

INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Initiative to limit industrial trans fats intakes in the EU		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	SANTE E1	DATE OF ROADMAP	11/10/2016
LIKELY TYPE OF INITIATIVE	Commission Regulation		
INDICATIVE PLANNING	3rd quarter 2017		
ADDITIONAL INFORMATION	-		
<p style="text-align: center;">This Inception Impact Assessment is provided for information purposes only and can be subject to change. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.</p>			

A. Context, Subsidiarity Check and Objectives
<p>Context</p> <p>Trans fatty acids (also called "trans fats" and sometimes abbreviated as TFAs) are a particular type of unsaturated fatty acids that are present in foods. Trans fats can be produced industrially ("industrial trans fats"), due to the food manufacturing process, and are present in foods in variable amounts (up to more than 50% of the total fat content of the food). The presence of industrial trans fats in foods is primarily the consequence of the use of particular oils because of costs or technological considerations. Trans fats can also be naturally present in food products derived from ruminant animals such as dairy products or meat from cattle, sheep or goat ("ruminant trans fats"). Ruminant trans fats are present in foods at levels most commonly around 3% and ranging from 2 to 9% of the total fat content of the food.</p> <p>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 heart disease 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 acids¹. For this reason, and taking into account that trans fats are not synthesised by the human body and are not required in the diet, health authorities all over the world recommend to reduce/limit their consumption. The World Health Organisation (WHO) recommends that less than 1% of dietary energy intake should come from consuming trans fats² and the European Food Safety Authority (EFSA) goes beyond by recommending that trans fats intakes should be as low as is possible within the context of a nutritionally adequate diet³.</p> <p>In the European Union, intakes of trans fats have decreased over recent years and the average daily trans fats intakes for the overall EU population are below 1% of daily energy intake (the recommended value by WHO). Nevertheless, the picture changes when looking at specific sub-groups of the population: available data indicates that these intakes are higher for population groups like low-income citizens in the UK, university students aged 18 to 30 years in Croatia or generally citizens of this age range in Spain. It has also been noted that up to 25% of individuals aged 20-30 years surveyed for trans fats consumption have intakes of trans fats above 1% of daily energy intake. This lack of homogeneity with respect to trans fats also characterises the composition of foods in the EU: while 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, products with high content of industrial trans fats are also present on the EU market, in particular in the Eastern and South-Eastern Member States (e.g. biscuits or popcorn with industrial trans fats values in the order of 40-50% of the total fat content of the food)⁴.</p>

¹ 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

² 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

³ 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

⁴ European Food Safety Authority (2010); Mouratidou T *et al.*, 2014, *Trans Fatty acids in Europe: where do we stand?* JRC Science and Policy Reports

Coronary Heart Disease is the single leading cause of mortality in the EU and creates significant costs for Member States' healthcare systems and more generally for their economies. 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. Stakeholders also broadly supported those national initiatives that set limits to the presence of industrial trans fats in foods by the means of legal measures (in Denmark in 2003 and in 3 other Member States adopting legislation in the following years).

Although different actions were taken in different Member States and intakes of trans fats have overall decreased over the past years, other Member States have not taken action. Industrial trans fats are still present at levels of concern in certain foods in the EU and intakes are still excessive in certain cases (especially having in mind EFSA's recommendation that trans fats intakes should be as low as is possible within the context of a nutritionally adequate diet). The issue is of particular relevance in certain Member States and for particular population groups. 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.

The Commission is currently considering an EU-based initiative to limit trans fats intakes, which would have the added value of coherent and simultaneous application in the entire EU. This initiative would focus on industrial trans fats, given that ruminant trans fats sources generally contribute in a limited way to the total daily energy intake and ruminant trans fats are naturally present in foods that are important in the EU diet and cannot therefore totally be avoided.

The Commission presented its first analysis on trans fats in its report to the European Parliament and the Council of 3 December 2015 *regarding trans fats in foods and in the overall diet of the Union population*⁵. The 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 consumers⁶ which stated: "By 13 December 2014, the Commission, taking into account scientific evidence and experience acquired in Member States, shall submit a report on the presence of trans fats in foods and in the overall diet of the Union population. The aim of the report shall be to assess the impact of appropriate means that could enable consumers to make healthier food and overall dietary choices or that could promote the provision of healthier food options to consumers, including, among others, the provision of information on trans fats to consumers or restrictions on their use. The Commission shall accompany this report with a legislative proposal, if appropriate".

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. In accordance with Better Regulation principles, the Commission communicated its intention to carry out an impact assessment, including a public consultation on the matter, in order to take an informed policy decision in the near future. This Inception Impact Assessment (IIA) marks the beginning of the announced work of the European Commission.

The reduction of trans fats intakes in the EU is high on the agenda of the European Parliament and Council, Member States, and stakeholders. For this reason, the publication of the Commission's report was awaited with interest and important discussions took place already before its publication.

Health EU Ministers exchanged views on trans fats in the informal Council meetings of April and September 2015. In the meeting of April 2015 in Riga, a large majority of those delegations having intervened expressed support to the necessity of reducing industrial trans fats levels in food products⁷. In the meeting of September 2015 in Luxembourg, Member States discussed possible solutions to reduce industrial trans fats levels in foods. Different views were raised, with some delegations supporting the adoption at EU level of legal limits to industrial trans fats presence in foods and other delegations supporting self-regulatory approaches for product reformulation⁸. Member States' concerns on industrial trans fats had also been voiced in the context of the High Level Group on nutrition and physical activity⁹ where 22 Member States indicated industrial trans fats as one of the priorities with respect to reformulation or nutrient policy¹⁰.

The conclusions of the Commission's report and the intention to carry out an Impact Assessment were welcomed by the European Parliament's Committee on the Environment, Public Health and Food Safety, which held an exchange of views on the subject on 17 March 2016¹¹.

⁵ COM (2015) 619 final

⁶ OJ L 304, 22.11.2011, p. 18

⁷ <https://eu2015.lv/news/media-releases/1353-health-ministers-in-riga-agree-on-the-need-for-common-eu-nutrition-and-alcohol-policies>

⁸ <http://www.eu2015lu.eu/en/actualites/articles-actualite/2015/09/25-info-sante/>

⁹ 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)

¹⁰ http://ec.europa.eu/health/nutrition_physical_activity/docs/overview_nationalinitiatives_selectednutrients_en.pdf

¹¹ http://www.emeeeting.europarl.europa.eu/committees/agenda/201603/ENVI/ENVI%282016%290316_1/sitt-2201601

At the same time, all the stakeholders that intervened in the debate on trans fats so far have welcomed the Commission's report and/or supported an EU initiative to set legal limits to industrial trans fats in foods, both on the consumers' side¹² and on the industry's side¹³.

The issue would therefore appear not controversial and the added value of an EU initiative in the field would seem undisputed. In several platforms, EU action on industrial trans fats has been defined by consumers' organisations and food business operators as a "low hanging fruit" that would improve consumers' health at very limited costs¹⁴.

In this context, of particular note is the joint letter¹⁵ 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 Health¹⁶. The positions of industry stakeholders (also well summarised in a statement by Food Drink Europe of 19 November 2015)¹⁷ indicate that the industrial trans fats content of foods can effectively be lowered without disproportionate costs (this was confirmed in Denmark, the first Member State introducing a legal limit for industrial trans fats in foods¹⁸), that an EU initiative would benefit not only to consumers but also to the industry by setting a level playing field in the Internal Market, and that particular support might be needed for SMEs.

In its Impact Assessment, the Commission will pay particular attention to the expected impacts of its initiative on the food industry, in particular SMEs, and will consider different types of mitigation measures to reduce possible negative impacts (e.g. transition periods).

Issue

General introduction to trans fats and Coronary Heart Disease

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*"¹⁹. Trans fats can be produced industrially (industrial trans fats) and the primary dietary source of industrial trans fats is partly hydrogenated oils. The hydrogenation process 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). 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)²⁰. 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). Trans fats can also be naturally present in food products

¹² 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.eph.org/a/6458>

¹³ 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>

¹⁴ By way of example, see the report on the meeting on trans fats organised by the Permanent Representation of Hungary to the EU on 5 April 2016 (<http://brusszel.eu.kormany.hu/tfa-reduction-a-low-hanging-fruit-to-reap-for-securing-better-health>)

¹⁵ http://eph.org/IMG/pdf/Open_Letter_industrially_produced_TFAs_freeEU.pdf

¹⁶ 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

¹⁷ <http://www.fooddrinkeurope.eu/S=0/news/statement/fooddrinkeurope-statement-on-trans-fats/>

¹⁸ 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>

¹⁹ Point 4 of Annex I to Regulation (EU) No 1169/2011

²⁰ European Food Safety Authority (2010)

derived from ruminant animals such as dairy products or meat from cattle, sheep or goat (ruminant trans fats), at levels most commonly around 3% and ranging from 2 to 9% of the total fat content of the food²¹.

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 product²².

Coronary Heart Disease (CHD) is the single leading cause of mortality in the EU²³. In the Commission's report on trans fats, it was noted that CHD accounted for some 660 thousand deaths in 2011 or some 14% of overall mortality with a wide variability observed among Member States²⁴. Also in the report, costs associated with CHD (healthcare costs, opportunity costs of informal care from relatives of the person suffering from CHD and productivity losses associated with premature death or morbidity) were estimated to amount in 2012 to more than €58 billion or 0.5% of the EU Gross Domestic Product (GDP). Healthcare costs of CHD were estimated to run up to more than €36 billion, 0.3% of the EU GDP or 2.9% of total healthcare costs²⁵.

Different risk factors contribute to the development of CHD, including high trans fats intake.

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 years²⁶ but that the situation is not homogeneous for all products consumed by all population groups in all EU Member States. In particular, the Joint Research Center (JRC) of the European Commission compiled recent studies on the two aspects described above and concluded that²⁷:

- 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. Examples of such sub-populations are low-income citizens (British male and female participants of the Low Income Diet and Nutrition Survey²⁸), male or female university students aged 18 to 30 years or generally citizens of this age range (data from Croatia²⁹ or Spain³⁰, respectively). As calculated by JRC, up to 25% of surveyed individuals aged 20-30 years have trans fats intakes above 1% of daily energy intake.
- 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). As noted by JRC, 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.

Consultation with Member States confirmed these findings and so did recent studies published after the finalisation of the JRC work. In particular, one of these recent studies³¹ 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 Eastern and South-Eastern 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 the Balkan region covered by the previous study (including two EU Member States)

²¹ 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

²² Mouratidou T *et al.*, (2014)

²³ Eurostat, Causes of death data, 2012

²⁴ COM (2015) 619, based on Eurostat, Causes of death data, 2011

²⁵ COM (2015) 619, based on Leal *et al.*, 2006, *Economic burden of cardiovascular diseases in the enlarged European Union*, European Heart Journal 27, 1610–1619; Eurostat, GDP and main components data, 2012, and WHO, European health for all database (HFA-DB), 2012

²⁶ EFSA (2010), Mouratidou T *et al.* (2014)

²⁷ Mouratidou T *et al.* (2014) and COM (2015) 619 final

²⁸ 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

²⁹ Satalic Z *et al.*, 2007, *Diet quality in Croatian university students: Energy, macronutrient and micronutrient intakes according to gender*, International Journal of Food Sciences and Nutrition, 58(5): p. 398-410

³⁰ Mayneris J *et al.*, 2010, *Diet and plasma evaluation of the main isomers of conjugated linoleic acid and trans-fatty acids in a population sample from Mediterranean northeast Spain*, Food Chemistry, 123: p. 296-305

³¹ Stender S *et al.*, 2014, *Tracing artificial trans fat in popular foods in Europe: a market basket investigation*, BMJ Open. 2014;4:e005218

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 2014³². Another study³³ 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.

What is the scientific advice on trans fats?

In the past years, observational and experimental studies have consistently demonstrated the adverse effect of trans fats intake on human health. In 2010, the European Food Safety Authority (EFSA) noted that “*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*”³⁴. It was 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 acids³⁵.

Trans fats are not synthesised by the human body and are not required in the diet. For this reason, and taking into account all the evidence on their adverse health effects, health authorities recommend to reduce/limit their consumption. The WHO recommends that less than 1% of dietary energy intake should come from consuming trans fats³⁶. According to EFSA, “*trans fatty acids intake should be as low as is possible within the context of a nutritionally adequate diet. Limiting the intake of trans fatty acids should be considered when establishing nutrient goals and recommendations*”³⁷.

What measures have been adopted on trans fats so far?

In line with the health recommendations described above, initiatives to reduce the consumption of trans fats by focusing on industrial trans fats are in place in many countries. In the EU, it is of particular note that legislative measures limiting the content of industrial trans fats to 2% of the total fat content of the food were adopted in Denmark (2003), Austria (2009), Hungary (2013) and Latvia (2015). In Belgium, Germany, the Netherlands, Poland, the UK and Greece, voluntary self-regulation measures have been agreed with the food industry³⁸. 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 food³⁹).

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)⁴⁰. Regulation (EU) No 1169/2011 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 hydrogenated⁴¹. The Regulation however does not require the indication of the exact trans fats content of foods in the nutrition declaration, given that further reflection on trans fats had to be carried out by the Commission in

³² 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

³³ Costa N *et al.*, 2016, *Trans fatty acids in the Portuguese food market*, *Food Control* 64, 128-134

³⁴ EFSA (2010)

³⁵ Mozaffarian D *et al.* (2009)

³⁶ WHO/FAO (2003)

³⁷ EFSA (2010)

³⁸ COM (2015) 619 final, based on the Commission Staff Working Document SWD (2015) 268, *Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'*, as well as Mouratidou T *et al.* (2014). Some derogations exist in certain Member States that have set legal limits for specific product categories (e.g. in Austria, the 2% of fat content threshold may be exceeded in the case of processed foodstuffs made from several ingredients, provided the total fat content of the foodstuff is less than 20% and the trans fats content does not exceed 4% of total fat, or provided the total fat content is less than 3% and the trans fats content does not exceed 10% of total fat, Ministerial Decree No. 267 of 20 August 2009).

³⁹ Under US law, the loss of the GRAS status means that food manufacturers will no longer be permitted to sell partially hydrogenated oils, either directly or as ingredients in another food product, without prior FDA approval.

⁴⁰ Commission Directive 2006/141/EC on infant formulae and follow-on formulae (OJ L 401, 30.12.2006, p. 1). The Directive will be replaced as of 2020 by Commission delegated Regulation (EU) 2016/127 (OJ L 25, 2.2.2016, p.1) which maintains the same maximum amount for trans fats, on the basis of the advice of EFSA (European Food Safety Authority, 2014, *Scientific Opinion on the essential composition of infant and follow-on formulae*. EFSA Journal 2014;12(7):3760)

⁴¹ Article 18 and Annex VII of Regulation (EU) No 1169/2011

its report. 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.

Summary of the problem

Trans fats are an important risk factor for the development of CHD 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** (especially having in mind EFSA's recommendation that trans fats intakes should be as low as is possible within the context of a nutritionally adequate diet). **The issue is of particular relevance in certain Member States and for particular population groups.** This causes the following problems:

- 1) **Functioning of the Internal Market and external trade:** 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.

The above described situation has also a negative impact on external trade: operators from third countries exporting their foods to the EU are subject to different conditions depending on where their foods are marketed (some find barriers to trade that others do not, some are subject to legal uncertainty over future developments while others are not). Similar considerations also apply to EU exporters to third countries : EU operators who engage into reformulation efforts incur into certain costs of production that make them less competitive, when trading outside the EU, than operators who did not reformulate (at the same time, operators not engaging into reformulation are subject to legal uncertainty over future developments and might find it more difficult to export their products to countries, like the US, that also introduced limits to industrial trans fats levels in foods).

- 2) **Protection of consumers' health / health inequalities:** 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 not-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 price) so that this situation contributes to the **perpetuation of health inequalities in the EU.**

Drivers

At this stage, the following causes can be identified for the problems described above:

- 1) **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. 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.
- 2) **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.** At the same time, **other considerations may influence consumer 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. In addition, it has to be kept in mind that Article 30 of Regulation (EU) No 1169/2011 requires the mandatory indication in the nutrition table of pre-packed foods of the energy content and the amounts of a number of nutrients present in the product (fat, saturates, carbohydrate, sugars, protein and salt) but does not foresee the indication of the amounts of trans fats. Therefore, the only way for consumers to infer from labelling that pre-packed foods contain trans fats is by looking at the ingredient list (where on the basis of Regulation (EU) No 1169/2011 it is now required to indicate the presence of partly hydrogenated oils). However, **not all consumers can relate the information on the use of partly hydrogenated oils 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. Finally, Regulation (EU) No 1169/2011 does not require to provide nutritional information or information on partly hydrogenated oils for non pre-packed foods (unless Member States require so), so that **consumers would lack information on a category of products that can be an important source of trans fats.**

- 3) 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, evidence shows that national authorities have different approaches to industrial trans fats, with some acting and others not.

Stakeholders affected

- EU consumers, in particular:
 - At risk groups with reported high trans fats intakes;
 - In those Member States where foods containing high levels of industrial trans fats are on the market.
- Food business operators placing products on the market in the EU (both EU-based and third-country based), in particular:
 - Manufacturers of pre-packed and non-pre-packed foods (different sizes of business, including SMEs);
 - Ingredient manufacturers, mainly large operators (producing ingredients which contain industrial trans fats and ingredients that can be used to replace industrial trans fats containing ingredients);
 - Retailers.
- Food business operators exporting foods outside the EU, in particular:
 - Food manufacturers (different size of business, including SMEs);
 - Ingredient manufacturers (mainly large operators);
- Member States, taking into account the healthcare costs associated with coronary heart disease;
- National enforcement authorities responsible for food controls and to verify trans fats presence in foods.

Subsidiarity check

As explained in the "issue" section, the existing situation on industrial trans fats hampers the effective functioning of the Internal Market, negatively affects the protection of consumers' health and contributes to the perpetuation of health inequalities. The form of EU action will vary depending on the policy option that is chosen at the end of the Impact Assessment process.

EU action in the area is justified because **action at Member States' level would not be sufficient**: industrial trans fats are still present at levels of concern in certain foods, in Member States where no national action has been undertaken so far (voluntary or regulatory) to reduce such levels. In the consultation that preceded the adoption of the Commission's report, several national competent authorities highlighted their readiness to go ahead with national measures in the absence of EU action and this could indeed happen. Similarly, other self-regulatory initiatives could be launched at national level in the future. However, there is no guarantee that this would happen in all Member States, taking into account that incentives for food business operators to act can vary significantly and national authorities have shown to have different approaches to industrial trans fats. If 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. As explained in the issue section, 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.

In this context, it is of note that both in the discussions in Council in 2015 and 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.

Main policy objectives
<p>General:</p> <ul style="list-style-type: none"> To ensure a high level of health protection for EU consumers; To contribute to reducing health inequalities, one the objectives of Europe 2020⁴²; To contribute to the effective functioning of the Internal Market for foods that could contain industrial trans fats. <p>Specific:</p> <ul style="list-style-type: none"> To reduce intake of industrial trans fats in the entire EU for all population groups; To ensure that the same conditions apply in the EU to the manufacturing and placing on the market of foods that could contain industrial trans fats; To 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.
B. Option Mapping
<p>Option 0 – No EU policy change (baseline scenario)</p> <p>In the baseline scenario, no initiative would be taken on trans fats at EU level.</p> <p>Option 1 – Establishment of a limit for the industrial trans fats content in foods</p> <p>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).</p> <p>Different limits will be considered in the context of the Impact Assessment, as appropriate. One possibility would be to set the limit at 2% of the total fat content of the food, in line with the approach followed in the four different Member States that have already taken legislative action on the matter (Denmark, Austria, Hungary and Latvia). The possibility for providing derogations in specific cases will also be further assessed in the Impact Assessment. This Option would apply only to industrial trans fats and would not cover ruminant trans fats that are formed naturally in relatively low and stable proportions in ruminant fats and cannot be avoided in ruminant products.</p> <p>This limit could be set through different instruments:</p> <ul style="list-style-type: none"> Sub-option 1a: a voluntary agreement with the relevant food business operators (as was done at national level already in Belgium, Germany, the Netherlands, Poland, the UK and Greece) or Sub-option 1b: a legally-binding measure: the appropriate legal basis could be Article 8 of the Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods⁴³. Article 8 of this Regulation establishes that the Commission can adopt, by regulatory procedure with scrutiny, decisions concerning a substance other than a vitamin or a mineral, or an ingredient containing the substance, that is used in the manufacture of foods under conditions that would represent a potential risk to consumers. On the basis of Article 8, the Commission can include that substance and/or ingredient in Annex III of Regulation (EC) No 1925/2006 and, if a harmful effect on health has been identified, prohibit or lay down conditions for its use. <p>Option 2 – Introduction of the obligation to indicate the trans fats content of foods in the nutrition declaration</p> <p>As explained above, under current legal provisions, consumers can infer from the ingredients labelling whether partly hydrogenated oils are contained in a product and that, therefore, the product could contain industrial trans fats. This however does not allow a precise estimation of the actual trans fats content.</p> <p>In this option, Article 30(1) of Regulation (EU) No 1169/2011 on the provision of food information to consumers would be modified to add trans fats to the list of nutrients that have to be included in the mandatory nutrition declaration of pre-packed foods, in order to inform consumers of the exact trans fats content of these foods. This modification would be carried out through a legislative measure to be adopted by ordinary legislative procedure.</p> <p>Option 3 – Prohibition of the use of partly hydrogenated oils (PHO) in foods</p>

⁴² COM (2010) 2020 final, Communication from the Commission, "EUROPE 2020 A strategy for smart, sustainable and inclusive growth"

⁴³ OJ L 404, 30.12.2006, p. 26

<p>In this option, the EU would follow the same approach as adopted in the US and would prohibit the use of PHOs in foods, on the basis of the consideration that these are the primary dietary source of industrial trans fats. As in the case of Option 1, 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). As in the case of Option 1, if Option 3 is pursued through a legally-binding measure, the appropriate legal basis could be Article 8 of the Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.</p>
<p>Baseline scenario – no EU policy change</p>
<p>In the absence of EU action, the problems identified in the "issue" section are not expected to be adequately addressed. On average, trans fats intakes in the EU could continue to decrease, as a result of a combination of:</p> <ul style="list-style-type: none"> • Further changes in consumers' behaviour: these would be due, for example, to increased media attention to trans fats that could increase consumers' willingness to reduce their intake, or to increased reliance on the recently introduced provision of Regulation (EU) No 1169/2011 which requires the mandatory labelling indication of partly hydrogenated oils in the ingredient list of pre-packed foods, and • Further reformulation by food business operators: this could be due to new self-regulatory initiatives or to the setting of legal limits for industrial trans fats in those Member States that have not acted so far and did not exclude intervention in the absence of EU action. <p>Nevertheless, important drawbacks are expected in the absence of EU action. More specifically:</p> <ul style="list-style-type: none"> • Not all consumers are expected to change their behaviour, given that not all consumers would have the necessary nutritional awareness and other factors (e.g. cost, taste, habits) could still have a stronger impact on their choices. • As explained before, the new provision of Regulation (EU) No 1169/2011 on the indication of partly hydrogenated oils does not apply to non-pre-packed foods, which can be an important source of trans fats. In addition, not all consumers would be able to compare pre-packed foods and identify the healthier choice based on the information available on the label. • Evidence available at this stage does not indicate that voluntary reformulation by food business operators can be expected to take place in all EU countries (recent data indicate that the number of foods with high industrial trans fats content is actually reported to be increasing in two Member States). Similarly, it cannot be confirmed that all Member States would adopt rules setting legal limits at national level (new national rules would have to be assessed on a case-by-case basis by the Commission, and would be permitted only if justified on public health grounds, and proportionate to reach the objectives). • National developments on trans fats would remain uncoordinated. This would contribute to the maintenance of conditions of unfair competition in the Internal Market (e.g. new reformulation costs would apply only to operators active in those Member States where new national developments take place) and would continue having a negative impact on imports and exports as described in the "issue" section. The situation would be more serious in the Member States adopting legal limits at national level (especially if different limits are set in the different Member States). • Legal uncertainty would persist on whether/when/how new national initiatives to reduce trans fats intakes would be adopted and this could have a negative impact on R&D investments of certain operators and therefore also negatively affect the functioning of the Internal Market.
<p>Options of improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation</p>
<p>This would be the case of Option 1 (establishment of a limit for industrial trans fats), and 3 (prohibition of the use of partly hydrogenated oils) should the limit or the prohibition be set through a Commission's implementing measure adopted on the basis of Article 8 of the already existing Regulation (EC) No 1925/2006.</p>
<p>Alternative policy approaches</p>
<p>This would be the case of Option 2 (introduction of the obligation to indicate the trans fats content of foods in the nutrition declaration) and Option 3 (prohibition of the use of partly hydrogenated oils (PHOs) in foods).</p>
<p>Alternative policy instruments</p>

This would be the case of Option 1a/3a (encouraging the development of a self-regulatory framework to limit the industrial trans fats content in food or to stop using PHOs).
Alternative/differentiated scope
In the Impact Assessment, all the options identified above will be analysed in terms of impact on SMEs. Adequate solutions to minimise such impacts where they exist, in particular on micro-enterprises, will be considered.
Options that take account of new technological developments
Not applicable. The initiative is about foods placed on the market in the EU and the requirements of EU food law are applicable to foods irrespective of the way through which the foods are offered to consumers. In the case of Option 2 (Introduction of the obligation to indicate the trans fats content of foods in the nutrition declaration), Regulation (EU) No 1169/2011 lays down specific rules on the provision of information on pre-packed foods offered for sale by means of distance communication (Article 14).
Preliminary proportionality check
As explained above, an EU initiative to reduce industrial trans fats intakes is justified on subsidiarity grounds, given that action at Member States' level would not be sufficient and there would be an added value in an EU-based decision. The different options identified so far are expected to contribute in different ways to achieving the identified objectives and at different costs for stakeholders. The proportionality check will be carried out in the Impact Assessment in order to identify the most appropriate policy option (in terms of content and instrument) to achieve the identified objectives while minimising costs/burdens for all stakeholders.
C. Data Collection and Better Regulation Instruments
Data collection
<p>The Commission has already collected an important amount of information on trans fats in the preparation of the report on the topic that was adopted on 3 December 2015. In this context, the study prepared by the Commission's Joint Research Center (JRC) "<i>Trans Fatty acids in Europe: where do we stand?</i>" is of particular note. The study provides an overview of recent publicly available literature regarding the amount of trans fats in foodstuffs and trans fats intakes in Europe. In addition, a study carried out by TNS European Behaviour Studies Consortium for the Commission on the <i>impact of food information on consumers' decision making</i>⁴⁴ analyses in detail EU consumers' behaviour with respect to trans fats.</p> <p>As underlined in the report's conclusions, the Commission intends to collect more information and develop a fuller analysis of the magnitude of the problem to be addressed and the different possible solutions, in particular the option of limits for industrial trans fats. In this context, an external contractor will be requested to produce a study whose results will feed into the preparation of the Impact Assessment. The study is expected to focus in particular on the impacts of the different policy options (taken individually, and in combination, if appropriate) on the different stakeholders (consumers, food business operators, including SMEs and manufacturers of non-pre-packed foods, and national authorities), having regard to different aspects (e.g. protection of consumers' health, costs and regulatory burden, offer of products to consumers, functioning of the Internal Market, competitiveness, external trade, enforcement).</p> <p>Further advice from the JRC will also be sought: the JRC will be in particular requested to provide advice on the development of a methodology to precisely and easily determine the industrial trans fats content in foods, in particular those foods that contain both ruminant and industrial trans fats.</p> <p>Additional data will be also collected through the different planned consultations (targeted and public, see below).</p>
Consultation approach
<p>The Commission services have already carried out the following consultations in the preparation of the report adopted on 3 December 2015 <i>regarding trans fats in foods and in the overall diet of the Union population</i>:</p> <ul style="list-style-type: none"> • Two surveys (one with the Working Group on Regulation (EU) No 1169/2011 on the provision of food information to consumers, comprising experts of Member States, Iceland and Norway, and one with

⁴⁴ TNS European Behaviour Studies Consortium, 2014, *Study on the Impact of Food Information on Consumers' Decision Making*, http://ec.europa.eu/food/safety/docs/labelling_legislation_study_food-info-vs-cons-decision_2014.pdf

stakeholders in the context of the Advisory Group on the Food Chain and Animal and Plant Health) on the following issues:

- Trans fats in foodstuffs and diets in Europe;
- Consumer knowledge and understanding of trans fats;
- Strategies to reduce population exposure to and consumption of trans fats;
- Impact and effectiveness of such measures.

The feedback gathered through these surveys was in line with the conclusions of the studies carried out by JRC and TNS European Behaviour Studies Consortium and contributed to informing the preparation of the Commission's report on trans fats.

- A consultation with the Advisory Group on the Food Chain and Animal and Plant Health on four possible future options for action:
 - The EU introduces mandatory trans fats content declaration;
 - The EU introduces a legal limit on the trans fats content of food;
 - Voluntary agreements towards reducing trans fats in foods and diets are made at EU level;
 - No further action towards reducing trans fats in foods and diets is taken at EU level.

In this latter consultation on different policy options, the majority of respondents (NGOs and food business operators) indicated a preference for introducing an EU-wide limit for trans fats and underlined how this would lead to public health benefits and establish the same standard across all EU countries. Some stakeholders linked their support for an EU-wide limit to the deletion of the requirement in the legislation to indicate full or partial hydrogenation of oils/fats. In their view, maintaining this labelling obligation together with the limit would lead to consumers' confusion.

The results of the abovementioned consultations are analysed in detail in the Staff Working Document accompanying the Commission's report⁴⁵.

The following future consultations are planned in order to obtain further feedback in preparation for the Impact Assessment:

- **Open Public consultation** (12 weeks): this consultation will be open to everyone and will be carried out on the basis of a consultation document that will take into account the comments submitted on the IIA. It will be aimed at obtaining feedback on the different policy options and the expected impacts.
- **Targeted consultation to be carried out by the contractor** in the context of its study: this consultation will cover stakeholders with a specific interest in the initiative (consumers' and health NGOs, food business operators and national authorities) and will be aimed at collecting feedback to triangulate (verify) the contractor's findings on the expected impacts that the options finally retained for the Impact Assessment will have in a number of different areas (e.g. protection of consumers' health, costs and regulatory burden, offer of products to consumers, functioning of the Internal Market, competitiveness, external trade, enforcement). The Commission will be particularly interested in collecting feedback at local level, from SMEs and manufacturers of non-pre-packed foods.

Will an Implementation plan be established?

Yes No

Irrespective of what policy option is chosen, the initiative will be of relatively simple application. Enforcement issues will be further analysed in the Impact Assessment.

D. Information on the Impact Assessment Process

An Inter-Service Group (ISG) chaired by DG Health and Food Safety will be established. The following Commission's services will be represented in the ISG: Secretariat General, Legal Service, DG Maritime Affairs and Fisheries, DG Agriculture and Rural Development, DG Trade, DG Research and Innovation, DG Internal Market, Industry, Entrepreneurship and SMEs and the Joint Research Centre.

The Impact Assessment process is expected to be finalised in 2017.

E. Preliminary Assessment of Expected Impacts

⁴⁵ SWD (2015) 268 final

Likely economic impacts

Operating costs

The setting via a legally-binding measure of a limit to industrial trans fats levels in foods (Option 1b) or of a ban on the use of PHOs (Option 3b) would result in **reformulation costs** for those operators placing foods with high levels of industrial trans fats on the market (need to change their recipes, to modify their supply chain in order to purchase different ingredients or to modify the manufacturing process). Costs would also exist for ingredients suppliers (e.g. oils/fats manufacturers would need to modify their products to meet the demands of manufacturers or would see a negative impact on their sales).

In case of mandatory trans fats labelling (Option 2), costs (of a lesser magnitude than reformulation costs) should be expected for operators placing pre-packed foods on the market (manufacturers, retailers). There would be **costs to detect the trans fats content in foods in order to indicate it on the label and costs to change the labels**. In case of self-regulation (Option 1a or 3a), reformulation costs would also exist for those operators abiding by the self-regulatory commitments, but these would not be imposed on them and operators would still have the choice to refuse to reformulate and not incur into any costs.

It is however important to note in this context that **some reformulation costs can be expected for some operators even in case of Options 2 (labelling) and 1a/3a (self-regulation) and even if no action is undertaken at EU level** (baseline scenario). Indeed, as explained in the description of the baseline scenario, in the absence of EU action, it can be expected that further action on industrial trans fats will be carried out at national level in some Member States. Operators active in these Member States could therefore be faced with reformulation costs while operators active in Member States where no action is carried out would not. The same considerations on reformulation costs would apply also in case of Options 2 and 1a/3a if Member States are not satisfied with the EU action and still decide to adopt rules at national level. The difference between Options 1b and 3b, on one side, and the remaining scenarios, on the other, would be that in the first case there would be certainty about the existence of these costs, as well as on their timing (thus allowing business to prepare), while in the second case, uncertainty would persist.

In addition, given that the reformulation trend with respect to industrial trans fats is already well established in some sectors of the food industry (in Europe and worldwide), it can be expected that the reformulation costs will be lower than those incurred by food business operators in the past (e.g. the market of replacement ingredients has been growing already for some years, and the cost of such ingredients can therefore be expected to be on a downward trend). Furthermore, in many cases these costs would occur only once.

Internal Market

The setting via a legally-binding measure of a limit to industrial trans fats levels in foods (Option 1b) would have a **positive impact on the functioning of the Internal Market** given that it would prevent further fragmentation resulting from adoption of (possibly different) new rules at national level and ensure legal certainty for food business operators (e.g. the same rules would apply to all operators at the same time). Similar effects can be expected in case of a ban on the use of PHO via a legally-binding measure (Option 3b) if Member States support the measure and consider that no further action at national level is needed.

In case of mandatory trans fats labelling (Option 2), this positive impact would not exist, given that some national competent authorities are likely to consider that mandatory labelling does not sufficiently address the problem of industrial trans fats presence in food (e.g. because mandatory labelling would not be relevant for non-pre-packed foods) and would still keep/lay down new compositional rules at national level. The same considerations would also apply to self-regulatory initiatives (Options 1a/3a).

Offer of products/consumer choice/prices

The reformulation obligations resulting from the setting via a legally-binding measure of a limit to industrial trans fats content in food (Option 1b) or of a ban on PHOs (Option 3b) could have a **negative impact on prices paid by consumers** (if food manufacturers decide to transfer their reformulation costs to consumers by raising the price of the final products), and could also **reduce the offer of products**, if operators are not able to replace the ingredients they currently use with ingredients that have the same technological properties and ensure the same characteristics of the final food. While there is no indication that reformulation would be impossible for any specific product, it has been argued that "*replacement of trans fats in certain food products such as fine pastries, specific long-life bakery products and confectionary coatings still poses technological challenges for achieving the required food functionality*"⁴⁶ (in terms of maintaining hardness of fats, oxidative stability, melting properties and aeration)⁴⁷. At the same time, it is interesting to note that according to the Danish authorities, following the

⁴⁶ Mouratidou T *et al.*, (2014); Trans-Fettsäuren: Gemeinsame Initiative der deutschen Lebensmittelwirtschaft und des Bundesministeriums für Ernährung, Landwirtschaft und Verbraucherschutz im Hinblick auf die "Leitlinien zur Minimierung von trans-Fettsäuren in Lebensmitteln", 2012

⁴⁷ SWD (2015) 268 final

introduction of legislation in Denmark limiting the content of industrial trans fats in food, "It is the impression that there was no increase in the price levels of relevant food categories (...). Also, the product supply on the Danish market appeared not to be affected by this new legislation. The Danish industry did not complain that they suffered financial losses (...). On the contrary, producers developed new methods of production, improving the production process (...). Thus, it appears that the economic consequences for the industry in Denmark (...) have been limited"⁴⁸. In any case, the Impact Assessment will look in detail into this issue and further consideration will be given to how possible negative impacts could be reduced by different types of mitigation measures (e.g. derogation to specific products, as it was the case in Member States like Austria, if appropriate).

In the case of mandatory trans fats labelling (Option 2) or self-regulation (Options 1a/3a), these impacts would only exist in case of adoption of rules at national level (as in the baseline scenario).

Likely social impacts

Protection of consumers' health

As noted in the Commission's report, **all existing industrial trans fats reduction strategies appear to be associated with significant reductions in industrial trans fats levels in foods**, with measures setting legal limits being evidently the most effective⁴⁹. Empirical evidence on the impacts of the different strategies on the protection of consumers' health is at this stage limited⁵⁰. Several modelling studies from the UK and the US⁵¹ have been carried out, however, which estimate that reducing consumers' industrial trans fats intakes (regardless of the measures taken) would provide important health benefits for the population (in terms of fewer deaths, or increase in Quality Adjusted Life Years⁵²), and/or savings for public authorities (in terms of health care costs).

Of course, as also highlighted in the report, it must be kept in mind that ultimate impacts in terms of trans fats intake (and health outcome) also depend on certain underlying factors (e.g. dietary habits of different groups of the population across Europe, consumption levels of ruminant trans fats or the way in which foods could and would be reformulated to reduce industrial trans fats content).

The **setting via a legally-binding measure of a limit on industrial trans fats (Option 1b) or of a ban on PHOs (Option 3b) would be expected to achieve the biggest reductions in trans fats intake** as the phasing out of products containing high levels of industrial trans fats from the market would be potentially complete, applying to all products (pre-packaged and non-packaged) in the entire EU at the same time. These options would also ensure that the health benefits would be relevant for all consumer groups (including those consumers with no awareness of the negative impact of trans fats on health or those for which the final food choice is more influenced by other factors such as taste or economic considerations).

Mandatory trans fats labelling (Option 2) would provide incentives to the industry towards reducing industrial trans fats from food products and enable consumers to make informed food choices. The positive impact of this Option would however depend on the level of consumer awareness as regards trans fats and of consumer understanding of nutrition labelling: in particular, in case of low understanding of nutrition labelling, consumers would find it possibly more difficult than today to identify the healthier food choice (considering the complexity of a decision making process that includes a number of nutritional elements)⁵³. Mandatory nutrition labelling would

⁴⁸ Ministry of Food, Agriculture and Fisheries of Denmark and the Danish Technical University, National Food Institute (2014)

⁴⁹ Downs S *et al.*, 2013, *The effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence*, Bulletin of the World Health Organisation, 91:262–269H

⁵⁰ It has been argued that mortality attributable to cardiovascular diseases decreased on average by about 14.2 deaths per 100,000 people per year in Denmark following the introduction of a legal limit (Restrepo B *et al.*, 2016, *Denmark's Policy on Artificial Trans Fat and Cardiovascular Disease*, American Journal of Preventive Medicine, Volume 50, Issue 1, Pages 69–76).

⁵¹ O' Flaherty M *et al.*, 2012, *Potential cardiovascular mortality reductions with stricter food policies in the United Kingdom of Great Britain and Northern Ireland*, Bulletin of the World Health Organisation, 90:522–531; Barton P *et al.*, 2011, *Effectiveness and cost effectiveness of cardiovascular disease prevention in whole populations: modelling study*, BMJ 2011;343:d4044; Bruns R, 2013, Memorandum to M Honigfort, *Estimate of Costs and Potential Health Effects of Removing Partially Hydrogenated Oils from the US Food Supply*, Department Of Health & Human Services, Food and Drug Administration, http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf

⁵² Quality Adjusted Life Years (QALY) and Disability Adjusted Life Years (DALY) are two common non-monetary approaches used in economic evaluations of specific health interventions. QALY uses available information on objective improvements in health/quality of life and combines it with the duration of that improvement. The longer the life expectancy, the higher the QALY gain. DALY measures the number of quality adjusted years *lost* because of illness/disability in comparison to the benchmark scenario. Originally a measure of the burden of disease, it is also used to estimate the cost-effectiveness of interventions in terms of cost per DALY averted.

⁵³ The behavioural experiments carried out in the study by TNS European Behaviour Studies Consortium (2014) suggest that "showing the amount of TFA in the nutrition information enables more healthy choices in a simple choice context and, in particular, in a scenario where the healthier option is the product with less TFA. However, this was not observed in a more

in addition have no impact on those consumers for which the final food choice is more influenced by other factors (e.g. taste, economic considerations). It is also expected that this Option would widen health inequalities (i.e. consumers with lower income would remain more likely to consume products with high industrial trans fats content that are generally sold at a lower price). Moreover, mandatory trans fats labelling would not apply to non-pre-packed foods, all of which may contain high levels of industrial trans fats. Finally, trans fat labelling would likely not distinguish between ruminant and industrial trans fats.

Self-regulation (Options 1a/3a) could also have a positive impact on the protection of consumers' health. However, the magnitude of such impact would depend on the scope of industry participation and the coverage of food products on the market.

In case of Options 2 and 1a/3a, national authorities could still decide to adopt rules at national level (because unsatisfied with the Commission's action). In this case, there would be additional positive impacts for the protection of consumers' health in those Member States.

Likely environmental impacts

No direct environmental impact is expected from any of the different Options.

As reported in the SWD accompanying the Commission's report on trans fats, operators aiming at reducing the industrial trans fats content of food sometimes replace PHOs with palm oil, whose intensive production in certain developing countries has resulted in important deforestation to make space for oil-palm monoculture. One could therefore argue that the different Options, as well as the baseline scenario, could all have different indirect negative environmental impacts (although with different magnitudes) because they would provide an incentive to operators to purchase palm oil. This issue will be analysed in detail in the context of the Impact Assessment. At this stage, it can already be noted that a number of alternatives are available to food business operators trying to reduce industrial trans fats content of foods. The choice largely depends on the food group and production process, and palm oil is only one of the possible options. In addition, while there is no European estimate of how much palm oil would be/is used in the reformulation efforts to replace industrial trans fats, a 2009 assessment of the environmental impact of diet changes in the EU indicates that limiting trans fats intake was "*not likely to have high environmental implications*" as it would "*not lead to major changes in primary food production*"⁵⁴. Finally, consumption statistics for the EU-27 show that palm oil use for food, personal care and oleo-chemical products has changed little (+6%) over the period 2006-2012⁵⁵. This could be supported by the consideration that PHOs use in food has been already reduced much in the EU and that any remaining PHOs would likely not be replaced with palm oil alone.

Likely impacts on simplification and/or administrative burden

Considering that legislation currently exists at national level in four Member States on industrial trans fats, the **setting of a limit on industrial trans fats at EU level via a legally-binding measure (Option 1b) would simplify the legal framework** and further **prevent the proliferation of national rules**. This would have a positive impact for food business operators placing their products on the market in different Member States. In this context, it has however to be acknowledged that existing national rules are very similar so that the positive simplification effect would be limited (unless new national measures with a different content are adopted before the EU intervention).

The same considerations would apply to the introduction via a legally-binding measure of a ban on PHOs (Option 3b) if Member States support the measure and consider that no further action at national level is needed. This positive impact is not expected to exist in case of adoption of rules on mandatory trans fats labelling (Option 2), or in case of self-regulation (Options 1a/3a).

Administrative costs are defined as "*the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties*"⁵⁶ (including labelling). For this reason, the only Option that would entail an administrative burden for operators is the one setting mandatory labelling of trans fats content (Option 2). This burden was however already identified when considering operating costs.

Likely impacts on SMEs

The relative magnitude of the different economic impacts resulting from the different Options that were identified

complex realistic context, where display of TFA can cause some overreactions in a scenario where the healthier choice had slightly more TFA but a significantly less healthy composition of other nutrients (salt, sugar, saturates). (...)". In light of the above the study concludes that "*The introduction of TFA amounts on food labels did not consistently enable consumers to identify the healthier choice*".

⁵⁴ Tukker et al. 2009, *Environmental impact of diet changes in the EU*. EUR 23783 EN

⁵⁵ Gerasimchuk & Koh, 2013, *The EU Biofuel Policy and Palm Oil: Cutting Subsidies or cutting rainforest?*
https://www.iisd.org/gsi/sites/default/files/bf_eupalmoil.pdf

⁵⁶ European Commission services, Better Regulation toolbox,
http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf

above (e.g. negative impacts of reformulation/relabelling costs and administrative burden, positive impact of more legal certainty) is expected to be higher for SMEs than for larger businesses. The Impact Assessment will look in detail into this issue and further consideration will be given to how possible negative impacts could be reduced by different types of mitigation measures (e.g. transition periods).

Likely impacts on competitiveness and innovation

The setting via a legally-binding measure of a limit on industrial trans fats (Option 1b), the introduction via a legally-binding measure of a ban on PHOs (Option 3b) or the establishment of mandatory trans fats labelling (Option 2) would lay down additional costs for operators which would **negatively impact, to different extents, on the competitiveness of the sector**. In case of mandatory trans fats labelling, there could be additional negative impacts if further action on trans fats is carried out at national level (this would be the case also in case of self-regulation (Options 1a/3a) and in the case of the baseline scenario). As underlined in the assessment of the expected costs for food business operators, the difference between Options 1b and 3b on one side, and the remaining scenarios on the other, is that in the case of Options 1b and 3b there would be certainty about the existence of these costs, as well as on their timing, thus setting a level playing field for industry to compete and thrive.

The costs identified above would also have a negative impact **on the international competitiveness** of operators exporting outside the EU. At the same time, in the case of Options 1b and 3b, there would also be a positive impact, given that similar restrictions on the manufacturing of food products already exist for some important EU trading partners (e.g. the US) and reformulated EU products would better compete on those markets. There would be on the contrary no such positive impact in the case of Options 2 and 1a/3a taking into account the regulatory divergences (as in the case of the baseline scenario).

In terms of **innovation**, mandatory labelling (Option 2) and self-regulation (Options 1a/3a) would leave the door open to the possible adoption of rules at national level (although to a lesser extent than in the baseline scenario). The legal uncertainty and fragmentation of the market would continue to constitute a negative environment for operators to innovate. On the contrary, action via a legally-binding measure (Options 1b and 3b) would establish the same set of rules at the same time, thus contributing to the legal certainty that is necessary to invest in R&D. In this context, the positive impact of Option 1b would be higher than in the case of Option 3b given that Option 1b (limit to industrial trans fats presence) would be outcome-related instead of process-related (Option 3b, ban on the use of PHOs), something which leaves more flexibility for operators to develop innovative products.

To summarize, the different Options identified above are expected to have mixed impacts on the competitiveness of the sector and the capacity of operators to innovate. Further reflection is needed on the impacts of the Options on different sub-sectors (e.g. manufacturers of non-pre-packed food, which are in most cases competing on a local level and are therefore not expected to import/export foods in the Internal Market or outside the EU).

Likely impacts on public administrations

Neither the setting via a legally-binding measure of a limit on industrial trans fats (Option 1b), nor the introduction via a legally-binding measure of a ban on PHOs (Option 3b) nor the establishment of mandatory trans fats labelling (Option 2) would need to be transposed into national law (taking into account that their relatively simple regulatory nature does not seem to require flexibility at national level for transposition). These Options would however impose a new obligation on national competent authorities to carry out controls to verify the compliance of foods with the new legal requirements (either as regards composition or labelling). It would be important to make sure that easily accessible effective detection methods are validated for national competent authorities (in this context, as previously explained, JRC will be consulted on detection methods for products that contain both ruminant and industrial trans fats).

The impact of self-regulation (Options 1a/3a) on public administrations would have to be further assessed in consultation with Member States. Indeed, while certain national competent authorities have the tradition to cooperate with the industry, others are less used to this type of action and could find it difficult to monitor it (possibly more difficult than regulatory measures).

Likely impacts on third countries, international trade or investment

The composition of food products with respect to their industrial trans fats content or the use of PHOs in the manufacturing of foods is not regulated at Codex Alimentarius level. At the same time, the Codex Guidelines on nutrition labelling⁵⁷ allow national/regional authorities to require mandatory trans fats labelling if the levels of trans fats intake are a public health concern in their territory. In light of the above, the setting via a legally-binding measure of a limit on industrial trans fats (Option 1b), the introduction via a legally-binding measure of a ban on PHOs (Option 3b) or the establishment of mandatory trans fats labelling (Option 2) would be compatible with international rules.

⁵⁷ Codex Alimentarius, Guidelines on nutrition labelling, CAC/GL 2-1985

These Options would, to different extents, have a negative impact in terms of costs for operators that would also negatively impact imports/exports of foods inside/outside the EU. On the other hand, however, Options 1b and 3b would contribute to ensuring better regulatory convergence with the EU trading partners that have already acted in the area of trans fats and would improve possibilities for market access for EU operators. In the case of the US, in particular, Option 3b could ensure full regulatory compatibility.

The impact of self-regulation (Options 1a/3a) on international trade would depend on whether or not food business operators importing/exporting into/from the EU decide to abide by the commitment on industrial trans fats even in these circumstances. These costs would however not be imposed on operators and should therefore not be included in the assessment.