 0 total: 1	a) 1 b) 0 c) 0 d) 0 e) 0 total: 1	a) 6 b) 2 c) 0 d) 1 e) 0 total: 9	a) 15 b) 6 c) 2 d) 1 e) 1 total: 25	a) 41 b) 7 c) 6 d) 21 e) 3 total: 78
Consumers lack information on the presence of trans fats in non pre-packed foods (e.g. bakery products) and these can be an importance source of trans fats.	a) 2 b) 2 c) 0 d) 0 e) 0 total: 4	a) 2 b) 2 c) 0 d) 0 e) 0 total: 4	a) 4 b) 4 c) 0 d) 1 e) 0 total: 9	a) 14 b) 4 c) 2 d) 2 e) 1 total: 23	a) 42 b) 3 c) 6 d) 20 e) 3 total: 74

a) consumers b) industry c) Member States d) NGOs e) others

Asked about their agreement with the approach to focus the EU trans fats initiative on industrial trans fats, 86 % of respondents agreed, whereas 8 % disagreed.¹⁶⁹

Concerning subsidiarity, most respondents that answered this question agreed (91 %) with the statement in the IIA that an EU level trans fats initiative was in line with subsidiarity considerations¹⁷⁰, 9 % disagreed.¹⁷¹

Table 18: Number of responses by stakeholder category in relation to the Inception Impact Assessment proposed focus on industrial trans fats and the analysis in relation to subsidiarity

	consumers	industry	public authorities	NGOs	others
Focus on industrial trans fats					
Agreement	53	14	8	21	4
Disagreement	5	3	0	2	0
I don't know	6	1	0	0	0
Trans fats initiative in line with subsidiarity					
Agreement	57	13	8	22	4
Disagreement	2	1	0	0	0
I don't know	5	4	0	1	0

Respondents were asked to rate the different policy options to address industrial trans fats intakes in the EU.

¹⁶⁹ The following reasons were given for the disagreement: all trans fats sources should be taken into consideration, if not controllable advise of limiting intake should follow and labelling could be requested; ruminant trans fats can be avoided, they are equally of health concern and could become relatively more important sources if industrial trans fats intakes are reduced; for labelling all trans fats should be declared; mammals should not be eaten at all

¹⁷⁰ In order to limit the intake of trans fats, different actions were taken in different Member States, other Member States have not taken action. There is added value of an EU-based, EU-wide action as this would ensure a level playing field in the Internal Market and the same high level of protection of consumers' health by the means of an initiative that would apply simultaneously in the entire EU and would minimise the risk of national regulatory interventions fragmenting the Internal Market

¹⁷¹ Only one respondent gave a reason, stating that the analysis is valid for pre-packed food traded within the Single Market but does not apply to non pre-packed food served by local food services where no risk of fragmentation of the Single Market was confirmed while this risk exists for ingredient suppliers of food service providers

Table 19 Number of respondents rating the different options to the OPC by stakeholder category

Option	Rating				
	not at all appropriate	not appropriate	somewhat appropriate	appropriate	very appropriate
1a limit industrial trans fats through self-regulation	a) 13 b) 1 c) 1 d) 6 e) 1 total: 22	a) 14 b) 3 c) 1 d) 14 e) 0 total: 32	a) 19 b) 6 c) 5 d) 1 e) 2 total: 33	a) 11 b) 4 c) 1 d) 1 e) 1 total: 18	a) 7 b) 3 c) 0 d) 2 e) 0 total: 12
1b limit industrial trans fats through a legally-binding measure	a) 2 b) 0 c) 0 d) 1 e) 0 total: 3	a) 3 b) 0 c) 2 d) 0 e) 0 total: 5	a) 10 b) 5 c) 0 d) 1 e) 1 total: 17	a) 16 b) 5 c) 3 d) 1 e) 1 total: 26	a) 33 b) 7 c) 3 d) 21 e) 2 total: 66
2: introduce mandatory labelling of the trans fats content in the nutrition declaration on labels	a) 2 b) 10 c) 1 d) 14 e) 1 total: 28	a) 6 b) 3 c) 3 d) 2 e) 0 total: 14	a) 7 b) 1 c) 4 d) 2 e) 1 total: 15	a) 11 b) 1 c) 0 d) 2 e) 1 total: 15	a) 38 b) 3 c) 0 d) 4 e) 1 total: 46
3a prohibit the use of partly hydrogenated through self-regulation	a) 14 b) 7 c) 1 d) 5 e) 1 total: 28	a) 12 b) 1 c) 1 d) 14 e) 0 total: 28	a) 19 b) 5 c) 4 d) 2 e) 2 total: 32	a) 7 b) 2 c) 2 d) 1 e) 1 total: 13	a) 12 b) 2 c) 0 d) 2 e) 0 total: 16
3b prohibit the use of partly hydrogenated through a legally-binding measure	a) 4 b) 7 c) 0 d) 2 e) 0 total: 13	a) 2 b) 2 c) 3 d) 9 e) 0 total: 16	a) 7 b) 2 c) 4 d) 2 e) 1 total: 16	a) 13 b) 4 c) 1 d) 5 e) 0 total: 23	a) 38 b) 2 c) 0 d) 6 e) 3 total: 49

a) consumers b) industry c) Member States d) NGOs e) others

Option 1b was considered by the highest number of respondents as very appropriate, followed by the other legal measure, option 3b and option 2, mandatory labelling. Few

respondents considered self-regulation, options 1a and 3a as very appropriate. Likewise, self-regulation, options 1a and 3a were considered as somewhat appropriate.

With regard to the open text replies, the most frequently made comments were that the protection of the health of consumers at EU level should be the central focus for the Commission. Furthermore, it was frequently suggested that the Commission should choose the legal option that best protects health and is already implemented successfully at Member State level. Many respondents urged the Commission to speed up the process and act swiftly.

Also frequently comments called for EU regulation, establishing legal limits as the measure to best protect health, ensuring the effective functioning of the Internal Market and contributing to reducing health inequalities. Legislation should be clear, practical and not include exceptions. National legislation should be avoided. A number of comments highlighted that self-regulation would not be effective.

Concerning mandatory labelling, views were varied. Most frequently, particularly from individuals, the provision of clear information on labels was requested. However, labelling ruminant trans fats was supported by some (predominantly from stakeholders active in the vegetable oils and margarine and spreads sectors). Also, particularly those stakeholders called for the abolition of the requirement to label partly and fully hydrogenated fats. However, a high number of respondents, mostly active in the dairy sector, requested that ruminant trans fats should be excluded from mandatory labelling. A high number of respondents viewed labelling as a not effective.

Further comments, particularly from individuals, called for effective sanctions and enforcement. A number of individuals called for citizen education campaigns. Many comments highlighted the need to protect vulnerable groups. There were calls for further research, consideration of availability and health effects of substitution fats as well as calls to consider SMEs that could face particular problems.

SMEs and associations representing them, active in the dairy or the margarines and spreads sectors voiced the views with regard to mandatory labelling of ruminant trans fats as described above. Furthermore, individual SMEs preferred legal limits, considered national legal measures to be problematic, and that consumer health should be considered by the Commission. Association preferred EU wide regulation or commented that future reductions of trans fats levels were likely due to further national legal measures and voluntary reformulation efforts.

6. CONCLUSION

A number of consultations have fed into the work on trans fats in the past years in a stepwise approach, results of the different consultations were taken into account for the documents developed during the stages leading to this IA report (Commission report of 2015, IIA, consultation strategy, study by the external contractor). Generally, results of the consultations provided additional information, which were taken into account; views by stakeholders remained rather stable over the years and were considered for drafting the final IA report. The feedback received from the last consultation, the OPC, generally

the feedback received confirmed the conclusions of the Commission's report of 3 December 2015, as well as the content of the IIA. Overall, there is a widespread support for introducing a legal limit of trans fats content in the EU, voluntary agreements are less supported and mandatory labelling of trans fats is supported by a number of individuals, while other stakeholders consider labelling to be not effective. No particular, important issues were raised during the OPC that have not been captured during previous consultations and considered in the IA report.

ANNEX 3: Who is affected and how?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

According to the preferred policy option, EU legislation would set a limit industrial trans fats content of 2% of the total fat content of final food products sold to the consumer, following the example of 2% limits to final food products in some Member States' legislation (Denmark (2003), Romania (2017) and Slovenia (2017) .

Alternatively, a more differentiated approach could be chosen, with higher limits (above 2% of total fat) for products with low fat content, and 2% of total fat for food categories with high fat content. Such differentiated limits have been adopted in Austria (2009), Hungary (2013), Latvia (2015) and Lithuania (2017). Austrian/ Hungarian legislation established a maximum content of trans fats at 10% of the total fat content where the total fat content is less than 3% of the product, and at 4% where the total fat content is between 3% and 20% of the product.

A transition period of 2 years is assumed, however, this could be modified during the negotiating and drafting phase of the legal measure.

With regard to **food business operators and public administrations**, financial and human resources are required to develop and implement the new legislation, develop and implement new products and processes, source alternative ingredients and monitor and enforce implementation.

Administrative costs are incurred by **businesses** in understanding the rules, determining responses and providing information, and by the public authorities in implementing and enforcing the rules, monitoring and reporting. Compliance costs are incurred by businesses in meeting the legal obligations. These may include the costs of reformulating products and purchasing alternative ingredients. Affected food business operators include those active in the pre-packed and non-prepacked food businesses, and food service companies. Only subsectors whose products are likely to contain industrial trans fats will be affected and businesses in countries with existing legislation are not affected.

With regard to the potentially significant impact on **SMEs** that is expected to be negative, such impacts are supported by the situation that all SMEs producing foods above the legal limit will be forced to take action and that SMEs may face relatively greater costs and challenges compared to larger firms. However, many SMEs will adopt solutions developed by suppliers, limiting costs. They are likely to be followers of ingredient substitution strategies developed by suppliers or larger firms already. Furthermore, there is a commitment by a large food business association to further encourage and support particularly SMEs, who still face technological difficulties in

achieving the elimination of trans fats from partial hydrogenated oils from their products.¹⁷²

In this context, FoodDrinkEurope supports the implementation of a recommendation of maximum 2% industrial trans fats of the total fat content of the product sold to the final consumer.

From the **business** perspective, after the introduction of new legal rules some further activities would be needed, such as the provision of information, new product development, sourcing of alternative ingredients (substitution of ingredients with high industrial trans fats content with polyunsaturated, monounsaturated and saturated fats), implementation of new products and processes. **Public administrations** would need to provide guidance and advice, while taking care of monitoring and enforcement.

The resulting output consists of a decrease of industrial trans fats content in food below 2% of fat, and the linked output consists of a reduction of industrial trans fats consumption for all population subgroups, ongoing product development and innovation by food business operators, achievement of a level playing field within Internal Market, including imports, and a shift in alignment with practice in export markets. The long-term impacts lead to a decrease in cardio vascular diseases prevalence and mortality, improved productivity in EU economy from healthier consumers, reduced health inequalities amongst consumers, reduced economic burden on healthcare systems, enhanced image, competitiveness and innovation of food industry and increased trade across EU Member States (and third countries).

¹⁷² FoodDrinkEurope announcement November 2015
http://www.fooddrinkeurope.eu/uploads/statements_documents/FoodDrinkEurope_statement_on_TFA_%28November_2015%29.pdf

2. SUMMARY OF COSTS AND BENEFITS

<i>I. Overview of Benefits (total for all provisions) – Preferred Option</i>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<i>Direct benefits</i>		
Direct & indirect cost savings: lower disease burden compared to the baseline, (M EUR), span: possible span under different baseline scenarios	58,611 - 304,366	Figures represent the reduction of health-related costs over 85 years EU consumers will benefit
Health gains in disability adjusted life years averted (EU28, Millions) compared to baseline, span indicates the possible span: possible span under different baseline scenarios	4 - 66	EU consumers will benefit
Internal Market benefits: harmonisation of standards and avoidance of legal complexity arising from differences in Member State law	Significant, strongly positive impact	Harmonisation removes industrial trans fats regulation as a factor contributing to differential operating conditions for firms in the Internal Market Food businesses will benefit
<i>Indirect benefits</i>		
Reduced health inequalities	Strongly positive impact , strong effect in reducing inequalities derived from industrial trans fats consumption	Measure expected to deliver strong health benefits for all groups, including for relatively disadvantaged groups
Environmental impacts	Potentially significant, could be positive or negative	

II. Overview of costs (M EUR) – Preferred option

		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action	<u>Direct costs</u>						
	<u>Administrative costs :</u>						
	- understanding requirements and verifying compliance			18.5			
	- cost for establishing the policy					5.0	
	- cost for inspection, monitoring and enforcement activities					6.1 year1-2	3.4 year ≥3
	<u>Compliance costs :</u>						
	- cost of product testing			3.6			
	- cost of reformulating products			9.8			
	- additional annual cost of ingredients				44.5		
	<u>Indirect costs</u>						
	Consumer price increases		Very small	Very small			
	Product attribute			Small negative impact			
	Impacts on SMEs		Potentially significant, negative				

ANNEX 4: Analytical methods

1. STUDY METHODOLOGY DEVELOPMENT

This section provides an outline of the methodology developed by ICF for their study that was used as the principal source of data for this IA report.

Firstly, a methodology refinement was performed by ICF, including adjustments to the data collection strategy and impact assessment approach, reflecting discussions held with the ISG. Here, the baseline and policy options specifications as well as associated theories of change were developed. Theories of change make explicit the mechanism by which each intervention is expected to lead to the intended outcomes, and the key assumptions that need to be satisfied for it to do so.

The theory of change provides a narrative description of cause and effect, and the principal assumptions made about behaviour, context, etc. This framework also supports identification and analysis of factors that contribute to uncertainty about benefits (the level of assurance one has that the intervention will achieve its intended results) and costs (the likelihood that the costs will be higher or lower than the central estimate). This includes uncertainty relating to estimation of benefits and costs, and uncertainty about whether the benefits or costs will be realised (e.g. due to lack of compliance).

The analysis of the options through the development of theories of change helped to identify their respective expected impacts. The analytical framework included to outline for the different questions to be answered for the IA judgment criteria, indicators, sources of evidence, and methods of triangulation and validation.

2. DATA COLLECTION AND REVIEW

Information and data gaps left after the analysis of available information by ICF were identified and closed. As many data had already been collected previously to the ICF study and some analysis had been undertaken for a number of the impacts to be assessed, targeted efforts by ICF were carried out to complement those data with additional information that would enhance the analysis. It was also focused on closing information gaps in relation to:

- The baseline scenario and basic data required to support option appraisal;
- Studies which could help to inform the analysis of the impact of agreed potential policy options, and especially environmental impacts, for which comparatively few data are available.

Given the tight timetable set for the ICF study, the research was concentrated over a short period of time and was entirely aimed at informing the tools for the impact assessment models. It involved two sub-tasks:

- An in-depth review of existing data; and
- The collection of primary data from stakeholders in countries that have implemented similar measures to tackle trans fats intake via:
 - A programme of interviews with competent authorities and food business representative organisations in the target countries;
 - Follow-up research with selected sectors in those target countries to gather supplementary information.

ICF also consulted a number of representative organisations at EU level. These additional consultations were conducted to map better at the EU level those elements of the food supply chain that are relevant to the trans fats problem. The results informed extrapolation from existing data on how different policy options may impact the whole EU industry.

Review of existing literature and data

The desk research of ICF focused on sources identified earlier in the project, and was completed with additional literature search in the language of the countries selected for further investigation. Data were collected according to a common framework and a list of keywords defined for use in the search of publications and data. All publications were reviewed in order to extract relevant information, which was then inserted into a common template.

Interviews

The ICF team carried out 24 interviews with competent authorities and food business representatives in EU Member States and third countries. These interviews were carried out following a common approach to fill out gaps identified during the desk research. This included also some interviews with EU-level representative organisations in order to obtain additional inputs on impacts. The full list of interviews is provided in Table 20.

Targeted follow-ups

A number of targeted follow-up actions by ICF followed the interviews and literature review. These solicited a number of email submissions, particularly from industry. A number of additional phone conversations were held with various actors from the industry and researchers with expert knowledge of the topic in the individual countries.

The full list of interviews and targeted follow-ups is provided in Table 20.

Table 20 List of interviews and targeted follow-ups carried out

Country	Organisation	Type	Date of Interview / email submission	Step / task
Austria	AGES - Austrian Agency for Health and Nutrition Safety	National Competent Authority	Interview request forwarded to the responsible Ministry (BMGF)	2.1
Austria	BMGF - Ministry for Health and Women	National Competent Authority	Joint submission with AGES received on 09/08/2017.	2.1
Austria	National Association of Bakers	Industry association	Interview - 04/08/2017	2.1
Austria	Austrian Industry Association and margarine producer	Industry association / Food business operator	Interview - 04/08/2017	2.1
Canada	Baking Industry Association	Industry association	Interview - 11/07/2017	2.1
Canada	Former official at Public Health Canada	National Competent Authority	Interview - 12/07/2017	2.1
Denmark	The Danish Veterinary and Food Administration (1)	National Competent Authority	Interview - 05/07/2017	2.1
Denmark	The Danish Veterinary and Food Administration (2)	National Competent Authority	Interview - 05/07/2017	2.1
Denmark	Food procurement company	Food business operator	Interview - 12/07/2017	2.2
Denmark	The Confederation of Danish Industry	Industry Association	Interview - 13/07/2017	2.2
EU	CEBP (European Confederation of National Bakery and Confectionery Organisations)	Industry Association	Interview - 06/07/2017	2.1
EU	European Dairy Association (as member of Food Drink Europe)	Industry Association	Email submission received on 10/07/2017	2.1
EU	EPHA	Public Health NGO	Interview - 05/07/2017	2.1
EU	HOTREC	Industry Association	Interview - 05/07/2017	2.1
EU	Food Service Europe	Industry Association	Interview - 03/07/2017	2.1
EU	CAOBISCO	Industry Association	Interview -	2.1

Country	Organisation	Type	Date of Interview / email submission	Step / task
			30/06/2017 – followed by email submission	
EU	Food Drink Europe	Industry Association	Interview - 28/06/2017	2.1
EU	FEDIOL	Industry Association	Interview - 29/06/2017 – followed by email submission	2.1
EU	IMACE	Industry Association	Interview - 06/07/17 – followed by email submission	2.1
EU	An international food and drink manufacturer (as member of Food Drink Europe)	Food business operator	Email submission received on 14/07/2017	2.1
Germany	German Federation for Food Law and Food Science	Industry Association	Interview - 10/07/2017; Email - 08/08/2017	2.1
Germany	Federal Ministry of Food and Agriculture (BMEL), Unit for residues and contaminants in foodstuffs	National Competent Authority	Interview request was rejected due to lack of capacity	2.1
Hungary	Ministry of Agriculture	National Competent Authority	Unavailable	2.1
Hungary	Ministry of Human Capacities	National Competent Authority	Unavailable	2.1
Latvia	Ministry of Health	National Competent Authority	Some answers provided via email on 30/06/2017	2.1
Latvia	Ministry of Agriculture	National Competent Authority	Some answers provided over the phone on 30/06/2017	2.1
Netherlands	Bakery supplier	Food business operator	Interview - 08/08/2017	2.2
Netherlands	Bakery supplier	Food business operator	Interview - 03/08/2017	2.2
Netherlands	Bakery supplier	Food business operator	Written submission – 28/08/2017	2.2
Netherlands	MVO	Industry association	Telephone conversation – 01/09/2017	2.2
Netherlands	Bakery supplier	Food business operator	Unavailable	2.2
Netherlands	Bakery supplier	Food business operator	Unavailable	2.2

Country	Organisation	Type	Date of Interview / email submission	Step / task
Netherlands	Bakery supplier	Food business operator	Unavailable	2.2
Netherlands	Bakery supplier	Food business operator	Forwarded to other contact	2.2
Netherlands	Bakery supplier	Food business operator	Unavailable	2.2
Netherlands	Bakery supplier	Food business operator	Could not provide information	2.2
Netherlands	Bakery supplier	Food business operator	Unavailable	2.2
Netherlands	VBZ - Baking Industry Association	Industry Association	Unavailable	2.1
Netherlands	NBOV - Baking Industry Association	Industry Association	Unavailable	2.1
Netherlands	NVB - Baking Industry Association	Industry Association	Unavailable	2.1
Poland	National Food and Nutrition Institute (1)	National Competent Authority	Interview - 29/06/2017	2.1
Poland	National Food and Nutrition Institute (2)	National Competent Authority	Interview - 29/06/2017	2.1
Poland	National Food and Nutrition Institute (3)	National Competent Authority	Interview - 24/06/2017	2.1
Poland	Polish Federation of Food Industry	Industry Association	Interview - 10/07/2017	2.2
Poland	Chief Sanitary Inspectorate	National Competent Authority	Interview - 03/07/2017	2.1
Poland	Polish food manufacturer	Food business operator	Not answered	2.2
Spain	FIAB (Spanish Federation of Food and Drink, member of Food Drink Europe)	Industry Association	Email submission received on 14/07/2017	2.2
Switzerland	Swiss Federal Office of Public Health	National Competent Authority	Not answered	2.1
Switzerland	Swiss Federal Food Safety and Veterinary Office FSVO	National Competent Authority	Email submission received 09/08/2017	2.1
UK	Food & Drink Federation	Industry Association	Rejected as information (from ~15 years ago) not retained	2.1
UK	Ministry of Health	National Competent	Rejected as	2.1

Country	Organisation	Type	Date of Interview / email submission	Step / task
		Authority	information not retained after new Government	
UK	Food Standards Agency	National Competent Authority	Transferred to Public Health England	2.1
UK	Large food chain operator	Food business operator	Unavailable	2.2
UK	Large food chain operator	Food business operator	Unavailable	2.2

Step/task 2.1: Review of existing literature and data

Step/task 2.2: Interviews

Synthesis

The evidence collected in the country research by ICF was consolidated into a single document for each country. These country case studies are provided in a separate document (Annex 32). They summarize the data collected from the desk research, interviews and targeted follow-ups. The information collected through interviews with EU level business associations is consolidated in Annex 29.

The evidence was also aggregated in a single MS Excel file document that includes, for each type of impact: a list of indicators; the description of the evidence obtained, either quantitative or qualitative; and sources for that evidence. This information has been replicated in Annex 30.

3. SCREENING OF IMPACTS AND ASSESSMENT OF SIGNIFICANCE

The ICF team carried out a screening of impacts and assessment of their significance, in line with the guidance on impact assessment set out in the EC Better Regulation guidelines. All potentially significant impacts were retained for more detailed analysis, while those which are insignificant were discarded. This screening was based on a thorough analysis of the evidence. The outputs of this task in this report appear in Annex 12.

4. ANALYSIS OF IMPACTS

Baseline assessment

This task involved qualitative and quantitative analysis to inform specification of the baseline scenario that describes the production and consumption of trans fats in the EU in a context of no additional EU intervention. The work was informed by the baseline

scenario of a study completed by the JRC¹⁷³, and the qualitative evidence collected before by ICF.

Analysis of impacts of each option

The assessment of impacts has been carried out by ICF on the basis of a detailed specification of the policy options, developed by ICF in conjunction with the Commission at the start of the study. The options that are compared to the baseline are defined in the main text of this IA report. The impacts of each option were then assessed by ICF.

The estimation of health costs was based on a model developed by the JRC and published in 2016.¹⁷⁴ A number of the assumptions have been modified. To assess impacts on health inequalities, the team used outputs information emerging from the JRC model to then produce a qualitative assessment of impact on health inequalities, informed by the scientific literature and available data.

The original specification of the JRC model is described here, together with a list of the assumptions that were modified and added for this assignment. These assumptions are explained in more detail below.

The model can be used to estimate the impact of EU-level policies that lead to changes in population industrial trans fats intake. It expresses the results in terms of changes in health treatment costs and overall health benefits (measured in disability-adjusted life years). The model considers only coronary artery disease. Other potential benefits of lowering trans fats intake, such as impacts on insulin sensitivity, obesity, diabetes, cancer, or early growth and development, are excluded because of inconsistent evidence and lack of data. As such the impact assessment can be considered to be conservative with respect to achievable health benefits resulting from (fast) industrial trans fats removal from the food supply.

It is a state-transition model (Markov model) built in Excel. The Markov model is used to simulate how people move in yearly cycles through four health states in each of the policy options. The four health states are as follows:

- Well: the state for each individual with no history of coronary heart disease; a person can remain here until death or move to “coronary heart disease”;
- Coronary heart disease: state for individuals who have coronary heart disease move to this state for a maximum of 1 year; from this state, individuals can move

¹⁷³ Commission staff working document SWD(2015) 268 final, Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'. Accompanying the document. Report from the Commission to the European Parliament and the Council regarding trans fats in foods, in the overall diet and means for their reduction. COM(2015) 619 final; https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf; Mouratidou et al. Trans Fatty acids in Europe: where do we stand? JRC Science and Policy Reports 2014 doi:10.2788/1070

¹⁷⁴ Martin-Saborido et al. Public health economic evaluation of different European Union–level policy options aimed at reducing population dietary trans fat intake. *Am J Clin Nutr* November 2016 vol. 104 no. 5 1218-1226

either to “History of coronary heart disease” or “Death” but not back to the “Well” state;

- History of coronary heart disease: state for post-acute coronary heart disease individuals; survivors from a “coronary heart disease” state move to this state until death or until they suffer a new coronary heart disease event, in which case they move to the “coronary heart disease” state;
- Death: any individual can move to this state at any time.

The model is applied to the EU population and accounts for all costs and effects applicable or resulting from the policy options over the course of a lifetime (85 years). The current industrial trans fats intake, defined as percentage of total energy intake, used as starting point for the model (“today”) is calculated as a weighted average of data at Member State level collected through existing evidence and a survey.

The JRC chose the 85 years 'life-time horizon' following relevant methodological guidance, such as NICE (UK) or ISPOR (international). The 85 years are slightly above the average life expectancy in the EU. The NICE guidelines (for assessment of alternative health technologies) notes on the appropriate time horizon: "Long enough to reflect all important differences in costs or outcomes between the technologies being compared". Downs et al.¹⁷⁵ reflect on modelling studies' limitations: 'There are several limitations to the assumptions used in many of the modelling studies included in the review that need to be considered. The time horizons used for the models were short, with the exception of the article by Martin-Saborido et al..¹⁷⁴ In one study, the deaths averted were only examined for 1 year. Longer time horizons would be more appropriate, because the implementation of a trans fats policy would not result in instantaneous effects on cardio vascular disease, the use of a lifetime approach as was used in the model examining the impacts of trans fats policies in the European Union would likely be more appropriate.'

The model calculates, for each option, coronary heart disease events and mortality in yearly cycles over a period of 85 years. The relative risks for coronary heart disease associated with the different industrial trans fats intakes are based on the calculations in Mozaffarian et al (in which the “pooled multivariable-adjusted relative risks for 2% of total energy intake of trans fats, as an isocaloric replacement for carbohydrate, was 1.23 (95% CI = 1.11–1.37).” This is then applied to the different industrial trans fats intakes to calculate the probability of a coronary heart disease event.

Costs (of policy implementation and healthcare related) and outcomes (expressed in disability-adjusted life years, which measures overall disease burden) are estimated as the population circulates through the model. These are calculated for each policy option and then compared with the baseline. The model applied some simple assumptions to assess the broad scale of costs of public sector interventions, but excluded costs for business. Because of the limited scope and detail of the cost assessment, the model’s capacity to estimate costs of policy implementation was not used in this appraisal and as such this aspect is not discussed further.

¹⁷⁵ Downs S. M. et al.: The Impact of Policies to Reduce trans Fat Consumption: A Systematic Review of the Evidence. *Curr Dev Nutr* 2017;1

Concepts of industrial trans fats -related diseases used in this report, coronary artery disease, coronary heart disease and cardio vascular disease are explained in Annex 6.

For the starting point of the model (“today”) the risk of coronary heart disease is calculated on the basis of hospital discharges and already includes the risks from current industrial trans fats intakes, which are specific according to country, age, and gender. The reduction in coronary heart disease risk linked to industrial trans fats reductions in the following years from “today” is then calculated by using the relative risks above. Subsequently, the resulting disability-adjusted life year are then calculated on the basis of the modelled number of coronary heart disease events and deaths.

Given the uncertainty related to trans fats intake data, the JRC model tests three scenarios for intake in addition to the baseline.

Table 21 industrial trans fats intakes across the baseline and alternative scenarios as considered in the JRC model

Scenarios	EU population current industrial trans fats intake (%E)
Baseline	0.3
Scenario 1	0.15
Scenario 2	0.45
Scenario 3	0.7

The reference case built into the model assumes the highest population trans fats intake over the modelled horizon. JRC assumed that in the absence of EU action industrial trans fats consumption decreases over time and would reach zero in 10 years' time.

The JRC used the model to test scenarios based on a voluntary agreement, mandatory labelling and a legal limit on industrial trans fats content. The details of these scenarios are provided below for comparison to the scenarios tested for the current study (which are explained in the main text of the IA report):

- **JRC - Voluntary agreement:** This option assumes the creation of a voluntary agreement between the food industry and policy makers across the EU. The model assumes a decrease in industrial trans fats intake which would reach zero in 5 years' time. Costs of the option are related to food inspections to monitor and evaluate the agreement as well as the healthcare costs;
- **JRC - Mandatory labelling:** This option assumes that the current European legislation on the nutrition declaration on foods (Regulation EU (No) 1169/2011) would be changed to include also the declaration of trans fats content. The measure would apply only to pre-packaged food. The resulting decrease in industrial trans fats intake is slower than in the voluntary agreement case because it would lead to reformulation only in pre-packaged foods. industrial trans fats intake related to pre-packaged food (it is assumed to be 50% of the total population intake) decreases to zero in 3 years' time. Costs of the option are related to information campaigns to increase consumers' understanding of harmful effects of trans fats, as well as the healthcare costs;

- **JRC - Legal measure:** This option assumes the introduction of legislation at European level that limits the content of industrial trans fats in the food supply. The model assumes that the industrial trans fats intake is completely eliminated after 2 years. Costs of the option are related to food inspections to enforce the legislation as well as the healthcare costs.

For this assignment the JRC model was adapted in the following ways:

- The baseline scenario was developed further to accommodate known uncertainty about the future trend in industrial trans fats intake in the absence of EU action. Three variants of the baseline were specified to represent the spectrum of expected possible trajectories – industrial trans fats intake remaining constant at current levels, a linear decline in industrial trans fats levels to zero over 15 years and an accelerated linear decline to zero over 10 years;
- More conservative assumptions were defined for the impacts of voluntary agreements;
- The assumed impact of a legal limit on industrial trans fats content on industrial trans fats intake was revised from zero in the JRC model to 0.009 % of total energy intake, which corresponds to the average intake in Denmark as of 2014;
- The option of a partly hydrogenated oils ban was added; the modelling of health impacts of the partly hydrogenated oils ban used the JRC modelling assumptions for the legal limit of 2% industrial trans fats content.

Economic impacts have been assessed with a cost model developed in MS Excel in parallel to the JRC model. The analysis provides a quantitative assessment of administrative and compliance costs for business, and administrative costs for public authorities. This, and evidence collected from the consultations, informed a more qualitative assessment of related impacts on consumers, the Internal Market, competitiveness and international trade. Quantitative estimates of the costs borne by SMEs were also made.

The details of the cost assessment methodology are set out in the main text of this IA report and the related Annexes. The analysis involved:

- Estimating the numbers of businesses in relevant subsectors potentially affected by each option;
- Estimating administrative burdens using the Standard Cost Model, by estimating administrative time burdens by business and valuing these at appropriate hourly rates, based on Eurostat labour cost data;
- Estimating the required changes in compliance, including product testing, product reformulation and additional costs of ingredients, informed by data collected through the consultations and literature review, and applying appropriate assumptions where required;
- Estimating administrative burdens on public authorities by estimating and valuing the time and costs involved for policy implementation, monitoring and enforcement, applying the Standard Cost Model;

- Calculating the present value of these costs using a 4%¹³⁸ discount rate, in order to facilitate comparison with the benefits estimates.

Environmental impacts were examined qualitatively by ICF, drawing on evidence from the literature review. The analysis examined the likely substitutes for partially hydrogenated oils and their relative environmental impacts. A key source was the study for the European Commission undertaken by 3Keel and LMC International which has examined the environmental impact of palm oil. The approach was informed by an interview with the contractors for that study, which highlighted the significant uncertainties and complexities inherent in the assessment of the environmental impacts of palm oil and alternatives, including soy. For these reasons it has been difficult to draw firm conclusions about the environmental impacts of the options.

Analysis of impacts of combined options

An analysis of the following combinations of options was performed:

- Options 2 and 1b
- Options 2 and 3b
- Options 2 and 1a or 3a

The analysis has focused on identifying both additive and non-additive combined impacts. It was informed by evidence collected by ICF during the data collection phase.

5. VALIDATION CONSULTATION

Targeted stakeholder consultation was undertaken by ICF in order to triangulate findings / validate the data gathered on the impacts of the different policy options.

Online consultations

ICF undertook consultations of stakeholder groups with the aim of validating the provisional findings. This used an online questionnaire structured around the key data, estimates, and findings that were established in the earlier stages of the work. This maximised our ability to validate the data and triangulate the findings from the impact assessment with a wide range of stakeholders. This did not duplicate in any way the public consultation that was undertaken separately, as respondents were not asked to provide the range of their views on this issue. Rather, the use of closed questions enabled ascertaining the validity of key elements of the analysis.

Content of the survey instrument

An online consultation questionnaire was prepared by ICF in conjunction with the Commission and the ISG. The survey instrument is given in Annex 31.

The consultation built on the results generated through the data review and collection, and the impact screening and impact assessment. Consultees were presented with the key data points, estimates, assumptions and findings from these tasks, and were asked to provide their feedback. The consultation by ICF was mostly made of closed questions, with some options for comments (for example, in case of consultee's disagreement with research findings).

The first part of the consultation posed general questions on current and predicted industrial trans fats use under different policy options and the definition of industrial trans fats. The next part of the consultation gave respondents a choice between six

separate sections, allowing them to answer as many as were relevant, depending on their area of expertise. The available sections were:

- Health impacts
- Economic impacts
- Consumer impacts
- Internal Market and trade impacts
- Impacts on SMEs and
- Environmental impacts

Selection of consultees – overall approach

To validate the data gathered before by ICF, ICF distributed the consultation tool to:

- Consumer and health NGOs;
- Food business operators representative associations, both at an EU and national level;
- National competent authorities; and
- Experts with relevant expertise to comment on the different types of impact assessed.

The consultation was provided in English. Responses were accepted in other languages.

A total of 85 completed questionnaires were received. The table below shows the composition of the respondent group.

Table 22 Validation consultation – Demographics

Stakeholder group	Number of consultees
Consumer organisations	2
Food manufacturing/ processing business	12
Food sector association	26
Food service business	2
Public authorities	6
Public health organisations	7
Academia	2
International organisations	1

As Table 23 shows, representatives from the business sector belonged to various sectors potentially affected by the measures.

Table 23 Sectors represented among food industry consultees

Sector	Number of consultees
Chocolates / confectionery	2
Dairy products	7
Fresh cakes / pastries / bakery products	3
Ingredients for the food sector	4
Margarines and spreads	1
Multi-category / all food and drink	7
Oil and fats	5
Other (please specify)	9
Restaurants / food services	3
Snacks	1
Soups / sauces / condiments	2

Of all individual businesses who contributed to the validation consultation of ICF (n=14), 9 were large businesses, and 5 SMEs.

Analysis

The data were anonymised and aggregated by ICF. The responses were assessed in detail to evaluate whether the findings from the online consultation should lead to revisions of the analysis of impacts, depending on how consultees evaluated the assumptions and the estimates used in the analysis. Their assessment of the implications of the consultation was then shared with the project management team, for critical evaluation and quality assurance purposes.

Overall the results from the consultation have confirmed the appropriateness of the assumptions and estimates made by the ICF study team, while they have helped to qualify the baseline scenario.

6. STRENGTHS AND LIMITATIONS OF THE METHOD

The main limitations from the ICF study that is the main basis for this IA report are linked to the data to support the impact assessment. In spite of extensive efforts deployed to collect relevant data from the EU and beyond, a number of gaps remain. There were a number of specific points for which no hard evidence could be found by ICF. In addition, limited data were available on SMEs and from businesses in the non-pre-packed food sector though business organisations representing those firms did contribute direct evidence through interviews and responses to the validation consultation. These gaps have been addressed by the study team of ICF by drawing reasonable assumptions. These assumptions have been tested through the validation consultation, which helped provide elements to confirm or sometimes adjust these assumptions.

The study of ICF is showing the order of magnitude of the impacts, who is impacted, and the distribution of the impacts, in a manner that delivers a very clear message: the relative impact of the different options is clearly demonstrated. The results appear to be robust in the face of the uncertainty against the baseline. Adjustments to data points that are uncertain do not change the overall findings, which demonstrate the robustness of the overall ICF study.

With regard to the validity and reliability of modelling results, a number of uncertainties need to be highlighted. Such uncertainties are linked to the modelling exercise of the health impact assessments and estimates provided should not give a false impression of scientific accuracy in this respect.

There are uncertainties on a variety of factors that may contribute to health impacts, as discussed in the original JRC study. Those refer to trans fats intake (and notably to the contribution of ruminant trans fats intake in determining overall health impacts), variability between countries, and various data gaps such as coronary artery disease events.

The relative risk estimates from Mozaffarian et al¹⁷⁶ that were used by the JRC for the model does factor in all substitution effects. Factored in to a certain degree are the

¹⁷⁶ Mozaffarian D et al., 2009, Health effects of trans-fatty acids: experimental and observational evidence, European Journal of Clinical Nutrition 63(S2): p. S5-S21

Relative Risks (RR) for replacement of trans fats with carbohydrates, with saturated fats, with monounsaturated fats and with polyunsaturated fats; the reality is a mix of all and this is reflected in the range of RR. However, not factored in in the model (inter alia, due to lack of evidence) are more complex dietary substitution effects where dietary patterns change due to implementation of policy options.

The JRC considered ruminant trans fats intake (and more general ruminant fat intake) as constant between reference scenario and with policy options; for no action, voluntary and legal trans fats limits or partly hydrogenated oils bans, this assumption is, in the JRC's view, defensible as these do not consider ruminant trans fats sources; for the mandatory labelling that includes all trans fats sources, this assumption could hold less true, as consumers could (more than currently, where this is only recommended by several Member States) opt for low fat dairy or non-ruminant meat and/or could reduce dairy intake – such a dietary change could come with a range of effects, positive or negative. Certainly, all those considerations are beyond the model and beyond the available evidence.

The JRC model that was used also by ICF clearly underestimates health risks due to trans fats intake due to lack of evidence; Mozzafarian mentions that beyond negative effects on blood lipids, trans fats has also been shown to increase inflammation, which is clearly linked to a range of degenerative diseases, as well as endothelial dysfunction.

Overall, there are limitations of the ICF modelling exercise due to the assumptions needed, data scarcity linked to intakes and future projections, paucity of evidence related to other trans fats health effects, possibilities to model more complex dietary changes making strong simplification necessary. The main purpose of the model was to support with modelling the relative comparison of the viable policy options against a reference of no policy; this outcome of a legal limit performing better under this specific framing of a public health economic evaluation in terms of health benefits and cost-effectiveness has been shown to be robust in sensitivity analyses; the finding is also in line with similar modelling efforts (in support of the US FDA partly hydrogenated oils ban; for the UK) and across shorter time spans (e.g., 20 years) and using slightly different approaches. Nevertheless, the relative findings are based on past experience and suggestions by stakeholders in various surveys conducted over the past years how the future trans fats intakes might develop under the alternative policy scenarios – this remains inevitably uncertain, and events, such as a negative image of palm oil (a key substitute for partly hydrogenated oils used by some food business operator sectors) as an economic vegetable oil source could lead to incentives of re-introducing partly hydrogenated oils in case industrial trans fats use is not restricted.

7. DISCUSSION OF INFORMATION GAPS AND UNCERTAINTIES

Uncertainties and gaps have been made explicit through the ICF document and also in this IA report in the main text and related Annexes. Sensitivity tests have been used to explore the implications of differences in the baseline scenario for health benefits, and of mis-specification of current mean intake.

The health impact modelling of ICF, which used a model developed by the JRC, is conducted at an EU population level rather than Member State level, and with EU-level cost factors (e.g. on healthcare care and productivity losses).

The country research of ICF did not identify robust ex post appraisals of the cost of familiarisation with legislative requirements or reformulation costs from countries that have already acted robustly to reduce industrial trans fats intake. Some information on changes in specific firms or sectors was identified.

There is uncertainty about some key parameters of several options, notably:

- The precise impact of a partly hydrogenated oils ban on industrial trans fats intake. In this analysis the impact has been assumed to equivalent to that of a 2% limit on industrial trans fats content, as specified in the JRC model;
- The extent of reformulation of food products and how that may vary depending on whether the measure consists in a limit on industrial trans fats content or a ban on partly hydrogenated oils;
- The costs of introducing a new testing regime for partly hydrogenated oils and of agreeing a definition of partly hydrogenated oils at EU level (options 3a and 3b);
- The potential level of participation of food business operators in voluntary agreements (options 1a, 3a) and the impact of that participation on intake (whether the firms that participate make a proportionate contribution to residual industrial trans fats intake at the time the agreement starts);
- The extent to which modifying the nutrient declaration to include industrial trans fats content will lead to changes in consumer behaviour;
- The scale and cost of the consumer awareness-raising campaigns required to support the labelling option and the prospects of Member State authorities providing such funding at a time of public spending restraint;
- Where the unit label adjustment costs developed in previous research studies accurately estimate the costs of an adjustment to the nutrient declaration;
- The number of food products on the EU market and thus the number of labels to be changed.

ICF expressed the view that resolving these uncertainties would lead to some movement in the figures but not change the fundamental results relating to:

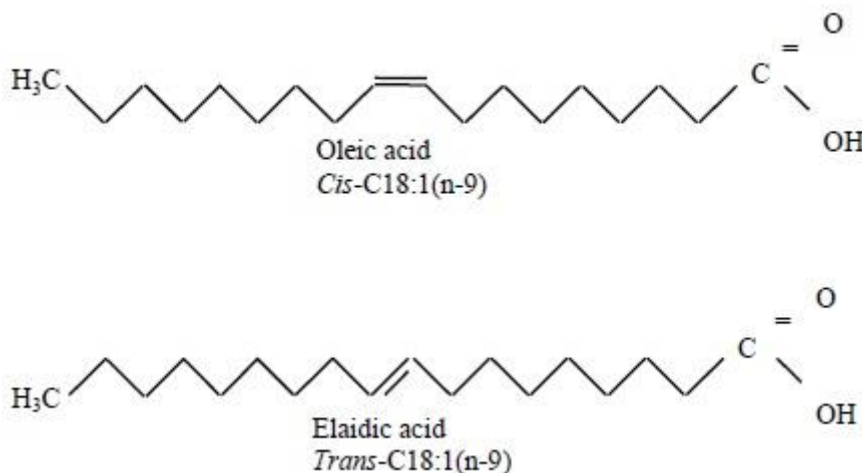
- The overall balance between benefits and costs of the legal options; and
- The relative performance of different options on measures of effectiveness and efficiency.

ANNEX 5: Trans fats – a general presentation

Trans fats are a particular type of unsaturated fatty acids and are defined, in Regulation (EU) No 1169/2011, 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'.¹⁷⁷

As explained by the European Food Safety Authority (EFSA), 'Fatty acids can be classified according to their number of double bonds. Saturated fatty acids (SFA) have no double bonds, while monounsaturated fatty acids (MUFA) have one double bond and polyunsaturated fatty acids (PUFA) have two or more double bonds (...). These double bonds can have either the *cis* or *trans* configuration. *Cis* means that the two carbon (C)-atoms (or hydrogen (H)-atoms) adjacent to the double bond point into the same direction, while in the *trans* configuration the two carbon atoms point into opposite directions'.¹⁷⁸ The figure below, edited from the EFSA's Scientific Opinion mentioned above, shows the difference between a fatty acid in its *Cis* form (oleic acid) and one in *trans* form (elaidic acid).

Figure 5 Structure of oleic acid and elaidic acid (Edited from EFSA (2004))



Most unsaturated fatty acids in the diet have the *cis* configuration, but *trans* fats are also present.¹⁷⁹

Trans fats can be produced industrially (industrial trans fats) or can be naturally present in food products derived from ruminant animals (ruminant trans fats).

¹⁷⁷ Point 4 of Annex I to Regulation (EU) No 1169/2011

¹⁷⁸ European Food Safety Authority, 2004, *Opinion related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids*. The EFSA Journal, 81, 1-49

¹⁷⁹ European Food Safety Authority, 2004, *Opinion related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids*. The EFSA Journal, 81, 1-49

As far as **industrial trans fats** are concerned, they are primarily present in the diet as partly hydrogenated oils, which generally contain saturated and unsaturated fats, and among them trans fats in variable proportions (up to more than 50% of the total fat content of the food). The hydrogenation process (i.e. the addition of hydrogen atoms) turns oils into semi-solid and solid fats thus giving them qualities desired by the food processing industry (e.g. increased tolerance against repeated heating, prolonged product shelf-life, sensory aspects)¹⁸⁰ at costs that are cheaper than the usual alternatives (e.g. solid animal fat like butter). Partial hydrogenation of oils is largely in use since the middle of the 20th century, however, there is no precise, legal definition for the chemical process. In accordance with Regulation (EC) No 1169/2011 on food information to consumers¹⁸¹, hydrogenated oils used as ingredients for foods must be accompanied by the expression 'fully hydrogenated' or 'partly hydrogenated' in the ingredient list.

Industrial trans fats can also be the result of refining of certain unsaturated oils or of heating and frying of oils at too high temperatures (> 220°C).¹⁸² Industrial trans fats can be found at varying amounts in several food products including certain bakery products (e.g. biscuits and pastries), vegetable fats (e.g. margarines and spreads), confectionary (fillings and creams) and some fried foods (e.g. potato crisps).

Examples of products found to contain trans fats in considerable amounts in Member States, generally of industrial origin, are 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.¹⁸³

Reduction of industrial trans fats in foods and thereby reduction of excessive intakes of trans fats by consumers is possible by carefully selecting the type of ingredients, for example by substituting partially hydrogenated oils with alternatives.

Ruminant trans fats, on the other hand, are generated in the rumen of animals by gut bacteria, absorbed and utilised by the animals. Therefore, ruminant trans fats are naturally present in the fat part of food products derived from ruminant animals such as dairy products or meat from cattle, sheep or goat, at levels most commonly around 3% and ranging from 2 to 9% of the total fat content of the food. Trans fats from ruminant sources, contribute between 0.3 and 0.8 % of energy intake, depending on dietary habits¹⁸⁴.

¹⁸⁰ Mouratidou T *et al.*, 2014, *Trans Fatty acids in Europe: where do we stand?* JRC Science and Policy Reports. It is important to note that Partial hydrogenation is different from full hydrogenation, as when all double bonds are hydrogenated, a saturated fatty acid is formed

¹⁸¹ Annex VII to 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

¹⁸² European Food Safety Authority, 2010, *Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol*, EFSA Journal 2010; 8(3):1461

¹⁸³ Commission Staff Working Document " Results of the Commission's consultations on 'TFA in foodstuffs in Europe'"

¹⁸⁴ Hulshof KF *et al.* Eur J Clin Nutr. 1999;53(2):143-57

Trans fats in foods can be identified and quantified using different validated methods that have different strengths and weaknesses (e.g. in terms of reproducibility, precision, time, costs). Further research is underway to improve how to distinguish between ruminant and industrial trans fats in the same product.¹⁸⁵

Some complexity arises when a product contains both industrial and ruminant trans fats (e.g. milk fat and partly hydrogenated soybean oil).

In Denmark, the approach followed to estimate the amount of industrial trans fats in these cases is to

- First, estimate the amount of milk fat present in the food based on its butyric acid content (C4:0), butyric acid occurs uniquely in milk fat;
- second, using this to estimate the amount of ruminant trans fats in the food based on an assumption about the fraction of milk fat that is trans fats;
- third subtracting the ruminant trans fats figure from the total amount of trans fats to derive an estimate of the industrial trans fats content.¹⁸⁶

The JRC carried out a literature review¹⁸⁷ confirming the complexity of the matter. The analytical method based on butyric acid is presented as a valid way to corroborate another method based on a different marker (9c, 11t-18:2 a unique marker to indicate the presence of ruminant fat). Limitations of the existing methodologies were also discussed. JRC is currently carrying out work in order to develop a reliable methodology to determine levels of industrial trans fats in food.

¹⁸⁵ Mouratidou T et al., (2014)

¹⁸⁶ ICF and Danish food institute. 'Analysis of trans fatty acids in Denmark, industrially produced versus ruminant trans fatty acids'

¹⁸⁷ European Commission, Joint Research Centre, 2016, *Possibilities to quantify trans fatty acids of ruminant origin in blends containing ruminant and industrially processed fats and oils* (Ref. Ares(2016)6994854 - 15/12/2016)

ANNEX 6: Trans fats consumption and its negative impact on health and intake recommendations

Trans fats consumption and its negative impact on health

There is scientific consensus that trans fats intake has a negative effect on human health and, more specifically, that trans fats intake is a risk factor for the development of coronary heart disease.¹⁸⁸

As noted by EFSA, "*consumption of diets containing trans-monounsaturated fatty acids (...) increases blood total and LDL cholesterol concentrations in a dose-dependent manner, compared with consumption of diets containing cis-monounsaturated fatty acids or cis-polyunsaturated fatty acids. Consumption of diets containing trans-monounsaturated fatty acids also results in reduced blood HDL cholesterol concentrations and increases the total cholesterol to HDL cholesterol ratio. (...) Prospective cohort studies show a consistent relationship between higher intakes of trans fatty acids and increased risk of coronary heart disease*"⁵.

It has also been argued that the consumption of trans fats increases the risk of heart disease more than any other macronutrient compared on a per-calorie basis and that the risk of dying from heart disease is 20-32% higher when consuming 2% of the daily energy intake from trans fats instead of consuming the same energy amount from carbohydrates, saturated fatty acids, cis monounsaturated fatty acids and cis polyunsaturated fatty acids.¹⁸⁹

There is still a scientific debate whether consumption of ruminant trans fats has similar effects for human health than that of industrial trans fats. In this context, the European Food Safety Authority noted that '*The available evidence indicates that trans fatty acids 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, '*The available evidence is insufficient to establish whether there is a difference between ruminant and industrial trans fatty acids consumed in equivalent amounts on the risk of coronary heart disease*'.¹⁹⁰ Recent draft guidance from the WHO on trans fats intakes for adults and children^{191 192} clarify that the definition of trans fats to be reduced includes both those from industrial sources and from ruminant sources.

¹⁸⁸ Different health indicators such as coronary heart disease, cardio vascular disease and coronary artery disease are used throughout this report, this Annex explains those different terminologies and the background of their use

¹⁸⁹ Mozaffarian D et al., 2009, *Health effects of trans-fatty acids: experimental and observational evidence*, European Journal of Clinical Nutrition 63(S2): p. S5-S21

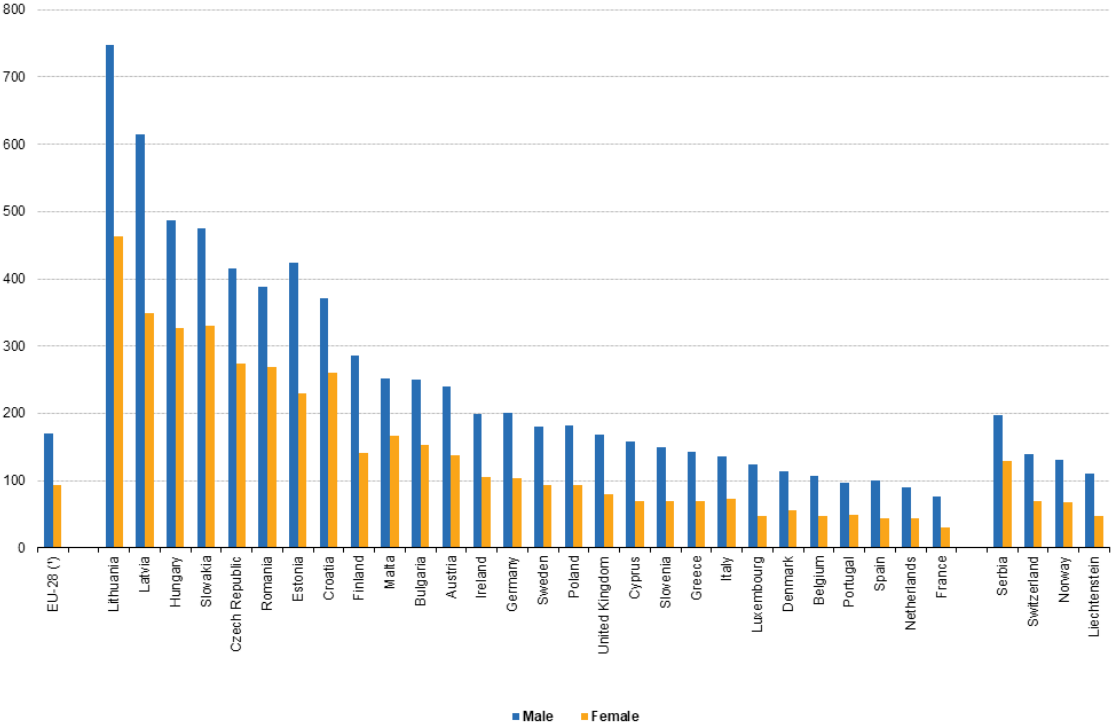
¹⁹⁰ European Food Safety Authority, 2010, Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol, EFSA Journal 2010; 8(3):1461

¹⁹¹ WHO: Draft guidelines on saturated fatty acid and trans-fatty acid intake for adults and children. [https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)

¹⁹² <http://www.who.int/nutrition/topics/sfa-tfa-public-consultation-4may2018/en/>

High trans fats intake is one of the risk factors for developing coronary heart disease^{5 37}, which is the single leading cause of mortality in the EU.¹⁹³ In the EU, coronary heart disease accounted for some 623 thousand deaths in 2014 or 12,6% of overall mortality with a wide variability observed among Member States.¹⁹⁴ Figure 6 illustrates those differences.

Figure 6 Deaths from coronary artery disease (also called ischaemic heart diseases)¹⁹⁵ — standardised death rate, 2014 (per 100 000 inhabitants) (source: Eurostat)



Note: the figure is ranked on the average of male and female.
 (*) For the age standardisation, among older people, the age group aged 85 and over was used rather than separate age groups for 85-89, 90-94 and 95 and over.
 Source: Eurostat (online data code: hlth_cd_asdr2)

Cardio vascular disease, including coronary heart disease, imposes substantial health burdens in the EU.

Costs associated with coronary heart disease (healthcare costs, opportunity costs of informal care from relatives of the person suffering from coronary heart disease and productivity losses associated with premature death or morbidity) can be estimated to amount in 2014 to more than €60 billion (€60 247 million) or 0.43 % of the EU Gross Domestic Product. Healthcare costs of coronary heart disease can be estimated to run up to

¹⁹³ Eurostat, Causes of death data, 2012
¹⁹⁴ Eurostat, Causes of death data, 2014
¹⁹⁵ The end of this Annex includes a note on concepts of trans fats-related diseases used in this impact assessment

more than €30 billion (€30 824 million), 0.22 % of the EU Gross Domestic Product or 2.33 % of total healthcare costs.¹⁹⁶

According to the ICF study, using European Heart Network cardio vascular disease statistics published in 2017, it is estimated that 49 million people live with cardio vascular disease and that the condition imposes costs of more than €200 billion each year in the EU.¹⁹⁷

It is of course difficult to quantify the exact impact of trans fats intakes on health at EU level (i.e. what percentage of coronary heart disease-caused deaths is caused by trans fats intakes) and the subsequent costs for the society, taking into account that coronary heart disease is linked to multiple risk factors and that limited data is available for trans fats intakes in the entire EU (see section 2.1 and Annex 9).

In order to potentially have an indication, however, it can be noted that in 2014, the standardised death rate for coronary heart disease in the EU-28 was 126 deaths per 100 000 inhabitants.¹⁹⁸ The introduction in Denmark of legal limits for industrial trans fats in foods (see Annex 8), which nearly eliminated those trans fats from the Danish food supply, has been estimated to reduce mortality attributable to Coronary Heart Disease on average by about 26.5 deaths per 100 000 people per year¹⁹⁹ in the three years after the implementation of the legal limit.

As coronary heart disease creates significant costs for Member States' healthcare systems and more generally for their economies, excessive trans fats intake should be reduced in the diet of consumers. In this context, initiatives to reduce intakes of trans fats in the population were launched in different EU Member States with the support of stakeholders both on the consumers' side and on the industry's side.

Intake recommendations

For the reason mentioned above, and taking into account that trans fats are not synthesised by the human body and are not required in the diet, the European Food Safety Authority and the World Health Organization recommend that their consumption is limited or minimised.

The European Food Safety Authority recommends that 'trans fatty acids intakes should be as low as is possible within the context of a nutritionally adequate diet'.²⁰⁰ This recommendation takes into account the fact that trans fats are intrinsically contained in several fats and oils that are also important sources of essential fatty acids and other

¹⁹⁶ Extrapolation assuming constant %GDP to EU-28 in 2014 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 2014

¹⁹⁷ European Heart Network CVD statistics 2017

¹⁹⁸ Eurostat, Causes of death data, 2014

¹⁹⁹ Restrepo BJ *et al.*, 2016 *Denmark's Policy on Artificial Trans Fat and Cardiovascular Disease*, American Journal of Preventive Medicine, Volume 50, Issue 1, January 2016, Pages 69-76

²⁰⁰ European Food Safety Authority, 2010, Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol, EFSA Journal 2010; 8(3):1461

nutrients in the diet. Thus, there is a limit to which the intake of trans fats, can be lowered without compromising adequacy of intake of essential nutrients. Ruminant foods that contribute ruminant trans fats are sources of some essential nutrients. Most public health authorities in Member States recommend that fat intake from animal source should be limited, mostly due to their high content of saturated fat, which is consumed in excess in the most EU Member States.⁵ Ruminant trans fats sources contribute between 0.3 and 0.8% of the daily energy intake depending on dietary habits across Europe.²⁰¹ Section 2.1 and Annex 9 provide additional information on trans fats intakes in the population. The most recent data suggest that in 2014 the average industrial trans fats intake in Denmark was 0.009 % of energy intake²⁰², this very low level of intake was achieved after the introduction of a legal limit for industrial trans fats of 2 % per 100 g fat in foods sold to the final consumer in Denmark. This very low level with regard to industrial trans fat intake could be considered as 'as low as possible'.

The World Health Organisation recommends that less than 1 % of total energy intake should come from consuming trans fats²⁰³, which translates to less than 2.2 g/day with a 2,000-calorie diet. The 2000-calorie diet is the reference intake set in EU food information legislation for labelling purposes²⁰⁴, in line with Codex Alimentarius guidance. WHO published new draft guidelines on trans fats intakes for adults and children on 4 May 2018 while launching a OPC calling for comments.^{205 206} In the draft version, trans fats intakes are recommended to be less than 1 % of energy intake, in line with the existing recommendation. While the proportions are the same, the original guidelines are based on 'population nutrient intake goals', meaning they were recommended averages for large groups. The draft guidelines would apply to individuals, according to information provided by WHO officials to the media on a conference call.²⁰⁷ Furthermore, the draft guidelines also clarify that the definition of trans fats includes both those from industrial sources and from animals. Also, the update includes a recommendation to replace trans fats with polyunsaturated fats.

A note on concepts of trans fats-related diseases used in this impact assessment

As it builds on a number of different studies, this impact assessment makes reference to three different concepts describing diseases linked to trans fats intake: coronary artery disease, coronary heart disease and cardio vascular disease. High cholesterol levels (which may result from high industrial trans fats intake) are a risk factor for both coronary heart disease and coronary artery disease. The two terms are often used interchangeably. However, coronary artery disease can be considered as an antecedent of coronary heart

²⁰¹ Hulshof KF et al. Eur J Clin Nutr. 1999;53(2):143-57

²⁰² Martin-Saborido CM et al. (2016) Public health economic evaluation of different European Union-level policy options aimed at reducing population dietary trans fat intake. American Journal of Clinical Nutrition, 104: 1218-26

²⁰³ WHO/FAO, 2003, Expert Report: Diet, nutrition and prevention of chronic diseases. Report of a Joint WHO/FAO Expert Consultation, WHO Technical Report Series 916

²⁰⁴ Annex XIII to Regulation (EU) No 1169/2011

²⁰⁵ WHO: Draft guidelines on saturated fatty acid and trans-fatty acid intake for adults and children.

[https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)

²⁰⁶ <http://www.who.int/nutrition/topics/sfa-tfa-public-consultation-4may2018/en/>

²⁰⁷ POLITICO Pro Alert: WHO issues draft guidelines on saturated and trans fats -- By Sarah Wheaton 5/4/18, 4:55 PM CET

disease, in that the build-up of plaque within coronary arteries (coronary heart disease) leads to the condition called coronary heart disease. Cardio vascular disease is a broader term to describe a range of diseases that affect the heart, including heart failure (which can be caused by coronary heart disease, among other factors), arrhythmia (abnormal heart beat) and heart valve problems. Studies have explored the impact of industrial trans fats intake on either coronary heart disease (e.g. Martin-Saborido et al. 2016³²), coronary heart disease (e.g. Mozaffarian et al. 2006²⁰⁸) or cardio vascular disease (e.g. Restrepo and Rieger 2016⁴⁴).

²⁰⁸ Mozaffarian D et al. (2006) Trans fatty acids and cardiovascular disease. *New England Journal of Medicine* Apr 13;354(15):1601-13.

ANNEX 7: Health effects of ruminant versus industrial trans fats and the potential to limit the associated health problem by addressing their intake

The European Food Safety Authority concluded in 2010 that the available evidence indicates that ruminant trans fats have adverse effects on blood lipids and lipoproteins similar to those from industrial sources when consumed in equal amounts²⁰⁹. The European Food Safety Authority further concluded that there is insufficient evidence to establish whether there is any difference in the risk of heart disease between ruminant and industrial trans fats consumed in equivalent amounts. The result of the observational study might reflect a true difference between sources or might be a function of consumption levels.²¹⁰

The WHO published new draft guidelines on trans fats intakes for adults and children while launching a OPC calling for comments on 4 May 2018.²¹¹ ²¹² The new draft guidelines clarify that the definition of trans fats to be reduced includes both those from industrial sources and from ruminant sources.

Reduction of industrial trans fats in foods is possible by changing the type of ingredients used in their preparation. An example is the substitution of partly hydrogenated oils with alternatives. Evidence from Denmark²¹³ demonstrates how, after legislation imposed a limit on industrial trans fats, industrial trans fats were reduced or eliminated from most products that originally had a high industrial trans fats content. Examples are French fries, microwavable popcorn and various bakery products. Industrial trans fats now make an insignificant contribution to overall intake of trans fats in Denmark.

The fat composition of ruminant fats with regard to their trans fats content is not modifiable to a significant degree, therefore their intake cannot totally be avoided when consuming ruminant derived foods that are important in the diet of the EU population. Also, ruminant trans fats sources generally contribute in a limited way to high total trans fats intake. Ruminant fats contain approximately 3 % trans fats and between 40 to 60 % of saturated fats, generally the proportions of those fats are fixed. Both types of fats increase the risk of dying from heart disease. The risk associated with trans fats is higher as compared to saturated fats. However, in order to address excessive intakes of saturated fats national nutrition policies aim to reduce the population intake of ruminant fats in the diet (for example with recommendation to prefer low fat versions of dairy products) and

²⁰⁹ EFSA (2010) Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal 2010; 8(3):1461. [107 pp.]. doi:10.2903/j.efsa.2010.1461. EFSA Journal, 2010; 8(3):1467

²¹⁰ De Souza, R. J., et al. (2015) Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. BMJ 2015;351:h3978

²¹¹ WHO: Draft guidelines on saturated fatty acid and trans-fatty acid intake for adults and children. [https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)

²¹² <http://www.who.int/nutrition/topics/sfa-tfa-public-consultation-4may2018/en/>

²¹³ Bysted, A., Aarendahl Mikkelsen, A., Leth, T. (2009) Substitution of trans fatty acids in foods on the Danish market. European Journal of Lipid Science. Volume 111, Issue 6. No. 6 June 2009. Pages 574–583

address automatically also the problem of ruminant trans fats. The Commission supports national efforts in this respect as part of the initiatives with the High Level Group on Nutrition and Physical Activity, a group composed of EU (and EFTA) government representatives led by the European Commission.²¹⁴ ²¹⁵ National policies to reduce saturated fat intake are in line with scientific advice of the European Food Safety Authority⁵, that concluded that saturated fat intake should be as low as is possible within the context of a nutritionally adequate diet.

²¹⁴ https://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/euframework_national_nutrients_en.pdf

²¹⁵ https://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/saturated_fat_eufnisen_en.pdf

ANNEX 8: Current status of EU and national measures addressing the trans fats problem and consumer knowledge regarding trans fats

Overview of existing policies in EU Member States

In line with the intake recommendations described in Annex 7, initiatives to reduce the consumption of trans fats are in place in many countries both within and outside the EU. In general, these initiatives focus on industrial trans fats, because the proportion of trans fats in those fat sources can be modified whereas the proportion of trans fats in ruminant fats is relatively stable. In addition, while the levels of industrial trans fats in foods can be as high as 50 % of total fat content, those of ruminant trans fats are around 3 % of the total fat content (normally below 6 %) and ruminant trans fats are consumed at relatively low levels in most populations .

There is currently no EU legislation regulating the content of trans fats in food products, with the exception of the legislation applicable to infant formula and follow-on formula and olive oil. There are no specific labelling requirements either, apart from the obligation to indicate on label whether refined fats/oils present in the product are partly hydrogenated (this might allow to infer that the product contains trans fats, but it is not required or possible to label the exact trans fats amount).

Table 24 Overview of existing policies in EU Member States

Policy/ measure	Country
Voluntary – self regulation	BE, DE, NL, PL, UK, EL
Voluntary – dietary recommendation	BG, MT, SK, UK, FI
Voluntary – composition criteria for specific products	EE
Legislation limiting trans fats content of foodstuffs*	AT, DK, LV, HU, LT, SI, RO ²¹⁶
Legislation limiting trans fats content of foodstuffs which voluntarily bear a specific nutrition claim (keyhole)	SE
Other legislation (e.g. limits on specific product categories)	ES, EL, FI

Notes: * All legal acts apply to products sold to final consumer. Ruminant trans fats are exempt in all cases. FI presence in two categories matches source document.

Source: EC, 2010. 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, updated in May 2018.

Table 2424 provides an overview of existing national measures in EU Member States that were in force at the point of completing this IA. Some Member States (i.e. AT, DK, LV,

²¹⁶ Notification 2017/535/RO, standstill period until 24 May 2018

HU, LT, SI) have implemented or adopted legislation on industrial trans fats content of foodstuffs. In other Member States voluntary measures can be observed, either industry self-regulation (e.g. BE, DE, NL, PL, UK, EL), voluntary dietary recommendations (e.g. BG, MT, SK, UK, FI) or voluntary composition criteria for specific products (e.g. EE). Romania transmitted to the Commission draft legislation to impose a legal limit to industrial trans fats content in food.²¹⁶

Member State legislation differs in approach. E.g., Austrian/ Hungarian legislation established a maximum content of trans fats at 10 % of the total fat content where the total fat content is less than 3 % of the product, and at 4 % where the total fat content is between 3 % and 20 % of the product.

A more complete overview can be found in Table 25 below:

Table 25 Overview of Member State measures

	Scope	Restriction	Derogations
Denmark (2003)	Industrial trans fats, products sold to final consumers	< 2g trans fats in 100 g total fat ²¹⁷	(not applicable anymore)
Austria (2009)	Industrial trans fats		D1: In processed foods with less than 20% total fat content, industrial trans fats up to 4% D2: In processed foods with less than 3% total fat content, Industrial trans fats up to 10%
Hungary (2013)	Industrial trans fats, products sold to final consumers		D1, D2
Latvia (2015)	Industrial trans fats		D1
Slovenia (2017)	Industrial trans fats		./,
Romania (2017)	Industrial TFAs		./.
Lithuania (2017)	Industrial TFAs		D1

D1: derogation 1

D2: derogation 2

²¹⁷ For Denmark: 100 g total fat or oil.

A very recently notified draft national measure²¹⁸ proposes to address the trans fats problem by banning the use of trans fats containing hydrogenated oils as an ingredient for a special type of food products.

In the consultation that preceded the adoption of the Commission's report on trans fats, several national competent authorities indicated that they were prepared to proceed with national measures in the absence of EU action.²¹⁹ Some food business operators have taken voluntary action to reduce or eliminate industrial trans fats from their products in action orchestrated at EU level by representative organisations (such as CAOBISCO and FEDIOL). In Belgium, Germany, the Netherlands, Poland, the UK and Greece, voluntary self-regulation measures have been agreed with the food industry.

EU legislation

EU legislation sets legal limits for trans fats in infant formula and follow-on formula (3 % of the total fat content of the food, to allow for the use of milk, which naturally contains ruminant trans fats, as a source of fat).

Regulation (EU) No 1169/2011 on the provision of food information to consumers requires since 13 December 2014 to specify in the ingredients list of all pre-packed foods (non pre-packed foods are not covered by this provision) whether refined fats/oils are partly hydrogenated. The Regulation however does not require the indication of the exact trans fats content of foods in the nutrition declaration. It is important to note in this context that Regulation (EU) No 1169/2011 also prohibits operators from declaring the trans fats content of foods on nutrition labels on a voluntary basis. It was indeed considered that this possibility would be used as a marketing tool by some operators only and lead to consumers' confusion.

Legal measures outside the EU

Legal measures limiting the content of industrial trans fats in foods exist also outside the EU (e.g. in Switzerland, Iceland, Norway as well as in the US, where the Food and Drug Administration concluded in 2015 that partially hydrogenated oils, the primary dietary source of industrial trans fats, are no longer to be considered as 'generally recognized as safe' (GRAS) for use in food). The U.S. Government introduced a ban on partly hydrogenated oils because they are the primary dietary source of industrial trans fats in the USA. Although all refined edible oils contain some industrial trans fats as an unintentional by-product of their manufacturing process, industrial trans fats are an integral component of partly hydrogenated oils and are purposely produced in these oils to affect the properties of the oil and the characteristics of the food to which they are added.²²⁰ For the purposes of this declaratory order, the Food and Drug Administration is defining partly hydrogenated

²¹⁸ Notification: 2018/0167/E, the purpose of the draft decree is to regulate the use of the term 'artisan' or 'artisanal' for food products

²¹⁹ EC, 2015. 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

²²⁰ USFDA (2017) Final Determination Regarding Partially Hydrogenated Oils (Removing Trans Fat). (<https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>)

oils as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value greater than 4. Use of partly hydrogenated oils in foods will be phased out in the U.S. market by June 2018. The US performed analysed the cost and benefits of the legal measure.²²¹

In 2017, Canada adopted a measure prohibiting the use of partly hydrogenated oils in foods by adding them to the list of contaminants and other adulterating substances in food, a decision which was confirmed in February 2018 by the adaptation of other rules.²²²

Consumer knowledge regarding trans fats

In 2013 and 2014, a study on the impact of food information on consumers' decision making was carried out, including substantial research on consumer knowledge about trans fats and partly and fully hydrogenated oil and the potential impact of a mandatory trans fats labelling on consumers' decision making.²²³

The online 'laboratory' experiments were conducted in eight member states (United Kingdom, France, Germany, Italy, Spain, Finland, Poland, and Romania) in September 2013, addressed to a total of 6337 respondents (number of responses are given in Figure 8). A questionnaire with online panellists included the simulation of various shopping and consumption scenarios to collect relevant choice observations on various policy areas, including trans fats.

The study identified potential awareness drivers for decision making of consumers, as one key requirement for making healthier choices in the tested scenarios is a minimum level of awareness and the correct evaluation of the various fat types. This data was collected by the contractor performing the study, TNS, before the experimental part of the survey with the following results:

- Almost everyone had heard of saturated fat previously and around half correctly classified it as something unhealthy;
- Compared to that, the general awareness of all of the other fat types (trans fats, partly hydrogenated oil, fully hydrogenated oil) is significantly lower. Around 30 % claim to have never heard of them. Amongst those aware of each type of fat, only around half were able to judge whether it is something healthy or unhealthy;
- Overall, trans fat seems to have a more unhealthy image than partly hydrogenated oils or fully hydrogenated oils;
- Fully hydrogenated oil seems to have a slightly unhealthier image than partly hydrogenated oils.

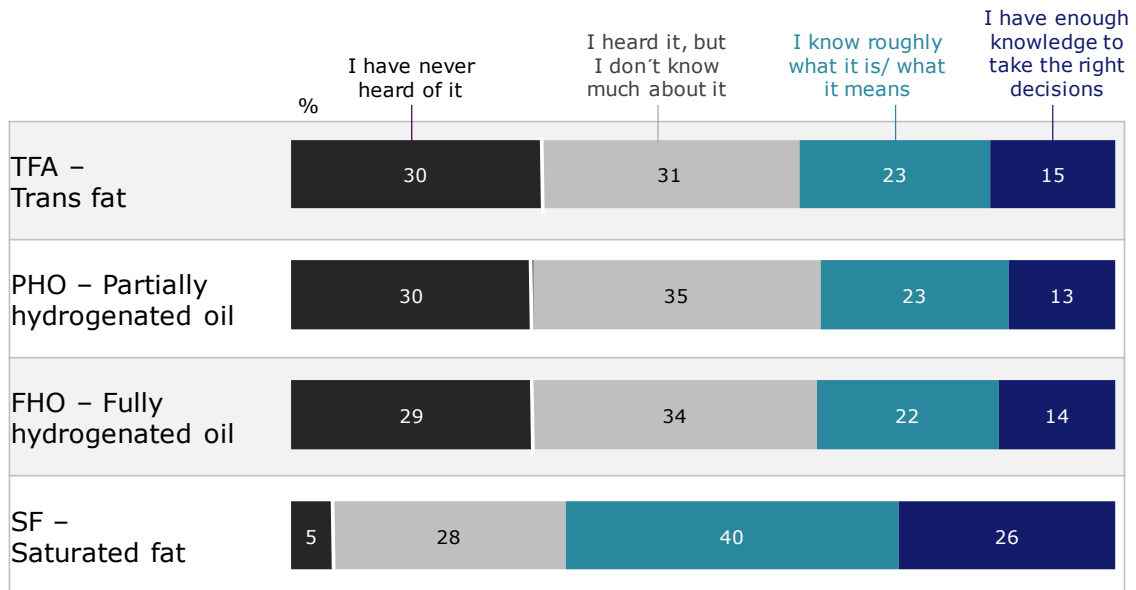
²²¹ Bruns R (2015) Estimate of Costs and Benefits of Removing Partially Hydrogenated Oils (PHOs) from the US Food Supply. US Department of Health and Human Services.

²²² Quote from the Canada Gazette accessible at <http://gazette.gc.ca/rp-pr/p1/2018/2018-02-10/html/reg2-eng.html>.

²²³ TNS (2014) Study on the Impact of Food Information on Consumers' Decision Making.

Figure 7 Awareness of fat types

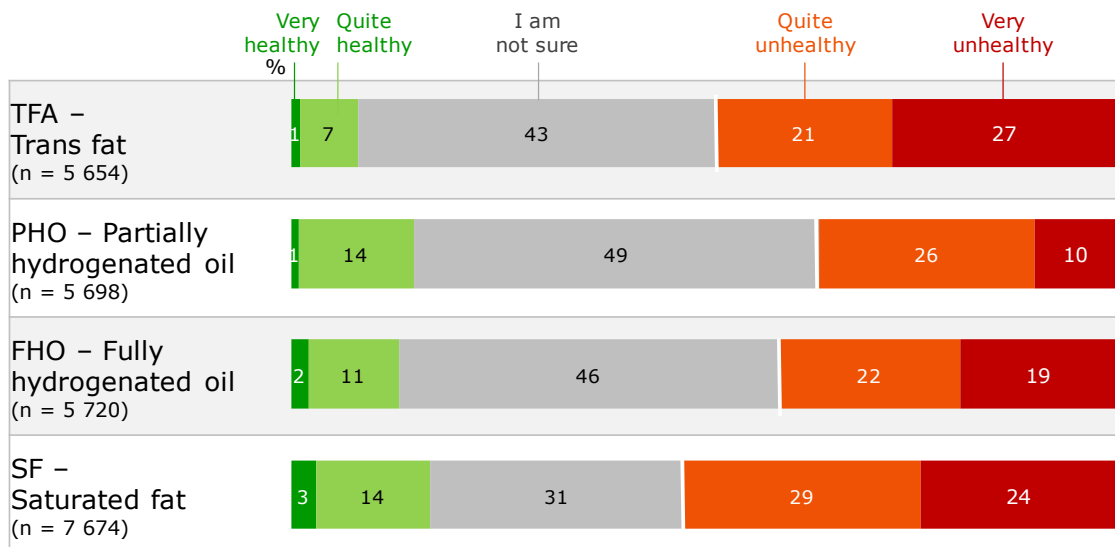
Awareness of fat types



Q12: Have you ever heard of these types of fat before? Which of the following applies to you regarding ...?
 Base: EU8 – all respondents (n = 8 076)

Figure 8 Evaluation of fat types

Evaluation of fat types



Q13: Based on what you know, how healthy do you think these types of fat are?
 Base: EU8 – respondents who heard of the term before (n = between 5 654 and 7 674)

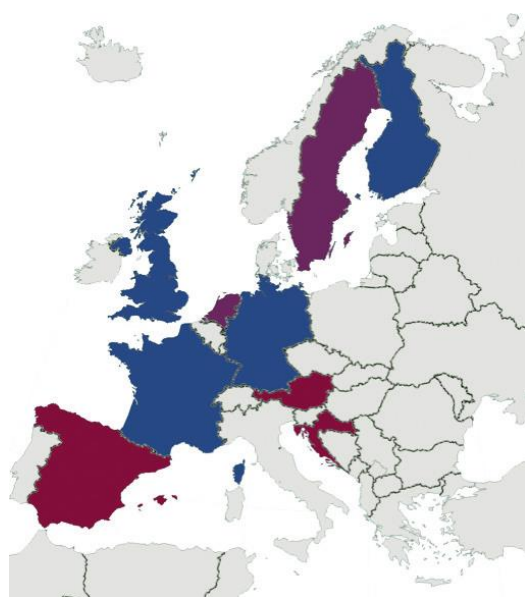
ANNEX 9: Additional information on trans fats intakes in the population and presence in foods

Data presented in this Annex is extracted from a JRC report published in 2014 with data collected before this year²²⁴.

Trans fats presence in foods in Europe

Data contained in 13 studies collected by JRC are analysed in detail in Table 21. These studies are national surveys, national reports, local surveys, original studies or market basket surveys providing estimated per capita exposure to trans fats. Not all studies report intakes of the same population groups and not all have provided information by gender and age groups. It is important to note the many differences between the studies considered and the limitations these differences entail. Importantly, the results presented below reflect only the data on the trans fats intake of the population groups analysed in the studies considered here and cannot be seen as representative of the European trans fats intake.

Figure 9 Availability of data on trans fats consumption/intakes in the EU28.



Red: Not representative country sample
Blue: Representative country sample (wide age range)
Violet: Representative country sample (narrow age range)
grey: no data available

²²⁴ Mouratidou T et al., 2014, Trans Fatty acids in Europe: where do we stand? JRC Science and Policy Reports <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC91353/lbna26795enn.pdf>

Table 26 provides an overview of mean and median trans fats intakes (trans fats percent of energy intake (E%) and trans fats g per day) by gender and age when possible. Among the population groups analysed here, male and female Croatian University students aged 18 to 30 years, Swedish boys aged 8 and 11 years respectively, Spanish males and females aged 18 to 30 years, British male and female participants of the Low Income and Nutritional Survey, and French females aged more than 55 and between 3 and 10 years, all have intake average values above the 1 % of energy intake. When the revised WHO recommendation is finally published in its current draft form, the analysis has to be performed again to assess the magnitude of the population that has intakes at or above 1 % of energy intake. The highest median trans fats intakes as a fraction of energy are observed in British male and female participants of the Low Income and Nutritional Survey, followed by Swedish males and females of all ages who also have the highest trans fats intakes in grams per day together with German males (data from 2013).

Table 26 trans fats intake of various population groups as reported in the thirteen studies analysed

Country	Study	Gender	Age or age range (yrs)	Mean TFA E%	Median TFA E%	Mean TFA (g/day)
Austria	<i>Elmadfa et al. 2008 (71)</i>	M/F	14-36	0.39	0.23	0.97
Finland	<i>Patury et al. 2008 (72)</i>	M	25-64	0.4		1.1
		M	65-74	0.4		0.8
		F	25-64	0.4		0.8
		F	65-74	0.4		0.6
	<i>Kyttälä P et al. 2008 (73)</i>	F	1	0.3	0.2	0.3
		F	2	0.4	0.5	0.5
		F	3	0.4	0.6	0.6
		F	4	0.5	0.6	0.7
		F	6	0.5	0.7	0.8
		M	1	0.2	0.2	0.3
		M	2	0.4	0.5	0.5
		M	3	0.4	0.6	0.6
		M	4	0.5	0.6	0.7
		M	6	0.5	0.7	0.8
France	<i>Afssa 2009 (74)</i>	M	18-34	0.93	0.95	2.66
		M	35-54	0.94	0.94	2.67
		M	55	0.96	0.94	2.56
		F	18-34	0.99	0.99	2.03
		F	35-54	0.97	0.95	2.03

		F	>55	1	0.99	2.02
		M	3-10	0.99	0.98	1.92
		M	11-14	0.93	0.91	2.11
		M	15-17	0.91	0.87	2.15
		F	3-10	1.02	0.99	1.77
		F	11-14	0.96	0.96	1.86
		F	15-17	0.93	0.9	1.71
		M/F	18+	1		2.3
		M/F	<18	0.8		1.9
Netherlands	<i>van Rossum et al. 20011 (76)</i>	M	7-8		0.5	1.1
		F	7-8		0.5	1.2
		M	9-13		0.5	1.3
		F	9-13		0.5	1.2
		M	14-18		0.5	1.4
		F	14-18		0.5	1.2
		M	19-30		0.5	1.5
		F	19-30		0.5	1.2
		M	31-50		0.5	1.5
		F	31-50		0.6	1.2
		M	51-69		0.6	1.5
		F	51-69		0.6	1.3
	<i>Ocke et al. 2008 (77)</i>	M	2-3	0.8	0.7	1.2
		F	2-3	0.7	0.7	1.1
		M	4-6	0.8	0.8	1.4
		F	4-6	0.8	0.8	1.4
Spain	<i>Mayneris et al. 2010 (78)</i>	M/F	18-30	1.05		
		M/F	31-50	0.88		
		M/F	51-65	0.79		
		M/F	65+	0.61		
United Kingdom	<i>Nelson et al. 2007 (80)</i>	M	19-34	1.2		3.1
		M	35-49	1.4		3.1
		M	50-64	1.3		2.7
		M	65+	1.3		2.5
		M	2-10	1.2		2.2
		M	11-18	1.2		3

		F	19-34	1.2		2.1
		F	35-49	1.2		2.1
		F	50-64	1.2		2.1
		F	65+	1.4		2.2
		F	2-10	1.1		1.9
		F	11-18	1.2		2.4
	<i>Lennox et al. 2013 (81)</i>	M/F	4-6*	0.1		0.1
		M/F	7-9*	0.2		0.2
		M/F	10-11*	0.3		0.3
		M/F	12-18*	0.5		0.6
	<i>Bates et al. 2011 (82)</i>	M	4-10	0.8	0.7	1.3
		M	11-18	0.7	0.7	1.6
		M	19-64	0.7	0.7	1.8
		M	65+	0.9	0.8	1.9
		F	4-10	0.8	0.7	1.3
		F	11-18	0.7	0.7	1.3
		F	19-64	0.7	0.7	1.3
		F	65+	0.8	0.8	1.4
		M/F	1.5-3	0.7		0.9
		M/F	4-10	0.8		1.3
		M/F	11-18	0.7		1.5
		M/F	19-64	0.7		1.5
		M/F	65+	0.8		1.6
Croatia	<i>Satalic et.al 2007 (83)</i>	M	18-30	1.1	1.2	
		F	18-30	1.2	1.1	
		M/F	18-30	1.1		
Sweden	<i>Barbieri et al. 2006 (79)</i>	F	4	0.9	0.9	1.6
		F	8	0.9	0.9	1.9
		F	11	0.9	0.8	1.8
		M	4	0.9	0.8	1.6
		M	8	1	0.9	2.1
		M	11	1	0.9	2.1
Germany	<i>BfR 2013 (75)</i>	M**	14-80	0.80	0.73	2.3
		F**	14-80	0.74	0.7	1.59
		M***	14-80	0.66	0.62	1.9

		F***	14-80	0.65	0.61	1.4
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SD: standard deviation; E%: percentage of energy; M/F: male/female, yrs: years; TFA: trans fats
 *age in months **data from 2009 ***data from 2013

Trans fats presence in foods in Europe

Examples of products found to contain trans fats in considerable amounts in Member States, generally of industrial origin, are 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.

The data contained in 23 studies analysed by the JRC in 2014 are provided here in detail. These studies are either scientific peer-reviewed articles or national reports. In total, they contain data on the trans fats content of 3333 food products. It should be noted however, that not all studies report trans fats content in a similar manner. For example, some studies discriminate different trans fats isomers while others report on total trans fats content only, some report trans fats content as g trans fats per 100 g total fat while others report g of trans fats per 100 g of food. Therefore, the results below do not always cover data derived from all 3333 food products but rather for which data was available. In few cases the sum of an x number of the same food products was reported as one mean value and as one value is considered in this analysis. It is important to note the many differences between the studies considered here and the limitations these differences entail. Importantly, the results presented below reflect only the data on the food products analysed in the studies considered here and cannot be seen as representative of the properties European food products in general.

Because the individual studies considered in the JRC analysis report food products/groups in different ways, for the purpose of the JRC analysis, these food products were re-assigned to one of the 14 food categories described below²²⁵. The choice of categories was based on products characteristics e.g. fast-food, retail products as reported in the publication and also reflected groupings used in other reports. Figure 10 shows the outcome of this re-distribution into fourteen different food group categories. The majority of the foods analysed for trans fats presence in the studies considered here are biscuit, bun, cake and pastry products (35%), followed by food products in the categories of fats and oils, convenience, fast food, and bakery products. Dairy products, milk-based desserts, savoury snacks and meat and meat products were also tested albeit less often and are therefore less represented in this analysis.

²²⁵ (1) Biscuits, buns, cakes and pastries (2) Fats and oils: Margarines, blended spreads, butter, vegetable oil shortenings (3) Convenience products: ready meals, canned food, instant soups, pizza (4) Fast food products: burgers, fries, takeaway desserts (5) Bakery products: bread, bread rolls, breadsticks (6) Dairy Products: cheese, cream (7) Varia: bullions, aloe vera juice, gluten-free products (8) Savoury biscuits, crackers, crisps, popcorn (9) Chocolate confectionery and chocolate spreads (10) Sugar products: candies, ice cream lollies (11) Meat and meat products: beef, lamp pork sausages (12) Cereal products: breakfast cereals, cereal bars (13) Milk-based desserts: ice-cream (14) Sauces, dressings etc.: gravy, curry sauce

Figure 10 Distribution of the food products considered in this analysis by fourteen food group categories. The data concerns 3333 food products analysed in 23 different studies.

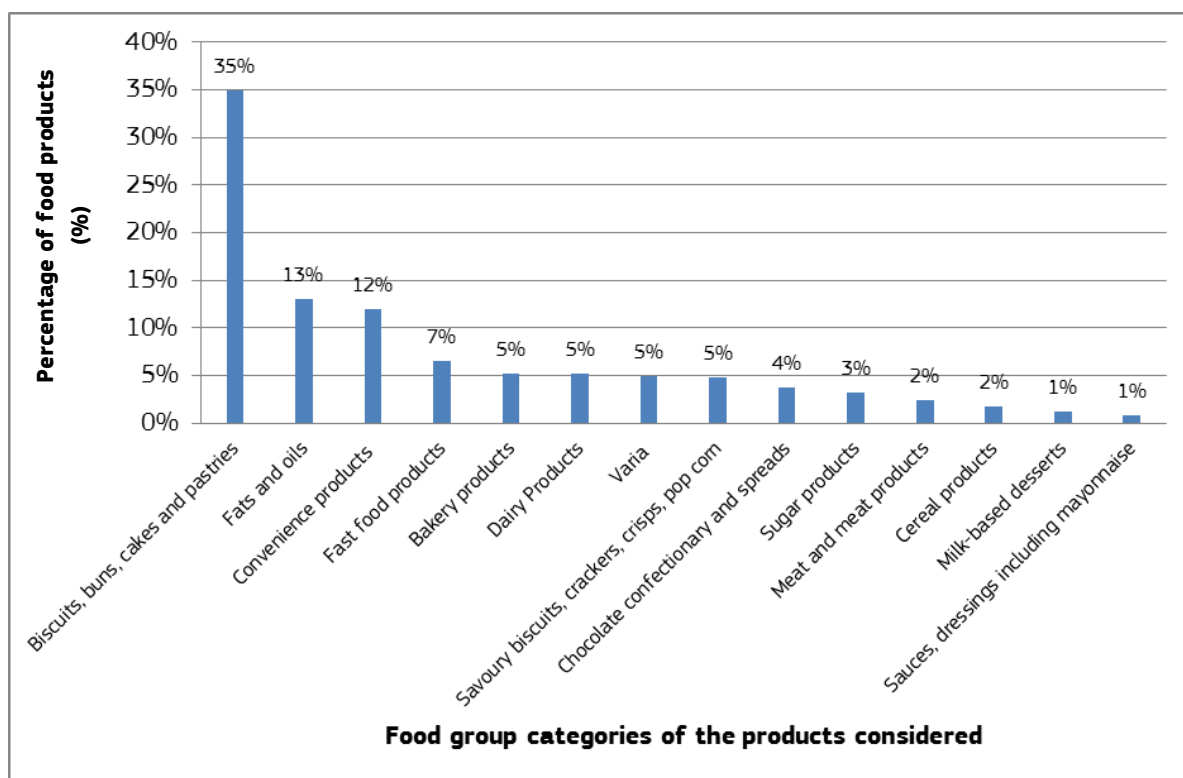
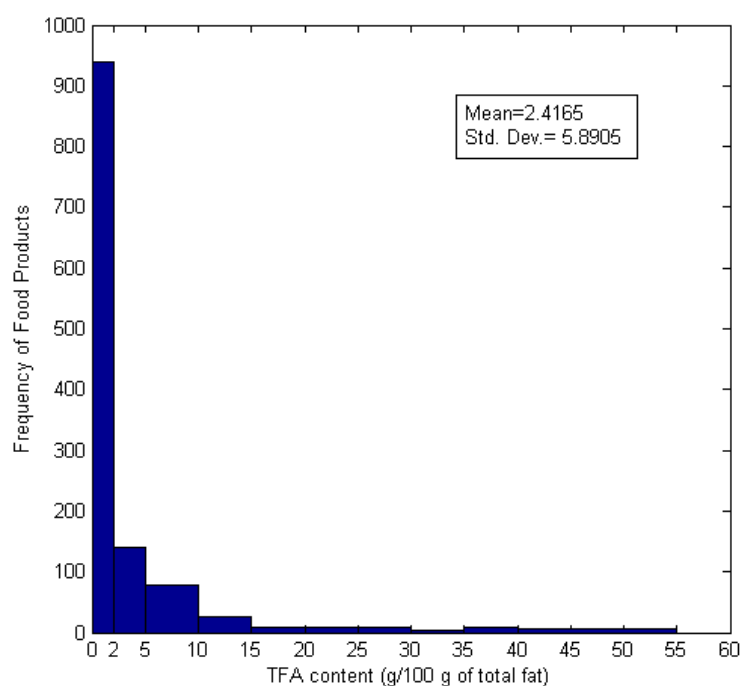


Figure 11 Distribution of trans fats content in the food products included in the analysis (n=1225). The products included are those where the trans fats content was expressed as TFA g/100 g of total fat.



Overall, as can be seen in Figure 11 the trans fats content of the majority of foods analysed is below 2 g of trans fats per 100 g total fat (77% of which is below 0.5 trans fats g per 100 g total fat). However, it must be noted that there are still foods available in the European market with high levels of trans fats

Table 27 provides an overview of the trans fats content values extracted from the 23 studies (detailed data in Table 23). A close analysis of the minimum and maximum values reported clearly show a high variation in the levels of trans fats present in different foods in terms of trans fats content per 100 g of total fat. These values can be as high as 54.00 g of trans fats per 100 g of total fat (a shortening reported in a Polish study), 49.2 g of trans fats per 100 g of total fat (popcorn reported in a Danish study) and 43.93 g of trans fats per 100 g of total fat (microwave popcorn reported in a Swedish study).

Table 27 Mean trans fatty acid composition of food products (n) sampled in the twenty-three studies analysed*

TFA (units as reported in original studies)	n	Minimum	Maximum	Mean**	Std. Deviation
TFA (g/ 100 g total fat)**	2503	0.00	54.00	2.42	5.89
TFA (g/ 100 g food product)	1193	0.00	16.80	1.30	2.96

TFA: trans fats

*The mean was calculated by the authors of this report, and was based on information reported by the authors of the original papers

** For the purposes of this analysis, we have assumed that the terms TFA% of total fat and TFA g per 100g of total fat can be used interchangeably. Hence, such values were merged and are presented in the results' section under the term 'g TFA per 100 g total fat'. Trans fats values expressed as % of total Fatty Acid Methyl Esters (FAME) were considered as % of total fat or, as above g trans fats per 100g total fat.

‡In a limited number of studies (22), trans fats values were reported as <2g/ 100g total fat, <1g/100g total fat rather than a concrete value. This data has also been included in the analysis as a mean value (i.e. 1 for a reported value of <2 and 0.5 for a reported value of <1).

Table 28 Food products, as reported in 17 studies, with trans fats content of ≥ 2 g per 100 g of total fat

Country	Study	Food products*	TFA (g per 100 g of total fat)
Poland	<i>Zbikowska et al. 2011</i>	Shortening 15	54
Denmark	<i>Bysted et al. 2009</i>	Popcorn 1	49.2
Sweden	<i>Mattisson et al. 2011</i>	Micro popcorn (USA) 2466	43.93

Serbia	<i>Kravic et al. 2011</i>	Biscuits 3A	42.5
Sweden	<i>Mattisson et al. 2011</i>	Tofutti creamy smooth 2428	40.31
Serbia	<i>Kravic et al. 2011</i>	Biscuits 4A	40
		Biscuits 9A	39.8
Estonia	<i>Meremäe et al. 2012</i>	Shortening 8	39.5
Sweden	<i>Mattisson et al. 2011</i>	Tofutti cheddar sliced 2429	38.23
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Chocolate egg	37.3
Serbia	<i>Kravic et al. 2011</i>	Biscuits 6A	36.9
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Other confectionery products ¹²	36.3
		Chocolate egg	36.2
Poland	<i>Zbikowska et al. 2011</i>	Shortening 14	35.6
Estonia	<i>Meremäe et al. 2012</i>	Margarine 6	34.96
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 70	30.2
		Chocolates 19	30.2
		Sweet biscuits, wafers, muffins 47	29.8
Serbia	<i>Kravic et al. 2011</i>	Biscuits 17B	28.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Fondant, candies 10	27.6
		Fondant, candies 5	27.5
		Sweet biscuits, wafers, muffins 65	27.2
Serbia	<i>Kravic et al. 2011</i>	Biscuits 5A	26.4
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Cereals 24	26.2
		Fondant, candies 6	25.8
		Margarines 14	25.3
Serbia	<i>Kravic et al. 2011</i>	Biscuits 2A	24.8
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Cereals 25	23.9
Poland	<i>Zbikowska et al. 2011</i>	Shortening 17	23.1
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(96) Dried Gravy	22.5
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 108	21.9
Serbia	<i>Kravic et al. 2011</i>	Biscuits 7A	21.1
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Chocolate egg	20.3
		Fondant, candies 11	20.1
		Sweet biscuits, wafers, muffins 90	19.5
		Sweet biscuits, wafers, muffins 110	18.8
		Powder creams and coffees 14	18.8

Ireland	<i>Food Safety Authority of Ireland 2008</i>	(97) Dried Gravy	18.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 124	18.2
Turkey	<i>Karabulut et al. 2007</i>	Wheat flour cookie	17.71
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 60	17.2
Poland	<i>Zbikowska et al. 2011</i>	Shortening 16	16.3
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 84	15.7
Serbia	<i>Kravic et al. 2011</i>	Biscuits 8A	14.6
		Biscuits 24C	14.5
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 17	14.1
Sweden	<i>Mattisson et al. 2011</i>	Wheat wholemeal rusks krisprolls 2450	14.1
Austria	<i>Wagner et al. 2008</i>	Instant soups	13.8
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 26	13.6
		Fondant, candies 7	13.4
		Margarines 20	13.1
Serbia	<i>Kravic et al. 2011</i>	Biscuits 19C	12.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 48	12.5
		Sweet biscuits, wafers, muffins 78	12.3
		Sweet biscuits, wafers, muffins 91	12.2
		Sweet biscuits, wafers, muffins 38	12.2
Serbia	<i>Kravic et al. 2011</i>	Biscuits 22C	12
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 16	10.9
		Sweet biscuits, wafers, muffins 33	10.9
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(71) Dried Chicken Soup	10.7
		(73) Dried Tomato Soup	10.7
		(75) Dried Chicken & Bacon Soup	10.6
		(72) Dried Beef & Vegetable Soup	10.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 28	10.5
		Powder creams and coffees 3	10.5
		Sweet biscuits, wafers, muffins 62	10.4
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(7) Reduced Fat Spread 59%	10.4
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 105	10.3
		Sweet biscuits, wafers, muffins 71	10.1
		Sweet biscuits, wafers, muffins 106	10.1
		Sweet biscuits, wafers, muffins 103	9.9

		Margarines 47	9.7
		Sweet biscuits, wafers, muffins 57	9.7
		Sweet biscuits, wafers, muffins 104	9.6
		Chocolates 14	9.5
		Sweet biscuits, wafers, muffins 29	9.1
Estonia	<i>Meremäe et al. 2012</i>	Blended spread 6	9.08
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 18	9
		Pastry, cakes 64	9
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(22) Fresh Lamb Gigot Chops	9
Denmark	<i>Bysted et al. 2009</i>	frozen potato 2	8.9
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 89	8.7
		Pastry, cakes 72	8.2
		Sweet biscuits, wafers, muffins 10	8
Denmark	<i>Bysted et al. 2009</i>	Cookies 17	8
Serbia	<i>Kravic et al. 2011</i>	Biscuits 13B	8
		Biscuits 23C	8
Austria	<i>Wagner et al. 2008</i>	Industrial margarines	7.83
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 11	7.8
		Margarines 23	7.7
		Sweet biscuits, wafers, muffins 107	7.7
Estonia	<i>Meremäe et al. 2012</i>	Shortening 3	7.64
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 27	7.5
		Bakery products 28	7.4
Germany	<i>Kuhnt et al. 2011</i>	Doughnuts	7.34
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 38	7.3
		Sweet biscuits, wafers, muffins 66	7.3
		Pastry, cakes 39	7.2
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(1) Vegetable Fat Spread 70%	7.2
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Bakery products 39	6.9
		Sweet biscuits, wafers, muffins 9	6.9
		Sweet biscuits, wafers, muffins 21	6.9
		Fondant, candies 14	6.9
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(30) Irish Cheddar	6.9
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Pastry, cakes 76	6.8
		Pastry, cakes 28	6.6

Ireland	<i>Food Safety Authority of Ireland 2008</i>	(2) Reduced Fat Blend 59%	6.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 29	6.5
		Margarines 30	6.5
		Sweet biscuits, wafers, muffins 96	6.5
		Pastry, cakes 69	6.5
		Semi-cooked food 13	6.5
		Pastry, cakes 83	6.3
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(31) Irish Cheddar	6.3
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 69	6.2
		Pastry, cakes 78	6.2
		Pastry, cakes 14	6.1
Switzerland	<i>Richter et al. 2009</i>	Fine bakery products	6.07
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 27	5.9
		Fondant, candies 13	5.9
		Margarines 50	5.8
		Bakery products 40	5.8
		Pastry, cakes 77	5.8
		Sweet biscuits, wafers, muffins 119	5.7
		Fondant, candies 8	5.7
		Pastry, cakes 74	5.7
		Margarines 36	5.6
		Sweet biscuits, wafers, muffins 18	5.6
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(9) Vegetable Fat Spread 70%	5.6
Turkey	<i>Karabulut et al. 2007</i>	Stick cracker	5.52
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 37	5.5
		Pastry, cakes 55	5.5
		Semi-cooked food 12	5.5
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(18) Vegetable Fat Spread 70%	5.5
		(29) Irish Cheddar	5.5
Turkey	<i>Karabulut et al. 2007</i>	Cake, filled and covered	5.33
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Pastry, cakes 4	5.3
		Pastry, cakes 57	5.3
Turkey	<i>Karabulut et al. 2007</i>	Wafer roll, filled	5.27
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Bakery products 26	5.2
		Pastry, cakes 56	5.2
		Pastry, cakes 70	5.2

		Pastry, cakes 73	5.2
		Pastry, cakes 90	5.2
		Semi-cooked food 11	5.2
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(32) English Cheddar	5.2
Switzerland	<i>Richter et al. 2009</i>	Ice creams	5.14
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 130	4.9
		Pastry, cakes 15	4.9
		Pastry, cakes 46	4.9
Austria	<i>Wagner et al. 2008</i>	Cooled ready to eat products	4.86
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Chocolate egg	4.8
		Pastry, cakes 42	4.8
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Fish and Chips (product 118)	4.8
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 45	4.7
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(10) Irish Butter	4.7
Turkey	<i>Karabulut et al. 2007</i>	Digestive, biscuit	4.69
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Bakery products 2	4.6
		Chocolate egg	4.6
Serbia	<i>Kravic et al. 2011</i>	Biscuits 14B	4.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Bakery products 35	4.5
		Pastry, cakes 7	4.4
		Pastry, cakes 8	4.4
Serbia	<i>Kravic et al. 2011</i>	Biscuits 10A	4.4
Austria	<i>Wagner et al. 2008</i>	Pasta dishes	4.39
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Pastry, cakes 36	4.3
Denmark	<i>Bysted et al. 2009</i>	Cookies 19	4.3
Estonia	<i>Meremäe et al. 2012</i>	Margarine 12	4.25
Austria	<i>Wagner et al. 2008</i>	Other products	4.2
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Hamburger 3	4.2
Sweden	<i>Swedish National Food agency 2010</i>	Dairy products (low price)	4.19
		Dairy products (standard price)	4.15
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Chocolate egg	4.1
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(28) Irish Cheddar	4.1
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Quarter Pounder 2	4.1

		Cheeseburger 4	4.1
		Quarter Pounder 3	4.1
Switzerland	<i>Richter et al. 2009</i>	Snacks, cakes and biscuits	3.99
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Beef Burger 10	3.9
Switzerland	<i>Richter et al. 2009</i>	Semi-solid fats	3.86
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 113	3.8
		Pastry, cakes 40	3.8
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Beef Burger 9	3.8
Austria	<i>Wagner et al. 2008</i>	Dough	3.78
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 61	3.7
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Beef Burger 8	3.7
Turkey	<i>Karabulut et al. 2007</i>	Hazelnut cocoa cream	3.68
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Bakery products 42	3.6
Turkey	<i>Karabulut et al. 2007</i>	Cookie, filled	3.54
Estonia	<i>Meremäe et al. 2012</i>	Blended spread 1	3.5
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 69	3.5
		Sweet biscuits, wafers, muffins 32	3.5
		Sweet biscuits, wafers, muffins 86	3.5
Denmark	<i>Bysted et al. 2009</i>	Cake 4	3.5
Switzerland	<i>Wagner et al. 2008</i>	Desserts	3.41
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 42	3.4
		Bakery products 22	3.4
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Chicken Nuggets 4	3.4
Turkey	<i>Karabulut et al. 2007</i>	Wafer	3.32
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 131	3.3
		Chocolate egg	3.3
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Hamburger 2	3.3
		Beef Burger 6	3.3
		Beef Burger 7	3.3
		Hawaiian Pizza 2	3.3
Switzerland	<i>Richter et al. 2009</i>	Whipped cream, cappuccino.	3.22
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Beef Burger 5	3.2
Germany	<i>Kuhnt et al. 2011</i>	Butter	3.15
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Pastry, cakes 6	3.1

		Pastry, cakes 53	3.1
		Pastry, cakes 86	3.1
		Margarines 35	3
		Sweet biscuits, wafers, muffins 59	3
		Fondant, candies 9	3
		Pastry, cakes 48	3
Turkey	<i>Karabulut et al. 2007</i>	Sandwich, biscuit	2.98
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 46	2.9
		Pastry, cakes 38	2.9
		Dairy Products 1	2.9
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Double Burger 3	2.9
		Cheeseburger 3	2.9
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 51	2.8
		Bakery products 24	2.8
		Fondant, candies 1	2.8
		Pastry, cakes 65	2.8
		Semi-cooked food 14	2.8
		Ice-creams 4	2.8
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Cheeseburger 2	2.8
		Beef Burger 4	2.8
		Margarita Pizza 1	2.8
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 118	2.7
		Pastry, cakes 33	2.7
		Pastry, cakes 68	2.7
		Pastry, cakes 93	2.7
		Powder creams and coffees 16	2.7
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Lamb Kebab	2.7
Germany	<i>Kuhnt et al. 2011</i>	Puff pastries	2.69
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 34	2.6
		Sweet biscuits, wafers, muffins 127	2.6
		Pastry, cakes 32	2.6
		Pastry, cakes 63	2.6
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Cheeseburger 1	2.6
		Beef Burger 3	2.6
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 48	2.5
		Chocolate egg	2.5

		Chocolate egg	2.5
		Pastry, cakes 66	2.5
Switzerland	<i>Richter et al. 2009</i>	Fried and fast food	2.5
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Hamburger 1	2.5
Turkey	<i>Karabulut et al. 2007</i>	Puff pastry dough	2.47
Austria	<i>Wagner et al. 2008</i>	Potato chips	2.4
United Kingdom	<i>Roe et al. 2013</i>	Cod, fried in batter, takeaway	2.4
Turkey	<i>Karabulut et al. 2007</i>	Mini cake, filled and covered	2.4
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Beef Burger 2	2.4
Sweden	<i>Mattisson et al. 2011</i>	Danish pastry bake off 2451	2.34
Turkey	<i>Karabulut et al. 2007</i>	Beef burger fried	2.33
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Margarines 3	2.3
		Sweet biscuits, wafers, muffins 64	2.3
		Pastry, cakes 3	2.3
		Savoury biscuits, crackers, chips 25	2.3
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(99) Hazelnut Milk Chocolate Spread	2.3
		Beef Burger 1	2.3
		Meat Pizza 4	2.3
Denmark	<i>Bysted et al. 2009</i>	Cookies 18	2.3
Sweden	<i>Mattisson et al. 2011</i>	Danish pastry bake off 2453	2.23
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Sweet biscuits, wafers, muffins 3	2.2
		Sweet biscuits, wafers, muffins 95	2.2
		Sweet biscuits, wafers, muffins 111	2.2
		Chocolate egg	2.2
		Other confectionery products 17	2.2
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Double Burger 2	2.2
		Fish and Chips (product 86)	2.2
		Meat Pizza 1	2.2
Germany	<i>Kuhnt et al. 2011</i>	Chocolate products	2.11
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Bakery products 1	2.1
		Bakery products 12	2.1
		Pastry, cakes 67	2.1
		Soups, convenience products 39	2.1
Poland	<i>Zbikowska et al. 2011</i>	Shortening 21	2.1
Ireland	<i>Food Safety Authority of Ireland 2008</i>	(11) Irish Butter	2.1
Ireland	<i>Food Safety Authority of Ireland 2009</i>	Margarita Pizza 2	2.1

United Kingdom	<i>Roe et al. 2013</i>	Potato chips, takeaway	2.05
Austria	<i>Wagner et al. 2008</i>	Hamburger	2.04
Turkey	<i>Karabulut et al. 2007</i>	Chocolate bar	2.04
Germany	<i>Kuhnt et al. 2011</i>	Instant products	2.02
Turkey	<i>Karabulut et al. 2007</i>	Sucuk (fermented sausage)	2.01
Hungary	<i>National Food and Nutrition Institute of Hungary. 2013</i>	Pastry, cakes 31	2
		Powder creams and coffees 4	2
		Powder creams and coffees 5	2
Poland	<i>Zbikowska et al. 2011</i>	Shortening 22	2
Serbia	<i>Kravic et al. 2011</i>	Biscuits 29C	2

* Numbers and/or letters e.g. biscuits 7A, shortening 16 represent coding of food product as reported in the original publication.

** Mean of composite samples ***Fast food products ****Retail products

ANNEX 10: Discussion of the baseline scenario

The evidence on trans fats content of food and consumption has been reviewed in depth by the JRC.

Most food products are low in trans fats but that is not the case in all Member States

The majority of food products contain less than 2 g trans fats/100 g fat (the lowest limit set in EU countries with limiting legislation). Seventy-seven per cent of products have less than 0.5 g trans fats/100g fat, according to an analysis of the most recent available data on the presence of trans fats in food in European food markets.²²⁶ However, data on trans fats content of selected foods sampled between 2006 and 2013 indicates also amounts of industrial trans fats higher than the 2% limit in products available in supermarkets in predominantly Eastern European countries, as well as in products manufactured in Eastern Europe, which are also available in ethnic shops in Western Europe.

The average level of industrial trans fats in food has been declining but further reductions are uncertain

The analysis of the JRC suggests that industrial trans fats levels in food have been declining in some, but not all, Member States. Looking at some sectors, the trend can be dated back to the mid-2000s, as for instance in business-to-business margarines (Figure 12 below). Data on the industrial trans fats content of foods manufactured and sold in predominantly Eastern Europe²²⁷ suggests that, in spite of reductions in certain categories of products, levels of industrial trans fats in other food products remain high. Further evidence collected in six South-Eastern European countries (including Croatia and Slovenia) has found that the number of packages of food products (considering the group of biscuits, cakes, wafers) that contained more than 2% of total fat as industrial trans fats had doubled between 2012 and 2014,²²⁸ indicating that food industry operators had expanded their offer of products with high industrial trans fats content, contradicting the notion of a general downward trend.

Trans fats intake in Europe has been decreasing

There is evidence that trans fats intake has decreased overall in the EU²²⁹ since the 1990s, from as high as 4.3 E% in elderly Dutch men in 1985 to average population intakes of less than 1 % of the energy intake in the 2000s. However less is known about dietary trans fats intakes in Eastern Europe. Whether trans fats intake will continue to decrease will depend on a variety of factors, and particularly on whether existing or future initiatives (other than EU intervention) may achieve further reductions in the levels of industrial trans fats in food products.

²²⁶ Mouratidou et al. (2014) Trans Fatty acids in Europe: where do we stand? JRC Science and Policy Reports 2014 doi:10.2788/1070

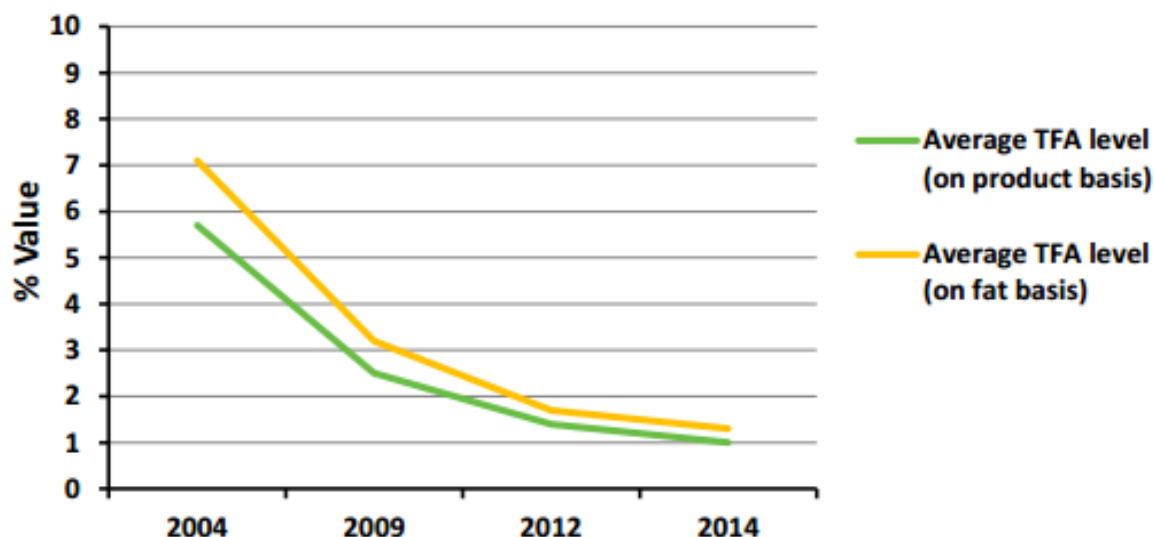
²²⁷ Stender S., Astrup A., Dyerberg J. (2014) Tracing artificial trans fat in popular foods in Europe: a market basket investigation BMJ Open 2014;4:e005218. doi: 10.1136/bmjopen-2014-005218

²²⁸ Stender S, Astrup A, Dyerberg J. (2014) Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries BMJ Open 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

²²⁹ See online supporting material for detailed information: Martin-Saborido CM et al. (2016) Public health economic evaluation of different European Union-level policy options aimed at reducing population dietary trans fat intake. Online Supporting Material. American Journal of Clinical Nutrition, 104: 1218-26

Robust pan-EU data on the variation in industrial trans fats consumption by socio-economic group are not available. However, the variation in industrial trans fats consumption by socio-economic group is expected to continue. Although the JRC publication does not estimate variation of trans fats intake across socio-economic groups, recent estimates exist for the UK.²³⁰

Figure 12 Industry data indicate that the level of trans fatty acids in business-to-business margarines has declined



TFA; trans fats

Source: European Margarine Association, IMACE position on trans fatty acids. Brussels, April 2015. trans fats intake in Europe is decreasing.²³¹

Future initiatives towards reductions in industrial trans fats levels are uncertain

Various public, private, or public-private initiatives at sectoral, national and EU level have been associated with reductions in industrial trans fats levels in Europe (and beyond²³²). There is evidence to suggest that both voluntary measures and legal initiatives have contributed to delivering positive results. Considering existing initiatives (whether voluntary or legislative) in the Member States, the evidence collected during the data collection phase and further during the validation consultation of this study suggests that most of the available gains (in terms of industrial trans fats elimination) have been achieved already. As a result, many of them are already compliant with the targets being discussed in this study. Whether further gains can be expected in the absence of EU action is not clear and will depend on whether the industry will act further, and whether Member States themselves may act if the EU does not.

²³⁰ Pearson-Stuttard J et al. (2015) Quantifying the Socio-Economic Benefits of Reducing Industrial Dietary Trans Fats: Modelling Study. PLOS One 10(8): e0132524

²³¹ IMACE (2015) IMACE position on trans fatty acids. Brussels, April 2015

²³² Hendry et al. 2015. Impact of regulatory interventions to reduce intake of artificial trans-fatty acids: a systematic review. *American Journal of Public Health* 105(3); Downs et al. 2013. The effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence. *Bulletin of the World Health Organisation* 91: 262-269

It appears that most existing voluntary initiatives – at Member State level or EU level – have delivered their goals and further progress is uncertain. The industry in some MS has not acted voluntarily on industrial trans fats, and the evidence from certain Member States suggests that a voluntary approach may not deliver any progress there.²³³

While some Member States have already passed legislation to limit industrial trans fats levels in food products, other Member States have indicated their intention to legislate. Whether further like-minded initiatives would be implemented elsewhere in the EU is unclear.

In the absence of EU action, each Member State might independently adopt measures or decide not to act. This lack of homogeneity in the EU hampers the effective functioning of the Internal Market and negatively affects innovation and the protection of consumers' health. Limited evidence exists to quantify the variation across Member States.

Finally, the abundance of products high in industrial trans fats manufactured in third countries that may export their products into some Member States makes it more likely that the industrial trans fats intake of at least some groups of consumers in those countries may remain too high or even increase.

Any further reductions in industrial trans fats in food are expected to translate quickly into health benefits

The relationship between industrial trans fats consumption and the scale of health impacts is important for the baseline scenario and all policy options. The evidence from Denmark suggests that changes in industrial trans fats consumption translate rapidly into reductions in cardio vascular disease.²³⁴ Three years after the policy was implemented, mortality attributable to cardio vascular disease decreased on average by about 14.2 deaths per 100,000 people per year. This effect is confirmed by evidence collected in the US, with a different measurement method.²³⁵

In some cases reformulation to reduce industrial trans fats has the potential to increase the saturated fat content of food. This has implications for the scale of the health benefits achieved by industrial trans fats reduction – higher levels of saturated fat are thought to be associated with increased risk of coronary heart disease (though even if trans fats was fully replaced by saturated fat there would still be a net health benefit). The data collected in the country research did not indicate that industrial trans fats have always been replaced with saturated fats.

The environmental impact will depend on the reformulation

With the exception of the most pessimistic variant (B3), the baseline assumes that foods are reformulated to reduce industrial trans fats content. The shift in consumption of ingredients has the potential to have environmental impacts, examples being changes in the

²³³ Stender S, Astrup A, Dyerberg J Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries *BMJ Open* 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

²³⁴ Restrepo, B. J., and Rieger, M. (2016) Denmark's Policy on Artificial Trans Fat and Cardiovascular Disease. *AJPM* January 2016 Volume 50, Issue 1, Pages 69–76

²³⁵ Brandt et al. (2017) Hospital Admissions for Myocardial Infarction and Stroke Before and After the Trans-Fatty Acid Restrictions in New York. *JAMA Cardiology* Jun 1;2(6):627-634. doi:10.1001/jamacardio.2017.0491; Restrepo B.J. and Rieger M. (2016) Trans fat and cardiovascular disease mortality: Evidence from bans in restaurants in New York *Journal of Health Economics* 45: 176-196

consumption of soya and palm oil. In Denmark the replacement fat that was used varied depending on the food product.²³⁶ The desk research from ICF indicates that in Denmark when palm oil has been used there has been a drive to use only sustainable palm oil. New fat alternatives have been developed during recent years, e.g. through enzymatic interesterification, and there are many commercially available alternatives to palm oil.²³⁷ The exact magnitude of environmental impacts will depend on the food business operator's choice of ingredients.

Initial assumptions

- industrial trans fats content in EU food will decline to zero over a 10 year period (linear decline assumed) OR over a 15 year period, OR remain stable;
- Reductions in industrial trans fats consumption have a commensurate and rapid impact on cardio vascular disease incidence;
- Reformulation is done so as to avoid potential unintended consequences (e.g. via an increase in saturated fat content);
- Single Market integrity issues will be more prominent in the baseline scenario than in the presence of a harmonised EU approach to industrial trans fats;
- Industrial trans fats reduction will prompt some changes in the aggregate demand for inputs to the food industry, changes that have the potential to have environmental impacts.

²³⁶ Ministry of Food, Agriculture and Fisheries of Denmark and DTU (2014) Danish data on trans fatty acids in food

²³⁷ Hinrichsen, N. (2016) Commercially available alternatives to palm oil, *Lipid Technol.* 2016 Apr; 28(3-4): 65–67

ANNEX 11: Intervention logic for the different options

Table 29 Intervention logic model for Option 1a: Voluntary agreement with food business operators on industrial trans fats content in food

Inputs	Activities	Outputs	Outcomes	Long-term impacts
Financial and human resources required to: Formulate agreement Develop and implement new products and processes Source alternative ingredients Monitor, oversee and report on new arrangements	Agreement between food businesses and EU authorities regarding scope and details of arrangements and implementation New product development Sourcing of alternative ingredients - substitution of industrial trans fats with poly/monounsaturated and saturated fats Implementation of new products and processes Monitoring, oversight and reporting	Decrease of industrial trans fats content in food below 2% of fat among participating businesses industrial trans fats content in products might vary based on which businesses adopted voluntary measures	Reduction of industrial trans fats consumption for most population subgroups (but likely slower reduction and of a minor magnitude than legal option) Ongoing product development and innovation Harmonisation of standards within Internal market, dependent on rate and geographical spread of voluntary participation Harmonisation of standards with some export markets	Decrease in cardio vascular diseases prevalence and mortality Improved productivity in EU economy from healthier consumers Reduced economic burden on healthcare systems Enhanced image, competitiveness and innovation of food industry Increased trade across EU Member States (and third countries)
Costs and potential unintended effects:	Administrative burdens for businesses – formulating the agreement, understanding the rules, monitoring and reporting Administrative burdens for authorities – formulating the agreement, monitoring and oversight Direct costs to businesses:	Potential increases in product prices Possible effects on product availability, taste and choice Risk of	Potential social implications - costs for low income groups Possible adverse effects on competitiveness vs imports in the EU market and vs exports in some third country markets Adverse impacts on some	Potential negative social impacts – inequalities in disposable income Potential negative economic impacts – competitiveness in export markets and competition with food business operators that did not adopt voluntary

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	investment in product development, new production processes, purchase of ingredients, operating costs	incomplete compliance with voluntary measures, especially among small producers Risk of increase of trans fats content for some categories of products targeted at lower income groups	suppliers of ingredients Potential increase in demand for environmentally damaging tropical oils	measures Potential negative environmental impacts - deforestation caused by demand for tropical oils Products with industrial trans fats from producers from third countries entering EU market with potential competitive advantage

Table 30 Intervention logic model for Option 1b: Legal limit on industrial trans fats content in food

Inputs	Activities	Outputs	Outcomes	Long-term impacts
Financial and human resources required to: Develop and implement new legislation Develop and implement new products and processes Source alternative ingredients Monitor and enforce implementation	Introduction of new legal rules, provision of information New product development Sourcing of alternative ingredients - substitution of ingredients with high industrial trans fats content with polyunsaturated, monounsaturated and saturated fats Implementation of new products and processes Guidance and advice Monitoring and enforcement by MS	Decrease of industrial trans fats content in food below 2% of fat [Derogation for higher trans fats limit for low fat foods]	Reduction of industrial trans fats consumption for all population subgroups Ongoing product development and innovation Level playing field within Internal Market, including imports Shift in alignment with practice in export markets	Decrease in cardio vascular diseases prevalence and mortality Improved productivity in EU economy from healthier consumers Reduced health inequalities amongst consumers Reduced economic burden on healthcare systems Enhanced image, competitiveness and innovation of food industry Increased trade across EU Member States (and third countries)
Costs and potential unintended effects:	Administrative burdens for authorities – implementation and monitoring, enforcement Administrative burdens for businesses – understanding the rules potentially testing Direct costs to businesses: investment in product development, new production processes, purchase of ingredients, operating costs	Potential increases in product prices Possible effects on product availability, taste and choice	Potential social implications - costs for low income groups Possible adverse effects on competitiveness (vs exports in third country markets) Adverse impacts on some suppliers of ingredients Potential increase in demand for oils whose production can be associated with negative environmental impacts	Potential negative social impacts – inequalities in disposable income Potential negative economic impacts – competitiveness Potential negative environmental impacts – e.g. deforestation caused by change in demand for tropical oils

Table 31 Intervention logic model for Option 2: Introduction of the obligation to indicate the trans fats content of foods in the nutrition declaration

Inputs	Activities	Outputs	Outcomes	Long-term impacts
Financial and human resources required to: Develop and implement new legislation Develop and implement new product labels for packaged food Monitor and enforce on implementation Support accompanying communications / awareness-raising actions to advise consumers about trans fats	Introduction of new legal rules, provision of information New product label and ingredients list development Potential sourcing of alternative ingredients - substitution of industrial trans fats with poly/monounsaturated and saturated fats Monitoring and enforcement by Member States Communication / awareness-raising campaigns	Declaration of trans fats content in food labels on prepacked foods Reformulation of foods to maintain product demand might lead to a decrease of industrial trans fats content in food	Reduction of trans fats consumption – potential variation across subgroups based on health literacy Inclusion of the trans fats content of foods in the nutrition declaration Enhanced and standardised consumer information, increased consumer confidence Changes in supply chain demand for ingredients that contain trans fats and their substitutes	Decrease in cardio vascular diseases prevalence and mortality Improved productivity in EU economy from healthier consumers Reduced economic burden on healthcare systems Enhanced image of food industry Trade impacts
Costs and potential unintended effects:	Administrative burdens for authorities – implementation, monitoring and enforcement Administrative burdens for businesses – understanding the rules and provision of information Direct costs to businesses: investment in product labels	Potential increases in product prices	Potential social implications – potential to increase the differential in trans fats intake if groups where trans fats intake is higher are also less responsive to labelling Adverse impacts on some food manufacturers where reformulation is difficult and impacts on foods containing	Potential to exacerbate inequalities in health outcomes even as overall position improves Negative image of products containing ruminant trans fats (in particular milk and dairy products) Potential negative economic impacts – competitiveness in

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	development, detection of trans fats in own products, purchase of ingredients, operating costs		ruminant trans fats Potential for less healthy options to be selected by consumers who are not equipped to interpret the trans fats information on the nutrition declaration	export markets; Reduced demands for certain food products; Potential for lack of consistency within the Internal Market if some MSs introduce national legal limits for trans fats alongside the EU labelling obligations

Table 32 Intervention logic model for Option 3a: Voluntary measures to prohibit the use of partly hydrogenated oils in foods

Inputs	Activities	Outputs	Outcomes	Long-term impacts
<p>Financial and human resources required to:</p> <p>Formulate agreement</p> <p>Develop and implement new products and processes</p> <p>Source alternative ingredients</p> <p>Monitor, oversee and report on new arrangements</p>	<p>Agreement between food businesses and EU authorities regarding scope (including a definition of “partly hydrogenated oils”)</p> <p>and details of arrangements and implementation (only businesses using partly hydrogenated oils)</p> <p>New product development</p> <p>Sourcing of alternative ingredients - substitution of partly hydrogenated oils with other oils</p> <p>Implementation of new products and processes</p> <p>Development of detection methods for partly hydrogenated oils</p> <p>Monitoring, oversight and reporting (acknowledging presence of partly hydrogenated oils in packaged foods is simpler than trans fats since they are already declared in the label)</p>	<p>Decrease of industrial trans fats content in food among participating businesses.</p> <p>This may be less than through direct limits on industrial trans fats, though partly hydrogenated oils are understood to be the main dietary source of industrial trans fats.</p> <p>industrial trans fats content in products might vary based on which businesses adopted voluntary measures to eliminate partly hydrogenated oils</p>	<p>Reduction of industrial trans fats consumption for all population subgroups, especially those with higher industrial trans fats intake from partly hydrogenated oils, but likely slower and of a minor magnitude than through legal measures</p> <p>Ongoing product development and innovation</p> <p>Harmonisation of standards within Internal market, depending on rate of uptake of voluntary agreement</p> <p>Harmonisation of standards with some export markets</p>	<p>Decrease in cardiovascular diseases prevalence and mortality</p> <p>Improved productivity in EU economy from healthier consumers</p> <p>Reduced economic burden on healthcare systems</p> <p>Enhanced image, competitiveness and innovation of food industry</p> <p>Small potential impact on trade across EU Member States (and with third countries)</p> <p>Impacts may be reduced compared to measures to limit industrial trans fats directly (depending on the strength of the partly hydrogenated oils to industrial trans fats relationship).</p>
<p>Costs and potential unintended effects:</p>	<p>Administrative burdens for businesses – formulating the</p>	<p>Potential increases in product prices</p>	<p>Potential social implications - costs for low</p>	<p>Potential negative social impacts – inequalities in</p>

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	<p>agreement, understanding the rules, monitoring and reporting</p> <p>Administrative burdens for authorities – formulating the agreement, monitoring and oversight. Costs of testing and monitoring may be reduced compared to Options 1a and 1b.</p> <p>Direct costs to businesses: investment in product development, new production processes, purchase of ingredients, operating costs</p>	<p>Possible effects on product availability, taste and choice</p> <p>Risk of incomplete compliance with voluntary measures, especially among small producers</p>	<p>income groups</p> <p>Possible adverse effects on competitiveness vs imports in the EU market and vs exports in some third country markets</p> <p>Adverse impacts on some suppliers of ingredients</p> <p>Potential increase in demand for tropical oils</p>	<p>disposable income</p> <p>Potential negative economic impacts – competitiveness in export markets and competition with food business operators that did not adopt voluntary measures</p> <p>Potential negative environmental impacts - deforestation caused by demand for tropical oils</p> <p>More MS may introduce national legal provisions leading to fragmentation, unless aligned to Danish model</p>

Table 33 Intervention logic model for Option 3b: Legal prohibition of the use of partly hydrogenated oils in foods

Inputs	Activities	Outputs	Outcomes	Long-term impacts
Financial and human resources required to: Develop and implement new legislation Develop and implement new products and processes Source alternative ingredients Monitor and enforce implementation	Agreement at EU level on a shared definition of “partly hydrogenated oils” Introduction of new legal rules, provision of information New product development Sourcing of alternative ingredients - substitution of partly hydrogenated oils with other oils Implementation of new products and processes Development of detection methods for partly hydrogenated oils Monitoring and enforcement by Member States	Elimination of partly hydrogenated oils content in food Decrease of industrial trans fats content in food	Reduction of industrial trans fats consumption for all population subgroups, especially those with higher industrial trans fats intake from partly hydrogenated oils Ongoing product development and innovation Harmonisation of standards within Internal market Harmonisation of standards with some export markets	Decrease in cardiovascular diseases prevalence and mortality Improved productivity in EU economy from healthier consumers Reduced health inequalities amongst consumers Reduced economic burden on healthcare systems Enhanced image, competitiveness and innovation of food industry Increased trade across EU Member States (and third countries)
Costs and potential unintended effects:	Administrative burdens for businesses –understanding the rules, potentially testing Administrative burdens for authorities – implementation and monitoring, enforcement. Costs of testing, monitoring and enforcement may be reduced compared to Option	Potential increases in product prices Possible effects on product availability, taste and choice	Potential social implications - costs for low income groups Possible adverse effects on competitiveness of exports in some markets Adverse impacts on some suppliers of ingredients Potential increase in demand for environmentally	Potential negative social impacts – inequalities in disposable income Potential negative economic impacts – competitiveness in export markets Potential negative environmental impacts - deforestation caused by

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	1b. Direct costs to businesses: investment in product development, new production processes, purchase of ingredients, operating costs		damaging tropical oils	demand for tropical oils

ANNEX 12: Impacts screening

The screening of impacts was informed by the literature review and interviews with stakeholders and national authorities, as well as analysis, by the contractor ICF. As the screening is based on analysis and understanding of all available evidence the risk of failing to consider potentially significant impacts should be minimised.

The contractor added to and refined the generic checklist of impacts in the Better Regulation guidelines to include additional and more specific impacts listed in the second column of the Table, and taking account of the specific policy context. For example, while the long list of impacts to be considered includes health and safety as well as social inclusion, more specific impacts in this context include impacts on consumer health, health inequalities and potential differences in costs for low income groups.

Table 34 Long list of possible impacts for screening

Impact type	Long list of impacts drawing on Commission IA guidelines	Additions and refinements to long list
Economic impacts	Growth and investment Sectoral competitiveness Facilitating SMEs growth Achievement of the Single Market Increased innovation and research Technological development Increased international trade and investment Competition	Business compliance costs Administrative burden Consumer prices
Social impacts	Employment Income distribution and social inclusion Health & safety Education Governance & good administration Social protection, health and educational systems Cultural heritage	Consumer health Health inequalities Income inequalities Consumer choice
Environmental impacts	Fighting climate change Fostering the efficient use of resources (renewable & non-renewable) Protecting biodiversity, flora, fauna and landscapes Minimizing environmental risks	Palm oil production (and associated climate and biodiversity impacts)
Other impacts	Economic and social cohesion Impacts in developing countries Sustainable development Fundamental Rights	
General impacts	Individuals, private and family life, freedom of conscience and expression Property rights and the right to conduct a	

Impact type	Long list of impacts drawing on Commission IA guidelines	Additions and refinements to long list
	business	

Source: Better Regulation Toolbox, p99

The screening took account of:

- Both positive and negative impacts;
- Direct and indirect effects – including direct effects on nutrition and public health, as well as indirect effects from changes in costs and product substitution (such as potential environmental impacts from use of palm oil);
- Intended and potential unintended consequences. The intended consequences include benefits for public health and the Single Market, while possible unintended consequences could include impacts on the environment and international competitiveness;
- Short and long term effects – e.g. short term product reformulation costs and long term production costs.

The significance of impacts was assessed with regard to:

- Their expected magnitude – taking account of the likely scale of the impact and resultant benefits and costs, the numbers of businesses and consumers affected, and the extent of change expected;
- Their relevance for stakeholders – taking account of existing representations made by stakeholders, the views expressed in the stakeholder consultations, as well as analysis of the impacts on different groups;
- Their likelihood – taking account of available evidence collected by ICF about the probability of positive and negative effects occurring, and prioritising those for which there is robust evidence; and
- Their timescale – examining whether effects are likely to be short-lived or lasting in duration;
- The importance for the Commission’s horizontal objectives and policies – taking account of the relationship to high level objectives for jobs and growth set out in the EU2020 strategy as well as other relevant policies and strategies such as those for the Internal Market and international trade, as set out in DG SANTE’s Strategic Plan for 2016-2020.²³⁸

Many of the screened impacts are inter-related. For example, growth and investment is clearly a highly policy relevant impact, but it is influenced by all of the other economic factors - sectoral competitiveness, SME growth, the functioning of the Single Market, innovation and research, technological development, international trade and investment, and competition. The screening process has therefore attempted to distinguish between those impacts which occur directly and those which may occur indirectly as a result of effects on other impact categories.

²³⁸ European Commission, Directorate General Health & Food Safety (2016) Strategic Plan 2016-2020

The impacts vary for different policy options in terms of their extent and significance. However, most impacts are relevant across the different options. The screening analysis was therefore undertaken for the options collectively rather than individually, with a view to assessing the differences in impacts between the options in more detail later in the impact assessment.

Screening of Impacts

Table 35 summarises the screening of impacts of action to address industrial trans fats in the EU.

Table 35 Significance of impacts for all the policy options under consideration

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
Economic Impacts					
Growth and investment	xx	xxx	xx	x	Growth and investment are EU policy priorities and any potential impacts need to be considered carefully. Measures to reduce industrial trans fats may require investment in product development and new production processes, but may have adverse impacts indirectly as a result of costs for business and the public sector. Available evidence collected by ICF is limited and suggests that costs and economic impacts to date have been limited for countries and businesses that have taken action to limit industrial trans fats, but that potential impacts of further change need to be considered carefully.
Sectoral competitiveness	xx	xxx	x	x	Sectoral representatives have expressed concern about possible effects of some options on business costs and competitiveness. Though evidence collected by ICF suggests that sectoral competitiveness need not necessarily be affected, the relative effects of different options need to be considered carefully. Assessment of the costs to business needs to be made in the first instance.
Facilitating growth	SME x	xxx	xx	x	SMEs account for the majority of food businesses in the EU. Any option to limit trans fats in food would potentially impact large numbers of SMEs. SMEs with fewer resources for R&D may face greater challenges in adapting to new rules than large companies. The potential impacts on SMEs and their growth therefore require more detailed assessment.

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
Achievement of the Single Market	xxx	xx	xxx	xxx	There are currently differences in policies and standards related to industrial trans fats in different Member States. One of the arguments for action at EU level would be to harmonise standards across the Single Market, creating a level playing field for producers and consumers in different Member States.
Increased innovation and technological development	xx	xx	xx	x	Reducing industrial trans fats in food products requires the use of alternative ingredients and frequently involves reformulation of food products. Action to limit industrial trans fats may therefore stimulate innovation and technological development, or require attention within existing R&D activities. While these effects may have a one-off nature, the ease of adapting or developing products may have a significant bearing on other impacts related to the costs of production and effects on competitiveness and growth.
Increased international trade and investment	x	x	x	x	Action to limit industrial trans fats in food have potential impacts on trade. There may be both benefits for EU exports (aligning EU product standards with those in export markets where there are limits on industrial trans fats) and potential negative effects (increasing costs relative to producers in some export markets). Evidence from ICF suggests that impact on levels of trade, and stakeholder concerns regarding trade effects, are limited.
Competition	-	-	-	-	No significant effects were identified, other than those described above in relation to the Single Market and international trade.
Compliance costs	- xxx	xxx	xxx	xx	Businesses will incur costs in testing products, substituting

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
product testing, reformulation, changing ingredients					ingredients and reformulating products. These costs vary by option. Direct costs to businesses may have an indirect effect on other impacts such as competitiveness, trade, growth and SME development; their analysis is therefore an important part of the impact assessment.
Administrative burden	xx	xxx	xx	x	Action to reduce industrial trans fats will depend on the transfer of information between the authorities, business and consumers, and require time to understand the rules, formulate appropriate responses, and monitor and report on progress. This will result in potentially significant time burdens and costs. Reducing administrative burdens is a major focus of the EC better regulation agenda.
Consumer prices and choice	xx	xx	xx	xx	Options will condition consumer choice through change to food products and product information, price impacts
Social Impacts					
Employment	x	x	x	x	Enhancing employment is a key policy priority for the EU. No evidence was found of a direct effect on employment (e.g. through effects on the labour intensity of food production). Jobs are potentially impacted indirectly, through changes in business costs, competitiveness and investment. However, no effect on employment has been identified in the literature or expressed as a concern by stakeholders.
Income distribution and social inclusion	xx	xx	xx	x	Action to limit industrial trans fats can be expected to have greater impacts on businesses and consumers in Member States and social groups where current levels of industrial trans fats in products and consumption are greatest. The analysis has considered differences in costs between

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
					different Member States and different social groups.
Health (& safety)	xxx	xxx	xxx	xx	Health impacts are the primary reason for taking action to reduce industrial trans fats levels in food, and are therefore central to the analysis of benefits.
Education	x	x	x	x	Action for trans fats is not expected to have general impacts on education; however, consumer awareness is a significant issue, particularly with respect to its role in changing consumption patterns and therefore delivering health benefits.
Governance & good administration	x	x	x	xx	This is closely related to the issue of administrative burden listed under economic impacts above, and can be considered alongside that issue.
Social protection, health and educational systems	-	-	-	-	No distinct issues related to social protection, health and educational systems were identified, other than impacts on consumer health and awareness identified above.
Cultural heritage, consumer choice	x	x	x	x	By requiring substitution of ingredients and reformulation of products, action to limit industrial trans fats could potentially impact on the quality and character of certain processed products, affecting the choice and experience of consumers.
Health inequalities	xx	x	xx	x	Health benefits are likely to be greater in those parts of the EU where industrial trans fats intake are currently highest. This may have the effect of reducing health inequalities. The distribution of health impacts, and their effect in different countries and social groups, is therefore a relevant and potentially significant issue.
Environmental Impacts					
Fighting climate	xx	xx	xx	xx	Reductions in industrial trans fats have the potential to lead

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
change					to the substitution of partly hydrogenated oils with palm oil. Production of palm oil is a significant driver of tropical deforestation and degradation of peatland soils, with significant impacts on carbon emissions. On the other hand this may combine with reduced consumption of source oils that are partly hydrogenated (such as soy), which could have a beneficial environmental impact. Current efforts to ensure that palm oil and other oils are produced and sourced sustainably may contribute to limiting adverse impacts. The overall environmental impact of these combined trends has to be evaluated.
Fostering the efficient use of resources (renewable & non-renewable)	-	-	-	-	This was not identified as an issue in the literature or stakeholder consultations.
Protecting biodiversity, flora, fauna and landscapes	xx	xx	xx	xx	Tropical deforestation, driven by increased palm oil production, as well as impacting on carbon emissions (see above) is a major driver of biodiversity loss and threatens a wide range of tropical species.
Minimizing environmental risks	xx	xx	xx	xx	Principal environmental risks relate to climate change and biodiversity – as identified above.
Other impacts					
Economic and social cohesion	xx	xx	xx	xx	Potentially impacted by other impacts identified above, especially health inequalities and differential impacts on costs between countries. These more specific impacts should be assessed in the first instance.
Impacts in developing countries	x	-	x	x	Not identified as an issue in the literature or stakeholder consultations. Potential impacts are possible as a result of

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
					trade; however, international trade in products containing industrial trans fats appears to be limited.
Sustainable development	x	x	x	x	A number of other issues identified (e.g. environmental, health and economic impacts) are relevant to sustainable development. However, no specific or distinct issues are identified in the literature or interviews.
Fundamental Rights	-	-	-	-	Not identified as an issue in the literature or stakeholder consultations.
General impacts					
Individuals, private and family life, freedom of conscience and expression	-	-	-	-	Not identified as an issue in the literature or stakeholder consultations.
Property rights and the right to conduct a business	-	-	-	-	Not identified as an issue in the literature or stakeholder consultations.

Key: - = not identified as an issue; x = moderate significance; xx = strong significance; xxx = very strong significance

Based on the screening assessment, the following potentially significant impacts were identified as priorities for more detailed analysis:

- Health benefits;
- Effects on health inequalities;
- Compliance costs for business, including the role of innovation and technological development;
- Administrative burdens for business and public authorities;
- Consumer impacts – prices, choice and product quality;
- Single Market impacts;
- Effects on international trade;
- Impacts on SMEs;
- Environmental impacts – particularly in relation to deforestation and implications for climate change and biodiversity.

The potential indirect effects of the above on competitiveness, growth and social cohesion also need to be considered in the analysis.

ANNEX 13: Assumptions for the health impacts assessment

Baseline (option 0)

The baseline assumes an initial industrial trans fats intake of 0.3 % of the energy intake (sensitivity analysis with +/- 50 % initial intake) and three alternative scenarios. The assumption for the baseline industrial trans fats intake from ICF follows the assumption in the JRC modelling study. An alternative worst case estimate of 0.7 % of the energy intake based on a paper by Micha et al (2014) was tested in the JRC study but did not provide additional insights for the overall outcome of our study. The alternative scenarios intend to capture the different ways in which intake might change over time in the absence of additional EU action:

- A ‘rapid decline’ scenario in which intake decreases linearly to zero in 10 years (the baseline assumption adopted by the JRC model in its model);
- A ‘mid-range’ scenario in which intake decreases linearly to zero after 15 years;
- A ‘no decline’ scenario in which industrial trans fats intake remains constant at of 0.3 % energy intake for the duration of the period.

The evidence gathered by ICF suggests that the current situation is characterised by fragmentation, with a number of Member States having taken initiatives alone, without coordination with other Member States, to tackle the industrial trans fats problem. Some Member States governments have acted, as have some industry associations and individual companies.

Voluntary agreement (option 1a and 3a)

For Options 1a and 3a (voluntary agreements) ICF assumed that 20% of food manufacturing enterprises and 10% of food service enterprises participate in the agreement. The basis for this assumption is described in 0, below.

The participating firms are assumed to be representative of the overall population of Food business operators in terms of the contribution that the industrial trans fats in their products makes to population industrial trans fats intake. As such the industrial trans fats intake is assumed to decrease by an additional 20 % for packaged food and 10 % for non-packaged food after three years, on top of any decrease already accounted for in the baseline scenario. For instance, relative to scenario B1 (continuous decrease to complete elimination in 10 years) the voluntary agreement would speed up the decrease relative to the baseline assumption during the 3 first years. Whereas, relative to scenario B3 (unchanged industrial trans fats intake), the voluntary agreement would trigger a decrease in the industrial trans fats intake to 80 % of the current industrial trans fats intake from packaged products, and 90 % of the industrial trans fats intake from non-packaged products.

Evidence 1: Evidence base of options 1a and 3a assumptions

Several voluntary initiatives around Europe have been launched in the context of efforts

to reduce industrial trans fats content in products.

At the national level, formal voluntary schemes have been running in Member States such as the Netherlands, the United Kingdom²³⁹, and Poland. In the Netherlands, the voluntary measures included representative organisations of various relevant industries, and also the Dutch Ministry for Public Health, Wellbeing and Sport²⁴⁰ as observer. For industrial trans fats the goal was to reduce the amount of industrial trans fats in food so that, in accordance with the guidelines from the Dutch Health Council, a maximum of 1 percent of energy intake originating from trans fatty acids could be achieved. The measure was adopted across the various relevant industries which together represent 80 % of the food industry that uses oils and fats. All participants reduced the content of industrial trans fats below 2%. However, The impact of voluntary initiatives in the UK is less clear: a number of food producers (particularly of non-pre-packed food) have not enrolled. Research has suggested that most companies who did sign up are likely to have initiated changes in their products before, and for other reasons than to comply with, the voluntary agreement.²⁴¹ Other research found that the measures adopted in Poland had limited effect.²⁴²

At the EU level, a number of initiatives have been sponsored by food business operators to reduce industrial trans fats (such as the reduction below 2 % of industrial trans fats in the vegetable oils sector promoted by FEDIOL²⁴³). There is also good evidence of unilateral action by large individual food business operators that operate in the whole EU market or a large part of it.²⁴⁴ Interviews with fat and oils sector representatives at European level (FEDIOL and IMACE) suggest that most of the products sold by their sectors have an industrial trans fats content of less than below 2 %. Such results have been achieved through voluntary measures. It seems unlikely that further reductions in industrial trans fats content will be achievable via the same mechanism since residual presence is concentrated in output of smaller firms that are not part of the major industry groupings (see also evidence on existing voluntary agreements at EU level summarized in **Error! Reference source not found.**). Hence it is likely that participation by firms from these associations would be purely symbolic and would not have any material impact on the residual industrial trans fats ‘problem’.

Interviews of ICF with representatives from the chocolate, biscuit and confectionary sectors (CAOBISCO) indicate that voluntary measures have been adopted by some but not all of the national federations and large businesses operating in the sector. This demonstrates the extent to which EU-level business organisations can help achieve changes in industry practices through voluntary agreements. In some Member States the industry is not so well organised, is not represented at EU level and cannot therefore

²³⁹ EC (2015) 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. European Commission, Brussels. SWD (2015) 268 final

²⁴⁰ Volksgezondheid, Welzijn en Sport.

²⁴¹ Knai C et al. (2017) An evaluation of a public-private partnership to reduce artificial trans fatty acids in England, 2011-16. *European Journal of Public Health*, 27: 605-608.

²⁴² Traill, W. B. et al. (2012) Reformulation for healthier food: a qualitative assessment of alternative approaches. AgEcon Search, Conference Paper/ Presentation, 2012.

²⁴³ [FEDIOL \(2014\) FEDIOL Position on TFA.](#)

²⁴⁴ Sodexo (2016) Sodexo corporate responsibility report 2016; McDonald's (2012) Do any of your products contain trans fats?; [Unilever \(2017\) Good fats & oils from plants.](#)

be a party to these voluntary agreements established at that level.

The evidence summarised above suggests that in countries and sectors where the industry has been well organised and committed to voluntary agreements already, and in the countries where legislation exists to limit industrial trans fats intake, the added value of the option will be limited. Besides, the option will also have limited or no value in enrolling businesses in those countries where the industry is not so well organised, and is therefore not represented at EU level. That includes most countries where industrial trans fats levels appear to be higher than the EU average. On that basis, the model assumes that for option 1a 20 % of the food manufacturing industry and 10 % of food services enterprises would reduce industrial trans fats content of their products as a result of joining a voluntary agreement at EU level.

Mandatory labelling (option 2)

The health impacts of option 2 are assessed by assuming that the industrial trans fats intake from packaged food decreases by a maximum of 50 % after two years (assumption of 2 year implementation period). After the two year period intake evolves as assumed in each of the three variants of the baseline scenario. Industrial trans fats intake from non-packaged food (which is not affected by the option) remains as in the baseline.

The reduction in industrial trans fats intake comes from a combination of consumer choice and induced reformulation (where food business operators reformulate foods to reduce the industrial trans fats content in order to avoid having to show a high industrial trans fats level on the label). The 50 % figure is replicated from the analysis of the JRC. The external contractor ICF regards it as an upper limit on the feasible impact of industrial trans fats labelling – low consumer awareness of industrial trans fats will reduce the scale of impacts mediated by consumer choice and may also reduce the scale of induced reformulation.

Evidence 2: Evidence base of option 2 assumptions

The link between labelling and changes in consumer behaviour is more tenuous than that between labelling and reformulation. Studies looking at the link between labelling and changing consumer behaviour show that the relationship is complex and difficult to discern:

Labelling may have unintended consequences e.g. in the US levels below 0.5 g can be labelled as 0 g of industrial trans fats leading to reductions in suggested serving size to meet labelling criteria.²⁴⁵ This may have no impact on consumption. Besides, the continued labelling of “fully/partly hydrogenated” oils on the food composition label as required by EU legislation, which consumers may use to detect trans fats may lead them to reject products that contain fully hydrogenated oils even though those products may have low levels of industrial

²⁴⁵ Hendry, V.L., Almirón-Roig, E., Monsivais, P., Jebb, S.A., Neelon, S.E.B., Griffin, S.J. and Ogilvie, D.B., 2015. Impact of regulatory interventions to reduce intake of artificial trans-fatty acids: a systematic review. *American Journal of Public Health (ajph)*

trans fats. It was also the view of most stakeholders consulted on this study that trans fats labelling will not lead to healthier product choices.

Trans fats intake can remain extremely high in pockets of the population. In Canada, even after mandatory labelling led to 76% of foods meeting voluntary trans fats limits, intake in the population still exceeded the WHO recommendation that less than 1 % of dietary energy intake should come from consuming trans fats. In particular, intake by teenage boys was double the recommended level.²⁴⁶

Some foods with low trans fats levels are costlier, which will be felt more by consumers with a low socioeconomic status. Ricciuto et al. found that some margarine companies in Canada offered products with a low trans fats level while continuing to sell products with a high level at a lower price. Thus, price-conscious consumers would be more likely to consume the less healthy product, thereby increasing their risk of diet-related chronic disease.²⁴⁷

For food labelling regulation to be effective, the population must be aware of trans fats and able to interpret nutrition labels accurately. A study financed by the European Commission²⁴⁸ produced evidence on the impact of food information on consumers' decision making. Findings show that consumers' ability to identify the healthier alternative depends on accessing the relevant information on the food label and understanding it. There is evidence that some sub-groups, and low-income populations are unable to interpret labels and/or have low awareness of trans fats and their health risks.²⁴⁹ More generally, the evidence on consumer awareness of industrial trans fats and issues linked to trans fats intake indicates that it is low in many EU countries (as documented in Annex 32), and comparatively lower than in the countries where labelling policies have been called successful (Canada and the United States), at the time these policies were introduced. It was also the view of most stakeholders consulted on this study that consumers would not understand the information on the product label. Additionally, respondents also believed that it is unlikely consumers would change their consumption of products high in industrial trans

²⁴⁶ Downs, S.M., Thow, A.M. and Leeder, S.R., 2013. The effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence. *Bulletin of the World Health Organization*, 91(4), pp.262-269h

²⁴⁷ Downs, S.M., Thow, A.M. and Leeder, S.R., 2013. The effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence. *Bulletin of the World Health Organization*, 91(4), pp.262-269h

²⁴⁸ TNS (2014) Study on the Impact of Food Information on Consumers' Decision Making

²⁴⁹ Lack of awareness of TFAs was identified as a limiting factor for effectiveness of labelling regulations in Latin America and the Caribbean (Colón-Ramos, U., Monge-Rojas, R. and Campos, H., 2013. Impact of WHO recommendations to eliminate industrial trans-fatty acids from the food supply in Latin America and the Caribbean. *Health policy and planning*, 29(5), pp.529-541). In contrast, high consumer awareness, driven by extensive media coverage of the issue was seen as a key reason for the success of the Canadian labelling initiative (stakeholder interview); Men and consumers under age 40 were least likely to be aware of food label information (Ellis, S. and Glanville, N.T., 2010. Trans Fat Information on Food Labels: Consumer Use and Interpretation. *Canadian Journal of Dietetic Practice and Research*, 71(1), pp.6-10.); Males and ethnic minority college students were less likely to use food labelling about trans fats (Jasti, S. and Kovacs, S., 2010. Use of trans fat information on food labels and its determinants in a multiethnic college student population. *Journal of Nutrition Education and Behavior*, 42(5), pp.307-314.)

fats as a result of reading and understanding labels.

On the basis of this evidence, some impact on industrial trans fats intake can be expected as a result of reformulation but not as a result of consumer responses to the information provided on labels.

Legislative limit 2% (option 1b)

Evidence from Denmark suggests that the introduction of legislation limiting the trans fats content of foods was very effective in reducing the population industrial trans fats intake. Since the introduction of the measure in 2002, the average intake of industrial trans fats decreased in all age groups of the Danish population.²⁵⁰ The most recent data suggest that in 2014 the average industrial trans fats intake in Denmark was 0.009 % of energy intake.²⁵¹

Based on the evidence discussed above, the health model assumes that for options 1b the industrial trans fats intake decreases to 0.009 % of energy intake after two years (assumption of 2 year implementation period) and then evolves as assumed in each of the three baseline scenarios.

Legal ban on partly hydrogenated oils (option 3b)

This option would introduce a ban on the use of partly hydrogenated oils as a food ingredient, through EU legislation, with a transition period of 2 years.

The U.S. Government introduced a ban on partly hydrogenated oils because they are the primary dietary source of industrial trans fats in the USA. Although all refined edible oils contain some industrial trans fats as an unintentional by-product of their manufacturing process, industrial trans fats are an integral component of partly hydrogenated oils and are purposely produced in these oils to affect the properties of the oil and the characteristics of the food to which they are added.²⁵² Use of partly hydrogenated oils in foods will be phased out in the U.S. market by June 2018.

While this option was not considered in the JRC model, this assignment has used the JRC modelling assumptions for the 2% limit in modelling the health impacts of the partly hydrogenated oils ban. Therefore, the model of ICF assumes that industrial trans fats intake will vary as in option 1b, i.e. that the removal of partly hydrogenated oils from the food supply will successfully eliminate the presence of food with high industrial trans fats content from the market.

To assess the robustness of the results a sensitivity analysis on the current EU population's industrial trans fats intake was performed by ICF (i.e. the intake at the point

²⁵⁰ Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods

²⁵¹ Martin-Saborido CM et al. (2016) Public health economic evaluation of different European Union-level policy options aimed at reducing population dietary trans fat intake. *American Journal of Clinical Nutrition*, 104: 1218-26

²⁵² USFDA (2017) Final Determination Regarding Partially Hydrogenated Oils (Removing Trans Fat)

in time when the analysis starts). The model was run with 0.15 industrial trans fats intake (-50 % than baseline initial intake assumption) and with 0.45 % of the energy intake industrial trans fats intake (+50 % than baseline initial intake). Annex 14 provides further details.

ANNEX 14: Additional information on the Sensitivity Analysis

1. IMPACT ON HEALTH CARE COSTS (DIRECT AND INDIRECT)

A sensitivity analysis has been conducted by ICF to show the impacts of alternative specifications of the starting point – i.e. the initial population industrial trans fats intake. This shows that, although the magnitude of costs is dependent on the industrial trans fats intake, all options deliver cost savings in all cases, and that options 1b and 3b provide the largest benefits. Table 36 compares the policy options cost variations with different current industrial trans fats intake assumptions for variant B2, 15 years elimination as the reference.

Table 36 Comparison of savings with different industrial trans fats intakes (M EUR)

Policy option	0.15 %E (baseline -50%)	0.3 %E (baseline)	0.45 %E (baseline +50%)
Option 1a	3,086	11,078	22,242
Option 1b	24,951	94,008	191,437
Option 2	4,283	15,353	30,770
Option 3a	3,086	11,078	22,242
Option 3b	24,951	94,008	191,437

Note: Figures represent the reduction in the present value of healthcare costs over 85 years, for variant B2, in million Euro

2. IMPACT ON DISABILITY-ADJUSTED LIFE YEARS

The sensitivity analysis shows that, although the magnitude of health benefits is greatly dependent on the current industrial trans fats intake, all options reduce the disease burden as compared to the baseline. Table 37 compares the performance of the policy options under different current industrial trans fats intake assumptions looking at the variant B2, 15 year elimination scenario.

Table 37 Health gains in disability adjusted life years averted (EU 28, Millions) by policy option under different industrial trans fats current intakes and considering the B2 variant of the baseline scenario

Policy option	0.15 %E (baseline -50%)	0.3 %E (baseline)	0.45 %E (baseline +50%)
Option 1a	0.2	0.7	1.5
Option 1b	1.7	6	12.5
Option 2	0.3	1	2
Option 3a	0.2	0.7	1.5
Option 3b	1.7	6	12.5

%E: % of energy intake

ANNEX 15: Impacts on health inequalities and details on appraisal of general objective 3: contribution to reducing health inequalities, one of the objectives of Europe 2020

Impact on health inequalities

Inequalities in health remain an important issue in the EU and across the globe. Within the EU there are, for example, substantial differences in life expectancy between countries (life expectancy varies from 74 in Bulgaria to 83 in France). There are also differences within countries. For example, in the UK life expectancy has risen consistently over the past few decades (until plateauing in 2016) but the gap between the life expectancy of the most affluent and most deprived in society has continued to grow. Although the mortality rate has more than halved, the difference in mortality between the rich and poor has not improved and in some cases, has worsened.²⁵³

Food policies have the potential to reduce non-communicable disease mortality and morbidity while tackling existing health inequalities. However, their effectiveness in this dual aim is dependent upon several factors including their coverage of the population, and the degree to which individuals must alter their own behaviour to reap the rewards or whether the individual behaviour change required is minimised.

A number of different approaches have been taken by governments across the EU to reduce industrial trans fats intake. They have had, and are likely to have, varying effects upon their respective health burdens and inequalities. While robust, systematic baseline evidence on industrial trans fats-related inequalities (of intake and outcome) is lacking, there is good evidence of problems in certain population segments as found by ICF. The health impact modelling provides results at population level rather than for particular socio-demographic groups. The potential effects of each option on health inequalities are therefore discussed in qualitative terms. This text is based on published estimates and empirical evidence of trans fats policies and wider food policies across the world collected by ICF.

Legally binding action (options 1b and 3b)

Options 1b and 3b are expected to have the largest beneficial effect upon health inequalities of all of the policies investigated:

- They deliver the largest overall health-related benefits;
- Health benefits are universal, i.e. socio-demographic groups that are unresponsive to information in food labels, or which consume products of food business operators that do not participate in industrial trans fats -related voluntary agreements will enjoy the benefits as much as those who choose foods on the basis of their industrial trans fats content and buy from food business operators that have reformulated their products to reduce industrial trans fats content;

²⁵³ Pearson-Stuttard J, Bajekal M, Scholes S, et al. Recent UK trends in the unequal burden of coronary heart disease. *Heart* 2012;98:1573-82

- Benefits are (providing there is compliance by the food sector/enforcement of the law) certain – there are no intervening uncertainties relating to food business operators’ propensity to collaborate or to consumer awareness.

Introducing legislation to limit industrial trans fats content in food sold to consumers across the EU could result in reducing the disease burden by 6 million disability adjusted life years in the B2 baseline variant through a lowering of the coronary heart disease incidence. It would also reduce spending on healthcare and the wider societal costs of coronary heart disease by €94,008 million in present value terms. There is evidence that industrial trans fats are consumed in higher amounts in countries with higher coronary heart disease mortality²⁵⁴ whilst also being consumed in higher amounts by the most deprived communities in each country. This evidence suggests that the largest reductions in industrial trans fats consumption will be enjoyed by more deprived groups who also have the highest baseline overall and coronary heart disease -specific mortality. This also suggests that the coronary heart disease -related mortality that is prevented will be much greater in deprived populations (between and within countries) than in more affluent populations whose industrial trans fats intake has already reduced and who have lower mortality rates. The reductions in health inequalities are likely to be greatest in younger populations where the largest inequalities often exist. Reducing these inequalities at a younger age is likely to yield the largest health and economic gains owing to the life expectancy of these groups compared to older groups. Modelling results from the UK highlight the potentially powerful reduction in coronary heart disease inequalities achieved by a legislative limit, projecting a reduction in coronary heart disease inequalities of 15%²⁵⁵ and 33% more prevented deaths in the most deprived groups compared to the most affluent.²⁵⁶

It was also the view of most stakeholders consulted on the study of the external contractor ICF that a legally binding action would ensure the highest protection of all socio-economic groups from the negative health effects of industrial trans fats intake.

If Option 1b was specified such that the 2% limit applied to all food products (i.e. ingredients as well as final products sold to the consumer) it seems likely that the health benefits would increase. A 2 % limit applied to all food products would, for instance, remove partly hydrogenated oils from the market, and would influence the reformulation options available to food business operators.

Mandatory labelling (option 2)

On the assumptions made by ICF, the labelling option is – at most – 16% as effective as legally binding actions (option 1b and 3b) in health benefit terms. Under the most optimistic plausible assumption about its efficacy, the labelling option is estimated to deliver a one million disability adjusted life years reduction as compared to the B2

²⁵⁴ Souza Russell J, Mente Andrew, Maroleanu Adriana, Cozma Adrian I, Ha Vanessa, Kishibe Teruko et al. Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies *BMJ* 2015; 351 :h3978

²⁵⁵ Allen K, Pearson-Stuttard J, Hooton W, Diggle P, Capewell S, O’Flaherty M. Potential of trans fats policies to reduce socioeconomic inequalities in mortality from coronary heart disease in England: cost effectiveness modelling study. *BMJ* 2015;351:h4583

²⁵⁶ Pearson-Stuttard J, Critchley J, Capewell S, O’Flaherty M. Quantifying the Socio-Economic Benefits of Reducing Industrial Dietary Trans Fats: Modelling Study. *PLoS One* 2015;10:e0132524

baseline variant. Food labelling with nutritional and other information is widely used with the aim to facilitate informed choice by the consumer.

The efficacy of adding trans fats content data to nutrient declaration as a mechanism for effecting changes in intake is highly uncertain. Whilst empirical evidence is in short supply, concerns have consistently been raised that labelling interventions, could potentially exacerbate health, and dietary inequalities.²⁵⁷ This is because labelling interventions require individuals to alter the behaviour to reap the rewards of the intervention. To alter their behaviour, they must be motivated to do so by understanding of both the health issue and of the label.

There is a possible indirect mechanism for labelling to have an effect – i.e. through reformulation by food business operators that is induced by having to explicitly state the industrial trans fats content of products in the nutrient declaration. The potential scale of such an effect is undetermined in this instance. Food business operators may take the view that low awareness of the health aspects of industrial trans fats consumption among many consumer groups means that the risk of economic losses from maintaining existing industrial trans fats levels is low.

Across the EU, there are variations in coronary heart disease mortality and industrial trans fats consumption. It is likely that labelling would have a negligible effect upon reducing relative health inequalities.²⁵⁸ Indeed, there is some risk of the labelling scenario resulting in a worsening of health inequalities as discussed in more detail below. It is very likely that this policy would be less effective at reducing health inequalities than the legislative limit or voluntary agreement. Unlike the legislative options the benefits for health inequalities are likely to be small and are not assured.

Voluntary agreement (option 1a and 3a)

On the assumptions developed in the analysis it is expected that the voluntary action options would be at most 12% as effective as the legally binding actions (option 1b and 3b) in terms of the health benefits generated.

A variety of voluntary reformulation policies have been deployed across the world for reducing salt intake. These have had mixed results. To date, the largest population-wide reductions in sodium consumption have been achieved in Finland, Japan and the UK via comprehensive “upstream” strategies involving population-wide, multicomponent policies. In contrast, more “downstream” approaches such as individual approaches and

²⁵⁷ Rothman RL, Housam R, Weiss H, et al. Patient understanding of food labels: the role of literacy and numeracy. *Am J Prev Med* 2006;31:391-8 ; Auchincloss AH, Young C, Davis AL, Wasson S, Chilton M, Karamanian V. Barriers and facilitators of consumer use of nutrition labels at sit-down restaurant chains. *Public Health Nutr* 2013;16:2138-45

²⁵⁸ Allen K, Pearson-Stuttard J, Hooton W, Diggle P, Capewell S, O'Flaherty M. Potential of trans fats policies to reduce socioeconomic inequalities in mortality from coronary heart disease in England: cost effectiveness modelling study. *BMJ* 2015;351:h4583

worksite or community interventions have been found to be less effective²⁵⁹, again demonstrating the effectiveness hierarchy of public health interventions.²⁶⁰

For trans fats policy specifically, the UK adopted a voluntary approach. This did reduce industrial trans fats intake²⁶¹, but much less than in Denmark where the legal limit forced the industry to reformulate (or to stop placing of the market) products containing partly hydrogenated oils/high industrial trans fats contents. The key aspect of a voluntary mechanism, for health inequalities, is that it has the potential of leading to product reformulation. In contrast, the labelling policy, which requires the consumer to read the label and change their behaviour, is likely to result in larger changes in the more health conscious, with lower coronary heart disease mortality, than the deprived groups. As the product has a reduced industrial trans fats content, reaping the benefit of the policy does not require individual behaviour change assuming the industrial trans fats content has been reduced equally across all products and locations. It is therefore likely to reduce the disparity between industrial trans fats consumption in the most affluent and deprived groups, in turn reducing health inequalities. The size of the reduction in health inequalities depends upon the size of the reduction in industrial trans fats achieved through the voluntary reformulation.

Table 38 Expected impact of each option on health inequalities

Policy option	Expected impact	Comments
Option 1a	Moderate effect in reducing inequalities derived from industrial trans fats consumption	Unlike option 2, Option 1a will directly change product characteristics rather than require change in consumer behaviour, thus benefiting all groups including those facing greatest health impacts at present. Weaker effect than Option 1b because of weaker effect on overall industrial trans fats intake resulting from slower reformulation in low price product segments, hence delaying inequalities reduction.
Option 1b	Strong effect in reducing inequalities derived from industrial trans fats consumption	Expected to deliver strong health benefits for all groups, including for relatively disadvantaged groups
Option 2	Weakest beneficial effect, and potentially even an increase in inequalities	Health benefits are expected to be weaker than under Options 1b and 3b, and may be reduced among disadvantaged groups because of challenges presented by education and awareness. Scale of induced reformulation is undetermined.
Option 3a	Moderate effect in	Unlike option 2, this will directly change product

²⁵⁹ Hyseni L, Elliot-Green A, Lloyd-Williams F, et al. Systematic review of dietary salt reduction policies: Evidence for an effectiveness hierarchy? PLoS One 2017;12:e0177535

²⁶⁰ Capewell S, Capewell A. An effectiveness hierarchy of preventive interventions: neglected paradigm or self-evident truth? Journal of public health (Oxford, England) 2017;1-9

²⁶¹ Trail B S et al. Reformulation for healthier food: a qualitative assessment of alternative approaches. 2012

Policy option	Expected impact	Comments
	reducing inequalities derived from industrial trans fats consumption	characteristics rather than requiring change in consumer behaviour, thus benefiting all groups including those facing greatest health impacts at present. Weaker effect than Option 3b because of weaker effect on overall industrial trans fats intake.
Option 3b	Strong effect in reducing inequalities derived from industrial trans fats consumption	Expected to deliver strong health benefits for all groups, including for relatively disadvantaged groups which experience greatest health impacts currently

Details on appraisal of general objective 3: contribution to reducing health inequalities, one of the objectives of Europe 2020

Table 39 Appraisal of options' performance under general objective 2: Contribution to reducing health inequalities

Policy option	Expected impact	Comment
Option 1a	(+)	Option is expected to have a positive impact on health inequalities but impact is expected to be reduced by limits to the participation in the voluntary agreement of food business operators servicing the residual high-intake socio-demographic groups. Unlike option 2, Option 1a will directly change product characteristics rather than require change in consumer behaviour, thus benefiting all groups including those facing greatest health impacts at present. It will have a smaller impact than Option 1b because of the weaker effect on overall industrial trans fats intake that results from slower reformulation in low price product segments, hence delaying inequalities reduction.
Option 1b	++	Strong, positive impact. Option is expected to eliminate industrial trans fats-related health inequalities with a high level of confidence.
Option 2	(-)	Option is expected to potentially increase health inequalities. Health benefits are expected to be weaker than under Options 1b and 3b. The scale of induced reformulation by industry is undetermined.
Option 3a	(+)	As for option 1a. The effect will be weaker than in Option 3b because less impact on overall industrial trans fats intake.
Option 3b	++	As for option 1b.
Option 1a/3a + 2	+	Some synergistic effect is anticipated between voluntary agreements and product labelling but core constraints with regard to disadvantaged consumers groups and non-participation by businesses producing products

Policy option	Expected impact	Comment
		containing industrial trans fats remain. The combination of labelling and voluntary agreement is expected to have a stronger effect than that of these options in isolation, and to reduce uncertainty by seeking to influence both actions by business and consumer demand. However, the effect will be weaker than Options 1b/3b and some uncertainty will remain.
Option 1b/3b + 2	++	No significant additional impacts are expected over and above those achieved by the legal options.

Note: scale of - - to + + indicates a range of strongly negative (- -) to strongly positive (+ +) impacts, with '0' being neutral.

ANNEX 16: Impacts on administrative costs for businesses, understanding the requirements and verify compliance

All businesses in relevant food industry subsectors that are potentially affected by the new rules will need to spend some time understanding their obligations, determining compliance and deciding on their response. This time has a cost. Businesses may also incur costs in testing their products to determine industrial trans fats content, either to assess compliance with legal limits or to inform labelling requirements.

These administrative burdens are likely to affect a large number of businesses - as well as businesses whose products currently contain high levels of industrial trans fats, businesses who are unsure of compliance are also likely to be affected.

The research performed by the external contractor ICF suggests that, if a model similar to those adopted in countries that have already legislated is specified, then businesses are not likely to face significant costs reporting information about industrial trans fats to regulators. In Denmark, the industrial trans fats legislation did not include an obligation for food businesses to provide information to the authorities. Latvia's legislation to limit industrial trans fats does not require businesses to provide information on their products' industrial trans fats status unless the responsible institution - Food and Veterinary Service – requests it in the context of an on-site inspection. In this case the company is required to provide information on the specification and the recipe of the product.

The value of administrative burdens associated with familiarisation and determination of compliance strategy can be estimated using the Standard Cost Model. The time associated with each additional activity for each business is estimated and valued it at a standard hourly rate. The cost determinants are therefore:

- The number of businesses incurring additional time burdens
- The average time taken by each business (hours)
- The cost of time spent (EUR per hour).

Numbers of businesses affected

The number of businesses potentially affected by the new rules or voluntary arrangements is a major determinant of costs. This varies between the options as follows (Table 40).

Table 40 Factors determining numbers of businesses affected by each option

Policy option	Businesses affected
Option 1a	Pre-packed and non-prepacked food businesses, and food service companies. Only subsectors whose products are likely to contain industrial trans fats will be affected. Businesses in countries with existing legislation not affected Number of businesses affected depends on rate of uptake of voluntary agreement – lower than in 1b
Option 1b	Pre-packed and non-prepacked food businesses, and food service companies.

Policy option	Businesses affected
	<p>Only subsectors whose products are likely to contain industrial trans fats will be affected.</p> <p>Businesses in countries with existing legislation not affected</p> <p>Mandatory limits will need to be understood by all potentially affected businesses – larger number of businesses affected than 1a</p>
Option 2	<p>Pre-packed food businesses only.</p> <p>Labelling requirements are mandatory so all producers of pre-packed foods affected</p> <p>Businesses in countries with existing trans fats legislation will be affected</p>
Option 3a	<p>Pre-packed and non-prepacked food businesses, and food service companies.</p> <p>Only subsectors likely to be using partly hydrogenated oils will be affected.</p> <p>Businesses in countries with existing trans fats legislation unlikely to be affected, as case for additional voluntary action is limited</p> <p>Number of businesses affected depends on rate of uptake of voluntary agreement – lower than in 3b</p>
Option 3b	<p>Pre-packed and non-prepacked food businesses, and food service companies.</p> <p>Only subsectors likely to be using partly hydrogenated oils will be affected.</p> <p>Businesses in countries with existing legislation may be affected if use partly hydrogenated oils in small quantities</p> <p>Partly hydrogenated oils ban will need to be understood by all potentially affected businesses – larger number of businesses affected than 3a</p>

Some other businesses not included in the above categories will also need to understand the legislative requirements. Examples are large retailers that use third party manufacturers to produce food sold under own brand labels. The number of such firms is not known, but we assume that it is limited, and that the large majority of affected businesses are in the food manufacturing/processing and food service sectors.

Tables presenting the numbers of food businesses in the EU by country and subsector are given as supplementary data by the contractor ICF, based on Eurostat data. Overall, there are 1.08 million businesses in food subsectors potentially subject to trans fats legislation, of which 15% are involved in food manufacturing and 85% in food service activities.

The timetable and resourcing for this assignment did not provide for empirical testing across Europe of business familiarisation costs for a trans fats initiative. The targeted country research investigated this issue in consultations with government and business stakeholders and in the review of literature.

Table 41 presents an estimate of the numbers of businesses incurring administrative costs under each option. This is based on the following assumptions:

- All businesses in relevant subsectors incur some degree of administrative burden as a result of the measures. This may vary from a few minutes spent in understanding the rules and verifying compliance, to greater expenditure of time and resources in assessing the implications and collecting information;

- 20% of businesses in food manufacturing sectors, but only 10% of food service businesses, are involved in the voluntary agreement options 1a and 3a²⁶²;
- Businesses in countries with existing industrial trans fats legislation (Austria, Denmark, Hungary, Latvia, Lithuania) are not affected by Options 1a or 1b;
- Businesses throughout the EU are affected by Options 2, 3a and 3b.

Table 41 Numbers of businesses assumed to be affected by each option

Policy option	Number of businesses affected
Option 1a	117,918
Option 1b	1,019,240
Option 2	260,397
Option 3a	124,403
Option 3b	1,081,514

Source: ICF estimates, applying above assumptions to Eurostat data²⁶³

The figures indicate that more than 1 million businesses are potentially affected by Options 1b and 3b, including those in affected subsectors that are already compliant but nonetheless may incur some time costs in understanding the rules and checking compliance. 85% of the affected businesses are in the food service sector. The number of businesses affected by Option 2 is smaller than for Options 1b and 3b, because only food manufacturers, and not food service businesses, are covered. It is assumed that a slightly larger number of businesses are potentially affected by Option 3b than Option 1b, since businesses in the five countries with existing legislation limiting industrial trans fats would be subject to slightly different rules imposing a ban on partly hydrogenated oils.

The number of affected businesses is expected to be much lower under the voluntary options 1a and 3a. It is assumed that only 10% of food service businesses will be involved in the voluntary measures (see sections on health impacts)

Administrative costs – understanding the requirements and verify compliance

The time taken for businesses in affected food subsectors to understand requirements, collect information and verify compliance is expected to vary widely.

No information was found on such time burdens in the literature review or stakeholder interviews, so it is necessary to make an assumption about the likely burden:

- Assumed time taken per business to understand the requirements and verify compliance = 1 hour
- Average cost per hour is based on Eurostat data for labour costs (including social security contributions and other non-wage labour costs) for

²⁶² The basis for this estimate is discussed in Annex 13

²⁶³ Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

manufacturing and accommodation/ food service sectors for each country. For R&D activities, labour costs for professional and scientific services are used. For public sector costs, labour costs for public service activities are applied.²⁶⁴

These assumptions are assumed to apply equally to all options – the main variable is therefore the number of businesses affected by each.

Employing these assumptions gives the following cost estimates at EU level (Table 42). The figures are one-off costs.

Table 42 Administrative costs: understanding requirements and verifying compliance (M EUR)

Policy option	Estimated one-off cost
Option 1a	3.3
Option 1b	18.5
Option 2	6.9
Option 3a	3.5
Option 3b	19.5

The figures suggest that these one-off costs are likely to be moderate for all options, but lower for the voluntary measures, given the much lower rates of engagement, particularly among food service businesses.

²⁶⁴ There are wide variations in labour costs by Member State, with the lowest costs in Bulgaria and highest in Denmark. For example, manufacturing labour costs vary from EUR 3.7 to 43.4 per hour, food service from 2.5 to 28.6 per hour, professional and scientific services from 7.3 to 50.7 per hour, and public service activities from 4.4 to 39.7 per hour. Source: Labour cost levels by NACE Rev. 2 activity [lc_lci_lev], 2016

ANNEX 17: Impacts on compliance costs for businesses

The principal compliance costs for food businesses arising from the options are:

- Costs of **product testing**. Compliance will require a number of food businesses to test their products to ascertain their industrial trans fats content, in order to inform action. Costs will be incurred in organising and commissioning tests. Tests will also be carried out by Member States authorities. The costs of those tests are accounted for later on in this section.
- Costs of **reformulating products**. Some products containing industrial trans fats will require reformulation rather than a mere substitution of ingredients. For some food businesses, this may merely require a few hours work to try out different recipes, while for others it may require more substantial investments of time and resources in product development.
- Cost of **ingredients**. Businesses sourcing alternative ingredients to reduce industrial trans fats content may incur additional costs. This may be the principal cost for some operators, e.g. food service companies sourcing different fats for frying.
- Costs of **labelling**. Option 2 requires all prepacked food products to include information about trans fats content on their labels, obliging many businesses to incur costs in relabelling their products.

1. COMPLIANCE COSTS – PRODUCT TESTING

Measures to limit industrial trans fats content in foods (mandatory and voluntary, Options 1a and 1b) as well as mandatory rules on trans fats labelling (Option 2) will require some businesses to analyse the industrial trans fats/ trans fats content of their products, and particularly raw materials producers as well as manufacturers using processing of a combination of ingredients. A ban or voluntary agreement on partly hydrogenated oils (Options 3a and 3b) is less likely to require trans fats testing of foods by the businesses since compliance checking will focus on whether partly hydrogenated oils are used as an ingredient. It is likely that a number of businesses will carry out testing as a precautionary measure as part of their internal due diligence processes, however those tests would not be required by the legislation and are not costed here.

Product testing will play an important role in providing the information that businesses need to enable them to decide whether they need to take action. Product testing will also play an important role in achieving compliance and is included here as a compliance cost. However a large number of businesses will not need to carry out tests as their effort to be compliant will involve choosing their ingredients.

The costs of product testing will depend on:

- The numbers of products tested; and

- The cost per product test. These include the time taken to arrange the test and provide samples, as well as the costs of undertaking the test itself.

The research by the external contractor found some evidence of the costs of testing products for industrial trans fats content. In Latvia, trans fats content is analysed by the Institute of Food Safety, Animal Health and Environment (BIOR). The cost of analysing one product was quoted in the national impact assessment as EUR 52.25 (excluding VAT).²⁶⁵ IMACE (the European Margarine Association) advised ICF that fatty acid profiling for food products costs EUR 50 to EUR 100 per profile (with an average price of about EUR 65). Contributors to the validation consultation put the price of testing at between 30 and 150 euros. FEDIOL advised that EUR 65 per test was a reasonable estimate given their own understanding of the range (EUR 30 to 100).

The likely scale of costs involved is assessed based on the following assumptions:

- Between 1 % (food service sector) and 10% (manufacture of fats, oils, margarines) of businesses in the subsectors that are subject to legal limits (Option 1b) or entering a voluntary agreement (Option 1a) need to test their products to assess compliance; only raw ingredient producers and manufacturers using process will need to do so;
- Three products per business are tested on average;
- Under Option 2, 5 % of all labelled food products are tested to ascertain trans fats content. This assumption is conservative and assumes that the majority of products can be declared trans fats free – or categorised according to their trans fats content - based on ingredients, without the need for testing;
- Each product test incurs a fee of EUR 65 (in line with estimates provided by IMACE);
- Each product test requires one hour of administrative time to arrange, provide samples and interpret results;²⁶⁶

Average cost per hour is based on Eurostat data for labour costs (including social security contributions and other non-wage labour costs) for manufacturing and accommodation/ food service sectors for each country.

The estimated costs of product testing in million euros are given in Table 43.

²⁶⁵ Cabinet of Ministers, Latvia (2015) Cabinet of Ministers draft Regulation "On the maximum permissible content of trans fatty acids in foodstuffs", Ex-ante impact assessment report (summary)

²⁶⁶ Responses to the validation consultation did not provide clear advice to revise this assumption either upwards or downwards.

Table 43 Compliance costs – costs of product testing (M EUR)

Policy option	Estimated one-off cost
Option 1a	0.5
Option 1b	3.6
Option 2	65.0
Option 3a	0
Option 3b	0

These one-off costs are found to be largest for Option 2, given the large number of food labels and expectation that many products will need to be labelled to ascertain trans fats content. This is in spite of conservative assumptions about the level of testing required.

One industry representative organisation commented that Option 2 (mandatory labelling) could result in substantially higher costs in food testing than the other options. While a legal limit on industrial trans fats would merely require producers to ensure that industrial trans fats levels were below the specified limit, a labelling requirement could require more frequent testing, particularly because of fluctuations in the trans fats content in oils. This might require the content of each batch to be monitored and labels to be changed accordingly. Moreover, this would require all producers of packaged dairy and ruminant meat products (for which natural trans fats content varies depending on feed regimes, seasonality, type of animals etc.) to frequently analyse the trans fats content of their products. It was predicted that this would generate substantial costs.

2. COSTS OF REFORMULATING PRODUCTS

The main factors affecting the total costs of product reformulation across the sector are:

- The number of products that require reformulation to reduce their industrial trans fats content or to phase out the use of partly hydrogenated oils; and
- The average cost for each product reformulated.

Estimating the number of products requiring reformulation is not straightforward. Firstly, there is a shortage of data on numbers of products that currently exceed the proposed limit on industrial trans fats (2 g per 100 g fat content) under Option 1, or that use partly hydrogenated oils as ingredients (and would therefore be affected by Option 3). Some assumptions need to be made in order to estimate the numbers of products affected.

Secondly, evidence is lacking on the proportion of products that require reformulation, rather than a simple substitution of ingredients. It is likely, for example, that more complex and processed food products such as oils, spreads, confectionery and seasonings will require reformulation. Some bakeries may be able to substitute partly hydrogenated oils with alternative oils and fats without the need to change recipes extensively, while food service businesses may also be able to switch ingredients comparatively easily, for example by changing the oils used for frying. The use of partly hydrogenated oils in conjunction with food additives used for technical reasons (e.g. in coatings) may be more difficult to phase out completely. Without access to a derogation mechanism, the phase-

out of partly hydrogenated oils for such ‘technical’ uses would be required under option 3b but not under option 1b. It is unclear how much more difficult (and potentially costly) reformulation efforts would be under a 3b scenario relative to those required under option 1b. Again, assumptions are required about the proportion of products requiring reformulation.

With regard to the costs of product reformulation, very little evidence was found in the literature or stakeholder interviews. The evidence that is available presents a mixed picture:

- Experience from Denmark suggests that the costs of compliance with the legal limit on industrial trans fats have been limited, with no evidence available to suggest major investments were required in product reformulation;
- In Canada, the national competent authority advised that most of the research and development and recipe testing for voluntary reformulation of food products was done by the large multi-national companies. There was a tendency for SMEs to copy these reformulated products rather than spending money on their own research and development. As a result, the measures were not as costly to SMEs as may be assumed. Reformulation required much work by companies, but businesses have been aware for many years that trans fats would need to be removed from food, and reformulation efforts have been ongoing before the labelling legislation came into force. Most costs fell with the oil and fat suppliers because of their position at the start of the supply chain. The vegetable oil industry has played a key role in developing alternative fats and oils to deliver change across the food sector, reducing the onus on food businesses to reformulate (see Box 1 below);
- For the general food sector, reformulation costs have been estimated by the US Department of Agriculture at USD 11,500 to 100,000 (EUR 10,000-85,000) per formula, with a mid-range of USD 50,000 (EUR 43,000). This includes a ten month development cycle and an eight month market cycle;
- One major US producer of processed foods reported that reformulating in less than a year would cost USD 25 million (EUR 21.74m) for 187 product lines, or USD 134,000 (EUR 116,500) per product. After the reformulation the products were fully competitive, with no significant change in price, consumer acceptance, or shelf life. However, the costs of reformulation would fall by more than 50% over a three year period. This drop in costs was because producers often reformulate products for their own reasons, and required reformulations are less expensive if they can be combined with planned reformulations. It was considered that reformulation costs for fast food and food prepared in restaurants, bakeries and other retail food establishments should be lower than for processed, packaged foods²⁶⁷;
- The Latvian government, in an impact assessment of the legislation introduced in that country, estimated that the cost of reformulation of products

²⁶⁷ Bruns R (2015) Estimate of Costs and Benefits of Removing Partially Hydrogenated Oils (PHOs) from the US Food Supply. US Department of Health and Human Services

could be as low as EUR 60 000 in total for the whole country (Latvian Cabinet of Ministers, 2015). This estimate was based on an assumption that each of the 1264 food production companies would each have to reformulate three products and would spend eight hours on each product;

- Unilever, a major multi-national food manufacturer, reported that the costs of reducing industrial trans fats in food products have been limited, and absorbed within ongoing programmes of product development²⁶⁸;
- An Austrian margarine producer reported that reformulation of commercial margarines was a relatively long process, taking 4-5 years of development, while reformulation of household margarines involved a shorter development phase of 2-3 years. Additional investment to improve the performance of machinery was also needed; machines had 20-30 % lower performance with the alternative fats because partly hydrogenated oils crystallize more rapidly than palm oil and palm oil derivatives. However, users of margarines in the bakery sector were provided with new ingredients with equal qualities, which they were able to use without further reformulation;
- Evidence collected by ICF suggests that a large proportion of reformulation costs will be met by the supply chain. For example, a Dutch supplier of ingredients (bread improvers, bread and pastry mixes) to the bakery sector, estimated that it incurred one-off costs of EUR 120,000-150,000 in reformulating its products to include fully rather than partially hydrogenated oils. However, this reformulation enabled the company to supply ingredients with similar properties to its customers, thus avoiding the need for reformulation of their products. The principal reformulation costs were therefore met by the supply chain rather than the producers of consumer products in this case (see Box 1 below);
- In the UK, Allen *et al* (2015)²⁶⁹ assumed that worst case industry costs for reformulation could be around £200m (EUR 224m), assuming that 8000 products would be reformulated at a cost of £25 000 (EUR 28,000) per product). The best case would be zero if reformulation is already built into the business model and occurs about every 18-36 months. Partial reformulation was assumed to lead to a proportionate scaling down of these costs;
- WHO (2015) commented that “*proposals to limit the content of trans-fat in foods have generated negative reactions from industry in many countries. Common concerns include the high cost of reformulating product compositions and reductions in sales due to altered product properties. These concerns appear to contradict the experience gained in countries that have implemented trans-fat bans where industry representatives have declared that the financial impact of the ban is minimal. In addition, the development of*

²⁶⁸ JRC (2013) Trans-fatty acids in Europe. Health and legislative implications. Workshop report. Zagreb, Croatia. 9-10 April, 2013

²⁶⁹ Allen K, Pearson-Stuttard J, Hooton W, Diggle P, Capewell S, O’Flaherty M. Potential of trans fats policies to reduce socioeconomic inequalities in mortality from coronary heart disease in England: cost effectiveness modelling study. *BMJ* 2015;351:h4583

suitable, cost-effective alternatives to foodstuffs containing trans-fat has progressed over the last 30 years and options for reformulation continue to increase. Evidence suggests that existing national bans have already driven product reformulation at the international level.”²⁷⁰

Box 1 Role of the vegetable oil industry in driving change in the food sector in Canada

“Overall, our industry has developed formulations to allow bakeries, margarine companies, the food service sector, and virtually all food companies to provide products with no trans fats and, in most cases, lower saturated fat. To give you some details, today virtually every national fast-food outlet is using a trans-fat-free frying oil. Trans-fat-free, low-unsaturated-fat margarines now have the largest market share in Canada. Virtually all the large bakeries in Canada are using trans-fat-free formulations. Many of the facilities within our industry that produce hydrogenated oil, which is the source of trans fat, have either been closed or converted.”

Source: President and CEO of the Vegetable Oil Industry of Canada; interview with ICF

Industry associations gave mixed views to ICF. FEDIOL reported that, in order to reduce industrial trans fats content, the oils sector is required to invest in new equipment and R&D, and that this results in extra costs. IMACE advised that its members have continuously worked to develop and improve their products and that, as a result, reductions in trans fats content have been achieved through ongoing product innovation – alongside other product improvements and health goals. Costs have therefore been absorbed in the ongoing costs of innovation and progress to date is not thought to have incurred significant additional or identifiable costs. Food and Drink Europe, a representative body for the European food and drink industry, stated that the needs for reformulation varies by product, but that solutions can be found for any product, particularly through dialogue between food businesses and their fat and oil suppliers. This may entail changes in equipment and processes for certain products, particularly if moving from solid fats to liquid oils. HOTREC, an association representing hotels, restaurants, cafés and similar establishments in Europe, commented that it did not expect significant reformulation needs or costs for the catering sector, although there may be some changes in the ingredients purchased from the food processing sector.

²⁷⁰ WHO (2015) Eliminating trans fats in Europe: A policy brief. WHO, Copenhagen.

Box 2 Dutch ingredient supplier – reformulation of ingredients for the bakery sector

A firm based in the Netherlands supplies ingredients to the bakery sector, such as bread improvers, bread and pastry mixes. In 2003, the company initiated a project to reformulate its products and replace partly hydrogenated oil with high levels of industrial trans fats content to fully hydrogenated oil with a industrial trans fats content below 2 %. The initiative responded to regulatory and customer demands, including the legislation proposed in Denmark and demands from large customers (supermarkets and producers of bakery products).

Fully hydrogenated oil remains solid at room temperature, a characteristic which is undesirable in the bakery industry where a soft texture at room temperature is a prerequisite for processing. This required products to be changed so that they would keep their soft texture while containing fully hydrogenated oil.

The project started in 2003 and ended in 2007, and ran parallel to similar projects executed by other large bakery ingredient producers. Although the research results were not exchanged amongst these parties, overall progress was reported to the Dutch Association of Manufacturers of Bakery Ingredients (NEBAFA, De Vereniging van Nederlandse Fabrikanten van Bakkerijgrondstoffen).

The available evidence in the examples given above therefore suggests that the costs of product reformulation are likely to vary widely, from zero to upwards of EUR 100,000, depending on the complexity of the product to be reformulated, the technical challenges involved, the extent of required changes in the production process, the position of the product in the supply chain, the timescale over which reformulation is required, and the degree to which changes can be addressed through ongoing product development activities.

Firms at the end of supply chains, such as small catering businesses, may be able to achieve compliance with industrial trans fats controls simply by purchasing alternative ingredients from their suppliers. The innovation challenge is likely to be concentrated on firms that are supplying products such as fats and oils into those supply chains. Their customers look to them to develop solution that retain the relevant functionality but lack the industrial trans fats content.

Data gaps and uncertainties preclude a robust assessment of the costs of reformulating food products. The possible scale of costs involved and the factors affecting them has been estimated by use of the following assumptions:

- Under Options 1a and 1b, businesses in countries with existing legislation (Austria, Denmark, Hungary, Latvia, Lithuania) are already compliant, and do not need to reformulate products. In other Member States, the proportion of food products exceeding the proposed 2% industrial trans fats limit varies between 1 % and 20 %, depending on the subsector and Member States

concerned.²⁷¹ It is assumed that this proportion is higher in the Central and Eastern European countries, and in oils, fats and spreads; and lower in other parts of the EU and in other sectors (baked goods, confectionery, condiments/seasonings, potato products, food service);

- The proportion of affected products which need to be reformulated (rather than merely changing ingredients) varies from 10 % in food service to 50 % in bakery and potato products and 100 % in the case of oils and fats, margarines and spreads, confectionery, and condiments and seasonings;
- Under Option 2, businesses are not directly required to reformulate their products, but some will do so in response to changing consumer demand. These costs will be incurred voluntarily, but will be necessary in order to secure the health benefits estimated above;
- Under Options 3a and 3b, businesses in all EU Member States would need to reformulate as a consequence of the partly hydrogenated oils ban. The extent of the reformulation required would be greater than that assumed under options 1a and 1b. There is uncertainty on the scale of the additional costs. The proportion of products in each subsector that require reformulation is assumed to be 20 % more under options 3a and 3b than under options 1a and 1b. It is also assumed that a much smaller proportion (between 0.2 % and 2 %) would be reformulated in the Member States that have already a 2 % industrial trans fats limit in place, recognizing that reformulation efforts have already taken place in those countries;
- Each affected business is assumed to need to change an average of three products, based on a similar assumption in the Latvian impact assessment;
- The average number of hours required for product redevelopment varies from 20 (fresh bakery goods, food service) to 100 for more complex processed products. This assumption is intended to reflect the wide ranging evidence of reformulation costs – some products will require no additional reformulation time, or can reformulate as part of ongoing product development programmes, while a small proportion may demand hundreds of hours of product redevelopment;
- The average cost of product development is estimated based on Eurostat data for labour costs, applying wage rates for professional, scientific and technical activities in the case of the food manufacturing sector, and accommodation and food service activities for the food service sector.

The above assumptions are designed to reflect the findings above that reformulation costs vary widely across the industry, and that some businesses will be able to reformulate costless while others will be required to devote significant resources to R&D.

²⁷¹ This is based on a review of the evidence, drawing on sources such as the JRC (2014) study "Trans fats in Europe: where do we stand". However, it has been necessary to make broad assumptions about average levels of TFA in different foods and countries, since the available data give examples and ranges rather than industry averages

The cost of reformulation is estimated for each option by multiplying the estimated number of businesses in each subsector and country subject to the new rules, the proportion of businesses in each subsector assumed to be required to reformulate their products, the number of products per business, the number of hours per product reformulation, and the wage cost per hour in each country and sector. Based on these assumptions, the cost of product reformulation is estimated as follows under the different options (Table 44).

Table 44 Compliance costs – costs of product reformulation (M EUR)

Policy option	Estimated one-off cost
Option 1a	1.9
Option 1b	9.8
Option 2	4.9
Option 3a	2.2
Option 3b	11.8

The cost of reformulation in Option 1b is based on the 2 % limit being applied to final products only. If the legislation was applied to all food products (including ingredients) it seems likely that the total reformulation costs would be higher as the set of solutions available to food business operators will be more constrained as a result of fats and oils with industrial trans fats levels above 2% being withdrawn from the market.

3. COSTS OF INGREDIENTS

One of the principal costs of action to limit industrial trans fats is the additional cost of ingredients for the food sector, as a result of the need to replace partly hydrogenated oils with more expensive alternatives. The external contractor found in his literature review and interviews limited evidence of the scale of these costs. However, the evidence available to ICF suggests that it is likely that the use of alternative fats and oils to reduce industrial trans fats will increase the costs of ingredients to the food industry.

- In the Netherlands, an ingredient supplier to the bakery sector estimated that reformulation of bread improvers, bread and pastry mixes had increased their price to the bakery sector by 2-3 %, but that the costs of these ingredients accounted for only 2-3 % of consumer product prices (suggesting extra costs of 0.04-0.09 % of the consumer price – see Box above).
- In Denmark, there is no evidence that any additional cost of ingredients has been significant enough to influence consumer prices. However, an interviewee reported that, in response to the legislation, some food businesses were forced to import oils in order to reduce the industrial trans fats content of their products, and that this had an impact on costs, at least in the short term.
- A margarine producer in Austria advised that substitution of partly hydrogenated oils with palm oil does not increase costs, because palm oil is at a similar price or even cheaper.

- In Hungary, the Federation of Hungarian Food Industries has reported that industrial fats with less than 2 % trans fats content are between 13% and 50% more expensive, and predicted that the additional costs of ingredients is likely to affect the price of products to the consumer. The actual impacts will only be clear when the legislation has been fully implemented, and that examples from other countries indicate that forecast price increases are not necessarily seen in practice.
- In Canada, the national competent authority advised that the Canadian Department of Agriculture funded a large amount of research on canola oil to develop non trans-fat alternatives. Once these variations were available, they were widely available to all businesses. While these alternatives were initially more expensive, their prices reduced significantly after two years. The President of the Baking Association of Canada stated that initially there was a higher cost for trans-fat alternatives, which caused some challenges for the industry.
- In the US, an *ex ante* cost benefit analysis of legislation to ban partly hydrogenated oils assumed that substitute ingredients for partly hydrogenated oils could cost an average of 25% more.²⁷²

These costs may vary depending on the type of substitute oils and fats used. Discussions at a JRC workshop *Trans-fatty acids in diets – Health and legislative implications* suggested that substitution with palm oil may be cost neutral but that the use of new hard fats as a replacement for trans fats may increase the cost of ingredients, and require a longer term approach to the development of cost effective alternatives.²⁷³

In order to assess the potential increased cost of food ingredients as a result of reductions in industrial trans fats in food products, the following assumptions were made:

- All products exceeding limits on industrial trans fats or partly hydrogenated oils will require a change of ingredients, substituting partly hydrogenated oils for alternative fats and oils;
- The proportion of different products requiring changes in ingredients is the same as the proportion requiring reformulation, as estimated in the previous sections of this Annex;
- Food ingredients account for 41 % of the value of output of the products affected²⁷⁴;
- partly hydrogenated oils account for 5 % of the overall value of ingredients used in products currently exceeding the 2 % industrial trans fats limit;

²⁷² Bruns R. (2015) Estimate of Costs and Benefits of Removing Partially Hydrogenated Oils from the US Food Supply. US Department of Health and Human Services

²⁷³ Mouratidou Th., Saborido C.M., Wollgast J., Ulberth F. and Caldeira S. (2013) *Trans Fatty Acides in Diets: Health and Legislative Implications*. A workshop report. JRC Scientific and Policy Report

²⁷⁴ Based on analysis of purchases by EU food manufacturing sector using SBS data and input: output tables; Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

- Substitute fats and oils are 25 % more expensive than partly hydrogenated oils.²⁷⁵

In combination, these assumptions would mean that the substitution of partly hydrogenated oils for alternative industrial trans fats free fats and oils will increase costs for businesses supplying products which currently exceed the 2% industrial trans fats limit by 0.51 % of the value of their output.

The estimated costs of additional ingredients under each option are summarised in Table 45.

Table 45 Compliance costs – additional costs of ingredients (M EUR)

Policy option	Estimated annual cost
Option 1a	7.7
Option 1b	44.5
Option 2	22.3
Option 3a	9.3
Option 3b	53.7

These costs can be expected to recur annually, at least until new ingredients are developed that are equal in cost to partly hydrogenated oils.

4. COSTS OF LABELLING

Option 2 imposes costs on businesses by requiring pre-packaged food products to be labelled according to their trans fats content.

This option places obligations on all pre-packaged food businesses, whether or not their products contain trans fats, and therefore affects a wider range of food business subsectors than Options 1 and 3. However, food service businesses and suppliers of non-prepacked foods are excluded.

The drivers of the costs of labelling are:

- The number of food product labels that need to be changed to give information about the presence or absence of trans fats;
- The cost of each new label required; and
- The timescale over which the labelling obligation is introduced. Because most food labels are changed every few years, a longer phase-in of the labelling obligation will reduce costs, since there will be little or no extra cost in changing labels that were already due for renewal.

²⁷⁵ Responses to the consultation validation of ICF did not provide justification for revising this estimate

An impact assessment study by RAND Europe (2008) on food labelling estimated that:

- The number of food product labels in the EU27 = 26,894,250, covering a total of 14,755, 458 products;
- The cost of relabelling ranged from EUR 225 (small change) to EUR 7,000-9,000 (extensive redesign);
- 37% of companies would change labels within 1 year, a further 26% within 2 years and a further 20% within 3 years; only 18% of labels would not be changed over 3 years.

Evidence collected from the study of the external contractor suggests that:

- In the UK, according to the British Retail Consortium, a label change costs an average of £1000-1500 (EUR 1150 - 1725). Updating the nutrition panel constitutes a substantial change, since the whole label will need to be re-plated or re-designed to accommodate the extra line in the nutrition panel.²⁷⁶
- In the baking sector in Canada, the average cost per SKU (Stock Keeping Unit) for updating labels is 3000 Canadian dollars (EUR 2055), according to an interview with the President of the Canadian Baking Association.
- In the US, the FDA estimates the average cost of relabelling at \$7,000 (EUR 6,000) per label, if the change must be made in one year. It is estimated that, if producers are given two years to relabel rather than one year, the one-time costs of relabelling would fall by about 70 %, while a change over three years would reduce costs by 80%.
- The food industry associations interviewed are all against the labelling option, because of the additional costs it would entail. For example, FDE commented that a new obligation to indicate trans fats level on food products would be a huge undertaking, similar to the Food Information for Consumers Regulation, and that entire management systems have to be changed. FEDIOL predicted an extra cost of several thousand Euros per product.

The potential costs of relabelling under Option 2 have been estimated using the following assumptions:

- Labelling is required for all pre-packed food products;
- Food product labels for 26,894,250 Stock Keeping Units will need to be changed (based on the RAND Europe estimate used in the impact assessment on general food labelling)²⁷⁷;

²⁷⁶ EC (2015) Commission Staff Working Document. Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'

²⁷⁷ EC (2008) Commission Staff Working Document accompanying the Proposal for a Regulation Of The European Parliament And Of The Council on the provision of food information to consumers - Impact Assessment Report On General Food Labelling Issues {SEC(2008) 92 final}

- Labels need to be changed over a 2 year period. Based on the estimates by RAND Europe, 63 % of labels would be changed over a 2 year period, suggesting that an enforced change would be required for 37 % of food labels;
- The average cost per label changed is assumed to be EUR 1,000.²⁷⁸

Based on these assumptions, the one-off cost of food labelling under Option 2 is estimated at EUR 9.9 billion (Table 46).

Table 46 Compliance costs – costs of relabelling (M EUR)

Policy option	Estimated one-off cost
Option 1a	-
Option 1b	-
Option 2	9,951
Option 3a	-
Option 3b	-

²⁷⁸ The validation consultation of ICF showed that most respondents were unsure of the costs of a label change. More respondents thought that an estimated cost of EUR1500 per unit was reasonable than those who thought it was too low. Given that the transition period envisaged would prevent costs/losses such as label stock destruction, the estimate has been revised down to EUR1000 per unit

ANNEX 18: Administrative cost for public authorities

The principal administrative costs for public authorities in the Member States of the industrial trans fats control options will be:

- Establishing the policy – including communicating the new arrangements to businesses, handling enquiries, and establishing the necessary systems and processes for delivery;
- Consumer information campaigns, designed to raise consumer awareness of trans fats and their impacts on health. This will be particularly important for the labelling option;
- Inspection, monitoring and enforcement, including the costs of product testing and enforcement actions.

1. COSTS OF ESTABLISHING THE POLICY

Options 1b, 2 and 3b each involve the introduction of legislation. New rules are most likely to be in the form of new EU regulations, binding throughout the EU and not requiring secondary legislation at Member State level. Nevertheless, Member States' authorities will be involved in communicating the new rules to affected businesses in each country, providing advice to businesses where required, and handling enquiries. In addition, each Member State will need to establish the systems and processes necessary for ongoing implementation of the policy.

The scale of costs is difficult to estimate precisely. In order to estimate the possible scale of these costs, we assume that:

- For all legislative options (1b, 2, 3b), each Member State will devote staff time averaging one full time equivalent to establish and promote the policy and to handle enquiries from business, with the exception of Denmark, Latvia, Hungary, Lithuania and Austria for Option 1b;
- Staff time is valued using Eurostat labour cost data for professional, scientific and technical activities;
- There will be additional costs for overheads, publications, events and website materials. These are assumed to amount to 50% of labour costs;
- The costs of establishing a voluntary agreement (Option 1a and 3a) are assumed to be similar to those of introducing legislation, but are reduced in proportion to the number of businesses participating, and amount to 11-12% of the costs of establishing Options 1b and 3b.

The estimated scale of public administration costs is shown in Table 47.

Table 47 Public administrative costs – costs of establishing policy (M EUR)

Policy option	Estimated one-off cost
Option 1a	0.6
Option 1b	5.0
Option 2	6.0
Option 3a	0.7
Option 3b	6.0

2. COSTS OF CONSUMER INFORMATION CAMPAIGNS

Available science suggests that, to be effective, a trans fats labelling initiative will need to be accompanied by a public education programme, which requires additional funding.²⁷⁹

Option 2 – the mandatory trans fats labelling option – is likely to need to be supported by a campaign to raise consumer awareness of the health impacts of trans fats. This will help to inform consumers of the label changes being introduced, and the reasons for these labelling requirements, and will aim to provide information that will enable consumers to make informed choices about whether or not to buy products that contain trans fats.

Evidence suggests that many consumers are unaware of the trans fats issue²⁸⁰, such that introducing changes to labels alone may have limited effect on them. As well as helping to raise awareness among these groups, an information campaign would draw attention to the label changes and encourage consumers to compare the labels on different products.

An international review by the OECD²⁸¹ estimated the costs of information campaigns to tackle obesity. The costs of interventions vary widely depending on the media used. Costs per individual targeted ranged from USD 2.27 (EUR 1.92) for mass media campaigns to USD 77.13 (EUR 65) for workplace interventions and USD 112.95 (EUR 96) for schools based initiatives. Averaged across the population as a whole, the costs per individual ranged from USD 1.80 (EUR 1.52) for mass media campaigns to USD 4.51 (EUR 3.82) for worksite interventions.

The costs of an information campaign on trans fats would depend on the type of intervention employed. The JRC assumed that a full suite of interventions would be employed, including a mass media campaign, physician counselling, and interventions in schools and workplaces³². The net costs of these actions are not given separately in the paper, but the model suggests recurrent costs amounting to many billions of Euro over time.³²

If it was assumed that the labelling option was accompanied by a mass media campaign, focused in those EU Member States where legislation is currently lacking, and designed

²⁷⁹ Hendry et al. (2015) Impact of regulatory interventions to reduce intake of artificial trans-fatty acids: a systematic review, *Am J Public Health*. 2015 Mar;105(3):e32-42. doi: 10.2105/AJPH.2014.302372

²⁸⁰ Please see Annex 8

²⁸¹ Sassi, F. et al. (2009), “Improving Lifestyles, Tackling Obesity: The Health and Economic Impact of Prevention Strategies”, OECD Health Working Papers, No. 48, OECD Publishing, Paris. <http://dx.doi.org/10.1787/220087432153>

to reach the quarter of the EU population most vulnerable to the health impacts of industrial trans fats consumption, and using the per capita cost of USD 2.27 (equivalent to EUR 2.15 at 2017 prices) estimated by Sassi et al, and multiplying this across 25 % of the population of 481 million of the 23 Member States currently lacking legislation, a mass media campaign designed to raise awareness of trans fats across the EU would involve a one-off cost in the order of EUR 260 million across the EU28.

No such costs would be incurred under Options 1b or 3b, as the introduction of legal limits on industrial trans fats or a ban on partly hydrogenated oils would obviate the need for an information campaign.

There would be a case for backing a voluntary agreement (Option 1a or 3a) with an information campaign, as raising consumer awareness and concern about industrial trans fats would increase the incentive for businesses to enter the agreement. However, alternative means of incentivising uptake, such as the threat of legal action to eliminate trans fats, could be employed. Information campaigns might also be carried out by industry bodies.

Table 48 Public administrative costs – costs of information campaign (M EUR)

Policy option	Estimated one-off cost
Option 1a	-
Option 1b	-
Option 2	258
Option 3a	-
Option 3b	-

3. COSTS OF MONITORING AND ENFORCEMENT

The options involving legislation (Options 1b, 2 and 3b) will each require the public authorities in each Member State to devote resources to monitoring compliance and enforcing the rules. Available evidence collected by the external contractor, though limited, gives some indication of the resources likely to be needed for monitoring and enforcement:

- In Latvia, the Food and Veterinary Service estimated that it will need EUR 86,000 to conduct additional controls and to commission laboratory tests in 2018. This cost was estimated to fall to EUR 63,000 annually from 2019. The figures are based on plans for 1,000 inspections and 100 product tests in 2018, representing 13 % and 1.3 % respectively of the 7800 establishments estimated to be possible using fats containing trans-fatty acids.
- In Canada, the director of the Trans Fat Monitoring Programme estimated that the administrative burden of monitoring arrangements linked to voluntary reformulation measures and labelling requirements had amounted to millions of Canadian dollars annually, and was likely to have greatly exceeded the costs of a regulatory approach. As well as in-kind support provided by the Canadian Heart and Stroke Foundation, the programme had funded three regional laboratories and employed several staff members for three years,

including a research scientist, three chemists and a senior policy officer at Health Canada. Other costs include laboratory instruments, and the purchase of market/sales data at a cost of C\$ 500,000. Ratnayake et al (2009)²⁸² argued that the costs of monitoring the voluntary reformulation policy were likely to have exceeded those of enforcing a trans-fat ban, because of the relatively complex measurement of population trans-fat intake required.

- In the US, a paper by Hendry et al (2015)²⁸³ argued that the cost of monitoring and evaluating a labelling policy includes costs associated with product and population-intake analyses, and that a labelling policy is likely to be the most costly to implement effectively.

The costs include:

- The time taken by the authorities to monitor and inspect foods for industrial trans fats content or labelling;
- The time and costs of commissioning laboratory tests on food products; and
- The time taken to undertake enforcement actions.

In order to estimate these costs, it is assumed that:

- 10 % of businesses undergo regulatory inspections in the first two years of the new policy, and 5 % thereafter. This compares with plans in Latvia to inspect 13% of businesses in the first year;
- Each inspection requires an average of 1 hour of officer time. Labour costs are estimated using Eurostat data for public service activities in each Member State;
- Samples are taken for testing from 1 % of establishments each year (compared to plans for 1.3 % in Latvia annually);
- Each product test costs EUR 75 for the authorities to commission;
- 1 % of products require action by the authorities annually, by means of a notice and/or subsequent enforcement action, with each taking an average of 10 hours of officer time.

The costs of monitoring compliance with a voluntary agreement (Option 1a and 3a) are assumed to be similar to those of monitoring compliance with legislation, but are reduced in proportion to the number of businesses participating, and amount to 11-12 % of the costs of monitoring and enforcement for options 1b and 3b.

²⁸² Ratnayake WMN, L'Abbe MR, Farnworth S, Dumais L, Gagnon C, Lampi B et al. Trans fatty acids: current contents in Canadian foods and estimated intake levels for the Canadian population. *Journal of AOAC International*. 2009;92(5):1258–76

²⁸³ Hendry VL, Almiron-Roig E, Monsivais P, Jebb SA, Benjamin Neelon SE, Griffin SJ et al. (2015) Impact of regulatory interventions to reduce intake of artificial trans-fatty acids: a systematic review. *American Journal of Public Health*. 2015;105(3):e32-e42

Table 49 shows the estimated costs of monitoring and enforcement activities under the different options.

Table 49 Public administrative costs – monitoring and enforcement costs (M EUR)

Policy option	Years 1-2	Year 3 onwards
Option 1a	0.7	0.4
Option 1b	6.1	3.4
Option 2	1.5	0.8
Option 3a	0.7	0.4
Option 3b	6.5	3.6

Higher costs are estimated for Options 1b and 3b than Option 2, given the large number of food service businesses excluded from that option. The costs of Option 3b are estimated to be slightly higher than those of Option 1b, since the costs of monitoring and enforcement are assumed to extend to those countries which currently have a legal limit on industrial trans fats but for which an outright ban on partly hydrogenated oils would need to be enforced.

ANNEX 19: Assumptions for the impact assessment on consumer prices

Increases in costs to food businesses would be expected to be reflected, at least partly, in increases in the price of food products to the consumer.

The extent of changes in food prices will depend on:

- The scale of the additional costs to the food industry; and
- The degree to which additional costs are absorbed within the food chain (resulting in lower business profits) rather than passed on to consumers.

Other things being equal, the policy options with higher costs on business would be expected to have a greater effect on consumer prices. Analysis in the section 6.2.1 suggests that Option 2 would have the highest cost for business, followed by Options 3b, 1b, 3a and 1a.

The ability of food businesses to pass cost increases to the consumer through higher prices depends on the intensity of competition in the industry. This may vary between food business subsectors and individual firms. The ability to pass on costs will depend on the willingness of consumers to pay higher prices and, in the retail supply chain; retailers will have an important role in determining whether price increases are accepted. The degree of international competition is also an important factor – producers are more likely to have to absorb extra costs if products can easily be substituted with imports.

Interviewees of ICF in trade associations gave mixed views about the effect of increased costs on consumer prices. While FEDIOL predicted that additional costs will be passed on to consumers, both CAOBISCO and Food and Drink Europe indicated that prices in their subsectors are largely set by retailers, and that any increase in costs would have to be absorbed by the industry. There would be a challenge for producers to reformulate products and source alternative ingredients as cost-effectively as possible, or to find cost savings elsewhere.

The evidence collected by ICF suggests that products containing industrial trans fats tend to be cheaper than industrial trans fats-free alternatives in national markets before the sector goes through the kind of supply chain transition that legislation and strong voluntary action supports. Furthermore it would appear that more expensive products have been reformulated earlier than cheaper ones. For example:

- In Canada, an analysis in 2002 found that margarines that were labelled as “trans fat free” cost \$4.62 per kg and those that were not “trans-fat free” cost \$3.05 per kg. *In comparison, in 2006 those that were “trans-fat free” cost \$5.10 per kg and those that were not “trans-fat free” cost \$3.55 per kg.*

*Similar research indicates that nutritionally improved products tend to be higher in price*²⁸⁴;

- A 2014 study looking at the changing trans fat content and price of cookies in the US and Canada²⁸⁵ concluded that price was significantly related to the presence of trans fat in cookies: trans-fat free cookies were more expensive than those with trans fats. Median price per 100 grams was US\$ 0.75 (interquartile range: US\$ 0.46, US\$ 1.48) in US cookies containing trans fat as compared to US\$ 1.36 (interquartile range: US\$ 0.82, US\$ 2.66) in cookies without trans fat (p<.001);
- In the EU, levels of industrial trans fats in food tend to be higher in lower income Member States in Central and Eastern Europe which might be more expected to be price-sensitive;
- These observations are consistent with evidence above that partly hydrogenated oils tend to be cheaper than alternative ingredients free of industrial trans fats. However, it may also be that these differences in prices are linked to marketing strategies from the food industry, targeting different products at different socio-economic groups.

While this evidence collected by ICF suggests that industrial trans fats tend to be found in cheaper products, it does not necessarily mean that efforts to reduce them will increase product prices. However, it does at least suggest that there may be challenges to reformulate products and to source alternative ingredients cost-effectively if prices are not to increase.

Available evidence suggests that reductions in industrial trans fats have had limited effect in increasing consumer prices in the EU to date. For example:

- In Denmark, a recent report suggests that there was no increase in the price levels of the affected products. The product supply to the Danish market also appears not to have been affected. The Danish industry did not complain about financial losses following the industrial trans fats limit.²⁸⁶
- IMACE reports that no impact on the price of products has been identified to date in its sector, even though industrial trans fats have largely been eliminated.
- The Dutch ingredients supplier to the bakery sector, reported above, indicated that reformulation of bread improvers, bread and pastry mixes required substantial effort and investment, but that, even if fully passed on to consumers, these costs are only likely to have increased prices by 0.04-0.09 % (see Box 2).

²⁸⁴ Krenosky et al. (2012) Risk Assessment of Exposure to *Trans* Fat in Canada. *International Food Risk Analysis Journal*, vol.2, 1-15

²⁸⁵ Hooker, N. and Downs, S. (2014) Trans-Border Reformulation: US and Canadian Experiences with trans Fat. *International Food and Agribusiness Management Review*. Volume 17 Special Issue A, 2014.

²⁸⁶ Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P.8

- However, an Austrian margarine producer indicated that there was probably an initial price increase in the order of 8-12 % following reformulation. No statistics are available. The interviewee commented that consumer prices are always dependent on the broader market situation. The price effect would have been influenced by the replacement oil used (palm, rapeseed, sunflower).

Overall, therefore, while some upward pressure on prices may be expected as a result of the increased costs resulting from action to reduce industrial trans fats, any effect on prices may often be too small to be observable in practice.

ANNEX 20: Evidence collected by the external contractor concerning the assumptions for the impact assessment on product attributes

The EU food sector now has experience in trans-fat replacement – in both the development of substitute fat/oil products and the use of those substances in the preparation and manufacture of final products. This experience is transferable across countries and within supply chains and should make the further reduction of trans fats more straightforward for countries now making the transition than it was for the first jurisdictions that acted in 2003.

In an interview of ICF with the VP of Food and Consumer Products of Canada, an association representing the food manufacturing industry in Canada, stated that, “Despite significant investment by industry, government, and academics, challenges still exist to find the appropriate substitute ingredients for some products and to ensure that reformulated and new products meet consumers' expectations for taste, texture, and quality”.

In the US, a number of concerns were expressed about the impact of local limits on trans fats and partly hydrogenated oils on the price and attributes of food in restaurants. However, the data show that most of these concerns have been refuted. Consumers have apparently not missed the presence of trans fat in food restaurants; sales of French fries, donuts, and other fried, formerly trans fats containing fast foods have not decreased significantly in the localities that have implemented trans fats bans; and the costs of switching to trans fats-free alternatives have not resulted in higher restaurant prices. In addition, trans fats-free alternatives have been readily available to restaurants because cooking oil and seed companies anticipated the shift away from hydrogenated oils years before trans fats bans went into effect. Companies began investing in research and accelerating production of trans fats-free alternatives in the 1990s, when the first major studies were released revealing the health risks of trans fat consumption.²⁸⁷

Some food products and sub-sectors appear to experience greater challenges than others. For example, substitution of oils and fats for frying appears to be achievable relatively easily and with limited effect on quality and taste, but with potential implications for cost. On the other hand, producers of baked goods report greater challenges in finding alternative ingredients and formulations which replicate the attributes of their products. The evidence collected by ICF suggests that these challenges would be greater in the context of a legal ban on partly hydrogenated oils (Option 3b) than under legislation imposing a 2% limit on industrial trans fats content in food products sold to consumers (Option 1b), particularly for the use of additives (for example in chocolate coatings). There is uncertainty on the scale of the reformulation challenges posed by a partly hydrogenated oils ban compared to a legal limit on industrial trans fats content.

²⁸⁷ Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants.

ANNEX 21: Expected impact of each option on the Internal Market

The Inception Impact Assessment²⁸⁸ cited concerns about the Internal Market as one of the main reasons for taking action at EU level:

“The fact that some Member States have taken action on industrial trans fats while others have not results in no single level playing field for business in the EU, creates conditions of unfair competition and hampers the effective functioning of the Internal Market: food business operators active in countries where no limit on industrial trans fats exists have no related reformulation costs and are therefore at a competitive advantage vis-à-vis operators active in countries where legal limits exist or operators abide by self-regulatory commitments. This is particularly relevant for operators active in different Member States. At the same time, operators active in countries where no limit on industrial trans fats exists are negatively affected by the legal uncertainty over whether/when/how new initiatives to reduce industrial trans fats intakes will be adopted at national level (e.g. in the absence of legal certainty over future regulatory developments, operators might have difficulties in planning R&D investments). This also negatively affects competition among operators active in different parts of the Internal Market.”

Neither the literature review nor the stakeholder consultations found firm evidence that national action on industrial trans fats has impacted on the functioning of the Internal Market so far.

Denmark faced some criticism that its action to impose limits on industrial trans fats content in foods represented a trade impediment, by banning the sale of imports of products containing industrial trans fats exceeding the new limit.²⁸⁹ It was argued that Danish products could therefore have an advantage relative to imports. No data has been found to substantiate such claims.

It seems clear that higher national standards could – in theory at least – limit imports into the relevant national markets. On the other hand, the scale of this problem is unclear, given that levels of industrial trans fats in food have been falling across the EU, that multinational food companies that are active in many national markets are at the forefront of action to reduce industrial trans fats, and that higher levels of industrial trans fats are arguably more likely to be found in products manufactured and sold by smaller businesses into domestic markets. There is evidence collected by ICF, however, that large players in some Member States have been developing new products with industrial trans fats levels that are widely distributed in supermarkets, alongside other products that are low in industrial trans fats levels (Stender et al. 2016).²⁹⁰ Furthermore, given concern about the health impact related to consumption of products containing high levels of industrial trans fats, there seems little case for promoting their movement within the EU,

²⁸⁸ European Commission (2016) Inception Impact Assessment - Initiative to limit industrial trans fats intakes in the EU

²⁸⁹ Interview with The Danish Veterinary and Food Administration (5 July 2017) by ICF

²⁹⁰ Stender S, Astrup A, Dyerberg J Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries *BMJ Open* 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

such that the case for harmonisation would involve raising standards across the EU to those countries which have already imposed limits.

With regard to potential cost impediments for producers obliged to meet higher standards, there is limited evidence to suggest that this has been a problem for those countries that have acted to date. Evidence collected by ICF suggests that costs and impacts on pricing have been small, while industrial trans fats many competitors across the EU have taken action to limit industrial trans fats, even in those markets where no national standards exist at present. However, there is growing evidence of products from a similar category but with very different levels of industrial trans fats content being sold together within a single Member States. Thus Stender et al. (2016) have documented how large manufacturers and retailers in several Southern Eastern European countries (including Croatia and Slovenia) have increased the variety of packaged products with high industrial trans fats content (which would be illegal under a 2% limit). In parallel, the variety of packaged products with low industrial trans fats content has also increased in those countries.²⁹¹ There are also concerns (raised among by stakeholders consulted for this study) that, in the absence of an EU-wide legislative measure products manufactured outside the EU with ingredients high in industrial trans fats content might still enter the Internal Market, leading to further unfair competition.

Such issues have been raised by an Austrian margarine producer, which has reported a difference in market conditions in different parts of the EU. In West and Central Europe, action to limit industrial trans fats has been widespread, evening out any potential cost disadvantages for producers in those countries that have introduced legislation. However, producers with higher standards are disadvantaged in Eastern Europe, where cheaper margarines are still on the market. One advantage of the legislation is that it has helped to enhance the image and reputation of the margarine sector.

There are also growing concerns (which were heeded by respondents to the validation consultation for this study) that some manufacturers may be selling different versions of a given product in different Member States, some of which may present high industrial trans fats content and others low industrial trans fats content. While the ICF study team has not been made aware of evidence that demonstrates dual quality relative to levels of industrial trans fats content in food products, a legislative measure to impose a shared standard across the EU could provide additional protection to consumers across the EU against the risk of dual quality and unequal protection against the risks of a high industrial trans fats intake.

Some of the stakeholders interviewed expressed support for action at EU level to harmonise standards on industrial trans fats across the EU. For example, FEDIOL told us that the different rules implemented across EU countries lead to possible trade and Internal Market issues. For this reason FEDIOL has (since 2014) advocated an EU limit at 2% trans fats on fat basis in the products intended for the final consumer together with the deletion of the existing hydrogenation labelling. FEDIOL argues that this will level the playing field for industry and address concerns relating to the trans fats issue in the EU market.

²⁹¹ Stender S, Astrup A, Dyerberg J Artificial trans fat in popular foods in 2012 and in 2014: a market basket investigation in six European countries *BMJ Open* 2016;6:e010673. doi: 10.1136/bmjopen-2015-010673

Seven Member States²⁹² have introduced or notified legislation to limit industrial trans fats in food products, others as well as some sectors have not yet acted or have introduced voluntary initiatives and standards.

Differences in product standards between Member States can distort the free movement of goods within the EU. National rules may impose higher costs on national operators, affecting competition in the market as a whole. They may also restrict access to domestic markets for producers in countries which do not adhere to the same standards.

Harmonising product standards for industrial trans fats across the EU could help to improve the operation of the Internal Market by reducing existing barriers to trade caused by differences in national legislation and preventing new barriers from future national action in Member States that are dissatisfied with the present situation. In the absence of legal action at EU level, future national actions are likely, leading to further differences in standards across the EU.

Overall, it may be anticipated that those options that impose mandatory legal limits across the EU will have the effect of harmonising standards, improving clarity and simplifying the Internal Market. The impacts on current patterns of trade are expected to be modest.

Table 50 Expected impact of each option on the Internal Market

Policy option	Expected impact	Comments
Option 1a	(+)/(-)	Small impact, unclear whether positive or negative. Existing differences in legal standards will remain. Voluntary standards will be extended towards the legal limits existing in 5 countries. However, variable uptake could lead to varying rates of progress and compliance in different Member States.
Option 1b	++	Significant, positive impact. Harmonisation of standards ought to remove industrial trans fats regulation as a factor contributing to differential operating conditions for firms in the Internal Market and avoid the legal complexity arising from differences in Member State law on this issue.
Option 2*	0	No change. No effect on product compositional standards, though the uniform requirement for transparency on industrial trans fats content provides information to facilitate informed consumer choice. Consumers not protected from high industrial trans fats products. Firms producing in countries that have imposed industrial trans fats limits may continue to face additional ingredient costs as compared to equivalent producers in other Member States.
Option 3a	(+)/(-)	Small impact, unclear whether positive or negative. Existing differences in legal standards will remain. Voluntary standards will aim to extend efforts to reduce industrial trans fats across the EU. However, variable uptake could lead to varying rates

²⁹² Details are provided in Annex 8

Policy option	Expected impact	Comments
Option 3b	+(+)	<p>of progress and compliance in different Member States. In addition, focusing voluntary action on eliminating partly hydrogenated oils, when legislation in four countries places limits on industrial trans fats, could cause confusion.</p> <p>Significant, positive impact via harmonisation of standards. EU legislation would differ from that in 7 Member States (given focus on partly hydrogenated oils ban rather than industrial trans fats limit), potentially creating some confusion and requiring harmonisation of existing national rules.</p>

Note: scale of - - to + + indicates a range of strongly negative (- -) to strongly positive (+ +) impacts, with '0' being neutral.

ANNEX 22: Details on the expected impact of each option on competitiveness and international trade

Table 451 Expected impact of each option on competitiveness and international trade

Policy option	Expected impact	Comments
Option 1a	Small	Voluntary action will position EU companies to exploit export markets where there is legislation limiting industrial trans fats Additional costs may be a disadvantage in price sensitive export markets Potential for increased competition from low cost imports
Option 1b	Small	Legal limits will position EU companies to exploit export markets where there is legislation limiting industrial trans fats Additional costs may be a disadvantage in price sensitive export markets
Option 2*	Small	Labelling requirement would apply equally to EU production and imports in domestic market Labelling may help to raise awareness of risk of high trans fats imports
Option 3a	Small	As for option 1a
Option 3b	Small	As for option 1b

ANNEX 23: Evidence on the impacts on SMEs and expected impact of each option on SMEs

The Federation of Hungarian Food Industries notes that the number of SMEs in the affected sectors is particularly high. It suggests that the obligation to reformulate their products might be particularly demanding, as they often struggle from lack of specialist knowledge, information, financial flexibility and means.

The EU project SALUX, targeting reformulation in SMEs in 12 Member States indicates that small enterprises are less active in reformulating their products²⁹³, and that SMEs might face greater challenges in given their smaller size. The barriers faced by SMEs in reformulating foods for health reasons are stated to include a lack of process knowledge; the high costs of reformulation (alternative ingredients, processing, training, etc.); category/products-specific process; change in product characteristics, quality and safety; lack of legislation; protected production constraints; need for “clean labels”; and that few health claims are permitted.²⁹⁴

These concerns are mirrored by international experience. In the US, a number of comments provided in response to the FDA’s 2015 final determination on partially hydrogenated oils noted the challenges faced by small businesses. Examples given included difficulties in securing access to alternative oils, inability to compete for supply, fewer resources to commit to research and development, and effect of ingredient costs on growth of the business. Another respondent claimed that small businesses would need at least five years to adapt due to their limitations in research and development expertise, inability to command supply of scarce ingredients, and economic pressures of labelling changes.

SMEs were less engaged than larger companies in the voluntary reformulation measures adopted in Canada, according to the NCA interviewee. The Canadian Department of Agriculture has a mandate to support SMEs with reformulation and the National Sciences and Engineering Research Council also supported different sectors/categories that faced particular problems. One interviewee suggested that SMEs were largely “followers” rather than “leaders”. Most of the research and development and recipe testing for reformulation was done by the large multi-national companies and SMEs would then copy the format of these reformulated products, rather than spending money on their own research and development. This made the transition less costly for SMEs than might have been assumed.

According to the President of the Baking Association of Canada, SME costs were not out of line with those of larger producers. It was suggested that the main problem for SMEs was finding the in-house technical resources and time to do the reformulation.

²⁹³ Salux (n.d.) Salux Project

²⁹⁴ Salux (2016) Food reformulation – supporting SMEs in improving the nutritional profile of their products (SALUX)

ANNEX 24: Evidence on substitutes for partly hydrogenated oils, environmental impacts of palm oil as well as environmental impacts of alternatives; expected impact of each option on the environment

Substitutes for partly hydrogenated oils

The principal source of industrial trans fats in food is partly hydrogenated oils, including soybean, cottonseed and other liquid oils.

There are a range of possible replacements for partly hydrogenated oils, including oils produced by modified hydrogenation, modified oils, butter and animal fat, natural saturated oils such as palm and coconut oil, natural unsaturated vegetable oils (olive, canola, corn or soy oil) and non-fatty texture-building substances (such as plant fibre or whole oats). Saturated fatty acids, particularly palm oil, are often used in reformulating bakery foods, while unsaturated fats are normally used for replacing trans fats in reformulating fried foods.²⁹⁵

Palm oil is an attractive substitute for industrial trans fats, both in hard fats and spreads, because of its properties, especially its natural stability, and its cost effectiveness. Consultees in the food industry, including IMACE and FEDIOL, confirmed that palm oil can be a good replacement for partly hydrogenated oils, on account of its functional benefits, but that it is only one of the options available. However, according to a margarine producer in Austria, consumer resistance to the use of palm oil has increased in the last 10 years, making it a less attractive substitute, such that further reformulation of products currently containing palm oil is now taking place.

Evidence from Denmark, after the introduction of the trans-fat ban, indicates that saturated fats (including palm oil) were the main replacement in 66 % of products.²⁹⁶

Similarly, in Canada, the President of the Baking Association advised in interview that in the baking industry, pre 2002, most oils used were vegetable oils but now they have primarily been replaced with palm fats and oils. Most of the trans fat-free alternatives being used by the baking industry come from palm oil.

The use of palm oil as a partly hydrogenated oils substitute needs to be viewed in the context of general trends in palm oil use by the food sector and concerns about its environmental impacts. For example, the Netherlands is the largest importer of palm oil in the EU. After a small increase from 2011 to 2012, there has been a slow but steady decline in the total use of palm oil in the food and feed industry (from 385,000 kg in 2011 to 279,804 kg in 2015) and a much larger increase in use of sustainable palm oil as a proportion of the total amount of palm oil. This decline in palm oil demand has occurred at the same time as voluntary measures to reduce industrial trans fats in the food chain.

²⁹⁵ European Parliament (2016) Trans Fats – Overview of recent developments. European Parliament, Briefing March 2016.

²⁹⁶ WHO (2015) Eliminating trans fats in Europe - A policy brief.

In the EU as a whole, after a decade of strong growth in palm oil consumption in the EU in the 2000s, demand has been stagnating since 2014. BMI Research forecasts this trend will continue to 2021. The two main growth drivers for palm oil consumption - namely the expansion of palm oil in food manufacturing and the growth of biodiesel consumption in the region - are coming under growing pressure. BMI Research forecasts that the EU's palm oil consumption will decline by 0.3 % on average annually between 2017 and 2021 to reach 6.5 million tonnes, compared with the 5.2 % annual growth rate recorded over the past 10 years.²⁹⁷ However, global demand for palm oil is forecast to continue to grow strongly.

Consultees in the food industry, such as FEDIOL and IMACE, stressed that their members had already taken action to eliminate industrial trans fats, using palm oil and other alternatives, and that they did not expect a major increase in demand for palm oil as a result of future policy.

Environmental impacts of palm oil

Any increase in palm oil production would be a cause for concern, since the expansion of palm oil plantations has led to large scale deforestation, with major impacts on biodiversity and climate. A recent European Parliament²⁹⁸ report and subsequent resolution²⁹⁹ noted that:

- Cultivation of palm oil over the last 20 years has been the cause of 20 % of all deforestation³⁰⁰;
- Tropical ecosystems, which cover 7% of the Earth's surface, are under increasing pressure from deforestation and the establishment of palm oil plantations, resulting in forest fires, the drying up of rivers, soil erosion, loss of groundwater, pollution of waterways, destruction of habitats, loss of ecosystem services, and adverse impacts on the global climate;
- Numerous species have been adversely impacted by palm oil production, including the Sumatran rhinoceros, Sumatran tiger and Orangutan;
- Companies trading in palm oil are generally unable to prove with certainty that the palm oil in their supply chain is not linked to deforestation.

In a response to the European Parliament resolution, the European Commission noted that palm oil can play an important role in the economies of producing countries and that the causes of deforestation are complex. The Commission stressed the importance of

²⁹⁷ BMI Research (2017) Industry Trend Analysis - Growing Obstacles for Palm Oil In Europe Despite Sustainability Efforts - JUNE 2017

²⁹⁸ European Parliament (2016) Draft Report - Palm oil and deforestation of rainforests.

²⁹⁹ European Parliament resolution of 4 April 2017 on palm oil and deforestation of rainforests (2016/2222(INI)).<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2017-0098+0+DOC+PDF+V0//EN>

³⁰⁰ This figure has been disputed. A study on Indonesia, one of the main producers of palm oil in the world, has linked palm oil production to a maximum of 16% of the total deforestation in the country. Abood, S. A., Lee, J. S. H., Burivalova, Z., Garcia-Ulloa, J., and Koh, L.P. 'Relative contributions of the logging, fiber, oil palm, and mining industries to forest loss in Indonesia'. Conservation Letters 8 (2015), 58-67

considering all agricultural drivers of deforestation, including soy, beef, cocoa and coffee.

Europe was the largest consumer of ‘imported deforestation’ in the period 1990-2008 and in 2008 committed to reduce deforestation by at least 50 % by 2020 and halt global forest cover loss by 2030. Palm oil is one of the large scale agricultural crops that have a contribution to the ongoing deforestation. The EU imported in 2014 close to 9 million tonnes of palm oil and about 0.7 million tonnes of palm kernel oil, representing around 12 % and 10 % respectively of the total world production. It is estimated that around 45% are processed by the food and feed industry, while 55 % are used in energy and in industrial applications.³⁰¹

The use of palm oil does not always come at the expense of tropical deforestation. Initiatives and voluntary certification schemes have been established to encourage sustainable palm oil cultivation. For example, the Roundtable on Sustainable Palm Oil (RSPO) now has 2500 members worldwide, representing all links along the palm oil supply chain, who have committed to produce, source and/or use sustainable palm oil certified by the RSPO. Nevertheless, while unsustainable practices remain widespread in the palm oil industry, any increase in usage could have significant environmental effects.

The European Commission commissioned a study on the environmental impact of palm oil consumption and on existing sustainability standards. The ICF study has collected extensive evidence of palm oil production and consumption, its environmental, economic and social impacts, and of certification schemes.

Data from the study suggest that approximately 20 % of palm oil output is certified, although only around half of this (10 % of world production) is sold as certified palm oil at premium prices. The remainder of certified production is sold as non-certified. There is currently excess supply of certified palm oil: more is available than consumers are prepared to pay a premium for. Since the EU accounts for about 10 % of overall palm oil demand, EU demand could be met wholly through certified production, if consumers were prepared to pay a price premium. A clear distinction needs to be made between new clearance of forests for palm oil production, and palm oil produced from previously cleared forests.

Consultees in the food industry argued that the sector is taking action to source ingredients sustainably, and that reformulation using palm oil need not have negative impacts on the environment. For example, FEDIOL emphasised the actions of its members to source raw materials sustainably, irrespective of their botanical origin, and stressed that members are heavily involved in actions to ensure the sustainability of palm and soy. The percentage of certified sustainable palm oil used by FEDIOL members has continued to increase over time, reaching 60 % at the end of 2016, albeit with a slower growth rate compared to the previous year.³⁰² 7.2 million tons of palm oil were imported into the EU in 2016, of which about 50% were refined by FEDIOL companies.³⁰³

³⁰¹ European Sustainable Palm Oil Advocacy Group (2016) Position paper on palm oil production and deforestation

³⁰² FEDIOL (2017). Palm Oil Monitoring

³⁰³ FEDIOL (2017) EU vegetable oils’ sector works towards meeting the 2020 commitments on sustainable palm oil. Press Release

Similarly, IMACE stressed that the margarines and spreads industry is committed to using sustainable palm oil, such that increased use of palm oil should not lead to deforestation. AIBI, CAOBISCO, FEDIMA, FEDIOL and IMACE are members of the European Sustainable Palm Oil Advocacy Group which aims to support the uptake of sustainable palm oil in Europe and to communicate scientific and objective facts and figures on environmental, nutritional and functional aspects.

In the US, the Final Determination regarding partly hydrogenated oils concluded that:

“We have carefully considered the potential environmental effects of this action. We have determined, under 21 CFR 25.32(m), that this action “is of a type that does not individually or cumulatively have a significant effect on the human environment” such that neither an environmental assessment nor an environmental impact statement is required”.³⁰⁴

Environmental impacts of alternatives

A consultee at LMC International stressed that, though palm oil plantations have caused deforestation and contributed to climate change; it is too simplistic to argue that palm oil is more environmentally damaging than alternatives. It should be noted that alternatives, such as soybeans, can also be environmentally damaging.

Palm oil has the advantage of very high rates of oil yield per hectare, meaning that the amount of land and other inputs required for its production are comparatively low. Soy beans, by contrast, comprise approximately 80 % protein meal to 20 % oil. This reduces oil yield per hectare and means that any attempt to substitute palm with soy would generate excess quantities of protein meal, depressing world prices. Soy is also one of the most significant drivers of deforestation. Estimates on the leading causes of deforestation vary between sources, with beef, soy and palm oil deemed response for a third of all recent deforestation in one estimate and 80 % in another.³⁰⁵ All three are regarded as key drivers of deforestation, however, and land clearance causes biodiversity and climate impacts whatever is planted.

Furthermore, alternatives to palm oil (soy, rapeseed and canola) are often genetically modified, which is not popular with consumers.

Table 52 Expected impact of each option on the environment

Policy option	Expected impact	Comment
Option 1a	Smaller than 1b; could be positive or negative	Net effect unclear because soy and palm oil both contribute to deforestation; sustainability of sourcing is an important factor Impact likely to be smaller than 1b because of smaller scale of change
Option 1b	Potentially significant; could be	Net effect unclear for reasons given above Impact likely to be greater than for voluntary or

³⁰⁴ FDA (2015) Final Determination Regarding Partially Hydrogenated Oils. A Notice by the FDA on 06/17/2015

³⁰⁵ COWI (2017). Feasibility Study on options to step up EU Action against Deforestation – Part II

Policy option	Expected impact	Comment
	positive or negative	labelling options
Option 2*	Potentially significant, negative	Net effect unclear for reasons given above Impact likely to be smaller than 1b because of smaller scale of change
Option 3a	Smaller than 3b, could be positive or negative	Net effect unclear for reasons given above Impact likely to be smaller than 1b because of smaller scale of change
Option 3b	Potentially significant; could be positive or negative	Net effect unclear for reasons given above Impact likely to be greater than for voluntary or labelling options

ANNEX 25: Impacts of combined options

Additionally, impacts of certain combinations of options have been investigated. These are:

- Combining mandatory labelling with legislation (Options 2 and 1b or 2 and 3b);
- Combining mandatory labelling with voluntary agreement (Options 2 and 1a or 3a).

1. COMBINING MANDATORY LABELLING WITH LEGISLATION (2 + 1B OR 2 + 3B)

Social impacts

Any additional benefit of adding labelling requirements to a legal limit on industrial trans fats or a ban on partly hydrogenated oils is expected to be limited.

As discussed before, options 1b and 3b are expected to have the greatest effect on industrial trans fats intake, delivering the largest savings in healthcare costs and the highest reduction in disability-adjusted life years. Combining one of the two options with labelling will not have a significant additional impact on the population industrial trans fats intake, which will already be reduced to very low levels under Options 1b and 3b. There are theoretical direct and induced effects arising from consumers having a preference for industrial trans fats content closer to zero than the 2 % legislated threshold.

Economic impacts

Some of the costs of combining labelling with legislation will be additive, while others will overlap between the two options. For example, some of the administrative burdens and many of the costs of product testing, reformulation and ingredients will be shared between the two options.

Based on an assumption made by the external contractor ICF that the overall costs of each of the types of action required by a combination of the two options is equivalent to the greater of the costs of the two individual options, the overall costs are estimated as follows.

Table 53 Present value of total costs of implementing combinations of options over 10 years (M EUR)

Policy option	Business administrative costs	Business compliance costs	Public administrative costs	Total costs
Option 1b + 2	17.8	9,568.8	250.6	9,837.2
Option 3b + 2	18.7	9,568.8	250.6	9,838.2
Option 1a + 2	6.7	9,568.8	250.6	9,826.2
Option 3a + 2	6.7	9,568.8	250.6	9,826.2

Because all of the four combinations of options include Option 2, which has high costs of relabelling, product testing and awareness raising, each combination of options also has high costs.

2. COMBINING MANDATORY LABELLING WITH VOLUNTARY AGREEMENT (2 + 1A OR 2 + 3A)

Social impacts

Combining labelling requirements with a voluntary agreement to limit industrial trans fats or partly hydrogenated oils is likely to deliver greater added value than a combination of legal limits and labelling.

As discussed above, options 2, 1a and 3a are expected to deliver weaker benefits in terms of health-related costs and disability-adjusted life years than options 1b and 3b. Combining a voluntary agreement with labelling may be expected to have a higher impact in reducing the population industrial trans fats intake and will lead to greater cost savings and disability-adjusted life years reduction than adopting only one of the two options.

The model assumes that when combining options 2 and 1a or 3a the industrial trans fats intake from packaged food decreases by 50 % after two years (model assumption for option 2) and additionally the industrial trans fats intake would decrease by 10% for non-packaged food after 3 years (model assumption for options 1a and 3a) and then evolves as assumed in each of the three baseline scenarios.

Table 54 illustrates the cost savings resulting from combining the assumptions for industrial trans fats intake of the two options together with those resulting from each option compared to the baseline scenario (main scenario 15 years). They are calculated by subtracting a given policy healthcare costs to the baseline ones.

Table 54 Health-related savings compared to baseline by policy option (M EUR)

Policy option	Total healthcare savings
Option 1a	11,078
Option 1b	94,008
Option 2	15,353
Option 3a	11,078
Option 3b	94,008
2 + 1a or 2 + 3a	19,248

According to these estimates, the two combinations of options (1a + 2, 3a + 2) are expected to deliver greater savings in healthcare costs compared to options 1a, 2 or 3a separately. However, these benefits are significantly less than those delivered by Options 1b and 3b.

Table 55 presents the estimated number of disability-adjusted life years avoided by combining the two options, compared to the baseline scenario (main scenario 15 years).

They are calculated by subtracting a given policy disability-adjusted life years to the baseline ones.

Table 55 Disability-adjusted life years averted by policy option (million)

Policy option	Total disability-adjusted life years averted
Option 1a	0.7
Option 1b	6
Option 2	1
Option 3a	0.7
Option 3b	6
2 + 1a or 2 + 3a	1.3

Options 1b and 3b lead to the highest reduction in disability-adjusted life years. However, the combination of options (2 with 1a or 3a) is estimated to avoid 1.3 million disability-adjusted life years, which is higher than the estimates for Option 2, 1a or 3a alone.

It was the view of most stakeholders consulted on this study that combining labelling with legally binding actions or voluntary agreements would not produce higher social benefits.

Economic impacts

The estimated costs of combining Options 1a and 2, and 3a and 2, are given in Table 45 above. These costs are high compared to Options 1b and 3b, as a result of the high relabelling and promotional costs of Option 2.

ANNEX 26: Further details for appraisal of General objective 1 specific objective 1

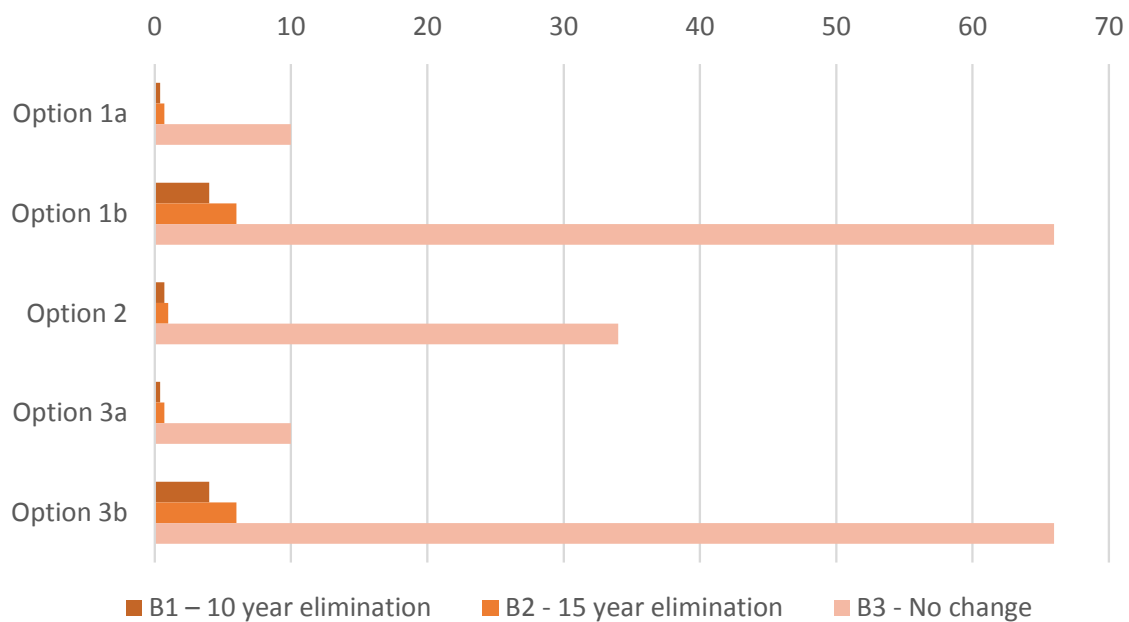
1. ADDITIONAL DETAILS FOR SECTION 7.1.1 ON DIRECT HEALTH IMPACTS

Table 56 Appraisal of options' performance in relation to General Objective 1: Health gains by option under different variants of the baseline scenario (total disability-adjusted life years gained, million)

Variant of the baseline scenario	Option 1a	Option 1b	Option 2	Option 3a	Option 3b
B1 – 10 year elimination	<0.4	4	< 0.7	<0.4	4
B2 - 15 year elimination	<0.7	6	<1	<0.7	6
B3 - No change	<10	66	<34	10	66

Source: ICF. Note: '<' indicates that the figure shown is regarded as an upper estimate of the likely impact. Actual impact is likely to lie in the range between zero and the figure shown.

Figure 13 Health gains by option under different variants of the baseline scenario (total disability-adjusted life years gained, million)



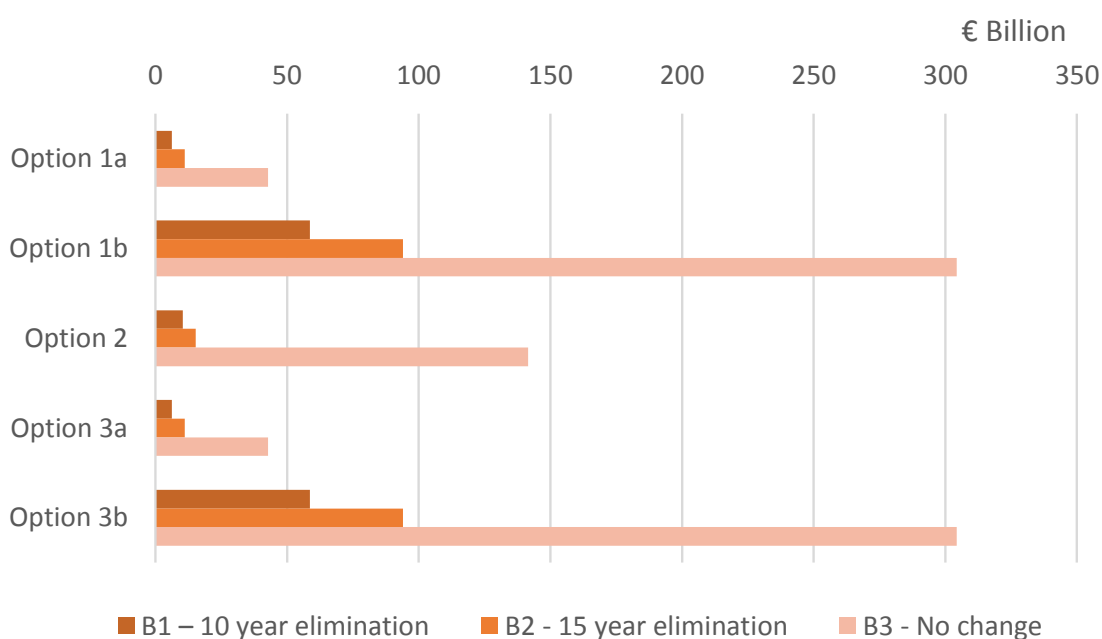
Source: ICF

2. ADDITIONAL DETAILS FOR SECTION 7.1.2 DIRECT AND INDIRECT ECONOMIC IMPACTS OF CHANGES IN HEALTH STATUS

Table 57 Direct and indirect cost savings associated with lower coronary artery disease disease burden by option under different variants of the baseline scenario (M EUR)

Policy option	Savings from lower disease burden		
	B1 – 10 year elimination	B2 - 15 year elimination	B3 - No change
Option 1a	6,197	11,078	42,798
Option 1b	58,611	94,008	304,366
Option 2	10,329	15,353	141,484
Option 3a	6,197	11,078	42,798
Option 3b	58,611	94,008	304,366
Option 1b/3b + 2	Not estimated	94,008	Not estimated
Option 1a/3a + 2	Not estimated	19,248	Not estimated

Figure 14 Direct and indirect cost savings associated with lower coronary artery disease burden by option under different variants of the baseline scenario (billion EUR savings, present value)



3. FURTHER DETAILS FOR APPRAISAL OF SPECIFIC OBJECTIVE 1: REDUCE INTAKE OF INDUSTRIAL TRANS FATS IN THE ENTIRE EU FOR ALL POPULATION GROUPS

The performance of options against this specific objective mirrors that for General Objective 2 on health inequalities. The performance of each option is summarised in Table 58 below.

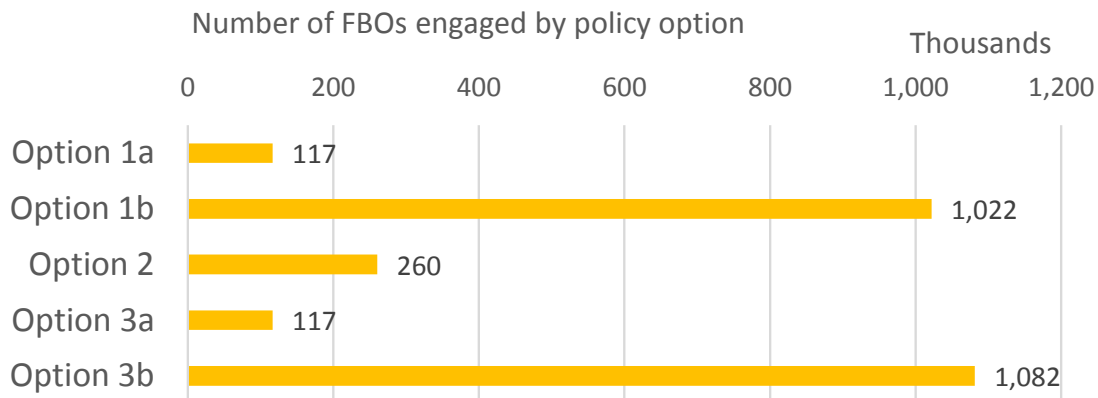
Table 58 Appraisal of options' performance under specific objective 1: reducing industrial trans fats intake for the entire EU for all population groups

Policy option	Expected impact	Comment
Option 1a	(+)	Option is expected to have a positive impact on health inequalities but impact is expected to be reduced by limits to the participation in the voluntary agreement of food business operators servicing the residual high-intake socio-demographic groups. Unlike Option 2 this will directly change product characteristics rather than requiring change in consumer behaviour, thus benefiting all groups including those facing greatest health impacts at present. Weaker effect than Option 1b because of weaker effect on overall industrial trans fats intake.
Option 1b	++	With compliance, this option is fully effective in bringing industrial trans fats intake down to a low level across the EU population.
Option 2	(+)	Labelling food products for industrial trans fats has the potential to reduce intake through two mechanisms – consumers uses the industrial trans fats data on the nutrient declaration to choose lower products that are lower in industrial trans fats and companies voluntarily reformulating their products so as to be able to quote a lower industrial trans fats figure on the nutrient declaration. Consumer awareness of the health consequences of high industrial trans fats intake is a necessary condition for the former effect and given evidence on the efficacy of labelling and consumer awareness it is concluded that this option is likely to have at a small positive effect on overall intake. There is the potential for those gains to be unevenly distributed across the potential and even for negative impacts in some cases as a result of confusion about interpretation of the nutrient data.
Option 3a	(+)	As for option 1a.
Option 3b	++	As for option 1b.
Option 1a/3a + 2	+	Combining labelling with voluntary agreements is expected to have a modest additional positive impact on industrial trans fats intake for all groups through synergistic effects between the two measures. The combination of labelling and voluntary agreement is expected to have a stronger effect than that of these options in isolation, and to reduce uncertainty by seeking to influence both actions by business and consumer demand. However, the effect will be weaker than Options 1b/3b and some uncertainty will remain
Option 1b/3b + 2	++	Combining labelling with legislation is not expected to provide significant added value in reducing intake; the possible impacts identified are positive

Note: scale of - - to + + indicates a range of strongly negative (- -) to strongly positive (+ +) impacts, with '0' being neutral.

ANNEX 27: Further details for appraisal of specific objective 2: Ensure that the same rules/conditions apply in the EU to the manufacturing and placing on the market of foods that could contain industrial trans fats, so as to ensure legal certainty of EU food business operators within and outside the EU

Figure 15 The legislative options are expected to directly impact the actions of many more firms than are the voluntary agreements and the labelling option



Source: ICF estimates, applying above assumptions to Eurostat data

Table 59 Appraisal of options performance under specific objective 3: Ensure legal certainty for food business operators as regards the rules applicable to the manufacturing and placing on the market of foods that could contain industrial trans fats

Policy option	Expected impact	Comment
Option 1a	0	No additional legal certainty beyond the baseline, which may involve additional Member States adopting national laws.
Option 1b	++	Provides legal certainty and consistency across the EU
Option 2	0	Option does not preclude the possibility of Member States adopting national legislation as in the baseline. Option applies to only packaged foods so no impact on certainty in the food service sector.
Option 3a	0	No additional legal certainty beyond the baseline, which may involve additional Member States adopting national laws.

Option 3b	+(+)	Provides a single legal solution to industrial trans fats, and associated certainty, across the EU but would require adjustment by those Member States that have already adopted a 2% limit.
Option 1a/3a + 2	0	No additional impact is foreseen on legal certainty by combining a labelling obligation with voluntary agreements
Option 1b/3b + 2	++ / +(+)	No additional impact is foreseen beyond those achieved by legislation through adding a labelling obligation

Note: scale of - - to + + indicates a range of strongly negative (- -) to strongly positive (+ +) impacts, with '0' being neutral.

ANNEX 28: Ex ante analyses in the US and Canada on Evidence on legislation to ban partly hydrogenated oils

Ex ante analyses in the US and Canada found large benefit:cost ratios for legislative limits on trans fats/ partly hydrogenated oils.

Costs and Benefits of TRANS FATS measures in Canada

A study undertaken by Gray, Malla and Perlich (2005) examined the potential economic impacts of a ban on industrial trans fats, at a time when industrial trans fats intake in the country was at high levels. It estimated that in all cases the total food costs of reducing TRANS FATS “would be less than \$1 billion. Oilseed growers, whose price is set in the global market, would largely be unaffected by a ban. Generally, the increase in cost would occur at the crusher and food processor sectors through the cost of product reformulation and the substitution of higher cost HO (High Oleic) Canola and soybean oils. These costs would ultimately be passed on to consumers, resulting in very modest increases in consumer expenditure. The overall result would be a large economic gain over a range of plausible scenarios.”

The estimated costs and benefits of different options were as follows:

Option	Business compliance costs	Health benefits
Voluntary Labelling	\$361 m	\$7,357m
Mandatory Labelling	\$471m	\$12,570m
2% trans fats Limit	\$941m	\$19,540m

Source: Gray R and Malla S (2007) Reducing Trans fats Consumption in Canada: Voluntary/Mandatory Labeling System or Trans fats Ban? Policy Brief, Canadian Agricultural Innovation Research Network, Saskatoon

Economic Analysis of partly hydrogenated oils ban in the US

The FDA conducted an economic analysis, reported in the 2015 Final Determination regarding partially hydrogenated oils, which estimated the net present value over 20 years of quantified costs to the action will be \$6.2 billion, with a 90 percent confidence interval of \$2.8 billion to \$11 billion. They estimated the net present value of 20 years of benefits to be \$140 billion, with a 90 percent confidence interval of \$11 billion to \$440 billion. Expected NPV of 20 years of net benefits (benefits reduced by quantified costs) were \$130 billion, with a 90 percent confidence interval of \$5 billion to \$430 billion.³⁰⁶

20-Year net present value of	Low Estimate	Mean	High Estimate
Costs (BN USD)	2.8	6.2	11
Benefits (BN USD)	11	140	440

³⁰⁶ FDA (2015) Final Determination Regarding Partially Hydrogenated Oils. A notice by the FDA on 06/17/2015.

Net Benefits (BN USD)	5	130	430
<i>Source: https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils</i>			