Study to support the impact assessment of the initiative to limit industrial trans fats in the EU

Final report

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ABSTRACT

This study has investigated the potential social, economic and environmental impacts of five policy options for reducing the dietary intake of industrial trans fatty acids (iTFA) in the European Union. The options were: an EU-level voluntary agreement to limit the iTFA content of food products sold to consumers to 2% of fat (option 1a); EU-level legislation limiting the iTFA content of such products sold to consumers to 2% of fat (option 1b); legislation requiring the addition of information on trans fatty acids content to the nutrition declaration on all pre-packed food products (option 2); an EU-level voluntary agreement to ban partially hydrogenated oils (PHOs) (option 3a); and EU legislation banning PHOs (option 3b). The assessment used quantitative models to estimate health impacts and economic impacts, while the impacts on health inequalities and the environment were assessed qualitatively. The legislative options (1b and 3b) deliver the greatest health benefits, reductions in health inequalities and improvements in the functioning of the internal market. They also score higher than other options on efficiency, coherence, and proportionality. A legal limit of 2% on iTFA content performs marginally better than banning legal ban on PHOs in terms of efficiency and coherence.

ONE-PAGE SUMMARY

- This study has investigated the potential impacts of five policy options designed to reduce the dietary intake of industrial trans fatty acids (iTFA) in the European Union.
- The options were: an EU-level voluntary agreement to limit the iTFA content of food products sold to consumers to 2% of fat (option 1a); EU-level legislation limiting the iTFA content of such products sold to consumers to 2% of fat (option 1b); legislation requiring the addition of information on trans fatty acids content to the nutrition declaration on all pre-packed food products (option 2); an EU-level voluntary agreement to ban partially hydrogenated oils (PHOs) in the EU (option 3a); and EU legislation banning PHOs (option 3b).
- The assessment used quantitative models to estimate health impacts and economic impacts, while the impacts on health inequalities and the environment were assessed qualitatively.
- The legislative options - a limit on iTFA content of 2% of fat for products sold direct to consumers and a ban on partially hydrogenated oils (PHOs) (Options 1b and 3b) – performed better than the alternative options in assessments of:
  - Social benefits: health benefits and reduction in health inequalities
  - Improvements in the functioning of the internal market
  - Efficiency
  - Proportionality
- These two options provide very substantial health benefits, eliminating most of the negative health impacts of iTFA intake seen in the baseline scenario. They result in commensurate savings in health service expenditure. They also provide assured protection to all socio-demographic groups and help to ensure a consistent standard of food quality across the EU.
- Furthermore, legislation imposing a maximum limit to iTFA content of products sold direct to consumers (option 1b) performs better in terms of efficiency and coherence than a legal ban on PHOs (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 PHO definition and establish the capacity across the EU to test oils for compliance with it.
- Adding a requirement for labelling of TFA content on pre-packed food products (option 2) to either of the two other legislative options (1b and 3b) would raise their overall costs significantly. The additional labelling requirement is unlikely to deliver added social benefits.
- The overall costs of the voluntary measures (1a or 3a) are smaller than the equivalent legislative options but their social benefits are modest.
- The conclusions on the relative performance of the different options are robust when tested against all variants of the baseline scenario in which there is no additional EU action. The slower the decline in iTFA levels in the baseline, the greater benefits of EU action.
- The analysis suggests that the options that justify further consideration are:
  - A legal limit of 2% on iTFA content on food products sold directly to consumers
  - A legal ban on PHOs.

EXECUTIVE SUMMARY

The problem

Industrial trans fatty acids (iTFA) are industrially produced unsaturated fatty acids that, despite important reduction over the last decades, are still found in a number of food products in the EU. In particular, the presence of iTFAs in foods differs between national markets and/or segments of the single market. iTFAs contribute to ill health, notably to the incidence of coronary heart disease (CHD) which is a leading cause of mortality in the EU. Higher levels of iTFA intake have been observed in lower income groups – population segments that also experience higher rates of coronary heart disease. As such, iTFAs contribute to health inequalities within the EU.

The case for EU action

Five Member States (MS) have legislated to tackle the iTFA problem, and some parts of the food chain have adopted voluntary measures to reduce the iTFA content of certain food products. The lack of a coordinated, consistent approach means that there is variation across the EU in the obligations placed on food business operators with regard to the iTFA content of products placed on the market, and variation in the level of protection provided to consumers against the harmful effects of iTFAs.

There has been a steady decline in iTFA intake, as assessed at EU level, as a result of legislative and voluntary action. Continuation of this trend would see iTFA levels decline even in the absence of EU action. Yet iTFA levels remain comparatively high in the products of some sectors and in some EU countries. There is some evidence of food businesses in some MS and sectors bringing new products with high iTFA content to the market in recent years. The research also suggests that current industry initiatives will not generate substantial additional benefits beyond those which they have already delivered.

In the absence of EU action, each Member State that has not already legislated might independently adopt measures or decide not to act. Evidence on the likely scale of Member State and industry action in the absence of new EU policies is mixed but, overall, the expected negative health impacts of this baseline scenario are higher than would be seen if there was concerted action to drive down iTFA intake by reducing levels in food across the EU.

In this context, the European Commission is examining options to limit the use of iTFAs in food products in the EU, and thus to reduce iTFA intake of the EU population.

EU policy objectives

The general objectives of EU action on iTFAs are:

- To ensure a high level of health protection for EU consumers;
- To contribute to reducing health inequalities, one of the objectives of Europe 2020;
- To contribute to the effective functioning of the Internal Market for foods that could contain iTFAs.

The specific objectives of EU action on iTFAs are:

- 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 iTFAs;
- 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 iTFAs.

The policy options

In this study the impact of the following five policy options were assessed: an EU-level voluntary agreement to limit the iTFA content of food products sold to consumers to 2% of fat (option 1a); EU-level legislation limiting the iTFA content of such products sold to consumers to 2% of fat (option 1b); legislation requiring the addition of information on trans fatty acids content to the nutrition declaration on all pre-packed food products (option 2); an EU-level voluntary agreement to ban partially hydrogenated oils (PHOs) in the EU (option 3a); and EU legislation banning PHOs (option 3b). The impact of combining the labelling obligation (option 2) with the other options was also assessed.

The PHO ban legislative is assumed to include provision for authorised derogations for certain food additives that are used in small quantities, such as in chocolate coatings.

Study methodology

Through a detailed review of the literature and collection of primary data, this study has developed an evidence basis that has been used in the assessment of the social, economic and environmental impacts of a set of alternative EU policy options that could be adopted to tackle this issue. The assessment has used quantitative models for the assessment of health impacts and economic impacts. The impacts on health inequalities and environmental impacts were assessed qualitatively. The appraisal was informed by research on the evidence and experience from countries that have already acted on iTFAs, including interviews with competent authorities and food business representatives. Selected representatives of the food industry and NGOs working on consumer and health issues were also invited to comment on draft assumptions and results.

The assessment methodology was explicitly designed to accommodate known uncertainty about the future trend in iTFA intake in the absence of EU action (the baseline scenario). The policy options were tested against three variants of the baseline that represent the spectrum of expected possible trajectories – iTFA intake remaining constant at current levels, a linear decline in iTFA intake to zero over 15 years and an accelerated linear decline to zero over 10 years.

Findings

The legislative policy options (1b and 3b) perform better than the alternatives in relation to:

- Health benefits (measured in disability-adjusted life year or "DALY")
- Reduction in health inequalities
- Improvements in the functioning of the internal market
- Efficiency
- Proportionality

Table E.1 - Effectiveness of all options and combinations of options under variant B2 of the baseline scenario (in which iTFAs decline to zero over 15 years)

	Option 1a	Option 1b	Option 2	Option 3a	Option 3b	Options 1a/3a + 2	Options 1b/3b + 2
DALYs 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.

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.

Table E.2 - 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

Furthermore, legislation imposing a maximum limit to iTFA content of products sold direct to consumers (option 1b) performs better in terms of efficiency and coherence than a legal ban on PHOs (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 PHO 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 TFA 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 iTFA levels or have eliminated iTFAs from their products completely. Research suggests that the businesses responsible for much of the residual iTFA 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 legislative alternatives.

Summary

The results of the assessment suggest that legislative action at EU level to reduce iTFAs in food would generate positive impacts on health that are substantial as compared to the costs. These measures would substantially remove iTFA-related health inequalities, provide assured protection to consumers across the EU, and address the internal market integrity issues caused by unilateral Member State action. 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 iTFA content on food products sold directly to consumers and a legal ban on PHOs. A legal limit of 2% on iTFA content performs marginally better than a legal ban on PHOs in terms of efficiency and of coherence with existing Member State legislation.

1 Introduction

This is the Final Report for the project "Study to support the impact assessment of the initiative to limit industrial trans fats intakes in the EU" (SANTE/2016/E1/055). The goal of the study was to analyse the impacts that would result from specified EU actions to reduce dietary intake of industrial trans fatty acids (iTFA). It involved the collection and analysis of quantitative and qualitative data on the expected significant economic, social and environmental impacts. The preparation of the report was guided by the methods and quality standards for impact assessment specified in the European Commission's Better Regulation guidelines and toolbox.

1.1 Political and legal context

The European Commission has been examining options to limit the consumption of trans fatty acids (TFAs) in the EU, on the grounds that this would address concerns about the impacts of their consumption on human health, while contributing to the functioning of the internal market. This is one the priorities of the current Commissioner and the Directorate General for Health and Food Safety. TFAs are a category of unsaturated fatty acids found in many food products. There are two sources of TFAs: those produced industrially (so called industrial trans fats, iTFAs) and those naturally produced by ruminant animals (ruminant trans fats, rTFAs) which then appear in derived food products such as dairy products or meat from cattle, sheep or goats in relative constant, low proportions. The fat composition of ruminant fats with regard to TFA 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. Also, rTFA sources generally contribute in a limited way to high total TFA daily energy. Reduction of iTFAs in foods is possible by carefully selecting the type of ingredients, for example by substituting partially hydrogenated oils (which are the principal source of iTFAs) with alternatives. Therefore, the European Commission is examining options to limit the use of iTFAs in the EU.

A number of external stakeholders have expressed a keen interest in this issue. The European Parliament adopted on 26 October 2016 a resolution calling on the Commission to propose legislation setting a limit on iTFAs within two years and to carry out an impact assessment evaluating impacts on operators and consumers.

Various studies of trans fats, their impacts, and the potential effects of alternative policy options to limit their use, have been undertaken at the EU level and internationally. In the EU, these include a Commission Staff Working document, an inception impact assessment and a report from the Commission to the European Parliament. These build on analyses by the European Food Safety Authority and Joint Research Centre, as well as international reports by the World Health Organization and others, and academic studies. There is also interest for this issue at a national level within the EU. A number of Member States have already taken action to reduce trans fat intake while others have been considering their options.

1.2 Objectives of the study

As per the terms of reference, the objectives of the study were "to identify, collect and analyse evidence concerning the impacts and trade-off of the alternative policy options considered by the European Commission to limit industrial trans fats intakes in the EU, against the reference of the baseline of no EU action."

1.3 Study methodology

This section provides an updated outline of the methodology for the tasks leading to the present report (Tasks 1 to 4).

1.3.1 Task 1: Structuring

1.3.1.1 Task 1.1: Mobilisation

The goal of this task was for ICF to mobilise the team to be involved in the project, scheduling staff time, and start detailed project planning.

1.3.1.2 Task 1.2: Kick-off meeting and report

ICF met the Commission's Steering Group for a Kick-off meeting, in which the purpose of the project was clarified and a number of clarifications were made from both sides on the scope of the study and the approach to implementing the tasks.

1.3.1.3 Task 1.3: Further information scoping

In this task, ICF conducted further information scoping beyond what has been done at the proposal stage. The study team also exchanged further with the representative from the Joint Research Centre (JRC) on the Inter-Service Steering Group (ISG) to gain a better understanding of the approach taken by the JRC in its work on iTFAs, and to discuss options for the approach to assessing impacts in the present study (in particular on health impacts and social inequalities impact).

1.3.1.4 Task 1.4: Refinement of the IA methodology

The goal of this task was to develop the methodology, including adjustments to the data collection strategy and impact assessment approach, reflecting discussions held with the SG.

In this task the study team also developed the baseline and policy options specifications as well as associated theories of change. 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 logic model formally sets out:

- The rationale and objectives of the policy - Why?
- The inputs and resources supporting the policy – How?
- The activities, actions and specific outputs from the policy - How?
- The intended outcomes and impacts of the policy – What?

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 which, in turn, has informed the approach to addressing each of the evaluation questions.

1.3.1.5 Task 1.5: Development of the analytical framework

This task involved further development of the analytical framework for the 13 impact assessment questions set out in the terms of reference, outlining for each:

- Judgment criteria
- Indicators
- Sources of evidence, and
- Methods of triangulation and validation

1.3.1.6 Task 1.6: Inception report and meeting

At the end of Task 1 the study team submitted an inception report to the Commission.

1.3.2 Task 2: Data collection and review

The goal of this task was to identify and close any information and data gaps left after the analysis of available information. As many data had already been collected by the Commission and some analysis had been undertaken for a number of the impacts to be assessed, this task involved targeted efforts 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 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 TFA 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 TFA problem. The results informed extrapolation from existing data on how different policy options may impact the whole EU industry.

1.3.2.1 Task 2.1: Review of existing literature and data

The desk research 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.

1.3.2.2 Task 2.2: Interviews

The 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 1.

1.3.2.3 Task 2.3: Targeted follow-ups

A number of targeted follow-up actions 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 1.

Table 1 List of interviews and targeted follow-ups carried out as part of Task 2

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 - 30/06/2017 – followed by email submission	2.1

Country	Organisation	Type	Date of Interview / email submission	Step / task
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
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	Unavailable	2.2

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

Country	Organisation	Type	Date of Interview / email submission	Step / task
	operator	operator		
UK	Large food chain operator	Food business operator	Unavailable	2.2

1.3.2.4 Task 2.4: Synthesis

The evidence collected in the country research was consolidated into a single document for each country. These country case studies are provided in a separate document (Annex 7). 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 6.

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 5.

1.3.3 Task 3: Screening of impacts and assessment of significance

The 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 section 4.1.1.

1.3.4 Task 4: Analysis of impacts

1.3.4.1 Task 4.1: 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 JRC of the European Commission,[1] and the qualitative evidence collected during Task 2.

1.3.4.2 Task 4.2: Analysis of impacts of each option

The assessment of impacts has been carried out on the basis of a detailed specification of the policy options, developed in conjunction with the Commission at the start of the study. The options that are compared to the baseline are defined in detail at section 3 but in summary are:

- Option 1: Establishment of a limit for iTFAs content in foods
  - 1a voluntary measure
  - 1b legally-binding measure

[1] 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.

- Option 2: Introduction of the obligation to indicate the TFAs content of foods in the nutrition declaration
- Option 3: Prohibition of the use of partly hydrogenated oils in foods
  - 3a voluntary measures
  - 3b legally-binding measure

The impacts of each option were then assessed.

The estimation of health costs was based on a model developed by the JRC and published in 2016[2]. 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 section 4.2.1.

The model can be used to estimate the impact of EU-level policies that lead to changes in population iTFA 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 TFA 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) iTFA 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 (CHD); a person can remain here until death or move to "CHD".
- CHD: state for individuals who have CHD move to this state for a maximum of 1 year; from this state, individuals can move either to "History of CHD" or "Death" but not back to the "Well" state.
- History of CHD: state for post–acute CHD individuals; survivors from a "CHD" state move to this state until death or until they suffer a new CHD event, in which case they move to the "CHD" 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 iTFA intake, defined as E%[3], used as starting point for the model ("today") is calculated as a weighted average of data at MS level collected through existing evidence and a survey.

The model calculates, for each option, CHD events and mortality in yearly cycles over a period of 85 years. The relative risks (RRs) for CHD associated with the different iTFA intakes are based on the calculations in Mozaffarian *et al* (in which the "pooled multivariable-adjusted RR for 2%E of TFA, as an isocaloric replacement for

[2] 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

[3] Percentage of total energy intake

carbohydrate, was 1.23 (95% CI = 1.11–1.37)." This is then applied to the different iTFA intakes to calculate the probability of a CHD event.

Costs (of policy implementation and healthcare related) and outcomes (expressed in disability-adjusted life year or "DALY", 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.

A note on concepts of iTFA-related diseases used in this report

As it builds on a number of different studies, this report makes reference to three different concepts describing diseases linked to iTFA intake: Coronary Artery Disease (CAD), Coronary Heart Disease (CHD) and Cardiovascular Disease (CVD). High cholesterol levels (which may result from high iTFA intake) are a risk factor for both CAD and CHD. The two terms are often used interchangeably. However, CAD can be considered as an antecedent of CHD, in that the build-up of plaque within coronary arteries (CAD) leads to the condition called CHD. CVD is a broader term to describe a range of diseases that affect the heart, including heart failure (which can be caused by CAD, among other factors), arrhythmia (abnormal heart beat) and heart valve problems. Studies have explored the impact of iTFA intake on either CAD (e.g. Martin-Saborido et al. 2016), CHD (e.g. Mozaffarian et al. 2006) or CVD (e.g. Restrepo and Rieger 2016).

For the starting point of the model ("today") the risk of CHD is calculated on the basis of hospital discharges and already includes the risks from current iTFA intakes, which are specific according to country, age, and gender. The reduction in CHD risk linked to iTFA reductions in the following years from "today" is then calculated by using the RR above. Subsequently, the resulting DALYs are then calculated on the basis of the modelled number of CHD events and deaths.

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

Table 2 iTFA intakes across the baseline and alternative scenarios as considered in the JRC model

Scenarios	EU population current iTFA 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 TFA intake over the modelled horizon. JRC assumed that in the absence of EU action iTFA 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 iTFA content. The details of these scenarios are provided below for comparison to the scenarios tested for the current study (which are explained in section 4):

- **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 iTFA 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 1169/2011) would be changed to include also the declaration of TFA content. The measure would apply only to pre-packaged food. The resulting decrease in iTFA intake is slower than in the voluntary agreement case because it would lead to reformulation only in pre-packaged foods. iTFA 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 TFA, as well as the healthcare costs.
- **JRC - Legal measure:** This option assumes the introduction of legislation at European level that limits the content of iTFAs in the food supply. The model assumes that the iTFA 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 iTFA intake in the absence of EU action. Three variants of the baseline were specified to represent the spectrum of expected possible trajectories – iTFA intake remaining constant at current levels, a linear decline in iTFA levels to zero over 15 years and an accelerated linear decline to zero over 10 years (see section 3.1).
- More conservative assumptions were defined for the impacts of voluntary agreements (see section 4.2.1)
- The assumed impact of a legal limit on iTFA content on iTFA intake was revised from zero in the JRC model to 0.009%E, which corresponds to the average intake in Denmark as of 2014.
- The option of a PHO ban was added; the modelling of health impacts of the PHO ban used the JRC modelling assumptions for the legal limit of 2% iTFA 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 Section 4. 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% discount rate, in order to facilitate comparison with the benefits estimates.

Environmental impacts were examined qualitatively, 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.

1.3.4.3 Task 4.3: Analysis of impacts of combined options

Task 4.3 involved analysis of the following combinations of options:

- 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 during the data collection phase.

1.3.4.4 Task 4.4: Interim report

An interim report was delivered by the study team to the ISG, presenting the detailed analysis and conclusions from the impact assessment, as well as supporting data.

1.3.5 Task 5: Validation consultation

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

1.3.5.1 Task 5.1 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 by the Commission, 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.

1.3.5.2 Content of the survey instrument

An online consultation questionnaire was prepared in this sub-task. The survey instrument is given in Annex 7.

The consultation built on the results generated through the data review and collection (Task 2), and the impact screening and impact assessment (Tasks 3 and 4). Consultees were presented with the key data points, estimates, assumptions and findings from these tasks, and were asked to provide their feedback. The consultation was mostly made of closed questions, with some options for comments (for example, in case of consultee's disagreement with our research findings).

The first part of the consultation posed general questions on current and predicted iTFA use under different policy options and the definition of iTFAs. 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

1.3.5.3 Selection of consultees – overall approach

To validate the data gathered though the previous tasks, we distributed the consultation tool to:

- Consumer and health NGOs;
- FBO 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 3 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 4 shows, representatives from the business sector belonged to various sectors potentially affected by the measures.

Table 4 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 (n=14), 9 were large businesses, and 5 SMEs.

1.3.6 Task 5.2 Analysis

The data were anonymised and aggregated. 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 study team, while they have helped to qualify the baseline scenario.

1.3.7 Task 5.3: Revisions

Based on the conclusions reached in Task 5.2, the team proceeded with final revisions of the impact analysis across all impacts and options.

1.4 Strengths and limitations of the method

The main limitations from this study 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 (as discussed in section 5.7). 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 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 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 to decision-makers: 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, as discussed in section 5 of this report. Adjustments to data points that are uncertain do not change the overall findings, which demonstrates the robustness of the overall study.

1.5 This report

The draft final report is structured as follows:

- Section 2 provides the problem definition and the case for EU action, as well as an outline of the objectives of EU policy intervention in this area;
- Section 3 provides the detailed outline of the policy options for TFAs: the nature and scope of intervention, the intervention logic, the types of businesses affected, the supply chain effects, and the effects on TFA levels in food;
- Section 4 provides a detailed discussion of the impacts of the different policy options, including a screening and classification of impacts, and an analysis of each category of impacts: social impacts, economic impacts, and environmental impacts;
- Section 5 provides a comparison of the options, including a discussion of their effectiveness, efficiency, coherence with other EU policy objectives, trade-offs and synergies, proportionality. Possible combinations of options are also discussed in that section;
- Section 6 provides a summary of the conclusions and key messages from the study.

A series of annexes provide supporting detail on the work completed.

2 The Trans Fats Problem

2.1 What is the problem and why is it a problem?

The problem definition for EU level action to reduce intakes of industrial trans fats in the EU is summarised below.

TFAs are a category of unsaturated fatty acids[4]. There are two sources of TFAs: those produced industrially (so called industrial trans fats, iTFAs) and those naturally produced by ruminant animals (ruminant trans fats, rTFAs), which are present in derived food products, such as dairy products or meat from cattle, sheep or goats.

The main dietary source of iTFAs is partly hydrogenated oils and fats. Popular products in which iTFAs can be found are categories of bakery products (e.g. biscuits and pastries), vegetable fats (e.g. margarines and spreads), confectionery (e.g. fillings and creams) and certain fried foods (e.g. potato crisps)[5].

2.1.1 Consumption of trans fats is associated with a higher risk of coronary heart disease

Coronary heart disease (CHD) is the leading cause of mortality in the EU. There is convincing scientific evidence that trans fats intake has a negative effect on human health. The World Health Organization (WHO) and the European Food Safety Authority (EFSA) therefore recommend that consumption is minimised. The risk of dying from heart disease is 20%-32% higher when consuming 2% of the daily energy intake from trans fats than from any other nutrient[6]. While a recent systematic review and meta-analysis of observational studies found that industrially produced, but not ruminant derived, trans fats are associated with risk of CHD, EFSA concluded in 2010 that the available evidence indicates that rTFA have adverse effects on blood lipids and lipoproteins similar to those from industrial sources when consumed in equal amounts.[7] EFSA further concluded that there is insufficient evidence to establish whether there is any difference in the risk of heart disease between ruminant and industrial TFA 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[8].

2.1.2 There is evidence that iTFAs contribute to 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[9]. As such the current situation can contribute to health inequalities. Systematic evidence of iTFA consumption by socio-economic status is not available but there is case study

[4] 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".

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

[6] Mozaffarian et al. (2009) Health effects of trans-fatty acids: experimental and observational evidence European Journal of Clinical Nutrition (2009) 63, S5–S21, doi:10.1038/sj.ejcn.1602973 ; de Souza 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; Gebauer, S., et al. (2011) Effects of Ruminant trans Fatty Acids on Cardiovascular Disease and Cancer: A Comprehensive Review of Epidemiological, Clinical, and Mechanistic Studies. Adv Nutr July 2011 Adv Nutr vol. 2: 332-354, 2011.

[7] 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

[8] 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.

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

evidence that demonstrates higher rates of intake within certain groups in certain locations. This evidence is fragmented and not necessarily representative of wider patterns.

Widening health inequalities in Europe are a major cause for concern.[10] Mortality rates from CHD are the highest in areas of greatest deprivation[11]. For example, in Scotland the mortality rate for most deprived groups is more than double the rate for the least deprived groups.[12] In some countries, relative inequalities[13] are expected to widen in the coming years[14].

2.1.3 iTFA levels can be reduced by reformulation

Reduction of iTFAs in foods is possible by changing the type of ingredients used in their preparation. An example is the substitution of partially hydrogenated oils with alternatives. Evidence from Demark[15] demonstrates how, after legislation imposed a limit on iTFAs, iTFAs were reduced or eliminated from most products that originally had a high iTFA content. Examples are French fries, microwavable popcorn and various bakery products. iTFAs now make an insignificant contribution to overall intake of TFAs in Denmark.

2.1.4 Current status

There is currently no EU legislation regulating the content of TFAs 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 TFAs, but it is not required or possible to label the exact TFAs amount).

Table 5 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 TFA content of foodstuffs*	AT, DK, LV, HU, LT
Legislation limiting TFA content of foodstuffs which voluntarily bear a specific nutrition claim (keyhole)	SE
Other legislation (e.g. limits on specific product categories)	ES, EL, FI

[10] WHO (2013) Review of social determinants and the health divide in the WHO European region: final report. WHO Regional Office for Europe

[11] Psaltopoulou, T. (2017) Socioeconomic status and risk factors for cardiovascular disease: Impact of dietary mediators. Hellenic Journal of Cardiology, 58, Issue 1, January–February 2017, 32-42.

[12] See for example figure 20 in ISD (2016) Scottish Heart Disease Statistics. Year Ending 31 March 2015. National Statistics, 2016.

[13] I.e., the ratio of mortality rates between the lowest socioeconomic group and the highest socioeconomic group.

[14] Allen, K. (2016) Future trends and inequalities in premature coronary deaths in England: Modelling study. Int J Cardiol. 2016 Jan 15;203:290-7.

[15] Bysted, A., Ærendahl 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.

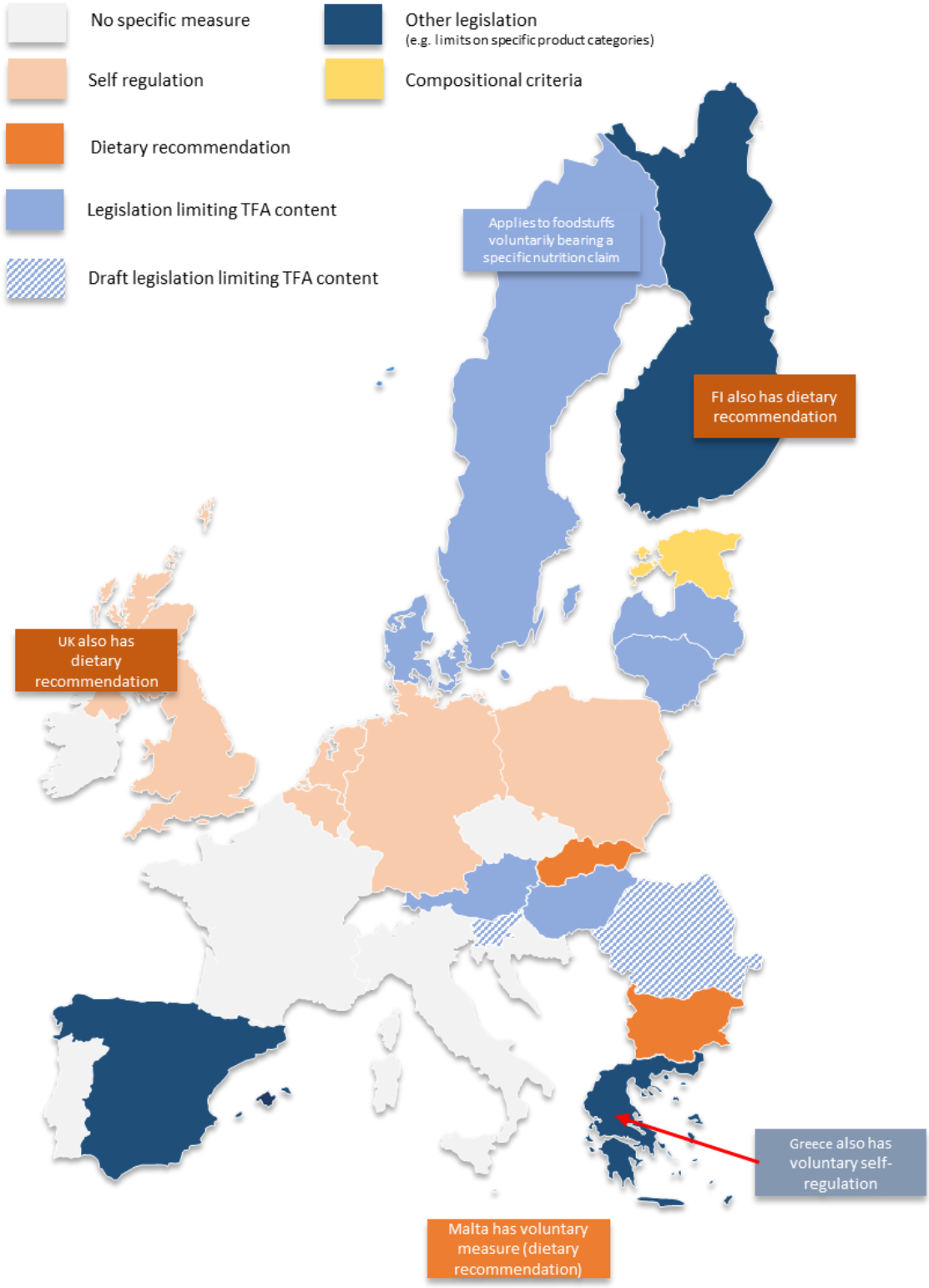
*Notes: * All legal acts apply to products sold to final consumer. Ruminant TFA is exempt in all cases. FI presence in two categories matches source document.*

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.*

Table 5 provides an overview of existing national measures in EU Member States that were in force at the point of completing this study. Some Member States (i.e. AT, DK, LV, HU, LT) have implemented legislation on iTFA content of foodstuffs, imposing a legal limit of 2% iTFAs of total fat in food products. 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). After this study was completed, Slovenia and Romania transmitted to the Commission draft legislation to impose a legal limit to iTFA content in food. Further action at Member State level is possible. In the consultation that preceded the adoption of the Commission's report on TFAs, several national competent authorities indicated that they were prepared to proceed with national measures in the absence of EU action.[16] Some food business operators have taken voluntary action to reduce or eliminate iTFAs from their products in action orchestrated at EU level by representative organisations (such as CAOBISCO and FEDIOL).

[16] 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}.

Figure 1 Member State action by type (as of December 2017)



Source: ICF

Table 6 Summary responses to the five dimensions of the problem definition described by the Better Regulation toolbox

Principal topics	Comment
The problem and why it is problematic	Industrial trans fatty acids (iTFAs) are a type of unsaturated fatty acids that can be generated artificially from vegetable oils. Alongside naturally occurring trans fatty acids, iTFAs are contributing to ill health and particularly to the incidence of coronary heart disease (CHD), which is a leading cause of mortality in the EU. iTFA intake is particularly high among consumers with lower income, who are also the most at risk of coronary heart disease. The current situation in the EU is one of decline in iTFA levels and iTFA intake in a number of sectors and MS, combined with enduring high levels and high intake in others. The evidence also suggests that gains obtained in recent years through voluntary industry initiatives and other factors may have reached their limits. Past efforts to tackle the iTFA problem indicate that industry practices would have to change, particularly in those MS and those sectors least organised to undertake or respond to a coordinated action on iTFA (e.g. in Eastern Europe). SMEs in the food manufacturing sector may also find it challenging to remove ingredients high in iTFA from their products and reformulate them in order to achieve desirable as well as feasible levels of iTFA. Consumers would also need to change their behaviour, by basing their consumption choices on iTFA content. There has been targeted action in some Member States to reduce dietary iTFA intake using either legislation or voluntary measures. In other Member States the issue has received less attention. This variation, and in the scope of voluntary measures to tackle iTFAs, creates the risk of fragmentation in the internal market and unequal levels of protection to consumers. The issue of iTFA has a transnational dimension, since products manufactured in one Member State having no requirements on iTFA content may be sold in another where such requirements apply. Legislation passed in some Member States (Hungary, Denmark) to limit iTFA level applies only to food sold in the Member State but not to food manufactured in the Member State and exported. Several third countries have implemented measures to tackle iTFA levels in food products and to reduce iTFA intake, most prominently Norway, Switzerland, Iceland, Liechtenstein (EEA) as well as the United States and Canada. Rules applicable to foods sold in those countries are therefore of relevance to this assessment, as they might play a role in the conduct of trade, the negotiation of trade agreements, and the competitive advantage of EU firms compared to third country operators.
The magnitude and EU dimension of the	CVD, including CHD that may result from a high iTFA intake, imposes substantial health burdens in the EU. It is estimated

Principal topics	Comment
problem	that 49 million people live with CVD and that the condition imposes costs of more than €200 billion each year[17]. Though iTFA intakes are low at the level of the population as a whole, they continue to contribute to the absolute health and economic disease burdens of CVD. The current situation with regard to dietary iTFA reduction and regulation of iTFA in the food chain is characterised by fragmentation, with a number of MS having taken uncoordinated initiatives to tackle the iTFA problem. Measures taken in some MS also have delivered inconsistent results, particularly when it comes to voluntary initiatives involving industry associations and individual companies to reduce iTFA content in food products. Lack of a consistent approach means that there is not a level playing field in the EU at present between operators that have reformulated their products in order to reduce or fully remove ingredients containing iTFAs, and those that have not. Producers that have not acted to reduce iTFAs may save money from not investing in reformulation and through use of lower priced ingredients. This may provide a competitive advantage in the market. The current situation may also entail the iTFA content of a product varying depending on the place of purchase (though in this study it has not been possible to definitively establish the extent of such 'dual standards' for relevant products in the single market).
The causes ("drivers") and their relative importance	The drivers of iTFA intake are partly a matter of industrial recipe and process, and partly one of consumer behaviour. iTFA intake results from consumption of food products containing ingredients high in iTFA, or/and cooked in such a way (e.g. using certain oils for frying) that contributes to increasing the level of iTFA in the cooked product. A key factor of iTFA intake is therefore the manufacturing and cooking process of the food. Ingredients containing iTFA, and prominently among them partially hydrogenated oils, present certain characteristics which make them of interest to food manufacturers. Cost can also be a factor where ingredients selected on price (having controlled for technical characteristics) also contain iTFAs. Alternative ingredients need to be found, and sometimes developed, so that the product presents similar characteristics (of texture, taste, etc.) after reformulation. Inertia and cost-related barriers to change may lead producers to continue to use inputs that contain iTFAs (such as PHOs) unless given a stimulus to change by the market or regulators, even where alternatives exist. Reformulation can entail substitution or development of a

[17] European Heart Network CVD statistics 2017

Principal topics	Comment
	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 products. The other cause of iTFA intake is the lack of consumer information on iTFA levels in food products, and consumer awareness of the health risks posed by the consumption of iTFAs. The evidence in the EU points to low levels of consumer information and consumer awareness on TFA, including which ingredient (stated on the label) may contain TFA.
The relevant stakeholders	The principal stakeholders in this matter are: **EU food business operators**, and chiefly food manufacturers operating in the following sectors: manufacture of oils and fats, 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, and restaurants and mobile food service activities. All have a role in determining the level of iTFA in their products, and therefore the iTFA intake in the EU. Large players are already well aware and many have addressed iTFA levels in their products through reformulation. Manufacturers of oils and fats have a critical role to play as suppliers of ingredients that may contain iTFA to a very large pool of manufacturers, and particularly to SMEs. A number of them have already acted on this issue, while others have not. The evidence indicates that those actors from the industry who are willing and able to act have acted already, while a range of smaller and less organised businesses are still to act on iTFA levels in their products. **The EU public as consumers**, have an interest in being offered food to purchase that contains low levels of iTFA at affordable prices. **Governments of EU Member States** that will: face obligations of implementing the legislation; and, benefit from longer term reductions in the incidence of cardiovascular disease that will result from further reductions in iTFA intake.
How the problem is likely to evolve with no new EU intervention?	The problem of iTFA intake is likely to evolve further as a result of future initiatives that might be taken at MS level to reduce iTFA intake if no action is taken at EU level. Indeed, a number of MS are considering introducing measures, which may contribute to fragmenting further the single market for food products. Whether the decline in iTFA levels in food product and iTFA intake observed in the past years will continue at the same speed and achieve a near elimination of iTFAs in the EU is not certain. The perspectives provided by stakeholders in the consultation conducted for this study suggested that the

Principal topics	Comment
	problem would continue in the absence of EU action but also that many individual Member States would act unilaterally if the EU did not act. There is some evidence of new products that contain high levels of iTFAs being introduced to the market in recent years[18].

2.2 The case for EU action

EU level action is justified on the basis that:

- Whilst action has been taken by some countries, and others may be expected to act in the absence of an EU initiative, rapid and universal action on iTFAs by Member States is not foreseen.
- Products with high iTFA content would therefore remain on the EU market and iTFAs would continue to contribute to health impacts and health inequalities.
- The protection provided to consumers against the negative health impacts of iTFAs varies in a context where (i) information on TFA content that would facilitate informed consumer choice does not appear on the food product label (ii) products can be freely traded within the Internal Market.
- Without EU action, operators will remain subject to different conditions for the manufacturing and placing on the market of foods that could contain iTFAs.
- Action at Member State level raises the possibility of differences in the approach and specification of the remedies required by different countries that would add complexity and cost for food business operators.

On this basis the Commission's inception impact assessment concludes that there is a: "***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"*.

2.3 Objectives of EU policy intervention

The objectives of EU action on iTFAs, as defined in the Commission's inception impact assessment, are:

General:

- To ensure a high level of health protection for EU consumers;
- To contribute to reducing health inequalities, one of the objectives of Europe 2020;
- To contribute to the effective functioning of the Internal Market for foods that could contain iTFAs.

Specific:

- 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 iTFAs;
- 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 iTFAs.

[18] 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 Policy Options for Trans Fatty Acids

This section defines in detail the specifications of the policy options addressed in the analysis. It presents logic models and theories of change for each option. These 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 analysis of the options has helped to identify their respective expected impacts which, in turn, has informed the approach taken to addressing each of the evaluation questions (as set out in Section 4 of this Report).

The options investigated were defined in the Commission's Inception Impact Assessment (IIA)[19]:

- Option 0: no EU policy change (baseline)
- Option 1: Establishment of a limit for iTFAs content in foods
  - 1a voluntary measure
  - 1b legally-binding measure
- Option 2: Introduction of the obligation to indicate the TFAs content of foods in the nutrition declaration
- Option 3: Prohibition of the use of partly hydrogenated oils in foods
  - 3a voluntary measures
  - 3b legally-binding measure

Additionally, certain combinations of options are foreseen. These are:

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

The policy objective and rationale is common to all options and is as specified at section 2.3. The policy options differ only in how they seek to achieve the given objective. For all options the detailed specification (such as the time period allowed before the legislation comes into effect) has the potential to influence benefits and costs.

3.1 Option 0 – Baseline

3.1.1 Specification

The impacts of new EU policy interventions are determined by comparing the expected 'with policy' situation with a reference scenario that describes what is expected to happen in the absence of new EU intervention targeting iTFAs. This reference, or baseline, scenario describes the expected change in the iTFA amounts present in the food chain, iTFA consumption, and associated health impacts.

The baseline scenario is not one of 'no change'. The baseline scenario needs to capture the effects of all the legislative and voluntary action that can be expected to be taken in the absence of a new EU initiative, and the impacts of any other changes relevant to iTFA consumption.

The evidence - discussed below - suggests that iTFA levels in food have been declining over time under the influence of various factors. This trend in iTFA levels in food suggests that iTFA-related health impacts have also been declining.

[19] EC (2016) Inception Impact Assessment on an initiative to limit industrial trans fats intakes in the EU. European Commission, Brussels.

In its recent public health economic evaluation[20], the JRC extrapolated from this evidence and adopted an assumption that iTFAs will be completely removed from the EU food supply chain in 10 years.

While data gathered for this study confirm a trend towards iTFA 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. Levels of iTFAs appear to remain high in certain countries and certain sub-groups of food businesses, particularly SMEs.

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 iTFA 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. A continuous downward trend in the years to come is therefore not assured. The evidence is discussed in more detail below (section 3.1.2). This means that there is uncertainty in the baseline that the analytical approach needs to respond to.

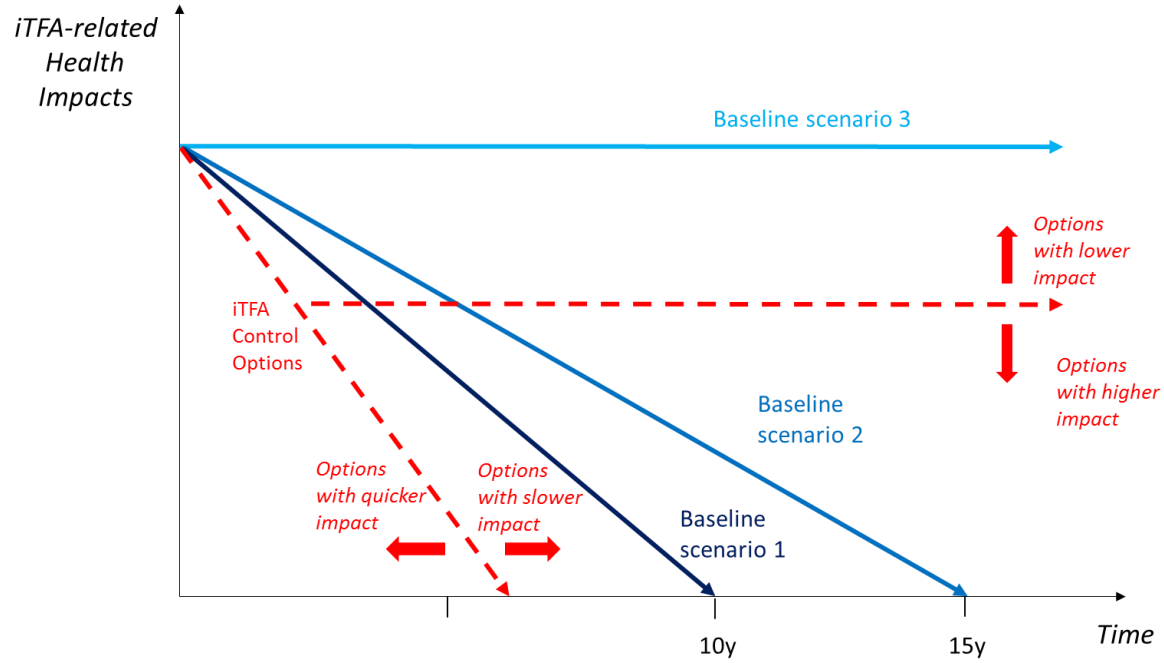
Three variants of the baseline scenario have been adopted to capture that uncertainty. The policy options are compared against each variant. This approach helps to ensure that the conclusions about the absolute and relative impacts of options are robust in the context of all foreseen reference scenarios, thereby accommodating the uncertainty about future evolution of the problem in the absence of further EU action. The variants are:

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

These three scenarios for the baseline are represented in Figure 2. This chart illustrates that, from an impact appraisal perspective, the first variant (B1) is conservative: an option that is cost-effective under this assumption would be even more cost-effective under the other variants.

[20] 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.

Figure 2 Illustrative representation of how benefits of iTFA control arise compared to the variants of the baseline scenario



Note: This illustrative chart shows a linear progression in iTFA consumption in either of the three scenarios. The actual shape of the curve in both baseline and with-policy options may be non-linear. Source: ICF.

3.1.2 Discussion

The evidence on TFA content of food and consumption has been reviewed in depth by the JRC[21].

Most food products are low in TFAs but that is not the case in all MS

The majority of food products contain less than 2 g TFA/100 g fat (the lowest limit set in EU countries with limiting legislation). Seventy-seven per cent of products have less than 0.5 g TFA/100g fat, according to an analysis of the most recent available data on the presence of TFA in food in European food markets[22]. However, data on TFA content of selected foods sampled between 2006 and 2013 indicates also amounts of iTFAs 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 iTFAs in food has been declining but further reductions are uncertain

The JRC's analysis suggests that iTFA 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 3 below). Data

[21] In accordance with the advice provided by the Commission, ICF did not repeat the evidence review conducted by the JRC.

[22] Mouratidou et al. (2014) Trans Fatty acids in Europe: where do we stand? JRC Science and Policy Reports 2014 doi:10.2788/1070.

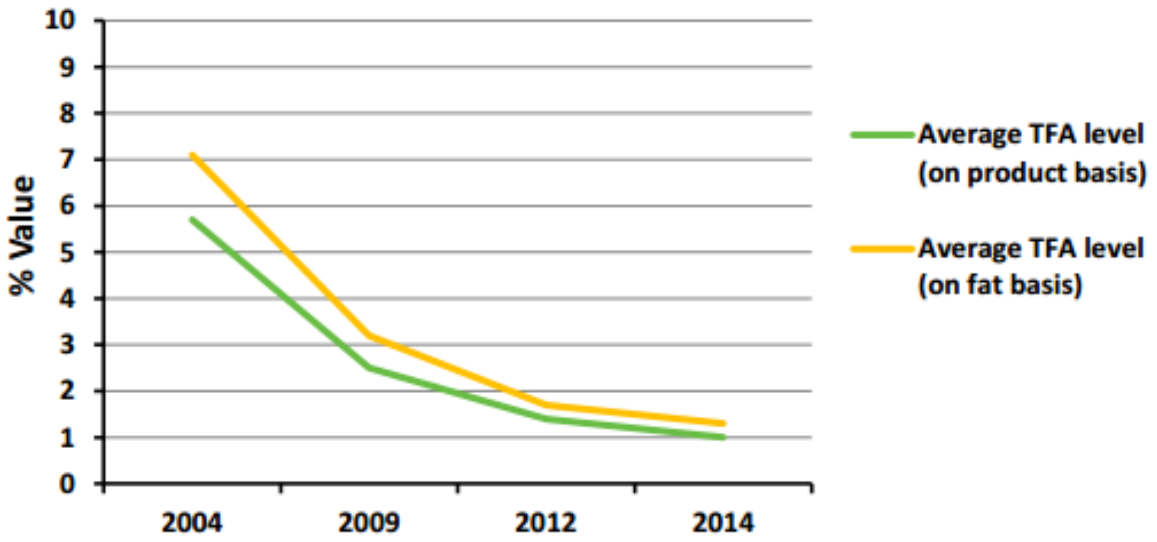
on the iTFA content of foods manufactured and sold in predominantly Eastern Europe[23] suggests that, in spite of reductions in certain categories of products, levels of iTFAs in other food products remain high. Further evidence collected in six South-Eastern European countries (including Croatia and 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 iTFA had doubled between 2012 and 2014,[24] indicating that food industry operators had expanded their offer of products with high iTFA content, contradicting the notion of a general downward trend.

TFA intake in Europe has been decreasing

There is evidence that TFA intake has decreased overall in the EU[25] since the 1990s , from as high as 4.3 E% in elderly Dutch men in 1985 to average population intakes of less than 1 E% in the 2000s. However less is known about dietary TFA intakes in Eastern Europe. Whether TFA 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 iTFA in food products.

Robust pan-EU data on the variation in iTFA consumption by socio-economic group are not available. However, the variation in iTFA consumption by socio-economic group is expected to continue. Although the JRC publication does not estimate variation of TFA intake across socio-economic groups, recent estimates exist for the UK[26].

Figure 3 Industry data indicate that the level of trans fatty acids in business-to-business margarines has declined



[23] 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

[24] 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

[25] 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.

[26] Pearson-Stuttard J et al. (2015) Quantifying the Socio-Economic Benefits of Reducing Industrial Dietary Trans Fats: Modelling Study. PLOS One 10(8): e0132524.

Source: European Margarine Association, IMACE position on trans fatty acids. Brussels, April 2015. TFA intake in Europe is decreasing[27].

Future initiatives towards reductions in iTFA levels are uncertain

Various public, private, or public-private initiatives at sectoral, national and EU level have been associated with reductions in iTFA levels in Europe (and beyond[28]). 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 MS, 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 iTFA 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 Members States themselves may act if the EU does not.

It appears that most existing voluntary initiatives – at MS level or EU level – have delivered their goals and further progress is uncertain. The industry in some MS has not acted voluntarily on iTFAs, and the evidence from certain MS suggests that a voluntary approach may not deliver any progress there.[29]

While five Member States have already passed legislation to limit iTFA levels in food products, other Member States have indicated their intention to legislate (including Slovenia and Romania, who have drafted legislation). 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 iTFA manufactured in third countries that may export their products into some MS makes it more likely that the iTFA intake of at least some groups of consumers in those countries may remain too high or even increase.

Any further reductions in iTFA in food are expected to translate quickly into health benefits

The relationship between iTFA 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 iTFA consumption translate rapidly into reductions in CVD[30]. Three years after the policy was implemented, mortality attributable to CVD

[27] IMACE (2015) IMACE position on trans fatty acids. Brussels, April 2015.

[28] 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.

[29] 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

[30] Restrepo, B. J., and Rieger, M. (2016) Denmark's Policy on Artificial Trans Fat and Cardiovascular Disease. AJPM January 2016Volume 50, Issue 1, Pages 69–76.

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.[31]

In some cases reformulation to reduce iTFAs has the potential to increase the saturated fat content of food. This has implications for the scale of the health benefits achieved by iTFA reduction – higher levels of saturated fat are thought to be associated with increased risk of CHD (though even if TFA 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 iTFAs 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 iTFA content. The shift in consumption of ingredients has the potential to have environmental impacts, examples being changes in the consumption of soya and palm oil. In Denmark the replacement fat that was used varied depending on the food product[32]. The desk research 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[33]. The exact magnitude of environmental impacts will depend on the food business operator's (FBO's) choice of ingredients.

Table 7 Summary of Option 0: Baseline – No EU action

Initial assumptions

- iTFA 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 iTFA consumption have a commensurate and rapid impact on CVD 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 iTFAs.
- iTFA reduction will prompt some changes in the aggregate demand for inputs to the food industry, changes that have the potential to have environmental impacts.

[31] 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.

[32] Ministry of Food, Agriculture and Fisheries of Denmark and DTU (2014) Danish data on trans fatty acids in food.

[33] Hinrichsen, N. (2016) Commercially available alternatives to palm oil, Lipid Technol. 2016 Apr; 28(3-4): 65–67.

3.2 Option 1a – Voluntary agreement to set a limit for industrial trans fats content in foods

In option 1a, a limit for iTFA content in foods would be established by a voluntary agreement secured at European level between the European Union and relevant food business operators. Food business operators would commit to the agreement individually or through industry associations. The agreement would be steered by 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 and countries are not organised and represented at EU level, this would not be fully inclusive. The assumption is that the voluntary agreement would primarily focus on final food products sold direct to the consumer (and not include ingredients that are sold within the food chain and used 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 may be commercially sensitive, and business associations would need to operate as a "safe space"[34], collecting and anonymizing the information from its members so that it may then be publicized. Such arrangements are in line with those implemented in voluntary agreements to reduce iTFA content in food in Germany and the Netherlands.

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

Reporting obligations (and so the associated costs) would continue to apply even after the participating firms/sectors had reduced iTFA 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 iTFAs had been reduced to levels below 2% of fat. There would be a credible threat to legislate in the absence of progress.

The intervention logic model for Option 1a is provided in Table 8.

[34] 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.

Table 8 Intervention logic model for Option 1a: Voluntary agreement with food business operators on iTFA 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 iTFAs with poly/monosaturated and saturated fats Implementation of new products and processes Monitoring, oversight and reporting	Decrease of iTFA content in food below 2% of fat among participating businesses iTFA content in products might vary based on which businesses adopted voluntary measures	Reduction of iTFA 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 CVD 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: investment in product development, new production	Potential increases in product prices Possible effects on product availability, taste and choice Risk of incomplete	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 suppliers of ingredients	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 measures

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	processes, purchase of ingredients, operating costs	compliance with voluntary measures, especially among small producers Risk of increase of TFA content for some categories of products targeted at lower income groups	Potential increase in demand for environmentally damaging tropical oils	Potential negative environmental impacts - deforestation caused by demand for tropical oils Products with iTFA from producers from third countries entering EU market with potential competitive advantage

Key: TFA: trans fatty acids; iTFA: industrial trans fatty acids; rTFA: ruminant trans fatty acids. CVD = Cardio Vascular Diseases

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

3.3.1 Specification

In Option 1b legislation is introduced by means of an EU Regulation that is binding across EU to limit iTFA content to 2% of the total fat content of final food products sold to the consumer. The application of the 2% limit to final food products sold to the consumer is consistent with such legislation already in force in some Member States. A 2% limit enables residual use of raw ingredients containing iTFA, which are used in the industry as additives.[35]

The two configurations examined are that the EU legislation would set a limit of:

- 2% of total fat content limit for iTFAs, without any derogations. Such a legislative measures limiting the content of iTFAs to 2% of the total fat content of food has been adopted in Denmark (2003), and has been drafted in Romania (2017) and Slovenia (2017).
- Differentiated limits, 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). For instance, the legislation in Hungary has established a maximum permissible content of trans fatty acids 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.

Consistently with the JRC modelling study, a transition period of 2 years is assumed.

The logic model for Option 1b is provided at Table 9.

[35] The oil and fats industry through its representative organisations has indicated its desire to see legislation imposing a 2% limit paired with the removal of the mentions "fully hydrogenated" and "partially hydrogenated" from Annex VII of Regulation (EU) No 1169/2011. This is out of scope of the present assignment and therefore is not part of the specification for option 1b.

Table 9 Intervention logic model for Option 1b: Legal limit on iTFA 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 iTFAs content with polyunsaturated, monosaturated and saturated fats Implementation of new products and processes Guidance and advice Monitoring and enforcement by MS	Decrease of iTFAs content in food below 2% of fat [Derogation for higher TFA limit for low fat foods]	Reduction of iTFAs 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 CVD 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	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

Inputs	Activities	Outputs	Outcomes	Long-term impacts
			production can be associated with negative environmental impacts	

Key: TFA: trans fatty acids; iTFA: industrial trans fatty acids; rTFA: ruminant trans fatty acids. CVD = Cardio Vascular Diseases

3.4 Option 2 – Introduction of the obligation to indicate trans fatty acid content in the nutrition declaration

Option 2 involves the adoption of legislation at EU level that extends the scope of the existing nutrition declaration legislation (EU Regulation 1169/2011) to the TFA content of the food. Mandatory TFAs content labelling would serve two purposes: i) to provide incentives to the industry to reformulate and reduce TFA from food products and ii) to enable consumers to make informed food choices leading to reduced iTFA intake[36].

The option is specified as follows:

- The labelling obligation would be required for all foods that carry a nutrition declaration, whether or not they contain TFAs. The label would therefore be required to state TFA content even if the content is zero (i.e. firms selling products that are free of TFAs would still incur labelling costs).
- The labelling obligation would be restricted to pre-packed foods; food that is not pre-packed, including food that is sold for consumption out of the home (e.g. through food service outlets) is out of scope of the obligation.
- The nutrition declaration would describe total TFA content(per 100g, per serving).
- The labelling option is assumed to be accompanied by a two-year transition period, which will allow a majority of businesses to process label changes into their normal cycle of label updating.[37]
- The labelling option would require an amendment of Regulation 1169/2011 through ordinary legislative procedure.

The intervention logic model for Option 1a is provided in 0.

[36] 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}.

[37] 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.

Table 10 Intervention logic model for Option 2: Introduction of the obligation to indicate the TFAs 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 TFAs	Introduction of new legal rules, provision of information New product label and ingredients list development Potential sourcing of alternative ingredients - substitution of iTFAs with poly/monosaturated and saturated fats Monitoring and enforcement by MS Communication / awareness-raising campaigns	Declaration of TFA content in food labels on prepacked foods Reformulation of foods to maintain product demand might lead to a decrease of iTFA content in food	Reduction of TFA consumption – potential variation across subgroups based on health literacy Inclusion of the TFAs content of foods in the nutrition declaration Enhanced and standardised consumer information, increased consumer confidence Changes in supply chain demand for ingredients that contain TFAs and their substitutes	Decrease in CVD 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	Potential increases in product prices	Potential social implications – potential to increase the differential in TFAs intake if groups where TFA intake is higher are also less responsive to labelling Adverse impacts on some food manufacturers where reformulation is difficult and	Potential to exacerbate inequalities in health outcomes even as overall position improves Negative image of products containing rTFA (in particular milk and dairy products)

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	information Direct costs to businesses: investment in product labels development, detection of TFAs in own products, purchase of ingredients, operating costs		impacts on foods containing rTFAs Potential for less healthy options to be selected by consumers who are not equipped to interpret the TFA information on the nutrition declaration	Potential negative economic impacts – competitiveness in 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 TFAs alongside the EU labelling obligations

Key: TFA: trans fatty acids; iTFA: industrial trans fatty acids; rTFA: ruminant trans fatty acids. CVD = Cardio Vascular Diseases

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

Partially hydrogenated oils (PHOs) are the primary dietary source of iTFAs. EU legislation already requires presence of fully hydrogenated or partially hydrogenated vegetable oils and fats to be declared.

In Option 3a, PHOs 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. The intervention logic would be similar to that for option 1a, with the difference that food business operators would agree to end the use of PHOs as an ingredient – i.e. the agreement would focus on the ingredients used rather than the content of food products sold directly to consumers.

For the implementation of Option 3a, PHOs would need to be defined at EU level. There is currently no definition of PHO in EU law or in the Codex Alimentarius. The US Food & Drug Administration's determination on PHOs being not Generally Recognized as Safe[38] (GROS) defined PHOs in terms of their "Iodine Value" (IV), which is measurable. Likewise, Option 3a would require that the definition of PHO is linked to a measurable indicator, which could then be relied on for monitoring and enforcement purposes.

[38] https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

Table 11 Intervention logic model for Option 3a: Voluntary measures to prohibit the use of partly hydrogenated oils (PHO) in foods

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 (including a definition of "PHO") and details of arrangements and implementation (only businesses using PHOs) New product development Sourcing of alternative ingredients - substitution of PHO with other oils Implementation of new products and processes Development of detection methods for PHOs Monitoring, oversight and reporting (acknowledging presence of PHOs in packaged foods is simpler than TFAs since they are already declared in the label)	Decrease of iTFA content in food among participating businesses. This may be less than through direct limits on iTFAs, though PHOs are understood to be the main dietary source of iTFAs. iTFA content in products might vary based on which businesses adopted voluntary measures to eliminate PHO	Reduction of iTFA consumption for all population subgroups, especially those with higher iTFA intake from PHO, but likely slower and of a minor magnitude than through legal measures Ongoing product development and innovation Harmonisation of standards within Internal market, depending on rate of uptake of voluntary agreement Harmonisation of standards with some export markets	Decrease in CVD 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 Small potential impact on trade across EU Member States (and with third countries) Impacts may be reduced compared to measures to limit iTFAs directly (depending on the strength of the PHO to iTFA relationship).
Costs and potential unintended effects:	Administrative burdens for businesses – formulating the agreement, understanding the rules, monitoring and reporting	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	Potential negative social impacts – inequalities in disposable income Potential negative economic impacts –

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	Administrative burdens for authorities – formulating the agreement, monitoring and oversight. Costs of testing and monitoring may be reduced compared to Options 1a and 1b. Direct costs to businesses: investment in product development, new production processes, purchase of ingredients, operating costs	Risk of incomplete compliance with voluntary measures, especially among small producers	imports in the EU market and vs exports in some third country markets Adverse impacts on some suppliers of ingredients Potential increase in demand for tropical oils	competitiveness in export markets and competition with food business operators that did not adopt voluntary measures Potential negative environmental impacts - deforestation caused by demand for tropical oils More MS may introduce national legal provisions leading to fragmentation, unless aligned to Danish model

Key: TFA: trans fatty acids; iTFA: industrial trans fatty acids; rTFA: ruminant trans fatty acids. CVD = Cardio Vascular Diseases

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

This option mirrors action taken in the USA. In June 2015 the US Food and Drug Administration (FDA) concluded that PHOs are not "generally recognized as safe" for use in human food, and introduced a ban on their use, with a compliance period of three years. This will allow food companies to either reformulate products without PHOs and/or petition the FDA to permit specific uses of PHOs. A similar ban is in prospect in Canada[39].

This option would introduce, via EU law, a ban on the use of PHOs as food ingredients. As for Option 3a, the matter of the definition / scope of 'PHO' would need to be determined, and a suitable test would need to be agreed for monitoring and enforcement purposes.

The intervention logic is similar to that for Option 1b, with the difference that the legal obligation would focus on the ingredients used rather than the content of final products. This should in turn lead to reductions in the iTFA content of foods and so to reductions in iTFA consumption.

[39] Government of Canada (2017) Notice of Proposal - Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods.

Table 12 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 "PHO" Introduction of new legal rules, provision of information New product development Sourcing of alternative ingredients - substitution of PHO with other oils Implementation of new products and processes Development of detection methods for PHOs Monitoring and enforcement by MS	Elimination of PHO content in food Decrease of iTFA content in food	Reduction of iTFA consumption for all population subgroups, especially those with higher iTFA intake from PHOs Ongoing product development and innovation Harmonisation of standards within Internal market Harmonisation of standards with some export markets	Decrease in CVD 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,	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 negative social impacts – inequalities in disposable income Potential negative economic impacts – competitiveness in export markets Potential negative environmental impacts -

Inputs	Activities	Outputs	Outcomes	Long-term impacts
	monitoring and enforcement may be reduced compared to Option 1b. Direct costs to businesses: investment in product development, new production processes, purchase of ingredients, operating costs		Potential increase in demand for environmentally damaging tropical oils	deforestation caused by demand for tropical oils

Key: TFA: trans fatty acids; iTFA: industrial trans fatty acids; rTFA: ruminant trans fatty acids. CVD = Cardio Vascular Diseases

3.7 Combinations of options

In addition to the above options, the impact assessment has considered the following combinations of some of the options:

- Options 2 (labelling) and 1b (legal limit on iTFA content in food);
- Options 2 (labelling) and 3b (legal ban on PHOs); and
- Options 2 (labelling) and 1a or 3a (voluntary agreements at EU level).

4 Impacts of the Policy Options

4.1 Overview of impacts

4.1.1 Screening of impacts

4.1.1.1 Method

It is important that the impact assessment is comprehensive, and considers all potential economic, environmental and social impacts. In line with the guidance on impact assessment set out in the EC Better Regulation guidelines, the first stage of the impact assessment involved screening of the options against the long list of impacts specified in Annex 1 of the specifications, and reproduced in Table 13 to identify those that are potentially significant.

The screening of impacts was informed by the literature review and interviews with stakeholders and national authorities, as well as analysis by the contractors. 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.

ICF 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 Table 13, 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 13 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	Consumer health Health inequalities

Impact type	Long list of impacts drawing on Commission IA guidelines	Additions and refinements to long list
	Health & safety	Income inequalities
	Education	Consumer choice
	Governance & good administration	
	Social protection, health and educational systems	
	Cultural heritage	
Environmental impacts	Fighting climate change	Palm oil production (and associated climate and biodiversity impacts)
	Fostering the efficient use of resources (renewable & non-renewable)	
	Protecting biodiversity, flora, fauna and landscapes	
	Minimizing environmental risks	
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 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 about the probability of positive and negative effects occurring, and prioritising those for which there is robust evidence over those subject to less informed speculation; 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[40].

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.

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.

4.1.1.2 Screening of Impacts

Table 14 summarises the screening of impacts of action to address iTFAs in the EU.

[40] DG Health & Food Safety (2016) Strategic Plan 2016-2020.

Table 14 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 iTFAs 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 is limited and suggests that costs and economic impacts to date have been limited for countries and businesses that have taken action to limit iTFAs, 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 competiveness. Though evidence 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 SME growth	x	xxx	xx	x	SMEs account for the majority of food businesses in the EU. Any option to limit TFAs 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 iTFAs 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 research; technological development	xx	xx	xx	x	Reducing iTFAs in food products requires the use of alternative ingredients and frequently involves reformulation of food products. Action to limit iTFAs 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 iTFAs 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 iTFAs) and potential negative effects (increasing costs relative to producers in some export markets). Evidence 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,

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
product testing, reformulation, changing ingredients					substituting 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 iTFAs 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 iTFAs can be expected to have greater impacts on businesses and consumers in MS and social

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
					groups where current levels of iTFA in products and consumption are greatest. The analysis has considered differences in costs between different MS and different social groups.
Health (& safety)	xxx	xxx	xxx	xx	Health impacts are the primary reason for taking action to reduce iTFA levels in food, and are therefore central to the analysis of benefits.
Education	x	x	x	x	Action for TFAs 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 iTFAs 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 iTFA intake are currently highest. This may have the effect of reducing health inequalities. The

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
					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 change	xx	xx	xx	xx	Reductions in iTFAs have the potential to lead to the substitution of partially 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 partially 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

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
					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 trade; however, international trade in products containing iTFAs 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	-	-	-	-	Not identified as an issue in the literature or stakeholder

Impact	Expected magnitude	Relevance for stakeholders	Likelihood	Duration of impact	Comment
a business					consultations.

Key: - = not identified as an issue; x = moderate significance; xx = strong significance; xxx = very strong significance

4.1.1.3 Identification of significant impacts

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.

4.1.2 Types of stakeholders affected

A variety of stakeholders will be affected by action to limit iTFAs in the food sector. These include:

- Consumers, who will benefit from healthier food and reduced risk of contracting coronary artery disease (see 'Health impacts'), but may experience an increase in the price and potentially a change in the quality and attributes of certain food products (see 'Consumer impacts');
- Healthcare providers, through reduced incidence of CHD and reduced costs of healthcare (see 'Health impacts');
- Food businesses, including SMEs, who will be required to take action to limit iTFAs in food, potentially incurring additional costs and experiencing effects in terms of competitiveness (see sections on costs, Internal Market and international competitiveness and trade);
- Member State authorities, who will be responsible for implementing, publicising, administering and enforcing the new rules, incurring costs as a result (see section on administrative costs to public authorities)
- Environmental interests and the global community, especially given concern about the potential impact on palm oil consumption and its effects on climate change and biodiversity (see section on Environmental impacts).

4.2 Analysis of impacts

This section provides an analysis of each of the categories of impact listed in section 4.1.1.3.

4.2.1 Social impacts

The only category of social impact to emerge from the screening was the impact of options on human health, including on health inequalities.

Actions to limit intake of iTFAs will have a range of potential health impacts, helping to reduce the negative effects of TFA consumption on blood cholesterol levels and the impact of this on CHD. It can also impact on health inequalities, having greatest effects on consumers in MS and social groups where current levels of iTFA in products and consumption and/or CHD prevalence are greatest.

4.2.1.1 Health impacts

Health impacts related to actions to limit intake of iTFAs are quantified in terms of:

- Health care costs (direct and indirect);
- DALYs (disability adjusted life years).

These impacts are influenced by the level of iTFA intake by the population, which will vary as a result of the different policy options. Impacts on health outcomes will also depend on a number of other factors, such as the dietary habits of population subgroups, consumption levels of rTFAs and the type of fat used to replace iTFA in reformulated products. These other factors can affect health outcomes (positively or negatively) independently from the iTFA intake by the population. In this analysis all factors are assumed constant.

The health impact assessment used the following assumptions:

Baseline (option 0)

The baseline assumes an initial iTFA intake of 0.3 %E (sensitivity analysis with +- 50% initial intake) and three alternative scenarios. The assumption for the baseline iTFA intake follows the assumption in the JRC modelling study. An alternative worst case estimate of 0.7 E% 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 iTFA intake remains constant at of 0.3 %E for the duration of the period.

The evidence gathered suggests that the current situation is characterised by fragmentation, with a number of MS having taken initiatives alone, without coordination with other MS, to tackle the iTFA problem. Some MS governments have acted, as have some industry associations and individual companies.

Voluntary agreement (option 1a and 3a)

For Options 1a and 3a (voluntary agreements) it is 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 FBOs in terms of the contribution that the iTFAs in their products makes to population iTFA intake. As such the iTFA 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 iTFA intake), the voluntary agreement would trigger a decrease in the iTFA intake to 80% of the current iTFA intake from packaged products, and 90% of the iTFA 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 iTFA content in products.

At the national level, formal voluntary schemes have been running in Member States such as the Netherlands, the United Kingdom[41], 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 Sport[42] as observer. For iTFA the goal was to reduce the amount of iTFAs 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 iTFA 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.[43] Other research found that the measures adopted in Poland had limited effect[44].

At the EU level, a number of initiatives have been sponsored by food business operators to reduce iTFAs (such as the reduction below 2% of iTFAs in the vegetable oils sector promoted by FEDIOL[45]). 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.[46] 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 iTFAs content of less than below 2%. Such results have been achieved through voluntary measures. It seems unlikely that further reductions in iTFAs 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 0). 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 iTFA 'problem'.

Interviews 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 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 iTFA 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 iTFA 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 iTFA content of their products as a result of joining a voluntary agreement at EU level.

[41] 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}.

[42] Volksgezondheid, Welzijn en Sport.

[43] 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.

[44] Traill, W. B. et al. (2012) Reformulation for healthier food: a qualitative assessment of alternative approaches. AgEcon Search, Conference Paper/ Presentation, 2012.

[45] FEDIOL (2014) FEDIOL Position on TFA.

[46] 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.

Mandatory labelling (option 2)

The health impacts of option 2 are assessed by assuming that the iTFA 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. iTFA intake from non-packaged food (which is not affected by the option) remains as in the baseline.

The reduction in iTFA intake comes from a combination of consumer choice and induced reformulation (where FBOs reformulate foods to reduce the iTFA content in order to avoid having to show a high iTFA level on the label). The 50% figure is replicated from the JRC analysis. ICF regards it as an upper limit on the feasible impact of iTFA labelling – low consumer awareness of iTFAs 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 0.5g can be labelled as 0 g of artificial TFAs leading to reductions in suggested serving size to meet labelling criteria[47]. This may have no impact on consumption. Besides, the continued labelling of "fully/partially hydrogenated" oils on the food composition label as required by EU legislation, which consumers may use to detect TFA, may lead them to reject products that contain fully hydrogenated oils even though those products may have low levels of iTFA. It was also the view of most stakeholders consulted on this study that TFA labelling will not lead to healthier product choices.
- **TFA intake can remain extremely high in pockets of the population.** In Canada, even after mandatory labelling led to 76% of foods meeting voluntary TFA limits,

[47] Hendry, V.L., Almíron-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)*.

intake in the population still exceeded the WHO recommendation that less than 1% of dietary energy intake should come from consuming TFAs. In particular, intake by teenage boys was double the recommended level[48].

- **Some foods with low TFA 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 TFA 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[49].
- **For food labelling regulation to be effective, the population must be aware of TFAs and able to interpret nutrition labels accurately**. A study financed by the European Commission[50] 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 TFAs and their health risks.[51] More generally, the evidence on consumer awareness of iTFA and issues linked to TFA intake indicates that it is low in many EU countries (as documented in Annex 7), 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 iTFA as a result of reading and understanding labels.

On the basis of this evidence, some impact on iTFA 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 TFA content of foods was very effective in reducing the population iTFA intake. Since the introduction of the measure in 2002, the average intake of iTFAs decreased in all age

[48] 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.

[49] 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.

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

[51] 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.).

groups of the Danish population[52]. The most recent data suggest that in 2014 the average iTFA intake in Denmark was 0.009 %E[53].

Based on the evidence discussed above, the health model assumes that for options 1b the iTFA intake decreases to 0.009 %E after two years (assumption of 2 year implementation period) and then evolves as assumed in each of the three baseline scenarios.

Legal ban on PHO (option 3b)

This option would introduce a ban on the use of PHOs as a food ingredient, through EU legislation, with a transition period of 2 years.

The U.S. Government introduced a ban on PHOs because they are the primary dietary source of iTFA in the USA. Although all refined edible oils contain some iTFAs as an unintentional by-product of their manufacturing process, iTFAs are an integral component of PHOs 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[54]. Use of PHOs 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 PHO ban. Therefore, the model assumes that iTFA intake will vary as in option 1b, i.e. that the removal of PHOs from the food supply will successfully eliminate the presence of food with high iTFA content from the market.

To assess the robustness of the results a sensitivity analysis on the current EU population's iTFA intake was performed (i.e. the intake at the point in time when the analysis starts). The model was run with 0.15 iTFA intake (-50% than baseline initial intake assumption) and with 0.45 %E iTFA intake (+50% than baseline initial intake).

Health-related costs

Both direct and indirect health-related cost estimates are expressed in 2016 prices (in €). The model considers two types of costs:

- 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). The costs are based on the European Cardiovascular Disease Statistics 2012[55]" (Martin-Saborido et al. 2016).
- Indirect costs of ill health: costs related to the disease, namely loss of productivity and informal care. The costs are based on the European Cardiovascular Disease Statistics 2012.

[52] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods.

[53] 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.

[54] USFDA (2017) Final Determination Regarding Partially Hydrogenated Oils (Removing Trans Fat).

[55] Nichols et al. European Cardiovascular Disease Statistics 2012. Brussels (Belgium): European Heart Network, European Society of Cardiology; 2012

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 value[56] 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.

0 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 legislative 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 (which assumes a decline to zero iTFA intake over 15 years rather than 10). In variant B3 (which assumes constant iTFA intake) disease-related costs savings are much greater than under the other two variants. In B3 there is no reduction of iTFA intake without an action at EU level so (for instance) legislating for iTFA reduction avoid health-related impacts that otherwise would continue in perpetuity. Options 1b and 3b deliver the highest savings in disease-related costs to healthcare funders, carers and the wider economy.

Table 15 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

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

A sensitivity analysis has been conducted to show the impacts of alternative specifications of the starting point – i.e. the initial population iTFA intake. This shows that, although the magnitude of costs is dependent on the iTFA intake, all options deliver cost savings in all cases, and that options 1b and 3b provide the largest benefits. Table 16 compares the policy options cost variations with different current iTFA intake assumptions for variant B2, 15 years elimination as the reference.

Table 16 Comparison of savings with different iTFA 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

[56] 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.

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

DALYs

The disability-adjusted life year (DALY) measures overall disease burden. It expresses that burden as the number of years lost due to ill health, disability or early death. Resulting DALYs are then calculated on the basis of the modelled number of CAD events and deaths.

In the case of no EU action (option 0) the DALYs for the entire EU population amount to 1,076 million over the course of a lifetime (85 y) under the best case scenario. Under variants B2 and B3 the total EU CAD burden in DALYs would be 1,079 million and 1,142 million respectively. The figures indicate the scale of the cardiovascular disease burden.

Table 17 illustrates the number of DALYs avoided thanks to the implementation each option as compared to the baseline scenario variants. They are calculated by subtracting the estimated DALYs in the baseline from the DALYs in the given policy.

Options 1b and 3b lead to the highest reduction in morbidity and mortality (as measured in terms of DALYs). The implementation of legislative measures (1b or 3b) would reduce the disease burden by 4 million DALYs for the EU population under variant B1 and by 6 million DALYs for the EU population under B2. In the B3 case (constant iTFA intake) the reduction in disease burden is much greater as in the baseline there is no longer a reduction of iTFA intake. Options 1b and 3b have the greatest positive impact.

Table 17 Health gains in DALYs averted (EU28, Millions) for each policy option compared to the baseline, under each of the baseline scenario variants

Policy option	Health benefits in DALYs 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

The sensitivity analysis shows that, although the magnitude of health benefits is greatly dependent on the current iTFA intake, all options reduce the disease burden as compared to the baseline. Table 18 compares the performance of the policy options under different current iTFA intake assumptions looking at the variant B2, 15 year elimination scenario.

Table 18 Health gains in DALYs averted (EU 28, Millions) by policy option under different iTFA current intakes and considering the B2 variant of the baseline scenario (elimination of iTFA in 15y)

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

4.2.1.2 Impact on health inequalities

Inequalities in health remain a leading 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. These inequalities in life expectancy are reflected in UK CAD inequalities. 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[57].

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 world and the EU to reduce industrial trans fat intake. They have had, and are likely to have, varying effects upon their respective health burdens and inequalities. As noted in section 2 robust, systematic baseline evidence on iTFA-related inequalities (of intake and outcome) is lacking, there is good evidence of problems in certain population segments. 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.

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. This is because:

- They deliver the ***largest*** overall health-related benefits;
- The health benefits are ***universal***, i.e. socio-demographic groups that are unresponsive to information in food labels, or which consume products of FBOs that do not participate in iTFA-related voluntary agreements will enjoy the benefits as much as those who choose foods on the basis of their iTFA content and buy from FBOs that have reformulated their products to reduce iTFA content.
- The benefits are (providing there is compliance by the food sector/enforcement of the law) ***assured*** – there are no intervening uncertainties relating to FBOs' propensity to collaborate or to consumer awareness.

Introducing legislation to limit iTFA content in food sold to consumers across the EU could result in reducing the disease burden by 6 million DALYs in the B2 baseline variant through a lowering of the CHD disease incidence. It would also reduce

[57] 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.

spending on healthcare and the wider societal costs of CHD by €94,008 million in present value terms. There is evidence that iTFA are consumed in higher amounts in countries with higher CHD mortality[58] whilst also being consumed in higher amounts by the most deprived communities in each country.

This evidence suggests that the largest reductions in iTFA consumption will be enjoyed by more deprived groups who also have the highest baseline overall and CHD-specific mortality. This also suggests that the CHD-related mortality that is prevented will be much greater in deprived populations (between and within countries) than in more affluent populations whose iTFA 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 CHD inequalities achieved by a legislative limit, projecting a reduction in CHD inequalities of 15%[59] and 33% more prevented deaths in the most deprived groups compared to the most affluent[60].

It was also the view of most stakeholders consulted on this study that a legally binding action would ensure the highest protection of all socio-economic groups from the negative health effects of iTFA 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 PHOs from the market, and would influence the reformulation options available to FBOs.

Mandatory labelling (option 2)

On the assumptions made, 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 DALY reduction as compared to the B2 baseline variant. Food and menu labelling with nutritional and other information is widely used with the aim to influence consumer choice. Labelling policies, are intended to facilitate informed choice by the consumer.

The efficacy of adding TFA 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[61]. This is because labelling

[58] 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.

[59] 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.

[60] 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.

[61] 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,

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, both of which are more likely in populations with greater education which is more prevalent in the more affluent compared to the most deprived groups.

There is a possible indirect mechanism for labelling to have an effect – i.e. through reformulation by FBOs that is induced by having to explicitly state the iTFA content of products in the nutrient declaration. The potential scale of such an effect is undetermined in this instance. FBOs may take the view that low awareness of the health aspects of iTFA consumption among many customer groups means that the risk of economic losses from maintaining existing iTFA levels is low.

Across the EU, there are variations in CAD mortality and iTFA consumption. It is likely that labelling would have a negligible effect upon reducing relative health inequalities[62]. 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 worksite or community interventions have been found to be less effective[63], again demonstrating the effectiveness hierarchy of public health interventions[64].

For trans fats policy specifically, the UK adopted a voluntary approach. This did reduce iTFA intake[65], but much less than in Denmark where the legal limit forced the industry to reformulate (or to stop placing of the market) products containing PHO/high iTFA 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 affluent, with lower CHD mortality, than the

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.

[62] 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.

[63] 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.

[64] 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.

[65] Trail B S et al. Reformulation for healthier food: a qualitative assessment of alternative approaches. 2012

deprived groups. As the product has a reduced iTFA content, reaping the benefit of the policy does not require individual behaviour change assuming the iTFA content has been reduced equally across all products and locations. It is therefore likely to reduce the disparity between iTFA 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 iTFA achieved through the voluntary reformulation.

In **summary**, while the JRC model does not produce quantitative estimates of the potential effects of options on health inequalities, evidence from trans fats policies and other dietary policies across the world suggest that the legislative 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.

Table 19 Expected impact of each option on health inequalities

Policy option	Expected impact	Comments
Option 1a	Moderate effect in reducing inequalities derived from iTFA 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 iTFA intake resulting from slower reformulation in low price product segments, hence delaying inequalities reduction.
Option 1b	Strong effect in reducing inequalities derived from iTFA 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 reducing inequalities derived from iTFA consumption	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 3b because of weaker effect on overall iTFA intake.
Option 3b	Strong effect in reducing inequalities derived from iTFA consumption	Expected to deliver strong health benefits for all groups, including for relatively disadvantaged groups which experience greatest health impacts currently

4.2.2 Economic impacts

Actions to limit the intake of iTFAs have the potential to have the following economic impacts:

- Direct costs for businesses and public authorities;
- Effects on consumer prices and choice;
- Implications for the functioning of the Single Market;
- Effects on competitiveness and trade; and
- Impacts on SMEs.

At the root of these impacts are the costs imposed by each of the policy options. There are two principal types of cost:

- **Administrative costs** 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** incurred by businesses in meeting the legal or voluntary obligations. These may include the costs of reformulating products, purchasing alternative ingredients, and product labelling.

Each of these is considered in turn below.

4.2.2.1 Administrative costs for businesses

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 iTFA 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 iTFAs, businesses who are unsure of compliance are also likely to be affected.

The project research 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 iTFAs to regulators. In Denmark, the iTFA legislation did not include an obligation for food businesses to provide information to the authorities. Latvia's legislation to limit TFAs does not require businesses to provide information on their products' iTFA 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).

Number 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 20).

Table 20 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 iTFAs 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. Only subsectors whose products are likely to contain iTFAs will be affected. Businesses in countries with existing legislation not affected Mandatory limits will need to be understood by all potentially affected businesses – larger number of businesses affected than 1a
Option 2	Pre-packed food businesses only. Labelling requirements are mandatory so all producers of pre-packed foods affected Businesses in countries with existing TFA legislation will be affected
Option 3a	Pre-packed and non-prepacked food businesses, and food service companies. Only subsectors likely to be using PHOs will be affected. Businesses in countries with existing TFA legislation unlikely to be affected, as case for additional voluntary action is limited Number of businesses affected depends on rate of uptake of voluntary agreement – lower than in 3b
Option 3b	Pre-packed and non-prepacked food businesses, and food service companies. Only subsectors likely to be using PHOs will be affected. Businesses in countries with existing legislation may be affected if use PHOs in small quantities PHO ban will need to be understood by all potentially affected businesses – larger number of businesses affected than 3a

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 in 0 , based on Eurostat data. Overall, there are 1.08 million businesses in food subsectors potentially subject to TFA 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 TFA initiative. The targeted country research investigated this issue in consultations with government and business stakeholders and in the review of literature.

Table 21 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 3a[66];
- Businesses in countries with existing iTFA 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 21 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 data[67]

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 iTFAs would be subject to slightly different rules imposing a ban on PHOs.

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 Section 4.2.1.1 above).

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. Some businesses may take only a few minutes to understand the requirements and satisfy themselves that they are compliant; others may expend much more time and effort in

[66] The basis for this estimate is discussed in Section 4.2.1.1 above

[67] Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

understanding the issue and the requirements for their business, and in collecting information on the iTFA content of ingredients and final products.

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 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[68].

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 22). The figures are one-off costs.

Table 22 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.

4.2.2.2 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 iTFA content, in order to inform action. Costs will be incurred in organising and commissioning tests. Tests will also be carried out by MS authorities. The costs of those tests are accounted for later on in this section.
- Costs of ***reformulating products***. Some products containing iTFA 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 iTFA content may incur additional costs. This may be the principal cost for some operators, e.g. food service companies sourcing different fats for frying.

[68] 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.

- Costs of ***labelling***. Option 2 requires all prepacked food products to include information about TFA content on their labels, obliging many businesses to incur costs in relabelling their products.

Compliance costs – product testing

Measures to limit iTFA content in foods (mandatory and voluntary, Options 1a and 1b) as well as mandatory rules on iTFA labelling (Option 2) will require some businesses to analyse the iTFA/ TFA 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 PHOs (Options 3a and 3b) is less likely to require TFA testing of foods by the businesses since compliance checking will focus on whether PHOs 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 found some evidence of the costs of testing products for iTFA content. In Latvia, TFA 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)[69]. 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 TFA content. This assumption is conservative and assumes that the majority of products can be declared TFA free – or categorised according to their TFA content - based on ingredients, without the need for testing;

[69] 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)

- 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;[70]

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 euro are given in Table 23.

Table 23 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 TFA content. This is in spite of conservative assumptions about the level of testing required.

FEDIOL, the EU vegetable oil and protein meal industry association, commented that Option 2 (mandatory labelling) could result in substantially higher costs in food testing than the other options. While a legal limit on iTFA would merely require producers to ensure that iTFA levels were below the specified limit, a labelling requirement could require more frequent testing, particularly because of fluctuations in the TFA 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 TFA content varies depending on feed regimes, seasonality, type of animals etc.) to frequently analyse the TFA content of their products. It was predicted that this would generate substantial costs.

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 iTFA content or to phase out the use of PHOs; 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 iTFAs (2g per 100g fat content) under Option 1, or that use PHOs 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

[70] Responses to the validation consultation did not provide clear advice to revise this assumption either upwards or downwards.

seasonings will require reformulation. Some bakeries may be able to substitute PHOs 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 PHOs 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 PHOs 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 iTFAs 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 4.1 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 foods (Bruns 2015).
- The Latvian government, in an impact assessment of the legislation introduced in that country, estimated that the cost of reformulation of products 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 iTFAs in food products have been limited, and absorbed within ongoing programmes of product development[71];
- 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 PHOs 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 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)[72] 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 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*."[73]

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*

[71] JRC (2013) Trans-fatty acids in Europe. Health and legislative implications. Workshop report. Zagreb, Croatia. 9-10 April, 2013.

[72] 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.

[73] WHO (2015) Eliminating trans fats in Europe: A policy brief. WHO, Copenhagen.

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. FEDIOL reported that, in order to reduce iTFA 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 TFA 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.

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 partially hydrogenated oil with high levels of iTFA to fully hydrogenated oil with a iTFA content below 2 per cent. 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 iTFA 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 iTFA 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 MS, the proportion of food products exceeding the proposed 2% iTFA limit varies between 1% and 20%, depending on the subsector and MS concerned[74]. 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 MS would need to reformulate as a consequence of the PHO 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% iTFA 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

[74] 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.

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 costlessly while others will be required to devote significant resources to R&D.

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 24).

Table 24 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 iTFA levels above 2% being withdrawn from the market.

Costs of ingredients

One of the principal costs of action to limit iTFAs is the additional cost of ingredients for the food sector, as a result of the need to replace PHOs with more expensive alternatives. The literature review and interviews found limited evidence of the scale of these costs. However, the evidence available suggests that it is likely that the use of alternative fats and oils to reduce iTFAs 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 iTFA 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 PHOs 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% TFA 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 PHOs (Bruns, 2015) assumed that substitute ingredients for PHOs could cost an average of 25% more.[75]

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* (Mouratidou *et al*, 2013) suggested that substitution with palm oil may be cost neutral but that the use of new hard fats as a replacement for TFA may increase the cost of ingredients, and require a longer term approach to the development of cost effective alternatives.[76]

In order to assess the potential increased cost of food ingredients as a result of reductions in iTFAs in food products, the following assumptions were made:

- All products exceeding limits on iTFAs or PHOs will require a change of ingredients, substituting PHOs 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 section;
- Food ingredients account for 41% of the value of output of the products affected[77];
- PHOs account for 5% of the overall value of ingredients used in products currently exceeding the 2% iTFA limit;
- Substitute fats and oils are 25% more expensive than PHOs.[78]

In combination, these assumptions would mean that the substitution of PHOs for alternative iTFA free fats and oils will increase costs for businesses supplying products which currently exceed the 2% iTFA limit by 0.51% of the value of their output.

The estimated costs of additional ingredients under each option are summarised in Table 25.

Table 25 Compliance costs – additional costs of ingredients (M EUR)

[75] 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.

[76] 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.

[77] 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]

[78] Responses to the consultation validation did not provide justification for revising this estimate.

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 PHOs.*

Costs of labelling

Option 2 imposes costs on businesses by requiring pre-packaged food products to be labelled according to their TFA content.

This option places obligations on all pre-packaged food businesses, whether or not their products contain TFAs, 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 TFAs;
- 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.
- 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 current study 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[79].
- 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

[79] EC (2015) Commission Staff Working Document. Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'

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 TFA 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 Euro 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 SKUs will need to be changed (based on the RAND Europe estimate used in the impact assessment on general food labelling)[80]
- 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.[81]

Based on these assumptions, the one-off cost of food labelling under Option 2 is estimated at EUR 9.9 billion (Table 26).

Table 26 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	-

4.2.2.3 Administrative costs for public authorities

The principal administrative costs for public authorities in the Member States of the iTFA 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 TFAs 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.

[80] 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 {COM(2008) 40 final}

[81] The validation consultation 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.

Costs of establishing the policy

Options 1b, 2 and 3b each involve the introduction of legislation. The new rules are most likely be in the form of new EU regulations, binding throughout the EU and not requiring secondary legislation at Member State level. Nevertheless, MS authorities will be involved in communicating the new rules to affected businesses in each country, providing advice to businesses where required, and handing 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 27.

Table 27 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

Costs of consumer information campaigns

Hendry *et al* (2015) argued that, to be effective, a TFA labelling initiative will need to be accompanied by a public education programme, which requires additional funding.[82]

Option 2 – the mandatory TFA labelling option – is likely to need to be supported by a campaign to raise consumer awareness of the health impacts of TFAs. 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 TFAs.

Evidence suggests that many consumers are unaware of the TFA issue, 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

[82] 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.

attention to the label changes and encourage consumers to compare the labels on different products.

An international review by the OECD (Sassi et al, 2009)[83] 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 TFAs would depend on the type of intervention employed. The JRC paper (Martin-Saborido et al, 2016) assumed that a full suite of interventions would be employed, including a mass media campaign, physician counselling, and interventions in schools and workplaces. 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.[84]

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 to reach the quarter of the EU population most vulnerable to the health impacts of iTFA 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 MS currently lacking legislation, a mass media campaign designed to raise awareness of transfats 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 iTFAs or a ban on PHOs 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 iTFAs 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 TFAs, could be employed. Information campaigns might also be carried out by industry bodies.

Table 28 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	-

[83] 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

[84] 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.

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, though limited, gives some indication of the resources likely to be needed for monitoring and enforcement:

- In Latvia, the Food and Veterinary Service (Pārtikas un Veterinārais dienests) 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)[85] 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)[86] 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 iTFA 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;

[85] 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.

[86] Hendry VL, Almíron-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.

- 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.

Table 29 shows the estimated costs of monitoring and enforcement activities under the different options.

Table 29 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 iTFAs but for which an outright ban on PHOs would need to be enforced.

4.2.2.4 Summary of Costs

Table 30 presents estimates of the total costs to business and the public authorities of implementing the five options, as compared to the baseline scenario. The figures present the sum of the present value of costs over 10 years, using a discount rate of 4%.

Costs are assumed to be zero after 10 years for each option. Many are one-off costs. It is likely that monitoring and enforcement will cease to generate costs after 10 years (by which time iTFAs will have disappeared from the food chain). By that time, iTFA monitoring would likely become part of the routine operations carried out by National Competent Authorities regarding food composition (i.e.food fraud prevention). The development of cost-effective alternative ingredients should mean that any additional ingredients costs should decline 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 over the 10 year period to give a total present value.

Table 30 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 have by far 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 TFAs.

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 31).

Table 31 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 iTFAs.[87] *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 PHOs.

4.2.2.5 Consumer impacts

The main impacts on consumers 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.

Health-related impacts are discussed in section 4.2.1.1 .

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

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

- 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 previous section 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 substituted with imports.

Interviewees 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 suggests that products containing iTFAs tend to be cheaper than iTFA-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 $3.55 per kg. Similar research indicates that nutritionally improved products tend to be higher in price*"[88];
- A 2014 study looking at the changing trans fat content and price of cookies in the US and Canada[89] concluded that price was significantly related to the presence of trans fat in cookies: trans-fat free cookies were more expensive than those with trans fats. Median price per 100 grams was US$ 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 iTFAs 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 PHOs tend to be cheaper than alternative ingredients free of iTFAs. However, it may also be that

[88] Krenosky et al. (2012) Risk Assessment of Exposure to *Trans* Fat in Canada. *International Food Risk Analysis Journal*, vol.2, 1-15.

[89] 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.

these differences in prices are linked to marketing strategies from the food industry, targeting different products at different socio-economic groups.

While this evidence suggests that iTFAs 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 iTFAs 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 I-TFA limit.[90]
- IMACE reports that no impact on the price of products has been identified to date in its sector, even though iTFAs 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).
- 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 iTFAs, any effect on prices may often be too small to be observable in practice.

The expected impact of each option on consumer prices is summarised in Table 32.

Table 32 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

[90] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P.8

Policy option	Expected impact	Comments
		under other options.
Option 3a	Very small increase	Low cost option, unlikely to impact on food prices
Option 3b	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

Product attributes

One of the challenges in reducing iTFAs 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.

Overall, evidence suggests that these issues do present challenges for some sectors of the food industry, but that these challenges are not insurmountable.

For example, in interview 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 PHOs 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 fat-laden fast foods have not decreased significantly in the localities that have implemented trans fat bans; and the costs of switching to trans fat-free alternatives have not resulted in higher restaurant prices. In addition, trans fat-free alternatives have been readily available to restaurants because cooking oil and seed companies anticipated the shift away from hydrogenated oils years before trans fat bans went into effect. Companies began investing in research and accelerating production of trans fat-free alternatives in the 1990s, when the first major studies were released revealing the health risks of trans fat consumption[91].

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 suggests that these challenges would be greater in the context of a legal ban on PHOs (Option 3b) than under legislation imposing a 2% limit on iTFA content in food products sold to consumers (Option 1b), particularly for the use of additives (for example in chocolate coatings). There is

[91] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants.

uncertainty on the scale of the reformulation challenges posed by a PHO ban compared to a legal limit on iTFA content.

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.

Options 1b and 3b – by mandating changes in product content – can be expected to have greatest potential impacts (Table 33).

Table 33 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	Action, if any, will be voluntary – products facing technical challenges can be excluded
Option 3a	Negligible	Action will be voluntary – products facing technical challenges can be excluded
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.

4.2.2.6 Internal market impacts

Five Member States (Austria, Denmark, Hungary, Latvia and Lithuania) have introduced legislation to limit iTFAs in food products. No universal legal limits on iTFAs or PHOs are in place in the other 23 Member States, although some countries and sectors 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 operators based in these Member States, 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.

EU policy on the free movement of goods, as set out in the Blue Guide (EC, 2016)[92] seeks to ensure that only safe and otherwise compliant products find their way on to the market, in such a way that honest economic operators can benefit from a level playing field, thus promoting at the same time an effective protection of EU consumers and professional users and a competitive single EU market.

Harmonising product standards for iTFAs 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. In the absence of legislative action at EU level, there is a strong likelihood that further Member States might take national action to limit iTFAs, thus leading to further differences in standards across the EU.

The Commission's Inception Impact Assessment[93] 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 iTFAs has impacted on the functioning of the Internal Market so far.

Denmark faced some criticism that its action to impose limits on iTFA content in foods represented a trade impediment, by banning the sale of imports of products containing iTFAs exceeding the new limit[94]. 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 iTFAs 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 iTFAs, and that higher levels of iTFAs are arguably more likely to be found in products manufactured and sold by smaller businesses into domestic markets. There is evidence, however, that large players in some MS have been developing new products with iTFA levels that are widely distributed in supermarkets, alongside other products that are low in iTFA levels (Stender et al.

[92] European Commission (2016) Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016.

[93] European Commission (2016) Inception Impact Assessment - Initiative to limit industrial trans fats intakes in the EU.

[94] Interview with The Danish Veterinary and Food Administration (5 July 2017)

2016).[95] Furthermore, given concern about the health impact related to consumption of products containing high levels of iTFAs , there seems little case for promoting their movement within the EU, 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 suggests that costs and impacts on pricing have been small, while many competitors across the EU have taken action to limit iTFAs, 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 iTFA content being sold together within a single MS. 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 iTFA content (which would be illegal under a 2% limit). In parallel, the variety of packaged products with low iTFA content has also increased in those countries.[96] 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 iTFA 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 iTFAs 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 MS, some of which may present high iTFA content and others low iTFA content. While the study team has not been made aware of evidence that demonstrates dual quality relative to levels of iTFA 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 iTFA intake.

Some of the stakeholders interviewed expressed support for action at EU level to harmonise standards on iTFAs 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% TFA 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 TFA issue in the EU market.

[95] 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

[96] 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

Overall, therefore, 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.

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 PHOs rather than placing limits on iTFAs, would introduce differences compared to existing legislation in the four MS, potentially creating some confusion in the market and requiring some further action to harmonise standards at national level.

Table 34 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 MS.
Option 1b	++	Significant, positive impact. Harmonisation of standards ought to remove iTFA 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 iTFA content provides information to facilitate informed consumer choice. Consumers not protected from high iTFA products. Firms producing in countries that have imposed iTFA 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 iTFAs across the EU. However, variable uptake could lead to varying rates of progress and compliance in different MS. In addition, focusing voluntary action on eliminating PHOs, when legislation in four countries places limits on iTFAs, could cause confusion.
Option 3b	+(+)	Significant, positive impact via harmonisation of standards. EU legislation would differ from that in 5 MS (given focus on PHO ban rather than iTFA limit), potentially creating some confusion and requiring harmonisation of existing national

Policy option	Expected impact	Comments
		rules.

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

4.2.2.7 Competitiveness and trade impacts

A number of countries have introduced legal limits on iTFAs in food (in the EU, Denmark, Latvia, Austria, Hungary, Lithuania) or banned the use of partially hydrogenated oils in food products (Canada, US). The majority of countries globally have yet to introduce legislation on iTFAs.

EU policy on iTFAs has the potential to impact on international trade in food products:

- Elimination of iTFAs from the EU food chain will help to position EU producers to sell to markets such as Canada and the US which have taken action to limit PHOs/ iTFAs;
- Limiting iTFA use, by increasing costs for food businesses, could potentially hamper competitiveness in price sensitive export markets;
- Legal limits on iTFAs/PHOs 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 iTFAs;
- Voluntary measures could potentially increase costs for EU producers, while exposing them to competition from low cost, high foreign TFA 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 to suggest that impacts on trade and competitiveness are likely to be significant, and in general the stakeholders interviewed 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 iTFA relevant food industry subsectors;
- Most companies active in international markets have already taken action to eliminate iTFAs from their products; and
- Any additional costs involved in eliminating iTFAs 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 commented on trade issues, a general view was that action to eliminate iTFAs from food is taking place internationally, and that taking action on iTFAs will tend to enhance rather than reduce competitiveness.

Table 35 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 iTFAs Additional costs may be a disadvantage in price sensitive export markets

Policy option	Expected impact	Comments
		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 iTFAs 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 TFA imports
Option 3a	Small	Voluntary action will position EU companies to exploit export markets where PHOs have been banned Additional costs may be a disadvantage in price sensitive export markets Potential for increased competition from low cost imports
Option 3b	Small	Legal limits will position EU companies to exploit export markets where there is legislation limiting iTFAs/ PHOs Additional costs may be a disadvantage in price sensitive export markets

4.2.2.8 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 employment (Food and Drink Europe, 2016)[97]. SMEs are particularly prevalent in particular subsectors – such as bakeries and food service – which face greater challenges in reducing iTFAs.

The Inception Impact Assessment (EC, 2016) noted that particular attention needs to be paid to the impacts of the different options, given the risk that any adverse effects may impact disproportionately on them.

Little specific evidence was found through the literature review or stakeholder interviews regarding the particular impact on SMEs resulting from action to address the iTFA issue. However, interviewees expressed a general view that SMEs may be disproportionately impacted, on the grounds that:

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

On the other hand, evidence also suggests that many SMEs will benefit from action by their suppliers to reformulate ingredients and this will provide simple routes to

[97] FoodDrinkEurope (2016) Data and Trends – European Food and Drink Industry 2016.

compliance with limits on iTFAs. 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[98]. 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.

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 products[99], 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. [100]

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.

Overall, therefore, the evidence suggests that:

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

[99] Salux (n.d.) Salux Project.

[100] Salux (2016) Food reformulation – supporting SMEs in improving the nutritional profile of their products (SALUX).

- 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 iTFAs 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 legislative 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 iTFAs may choose to opt out of a voluntary agreement (Options 1a and 3a). These options are therefore likely to have least impact on SMEs;

Transition periods will help to mitigate the above mentioned costs.

Table 36 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 PHOs 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

4.2.3 Environmental impacts

Measures to reduce the use of iTFAs 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, relates to the substitution of palm oil for PHOs, and the potential of increased palm oil production to cause deforestation.

The Inception Impact Assessment noted that the potential for options to limit use of trans fats to have negative environmental impacts by increasing palm oil use, but also observed that palm oil is only one of a number of the substitute ingredients available, that there was some evidence that major changes in production might not be expected, and that palm oil use has been relatively stable in recent years.

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 PHOs, and hence the extent to which limits on iTFA production result in increased demand for palm oil;
- 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 partially hydrogenated oils (typically soy) and alternatives.

4.2.3.1 Substitutes for PHOs

The principal source of iTFAs in food is partially hydrogenated vegetable oils, including soybean, cottonseed and other liquid oils.

There are a range of possible replacements for PHOs, 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[101].

Palm oil is an attractive substitute for iTFAs, 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 PHO, 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.

[101] European Parliament (2016) Trans Fats – Overview of recent developments. European Parliament, Briefing March 2016.

Evidence from Denmark, after the introduction of the trans-fat ban, indicates that saturated SFAs (including palm oil) were the main replacement in 66% of products[102].

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 PHO 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 iTFA in the food chain.

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[103]. 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 iTFAs, 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.

4.2.3.2 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 Parliament[104] report and subsequent resolution[105] noted that:

- Cultivation of palm oil over the last 20 years has been the cause of 20% of all deforestation[106];
- Tropical ecosystems, which cover 7% of the Earth's surface, are under increasing pressure from deforestation and the establishment of palm oil

[102] WHO (2015) Eliminating trans fats in Europe - A policy brief.

[103] BMI Research (2017) Industry Trend Analysis - Growing Obstacles for Palm Oil In Europe Despite Sustainability Efforts - JUNE 2017.

[104] European Parliament (2016) Draft Report - Palm oil and deforestation of rainforests.

[105] 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

[106] 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.

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 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[107].

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.

DG Environment of the European Commission commissioned 3Keel and LMC International to undertake a study on the environmental impact of palm oil consumption and on existing sustainability standards. This study has collected extensive evidence of palm oil production and consumption, its environmental, economic and social impacts, and of certification schemes.

LMC International advised ICF 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,

[107] European Sustainable Palm Oil Advocacy Group (2016) Position paper on palm oil production and deforestation.

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[108]. 7.2 million tons of palm oil were imported into the EU in 2016, of which about 50% were refined by FEDIOL companies[109].

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 PHOs 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"[110].

4.2.3.3 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.[111] 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.

4.2.3.4 Possible impacts of alternative options

Overall, while there is widespread concern about the possible effects of limits on iTFAs in driving increased palm oil consumption, the situation is complex and the resulting environmental impacts are difficult to predict. It is clear that:

[108] FEDIOL (2017). Palm Oil Monitoring.

[109] FEDIOL (2017) EU vegetable oils' sector works towards meeting the 2020 commitments on sustainable palm oil. Press Release.

[110] FDA (2015) Final Determination Regarding Partially Hydrogenated Oils. A Notice by the FDA on 06/17/2015.

[111] COWI (2017). Feasibility Study on options to step up EU Action against Deforestation – Part II.

- Palm oil is an attractive substitute for PHOs, particularly in the baked goods sector, on account of its physical properties and cost-effectiveness;
- It is therefore likely that limits on iTFAs will lead to increases in use of palm oil in products currently using PHOs. Overall consumption of palm oil in the EU will not necessarily increase, as it is forecast 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 PHOs could be met from sustainable sources, if consumers were willing to pay a price premium;
- As a result, action on iTFAs need not necessarily have an adverse environmental impact. However, there are no guarantees that any palm oil used to replace PHOs 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 PHOs 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 iTFAs 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 iTFAs. On this basis, options 1b and 3b can be expected to lead to greater environmental changes than Options 1a, 2 and 3a.

Table 37 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 positive or negative	Net effect unclear for reasons given above Impact likely to be greater than for voluntary or 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

Policy option	Expected impact	Comment
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

4.2.4 Combined options

Additionally, certain combinations of options are to be investigated. These are:

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

4.2.4.1 Combining mandatory labelling with legislation (2 + 1b or 2 + 3b)

Social impacts

Any additional benefit of adding labelling requirements to a legal limit on iTFAs or a ban on PHOs is expected to be limited.

As discussed before, options 1b and 3b are expected to have the greatest effect on iTFA intake, delivering the largest savings in healthcare costs and the highest reduction in DALYs. Combining one of the two options with labelling will not have a significant additional impact on the population iTFA 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 iTFA 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 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 38 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.

4.2.4.2 Combining mandatory labelling with voluntary agreement (2 + 1a or 2 + 3a)

Social impacts

Combining labelling requirements with a voluntary agreement to limit iTFAs or PHOs 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 DALYs than options 1b and 3b. Combining a voluntary agreement with labelling may be expected to have a higher impact in reducing the population iTFA intake and will lead to greater cost savings and DALYs reduction than adopting only one of the two options.

The model assumes that when combining options 2 and 1a or 3a the iTFA intake from packaged food decreases by 50% after two years (model assumption for option 2) and additionally the iTFA 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 39 illustrates the cost savings resulting from combining the assumptions for ITFA intake of the two options together with those resulting from each option compared to the baseline scenario (main scenario 15y). They are calculated by subtracting a given policy healthcare costs to the baseline ones.

Table 39 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 40 presents the estimated number of DALYs avoided by combining the two options, compared to the baseline scenario (main scenario 15y). They are calculated by subtracting a given policy DALYs to the baseline ones.

Table 40 DALYs averted by policy option (million)

Policy option	Total DALYs 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 DALYs. However, the combination of options (2 with 1a or 3a) is estimated to avoid 1.3 million DALYs, 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 38 above. These costs are high compared to Options 1b and 3b, as a result of the high relabelling and promotional costs of Option 2.

5 Comparison of Options

This section considers:

- How the options compare in the expected performance against the stated general and specific objectives;
- How the options compare in effectiveness, efficiency, coherence and with reference to the proportionality principle.

5.1 Appraisal of options' performance against the stated objectives

This section considers how the options perform against the stated general objectives:

- Ensure a high level of health protection for EU consumers;
- Contribute to reducing health inequalities, one of the objectives of Europe 2020;
- Contribute to the effective functioning of the Internal Market for foods that could contain iTFAs.

…and the specific objectives, which are to:

- Reduce intake of industrial trans fats in the entire EU for all population groups;
- Ensure that the same conditions apply in the EU to the manufacturing and placing on the market of foods that could contain iTFAs;
- 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 iTFAs.

5.1.1 General objective 1: Ensuring a high level of health protection for EU consumers

5.1.1.1 Direct health impacts

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

The legislative options (option 1b, 3b) deliver larger benefits than the voluntary agreements (VAs; 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 FBOs that are still placing products high in iTFAs 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' TFA content. In that context, the figures for options 1a, 3a and 2 in Table 41 and Figure 4 may be regarded as upper estimates of potential impact.

The stream of health benefits is expected to follow close behind the action taken by FBOs to reduce iTFAs. Experience from countries that have acted to reduce iTFA intake suggests that signalling that action is going to be taken can result in benefits starting before the legislation comes into force as some firms take proactive action in advance of the deadline.

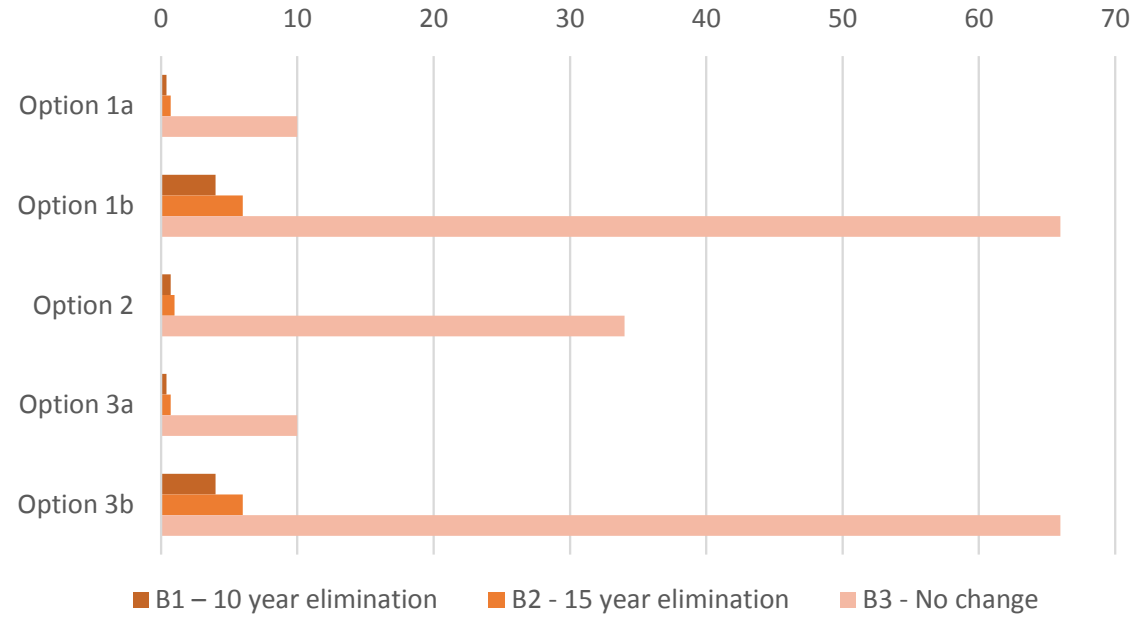
The health impacts of derogations providing for authorised use of iTFAs for technical applications in low fat products under option 1b or PHOs under option 3b are uncertain.

Table 41 Appraisal of options' performance in relation to General Objective 1: Health gains by option under different variants of the baseline scenario (total DALYs 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 4 Health gains by option under different variants of the baseline scenario (total DALYs gained, million)



Source: ICF

5.1.1.2 Direct and indirect economic impacts of changes in health status

The appraisal suggests that all options deliver savings in direct and indirect economic costs of iTFA-related disease. These comprise changes in:

- healthcare expenditure: This is a benefit that accrues principally to healthcare service providers and thence 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 CAD incidence triggered by EU iTFA 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 CAD is avoided).

The analysis, using the JRC model, has calculated the present value of benefits over an 85 year horizon[112]. In baseline variants B1 and B2 iTFAs would be phased out after 10 and 15 years respectively so iTFAs would not be causing new and additional health impacts after those dates, although short term changes in intake would continue to impact on health outcomes over the 85 year period. In variant B3 iTFA 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 (and associated

[112] The presentation here replicated the JRC model outputs in combining the direct and indirect costs. ICF will look at separating the two categories of impact in future presentations of the results.

healthcare expenditures). The monetary benefits under B3 are therefore substantially larger than under the other two variants (Table 42,

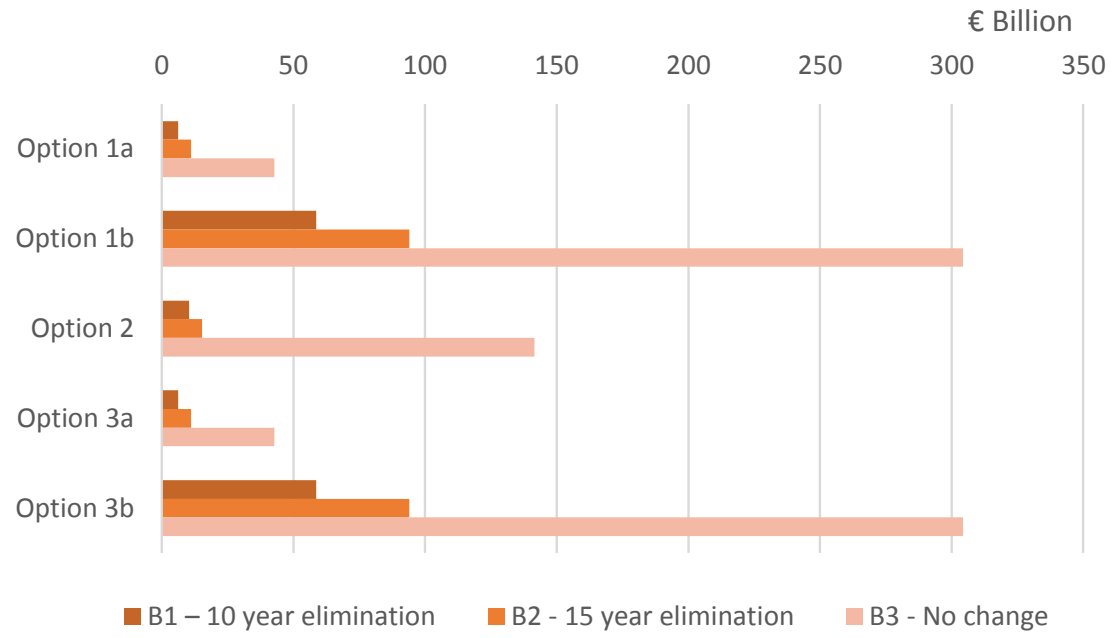
Figure 5).

The analysis shows that the uncertainty in the baseline is not grounds for inaction – the slower the phase-out of iTFAs in the baseline then 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.

Table 42 Direct and indirect cost savings associated with lower CAD disease burden by option under different variants of the baseline scenario (M EUR)

	Savings from lower disease burden		
Policy option	**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 5 Direct and indirect cost savings associated with lower CAD disease burden by option under different variants of the baseline scenario (billion EUR savings, present value)



The legislative 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 iTFA intake under a PHO ban is the same as the intake under a 2% limit) mean that 1b and 3b are equivalent in the healthcare savings delivered. The substantive point is that both legislative options 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 PHO 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 incremental effects are not available.

As with the human health benefits, there is a much higher level of confidence (assurance) that the legislative options will deliver the scale of benefits indicated – there are significant uncertainties attached to the estimate of benefits of the VAs and labelling, and the values indicated are likely to be upper limits. This assumes compliance by FBOs with the legislation, compliance that will be encouraged by effective communication with FBOs, and 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 iTFA 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 between the two measures. Avoided costs have been 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.

5.1.2 General objectives 2: Contribution to reducing health inequalities

The legislative options (1b, 3b) are expected to do much more to tackle present iTFA-related health inequalities than the alternative options. All food consumers would benefit irrespective of social-economic, demographic status or consumption patterns (e.g. propensity to eat out of the home). As such, the legislation options are expected to have a much stronger (positive) impact on the health inequalities linked to iTFA intake than either a voluntary agreement or labelling approach. Indeed, the legislation options could potentially remove all iTFA-related health inequalities. The greatest absolute benefits are expected to occur where the prevalence of iTFA-related CAD morbidity and mortality is largest.

The impact of the alternatives is constrained by the limits to engagement by FBOs that have not already acted, and limits to responsiveness of consumers to TFA-related additions to the back-of-pack nutrient declaration.

The performance of each option is summarised in Table 43.

Table 43 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 FBOs servicing the residual high-intake socio-demographic groups. Unlike option 2, Option 1a will

Policy option	Expected impact	Comment
		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 iTFA 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 iTFA-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	(+)	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 FBOs 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. The effect will be weaker than in Option 3b because less impact on overall iTFA intake.
Option 3b	++	Strong, positive impact. Option is expected to eliminate iTFA-related health inequalities with a high level of confidence.
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 containing iTFAs 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 action 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 legislative options.

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

5.1.3 General objective 3: Contribute to the effective functioning of the Internal Market for foods that could contain iTFAs

The current variation across the EU in the extent to which iTFA intake is actively controlled through legislation and other measures potentially inhibits the smooth and efficient functioning of the Internal Market.

The options vary in the extent to which they address this issue. The legislative options (Options 1b and 3b) imposes a uniform approach across all entities that place food on the market, from food manufacture to food service and across all Member States.

Option 2, which imposes a labelling obligation, would provide a consistent level of visibility for consumers of iTFA content in products but not provide consistent protection against the health impacts of high iTFA products for those not aware of the risks. As it does not set limits for iTFA content, it would also not fully address legislatively-driven cost differentials between producers in national markets where limits on TFA 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 suggests that participation will be at best partial and they will not achieve the systematic reformulation across food manufacturing and food service that the legislation options would deliver.

Options 3a and 3b, which aim to eliminate PHOs rather than place limits on iTFAs, would introduce differences compared to existing legislation in the five MS, 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 44 (which replicates Table 34) summarises the options' performance against this general objective.

Table 44 Appraisal of options' performance under general objective 3: Contribute to the effective functioning of the Internal Market for foods that could contain iTFAs

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 five countries. However, variable uptake could lead to varying rates of progress and compliance in different MS.
Option 1b	++	Significant, positive impact. Harmonisation of standards ought to remove iTFA 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

Policy option	Expected impact	Comment
		standards, though the uniform requirement for transparency on iTFA content provides information to facilitate informed consumer choice. Consumers not protected from high iTFA products. Firms producing in countries that have imposed iTFA 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 iTFAs across the EU. However, variable uptake could lead to varying rates of progress and compliance in different MS. In addition, focusing voluntary action on eliminating PHOs, when legislation in five countries places limits on iTFAs, could cause confusion.
Option 3b	+(+)	Significant, positive of impact via harmonisation of standards. EU legislation would differ from that in five MS (given focus on PHO ban rather than iTFA limit), potentially creating some confusion and 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 legislative 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.

5.1.4 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 45.

Table 45 Appraisal of options' performance under specific objective 1: reducing iTFA 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 FBOs servicing the residual high-intake socio-demographic groups. Unlike Option 2 this will directly

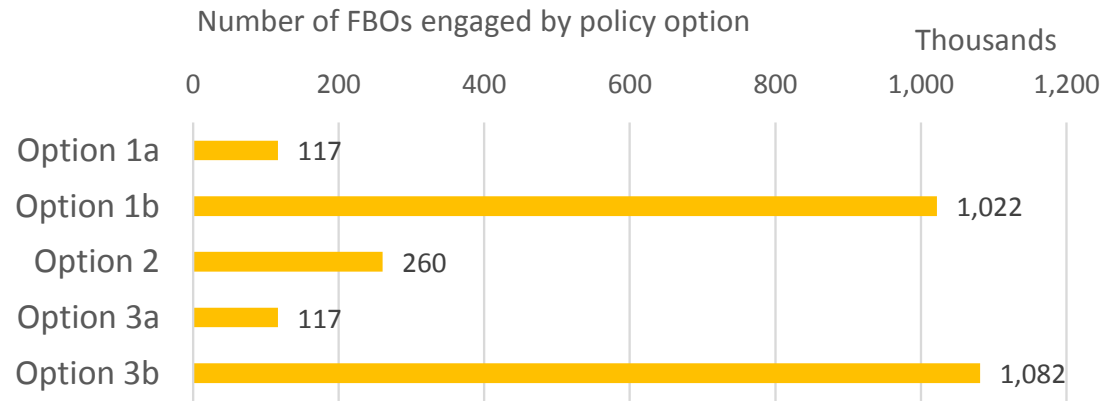
Policy option	Expected impact	Comment
		change product characteristics rather than requiring change in consumer behaviour, thus benefiting all groups including those facing greatest health impacts at present. Weaker effect than Option 1b because of weaker effect on overall iTFA intake.
Option 1b	++	With compliance, this option is fully effective in bringing iTFA intake down to a low level across the EU population.
Option 2	(+)	Labelling food products for iTFA has the potential to reduce intake through two mechanisms – consumers uses the iTFA data on the nutrient declaration to choose lower products that are lower in iTFA and companies voluntarily reformulating their products so as to be able to quote a lower iTFA figure on the nutrient declaration. Consumer awareness of the health consequences of high iTFA 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	++	With compliance, this option is fully effective in bringing iTFA intake down to a low level across the EU population.
Option 1a/3a + 2	+	Combining labelling with voluntary agreements is expected to have a modest additional positive impact on iTFA 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 action 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.

5.1.5 Specific objective 2: Ensure that the same conditions apply in the EU to the manufacturing and placing on the market of foods that could contain iTFAs

The results for this specific objective mirror those for General Objective 3 on the internal market, as described in Table 45. The options vary in the number of FBOs directly affected (Figure 6). These differences are determined by the sectors engaged (e.g. non-packaged goods are excluded from Option 2) and the level of participation expected (which is less than 100% for voluntary agreements). An important qualifying comment is that most of those subject to legislation will not need to act to reformulate products (because they do not sell products that contain iTFAs or because they have already acted to reduce iTFA levels). There is uncertainty about the number of firms that will engage in the voluntary agreements.

Figure 6 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

5.1.6 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 iTFAs

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 PHO 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.

Table 46 Appraisal of options performance under specific objective 3: Ensure legal certainty for FBOs as regards the rules applicable to the manufacturing and placing on the market of foods that could contain iTFAs

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 iTFAs, 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.

5.2 Effectiveness

Effectiveness is measured by the extent to which options are expected to achieve the target objectives. We recall at this point that the general objectives of EU action on iTFA are to:

- Ensure a high level of health protection for EU consumers;
- Contribute to reducing health inequalities;
- Contribute to the effective functioning of the Internal Market for foods that could contain iTFAs.

The main findings relevant for assessing the effectiveness of each option in achieving these objectives is specified in Table 47.

Table 47 Effectiveness of all options and combinations of options under variant 2 of the baseline scenario

	Option 1a	Option 1b	Option 2	Option 3a	Option 3b	Options 1a/3a + 2	Options 1b/3b + 2
DALYs 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, both of which would impose legal restrictions on the use of ingredients high in iTFA in food production 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, which would impose new labelling rules, 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 iTFAs.

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

5.3 Efficiency (balance of costs and benefits)

Efficiency considers the relationship between benefits and costs. 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. It is also important to have regard for the degree of uncertainty surrounding the quantified estimates.

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. The authors believe that the significant costs have been quantified. There is uncertainty about the environmental impacts, which could be positive or negative. The costs of agreeing a shared definition of PHOs and defining a common test for detecting PHOs (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 is 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 reduced incidence of CHD. Other adverse health effects linked to TFAs 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 48 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 48 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 iTFAs in food sold direct to consumers appears to be a very efficient use of resources. Legislation to limit iTFAs offers the largest potential net gains, followed by legislation to ban PHOs. A legal limit on iTFA content avoids the need to agree a PHO definition and to establish the capacity across the EU to test oils for compliance (both for enforcement and for assurance within the supply chain).

The finding that legislation to limit iTFAs or ban PHOs 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 legislative limits on TFAs/ PHOs.

Costs and Benefits of TFA 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 iTFA intake in the country was at high levels. It estimated that in all cases the total food costs of reducing TFA "*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% TFA 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 PHO 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[113].

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
Net Benefits (BN USD)	5	130	430

Source: https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

The same result emerges when looking at cost-effectiveness as measured by the cost (in EUR) of the average DALY saved, as shown in Table 490. Option 1b delivers DALYs 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 legislative options emerge as a highly cost-effective mechanism for 'purchasing' health improvements in the EU.

Option 2 imposes significant 'deadweight costs' on the food manufacturing sector – it imposes additional labelling costs on FBOs for products that contain no iTFAs and where there is therefore no direct benefit (except to provide a point of reference against which other high-iTFA products might be assessed). Firms that have already removed iTFAs from their products and firms whose products will never contain iTFAs 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.

Table 49 Cost-effectiveness measure of options by variant of the baseline scenario

Policy option	EUR per DALY 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 DALY given the greater uncertainty about the efficacy of labelling and voluntary agreements in changing intake.

5.4 Coherence with other EU policy objectives

The evidence collected for this report raised some concerns from stakeholders regarding the coherence of some of the proposed interventions with existing EU

[113] FDA (2015) Final Determination Regarding Partially Hydrogenated Oils. A notice by the FDA on 06/17/2015 .

legislation. The principal issue was an industry concern that a legal ban on PHOs (Option 3b) would not be aligned with the objectives pursued in Regulation (EU) No 1169/2011 on Food Information to Consumers and in Regulation (EC) No 1924/2006 on Nutrition and Health Claims.

There were also 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 the quantity of iTFA. That is because consumers who have been monitoring the mention of "hydrogenated oil" on labels to avoid iTFAs may not understand the difference between "partially" and "fully" hydrogenated oil. As a result, products compliant with the legal limit on iTFA content but containing fully hydrogenated oil could be penalised, according to industry.

5.5 Proportionality

Based on the appraisal summarised above the legislative options appear to be the most proportionate solution to the problem of the health consequences of iTFAs consumption and the internal market effects of uncoordinated approaches to tackling them. They are broad in scope but the more significant costs are imposed only on FBOs that have a problem to be addressed (i.e. where a firm needs to reformulate a product to achieve compliance). 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.

5.6 Specific tests

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 FBOs affected. The study team has collected evidence to document the perspective from SMEs. This has included direct interviews with a small number of SME representatives (see Table 1). 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.

The assessment of the impacts on SMEs is summarised below.

5.6.1 SME test

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 50. 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 50 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 iTFAs), 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 51. 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 51 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 process.

5.7 Discussion of information gaps and uncertainties

Uncertainties and gaps have been made explicit through the document, and are also outlined in Annex 5 of this report. 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, 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 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 iTFA 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 PHO ban on iTFA intake. In this analysis the impact has been assumed to equivalent to that of a 2% limit on iTFA 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 iTFA content or a ban on PHOs;
- The costs of introducing a new testing regime for PHOs and of agreeing a definition of PHOs at EU level (options 3a and 3b);
- The potential level of participation of FBOs 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 iTFA intake at the time the agreement starts);
- The extent to which modifying the nutrient declaration to include iTFA 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.

Our view is 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 legislative options; and
- The relative performance of different options on measures of effectiveness and efficiency.

6 Conclusions and recommendations

This study to support the impact assessment of the initiative to limit iTFAs in the EU delivers a clear message. Having considered social, economic and environmental impacts of the policy options identified by the European Commission in its Inception Impact Assessment, the study has come to the following conclusions:

- The legislative policy options (1b and 3b) are those that would perform best against all the criteria of the assessment:
    - Health benefits
    - Reduction in health inequalities
    - Improvements in the functioning of the internal market

  - Efficiency
  - Proportionality
- They provide assured protection to consumers against the health impacts of iTFAs across all socio-demographic groups. They would also help to ensure a consistent standard of food quality across the EU.
- Legislation imposing a maximum limit to iTFA content of products sold direct to consumers (option 1b) performs better in terms of efficiency and coherence with existing Member State law on TFAs than a legal ban on PHOs (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 PHO 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 TFA 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), whilst positive, are smaller and much less certain than those of the legislative alternatives. The members of the food business organisations that are most likely to participate in EU voluntary agreements have already reformulated their products to reduce iTFA levels or eliminated iTFAs from their products completely. Research suggests that the businesses responsible for much of the residual iTFA 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 legislative alternatives.
- The findings above, in terms of the relative performance of the different options, hold across all foreseen variants of the baseline scenario.

The analysis suggests that a legal limit on iTFA content set at 2% of fat and the ban on PHOs are the best performing options. The application of a 2% limit is consistent with the approach taken in those Member States that have already legislated, and industry voluntary initiatives.

Annex 1 Terms of reference

1. TITLE OF THE ASSIGNMENT

SANTE/2016/E1/055 - Study to support the Impact Assessment on the initiative to limit industrial trans fats intakes in the EU

2. CONTEXT OF THE ASSIGNMENT

2.1. Issue at stake

Trans fatty acids (also called "trans fats" and abbreviated as TFAs) are a particular type of unsaturated fatty acids that are present in foods. Trans fats can be produced industrially, due to the food manufacturing process, and can also be naturally present in food products derived from ruminant animals. Consumption of trans fats increases the risk of Coronary Heart Disease (CHD) more than any other macronutrient compared on a per-calorie basis. For this reason, health authorities all over the world recommend to reduce their intake in the diet.

Although different actions were taken in different Member States on trans fats and intakes of trans fats in the EU 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. 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.

In light of the above, the Commission is currently considering an EU-based initiative to limit trans fats intakes in the diet of EU consumers, 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 Inception Impact Assessment (IIA) on the initiative to limit industrial trans fats intakes in the EU (published on 11 October 2016) provides more detailed info on the context and all the different aspects of the EU initiative (see link at the end of these terms of reference).

2.2. Evolution

In a report adopted on 3 December 2015 regarding *trans fats in foods and in the overall diet of the Union population*[1], the European Commission concluded that setting 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.

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3. DESCRIPTION OF THE ASSIGNMENT

3.1. Purpose and objective of the assignment

The purpose of the study is to identify, collect and analyse evidence concerning the impacts and trade-off of the alternative policy options considered by the European Commission to limit industrial trans fats intakes in the EU, against the reference of the baseline of no EU action, as described in the IIA.

Quantitative and qualitative data on the expected significant economic, social and environmental impacts should be provided and analysed in line with the quality standards required in the European Commission's Better Regulation guidelines.

3.2. Specific Tasks

The contractor shall quantitatively characterise the baseline taking as starting point the important amount of information on trans fats that the Commission has already collected in the preparation of the report on the topic that was adopted on 3 December 2015 (to ensure data comparability) and integrating such data with additional quantitative elements as appropriate to its analysis (e.g. costs resulting from the fragmentation of the Internal Market for a food business operator active today in different Member States).

The contractor shall objectively screen key impacts of the selected policy options (an indicative list of impacts to be screened is to be found in Annex I for reference) in order to identify all potentially important impacts to be retained for detailed analysis – considering both positive/negative, direct/indirect, intended/unintended as well as short-/long-term effects. The significance of the impacts shall be assessed taking into account their expected magnitude, their relevance for the stakeholders, the importance for the Commission's horizontal objectives and policies, their likelihood and their timescale. A well-justified choice should be provided on the most significant impacts to be retained for detailed analysis.

The retained impacts should be assessed quantitatively, if possible, as well as qualitatively. The contractor shall gather data and analyse positive (i.e. the benefits), negative (i.e. the costs or adverse impacts), intended, unintended, direct, indirect, short-term and long-term impacts.

The policy options should be analysed individually.

The combination of different policy options should also be analysed by the contractor if the impacts resulting from these combinations are different than a simple addition of the impacts of the options taken individually.

Certain aspects of the policy options described in the IIA (e.g. different limits) are left open for further consideration and the contractor might have to assess how the impacts of the options would vary depending on the chosen value of these variables. The details of this task will be further agreed with the Commission.

When analysing each impact resulting from the different policy options, the contractor should identify who would be specifically affected. An indication of the categories of stakeholders that are expected to be affected by the different policy options is provided in the IIA and an indicative list of relevant stakeholders at EU level is provided in Annex II to these terms of reference. The contractor should take this information into account for its assessment. Particular focus should be on SMEs and manufacturers of non-pre-packed foods. Evidently, impact on other stakeholders should also be considered by the contractor, if significant impacts result from the analysis.

In order to triangulate its findings (to validate the data gathered) on the impacts of the different policy options, the contractor shall carry out targeted consultations of stakeholders with a specific interest in the initiative at national, EU and international level (consumers' and health NGOs, food business operators) and with public authorities, as appropriate.

Taking all the elements provided above into account, the contractor is required to answer the following questions on the impacts of the different policy options:

Economic impacts

What will be the **operating costs** for food business operators? When analysing these costs, the contractor shall also estimate whether specific sectors will be particularly affected and how these costs could be mitigated by the introduction of different transition measures or derogations (to be discussed with the Commission).

What will be the impact on the **functioning of the Internal Market**, having regard in particular to the **free circulation of goods** and **legal certainty**?

What will be the impact on the **offer of products to consumers**, the **prices** paid by them and, more generally, **consumers' choice**? Regarding consumer choice, some 'emblematic' food products where substitution of trans fats may be a challenge (confectionary chocolate, "éclairs", doughnuts, etc.) should be specifically covered.

What will be the impact on **industry competitiveness** and the ability of business to **innovate**? When analysing the impact on competitiveness, the contractor shall distinguish between competitiveness in the EU and competitiveness on the global scene as well as between sectoral competitiveness and competitiveness in the broader food sector.

What will be the impact on **simplification of legislation?** Would there be **administrative burden** related to information obligations derived by EU requirements imposed on food business operators? (this should be then estimated in a quantitative way).

What will be the impact on **international trade** with third countries? When analysing this impact, the contractor shall focus on imports in the EU, exports outside the EU and on regulatory convergence.

What will be the impact for **public administrations** in terms of enforcement or other? The contractor shall pay particular attention to how the different policy options can be effectively enforced by competent authorities (in particular as regards distinguishing between industrial and ruminant trans fats) and at what costs. In this context, the contractor shall keep in mind that upon SANTE request, JRC has agreed to carry out further research on methods to distinguish between ruminant and industrial trans fats in the same product. This research will be finalised by the end of next year. The impact on public budget related to the reduction of CHD will be assessed in Question 9.

What will be the impact on **SMEs and micro-enterprises**? The contractor shall estimate how these costs could be mitigated by the introduction of different transition measures or derogations (see question 1).

Social impacts

What will be the impact on **protection of consumers' health**? When analysing this impact, the contractor shall pay particular attention to a modelling study carried out by JRC comparing the cost-effectiveness of different strategies to reduce industrial trans fats intakes in the EU population[2]. Further data collected by the contractor will be used to integrate the JRC's conclusions. The contractor shall also look at the impact of the different options on specific population groups and their potential for **reducing health inequalities**.

What will be the impact for **consumers' information**?

Environmental impacts

What will be the impact on the **environment**? The contractor shall pay particular attention to the impact of the options on palm oil consumption and production, with a special focus on developing countries.

Other questions

Is there any other significant impact that can be expected from the implementation of the different policy options? If so, please analyse these impacts.

Are there Member States currently working on the preparation of legislation on trans fats? What other Member States will adopt legislation in the absence of EU action?

3.3. Methodology

The methodology of the study should be drawn up by the contractor and will have to be agreed by the Commission. The contractor must develop a sound methodology and comply with the policy requirements, quality and standards necessary to conform with the Commission's Better Regulation Guidelines. In particular, all relevant impacts should be assessed quantitatively, if possible, as well as qualitatively.

The entire approach proposed by the contractor must be clearly set out in the bid. The contractor should provide, as part of the offer submitted, the choice and a detailed description of the methods and tools that are considered appropriate to successfully address the assignment in general and the specific tasks/questions listed in section 3.2 in particular. The methodology proposed in the offer shall be further developed in the Inception Report. Advantages, limitations and risks involved in

using the proposed tools and techniques should be explained. There should be a clear link between ~~the questions addressed and the c~~orresponding methodology proposed. The questions can be further elaborated, e.g. by providing operational sub-questions under each question.

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–

The contractor can propose different tools for data collection and analysis as they see fit, including where relevant (but not limited to): systematic literature review / desk research, questionnaires, surveys and interviews, workshops, bibliometrics, focus group interviews, concept mapping, case studies based on purposive sampling, etc. However, it is essential that the contractor:

Carries out an appropriate systematic literature review / desk research in different languages covering for example, but not limited to: academic scientific papers, publications from competent authorities of EU/non-EU countries having taken action on trans fats, documents of EU institutions, relevant stakeholders' positions at national/EU/international level, databases…

Incorporates to its data the important amount of data on trans fats that the Commission has already collected in the preparation of the report on the topic that was adopted on 3 December 2015. The contractor must build on such previously collected data in order to ensure data comparability and avoid duplication of work. In this context, the study prepared by the Commission's Joint Research Center (JRC) "*Trans Fatty acids in Europe: where do we stand?*" is of particular note.

Carries out targeted consultations of stakeholders with a specific interest in the initiative at national, EU and international level (consumers' and health NGOs, food business operators) and with public authorities, as appropriate, in order to triangulate its findings (to validate the data gathered) on the impacts of the different policy options[3]. The contractor should in particular aim at collecting data at local level, from SMEs and manufacturers of non pre-packed foods. Such consultation should be based on a representative sample of SMEs and manufacturers of non pre-packed food. The contractor should also reach out to public authorities of countries (EU and non EU) having taken action on trans fats (in particular through legally-binding measures) in order to collect data on enforcement issues (see question 7). The tools and consultation material to be used for the targeted consultations shall be proposed by the contractor and will have to be agreed by the Commission.

Data should be aggregated for presentational purposes but raw data shall also be provided to the Commission. Data shall be presented in a consistent format, to allow for comparisons.

The reasoning followed in the study, indicating among other things, the underlying hypotheses of the reasoning, and the limitations of the analysis, must be clearly described. The contractor must support findings and recommendations by explaining the degree to which these are based on opinion, analysis and objectively verifiable evidence. Where opinion is the main source, the degree of consensus and the steps taken to test the opinion should be given.

In case of quantitative estimation/assumption, these should be clearly presented. Whenever an assumption is particularly important or uncertain, sensitivity analysis should be used to check whether changing it would lead to significantly different results.

If the identified impacts are considered to occur at different times, this should be reflected in the assessment, discounting monetized estimates as appropriate when these are available.

The targeted consultations to be carried out by the contractor in the context of the assignment are not to be confused with the open public consultation that shall be carried out by the Commission at a later stage (after the contractor has finalised its targeted consultations), in order to provide a final possibility for the general public to comment on the trans fats initiative.

Impacts should be assessed from the point of view of society as a whole although distributional effects and cumulative burdens on individual parties should also be proportionately assessed and considered.

Whenever impacts are aggregated, any double counting should be avoided.

The data gathering and analysis carried out by the contractor shall cover the EU28 Member States. While it is possible that detailed data cannot be obtained for all the EU Member States, the study should be based on data from as many Member States as possible in order to ensure representativeness of the EU28. Extrapolations should be carried out only if they can be adequately justified. They should be strongly evidence-based and the methodology and assumptions used should be clearly described.

3.4. Reporting and deliverables

3.4.1 General reporting requirements

The present assignment includes the submission of a series of deliverables: data, reports and presentations.

The contractor will deliver the following **reports** at key stages of the study process *: inception report, interim progress report, draft final report* and *final report*. Each report should be written in English, professionally edited, and critically assessed as it provides the basis for tracking the quality of the work done by the contractor.

These reports will be submitted to the Commission who will transmit them to the established Inter Service Steering Group (ISG), which may ask for complementary information or propose adjustments in order to redirect the work as necessary. Reports must be approved by the Commission. With work progressing and in the light of new findings, revisions of reports already approved may be necessary.

The reports have to be clear, concise, unambiguous and comprehensive. They should also be understandable for non-specialists. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published. A structured and precise elaboration of add-ons based on previous deliverables at every stage of the process is requested (for example, this could be done via colour-coding parts of the report developed at the offer, inception, interim and draft final stage). Each report (except the final version of the Final Report) should have an introductory page providing an overview and orientation of the report, and an update on the progress of the study work.

The reports should be provided to the Commission in both MS-Word and Adobe Acrobat (PDF) format with the charts in Excel. They should be accompanied, where requested, by appropriate annexes and delivered in accordance with the deadlines and requirements set out in the Terms of Reference and agreed with the Commission. The Final Report shall in addition be delivered in five hard copies. The Commission will hold the copyright of the reports.

Furthermore, the following **report** shall be delivered:

Kick-off meeting report

Within 2 weeks after signature of the contract, the contractor will participate in a kick-off meeting with the Commission services, which will be held in Brussels. The overall objective of a kick-off meeting is to arrive at a clear shared understanding of what is required by the Commission. In particular, the meeting should therefore accomplish the following:

Introduction to the contractor's team members and verification of the composition and eligibility of the contractor's team.

Review of the project scope and objectives and ensure the contractor's general understanding of the Terms of Reference.

Review of the proposed general approach to the work (overall planning/timelines and milestones, methodology, project responsibilities and deliverables etc.).

Identification of main challenges.

Confirming next steps.

Following the meeting, a clear report detailing agreements and conclusions should be drawn up by the contractor and approved by DG SANTE.

3.4.2. Key deliverables

Inception Report – *within 1,5 months of the start of the execution of the tasks (article III.2.2. of the specific contract)*

The Inception Report, which shows the understanding of the task by the contractor, completes the structuring phase of the study. It aims to describe the organisation of the work, and to adapt and substantiate the overall approach, the methodology required for each task and/or study question and the work plan outlined in the proposal. It should set out in detail how the proposed methodology will be implemented, and in particular lay out clearly in tabular form how the method allows each task and/or study question to be answered via establishment of judgement criteria and within these, of indicators. In addition, the table should have a further column indicating the tools chosen. The Inception Report should include enough detail for the ISG to gain a good understanding of the tools and related methodological steps proposed.

The Report may complete and/or suggest additional study questions the contractor considers suitable. As such, this document will provide an opportunity to make a final check on the feasibility of the method proposed and the extent to which it corresponds with the task specifications and questions.

The known sources of information, use of tracers, contact persons in Member States, as well as the way the contractor will interact with Member States representatives will be fully clarified at this stage.

The ISG will discuss the submitted Report with the contractor in a meeting to be held in Brussels, and may request changes and improvements. The final version of the study questions suggested by the contractor and the indicators to be used will be validated by the ISG at this stage.

After the meeting, the contractor will submit a final version of the Inception Report within two weeks.

Interim Report – *within* 4,5 *months of the start of the execution of the tasks*

This Report is an opportunity to check whether the study is on track and whether it has focused on the specified information needs. The Report is to be produced after the desk and field research has been completed, and should, to the extent possible, include some preliminary conclusions. The Report must as a minimum provide:

An overview of the status of the project;

A description of problems encountered and solutions found;

A description of data gathered;

A summary of initial findings and results of the data gathering;

An assessment of the data, whether it meets expectations and will provide a sound basis for responding to the questions;

A conclusion whether any changes are required to the work plan, or any other solutions should be sought in order to ensure that the required results of the study are achieved. If any such issues are to be identified, they must be discussed in the meeting with the ISG dedicated to this Report;

A proposal for the final structure of the Final Report, as well as a structure of the Executive Summary.

The contractor will submit a final Interim Report with the necessary updates after discussion with the ISG.

Draft Final Report – *within 6,5 months of the start of the execution of the tasks*

This document should deliver the results of all tasks covered by these Terms of Reference, and must be clear enough for any potential reader to understand.

The structure of the Report should follow a broad classification into the following parts:

Main report: The main report must contain a description of the subject evaluated, the context of the study, the study process and the methodology used (including an analysis of its strengths, limitations and possible bias). It must also present, in full, the results of the analyses, conclusions and recommendations arising from the study.

Annexes: These must collate the technical details of the study, and must include, by way of example, questionnaire templates, interview guides, any additional tables or graphics, and references and sources. One of the Annexes will contain the Task Specifications/questions.

The draft Final Report will be discussed with the ISG and the contractor in a meeting. The contractor is expected to present the draft Final Report in a summarized way at the occasion of the meeting.

Raw data

Together with the draft final report, before its approval, the contractor shall deliver all raw data collected during the contract execution. Raw data is considered to be any primary data that is directly gathered from the source (survey answers, interview transcripts, etc.)

Final Report – *within 9 months of the start of the execution of the tasks*

The Final Report follows the same format as the draft Final Report. Furthermore, it is accompanied by:

An **Executive Summary** of no more than **10** pages in at least EN and FR[4]. The Executive Summary summarises the study's main conclusions, the main evidence supporting them and the recommendations arising from them.

An **Abstract** of no more than 200 words. The purpose of the abstract is to act as a reference tool helping the reader to quickly ascertain the study's subject.

A **One-Page Summary** of key messages (conclusions in bullet form) of the study.

The Final Report must take into account the feedback from the ISG on the draft Final Report, insofar as this does not interfere with the autonomy of the contractor in respect of the conclusions they have reached and the recommendations made.

The Commission will publish the Final Report, the Executive Summary, the Abstract, the key messages and the annexes on the Commission's central website.

The Final Report must be structured along the lines of common standards, formatted as requested by Publication Office, respecting the Commission's visual identity and containing all identifiers and disclaimers.

In view of its publication, the Final Report by the contractor must be of high editorial quality.

The contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes. At the request of the Commission, the contractor should provide a maximum of two presentations to interested stakeholder groups.

3.5. Organisation and timetable

The contract will be managed by Unit E1 (Food Information and composition, food waste) of the European Commission Directorate-General for Health and Food Safety.

An Inter Service Steering Group (ISG) will be involved in the management of the study. The responsibilities of the ISG will include:

Establishment of the Terms of Reference;

Providing the external contractor with access to information;

Supporting and monitoring the work of the external contractor;

Assessing the quality of the reports submitted by the external contractor, while ensuring that the contractor's independence is not compromised.

3.5.1 Expertise required from the study team

As part of the tender documentation, the contractor is responsible for proposing the adequate team to be involved in the study, describing their skills and qualifications, quantifying the input of each member of the team in terms of days and explaining the distribution of tasks within the team. The team must have the capacity to work in the different fields and languages needed.

Considering the scope of the study, the team must have proven experience in the fields of law (e.g. regulatory measures), nutrition, health and economics in relation to the questions presented.

1 page = 1500 characters

In particular, among the members of the team, the following should be clearly identified:

A member of the team with at least 5 years expertise in impact assessments/evaluations of public policy initiatives. Experience with similar initiatives in the field of public health/nutrition at EU level and with impact assessments carried out in conformity with the Commission's Better Regulation Guidelines will be an asset.

A member of the team with at least 5 years expertise in food law (both at EU and national level), with proven knowledge of the EU food market.

A member of the team with at least 2 years expertise in economics of small businesses. Experience with non pre-packed food business operators will also be an asset.

All staff-related issues will be clarified during the kick-off meeting.

3.5.2 Meetings

It is expected that the contractor participates in 4 to 6 meetings in Brussels with the ISG. For these meetings, minutes should be drafted by the contractor, to be agreed among the participants.

3.5.3 Timetable

The specific contract period is expected to run for a duration that will not exceed 9 months. More details are given in the table below

Deadline (from starting date of execution of the tasks)	Deliverable/report/meeting	Payment
2 weeks	***Kick-off Meeting***	
Month 1,5	***Inception Report***	First interim payment
	A meeting is organised with the ISG and the contractor in Brussels - at the latest 2 weeks after the meeting, delivery of the final version of the Inception Report.	
Month 4,5	***Interim Report***	Second interim payment
	An meeting is organised with the ISG and the contractor in Brussels - The contractor submits a final Interim Report with the necessary updates after discussion with the ISG.	
Month 6,5	***Draft Final Report and raw data***	
	A meeting is organised with the ISG and the contractor in Brussels	
Month 9	***Final Report***	Final payment request

A detailed work plan should be submitted together with the bid. It should be updated with the Inception Report.

3.5.4 Quality assessment

In order to ensure the necessary level of quality for the independent study, the contractor should always bear in mind that:

The study must respond to the information needs, in particular as expressed in the Task Specifications/questions and following discussions with the Commission;

The methodology and design must be appropriate for obtaining the results needed to address the tasks and answer the study questions;

The collected data must be appropriate for their intended use and their reliability must be ascertained;

Data must be analysed systematically to address the tasks and answer the study questions and to cover all the information needs in a valid manner;

Findings must follow logically from and be justified by the data/information analysis and interpretations based on the pre-established criteria and rationale;

To be valid, conclusions must be non-biased and fully based on findings;

Particular attention will be given to the conclusions. All areas which need improvements must be identified in conformity with the conclusions.

3.6. Budget

The estimated budget for the study, covering all the results to be achieved by the contractor as listed above, is within the range of EUR 130 000 up to a maximum of EUR 155 000.

3.7 Resources

The contractor shall ensure that experts are adequately supported and equipped. In particular, sufficient administrative, secretarial and interpreting resources, as well as junior experts, must be available to enable senior experts to concentrate on their core study tasks.

3.8 Absence of conflict of interests

The contractor shall ensure that both their organisation and the individual experts proposed for this study are not in a situation of conflict of interest regarding this specific assignment, and shall include a Declaration of absence of conflict of interest as part of their offer.

4. REFERENCES

4.1. Annexes to the Task Specifications

Annex I: Indicative list of impacts to be screened

Annex II: Indicative list of relevant stakeholders at EU level

4.2. Other existing documentation/data and how to access it

Commission Better Regulation Guidelines http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf

Commission Better Regulation Toolbox

http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf

Inception Impact Assessment on an initiative to limit industrial trans fats intakes in the EU

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

Report by 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 http://ec.europa.eu/food/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf

Staff Working Document by the Commission services - *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 SWD (2015) 268 http://ec.europa.eu/food/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

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

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

Annex I Indicative list of impacts to be screened

Economic

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

Social

Employment

Income distribution and social inclusion

Health & safety

Education

Governance & good administration

Social protection, health and educational systems

Cultural heritage

Environmental

Fighting climate change

Fostering the efficient use of resources (renewable & non-renewable)

Protecting biodiversity, flora, fauna and landscapes

Minimizing environmental risks

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 business

Annex II

Indicative list of relevant stakeholders at EU level

Acronym	Full Name	Contact
BEUC	The European Consumer Organisation	http://www.beuc.eu
EuroCommerce	Retail, Wholesale and International Trade Representation to the EU	http://www.eurocommerce.be/
FoodDrinkEurope	Confederation of the food and drink industries of the EU	www.fooddrinkeurope.eu
EHN	European Heart Network	http://www.ehnheart.org/
EPHA	European Public Health Alliance	http://www.epha.org/
CAOBISCO	Association of the Chocolate, Biscuit and Confectionery Industries of Europe	http://caobisco.eu/
EDA	European Dairy Association	http://eda.euromilk.org/home.html
CLITRAVI	Liaison Center for the Meat Processing Industry in the European Union	http://www.clitravi.eu/
ESA	European Snack Association	http://www.esasnacks.eu/
FEDIOL	EU Oil and Proteinmeal Industry (seed and bean crushers, meals producers, vegetable oils and fats producers/processors)	http://www.fediol.be/
IMACE	International Margarine Association of the Countries of Europe	http://imace.org/en/homepage/
UEAPME	European Association of Craft, Small and Medium-sized Enterprises	www.ueapme.com

Annex 2 List of acronyms

Acronym	Meaning
CAD	Coronary Artery Disease
CAOBISCO	Association of Chocolate, Biscuit and Confectionery Industries of the European Union
CVD	Cardiovascular Disease
CHD	Coronary Heart Disease
CI	Confidence Interval
DALY	Disability Adjusted Life Year
FEDIOL	EU vegetable oil and protein meal industry association
HOTREC	Association of hotels, restaurants and cafés in Europe
IMACE	European Margarine Association
iTFA	Industrial Trans Fatty Acids
JRC	Joint Research Centre of the European Commission
PHO	Partially Hydrogenated Oil
RR	Relative Risk
rTFA	Ruminant Trans Fatty Acids
SKU	Stock Keeping Unit
TFA	Trans Fatty Acids

Annex 3 Glossary

- **Baseline scenario**: scenario of 'no change' in terms of no additional EU intervention.
- **Cardiovascular disease (CVD)**: a class of diseases affecting the heart or blood vessels. It includes coronary artery disease (CAD) as well as stroke, heart failure, arrhythmia, aortic aneurysms, among others.
- **Coronary artery disease (CAD)**: a group of diseases that includes: stable angina, unstable angina, myocardial infarction, and sudden cardiac death. It is within the group of cardiovascular diseases of which it is the most common type.
- **Coronary heart disease (CHD)**: 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 (CAD).
- **Deforestation**: the action or process of clearing of forests.
- **Disability adjusted life year** (DALY): One DALY can be thought of as one lost year of "healthy" life. The sum of DALYs 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.
- **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**: loose foods.
- **Partially hydrogenated oil**: a liquid oil which has only been through partial hydrogenation and is semi-solid.
- **Pre-packed food**: any food that’s put into packaging before being put on sale and that cannot be altered without opening or changing the packaging.
- **Trans fatty acids** (TFAs): a category of unsaturated fatty acids. There are two sources of TFAs: those produced industrially (so called industrial trans fats, iTFAs) and those naturally produced by ruminant animals (ruminant trans fats, rTFAs), which are present in derived food products, such as dairy products or meat from cattle, sheep or goats.

Annex 4 References

A4.1 Publications

EU documentation

- EC (2015) Commission Staff working Document - Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'. European Commission, Brussels.
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Economic impacts

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Annex 5 Indicators and sources

Table 52 Indicators, data and sources

Economic Impacts				
	Judgement criteria	**Indicators**	**Description**	**Source**
Costs	Extent and nature of affected activities – numbers and types of businesses, types product and levels of TFA content, nature of production processes Strategies to reduce iTFAs in food Types of operating costs affected (e.g. costs of ingredients, costs of production, costs of information and labelling) One-off costs of intervention to FBOs, e.g. learning and familiarisation costs (aspect of admin burden) Type, nature and extent of investment required to reformulate products	Number of active food businesses within scope of each option	Number of enterprises by food industry sector, depending on the option one or more sectors should be counted	Eurostat See Annex 8
		Estimates of number of food businesses producing products with iTFAs	NA	
		Value of output of products containing iTFAs (€)	NA	
		iTFA content of different food types / iTFA 'hot spots'	TFA content in food is described by data collected through a literature review of existing studies	Annex II–Table S2. Food products with trans fatty acid content of ≥2g per 100g of total fat http://publications.jrc.ec.europa.eu/repository/bitstream/JRC91353/lbna26795enn.pdf
		Typical cost of product reformulation process (per product/ business, €)	The available evidence 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.	Country research JRC workshop Trans-fatty acids in diets – Health and legislative implications (Mouratidou et al, 2013)

		Cost of ingredients	In order to assess the potential increased cost of food ingredients as a result of reductions in iTFAs in food products, the following assumptions were made based on the available evidence: - All products exceeding limits on iTFAs or PHOs will require a change of ingredients, substituting PHOs for alternative fats and oils; - Food ingredients account for 41% of the value of output of the products affected ; - PHOs account for 5% of the overall value of ingredients used in products currently exceeding the 2% iTFA limit; - Substitute fats and oils are 25% more expensive than PHOs.	Country research JRC workshop Trans-fatty acids in diets – Health and legislative implications (Mouratidou et al, 2013)
	Magnitude of increase or decrease in ongoing operating costs under each option Time profile and duration of cost changes Distribution of costs between different types of business Possible mitigating/ transitional measures Reporting costs per firm associated with each specific option Whether conditions are	Aggregate change in operating costs of each option, EU (€, %)	NA	
		Standard TFA profiling costs / SKU	NA	
		Food industry attitudes to voluntary measures	Industry sources have indicated they welcomed voluntary measures. However, most have already acted on iTFA: a voluntary measure would have no significant impact on them.	Interviews with EU level associations
		Wider stakeholder attitudes to voluntary measures	Major players in the industry have already acted.	Interviews with EU level associations Country research

	favourable for a voluntary agreement to secure participation from relevant food business sectors	Costs of product testing	The research found some evidence of the costs of testing products for iTFA content. In Latvia, TFA 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 52.25 € (excluding VAT). IMACE (the European Margarine Association) advised ICF that fatty acid profiling for food products costs 50 € to 100 € per profile (with an average price of about 65 €).	Country research
		Evidence on product reformulation cycles	In the US, A major producer of processed foods reported that reformulating in less than a year cost $25 million for 187 product lines. EU level associations indicated a 2 to 3 years reformulation cycle	Country research Interviews with EU associations
		Labelling costs/SKU	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 SKUs will need to be changed (based on the RAND Europe estimate used in the impact assessment on general food labelling) - Labels need to be changed over a 2 year period. Based on the estimates by RAND Europe, 82% of labels would be changed over a 2 year period, suggesting that an enforced change would be required for 18% of food labels; - The average cost per label changed is assumed to be EUR 1500.	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 {COM(2008) 40 final} EC (2015) COMMISSION STAFF WORKING DOCUMENT. Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe'
al marke	Extent of current differences in standards	Number of MS with legal limits on iTFAs/ PHOs	5 (Hungary, Denmark, Latvia, Austria, Lithuania)	Country research, EC & JRC documentation

	between Member States Effect of current situation on free circulation of goods and legal certainty Trends in iTFA policy, including current legislative proposals and voluntary initiatives in MS. Effects of this baseline trend on free circulation and legal certainty Effect of proposed options on free circulation and legal certainty Potential winners and losers, by MS and type of business	Number and % of businesses engaged in voluntary agreements (all businesses/ SMEs)	As detailed in Table 53	Country research, evidence from interviews with EU level associations
		Value and % of EU production covered by voluntary agreements	For VAs: as detailed in Table 530	Country research, evidence from interviews with EU level associations
		'Spillover effects' from national action – e.g. FBOs providing reformulated product to all Member States	Products with high concentration of iTFAs produced in eastern Europe are found in Western Europe in supermarkets	http://bmjopen.bmj.com/content/4/5/e005218
Consumers	Current rates of consumption of iTFAs in different products, MS and societal groups Attributes of products containing iTFAs vs. alternatives Price of products containing iTFAs vs alternatives Effects of each option on:	Number and proportion of products of different types containing different levels of iTFAs	NA	
		% price differential between products with iTFAs and alternatives	Especially in eastern Europe some producers can have the premium brand without trans fat and the cheap/family pack option with. Some margarine companies in Canada offered products with a low TFA level while continuing to sell products with a high level at a lower price.	Ricciuto et al., referenced in 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

	- Type and choice of available products - Consumer prices - Effect on quality and nature of 'emblematic' products (e.g. doughnuts, eclairs, chocolate, confectionery)	Product attributes	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.	Public Health Law Center, (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants
		Impact on consumer prices of affected products (%)	Available evidence suggests that reductions in iTFAs 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 IP-TFA limit. - IMACE reports that no impact on the price of products has been identified to date in its sector, even though iTFAs have largely been eliminated. - A Dutch ingredients supplier to the bakery industry 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%. - A margarine producer in Austria estimated that reformulation of domestic margarines may have increased prices by 1-2%.	Interviews with EU level associations Country research
Industry competitiveness	Industry structure and types and sizes of firm affected Extent of intra- and	Number of SMEs/ large businesses involved in manufacture of products with iTFAs	Number of enterprises by food industry sector likely to have products containing iTFAs.	Eurostat Assumptions in lieu of evidence

	extra-EU trade in products affected Effects of options on: - Differences in costs of production and product attributes for different sizes of firm, different MS, EU vs non EU firms - Ability of producers to access export markets - Degree of competition from imports in domestic market - Ability of business to innovate Effects on overall food sector and particular sub-sectors, including innovation effects Did action on iTFA lead to changes in product prices/sales	% of relevant products traded between MS/ internationally	NA	
		Product innovation rates	NA	
		Research evidence on product price/sales effects following reformulation	Available evidence suggests that reductions in iTFAs 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 IP-TFA limit. - IMACE reports that no impact on the price of products has been identified to date in its sector, even though iTFAs have largely been eliminated. - A Dutch ingredients supplier to the bakery industry indicated that reformulation of bread improvers, bread and pastry mixes required substantial effort and investment by the ingredients supplier, 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 4.4). - A margarine producer in Austria estimated that reformulation of domestic margarines may have increased prices by 1-2%.	Country research & interviews
ion and administrative	Number of businesses affected by each option Actions and information needed to comply with	Number of businesses required to understand the rules; number required to provide information	See 'Number of active food businesses within scope of each option'	Eurostat + assumptions on number of affected businesses under each option

	each option Time and associated costs resulting from information requirements Effect of options on the overall complexity of legislation and regulatory requirements within EU and its MS	Time/effort/other costs incurred per business	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 requirements = 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 manufacturing and accommodation/ food service sectors for each country.	Assumptions + Eurostat data for labour costs
		Data compilation / verification and reporting costs incurred by intermediaries	NA	
		Cost of information provision (€)	NA	
		Inspection and verification costs incurred by (i) public authorities (ii) via private assurance mechanisms within the food chain	NA	
		Reporting costs	NA	

International trade	Extent of current trade (exports and imports) of products containing industrial trans fats Expected effects of each option on: - Competitiveness of, and demand for EU exports - Competitiveness of, and EU demand for, imports from outside the EU - International regulatory convergence	NA	Little evidence was found from the literature review to suggest that impacts on trade and competitiveness are likely to be significant, and in general the stakeholders interviewed did not express this as a concern.	Country research
Public administration	Enforcement needs and methods for each policy option Implications for product monitoring, including technical difficulties of monitoring presence of industrial vs ruminant trans fats Administrative burden on public authorities (implications for staffing, time and cost of implementation and enforcement activities)	Cost of establishing the policy	The scale of costs is difficult to estimate precisely. In order to estimate the possible scale of these costs, we assume that: • 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 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.	Assumptions + Eurostat data for labour costs
		Cost of consumer information campaigns	Assumption that the labelling option is accompanied by a mass media campaign, focused in those EU Member States where legislation is currently lacking, and designed to reach the quarter of the EU population most vulnerable to the health impacts of iTFA consumption, and using the per capita cost of USD 2.27 estimated by Sassi et al, a mass media	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/10.1787/22008743

			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.	2153
		Cost of monitoring and enforcement	Available evidence, 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 86 000 EUR to conduct additional controls and to commission laboratory tests in 2018. This cost was estimated to fall to 63 000 EUR annually from 2019. The figures are based on plans for 1000 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 Austria, the cost of examining a sample for trans fatty acids at the AGES is about € 130, depending on the official fee tariff. Costs can vary depending on the matrix. In addition there are about € 6.- for the sample administration and approx. € 30.- for the evaluation. - 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) argued that the costs of monitoring the voluntary reformulation policy were	Country research 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. Hendry VL, Almíron-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.

			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) 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.	
		Compliance rates	Compliance rates vary by country, both in countries with legislation on iTFAs and countries where voluntary agreements are in place. E.g. In the UK voluntary agreement seems to be working while in Poland it had no real impact on iTFA content in food.	https://www.researchgate.net/publication/254384473_Reformulation_for_healthier_food_a_qualitative_assessment_of_alternative_approaches
SMEs and micro-enterprises	Number of SMEs and micro-enterprises producing food products containing trans fats Value of trans fat related output among SMEs and micro-enterprises Burden of investment and operating costs (Q1) on SMEs and micro-enterprises Ability of SMEs and micro-enterprises to adapt/ absorb costs	Number of SMEs and micro-enterprises (i) directly obligated (ii) indirectly influenced by each option	The EU food and drink industry includes more than 280,000 SMEs which generate almost 50% of the food and drink industry turnover and value added and provide two thirds of the employment of the sector.	
		Number of SMEs and micro-enterprises producing food products containing trans fats	NA	
		Value of trans fat related output among SMEs and micro-enterprises (€, % of total output)	NA	
		Ability of SMEs and micro-enterprises to adapt/ absorb costs	The evidence 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 iTFA content. However, the evidence also indicates that challenges will be greater in the food manufacturing industry, where SMEs are	Validation consultation

			likely to encounter difficulties when reformulating their products. 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.	

Social Impact				
	Judgement criteria		**Judgement criteria**	
Consumer health	• Current health impacts of iTFA intake Effect of each option on: • Extent of reduction of trans fat intake • Health benefits arising from these reductions • Consumption of alternatives and their health effects • Health of different social groups • Health inequalities	Number of incidences of cardiovascular disease (CVD) in EU, by MS and by social group	In 2015, there were just under 11.3 million new cases of CVD in Europe and 6.1 million new cases of CVD in the EU. In 2015, more than 85 million people in Europe were living with CVD and almost 49 million people were living with CVD in the EU.	http://www.ehnheart.org/cvd-statistics.html [pag 55]
		% increase in risk of coronary heart disease (CHD) for consumers with >2% TFA intake	The consumption of TFA 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 higher when 2% of the daily energy intake is consumed as TFA instead of an exchange of carbohydrates, saturated fatty acids, cis monounsaturated fatty acids and cis polyunsaturated or other types of fatty acids, respectively if the exchanged amounts of calories remain the same (evidence available quantifies the **increase in risk between 20-32%**). Note that a more recent study from the same author (second source) shows an inverse relationship. However the study population is already sick individuals hence results should not be directly used for general population.	https://www.nature.com/ejcn/journal/v63/n2s/full/1602973a.html https://academic.oup.com/eurheartj/article/37/13/1079/2398446/Natural-trans-fat-dairy-fat-partially-hydrogenated http://www.sciencedirect.com/science/article/pii/S1567568806000262 [paying article]
		Overall intake of iTFAs as % of calorific intake	Intake by country and age group used in the JRC study	http://ajcn.nutrition.org/content/104/5/1218/suppl/DCSupplemental

Social Impact				
	Judgement criteria		**Judgement criteria**	
		Number and % of consumers with >2% calorific intake from TFAs	Intake by country and age group used in the JRC study	http://ajcn.nutrition.org/content/104/5/1218/suppl/DCSupplemental
		Scale of risk reduction delivered by reformulation (e.g. whether reformulation typically elevates saturated fat content)	Product reformulation that involves the removal of TFAs from food may simply lead to higher levels of saturated fatty acid, thereby limiting the public health effect of TFA policies. However, our findings indicate that reformulation resulted in the removal of TFAs with little change in saturated fatty acid content in the majority of products; bakery products were an exception. Moreover, the fatty acid profile of many reformulated products improved while the total fat content remained constant. The resulting health benefits may exceed those associated with simply removing TFAs from food.	http://www.who.int/bulletin/volumes/91/4/12-111468/en/
		Expected reduction in incidences of CHD resulting from each option (total and by social group)	Estimated through the help of the JRC model. The model does not allow to distinguish impacts by different socio-economics groups.	http://ajcn.nutrition.org/content/104/5/1218.full own calculations based on new assumptions
		Costs associated with CHD	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). The costs are based on the European Cardiovascular Disease Statistics 2012. Indirect healthcare costs: costs related to the disease, namely loss of productivity and informal care. The costs are based on the European Cardiovascular Disease Statistics 2012.	Nichols et al. European Cardiovascular Disease Statistics 2012. Brussels (Belgium): European Heart Network, European Society of Cardiology; 2012 http://ajcn.nutrition.org/content/104/5/1218.full

Social Impact				
	Judgement criteria		**Judgement criteria**	
Consumer information	Current availability of information on iTFA content of food, health impacts of iTFAs Current consumer awareness of iTFAs and health impacts Effects of each option on: • Provision of consumer information • Levels of consumer awareness Evidence on labelling changing purchase / consumption choices	% of relevant products giving information on TFA content	NA	
		% of consumers aware of TFAs and health impacts	The majority of Europeans do not know about TFA, industrial TFA or ruminant TFA and partially hydrogenated or fully hydrogenated oils. Also, only a small fraction of people seems to be concerned about TFA intake	https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf Country research

Environmental Impacts, Member State Plans and Activities, Other Significant Impacts				
	Judgement criteria		**Judgement criteria**	

Environmental Impacts, Member State Plans and Activities, Other Significant Impacts				
	Judgement criteria		**Judgement criteria**	
Environmental impacts	Changes in food content and production methods resulting from shift away from trans fats Change in palm oil use resulting from different options - Change in use of other ingredients Environmental impact of changes in palm oil use - Environmental impacts of other ingredients Environmental impacts of production process (energy use, climate impacts)	substitutes for PHOs	• Evidence from Denmark, after the introduction of the trans-fat ban, indicates that saturated SFAs (including palm oil) were the main replacement in 66% of products. • Similarly, in Canada, the President of the Baking Association, Canada, 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. • Consultees in the food industry, such as FEDIOL and IMACE, stressed that their members had already taken action to eliminate iTFAs, 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.	http://www.euro.who.int/__data/assets/pdf_file/0010/288442/Eliminating-trans-fats-in-Europe-A-policy-brief.pdf?ua=1 Interviews with EU level associations Country research
		Environmental impacts of palm oil	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, 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. 7.2 million tons of palm oil were imported into the EU in 2016, of which about 50% were refined by FEDIOL companies.	FEDIOL (2017). Palm Oil Monitoring. FEDIOL (2017) EU vegetable oils' sector works towards meeting the 2020 commitments on sustainable palm oil. Press Release. www.fediol.eu

Environmental Impacts, Member State Plans and Activities, Other Significant Impacts				
	Judgement criteria		**Judgement criteria**	
			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.	
Member State plans and activities	Legislative proposals and initiatives underway in Member States	Number of MS considering legislation on iTFAs	Romania and Slovenia have notified to the Commission draft national legal measures setting a limit to iTFA content. During the validation consultation most EU MS were cited by at least one consultee as likely to act in the absence of EU action. At the same time, consultees indicated in their majority that they did not expect the iTFA problem to be resolved in case there was no EU action.	Validation consultation
		Number of MS considering voluntary agreements/ other initiatives	Contributors to the validation consultation mentioned Denmark, Poland, Lithuania, Italy, Sweden and Germany.	Validation consultation
Other significant impacts	Any other impacts judged to be significant in screening exercise	NA		

Table 53 Profile of the existing voluntary agreements on iTFAs

NACE Rev. 2 classification	# businesses firms	Sector structure	EU rep. association	Characteristics of the membership	Progress made	Opportunity for change through EU V.A.
Manufacture of oils and fats[1]	7,856	Relatively concentrated sector	FEDIOL	Membership through national organisations in Belgium, Denmark, Finland, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain and the UK. Including corporate members, reach extends to: Austria, the Czech Republic, Greece, Portugal, Romania and Sweden. This covers 80% of the sector No presence in BG, HR, CY, EE, IE, LV, LT, LU, MT, SK, SI. Number of members are SMEs. Estimated approx. 7-8% of total value/turnover of the sector.	Members have been supporting industry initiatives to reduce TFA in vegetable oils and fats. The average TFA content in vegetable oils and fat formulations has decreased over the last 15 years from 5.3 to 1% on fat basis, which corresponds to a relative decrease of 81%.	Very low Gains have been already achieved.
Manufacture of margarine and similar edible fats[4]	103	Relatively concentrated sector	IMACE	Membership through national organisations in Austria, Denmark, Greece and Italy, as well as Norway and Switzerland. Including corporate members, reach extends to: Belgium, the Netherlands and Germany. No presence in BG, HR, CY, CZ, EE, FI, FR, HU, IE, LV, LT, LU, MT, PL,	Voluntary code for several years and reports that its members have already largely taken action to phase out TFAs in their products. Activities have achieved good results with average TFA content of 1.2%	Very low Gains have already been achieved

NACE Rev. 2 classification	# businesses firms	Sector structure	EU rep. association	Characteristics of the membership	Progress made	Opportunity for change through EU V.A.
				PT, RO, SK, SI, ES, SE, UK. 75% of IMACE members are SMEs.	achieved for consumer products and less than 2% for B2B products in 2016.	
Manufacture of bread; manufacture of fresh pastry goods and cakes[4]	139,199	Fragmented sector	FoodDrinkEurope	FDE has members across the whole EU. Number of members are SMEs. For the industry as a whole in Europe, SMEs make up 99.1% of enterprises and about half of the sector's turnover (49.5%).	The large majority of members are below the threshold of 2% of the total fat content.	Low Gains have been achieved where possible. Reach is limited due to mixed nature of the membership
Manufacture of rusks and biscuits; manufacture of preserved pastry goods and cakes[4]	6,401	Fragmented sector, some big players and many SMEs	CAOBISCO	CAOBISCO does not cover LV, LT, EE, CZ, BG, EL, MT, CY, SE, DK, NL, HR, FI, LU, RO, SK. The country federations already participating in its voluntary initiative are Belgium, France, Germany, Italy, Spain, the UK and Poland. Around 99% SMEs.	The organisation has set up a voluntary commitment to reduce TFAs in products below 2% of the total fat content. Most members have already achieved the target and those who have not are on track to achieve it in 2017. Some national federations have not signed up.	Low Some gains achieved already, but possibly to improve by including remaining members
Manufacture of cocoa, chocolate and sugar confectionery[4]	6,246	Fragmented sector, some big players and many SMEs	CAOBISCO	CAOBISCO does not cover LV, LT, EE, CZ, BG, EL, MT, CY, SE, DK, NL, HR, FI, LU, RO, SK. The country federations already participating in its voluntary initiative are Belgium, France, Germany, Italy, Spain, the UK and Poland.	The organisation has set up a voluntary commitment to reduce TFAs in products below 2% of the total fat content. Most members have already achieved the target and those	Low Some gains achieved already, but possibly to improve by including remaining members

NACE Rev. 2 classification	# businesses firms	Sector structure	EU rep. association	Characteristics of the membership	Progress made	Opportunity for change through EU V.A.
				Around 99% SMEs.	who have not are on track to achieve it in 2017. Some national federations have not signed up.	
Manufacture of condiments and seasonings[4]	1,941	Relatively concentrated sector	FoodDrinkEurope	FDE has members across the whole EU. Number of members are SMEs. For the industry as a whole in Europe, SMEs make up 99.1% of enterprises and about half of the sector's turnover (49.5%).	The majority of members are below the threshold of 2% of the total fat content.	Low Gains have been achieved where possible. Reach is limited due to mixed nature of the membership
Processing and preserving of potatoes[4]	780	Fragmented sector, some big players and many SMEs	FoodDrinkEurope	FDE has members across the whole EU. Number of members are SMEs. For the industry as a whole in Europe, SMEs make up 99.1% of enterprises and about half of the sector's turnover (49.5%).	The majority of members are below the threshold of 2% of the total fat content.	Low Gains have been achieved where possible. Reach is limited due to mixed nature of the membership
Restaurants and mobile food service activities[2]	915,668	Highly fragmented sector: 91% micro-enterprises, 99.5% SMEs	HOTREC Food Service Europe	HOTREC has members across the whole EU. SMEs are strongly represented in HOTREC membership through its member associations. For the sector	Few isolated national initiatives. FIPE (Italian member) co-signed an agreement with the Italian food industry	Low Industry is highly fragmented, and does not perceive iTFA has an issue it

NACE Rev. 2 classification	# businesses firms	Sector structure	EU rep. association	Characteristics of the membership	Progress made	Opportunity for change through EU V.A.
				as a whole, 91% are micro-enterprises and 99.5% are SMEs.	and the national authorities concerning the reduction of iTFAs contents in food for young people. It exclusively concerns categories of food from the processed/manufacturing industry (e.g. breakfast cereals, biscuits, etc.) DEHOGA (German member of HOTREC) engaged in an initiative with the Federal Ministry of Agriculture and Food that aims to reduce TFAs in food.	is its responsibility to solve; dependent on suppliers

Annex 6 Consultation with EU business associations

A6.1 Trans fatty acids in products

Do you have data and trends on the TFA content in products of your members? Do you have details on iTFA and rTFA content?	**HOTREC**: HOTREC does not have data on TFA content of food cooked and served by hospitality businesses. However, it is important to understand that hospitality businesses cook food for immediate serving and consumption (by opposition to the food processing/manufacturing industry). As a consequence, most hospitality businesses cook meals using raw products, meaning that food served by hospitality businesses may contain natural transfats (contained in meat, dairy products, etc.) but will normally not contain industrial Transfats, unless a dish is prepared using industrial products (bought from a supplier) already containing industrial transfats. Moreover, to prepare French fries, restaurants normally use vegetable oils (or in some countries – e.g. Belgium – animal fat for French fries), therefore making deep frying safe in terms of industrial transfats. **FEDIOL**: Over the past 15 years, FEDIOL members have been supporting industry initiatives to reduce TFA in vegetable oils and fats. Thanks to these numerous industry actions, new low TFA vegetable oil and fat formulations are provided to consumers, enabling overall reductions in the TFA content of food products. To estimate the extent of this reduction for the vegetable oil and fat sector, FEDIOL undertook a data collection and analysis on the basis of which it was concluded that the average TFA content in vegetable oils and fat formulations has decreased over the last 15 years from 5.3 to 1% on fat basis, which corresponds to a relative decrease of 81%. In bottled vegetable oils, refining practices also ensure that TFA levels are well below 2% on fat basis. The TFA reductions achieved in vegetable oils and fats by FEDIOL members are reflected in various EU Member State surveys, where considerably reductions in dietary TFA intake have been demonstrated in recent years.

This decrease was also highlighted by EFSA in its opinions of 2004 and 2009, based on data analysis at national level.[114] It was also highlighted in the Commission report on TFA released in 2015.

See also FEDIOL document 09NUT242 for more details on FEDIOL data collection.

IMACE:

IMACE has worked with its members to reduce TFA content of products since 2004, through a Code of Conduct. The voluntary approach has worked well and all members have been actively involved. There have been some variations in the rate of progress, with some smaller companies requiring more time to reduce TFA in their products.

Activities have achieved good results with average TFA content of 1.2% achieved for consumer products and less than 2% for B2B products in 2016. As a result the industry can be considered as almost TFA free. These efforts and successes have been acknowledged by EFSA.

Product functionality requires PHO to be replaced with another solid fraction. Options include palm oil, coconut oil, fully hydrogenated vegetable oils, or butter/ animal fats. There is a preference not to use SFAs for health reasons. Some effort is required for product reformulation – it is not simply a case of substituting one ingredient for another – but finding an overall formula that achieves product functionality and quality.

CAOBISCO:

CAOBISCO does not have data on this.

[114] "*Evidence from a number of countries indicates that the intake of TFA in the EU has decreased considerably over recent years, owing to reformulation of food products, e.g. fat spreads, sweet bakery products and fast food. More recent reported intakes in some EU Member States are close to 1 to 2 E% (EFSA, 2004). For example, in the UK the average intake of TFA has been halved to less than 1 E% (SACN, 2007). In France, intake data from 4079 individuals 3 to 79 years of age collected with 7-day food diaries and calculated with tables of TFA content of foods from 2008 show that TFA intakes have decreased by 40 % and are, on average, 1 E% in adults (1.4 E% at the 95th percentile), including 0.6 % for TFA from ruminant sources and 0.4 % for TFA from other sources (AFSSA, 2009). Average intakes of TFA in Denmark, Finland, Norway and Sweden have decreased to around 0.5 to 0.6 E% (Johansson et al., 2006; Lyhne et al., 2005; Männistö et al., 2003; Becker et al., 2005).* " EFSA opinion of the scientific panel on dietetic products, nutrition and allergies on a request from the Commission related to the presence of *trans* fatty acids in foods and the effects on human health of the consumption of trans fatty acids (Request EFSA-Q-2003-022) adopted on 8 July 2004.

	Food Drink Europe: FDE have not collected information on this. The absolute vast majority of members say that this is not an issue any more. They are below the threshold of 2% (Danish reference threshold). We receive feedback that most of our members have already complied, or that they have virtually eliminated TFAs from their products (the total elimination is not possible due to the presence of iTFAs in additives. At federation level there are also many indications that this is not an issue any more. There are a number of MS measures and voluntary agreements in place. The feedback that we get is that this has been evaluated by public authorities in a number of member states (Germany, Belgium, Spain) and this indicates that the intake is below the 2% limit. As a result it is not an issue of public health any more in these countries and sectors. That is what EFSA's Opinion said already. But there might still be problems in some countries and products. For instance in Czech Republic: companies there are often small, and they did not understand how to remove iTFA from their products. Confusion exists on terminology. **Swedish Food Federation (on behalf of CEBP):** The level of trans-fats in foods is monitored in Sweden. It is approximately 1.7g / day on average, of which 25% is industrial trans fats. This is below the target level from the WHO. This is a similar level to that seen in Denmark, which has legislation. The level of industrial trans fats used in Sweden decreased sharply in the 1990s. This was not driven by legislation, but largely by consumer demand. Consumers in SE did not want industrial trans fats in their food, therefore consumption went down, and producers responded to the change in demand. In the early 2000s, a voluntary measure was introduced in Sweden. This type of arrangement is known as "the Swedish model" (collaboration and integration), to set an agreed voluntary measure for industrial trans fats. The model does not specify a particular level of industrial trans fats, just a commitment to make it as low as is possible. Despite no committed level, this approach seems to work in Sweden. It is not regulated in any way. However, due to consumer pressure (and a media campaign in the mid 2000s), producers do stick to the agreement. The main driving force behind this commitment is the reputational damage (a loss of sales) to a business if they were found to be flouting this agreement.
Are there specific countries where iTFAs are used the most? For	**FEDIOL:** iTFAs are nutrients, which can come from the hydrogenation of vegetable oils and fats and also arise during the refining process of vegetable oils and fats, as highlighted by the European Food Safety Authority (EFSA) in its opinion published in 2004.

which products?	FEDIOL does not collect data at country level but for the EU. FEDIOL does not have either data identifying in which countries and which products higher iTFA are used in. This work has however already been done in the previous stages of the Commission work on TFAs. The JRC published a first report in 2013. Based on stakeholder input in which FEDIOL participated, the JRC produced another report in 2014. It served as the basis for the Commission report published in 2015 and gives an overview of the types of products and countries where higher TFAs can be used. Looking at the Commission report on TFA (December 2015), it highlights food products such as biscuits or bakery products or popcorn where higher TFA can be found in some countries (e.g. Sweden, Croatia or Poland are mentioned in the Commission report). Whilst major efforts have been conducted by industry to lower TFA levels in an overall reformulation strategy, some products can be more challenging due to the need to maintain the same functionality, taste and mouthfeel, whilst replacing TFA. Reducing TFA, therefore, also involves looking for innovation in processing, using alternative raw materials, replacing TFA by other fatty acids, using antioxidants, etc.; whilst also reducing SFA at the same time, as per existing EU and international recommendations. This can prove more difficult for some products and in some countries as identified in the Commission report on TFA. Further efforts have to be pursued. For example, in applications like frying oils TFA's were replaced partially by MUFA. In other applications where structure is needed, TFA's were rather replaced by SAFA. Overall there is a decrease in SAFA, as confirmed by FEDIOL data collection. The implementation of an EU 2% maximum limit on TFA on fat basis in the product intended to the final consumer will create the same level playing field for all products in all EU countries. *What are the implications for FEDIOL members of the current situation whereby TFAs are being tackled by individual Member States and industry initiatives, rather than at EU level?*

FEDIOL members have contributed to a decrease of TFA content in food overall. Whilst initiatives – undertaken at national and industry level have been successful, there are still some issues identified for some types of products and in some countries – where higher iTFAs content can be found. Moreover, the different rules implemented across EU countries lead to possible trade and internal market issues. This is why and since 2014, FEDIOL has been calling for the setting of an EU max limit at 2% TFA on fat basis in the products intended for the final consumer together with the deletion of the existing hydrogenation labelling. This will settle a level playing field for industry and eliminate the TFA issue from the EU market.

It should also be noted that we depend on customers' request. Hence, we cannot force lowered TFA content products to be used by customers if they prefer to rely on other solutions.

How would you define PHOs in Europe?

An EU definition of "partially hydrogenated oil" (PHO) linked to TFA would be expressed as follows:

"Partially hydrogenated" means that the hydrogenation was not fully performed to the extent possible under practical conditions, correlating and results with a trans fatty acids (TFA) content above 2% on fat basis.

It would better address TFA in the EU context for the following reasons:

a) Modern processing ensures that the fatty acid composition of vegetable oils and fats, including TFAs, is checked routinely by manufacturers.

b) Legislation based on TFA limits on fat basis in products intended for final consumers therefore, enables an easier control by authorities on the proper implementation of the hydrogenation labelling.

c) Given the existing national legislations on TFA, which are referring to a 2% TFA on fat basis, similar EU harmonised legislation is aligned with such practices and therefore seems appropriate.

d) FEDIOL code of practice on refining refers to a max 2% TFA on fat basis to be achieved during refining. Such definitions are therefore matching current refining requirements.

e) An EU harmonised legislation will ensure a level playing field and avoid diverging definitions across EU Member States.

	f) This is in line with the EU report on TFA, which confirms the need for an EU solution. On the contrary, the US definition of PHO – linked to iodine value – is not the way forward for Europe. FEDIOL has prepared a detailed explanation which we are happy to further highlight. See FEDIOL 17NUT054. **IMACE:** Greater challenges have been faced in the B2B market due to difficulties in achieving product functionality while reducing TFA input for certain specialist products. This is particularly the case for specific types of products, such as coatings, fillings and emulsifiers, used, for example in certain types of confectionary and biscuits. Such products may have low overall fat content but a high % of TFA within this fat content. Experiences of IMACE members are probably typical of those of the industry as a whole, though it is noted that there has been less progress to reduce TFAs in some Eastern European markets. IMACE members' products meet similar standards to those elsewhere in Europe, but TFA content of other products on the market (either domestically produced or imported, e.g. from Russia) may be higher. **CAOBISCO:** CAOBISCO have data that dates back from the 1990s and therefore would provide a very inaccurate picture of the reality. **Food Drink Europe:** See above
Has your organisation (or your members) committed to reduce TFA content in own products? In which ways?	**FEDIOL:** Over the past 15 years, FEDIOL members have been supporting industry initiatives to reduce TFA in vegetable oils and fats. Thanks to these numerous industry actions, new low TFA vegetable oil and fat formulations are provided to consumers, enabling overall reductions in the TFA content of food products. The average TFA content in vegetable oils and fat formulations has decreased over the last 15 years from 5.3 to 1% on fat basis, which corresponds to a relative decrease of 81%. In bottled vegetable oils, refining practices also ensure that TFA levels are well below 2% on fat basis. **CAOBISCO:** The organisation has set up a voluntary commitment to reduce

	TFAs in products below 2% of the total fat content. Most members have already achieved the target and those who have not are on track to achieve it in 2017. The agreement is in fact a recommendation to CAOBISCO's members. It has been discussed internally and has been influenced by various factors, including legislation introduced in some countries. The agreement is not being enforced via a third party certification system. All corporate members have signed up, as well as the national federations from Belgium, France, Spain, Germany, Hungary, the United Kingdom and Italy.
Is your organisation (or your members) involved in a voluntary agreement to reduce TFA content in food?	**HOTREC:** HOTREC member FIPE in Italy co-signed an agreement with the Italian food industry and the national authorities concerning the reduction of industrial transfats contents in food for young people. It exclusively concerns categories of food from the processed/manufacturing industry (e.g. breakfast cereals, biscuits, etc.) DEHOGA (German member of HOTREC) engaged in an initiative with the Federal Ministry of Agriculture and Food that aims to reduce transats in food. As part of it, DEHOGA has produced a guide for hospitality businesses to help them with recommendations in the choice of oil and cooking methods for frying food.[115] **FEDIOL:** FEDIOL alone took voluntary measures as an industry (see answers to questions above). One example of industry voluntary actions has been the optimisation of refining processes that has led to the development of a FEDIOL Code of Practice to ensure that "during the refining process and depending on the raw material a max. 2% TFA on fat basis can be formed (unavoidable presence)." This contributed, together with the numerous initiatives from FEDIOL members, to significantly decrease TFA levels across the sector. FEDIOL members also collaborate with sectors downstream to work together on reducing TFA content in food. As explained above, this can be done by looking for innovation in processing, using alternative raw materials, replacing TFA by other fatty acids (SAFA, MUFA), using antioxidants etc. FEDIOL members offers solutions to achieve this. **Food Drink Europe:** The voluntary approach has been very successful. The evidence

[115] See: http://www.dehoga-bundesverband.de/branchenthemen/reduktion-von-transfetten/; http://www.dehoga-bundesverband.de/fileadmin/Startseite/05_Themen/Transfette/05_TFA_PL_Frittieroele_final.pdf; http://www.dehoga-bundesverband.de/fileadmin/Startseite/05_Themen/Transfette/TFA_Leitlinie_Siedeoele.pdf

	for it is in the dietary intake surveys conducted at national level. A recent development following last year's Council conclusions: there are reformulation plans for the governments at national level, which include also TFA. • Reformulation has been possible thanks to the fat suppliers' efforts. They can provide products with little TFA. Even the suppliers of functional ingredients: a few of them are able to provide products without any TFA. European margarine association has come up with a code of conduct to reduce iTFA in B2B. This was voluntary. In the EU Platform on diet FDE are also proposing commitments to the platform.

A6.2 Policy options impacts

(a) Reformulation

If products were/ will be reformulated, which ingredients replace TFA? Are there differences by product type, firm size? *[e.g. would it be more difficult to reformulate in certain countries?]*	**HOTREC:** Concerning industrial transfats, examples in Austria and Denmark showed that the food processing/ manufacturing industry has options available to replace iTFAs. In Denmark, the Danish food administration claims that transfats were often (but not always) replaced by saturated fats such as coconut fat and palm fat. Reformulation is something which mostly concerns the food processing/manufacturing industry, as restaurants usually do not produce themselves iTFAs. Concerning natural transfats, they simply cannot be replaced in the hospitality sector. **FEDIOL:** See FEDIOL evolution of the fatty acid composition of vegetable oils and fats sold to the food industry in the EU over the last 10 years 09NUT242 Replacing levels of TFA has been done via different ways i.e. looking for innovation in processing, using alternative raw materials and tropical oils (containing naturally a certain amount of solid fat such as in palm, palm kernel, coconut), replacing TFA by other fatty acids, using antioxidants, using fully hydrogenated oils etc. It depends ultimately on the customer requests in the type of vegetable oil/fat solution he needs, which is triggered by the type of products he is going to use it for. Hence, it is not possible to give an exact figure of the content of fatty acids as it depends on each end products. However, In general, whilst the TFA level has obviously decreased to meet the FEDIOL Code of Practice but also the customers requests, the other fatty acids have varied. Looking at FEDIOL data, a decrease of the SAFA content along with the TFA content was observed in 2008. This can be explained by further innovation and reformulation by the vegetable oils and fats sector that worked at reducing the SAFA content of food

	products. In certain applications like frying oils this has proven successful. For example, highly saturated fats were replaced by high oleic sunflower oil and palm olein. Replacing TFA has also lead to increase in unsaturated fatty acids (UFA).This is done for example by blending vegetable oils and fats to modify the fatty acid profile and improve health. Another way is to select seeds to obtain a better profile. For example, using high oleic sunflower or rapeseed oils to replace TFA has led to a higher MUFA content and a better nutrition profile. But such reformulation is less obvious for food applications, where structure is needed, where TFA's were rather replaced by SAFA. Fully hydrogenated oils and fats have also been used to a certain extent to replace TFAs, but this option tends to be less implemented due to the existing fully and partially hydrogenation labelling, where consumers lack understanding and tend to think that a fully hydrogenated oil is hence less healthy than a partially hydrogenated oil. The vegetable oil and fat industry continues to invest heavily in innovation and initiatives to further address this issue. **CAOBISCO:** A member would work with their oil and fat supplier. It's then a matter of finding an alternative. There are issues of texture, taste, etc. One may go for a blend of fats or for a fully hydrogenated oil. The disadvantage of the latter is that it must be labelled. Consumers may question that, and it may actually be understood the wrong way. For example, in the UK the Food Standards Agency has advised consumers to look for "hydrogenated" on the labels in order to detect TFA. Alternatively you may carry out your own R&D work at manufacturer level, which is what the big players will do.
What was the cost of reformulation ? Do you have data on costs by product type, firm size?	**FEDIOL:** Reducing PHVO usage and hence TFA levels raises technical challenges for certain food applications. In practice, some types of food applications (such as confectionery coatings and cream, fillings, puff pastry, etc.) need to maintain the same functionality, taste and mouthfeel, whilst replacing TFA. This can imply challenges in terms of hardness, crystallisation speed, oxidative stability, other specific technical functions (e.g. aeration, melting behaviour, etc.). FEDIOL does not collect data per product type. **IMACE:**

	IMACE members have continuously worked to develop and improve their products. As a result reductions in TFA 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. **CAOBISCO:** Cost is not a discussion point at CAOBISCO. Manufacturers absorb the cost, in a context where they are not allowed to set the price of their products anyway (retailers set the price). The reformulation would be done silently. Besides, you would not market a product that says "has less TFA" because that is a nutrition claim, and because it would not sell. You would look at other options, such as achieve cost savings elsewhere. If you are merely substituting one fat for another then there would be almost no cost anyway. But if you are going for a different kind of fat, and therefore you need to rework other aspects of your formula in order to achieve the same product, then you might need to do much more and that would cost more. **Food Drink Europe:** It is difficult for FDE to provide information on this. Cost data cannot be shared at federation level. Besides prices are set by retailers. The detailes of what reformulation entails depend on the product. You could find a solution for any product. All you have to do is talk to your at and oil supplier and describe the characteristics of what you need. It is a dialogue with the supplier. Sometimes the installations have to be revised to make them compatible with the new fat: you will need an extractant to store one or two other oils. If the fat will be more liquid than the previous one then you will need extra sieves.
Did reformulation led to / leads to higher price for the reformulated product? How do your members handle this issue *[e.g. produce small product at same price point, adjust other*	**HOTREC:** Unknown for industrial transfats, as the hospitality industry is not much concerned directly (only some of its supplies may occasionally be affected). Concerning natural transfats, they usually cannot be replaced in meals offered by hospitality businesses, so reformulation is simply not really feasible for natural TFAs. **FEDIOL:** Yes. It also involves costs for the sector in terms of resources, investments in equipment, R&D, packaging etc. Similar costs will also touch users of vegetable oil and fat. Ultimately, such costs were passed on through the chain and to the consumers at the end. **IMACE:**

ingredients, pass the cost to consumers]	No impact on the price of products has been identified to date.
Are you aware of any environmental impact of reformulation decisions?	**FEDIOL:** TFA reformulation per se does not have an environmental impact. FEDIOL members supports raw materials sourced sustainably– irrespective of their botanical origin. FEDIOL and its members are heavily involved in actions directed to sustainability of palm or soy for example. Palm oil is one of the possible instruments for lowering TFAs. But reformulation has already happened in the utmost majority of cases either by using palm, or using other vegetable oils and fats or other technologies. In the current situation where the sustainability at large, but also other issues linked to safety are raised, we would not see how actions on TFAs would lead to significant increase, as long as the situation remains as such and as long as customers impressions and issues are not solved. As regards alternatives to palm oil, other options are not necessarily easy to implement and the whole situation is rather complex. Each solution has its own specificities and related issues. **IMACE:** Environmental impacts are difficult to assess: • Palm oil can be a good replacement for PHO, on account of its functional benefits, but is only one of the options available • Other oils (e.g. soy) also have negative environmental impacts • The industry is committed to using sustainable palm oil, such that increased use of palm oil should not lead to deforestation • Much of the required substitution has taken place already, so we would not expect a surge in palm oil consumption in response to limits on TFA **CAOBISCO:** Not in relation to TFAs. But CAOBISCO is part of a group on palm oil and part of the discussion is on sustainable palm oil. **Swedish Food Federation:** As the organisation covers a wide range of food producers, they could not give information on exactly how all industrial trans fats would be replaced. Originally in Sweden, palm oil was seen as a good replacement. However, this is not the case anymore, with producers avoiding using palm oil due to the environmental

	effect and consumer demand. Other than the effect of palm oil, they were not aware of any other environmental effects. They did not think that any reformulation in the past had led to an increase in the cost of food, but did not have any data on this.

(b) Voluntary measure/ agreement

When was the agreement introduced? When did the measures come into effect?	**FEDIOL:** FEDIOL alone took voluntary measures as an industry (see answers to questions above). One example of industry voluntary actions has been the optimisation of refining processes that has led to the development of a FEDIOL Code of Practice in 2002 to ensure that "during the refining process and depending on the raw material a max. 2% TFA on fat basis can be formed (unavoidable presence)". This contributed, together with the numerous initiatives from FEDIOL members, to significantly decrease TFA levels across the sector. In other sectors and at country level, FEDIOL members have also been involved in other voluntary measures. For example, the margarine industry has also significantly decreased the TFA content in their products, by adopting a Code of Practice in 1995 by which margarines and fat spreads should not contain more than 2% on a fat basis. Similar work has been done in other countries. At the same time, this has also limitations as explained in the EU Commission report on TFA – where some higher TFA content are reported in some products and some countries. The implementation of an EU 2% maximum limit on TFA on fat basis in the product intended to the final consumer will create the same level playing field for all products in all EU countries. The setting of such EU TFA limit hence makes the existing labelling of partially/fully hydrogenation redundant. We will explain this under c) legislative measure.
Who is involved in the agreement (number, size, types of businesses; role of industry bodies)?	**FEDIOL:** FEDIOL members. **CAOBISCO:** Members, but not all of them. Some national federations have not signed up. It is not clear why.

Please outline the scope of the agreement in terms of: Types of foods covered (pre-packed/ non-prepacked; food types); Basis for the limit imposed (iTFA, TFA, PHO etc); Limit imposed (%)	**FEDIOL:** Types of foods covered (pre-packed/ non-prepacked; food types): refined vegetable oils and fats Basis for the limit imposed (iTFA, TFA, PHO etc) - iTFA Limit imposed (%): max 2% TFA on fat basis
In your opinion, is there a risk of non-compliance? Are there measures in place to address this issue?	**FEDIOL:** FEDIOL Codes are non legally binding as such but are observed by its members.
Please explain the arrangements for enforcing the agreement and monitoring compliance? How well have these arrangements worked? What was the cost your organisation (or your members) incurred?	**FEDIOL:** FEDIOL undertook a data collection in 2009, where the outcome was that TFA content in vegetable oils and fat formulations has decreased over the last 15 years from 5.3 to 1% on fat basis. *If members are involved in voluntary agreements how do these: monitor compliance; encourage compliance; respond to non-compliance.* Monitor compliance: through FEDIOL data collection (see above) Respond to non-compliance: Within FEDIOL membership and whilst FEDIOL codes are non legally binding, they are positively endorsed and supported by its membership. They often serve as a benchmark for the sector. Once public, such codes are also linked to trust and reliability of the industry *How well have these arrangements worked?* Given the last data collection undertaken by FEDIOL and as highlighted in EFSA opinions in 2004, 2009, in the JRC reports in 2014 and in the Commission report in 2015, overall all industry and national measures taken have worked successfully as TFA content has decreased and is low in the majority of food products

	in Europe. However, there are still some products in some countries where high iTFA levels have been identified. This is why an EU 2% TFA max limit on fat basis in food destined to the final consumer is needed. *What are the typical costs of participating in such an agreement?* Costs are related to data collection and analysis only. There are no extra costs linked to participation as the test data is provided as part of routine testing by each manufacturer and hence does not generate additional costs. *What are the principal challenges associated with reducing TFAs via voluntary agreements in the industry in the EU and how could those challenges be overcome?* In general, we see that voluntary agreements have been successful overall across EU. But looking at some types of products and some countries, some high iTFAs persist. Our industry develops and offers solutions to reduce TFAs, but finally it's the customer that decides on implementation and that needs to be convinced. Challenges are numerous and can come from different sources such as possibly as follows: the types of products where solutions are not so obvious, perhaps due to specific technical challenges, or require extra costs from the customers to adapt its recipes, awareness is maybe less a concern for some countries than others, other priorities have been set by countries than TFAs, the composition of imported non EU food is also outside the scope …. Ultimately and as already highlighted in the Commission report on TFA in 2015, the magnitude of impacts of such an option (in terms of all types of benefits and costs) "would clearly depend on the scope of industry participation and the coverage of food products on the market." *Under what conditions would your organisation participate in an EU level voluntary agreement: (1) to apply a 2% limit on iTFA content in food;* *and (2) to stop the use of partially hydrogenated oils in foods?* In general, FEDIOL prefers the setting of voluntary agreements and self-regulation to address such kind of issues. Voluntary initiatives have indeed helped to reduce TFA over the last years.

	However, in the specific case of TFA, although much has been achieved in recent years through industry self-regulation, they have reached their limits. We do not envisage further significant reductions in TFA by establishing an EU agreement. FEDIOL is therefore not in favour of this option to address the TFA issue as: - it will not contribute to eliminating the TFA issue across all EU countries and across all food products in the same way as would be achieved by EU legislation, - it will maintain the discrepancies between those Member States having addressed the issue and those that did not, - it will maintain the consumers' confusion with the current full/partial hydrogenation labelling. - it would not apply to non-EU food production and/or food composition

(c) Legislative measure

What would be the economic burden for your organisation (or your members) of understanding legislation on iTFA/ PHO content in food?	**HOTREC:** Concerning policy options about industrial TFAs: A ban on PHO would impact mostly the food processing/ manufacturing industry, but would not impact much hospitality businesses, as they do not use PHO and do not produce industrial Transfats. A ban may impact some supplies in some hospitality businesses bought from wholesale in case of short transition periods. Concerning a possible establishment of a limit on industrial transfats: experience shows impact is limited or non-existent for the hospitality industry: industrial transfats contained in meals prepared by hospitality businesses are only the result of the content of such transfats 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 iTFAs), meaning that they will easily comply with limits. Concerning an obligation to indicate TFAs content of foods in the nutrition declaration: hospitality businesses offer non-pre-packed meals and do not have at EU level any obligation to provide a nutrition declaration, though Member States may decide otherwise at national level. In general, nutrition declaration are a completely disproportionate burden for hospitality businesses producing non-prepacked food for immediate serving/consumption, are extremely expensive, and may prevent businesses from changing their menus regularly depending on local/daily supplies (therefore limiting innovation and decreasing quality). Therefore, creating an obligation for hospitality businesses to indicate iTFA content in nutrition declaration would be an unbearable burden for the vast majority of hospitality businesses, while being completely disproportionate given the fact that hospitality businesses do

not create industrial transfats themselves (iTFAs contents are usually the result of the content in the supplies which were bought from the processing industry, while the majority of hospitality businesses cook raw materials, therefore not producing any iTFA).

FEDIOL:

Since 2014, FEDIOL supports the introduction of an EU TFA legal limit.

Introducing an EU TFA legal limit will:

- consolidate progresses made on a voluntary basis,
- ensure a level playing field to food business operators across EU Member States (due to the multiplication of national TFA legislations) and for imports from 3rd countries,
- eliminate the TFA issue and establish the same standard across all EU countries.[116]
- Reflecting on how to eliminate the TFA issue across EU, FEDIOL strongly advocates the introduction of an EU TFA legal limit which is:
- based on a 2%* TFA on fat basis in products intended to final consumers
- applicable to non-ruminant TFA
- The EU legal limit would only apply to non-ruminant/industrial TFA not because of health grounds, but because of technical reasons. In practice, "technically, ruminant TFA cannot be covered by this measure as TFA are formed (…) in relatively stable proportions in ruminant fats, and cannot be avoided in ruminant products (…)".
- *The 2% TFA legal limit on fat basis is equivalent to the 2g TFA per 100g of oil/fat, in the product intended for the final consumer.

With the introduction of such an EU TFA limit legislation as described above, the existing fully/partially hydrogenation labelling will not have any "raison d'être" anymore and should be deleted for the following reasons:

- one of the rationale behind such labelling was to inform consumers on the presence of partially hydrogenated oils which contain much higher TFA levels than 2%, contrary to fully hydrogenated oils where TFA levels are below 2% TFA. With such a new EU TFA 2% legal limit, all those high non-ruminant TFA food products will be gone from the EU market

[116] See for example Stender S. *et al.*, Tracing artificial *trans* fat in popular foods in Europe: a market basket investigation. BMJ Open 2014.

as they will be forbidden in Europe.

- consumers do not know the difference between partially ("partly" according to Regulation 1169/2011) or fully hydrogenated oils.
- consumers confuse both terms, thinking that products labelled as fully hydrogenated contain high levels of TFA.

Hence, if an EU TFA legal limit was to be introduced whilst keeping the current mandatory hydrogenation labelling, consumers would continue to think fully hydrogenated oils and food products thereof contain high TFA levels. This would further mislead consumers and lead to discrimination for the vegetable oil and fat sector and particularly for all sectors using such ingredients.

This lack of consumers understanding has been demonstrated in studies and in the Commission report on TFA, which states that "(…) the little information available suggests that the majority of Europeans do not know about TFA (…) partially hydrogenated or fully hydrogenated oils. (…)".

What are the expected consequences for FEDIOL members of the EU legislating to limit TFA content to 2% of fat?

It is difficult to estimate possible consequences.

The major steps in TFA reduction took already place in the past (cf. Fediol data collection). For the majority of applications, solutions have been developed and are available. All associated costs were already made by our industry in the past.

In general, we do not anticipate substantial impacts, as all bottled vegetable oils and fats are already below 2% as per FEDIOL Code of Practice. Ultimately, it will depend on what customers are requiring and the types of solutions (as already emphasised above) they will want to have for their products.

What changes would occur in the market if such a limit was introduced? What changes, if any, would such legislation prompt in the formulation of members' products?

Again, it is difficult to estimate. From one side, the issue has already been addressed for most of sectors where this is not an issue anymore. For other sectors and some products in some countries as highlighted in the Commission report in 2015, such work could be more challenging and could involve either technological adaptations or higher costs. But it is not possible to state which vegetable oils/fats solutions would be used instead in these cases as there are various different options such as for example, the types of botanical oils i.e. use of palm oil or high oleic sunflower oil, rapeseed oil or change in production process i.e. full hydrogenation. Often it is a combination of those options which is used to get a final product with a better health profile whilst keeping the needs of the specific final product. Such recipes cannot be changed overnight and require adaptation.

	It is important to have maximum flexibility in the choice of raw materials that replace high TFA products. This can help to minimise costs for adaptations at customer level. One can also raise the question as to whether this could lead to having some products disappearing from the market. This will mostly depend on available solutions and costs of final products and what customers want. **IMACE:** This would be IMACE's favoured option. Because 2% limit has already been achieved, such a limit would not impose additional costs on the sector but would consolidate gains achieved to date. Imposing a legal limit would contribute to consumer certainty and remove the need for labelling. IMACE would favour a differential limit for low fat products. This is because technical challenges make it difficult to eliminate TFAs for specialist ingredients (e.g. coatings, fillings and emulsifiers as mentioned above) which are used in small quantities. In such cases it may be difficult and costly to reduce TFA to less than 2% of overall fat content, even though it may account for a tiny proportion of overall nutritional content. **CAOBISCO:** There would be no issue. CAOBISCO, will draw guidance following legislation. THe cost is borne by the secretariat. **Food Drink Europe:** FDE had quite some discussion internally on this matter. As a general principle FDE's members feel that the success of voluntary agreements has been such that there is a preference to continue that way instead of regulating. But there is also acceptance by many of being able to comply with legislation. Looking at the small companies they do not necessarily have the means to comply. It is not a matter of will. It is more a matter of know-how and containment of costs. FDE support the recommendation to set a limit of a maximum of 2% , et discussed. This can be achieved by volunarty agreement or legislation.
What would be the economic burden for your organisation (or your members) of changing labels in your	**HOTREC:** Hospitality businesses do not use label, as they produce non-prepacked food/meals for immediate consumption. New labelling/information obligations would be extremely costly and likely to be unfeasible by the majority of hospitality businesses (91% being micro-enterprises, 99.5% being SMEs). **FEDIOL:** For vegetable oils and fats, we do not anticipate costs linked to the changing of labels due to the setting of a 2% TFA legal

products? Would this be more burdensome for SMEs?	limit. This is because all bottled vegetable oils and fats are already below 2% as per FEDIOL Code of Practice. The situation would be completely different if a TFA labelling content was introduced. We will explain under section d) why such labelling is really not the way forward in Europe. **CAOBISCO:** IT would depend on the range of the proposed obligation. If we look at having to label the total TFA content, then it requires analysis, which has one type of cost. There is no method to distinguish naturally occurring TFA from iTFA. You can do it at ingredient level. You can't distinguish rTFA and iTFA on a label: that would only confuse consumers. As long as a transition period is possible, then the cost can be incorporated in the product changes that will be made anyway. Every now and then companies change the product. Ideally you would change the label when you change the product. That is what was available with the Food Information Regulations, which means you could combine the different label changes together. Would it be a necessity to label if intake levels are already below 2%? **Food Drink Europe**: FDE are playing with the idea of making a toolbox on reformulation. Make a decision tree of what you need to do. That would be a technical document, exploring what one fat could be replaced with, and what one would need to look at when considering reformulating their product. It is important that SMEs receive the required technological support. That way you can mitigate the costs. It would be even better if it was carried over by the EC and the industry. There was something similar on acrylamide: a code of practice has been published on the EC's website for anyone who is interested in reducing acrylamide in food products. Something similar could be done here.
Are you aware of any iTFAs detection method? What is the testing capability in your sector?	**HOTREC:** Not aware. Testing capabilities are extremely limited as the sector is completely dominated by micro-enterprises and SMEs, and as hospitality businesses are subject to light/flexible hygiene requirement in application of HACCP rules. **FEDIOL:** Modern quality control procedures ensures that the fatty acid composition, including the amount of TFA, of vegetable oils and fats, is checked routinely by manufacturers. Having an EU 2% legislation and using the TFA parameter for a definition of fully/partially hydrogenated oils is possible to do in official controls done by authorities. We understand that this is how it works in those countries like Denmark or Austria, where there has been a legislation on TFA already for some time. In

addition, analytical methods exist today to test the TFA content in the final food product sold to the consumers (e.g. biscuits, margarines, ready-made meals etc.).

As indicated above, using iodine value (IV) as specified in the US legislation to identify the potential presence of partially hydrogenated oils in products sold to the consumers is not always possible as vegetable oils and fats are only one ingredient of the product. Furthermore, fully hydrogenated oils and fats are often used in combination with other vegetable oils and fats. The other vegetable oils and fats will have in many cases higher IV values, whilst being below the 2% TFA limit.

We understand that when testing end food products containing both ruminant and industrial TFAs (e.g. a biscuit or a margarine with both butter and vegetable oils/fats), there are analytical methods available today (e.g. GC-MS method) which enables to test the TFAs levels and quantify them in general.

However, it is not possible today to our knowledge to separate precisely ruminant from non ruminant TFA directly using an analytical method. Indeed, there can be an overlap between the two sources of TFA in some of the specific TFA molecules. This is, among others, the case where levels of one origin are very low (e.g. a fat blend with both vegetable and animal fat origin). An estimation of the non ruminant TFA content in a product where both ruminant and non ruminant TFAs are present, can only be done by calculating the total TFA (ruminant and non ruminant content) based on the quantity and type of dairy ingredients in the product.

It would also be important to know in advance the various ingredients used.

IMACE:

IMACE members test products regularly, typically once per year.

It is not currently feasible to test specifically for iTFA – so tests cover total TFA content. As members do not supply products with ruminant TFA, total TFA = iTFA for members' products. However, TFA in end products may include ruminant TFA (e.g. from dairy products) as well as iTFA. A calculation would be needed to assess iTFA content.

IMACE does not have data on the costs of product testing – however, it may be possible to ask members for this.

CAOBISCO:

There would be four ways: (i) you analyse the product (ii) you analyse the ingredients (iii) you rely on suppliers to tell you (iv) you rely on nutrition data.

Food Drink Europe:

That is a very technical question. There is a discussion at the Codex Alimentarius, a committee on methods of assessment and sampling is working on establishing the conditions of a

	"free TFA" claim. At the last meeting it was said that it would be very difficult to accurately detect the level of TFA in food products. It was also said that it would be difficult to establish a single level of TFA in food. There will be a follow up discussion at the CA in November or December. It would be important to give account of that discussion.
In case of a 2% limit, what share of your members would need to reformulate their products? To what extent would SMEs be affected?	**HOTREC:** If a 2% limit on industrial TFAs applies to all products sold by the food processing/manufacturing industry, hospitality businesses should not have difficulties, as the majority of restaurants cook dishes with raw ingredeints, and when there are iTFAs content in meals served by hospitality businesses it is usually only the result of iTFAs content in supplies acquired from the processing industry. What matters for the hospitality industry is that any legislative measure focuses exclusively on industrial Transfats, leaving aside natural transfats (which simply cannot be replaced in the hospitality sector). Moreover, labelling/information obligation are disproportionate/unfeasible in the restaurant sector given its structure (micro-enterprises) and operating methods (non-standardised food, change of ingredients/supply menus on a very regular basis – e.g. menu of the week, dish of the day, etc.) **FEDIOL:** NO available FEDIOL information on this so far. From the feedback we gather, setting an EU TFA limit of 2% on fat basis in food destined to consumers is not expected to have big impact on the sector, as many efforts have already been achieved in the last years to reduce TFA content. *If such 2% TFA legislation was adopted, what level of effort would a typical firm have to invest?* FEDIOL does not have data to answer, also given the too short time between receiving the question and answering (2 days). We do not anticipate substantial efforts for FEDIOL members within the vegetable oil/fat sector. Having said that, the discussions and work taking place between FEDIOL members and their customers in their quest for the best solution fitting their products should not be forgotten. But we cannot answer for other players or other sectors. *How could the costs or disruption of such a requirement be minimised?* It is important to have maximum flexibility in the choice of raw materials that replace high TFA products. This can help to minimise costs for adaptations at customer level. A clear asset – which FEDIOL and many other sectors have been advocating for years – would be to have the deletion of

	the fully/partially hydrogenation labelling deleted. **Food Drink Europe:** FDE would hope that other models are considered as well, such as the Austrian model which is more nuanced. **Swedish Food Federation:** As most food produced in Sweden is already below the suggested regulatory level, the legislative measures would have little impact in Sweden. There may be a slight cost to some firms to change recipes and labels, but this would be a minority, and given the experience of firms in Sweden previously, it would not be a large cost. There would be no additional costs for testing or monitoring, as this would be incorporated into existing control specifications. New industrial standards come in fairly regularly, so producers are used to changing the things they monitor and build it into their existing costs. So it is estimated that there is no additional cost.

(d) Labelling

What would be the economic burden for your organisation (or your members) of understanding a new obligation to indicate the TFAs content of foods in the nutrition declaration?	**FEDIOL:** FEDIOL strongly believes that mandatory TFA labelling is not the way forward. It would further increase consumer confusion and lack of awareness in general on what is written on the label. Instead, in order to consolidate progresses made on a voluntary basis and ensure a level playing field applicable to food business operators across Member States (due to the multiplication of national legislation), introducing EU legislation setting a 2% TFA limit on fat basis would better address the issue. It would eliminate the TFA issue across all EU countries once and for all. This is confirmed by many studies such as: • Stender S. et al., Tracing artificial trans fat in popular foods in Europe: a market basket investigation. BMJ Open 2014 which states that "The effectiveness of policies for reducing dietary TF was recently assessed based on studies published between 2005 and 2012 It was found that 'bans were most effective in eliminating TF from the food supply, whereas mandatory TF labelling and voluntary TF limits had a varying degree of success'. This statement is strongly supported by the findings in the present study concerning the current availability of popular foods with high amounts of I-TF in Europe, thus lending support to a legislative TF restriction by the EU. This is a low hanging fruit to pick in the prevention of coronary heart disease among 500 million EU citizens." • Downs S. et al., the effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence, Bulletin of the World Health Organization 2013."Our observation that national and local bans were far more effective than mandatory TFA labelling reflects the Danish

Nutrition Council's decision to opt for a ban when considering how to remove TFAs from the food supply. Labelling policies have several limitations. First, TFA intake can remain extremely high in pockets of the population. In Canada, even after mandatory labelling led to 76% of foods meeting voluntary TFA limits, intake in the population still exceeded the WHO recommendation that less than 1% of dietary energy intake should come from consuming TFAs. In particular, intake by teenage boys was double the recommended level. Second, some foods with low TFA 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 TFA 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. Third, for labelling regulation to be effective, the population must be both aware of TFAs and able to interpret nutrition labels accurately. In high-income countries, where literacy levels are high, labelling is more likely to be effective in reducing TFA intake than in low- and middle-income countries."

It should also be noted that if this option was chosen, it would target both ruminant and industrial/non ruminant TFAs, as highlighted in the Commission report on TFAs. Hence, in that case, the labelling would need to include the total TFA content – from both ruminant and non ruminant.

IMACE:

IMACE members previously labelled TFA content of their products. This helped to provide information to consumers, though effectiveness may have been limited by consumer awareness of TFAs.

Current rules regarding labelling of partially and fully hydrogenated oils are unhelpful, because of a lack of consumer understanding. As a result, the current rules unfairly and unnecessarily stigmatise the sector.

Labelling of TFAs would be preferable to the current rules relating to PHVO/FHVO. Any such labelling should cover whole TFA content because this determines health impacts.

Companies regularly review and update product labels. Therefore, if there was a sufficient lead-in time for a new labelling requirement (e.g. 2 years or more) it should not have significant costs.

Food Drink Europe:

A new obligation to indicate TFA level on food products would be a huge undertaking, similar to the FIR. Entire management systems have to be changed. This is broader than changing a label. That is an option that FDE would not support. If there was a desire by policymakers to go for a regulatory limit on iTFA FDE would request a deletion of the obligation to label partially

	hydrogenated oil on food products. Consumers do not understand the difference between fully and partially hydrogenated. There is also confusion among smaller producers about those terms. From a consumer understanding this is not working. A total ban on TFAs is not realistic and feasible. Costing the burden is something to ask individual companies about. The FIR required relabelling of 30,000 products. The cost of change in one SKU is what needs to be ascertained. From a theoretical point of view, the costs might be higher for the bigger companies because they have more products, but smaller companies might not have the sresourcs to do the analysis. They will need to outsource the work.
What would be the economic burden for your organisation (or your members) of testing iTFA/ PHO in your products? Would this be more burdensome for SMEs?	**HOTREC:** See above: very high impact / completely disproportionate given the origins of iTFAs. **FEDIOL:** Modern quality control procedures ensures that the fatty acid composition, including the amount of TFA, of vegetable oils and fats, is checked routinely by manufacturers. Having an EU 2% legislation and using the TFA parameter for a definition of fully/partially hydrogenated oils is possible to do in official controls done by authorities. We understand that this is how it works in those countries like Denmark or Austria, where there has been a legislation on TFA already for some time. In addition, analytical methods exist today to test the TFA content in the final food product sold to the consumers (e.g. biscuits, margarines, ready-made meals etc.). Would the labelling requirement mean that any additional testing of products would be required? If so, what would be needed and how many tests would be required? We clearly see no benefit in such option. Also, the impacts of the labelling change should not be underestimated. All labels have been changed recently following the FIC implementation and any change will require additional costs for the entire food industry. As the labelling option would target both ruminant and non ruminant TFAs (as highlighted in the Commission report on TFA 2015), we can anticipate quite numerous extra costs required for the dairy sector and for all products containing dairy fats, as well as for the vegetable oils and fats sector and food products containing vegetable oils and fats or both dairy and vegetable oil/fat. This is also irrespective of whether there is any benefit in such an option and of the changes in labelling. Ultimately, we see huge impacts and either loss in flexibility given and volatility of costs or the need to change labels

continuously to adapt to changing TFAs content.

If the EU was to legislate to require nutrition declarations to include details of the TFA content what would be the impact on FEDIOL member firms?

This would have clear impacts as it would mean a complete change of the way industry is functioning and a change of all labels. We would also have strong objections on the approach behind, knowing the lack of consumers understanding on labels. If bottled oils need to be labelled, the impact could be very negative, since they could be seen as a source of TFA, while in reality the MUFA and PUFA have a very positive effect. Even at very low levels of presence, the consumer could consider TFA as a contaminant. This could give a wrong stigma to bottled oils, with a very negative impact on the whole Oils and Fats business.

If such legislation was adopted, what level of effort would a typical firm have to invest (expressed either in person days or euro) in: review of the legislation and appraisal of the implications for the firm; internal staff communication/engagement; supply chain communication/engagement; customer communication/engagement; changes to product labels and product documentation; or other (please specify).

Given the short time it is impossible to provide detailed figures. Comparing it to other assessments done for other issues (origin labelling), adding on top a labelling and having to add the measurement of exact TFA content on labels will entail clear changes in the sector. Whilst FEDIOL members deliver vegetable oils and fats as per FEDIOL Code of refining ensuring that no more than 2% TFA is produced during the refining and whilst testing of TFA content is done routinely, this is not an information which is passed to customers today as this is not a mandatory EU requirements.

Hence, this means that additional costs will come from:

- tracking the TFA level in each batch/product delivered to customers

- possible stocks of every batch given the fluctuations in TFA content

- adding this information up to the customers (vegetable oil/fat as ingredient) or to the consumer directly (labels for bottled oils)

- additional work force required

- lack of flexibility for customers using the vegetable oils/fats

We can anticipate that this would generate substantial costs. We are currently working on a more detailed economic assessment which we will share in the coming weeks.

	The additional costs for the processors would be passed on to the next steps in the processing, then to the retailers/wholesalers and ultimately to the consumers who would have to pay a higher price on each bottled oil bought. The price of a bottled oil, irrespective of its botanical origin, would rise. Would the labelling requirement mean that any additional testing of products would be required? If so, what would be needed and how many tests would be required? As highlighted above, such tests are routinely done. This is done to ensure that the product complies with the requirements and specifications set. But the exact levels is not necessarily passed on to the chain. Adding this extra requirements will have clear impacts for the sector and for downstream users. It will also add to the complexities of end products producers to ensure the exact figures are set, and hence any change of the recipe will have to be weighted against the changes of the labelling that this will have. What would be the typical cost of amending a label to introduce details of the TFA content to the nutrition declaration? See above. Several thousands euros will have to be added to change the labels – for those going directly to bottled oils and fats - and add this extra information in top of what exists today. Such costs would include the design, reprint of labels etc. How many label designs would need to be changed across FEDIOL members? All labels for bottled oils and fats will have to be changed. But also all products where vegetable oils are an ingredient. How frequently, on average are such labels updated or 'refreshed' (in the absence of new legislation / regulatory requirements)? It is difficult to estimate as there are often changes due to new legislation/labelling requirements. How could the costs or disruption of such a requirement be minimised? We do not see how this would be minimised, except by not introducing such labelling requirement at all but rather set an EU TFA max limit on 2% in final product for the final consumer.
On average, how many products would be affected in your opinion?	**Swedish Food Federation:** They did not believe that it would be possible to introduce the labelling legislation. This is because for some products, it would not be possible to say the exact amount of industrial trans fats in a product. Even where it is possible, they do not think it would be a good idea. This is because consumers do not know what a high or low level of industrial trans fat is. As soon as they see a label with industrial trans fats on it, they will think it

	is a bad product, even if the level of industrial trans fats is low and within any guidelines.

(e) Prohibition of the use of partially hydrogenated oils in foods

If the EU was to legislate on use of partially hydrogenated oils in food what would be an appropriate definition to use?	**FEDIOL:** FEDIOL does not support the US approach which "bans" PHOs for the following reasons: • It sets a dangerous precedent in banning a process. • It will clearly also impact on consumer perception overall on hydrogenation. Already today, there is a clear lack of consumer understanding on TFAs or on hydrogenation. Banning the partial hydrogenation will also have consequences on the use of full hydrogenation in the future, as consumers will not understand the difference between the 2 hydrogenation process – where one is banned and the other is allowed. • The US approach is not relevant as it targets a process rather than a nutrient As highlighted in the EU Inception Impact Assessment on TFA , "consumption of trans fats (…) increases the risk of heart disease more than any other macronutrient compared on a per calorie basis." It is therefore more relevant to limit the level of a nutrient with an adverse health profile – TFA in this case - than a process - partial hydrogenation of oils and fats. The US approach is not clear and difficult to understand for consumers Setting a 2 % TFA max limit is clearer and easier to understand from a consumer perspective, as advocated by EU consumers' organisation. • The US approach does not fit the EU system • The US approach is not in line with the overall approach and objectives pursued in Regulation (EU) No 1169/2011 on Food Information to Consumers and in Regulation (EC) No 1924/2006 on nutrition and health claims. It is contrary to findings of the EU Commission report , which states that "Although average intake in the EU has been reported below nationally and internationally recommended levels, this is

	not true for all groups of population. Food products with high industrial TFA content are available on the market and there are public health gains to be reaped by reducing intake." • It does not take into account scientific and technical progresses. Having said that and answering the question of the definition, an EU definition of "partially hydrogenated oil" (PHO) linked to TFA would be expressed as follows: "Partially hydrogenated" means that the hydrogenation was not fully performed to the extent possible under practical conditions, correlating and results with a trans fatty acids (TFA) content above 2% on fat basis. It would better address TFA in the EU context for the following reasons: a) Modern processing ensures that the fatty acid composition of vegetable oils and fats, including TFAs, is checked routinely by manufacturers. b) Legislation based on TFA limits on fat basis in products intended for final consumers therefore, enables an easier control by authorities on the proper implementation of the hydrogenation labelling. c) Given the existing national legislations on TFA, which are referring to a 2% TFA on fat basis, similar EU harmonised legislation is aligned with such practices and therefore seems appropriate. d) FEDIOL code of practice on refining refers to a max 2% TFA on fat basis to be achieved during refining. Such definitions are therefore matching current refining requirements. e) An EU harmonised legislation will ensure a level playing field and avoid diverging definitions across EU Member States. f) This is in line with the EU report on TFA, which confirms the need for an EU solution. On the contrary, the US definition of PHO – linked to iodine value – is not the way forward for Europe. FEDIOL has prepared a detailed explanation which we are happy to further highlight. See FEDIOL 17NUT054.
What is the volume / value of the products in the EU that would be	**FEDIOL:** FEDIOL does not have data.

affected by such legislation?	
What would be the consequences for the EU market for oils and fats of prohibiting use of partially hydrogenated oils in foods? What specific changes would occur?	**FEDIOL:** Basically the same consequences as a max 2% TFA level, but with even more negative consequences as flexibility would be limited due to the banning of a process.
What are the expected consequences for your members in the EU legislating to prohibit partially hydrogenated oils from being used in food?	**FEDIOL:** • The US type approach goes against all national and voluntary measures undertaken so far in Europe. Rather than looking at the impacts, the approach should be challenged. • It suppress any flexibility for food business operators in finding tailr-made solutions for each customers products • It is difficult for a consumer to understand. Particularly in the case where the fully hydrogenation is still one of the solutions to address TFAs. • The implementation of the same iodine value definition than in USA will lead actually to higher TFA on the market compared to setting a max 2% TFA legal limit. • It contradicts previous voluntary and national regulatory initiatives taken in Europe for many years. • It goes against the overall approach and objectives pursued in Regulation (EU) No 1169/2011 on Food Information to Consumers and in Regulation (EC) No 1924/2006 on nutrition and health claims. • it does not take into account scientific and technical progresses. • Ultimately it also sets a dangerous precedent in banning a process. **IMACE:** IMACE would oppose an EU limit on PHO because: • There are problems in defining and measuring PHO content. A robust definition of PHO is lacking. The US definition

	based on iodine content is unreliable as an indicator of TFA. FEDIOL may be able to provide more details. • It would be better to target TFA, which are more directly related to health impacts. Limiting TFA content is more closely related to the health objective of limiting consumer TFA intake. • Eliminating use of PHO would be disproportionately costly, because of the difficulties imposed on particular suppliers of specialist products.

(f) Conclusions and Future Policy

Are the measures regarded as a success in your sector?	**FEDIOL:** • FEDIOL actions have been successful in reducing significantly TFA content in their products. However, and as highlighted in the Commission report, there are still high content in some products in some countries. • There is also a clear lack of consumers knowledge on TFA and on the difference between partially and fully hydrogenated oil. Due to this, consumers believe that products containing partially hydrogenated oils are "safer" than fully hydrogenated oils. • This is why FEDIOL strongly believe that the only ways forward lies in: • The setting of an EU 2% non-ruminant TFA legal limit on fat basis in products intended to final consumers. • TOGETHER WITH • The deletion of the existing full/partial hydrogenation labelling as prescribed by Regulation (EU) No 1169/2011 • An EU 2% maximum limit of TFA on fat basis in the product intended to the final consumer would therefore set a level playing field across Europe, get rid of the higher levels still present on the market in some EU countries and prevent the imports of high TFA products from 3rd countries. Such deletion of labelling would finally avoid consumer confusion and lack of understanding. All in all, the 2 measures will contribute to a better regulatory framework.
What lessons have been learnt regarding implementation? In hindsight, would the organisation do	

anything differently if it had the chance again?	
Are there any plans for new rules? Are there any plans to modify or extend the existing rules or arrangements for their implementation? If so, what are these plans and why?	**FEDIOL:** There are no plan to modify FEDIOL Code of Practice. Actions at the level of industry has contributed to improve the situation. But there are still pockets of issues in some countries in some products and there industry actions has also some limits. In this context, to tackle the situation once and for all, the only way forward is to: Set an EU 2% non-ruminant TFA legal limit on fat basis in products intended to final consumers TOGETHER WITH the deletion of the existing full/partial hydrogenation labelling as prescribed by Regulation (EU) No 1169/2011
What can the EU and other countries learn from the experience in your country?	No information provided.
Would you welcome the introduction of EU wide measures to limit iTFAs? If so, what type(s) of measure would you support and why?	**HOTREC:** Labelling on pre-packed products is acceptable. Limit on iTFAs also acceptable. No obligation for non-prepacked food, no testing obligation. **FEDIOL:** YES. As highlighted, FEDIOL supports since 2014 the setting of an EU 2% non-ruminant TFA legal limit on fat basis in products intended to final consumers TOGETHER WITH the deletion of the existing full/partial hydrogenation labelling as prescribed by Regulation (EU) No 1169/2011. In this context, we support the Danish approach by which an EU

TFA legal limit would be

based on a 2%* TFA on fat basis in products intended to final consumers. *The 2% TFA legal limit on fat basis is equivalent to the 2g TFA per 100g of oil/fat, in the product intended for the final consumer.

Such a 2% TFA limit is:

- in line with existing national initiatives such as in Denmark, Austria or Hungary,

- in line with EFSA acknowledgment that TFA are close to 1 to 2% Energy in Europe,

- enabling to get rid of higher levels found in countries such as Croatia, Sweden, Bulgaria,

Slovenia or Poland as per the Commission report on TFA,

- consistent with the FEDIOL Code of Practice on refining, which ensures that, during

refining, no more than 2% TFA on fat basis is formed, including in bottled vegetable oils.

With the introduction of such an EU TFA limit legislation as described above, the existing fully/partially hydrogenation labelling will not have any "raison d'être" anymore and should be deleted for the following reasons:

- one of the rationale behind such labelling was to inform consumers on the presence of partially hydrogenated oils which contain much higher TFA levels than 2%, contrary to fully hydrogenated oils where TFA levels are below 2% TFA. With such a new EU TFA 2% legal limit, all those high non-ruminant TFA food products will be gone from the EU market as they will be forbidden in Europe.

- consumers do not know the difference between partially ("partly" according to Regulation 1169/2011) or fully hydrogenated oils.

- consumers confuse both terms, thinking that products labelled as fully hydrogenated contain high levels of TFA.

Hence, if an EU TFA legal limit was to be introduced whilst keeping the current mandatory hydrogenation labelling, consumers would continue to think fully hydrogenated oils and food products thereof contain high TFA levels. This would further mislead consumers and lead to discrimination for the vegetable oil and fat sector and particularly for all sectors using such ingredients.

This lack of consumers understanding has been demonstrated in studies and in the Commission report on TFA, which states that

"(…) the little information available suggests that the majority of Europeans do not know about TFA (…) partially hydrogenated or fully hydrogenated oils. (…)".

On the contrary, FEDIOL does not support the US approach which "bans" PHOs. As

highlighted in the EU Inception Impact Assessment on TFA , "consumption of trans fats (…)

increases the risk of heart disease more than any other macronutrient compared on a per

calorie basis."

It is therefore more relevant to limit the level of a nutrient with an adverse health profile – TFA in this case - than a process - partial hydrogenation of oils and fats.

It is also clearer and easier to understand from a consumer perspective, as advocated by EU consumers' organisation.

It also fits the EU regulatory system and public health platform better, as it is in line with the overall approach and objectives pursued in Regulation (EU) No 1169/2011 on Food Information to Consumers and in Regulation (EC) No 1924/2006 on nutrition and health claims. It is also confirmed in the EU Commission report , which states that "Although average intake in the EU has been reported below nationally and internationally recommended levels, this is not true for all groups of population. Food products with high industrial TFA content are available on the market and there are public health gains to be reaped by reducing intake."

Also, it does not take into account scientific and technical progresses.

IMACE:

IMACE reiterated the following key points:

- Total and not just industrial TFA should be considered when examining health effects
- The 2% limit has already been achieved by members. These efforts should be consolidated, but eliminating TFA completely would have disproportionate impacts
- The focus should be on TFA, not on PHO

Food Drink Europe:

As mentioned above FDE supports the 2% limit but would invite a

	nuanced approach such as that implemented in Austria. FDE's preference is through voluntary agreements, which work well. But FDE would also work to comply with a legal obligation. FDE does not favour a labelling obligation. **Swedish Food Federation:** The model currently used in Austria would be the preferred option. But as stated earlier, reducing the consumption of industrial trans fats is only tackling part of the problem. The measures currently in place in Sweden are seen as a success. Other countries could learn from the Swedish experience in both this field and others – it is fruitful to have an open dialogue between concerned parties and form a commitment on the way to proceed.
What consequences, if any, would the proposed measures have for export of products beyond the EU?	**FEDIOL:** The EU system is a very complex system which enables a high safety and quality standard of all products complying with it. We do not see major consequences for exports of vegetable oils/fats outside the EU. But it will impact on final products (biscuits etc.) manufactured in EU but exported outside EU. **IMACE:** In general a small % of production is traded internationally. Therefore members are more affected by standards in the domestic market than in export markets, and the risk of low cost imports meeting lower standards is not significant.

Annex 7 Validation questionnaire

A7.1 Introduction

Thank you for your interest in the consultation. Its purpose is to allow stakeholders to verify and challenge the inputs, assumptions and conclusions of ICF's study.

The study has considered the impact of potential EU action targeting industrially produced trans fatty acids (iTFAs) (ruminant TFA sources generally contribute little to overall TFA intake). The policy options considered are:

Option 1: **Setting a limit on the level of iTFAs in food** (at 2% of the total fat content), either via a voluntary agreement between the EU and the industry or via new EU legislation.

Option 2: **Imposing a labelling obligation** to specify the product's TFA content in the nutrient declaration that is provided on the product's packaging.

Option 3: **Prohibiting the use of partly hydrogenated oils (PHOs) in food**, either via a voluntary agreement between the EU and the industry or via new EU legislation.

The potential impacts of these options have been assessed by comparing the expected 'with policy' situation with a 'no policy' scenario in which there is no new EU action on TFAs.

This consultation is structured as follows. First, you are asked to give your opinion on how the iTFA situation will evolve if no new action is taken at EU level. You are then invited to comment on the alternative policy options and their health, economic and environmental impacts. Finally, you will have the opportunity to provide any information that you have that would justify revision of our analysis.

You may provide your responses in other languages than English.

A7.2 About you

1) I am responding to this consultation as:

( ) An individual

( ) A representative of a business or organisation

2) What type of organisation do you represent?

( ) A food manufacturing/ processing business

( ) A food service business

( ) A food distribution/ retail business

( ) A food sector association

( ) A public authority

( ) An international organisation

( ) Academia

( ) A consumer organisation

( ) A public health organisation

( ) An environmental organisation

3) If you are representing and organisation from the food business, please specify the sub-sector:

( ) Biscuits / preserved cakes and pastries

( ) Chocolates / confectionery

( ) Dairy products

( ) Drinks

( ) Food distribution / wholesale / retail

( ) Fresh cakes / pastries / bakery products

( ) Ice cream

( ) Ingredients for the food sector

( ) Margarines and spreads

( ) Meat and fish products

( ) Oil and fats
( ) Potato products
( ) Ready meals
( ) Restaurants / food services
( ) Snacks
( ) Soups / sauces / condiments
( ) Other (please specify)

4) If "other", please specify:

_____

5) What is the size of your organisation?

( ) Less than 250 employees
( ) More than 250 employees

6) Please indicate which share of your membership (in %) consists of SMEs:

_____

7) Please indicate in which EU Member State you are based:

( ) Austria
( ) Belgium
( ) Bulgaria
( ) Croatia
( ) Cyprus
( ) Czech Republic
( ) Denmark
( ) Estonia
( ) Finland
( ) France
( ) Germany
( ) Greece
( ) Hungary
( ) Ireland
( ) Italy

( ) Latvia

( ) Lithuania

( ) Luxembourg

( ) Malta

( ) Netherlands

( ) Poland

( ) Portugal

( ) Romania

( ) Slovakia

( ) Slovenia

( ) Spain

( ) Sweden

( ) United Kingdom

( ) Not EU-based

8) In which country are you based?

_____

A7.3 General

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

9) Levels of iTFA in food products sold in the EU have reduced significantly in recent years. Assuming no new EU policy on this topic, the most likely future scenario is that:

( ) iTFA levels in food will remain at, or close to, today's levels.

( ) iTFA levels will fall until they disappear almost completely from the food chain in 15 years.

( ) iTFA levels will fall until they disappear almost completely from the food chain in 10 years.

( ) None of the above. Please indicate what is likely to happen and why::

_____

( ) Unsure

Please explain:

_____

_____

_____

_____

10) To what extent do you agree with the following statement:
"The principal source of iTFAs in food is partially hydrogenated vegetable oils (PHOs), including soybean, cottonseed and other liquid oils."

( ) Strongly disagree

( ) Disagree

( ) Neutral

( ) Agree

( ) Strongly agree

( ) Don't know

Comments:

11) To what extent do you agree with the following statements:

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
A food manufacturer/processor that sells its products in more than one country will generally use the same recipe/formulation for the same product in all of those markets	( )	( )	( )	( )	( )	( )
A food manufacturer/processor that reformulates a product to reduce iTFA content in order to comply with one	( )	( )	( )	( )	( )	( )

Member State's legislation will use that reformulation in other Member States.						

Comments:

12) If the EU does not act, which countries will adopt new public policies to reduce iTFA intake?

[ ] Austria

[ ] Belgium

[ ] Bulgaria

[ ] Croatia

[ ] Cyprus

[ ] Czech Republic

[ ] Denmark

[ ] Estonia

[ ] Finland

[ ] France

[ ] Germany

[ ] Greece

[ ] Hungary

[ ] Ireland

[ ] Italy

[ ] Latvia

[ ] Lithuania

[ ] Luxembourg

[ ] Malta

[ ] Netherlands

[ ] Poland

[ ] Portugal

[ ] Romania

[ ] Slovakia

[ ] Slovenia

[ ] Spain

[ ] Sweden

[ ] United Kingdom

13) If the EU does not act, which food sectors in which countries are likely to take additional concerted measures to further reduce iTFA content of food?

	Biscuits preserved cakes and pastries	Chocolates / confectionery	Dairy products	Drinks	Food distribution/ wholesale / retail	Fresh cakes / pastries / bakery products	Ice cream	Ingredients for the food sector	Margarines and spreads	Meat and fish products	Oil and fats	Potato products	Ready meals	Restaurants / food services	Snacks	Soups / sauces / condiments
EU-wide	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Austria	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Belgium	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Bulgaria	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Croatia	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Cyprus	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Czech Republic	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

	Biscuits preserved cakes and pastries	**Chocolates / confectionery**	**Dairy products**	**Drinks**	**Food distribution/ wholesale / retail**	**Fresh cakes / pastries / bakery products**	**Ice cream**	**Ingredients for the food sector**	**Margarines and spreads**	**Meat and fish products**	**Oil and fats**	**Potato products**	**Ready meals**	**Restaurants / food services**	**Snacks**	**Soups / sauces / condiments**
Denmark	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Estonia	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Finland	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
France	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Germany	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Greece	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Hungary	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Ireland	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

	Biscuits preserved cakes and pastries	**Chocolates / confectionery**	**Dairy products**	**Drinks**	**Food distribution/ wholesale / retail**	**Fresh cakes / pastries / bakery products**	**Ice cream**	**Ingredients for the food sector**	**Margarines and spreads**	**Meat and fish products**	**Oil and fats**	**Potato products**	**Ready meals**	**Restaurants / food services**	**Snacks**	**Soups / sauces / condiments**
Italy	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Latvia	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Lithuania	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Luxembourg	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Malta	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Netherlands	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Poland	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Portugal	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

	Biscuits preserved cakes and pastries	**Chocolates / confectionery**	**Dairy products**	**Drinks**	**Food distribution/ wholesale / retail**	**Fresh cakes / pastries / bakery products**	**Ice cream**	**Ingredients for the food sector**	**Margarines and spreads**	**Meat and fish products**	**Oil and fats**	**Potato products**	**Ready meals**	**Restaurants / food services**	**Snacks**	**Soups / sauces / condiments**
Romania	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Slovakia	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Slovenia	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Spain	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Sweden	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
United Kingdom	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

General - part 2

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

14) If the European Commission and EU level business associations jointly agreed a voluntary agreement to reduce iTFA levels in food products, what level of participation would you expect from businesses that have not already reduced iTFA levels in their products:

( ) Low (

( ) Medium (21-50% of businesses in relevant food sub-sectors)

( ) High (51-100% of businesses in relevant food sub-sectors)

Comments:

15) Would you expect rates of participation in a voluntary agreement to differ between suppliers of prepacked and non-prepacked foods?

( ) Higher rate of participation for prepacked compared to non-prepacked food businesses

( ) Higher rate of participation for non-prepacked compared to prepacked food businesses

( ) No difference in rates of participation

( ) Don’t know

16) Please indicate the scale of the reduction in iTFAs in food products that an EU voluntary agreement can be expected to deliver, compared to current levels

0 _____[__]_____ 100

[ ] Don't know

17) How likely are each of the following possible consequences of requiring the inclusion of a food product’s TFA content in the nutrient label?

	Very unlikely	**Unlikely**	**Neutral**	**Likely**	**Very Likely**	**Don't know**
Consumers will read	( )	( )	( )	( )	( )	( )

and understand the information on the label and reduce their consumption of products high in iTFA						
Consumers will read and understand the information on the label but they will not change their consumption habits	( )	( )	( )	( )	( )	( )
Consumers will read but they will not understand the information on the label and will not change their consumption habits	( )	( )	( )	( )	( )	( )
Consumers will ignore the information on the label and will not change their consumption habits.	( )	( )	( )	( )	( )	( )
TFA labelling will lead to overall healthier product choices of	( )	( )	( )	( )	( )	( )

consumers						
TFA labelling will not lead to overall healthier product choices	( )	( )	( )	( )	( )	( )
TFA labelling will not influence the overall healthiness of product choices	( )	( )	( )	( )	( )	( )

18) Partially hydrogenated oils (PHOs) are not defined in EU law or in the Codex Alimentarius. The US Food & Drug Administration (FDA) has defined PHOs as, "fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an IV greater than 4 as determined by a method that is suitable for this analysis (e.g., ISO 3961 or equivalent)." In this definition 'IV' means 'iodine value' or iodine number. The FDA explains that, "the IV of a fat or oil is not a direct measure of the TFA content, but is a measure of the degree of unsaturation. In your opinion is the FDA's definition of PHOs applicable to the European market?

( ) No

( ) Yes

( ) Don't know

6.1.1 19) If "No" please explain:

_____

_____

_____

_____

(untitled)

You have now completed the general section of the consultation. The remaining questions focus on specific subjects. You may choose to respond to all of them, or to some of them only.

20) Which of the survey sections below would you like to respond to? You may select as many as you like.

[ ] Health impacts

[ ] Economic impacts

[ ] Consumer impacts

[ ] Internal Market and trade impacts

[ ] Impacts on SMEs

[ ] Environmental impacts

Health impacts

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

21) The European Commission's Joint Research Centre has estimated that current adult iTFA intake (as a weighted average across the EU) is 0.3% of total energy intake. In your view is this estimate:

( ) An overestimate of the current average iTFA intake in the EU (please provide your estimate and source):
_____*

( ) An underestimate of the current average iTFA intake in the EU (please provide your estimate and source):
_____*

( ) A reasonable estimate

( ) I don't know

22) Some socio-economic groups have a greater iTFA intake than others, and are at greater risk of suffering negative health effects. To what extent do you agree with each of the following statements:

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
EU legislation to regulate iTFA content of foods / ban use of PHOs will protect all socio-economic	( )	( )	( )	( )	( )	( )

groups from the negative health effects of iTFA intake						
Mandatory labelling of TFA content of food will protect all socio-economic groups from the negative health effects of iTFA intake	( )	( )	( )	( )	( )	( )
An EU wide voluntary agreement to limit iTFA content of foods / remove PHOs will protect all socio-economic groups from the negative health effects of iTFA intake	( )	( )	( )	( )	( )	( )

Comments:

23) To what extent do you agree with the following statements on the social benefits (improved health outcomes and reduced healthcare costs) of combining different policy measures with a requirement for the TFA content of a food product to be stated on the label:

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
The social benefits of a voluntary agreement will be increased if products' TFA levels must be specified on the nutrient label.	( )	( )	( )	( )	( )	( )
The social benefits of a legal limit on TFA content will	( )	( )	( )	( )	( )	( )

be increased if products' TFA levels must be specified on the nutrient label.						

Economic impacts for businesses

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

24) ICF has estimated that, on average, food business operators (food service and manufacturing) will each spend one hour of staff time reading and understanding guidance issued on how to comply with legislation regulating iTFA content of food. Is this estimate:

( ) Too low (please provide your estimate, what kind of business it applies to, and its source): _____*

( ) Too high (please provide your estimate, what kind of business it applies to, and its source): _____*

( ) A reasonable estimate

( ) Don't know

25) ICF has estimated the cost of a test to determine the iTFA/TFA content of a food product at EUR 65 per test. Is this estimate:

( ) Too low (please provide your estimate and its source): _____*

( ) Too high (please provide your estimate and its source): _____*

( ) A reasonable estimate

( ) Don't know

26) ICF has estimated that a typical food business commissioning a test of a product's TFA content will spend an average one hour of staff time arranging each test and reviewing the results. Is this estimate:

( ) This estimate is too low (please provide your estimate and its source): _____*

( ) This estimate is too high (please provide your estimate and its source): _____*

( ) This is a reasonable estimate

( ) Don't know

27) Which sectors of the industry are most likely to be affected by:

An EU legal limit on iTFA content in food?

[ ] Biscuits / preserved cakes and pastries

[ ] Chocolates / confectionery

[ ] Dairy products

[ ] Drinks

[ ] Food distribution / wholesale / retail

[ ] Fresh cakes / pastries / bakery products

[ ] Ice cream

[ ] Ingredients for the food sector

[ ] Margarines and spreads

[ ] Meat and fish products

[ ] Oil and fats

[ ] Potato products

[ ] Ready meals

[ ] Restaurants / food services

[ ] Snacks

[ ] Soups / sauces / condiments

[ ] Other (please specify):

_____*

6.1.1.1 An EU ban on PHOs?

[ ] Biscuits / preserved cakes and pastries

[ ] Chocolates / confectionery

[ ] Dairy products

[ ] Drinks

[ ] Food distribution / wholesale / retail

[ ] Fresh cakes / pastries / bakery products

[ ] Ice cream

[ ] Ingredients for the food sector

[ ] Margarines and spreads

[ ] Meat and fish products

[ ] Oil and fats

[ ] Potato products

[ ] Ready meals

[ ] Restaurants / food services

[ ] Snacks

[ ] Soups / sauces / condiments

[ ] Other (please specify):
_____*

28) Given progress already achieved to reduce iTFA levels in a number of countries, in which countries would the industry be most likely to be affected by:

An EU legal limit on iTFA content in food?

[ ] Austria

[ ] Belgium

[ ] Bulgaria

[ ] Croatia

[ ] Cyprus

[ ] Czech Republic

[ ] Denmark

[ ] Estonia

[ ] Finland

[ ] France

[ ] Germany

[ ] Greece

[ ] Hungary

[ ] Ireland

[ ] Italy

[ ] Latvia

[ ] Lithuania

[ ] Luxembourg

[ ] Malta

[ ] Netherlands

[ ] Poland

[ ] Portugal

[ ] Romania

[ ] Slovakia

[ ] Slovenia

[ ] Spain

[ ] Sweden

[ ] United Kingdom

An EU ban on PHOs?

[ ] Austria

[ ] Belgium

[ ] Bulgaria

[ ] Croatia

[ ] Cyprus

[ ] Czech Republic

[ ] Denmark

[ ] Estonia

[ ] Finland

[ ] France

[ ] Germany

[ ] Greece

[ ] Hungary

[ ] Ireland

[ ] Italy

[ ] Latvia

[ ] Lithuania

[ ] Luxembourg

[ ] Malta

[ ] Netherlands

[ ] Poland

[ ] Portugal

[ ] Romania

[ ] Slovakia

[ ] Slovenia

[ ] Spain

[ ] Sweden

[ ] United Kingdom

29) Which categories of businesses are most likely to be affected by:

An EU legal limit on iTFA content in food?

( ) SMEs (under 250 employees)

( ) Large (over 250 employees)

An EU ban on PHOs?

( ) SMEs (under 250 employees)

( ) Large (over 250 employees)

30) To what extent do you agree with the following statements regarding the reformulation of food products to reduce iTFAs in response to legislation to limit iTFA content to 2% of fat or to remove PHOs:

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
Most food manufacturing businesses will face significant challenges in reformulating products that contain iTFAs	( )	( )	( )	( )	( )	( )
Most food manufacturing businesses will not need to reformulate products but will rely on alternative ingredients from their suppliers	( )	( )	( )	( )	( )	( )
Most food service businesses will face significant challenges in reformulating products that	( )	( )	( )	( )	( )	( )

contain iTFAs						
Most food service businesses will not need to reformulate products but will rely on alternative ingredients from their suppliers	( )	( )	( )	( )	( )	( )
The effort required to reformulate products to reduce iTFAs will amount to a few hours for most food manufacturing businesses, but a minority will need to invest weeks or months of time in product redevelopment	( )	( )	( )	( )	( )	( )
The effort required to reformulate products to reduce iTFAs will amount to a few hours for most food service businesses, but a minority will need to invest weeks or months of time in product redevelopment	( )	( )	( )	( )	( )	( )
Most of the costs of product reformulation will be incurred	( )	( )	( )	( )	( )	( )

by suppliers of ingredients (such as fats, oils, coatings, fillings)						

Comments:

31) ICF has assumed that fats and oils used in reformulated products are, on average, 25% more expensive than the ingredients they replace. Is this estimate:

( ) Too low (please provide your estimate and its source):
_____*

( ) Too high (please provide your estimate and its source):
_____*

( ) A reasonable estimate

( ) Don't know

32) A previous Commission study estimated that EU food product labelling requirements apply to around 27 million different Stock Keeping Units (SKUs). Is this estimate:

( ) Too low (please provide your estimate and its source):
_____*

( ) Too high (please provide your estimate and its source):
_____*

( ) A reasonable estimate

( ) Don't know

33) A previous Commission study has estimated that over a three year period the labels of 82% of the food products on the EU market are updated. Is this estimate:

( ) Too low (please provide your estimate and its source):
_____*

( ) Too high (please provide your estimate and its source):
_____*

( ) A reasonable estimate

( ) Don't know

34) ICF has estimated that an adjustment to a food product label costs, on average, EUR 1,500. Is this estimate:

( ) Too low (please provide your estimate and its source):
_____*

( ) Too high (please provide your estimate and its source): _____*

( ) A reasonable estimate

( ) Don't know

35) ICF has assumed that each Member State would invest 12 person-months of staff time to establish and promote legislation that regulated iTFA content of food products or to label TFA content (assuming EU law did not require secondary legislation at Member State level). Is this estimate:

( ) Too low (please provide your estimate and its source): _____*

( ) Too high (please provide your estimate and its source): _____*

( ) A reasonable estimate

( ) Don’t know

36) New legislation would require that Member State authorities in each Member State monitor compliance and enforce violations. What do you think is most likely to happen?

( ) Public authorities will reallocate existing resources to monitoring and enforcement of the new rules;

( ) Public authorities will spend additional resources to monitoring and enforcement of the new rules;

( ) Don’t know

Consumer impacts

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

37) To what extent do you agree or disagree with each of the following statements?

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Don't know**
Previous steps taken	( )	( )	( )	( )	( )	( )

to reduce the iTFA content of food have not led to an increase in consumer food prices.						
EU legislation to limit the iTFA content of food will not lead to an increase in consumer food prices.	( )	( )	( )	( )	( )	( )
EU legislation to limit the iTFA content of food will result in a small (<1%) increase in the price of those products that currently contain iTFAs	( )	( )	( )	( )	( )	( )
EU legislation to require the nutrient label to state products' TFA content will not lead to an increase in consumer food prices.	( )	( )	( )	( )	( )	( )

It is possible to reformulate products to reduce their iTFA content without affecting the attributes that matter to consumers.	( )	( )	( )	( )	( )	( )
There will be major challenges in reformulating some products to ensure that the attributes that matter to consumers are not affected.	( )	( )	( )	( )	( )	( )

Comments:

Internal market and trade impacts

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

38) The differences in the level and type of action taken across the EU to reduce iTFA intake has the potential to affect the integrity of the EU's Internal Market. Please indicate the extent to which you agree or disagree with each of the following statements:

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
Current differences in rules governing iTFA presence in food create	( )	( )	( )	( )	( )	( )

difficulties for producers who wish to supply different EU markets.						
Current differences in rules governing iTFA presence in food affect competition and trade within the EU market.	( )	( )	( )	( )	( )	( )
In the absence of EU action on iTFAs, more Member States will take action, so differences in rules will increase.	( )	( )	( )	( )	( )	( )
EU legislation to limit iTFAs in food will help to promote competition and trade within the EU Internal Market.	( )	( )	( )	( )	( )	( )
Mandatory product labelling on TFAs in food will help to promote competition and trade within the EU Internal Market.	( )	( )	( )	( )	( )	( )
EU legislation to ban PHOs in food will help to promote competition and trade within the EU Internal Market.	( )	( )	( )	( )	( )	( )

A voluntary agreement to limit iTFAs or phase out PHOs will help to promote competition and trade within the EU Internal Market.	( )	( )	( )	( )	( )	( )
EU legislation to reduce iTFAs in food will help to promote trade in food products (including ingredients) within the EU by harmonising rules.	( )	( )	( )	( )	( )	( )
EU legislation to reduce iTFAs in food will reduce the competitiveness of EU food products in comparison with foods imported from outside the EU.	( )	( )	( )	( )	( )	( )
EU legislation to reduce iTFAs in food will reduce the competitiveness of exported EU food products in third country markets.	( )	( )	( )	( )	( )	( )

Comments:

Impacts on SMEs

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

39) To what extent do you agree with each of the following statements, regarding small and medium enterprises (SMEs):

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
Most small and medium sized food businesses (SMEs) that sell products containing iTFAs will be able to comply with EU legislation on iTFAs (e.g. a 2% limit) without significant difficulty.	( )	( )	( )	( )	( )	( )
Most of the small and medium sized food businesses that sell products containing iTFAs will comply with EU legislation (e.g. a 2% limit) by purchasing alternative ingredients (e.g. fats and oils) from their suppliers.	( )	( )	( )	( )	( )	( )
SMEs will be able to adopt solutions already developed by	( )	( )	( )	( )	( )	( )

larger firms.						
Overall, SMEs in the food manufacturing sector will face greater challenges and costs than SMEs in the food service sector.	( )	( )	( )	( )	( )	( )
Legislation to limit iTFAs will not impose significant reformulation costs on SMEs.	( )	( )	( )	( )	( )	( )

Comments:

Environmental impacts

[Reminder] The policy options considered in ICF's study are: Option 1: a 2% limit on iTFA content; Option 2: a labelling obligation; Option 3: a prohibition of PHOs

40) To what extent do you agree with each of the following statements?

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
Palm oil is the most attractive substitute for PHOs, so any action to limit iTFAs/ PHOs will increase	( )	( )	( )	( )	( )	( )

demand for palm oil.						
The net environmental impacts of each of options for EU action to reduce iTFAs are difficult to predict, because PHOs, palm oil and other alternatives all have impacts on the environment.	( )	( )	( )	( )	( )	( )
Any increase in palm oil use resulting from EU action to reduce iTFA intake could be met from certified sustainable sources.	( )	( )	( )	( )	( )	( )

Comments:

Annex 8 Country profiles

Austria

Policy status

	Existing	Proposed/ considered
Legislation	X	
Voluntary measures		
Labelling		
Consumer information		

Description of existing measure(s)

Type of measure	Legislation
Description of measure *(if legislation paste exact text of legislation)*	Ministerial Decree No. 267 of 20 August 2009 on trans fatty acids content in food (267. Verordnung des Bundesministers für Gesundheit über den Gehalt an trans-Fettsäuren in Lebensmitteln)
Scope of measure	The decree prohibits the production or marketing of foodstuffs with a trans fatty acid content exceeding 2 g per 100 g of total fat content. The limit value can 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 fatty acid content does not exceed 4 g per 100 g of total fat, or provided the total fat content is less than 3% and the trans fatty acid content does not exceed 10g per 100g of total fat. This limit is also applicable to imported food.[117] The underlying motivation for the introduction of the measure is indicated as a public health measure following a precautionary approach (protecting the most vulnerable such as socially disadvantaged groups more exposed to trans fatty acids in their diet).[118]
FBOs covered	N/A

117 https://www.konsument.at/presse/transfette-in-lebensmitteln-erhoehter-gehalt-bei-importprodukten-moeglich-26-02-2014

118 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

Derogations *(e.g. low fat products, local products)*	This regulation does not apply to milk and milk products which have naturally occurring TFA content.[119]
Share of SMEs involved *(in case of voluntary measures)*	N/A
Length and characteristics of transition period	(1) Fats and oils as well as other foodstuffs which do not comply with the Ordinance, but which have hitherto been allowed, may be placed on the market until stocks are reduced. (2) Foodstuffs may be produced and placed on the market from or with fats and oils in accordance with paragraph 2 of the Ordinance, a maximum of twelve months after the entry into force of the Regulation.
Arrangements for measure enforcement and compliance monitoring	According to an interview with Austrian Food Industry representatives, companies did not have to report. The regulation applied and businesses had to comply with the provisions of the regulation. The Food Inspectorate carried out regular studies (by sampling) from the beginning. There have been no major infringements. The number of samples was later reduced.
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	No information found.

119 http://www.forum-ernaehrung.at/artikel/detail/news/detail/News/trans-fettsaeuren-unter-beschuss/

Tests used to assess TFA content	From October to November 2014, 71 products were examined for their trans fat content in supermarkets, retail stores and in various restaurants.[120] The results of the tests were assessed according to the British traffic light model: • Green light was only available for products containing less than three grams of fat per 100 grams or a maximum of 1.5 grams of saturated fats per 100 grams. • The yellow light flashes at grease contents of three to 20 grams per 100 grams or a maximum of five grams of saturated fats. • All values above have a warning red. Main results: • All samples tested stayed within the limits defined by the trans fatty acid regulation; • The fear that the reduction in trans fatty acids is at the expense of an increase in the content of - also undesirable - saturated fatty acids has not been confirmed. • The content of saturated fatty acids has largely remained the same as in 2007. Therefore, the content of many product groups (in particular pastries, doughs, snacks, biscuits) is still to be assessed as high. • Two-thirds of the examined snacks, such as popcorn and biscuits, half of baked goods and three-quarters of the doughs were classified as "red" due to the total fat content. • Of the 71 investigated products, on average, one in three would be labeled "red." According to the Austrian Ministry of Health, until 2012 a test specific to trans fats was used, but since then this test has been integrated into a general test for fatty acid methyl esters. The current test works as follows: The fatty acids (extracted directly from oil or from a fat-containing foodstuff), which are present in the form of triglycerides, are subjected to an alkaline transesterification to extract fatty acid methyl esters from the fat. The obtained fatty acid methyl esters are identified by gas chromatography through a flame ionization detector (FID). The individual trans fatty acids are summed and this content is compared to the overall fat content of the sample.

120 http://www.konsumentenfragen.at/cms/konsumentenfragen/attachments/1/5/7/CH0948/CMS1424769941810/transfettsaeuren_2015.pdf

Steps taken to raise consumer awareness	According to the Austrian Ministry of Health, since the implementation of the legislation it has become increasingly unlikely that consumers are exceeding the daily limit for trans fats. Due to this, they have not felt it necessary to take steps toward raising consumer awareness.
Guidance provided to affected businesses	According to the Austrian Ministry of Health, they provided no specific guidance to businesses. They have a section of their website dedicated to information on trans fats.
Effectiveness of the measure	The legal limit imposed in Austria was considered effective in achieving the desired reduction in food TFA levels and hence population TFA exposure.[121] Market control actions (2011 and 2013) found that no product contained more than 2% TFA (based on total energy intake), although bakery products, popcorn or sweet spreads were investigated. In doughnuts less than 0.5 g/100 g or in Danish or puff pastry less than 0.2 g/100 g TFA were found. Data from national food consumption surveys in Austria suggest that there were no differences in population SFA intake before and after the introduction of the legal limit in 2009.[122] The Austrian Ministry of Health tested a variety of foods between 2008 and 2013 for trans fat contents. An evaluation of the results is forthcoming.
Describe (if any) other measures that are currently being considered	No information found.

TFAs in foods and diets

121 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, p. 36-37

122 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf p. 34

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	- Before the TFA-Regulation TFA content in certain problematic food groups was as follows:[123] - Doughnuts: 2.36 g TFA/100 g - Puff pastry spread: 0.56 g TFA/100 g - Danish pastry spread: 0.44 g TFA/100 g - French fries: 0.18 g TFA/100 g 42% of the samples showed a TFA content over 2%, more than 10% were even higher than 10% of total energy. [Information provided did not specify whether g TFA/100 g refers to g total fat or g product]
Variation in TFAs content in food after implementation of measure	See above: Results of market control actions (2011 and 2013) proved that no product contained more than 2% TFA (based on total energy intake), including bakery products, popcorn and sweet spreads among others. In doughnuts less than 0.5 g/100 g or in Danish or puff pastry less than 0.2 g/100 g TFA were found. Data from national food consumption surveys in Austria suggest however that there were no differences in population SFA intake before and after the introduction of the legal limit in 2009.[124]
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	No information found.

123 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

124 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf p. 34

TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	- Average TFA intake 0.97± 1.3 g/day - High TFA intake (P95) between 2-11.5 g/day [year of analysis: 2008]
Variation in TFAs intake after implementation of measure	TFA exposure was reduced to under the legal limit but data from national food consumption surveys in Austria suggest that there were no differences in population SFA intake before and after the introduction of the legal limit in 2009.[125]
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	More than half (55%) of Austrians cannot provide an estimate on which fatty acids are healthy or unhealthy in their diet, as evidenced by a survey conducted by the Forsa Institute on behalf of Unilever. There is considerable educational demand with regard to unhealthy fatty acids, such as saturated or trans fatty acids. In addition, the health effect of poly-unsaturated fatty acids is underestimated by respondents. According to the study, the average Austrian consumes about 6.2 kg of fat per year - and far more unhealthy than healthy fatty acids. 67% of the respondents have heard of healthy poly-unsaturated fatty acids, but only 40% can assess their effects correctly. The respondents were most aware of Omega-3 fatty acids and these are regarded as healthy by 84% of respondents. Less known, however, are omega-6 fatty acids, with only 46% of respondents aware of their existence. Nevertheless, 57% of the respondents attributed a positive effect to these fatty acids. About half of the Austrians surveyed, on the other hand, know of trans fatty acids and over half (54%) already know about their harmful effects.[126]

Measure impacts

Business responses and costs

125 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf p. 34

126 http://www.agrar.basf.at/agroportal/at/de/aktuell_at/ps_news_agro_market/ernaehrung-226820.html

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	No information found.

Evidence of FBO sector facing specific challenges	Some smaller industries expressed concerns during the discussion phase of the regulation. The soup industry, for example, where soup cubes might have a fairly low fat content overall, had problems with the reduction. It was later decided to construct the regulation to differentiate requirements depending on fat content: for certain products with a lower total fat content, higher trans fat contents are allowed. For frying fats, it is technologically relatively easy to replace fats with palm oil or vegetable oils (sunflower oil ("high oleic sunflower") and rapeseed oil). These fats are solid or liquid. There were some problems with this transition as frying fats need to be as tasteless and as odourless as possible. In Austria, these fats are of particular importance due to the tradition of baking goods. For the production of margarine the process was relatively complicated because crystallization of fats is complex. In the commercial (B2B) sector, it was more difficult. The measures taken were similar: partially hydrogenated fats had to be replaced with alternative fats (palm oil and palm oil derivatives, rapeseed oil, sunflower oil). This was associated with high technological effort. Derivatives of palm oil do not crystallize as well, therefore more complex machines with a smaller flow rate are needed. From the perspective of raw materials, the switch did not necessarily result in more costs because palm oil costs either the same or is cheaper. The additional cost was in the processing. Today, palm oil is no longer desired by all consumer groups. Between 2005-09, this was not yet an obstacle. Costs would have been higher had palm oil not been an option. In the commercial margarine sector it was a relatively long process (4-5 years of development) until the new margarines were available. In the household sector (B2C) it was somewhat easier: good taste, good nutritional values are the most important consumer factors. The development phase took around 2-3 years. The margarine market in Austria is not very heterogeneous (Senna and Unilever dominate). Both companies implemented this at the same speed and all measures were implemented before the regulation was introduced. This had a positive effect on competition within Austria because all companies had the same basic conditions. The same conditions of competition also apply to importers.

For which oils/fats was there a reduction in use and with what were they replaced?	The reduction in trans fatty acids at the expense of an increase in the content of saturated fatty acids (such as palm oil) has not been confirmed.[127]
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	According to one Austrian margarine producer, it was "cost-neutral for raw materials if you can use palm oil. If not then the costs are significantly higher. Personnel expenditure for the development can only be estimated: In the 4-5 years which were necessary for the development of alternatives we had two persons (8-10 man years). Further processing also has development costs, but these are estimated as less. The greatest effort was certainly in the commercial margarine sector but also in the household margarine sector. Investment expenditure: Machines had 20-30% lower performance with the alternative fats. To restore the machines' performance to their old condition required additional investment. That is because partly hydrogenated fats crystallize more rapidly than palm oil and palm oil derivatives." For the small bakery interviewed, costs were minimal. The bakery worked with their supplier to find appropriate solutions, and the costs for this were carried by the supplier. For the reformulation of recipes themselves, only a few man hours were needed.
Cost of understanding / learning the measure for FBOs	Big margarine and oil producers anticipated the transition following the Danish regulation. This led to voluntary measures so that these producers were already compliant by the time the regulation came into effect. According to the margarine producer interviewed, these companies then bore the brunt of the burden, as they then produced products that were compliant and could be used by their commercial customers.

127 http://www.konsumentenfragen.at/cms/konsumentenfragen/attachments/1/5/7/CH0948/CMS1424769941810/transfettsaeuren_2015.pdf

Consumer prices and choice

Evidence of changes in the price of reformulated products	According to one Austrian margarine producer, there was probably a slight price increase (somewhere around 8-12%). No statistics are available. 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). According to the small bakery interviewed, there was a slight price increase at the time of the switch but this would have happened with or without the change in trans fats.
Evidence of price differences between products with iTFAs and alternatives	Not applicable.
Evidence of changes in the range, quality or taste of products available	No information found.
Evidence of changes in TFAs consumption	No information found.
Effect on consumer information and awareness	Following the regulation, there has been less negative press around margarines and their bad reputation regarding trans fats has disappeared.

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	According to the Austrian Ministry of Health, a study is currently being undertaken by WHO Europe to address this question. The results of this study are not yet available.
Evidence of change in saturated fats intake	No information found.

Competition, innovation and trade

Effect on competition in the domestic market	There were no disadvantages on the Austrian market as all businesses as well as importers had to comply with the regulations.
Changes in trade of affected goods	One interviewee indicated that there was competitive disadvantage in Central and Western Europe at first, due to the higher costs and quality issues, but this disadvantage quickly dissipated. In Eastern Europe, where cheaper margarines are still on the market, however, Austrian producers are still in a poorer position. This disadvantage has been experienced for a ong time.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	No information found.

Administrative burdens

Number of businesses required to provide information	No information found.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	According to an interview with a margarine producer, alternative products were provided by large companies to the small ones, so there were no major problems. The upstream suppliers bore the brunt of the regulation more than businesses further down the supply chain. The one year transition period was considered to be relatively short. The total cost to test a sample for TFAs through the Austrian Food Safety Authority is around €170. Local authorities also provide these tests with varying costs.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	No information found.

Environmental impacts

Evidence of any environmental costs or benefits	No information found.
Evidence of increase in demand for palm oil / other ingredients	Initially, mostly palm oil and palm oil derivatives were used. Since 2015, however, there has been a movement against the use of palm oil (due to the impact of palm oil production on deforestation). This was noticeable too for companies that exported their products to other countries. There was a strong response in Italy, while in other countries it was more differentiated. In 2009 the plant origin of oils did not have to be listed in ingredients, but this is now obligatory and thus there is better consumer information with regard to the use of palm oil in food products. If that had already been the case in 2009, the cost would have increased greatly. There are alternatives to palm oil on the market, such as cocoa butter and shea oil. However, the markets for these fats are much smaller and the prices are difficult to calculate (the variances in demand-driven prices are very large). A good alternative, according to one margarine producer, would be to use fully hydrogenated oils that do not contain trans fats. The industry is working on such products (replacing palm oil with fully hydrogenated oils from sunflower and rapeseed oil). The capacities are currently low but can increase quickly. This would be a real alternative, as there would be no trans fats and it would be acceptable from a technical point of view.
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found.

Additional references

https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

Canada

Policy status

	Existing	Proposed/ considered
Legislation	X	X
Voluntary measures	X	
Labelling	X	
Consumer information	X	

Description of existing measure(s)

Type of measure	Legislation/voluntary/labelling/consumer information
Description of measure *(if legislation paste exact text of legislation)*	**Labelling measures (mandatory and voluntary):** ■ **Legislation** – mandatory nutrition labelling. Introduced in December 2002, effective December 2005, *Canada was the first country in the world to introduce mandatory labelling of TFAs.* The measure requires declaration of TFAs on most pre-packaged foods.[128] Trans fats are a core piece of nutritional information that is required to be declared in a Nutrition Facts Table (NFT): they must be declared under the "fat" declaration, in the same section as the "saturated fatty acid" declaration. The trans value is expressed in grams and the sum of saturated and trans is expressed as a percentage of the daily value.[129] However, products containing less than 0.2g of trans fat per serving are regarded as trans fat free for labelling purposes, and labels do not distinguish between naturally occurring and artificially produced trans fats.[130] Three nutrient content claims can be made on a label or in an advert for a food with trans fats: free

[128] L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

[129] http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/nutrition-labelling/additional-information/labelling-of-trans-fatty-acids/eng/1415805355559/1415805356965

[130] http://www.news-medical.net/health/Trans-Fat-Regulation.aspx

of trans fatty acids; reduced in trans fatty acids; or lower in trans fatty acids, with strict conditions regarding when they can be used. The only health claim that can be made is that low trans fat diets may reduce the risk of heart disease (although exact wording is prescribed in the legislation).[131]

- Voluntary guidelines developed by the Canadian Restaurant and Foodservices Association in consultation with Health Canada in 2006 to provide nutrition information i.e. TFA content, through in-store brochures, pamphlets, posters and websites.
- In February 2007 Health Canada updated and released revised "Canada's Food Guide" which, for the first time, contains explicit recommendations to limit TFA and SFA intakes and encourages consumers to read the Nutrition Facts table on food labels.[132]

Reformulation measures (voluntary):

- In 2004, the Parliament of Canada passed a motion "to enact regulation, or if necessary present legislation that effectively eliminates processed trans fats, by limiting the processed trans fat content of any food product sold in Canada to the lowest level possible". Motion included development of a multi-stakeholder task force (the Trans Fat Task Force - TFTF), which, in their 2006 report to the Minister of Health (TRANSforming the Food Supply) recommended limiting the total amount of TFAs in foods through regulation. More specifically: **limiting the TFA content of vegetable oils and soft, spreadable margarines to 2% of the total fat content; and for all other foods to 5% of total fat content (incl. ingredients sold to restaurants).** The recommendations were in line with nutrition labelling to help level the playing field for all players in the food industry. On June 20th 2007, the Minister of Health announced that Health Canada would adopt the TFTF's recommendations and industry was given a 2 year window to reduce TFA to recommended levels, encouraging substitution of TFAs with unsaturated fats during reformulation. **If significant progress had not been made, the department would develop regulations to enforce the limits.** Progress towards recommendations was tracked by the Trans Fat Monitoring Programme.[133]
  - One interviewee from the National Competent Authority stressed the importance of defining the approach as a "**structured voluntary approach**". This approach must have the following components (which – it was argued - were key reasons for the success of this approach in Canada): targets must be published; the approach must

131 http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/nutrition-labelling/additional-information/labelling-of-trans-fatty-acids/eng/1415805355559/1415805356965

132 L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

133 Ibid.

	have defined timelines, a clear mechanisms for public consultation and public disclosure of all data, a plan for monitoring; and the option of including a regulatory approach if the voluntary measure wasn't successful. **State/Province level legislation:** ■ **Ontario.** On September 1, 2008 the Healthy Food for Healthy Schools Act and Trans Fat Regulation came into effect. The regulation requires schools to drop trans fat from food and beverages sold on their premises. This includes some baked goods, packaged snack food and deep fried food, among others.[134] ■ According to the NCA interviewee, while the trans fat task force was deliberating the introduction of the voluntary national-level measure, a number of jurisdictions had already introduced measures to reduce or ban trans fats e.g. Alberta banned trans fats in French fries. These sub-national initiatives acted as a bottom-up level driver for government to introduce a national-level measure. In particular, because the labelling measure introduced in 2002 did not cover trans fats in the restaurant and food services industry, restaurant and food service establishments wanted something nationwide and standardised. Most local level measures also related to restaurants because this was the easiest sector for local governments to develop regulations for. Standardisation of these different measures was one of the strongest driving forces for the national level initiative. – VP, Canadian Restaurant and Foodservices Association: Fully supportive of the new trans fat limits*: "The restaurant industry is not usually an industry that comes before government and makes requests for regulations or government interventions per se; however, trans fat has evolved, and in a unique way, and in this case, given what has evolved in the past number of years, I want it to be on record that the restaurant industry has in fact made requests of the Government of Canada to establish a national regulatory framework so as to ensure consistency with respect to reductions in trans fat across Canada."*[135]
Scope of measure	**Labelling regulation** (to include the Nutrition Facts Table) is mandatory for most pre-packaged foods. **Voluntary reformulation** measure covers most pre-packaged

[134] http://www.edu.gov.on.ca/eng/healthyschools/healthier.html

[135] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

	foods **and** restaurant foods.
FBOs covered	**Labelling regulation**: all producers of pre-packaged foods. **Voluntary reformulation**: all producers of pre-packaged food **and** owners of restaurants and food service establishments.
Derogations *(e.g. low fat products, local products)*	**Labelling regulation** (Nutrition Fact Tables): Foods sold at restaurants and food service establishments fall outside of regulations (the NCA interviewee estimated this equated to around a quarter of foods consumed). However a number of restaurants committed to implementing industry-led voluntary guidelines (approximately 40% of all chain establishments).[136] ■ The following pre-packaged products are always exempt from displaying a Nutrition Facts table (NFT): one-bite confectionary sold individually e.g. small individually wrapped mints; a pre-packaged individual portion of food solely intended to be served by a restaurant or other commercial enterprise with meals or snacks e.g. creamers served with coffee, and milk, partly skimmed milk, skimmed milk, goat's milk, partly skimmed goat's milk, skimmed goat's milk, (naming the flavour) milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk or cream sold in refillable glass container. ■ The following foods are specifically prohibited from displaying a NFT: formulated liquid diets, infant formula, foods containing infant formula, meal replacements, nutritional supplements and foods represented for use in very low energy diets. These products have their own nutrition labelling requirements that are different from those of the NFT.[137] The NCA interviewee also mentioned that artisanal products were excluded (but these products made up an almost negligible proportion of the food supply).
Share of SMEs involved *(in case of voluntary measures)*	For the **voluntary reformulation** measure, according to the NCA interviewee, SMEs were less engaged than larger companies. However 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. Furthermore, the interviewee said that SMEs were largely "followers" rather

[136] L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

[137] http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/nutrition-labelling/prohibitions/eng/1386948927357/1386948928185

	than "leaders". Most of the research and development and recipe testing etc 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 i.e. it was not as costly to SMEs as may be assumed. See rate of compliance section below for more info.
Length and characteristics of transition period	For **voluntary reformulation** measure, companies had two years to make changes or a regulation would be introduced. However, the Trans Fat task Force specified that: *"Extended phase-in periods [may] be specified for certain applications (e.g. baking) and for small and medium-sized firms, recognizing that in most cases the transition could be made within two years of the date of entry into force of the final regulations"*[138] (so a four year transition period in total). For the **mandatory labelling** legislation, larger companies had to comply with the legislation by December 2005, but smaller enterprises had a grace period of two years.[139]
Arrangements for measure enforcement and compliance monitoring	**Labelling measure:** the Food Inspection Association of Canada has a broad mandate to inspect food and enforce regulations. For labelling they used a risk-based approach to determine priority inspection and analysis plans (NCA interview). This was always a point of contention as it was seen as too minimal i.e. based on complaints or spot checks rather than comprehensive inspection and analysis. **Voluntary reformulation measures:** the Trans Fat Monitoring Programme (TFMP), established by Health Canada in 2007, was a two-year programme analysing the trans fat content of over 1100 foods known to contribute high levels of trans fat to the Canadian diet.[140] This programme was clearly a monitoring initiative rather than inspection (NCA interviewee). Product labels and food content were analysed in certified labs by Health Canada and results were sent to companies. Companies then had one month to review the data and provide a correction/ more up-to-date data. This process worked well (NCA interviewee). The monitoring programme was conducted twice a year for over three years. Health Canada also conducted several teleconferences with the food industry to ensure everything was compliant and offered training to businesses at no cost (three or four day course) to

[138] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence.

[139] http://www5.agr.gc.ca/resources/prod/doc/agr/pdf/PotentialEconomicReport_e.pdf

[140] https://www.canada.ca/en/health-canada/programs/banning-partially-hydrogenated-oils-in-foods/consultation-document.html#c11

	teach industry how to analyse their own products if they wanted to.
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	**Voluntary reformulation:** Despite the presence of the trans fat monitoring programme, the rate of compliance was not extensively monitored. The NCA interviewee said that the number of businesses achieving compliance wasn't identified, however the supplemental table S1 found in Arcand *et al*'s (2014) paper identify all of the businesses that disclosed their trans fat levels and those that did not.[141] During the monitoring programme, Health Canada looked at all the leading fast food restaurants (at least 50) and identified the foods with trans fats that took up the most space on shelves in three different cities. For some food categories this equated to 90% of the market share but their aim was to select 70-80% of the market share per category. The large majority were found to be compliant (see TFA content section below). However, due to the research methodology, some categories may have been under-represented, meaning the compliance rate in these categories is less clear: ■ Smaller manufacturers (although arguably most small manufacturers did not make products with different ingredient profiles to the larger manufacturers); ■ In the second monitoring stage, the trans fat monitoring programme used the same sampling plan as the sodium monitoring programme which **picked up some additional food products that were not detected in the first monitoring phase**. These additional products were equivalent to about 7% of the food supply. ■ Once products were identified as falling below the threshold level of trans fat content, they were no longer monitored by the programme i.e. food categories changed during each round of monitoring. **Other evidence:** Results from the TFMP suggest that while a number of popular fast-food and family restaurant chains in Canada have been successful in decreasing TFA levels, there are still establishments

[141] http://ajcn.nutrition.org/content/early/2014/08/06/ajcn.114.088732/suppl/DCSupplemental

	that continue to offer menu items high in TFAs.[142]
Tests used to assess TFA content	**Labelling**: The CFIA recommends using the Official Methods of Analysis of AOACR International, Official Method 996.06 to determine the *trans* fatty acid content of foods.[143] Trans fat monitoring programme for **voluntary measure**: (NCA interviewee). Health Canada's Chief Chemist was leading the testing for this programme. The interviewee was not sure of all the tests used but mentioned capillary GC testing. **Concern regarding monitoring of the PHO ban:** A representative of the baking industry mentioned that a key problem with lab testing is that no test is able to distinguish between animal fats and iTFAs. This is problematic as the new legislation excludes animal fats.
Steps taken to raise consumer awareness	The media and other stakeholders have played an important role in raising consumer awareness by: helping to increase consumer awareness about TFA; highlight the actions taken by industry to remove TFA from products and highlighted worst performers from the trans fat monitoring programme.[144] A representative of the baking industry mentioned that the labelling measure itself played a vital role in raising consumer awareness and put pressure on industry to reformulate as consumers wanted trans fat-free products. They argued that consumer awareness and pressure alone was the key driver in reducing trans fats, not any regulation by Governments. They think that had consumers not been so aware, the voluntary measure would have been less successful. Consumer awareness also came from a lot of prior published research from health professionals on the health effects of trans fats which was

142 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

143 http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/nutrition-labelling/additional-information/labelling-of-trans-fatty-acids/eng/1415805355559/1415805356965

144 L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

	extensively spread by the media.
Guidance provided to affected businesses	Guidance on labelling was provided on the Canadian Government website.[145] Guidance on voluntary trans fat reduction: The Canadian Restaurant and Foodservices Industry developed a "how-to" guide which provided advice and counsel to members of the industry on how to actually go about reducing trans fats in their menu items and offerings.
Effectiveness of the measure	"Data published over the last decade suggest that initiatives to decrease the trans fat consumption of Canadians have been highly effective."[146] See below sections for quantitative data.
Describe (if any) other measures that are currently being considered	**Proposed legislation for summer 2018**: Health Canada intends to implement a prohibition on the use of PHOs in foods by adding PHOs to Part 1 of the List of Contaminants and other Adulterating Substances in Foods. This would mean that any food containing PHOs would be declared adulterated and its sale in Canada prohibited in accordance with section 4 of the Food and Drugs Act.[147] **Regulation of the proposed measure:** Food and drug regulations fall under criminal law so the Food Inspection Agency could take businesses to court after several breaches to regulation (NCA interview). **Reasons for the introduction of the legislation:** ■ **Further reductions in trans fats are required.** The WHO recommends that trans fat intake (from both naturally occurring and industrially produced sources) should be less than 1% of total energy intake. Despite significant progress (as highlighted

145 http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/nutrition-labelling/additional-information/labelling-of-trans-fatty-acids/eng/1415805355559/1415805356965

146 https://www.canada.ca/en/health-canada/programs/banning-partially-hydrogenated-oils-in-foods/consultation-document.html#c11

147 http://www.hc-sc.gc.ca/fn-an/consult/nop-adp-c-2017-3/nop-adp-c-2017-3-eng.php

in the sections on intake and content below), there are still certain food categories that continue to have large proportions of foods not meeting the trans fat targets and some subpopulations are still at higher risk.[148] In addition, the last official results from the trans fat monitoring programme (in 2008) suggest that average trans fat content was still above the WHO 1% recommendation (1.42% of total energy intake).

- **Cost savings.** A study undertaken by Gray, Malla and Perlich (2005) which examined the economic impacts of a ban on industrial trans fats, suggests that a full ban would create health benefits in an order of magnitude larger than the increase in food cost associated with the ban.[149] They estimated that several billion dollars in benefits would be forgone if TFA reduction is encouraged through labelling alone. The present value of health cost savings of a ban to Canadians would exceed $19 billion. Oilseed growers, whose price is set in the global market, would be largely unaffected by a ban.
- **Prevent slippage.** The NCA interviewee mentioned that although most products are now trans fat-free in Canada, the regulation allows for a "mop-up" of those products that still have not reformulated. They argued that processes and products are now available in Canada for all products to be trans fat-free so products that still contain artificial trans fats are the result of laziness/lack of legislative pressure. They also mentioned it is a good way to prevent slippage. For example, after the trans fat monitoring programme her team found that some shortenings that reduced trans fat levels went back to their original levels.

Stakeholder views on the proposed legislation:

- "Health Canada sees the value of a regulatory approach, which may be especially beneficial in controlling the level of trans fat in oils used by the food service industry."[150]
- CEO, Heart and Stroke Foundation of Canada: progress in small and medium-sized food service operators has been slower and "frankly, we are not getting at the suppliers to that sector, and without regulation, we don't believe we can."[151] "The other issue that came up in the trans fat task force was that regulations would send a clear signal to suppliers to create healthier

[148] https://www.canada.ca/en/health-canada/programs/banning-partially-hydrogenated-oils-in-foods/consultation-document.html#b11

[149] http://www.ag-innovation.usask.ca/final%20policy%20briefs/GrayMalla_TransFat10.pdf

[150] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

[151] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

alternatives.

- Canadian Nutrition Society: "a prohibition of PHOs would align Canada's regulation with that of several countries in Europe and the United States who have already established this policy."[152]

- Views of industry:
  - Baking Association of Canada. From the outset, BAC supported an orderly replacement of trans fats in the food supply to alternatives that are low in trans fats and saturated fats.[153] However, in an interview with a representative from the association, it was felt that the legislation is not required as the voluntary measure already led to a reduction of trans fats to within the WHO limits across almost bakery products. They said that the baking industry has been trans fat-free for years.

Learnings for the EU. The NCA interviewee mentioned that at the time Canada's voluntary measure was introduced, legislation was decided against for political reasons i.e. it was a political decision to limit the amount of legislation introduced. However, they argued that the introduction of legislation with a three year time-lag could probably have been just as effective: it would have been more cost-effective and less labour-intensive (see administrative costs section below). They stressed that any legislative measure needs to be introduced with a measure alongside to ensure that the food supply doesn't become over-burdened with saturated fats. In the case of Canada, they were fortunate to have had good saturated fat-free replacement oils available at a good price.

TFAs in foods and diets

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	Detailed fat analysis of over 200 locally and nationally available foods indicated that TFA levels in some foods reached as high as 50-56% TFA as % of total fat. Also large variation in TFA levels in some food categories.

[152] https://cns-scn.ca/sites/default/uploads/files/HC%20Consultation%20-CNS%20response-FINAL.pdf

[153] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

Variation in TFAs content in food after implementation of measure	Overall comments from the NCA interview and the baking industry interview indicated that the large majority of products in Canada are now trans fat-free as a result of the labelling and reformulation measures. TFAs have been reduced or eliminated in certain foods – bread products and salad dressings are now TFA free.[154] **Labelling:** One study looking specifically at the change in fat composition of a survey of all margarines sold in Toronto between 2002 and 2006 when the new Canadian **labelling regulations** came into effect found that average amounts of *trans* fatty acids (TFA) and MUFA decreased, while average amounts of PUFA (poly-unsaturated fatty acids) increased significantly from 2002 to 2006.[155] The proportion of margarines with less than 0·2 g TFA/10 g serving rose significantly from 31 % in 2002 to 69 % in 2006. However, TFA reductions appeared to be restricted to higher-priced margarines. Another reference noted that *"the availability of trans fat information on the Nutrition Facts table helped draw the attention of consumers and public health professionals to the presence of TFAs in pre-packaged foods, which resulted in a significant reduction of the trans fat content of these foods."*[156] **Voluntary reformulation (and labelling):** A study by Arcand et al. (2014) , updating results from the trans fat monitoring programme, found that 95% of packaged foods and 96% of restaurant foods, overall, had TFA amounts that fell within recommended limits. When examining top contributors of industrial TFAs to the Canadian diet, there was a striking improvement in the proportion of foods meeting the recommended limits, increasing from 75% in 2005-2009 to 97% in 2010-2011, particularly in the following packaged foods: croissants (25% to 100%), pies (36% to 98%), cakes (43% to 90%), and garlic spreads (33% to 100%).

[154] L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

[155] Ricciuto L, Lin K, Tarasuk V. A comparison of the fat composition and prices of margarines between 2002 and 2006, when new Canadian labelling regulations came into effect. Public Health Nutr 2009; 12: 1270-5 http://dx.doi.org/10.1017/S1368980008003868

[156] https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

	Most restaurant categories assessed by the TFMP had 100% of foods meeting TFA limits. Supplementary tables provide breakdowns of fat content by product.[157] However, some categories had a large proportion that still exceeded TFA limits: dairy-free cheeses (100%), frosting (72.0%), lard and shortening (66.7%), coffee whiteners (66.7%), and restaurant-prepared biscuits and scones (47.4%)[158]. Furthermore, among foods that exceed the TFA limits, many contain very high amounts of TFAs (e.g., coffee whiteners, doughnuts, dairy-free cheese, refrigerated dough). Many of these were in food categories that contained a large proportion of products that meet the TFA limits, which suggests that technologies clearly exist for reformulation. In general, pre-packaged foods have seen the greatest reduction in trans fats, with restaurants and the food service sector having less success as it is more difficult to control the level of trans fat in the final products.[159]
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	Following the TFMP which ended in 2008/9, a cost benefit analysis (CBA) was commissioned by Health Canada to estimate the potential costs and benefits of further efforts to reach the target of trans fat intake being no more than 1% of overall energy. Interviews conducted as part of the CBA indicated that some other companies were ready to introduce new products that were meeting the trans fat limits in a matter of weeks or by the end of 2009, suggesting that there were further reductions in trans fat content and intake after 2009.[160] Thus it is possible that there were further reductions since the 1.42% were calculated, however decreases are likely to be lower given that most companies have already implemented measures to reduce TFA content. **The authors of the CBA estimate average trans fat intake in 2009 to be 1.35% (but 1.49% in children). Continuing with that assumption, in 2012 the level should be 1.12% of energy and 1.27% of energy in children.** However the CBA, after interviews with food industry stakeholders about their intent

[157] http://ajcn.nutrition.org/content/early/2014/08/06/ajcn.114.088732/suppl/DCSupplemental

[158] Arcand, J., Scourboutakos, M. J., Au, J. T., & L'abbe, M. R. (2014). trans Fatty acids in the Canadian food supply: an updated analysis. *The American journal of clinical nutrition*, ajcn-088732.

[159] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

[160] https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

	to make further reductions, **assumed that there would be no further decrease in trans fat intakes in Canada beyond 2009 levels.**
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	Researchers estimated that Canadians had one of the highest intakes of TFAs in the world in the mid-1990s due to widespread use of hydrogenated canola and soybean oils (8.4g/day in 1995).[161] The move to such widespread use of hydrogenated oils came in the 1970s when they were viewed as a healthier alternative to saturated fats. Trans fat intake was estimated to be 3.7% of total energy.[162] ■ Foods contributing to the high trans fat intake included crackers, margarines, shortening, donuts, cookies, pie shells, breaded chicken, cake mixes and cakes, French fries, sauces and gravies. ■ Information from nutrition surveys indicates that 22% of the average trans fat intake of Canadian adults (and as much as 31% in the case of males aged 19 to 30 years) is provided by foods consumed away from home, often in fast food restaurants and other food service environments.[163] Variation by sub-groups: ■ Exposure in children tends to be higher than exposure in adults .[164] ■ Canadian Inuit populations – over the last 5 decades or so, Inuit populations have transitioned from a traditional, marine diet to one which incorporates more processed foods, typical of a western diets. Foods containing industrially produced trans fats are also beneficial in these communities because of their storability at room temperature and a longer shelf life. A dietary survey in 2004-05 in Inuit populations from Nunavik Canada

[161] L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

[162] https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

[163] https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

[164] https://www.canada.ca/en/health-canada/programs/banning-partially-hydrogenated-oils-in-foods/consultation-document.html#c11 ; (see appendix 1 for breakdown by gender and age)

	and Greenland found that despite consuming similar percentages of store-bought foods, the Nunavik Inuit were three times higher than those of the Greenland Inuit (as measured by the fatty acid composition of erythrocyte membrane phospholipids). Nunavik youth also had significantly higher erythrocyte TFA levels than their elders (0.67% vs 0.39%).[165] The NCA interviewee said that extensive data was gathered through the 1990s, particularly the data collected through a breast milk monitoring programme, and this supported the introduction of the labelling measure in 2002. At this point, so much data had been collected there was not much objection to the introduction of the legislation because the health impacts were clear. The only objections from business were regarding how much time they had for labelling and reformulation.
Variation in TFAs intake after implementation of measure	TFA intakes have been decreasing – 8.4g/day in the mid-1990s versus 4.9g/day in 2005 (2% of total energy).[166] A 2007 assessment by Health Canada estimated that trans fat intakes for all Canadians (aged one year and older) has decreased to 1.42% of total energy (equivalent to 3.4 grams per day). The usual intake distributions of trans fat (as % of energy) were also calculated for certain age-sex groups (see Annex 2 for breakdown table). The 95th percentiles for all age-sex groups have dropped from approximately 3.00% in 2004 to 2.12% in 2008. The 95th percentile for males 51 years and older is the highest at 2.30% of overall energy. The 5th percentile for both boys and girls 9-18 years of age are reported to be 1.22% and 1.06% of energy. This indicates that almost all children and teenagers exceed the trans fat limit of 1% energy intake recommended by the WHO.[167]

165 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

166 L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

167 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

	Subsequent study of Canadian nursing mothers showed decline in trans fat concentrations in human milk samples between 2009 and 2011, suggesting further declines since the 2007 assessment (at least in this population).[168] However, in 2011 a risk assessment conducted by Health Canada showed that some sub-populations were at risk of higher trans fat intake including: children and teens, Canadians living in remote areas, price-sensitive consumers (i.e. lower income groups) and those who regularly consumed foods remaining high in trans fats.[169] Similarly, a 2012 study looking at the amount of trans fatty acids in Canadian adults between 2004 and 2010 found that, relative to 2004, total TFA levels were significantly lower in 2005-2009, however not in 2010, suggesting that young Canadians may still remain vulnerable.[170]
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	45% of Canadians in 1995 claimed that they have heard or that they understand the term "trans fat" compared to 79% in 2005.[171]

[168] Ratnayake WMN, Swist E, Zoka R, Gagnon C, Lillycrop W, and Pantazapoulos P. (2014). Mandatory trans fat labelling regulations and nationwide product reformulations to reduce trans fatty acid content in foods contributed to lowered concentrations of trans fat in Canadian women's breast milk samples collected in 2009-2011. American Journal of Clinical Nutrition, 100 (4):1036-1040.

[169] https://www.canada.ca/en/health-canada/programs/banning-partially-hydrogenated-oils-in-foods/consultation-document.html#c11

[170] https://www.ncbi.nlm.nih.gov/labs/pubmed/28401129-circulating-concentrations-and-relative-percent-composition-of-trans-fatty-acids-in-healthy-canadian-young-adults-between-2004-and-2010-a-cross-sectional-study/

[171] L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	Most of the top fast food and restaurant chains in Canada have been successful in reducing TFA from menu items that were previously high in TFA (e.g. French fries, chicken products, fish products and pizzas):[172] ▪ 78% of restaurants and fast food chains had French fries that met the 5% TFA limit by 2007-08, 59% had chicken products, 100% had pizzas and 85% had fish products. In response to the Minister of Health's recent commitment to introduce tougher measures to eliminate industrially produced trans fats in the food supply, Health Canada launched a Call for Data in 2016 to collect information on the current use of PHOs in the food supply. Data was submitted by seven manufacturers, two fats and oils processors, one restaurant, two industry associations and one academic. Many respondents indicated that they were moving away from PHO use, however the response rate was low. President and CEO of the Vegetable Oil Industry of 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.* *The acreage dedicated to producing high-stability oil that does not create trans fat has substantially increased. High-oleic canola now comprises 900,000 tonnes of Canada's canola production, and is expected to increase to 3.75 million tonnes, or 25% of production, by 2015. We estimate that more than 80% of the market is now meeting the task force trans fat limits of 2% for liquid oils and 5% for all other foods.*"[173]
Evidence of	The interviewee from the baking industry in Canada identified the

[172] L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

[173] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

FBO sector facing specific challenges	following challenges, noting that overall the challenges of moving to trans fat-free foods were substantial: • Finding a hard fat for some products e.g. those that use laminated doughs. Butter is not usually used as it is expensive and is often hard to procure. Palm fats were identified as the best substitute in most cases. • Industry suppliers were making inaccurate claims about the functionality of new products meaning that they were not effective when used in bakery products. Functionality is particularly important for icings and laminate doughs. • SME costs were not particularly out of line with larger producers; the main problem for SMEs was finding the in-house technical resources and time to do the reformulation. • Butter is still being used as a trans fat alternative but this is problematic because it is expensive and causes problems for vegans/individuals of particular religious backgrounds. VP of the Canadian Restaurant and Foodservices Association: "*The challenges during the transition period were significant for food service"* including: ▪ Supply challenges: challenges in getting adequate online supply of oils from national chain operators. "*I want to be clear that it was not easy. Our member companies put a lot of resources, both human and fiscal, into their efforts to reduce trans fats.*" ▪ "*The food service industry is and has been uniquely challenged because of the nature of Canada's food regulatory regime; that is, the jurisdictional purview for enforcement and compliance around these kinds of issues is such that restaurants really have been singled out as policemen, if you will, to police the entire Canadian food supply with respect to trans fat. This has posed significant challenges for our members across the country. In response we have come back to the federal government. We have made our case, in this instance, to have a consistent national regulatory framework so that we can ensure that our members are operating in an environment in which they have a level playing field with their direct competitors along the food value chain.*"[174] VP, Food and Consumer Products of Canada: (represents the food manufacturing industry in Canada): "*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.*"
For which oils/fats was there a	In 2013 a total of just over one million (1,080,885) metric tonnes of vegetable oils were consumed in food in Canada. Of that total, approximately 20 per cent was soybean oil. The remaining 50 per

[174] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

reduction in use and with what were they replaced?	cent comprised canola (42 per cent) and high oleic low linoleic canola (HOLL – at eight per cent). The residual was imported oils and blends from 11 other plants such as palm, olive, coconut and corn. Canola, soy and flax oils – otherwise classified as "omega 3" oils – comprise 62 per cent of the oils in Canadian foods. Corn, cotton and sunflower ("omega 6" oils) make up five per cent, and HOLL, olive and peanut oils ("omega 9" oils) comprise another 12 per cent. Paska noted HOLL canola oil has a growing presence in Canadian food. In 2010, HOLL canola represented only four per cent of the oil used in Canadian food; by 2013, that had increased to 11.5 per cent. HOLL oil has gained popularity because it replaces hydrogenated vegetable oils that were once more commonplace in baked goods.[175] The NCA interviewee mentioned that the Canadian Department of Agriculture funded a lot of research on canola oil to develop non trans fat alternatives. Once these variations were available, they were widely available to all businesses. At first they were more expensive but after a couple of years the price reduced considerably. The interviewee from the baking industry mentioned 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. More information in the health benefits section below on saturated fat content.
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	The NCA interviewee was not aware of any studies that assessed the actual costs that occurred as a result of the labelling or reformulation measures. Data reported here are therefore qualitative or based on prediction/estimation. In reference to the PHO ban recommendation: CEO, Heart and Stroke Foundation of Canada: "*There is no evidence that regulations are cost prohibitive, that implementation costs to government are high. There is no evidence that regulations are cost prohibitive for industry.*"[176] A study undertaken by Gray, Malla and Perlich (2005)[177] which examined the economic impacts of a ban on industrial trans fats estimated that in all cases the total food costs of reducing TFA would be less than C$ 1 billion.[178] Oilseed growers, whose price is

[175] http://www.foodincanada.com/food-in-canada/the-other-big-oil-132907/

[176] http://www.ourcommons.ca/DocumentViewer/en/40-3/HESA/meeting-15/evidence

[177] http://www.ag-innovation.usask.ca/final%20policy%20briefs/GrayMalla_TransFat10.pdf

[178] Though not indicated specifically in the source, the values are understood to be in Canadian dollars.

	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 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 following best estimates (most realistic) of the additional cost or cost that firms would incur if different options were implemented were calculated: ■ Voluntary labelling system: the testing/labelling cost is C$66 million while the product reformulation cost is C$295 million, which together account for C$361 million in expenditures. The CHD health benefit estimate is C$7,357 million. ■ Mandatory labelling: The testing/labelling cost, for testing and labelling of all products, is equal to C$187 million. The mandatory labelling stimulates an increased product reformulation cost of C$471 million. Thus, the total estimated industry cost of mandatory labelling is equal to C$658 million. However, the CHD health benefits are estimated at C$12.57 billion. ■ Ban on foods with greater than 2% TFA: the testing/labelling cost is equal to C$187 million and the product reformulation cost is C$754 million, accounting for a total industry cost of $941 million. Under this scenario the CHD health benefits increase to C$19.54 billion. **Specifically within the baking sector**, the baking industry interviewee said that the average cost per SKU (Stock Keeping Unit) for updating labels is C$3000. For the general food sector, they said that reformulation costs (calculated by the US Department of Agriculture) were estimated to be USD 11,500 to 100,000 per formula, with a mid-range of USD 50,000. This includes a ten month development cycle and an eight month market cycle.
Cost of understanding/ learning the measure for FBOs	No information found.

Consumer prices and choice

Evidence of	One of the top factors influencing food buying practices is cost. It

changes in the price of reformulated products	was reported that margarines sold on the Canadian market that are lower in SFA, TFA and the sum of SFA+TFA cost significantly more than margarine with higher levels of these fats.[179] More recent data is consistent with these findings. In 2002, 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[180]. 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.[181] Similar research shows that nutritionally improved products tend to be higher in price. The baking industry interviewee also mentioned that initially there was a higher cost for trans fat alternatives and this was a challenge for industry.
Evidence of price differences between products with iTFAs and alternatives	The baking industry interviewee mentioned that when fat and oil suppliers first introduced trans fat-free products, they were also producing the trans fat versions. Splitting productions costs meant that initially the costs of trans fat-free products were high. However now they are predominantly producing only trans fat-free products so the cost is going down.
Evidence of changes in the range, quality or taste of products available	No information found.
Evidence of changes in TFAs consumption	No information found.
Effect on consumer information and awareness	No information found.

179 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

180 Currency not stated in primary source but understood to be USD.

181 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	Heart disease has remained the second most likely cause of death for Canadians after malignant neoplasms.[182] However there has been an overall decrease in the number of deaths from heart diseases between 2000 (55,070 deaths) and 2013 (49,891 deaths). According to the CBA commissioned by Health Canada that factored in the reduced risk of CHD along with annual growth rate of heart attack cases in Canada, the further reduction of average trans fat intake to 1% of energy is conservatively estimated to prevent an average of 12,354 heart attack cases in Canada over 2010-2029.[183] A study undertaken by Gray, Malla and Perlich (2005)[184] which examined the economic impacts of a ban on industrial trans fats estimated that a voluntary labelling initiative alone would result in a present value of health cost savings exceeding C$7 billion. Mandatory labeling would increase the saving to over C$12 billion. With a ban present value of health cost savings Canadians would exceed C$19 billion. Meanwhile, the extra CHD health benefits of the mandatory labelling system are equal to C$5.21 billion.
Evidence of change in saturated fats intake	In many cases the reduction in TFA has been achieved by finding healthier alternatives and not increasing level of SFA.[185] Results of the TFMP from 2005-2009 showed that industry has made progress in reducing TFA levels in their products **while not increasing saturated fat content**, with **evidence that average**

182 http://www5.statcan.gc.ca/cansim/a26?lang=eng&retrLang=eng&id=1020561&pattern=&csid=

183 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

184 http://www.ag-innovation.usask.ca/final%20policy%20briefs/GrayMalla_TransFat10.pdf

185 L'Abbe (2009) Case study – taking trans fat out of the food supply – the Canadian Experience. Health Canada (PHD presentation): available online at: http://www.pmaconference.mahidol.ac.th/index.php?option=com_docman&task=doc_download&gid=120

	saturated fat intakes of Canadians have remained constant since 2004 (an average of 25g/day on average for all Canadians aged one year and above).[186] It suggests that many food manufacturers are replacing TFAs with mono- and poly-unsaturated fats and not with saturated fats. This was confirmed through scientific assessment of the full fatty acid profile of the foods that were included for analysis in the TFMP. A second study[187] found that, among the major grocery and restaurant food products in Canada that might contain TFA, in 2005-07, nearly half (42%) contained over 5% TFA on initial assessment. However most were discontinued or underwent reformulation (nearly three quarters had undergone reformulation with an average reduction to less than 2%). After this reformulation only one product had unchanged content of *cis* unsaturated fats; all others had increased *cis* unsaturated fats, most with absolute increase of over 10% of fatty acids and half with absolute increase of over 20%. The total fat content was generally unchanged. However, a 2014 study[188] found that saturated fat amounts were significantly higher (P , 0.05) among some foods with the lowest TFAs, such as cookies, brownies and squares, cakes with pudding/mousse, dessert toppings, and lard and shortening. Particularly within the baking industry, almost all products replaced high trans fat ingredients with those high in saturated fats as these were the only alternatives.

Competition, innovation and trade

Effect on competition in the domestic market	No information found.
Changes in	The baking industry interviewee indicated that there is an

186 https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

187 Ratnayake WMN, L'Abbe MR, Mozaffarian D. Nationwide product reformulations to reduce trans fatty acids in Canada: when trans fat goes out, what goes in? Eur J Clin Nutr 2009; 63: 808-11 http://dx.doi.org/10.1038/ejcn.2008.39 pmid: 18594558

188 Arcand, J., Scourboutakos, M. J., Au, J. T., & L'abbe, M. R. (2014). trans Fatty acids in the Canadian food supply: an updated analysis. *The American journal of clinical nutrition*, ajcn-088732.

trade of affected goods	opportunity for the Canadian industry to take trans fat-free products to the US market-place because they are ahead of the US in terms of reformulation. They said that if the EU were to move towards trans fat-free products then it could create a new market for Canada.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	No information found.

Administrative burdens

Number of businesses required to provide information	No information found.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	The NCA interviewee mentioned that reformulation was a lot of work for companies, but that most of the costs were spent years ago as businesses have been aware for years that trans fats would need to be removed from food. Reformulation started even before the labelling legislation came into force. They said that most of the costs fell with the oil and fat suppliers as they were the start of the supply chain. When it came to regulation for labelling, the enforcement letters were usually sent to the oil and fat producers, and restaurants and food services relied on suppliers to provide updated products and labelling, rather than paying to monitor trans fat levels themselves.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	**Voluntary reformulation measure:** The NCA interviewee was not sure of actual costs, but from their knowledge of the Trans Fat Monitoring Programme, they were able to confirm that the **administrative burden was high (i.e. in the millions of Canadian dollars)**, and much higher than for a regulatory approach. A lot of in-kind support was provided by the Canadian Heart and Stroke Foundation. It also funded three regional laboratories and employed several staff members for three years e.g. a research scientist, three chemists and a senior policy officer at Health Canada (the latter liaised with industry). Each employee had an average salary of C$100k a year plus benefits. Other costs include laboratory instruments and C$500k to buy market/sales data to support the analysis.

	Labelling measure: In comparison to the voluntary reformulation, the Canadian Food Inspection Agency did not spend that much money on monitoring nutrition labelling.

Environmental impacts

Evidence of any environmental costs or benefits	Most of the trans fat-free alternatives being used by the baking industry come from palm oil.
Evidence of increase in demand for palm oil / other ingredients	No information found.
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found.

Additional references

Estimated trans fat intake as a percentage of energy

DRI age-sex group	Sample Size	*Trans* % of Energy	
		2004	2008
Children 1-3y	2117	2.07	1.55
Children 4-8y	3235	2.31	1.57
Boys 9-13y	2080	2.31	1.54
Boys 14-18y	2288	2.25	1.53
Girls 9-13y	1980	2.32	1.54
Girls 14-18y	2277	2.17	1.52
Males 19-30y	1804	2.01	1.40
Males 31-50y	2596	1.94	1.38
Males 51-70y	2550	1.89	1.36
Males 71+y	1520	1.92	1.44
Females 19-30y	2017	2.05	1.39
Females 31-50y	2755	1.94	1.39
Females 51-70y	3201	1.87	1.36
Females 71+y	2610	1.96	1.47
All Adults 19+y	19053	1.94	1.39
All Person 1+y	33030	2.01	1.42

Table 1. Estimated *trans* fat intakes as percent of energy in 2004 vs. 2008 in different age-sex groups in Canada [28]. The results contained in this table are based on the Canadian Community Health Survey – Cycle 2.2 on Nutrition, Statistics Canada, 2004.

Source:
https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

Usual distributions of estimated trans fat intakes as % of energy

Age-Sex	Sample Size	Year	Percentile						
			5th	10th	25th	50th	75th	90th	95th
Boys 9-18y	4368	2004	1.55	1.70	1.96	2.27	2.62	2.96	3.18
		2008	1.22	1.20	1.34	1.51	1.71	1.91	2.04
Girls 9-18y	4257	2004	1.58	1.71	1.94	2.22	2.53	2.82	3.00
		2008	1.06	1.15	1.30	1.49	1.73	1.96	2.12
Males 19-50y	4400	2004	1.16	1.31	1.58	1.92	2.29	2.67	2.91
		2008	0.90	0.99	1.15	1.36	1.59	1.81	1.96
Males 51+y	4070	2004	0.96	1.11	1.40	1.80	2.27	2.78	3.12
		2008	0.71	0.82	1.03	1.31	1.66	2.04	2.30
Females 19-50y	4772	2004	1.27	1.40	1.65	1.95	2.30	2.64	2.85
		2008	0.92	1.00	1.16	1.36	1.59	1.82	1.97
Females 51+y	5811	2004	1.10	1.24	4.50	1.84	2.23	2.63	2.89
		2008	0.79	0.89	1.08	1.33	1.64	1.96	2.18

Table 2. Usual distributions of estimated *trans* fat intakes as percent of energy in 2004 vs. 2008 in different age-sex groups in Canada [28]. The results contained in this table are based on the Canadian Community Health Survey – Cycle 2.2 on Nutrition, Statistics Canada, 2004.

Source:
https://docs.google.com/viewerng/viewer?url=https://cdn.intechopen.com/pdfs/42954.pdf&time=c3344365842b3bf1453a3bbb133492b0

Denmark

Policy status

	Existing	Proposed/ considered
Legislation	X	
Voluntary measures		
Labelling		
Consumer information		

Description of existing measure(s)

Type of measure	Legislation
Description of measure	ANNEX 1 ORDER ON THE CONTENT OF TRANS FATTY ACIDS 1. ------IND- **2002 0216 DK- EN-** ------ 20020619 --- --- PROJET Order No. 160 of 11 March 2003 **Courtesy translation** Order on the content of *trans* fatty acids in oils and fats etc. The following is laid down pursuant to Section 13, Section 55, subsection 2 and Section 78 subsection 3 of Act No 471 of 1 July 1998 on foodstuffs etc. (Foodstuffs Act): Chapter 1 *Scope* **Section 1.** This Order applies to oils and fats, including emulsions with fat as the continuous phase which, either alone or as part of processed foodstuffs, are intended, or are likely, to be consumed by humans. *Subsection 2.* The Order does not apply to the naturally occurring content of trans fatty acids in animal fats or products governed under other legislation. *Subsection 3.* The Order only applies to products sold to the final consumer. **Section 2.** It is prohibited to sell the oils and fats covered by the Order to consumers if they contain a higher level of the trans fatty acids defined in the Annex than that stated in Section 3. **Section 3.** As from 1 June 2003, the content of trans fatty acids in the oils and fats covered by this Order must not exceed 2 grams per 100 grams of oil or fat, cf. however subsection 2. *Subsection 2.* From 1 June 2003 until 31 December 2003 the oils and fats covered by this Order and included in processed foodstuffs which also contain ingredients other than oils and fats and which are produced by the foodstuffs industry, in retail outlets, catering establishments, restaurants, institutions, bakeries etc. may, however, contain up to 5 grams of trans fatty acids per 100 grams of oil or fat. **Section 4.** In products which are claimed to be "free from trans fatty acids", the content of trans fatty acids in the finished product shall be less than 1 gram per 100 grams of the individual oil or fat.

Chapter 2

Penalty provisions etc.

Section 5. A fine shall be imposed on anyone who contravenes Section 2 or Section 4 of Order.

Subsection 2. The penalty may increase to imprisonment for up to two years if the contra was committed wilfully or through gross negligence, and the contravention

1) caused damage to health or led to the risk thereof, or
2) resulted in, or was intended to result in, financial gain for the perpetrator themselves o others, including as a result of savings made.

Subsection 3. Criminal liability may be incurred by companies etc. (legal entities) in accor with the rules of Chapter 5 of the Penal Code.

Section 6. This Order shall enter into force on 31 March 2003.

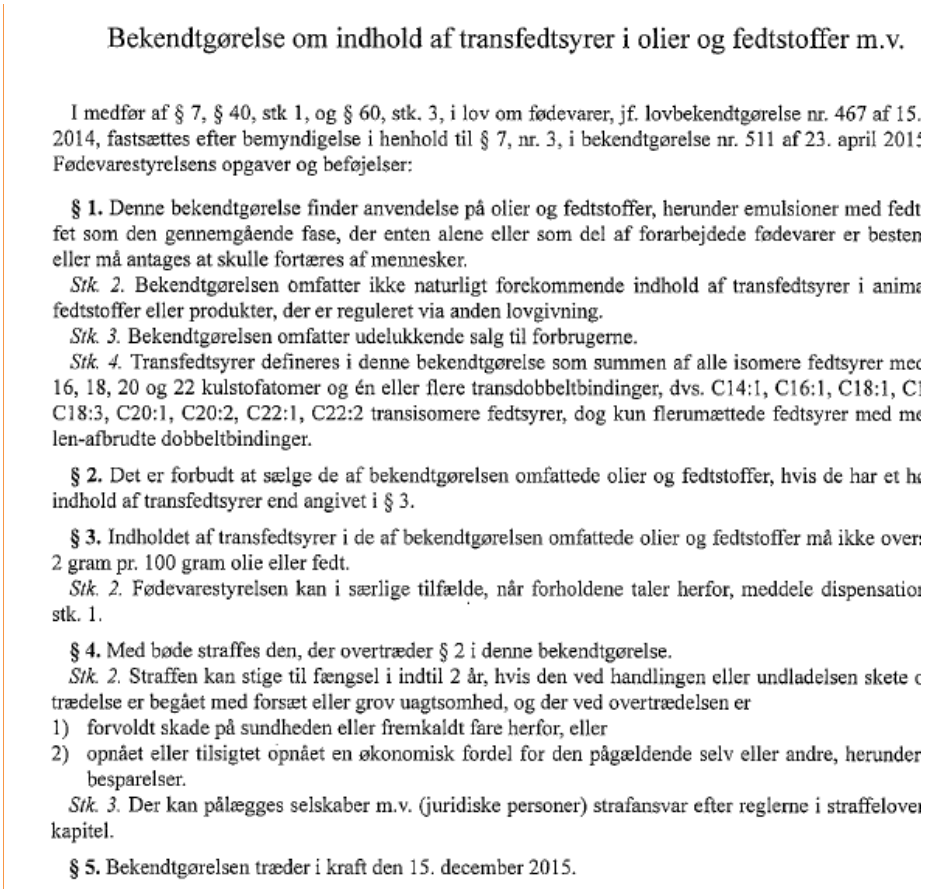
Subsection 2. Products manufactured before this Order has entered into force, as well as manufactured within the periods stated in Section 3(2), may be sold until expiry of the best date.

Definition of trans fatty acids

For the purposes of this Order, trans fatty acids are defined as the sum of all fatty acid ison 14, 16, 18, 20 or 22 carbon atoms and one or more trans double bonds, i.e. C14:1, C16:1, C C18:2, C18:3, C20:1, C20:2, C22:1, C22:2 fatty acid trans isomers, but only polyunsaturat acids with methylene interrupted double bonds.

Source: Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on trans fatty acids in foods. Annex 1.

An amendment to the Order 160 above (Order 1427/2015, see below) deletes section 4 to harmonise the Order with the EU regulation on nutrition and health claims made on foods (Order 1924/2006).



Bekendtgørelse om indhold af transfedtsyrer i olier og fedtstoffer m.v.

I medfør af § 7, § 40, stk 1, og § 60, stk. 3, i lov om fødevarer, jf. lovbekendtgørelse nr. 467 af 15. 2014, fastsættes efter bemyndigelse i henhold til § 7, nr. 3, i bekendtgørelse nr. 511 af 23. april 201 Fødevarestyrelsens opgaver og beføjelser:

§ 1. Denne bekendtgørelse finder anvendelse på olier og fedtstoffer, herunder emulsioner med fedt fet som den gennemgående fase, der enten alene eller som del af forarbejdede fødevarer er besten eller må antages at skulle fortæres af mennesker.

Stk. 2. Bekendtgørelsen omfatter ikke naturligt forekommende indhold af transfedtsyrer i anima fedtstoffer eller produkter, der er reguleret via anden lovgivning.

Stk. 3. Bekendtgørelsen omfatter udelukkende salg til forbrugerne.

Stk. 4. Transfedtsyrer defineres i denne bekendtgørelse som summen af alle isomere fedtsyrer mec 16, 18, 20 og 22 kulstofatomer og én eller flere transdobbeltbindinger, dvs. C14:1, C16:1, C18:1, C C18:3, C20:1, C20:2, C22:1, C22:2 transisomere fedtsyrer, dog kun flerumættede fedtsyrer med me len-afbrudte dobbeltbindinger.

§ 2. Det er forbudt at sælge de af bekendtgørelsen omfattede olier og fedtstoffer, hvis de har et hø indhold af transfedtsyrer end angivet i § 3.

§ 3. Indholdet af transfedtsyrer i de af bekendtgørelsen omfattede olier og fedtstoffer må ikke over 2 gram pr. 100 gram olie eller fedt.

Stk. 2. Fødevarestyrelsen kan i særlige tilfælde, når forholdene taler herfor, meddele dispensatio stk. 1.

§ 4. Med bøde straffes den, der overtræder § 2 i denne bekendtgørelse.

Stk. 2. Straffen kan stige til fængsel i indtil 2 år, hvis den ved handlingen eller undladelsen skete o trædelse er begået med forsæt eller grov uagtsomhed, og der ved overtrædelsen er

1) forvoldt skade på sundheden eller fremkaldt fare herfor, eller
2) opnået eller tilsigtet opnået en økonomisk fordel for den pågældende selv eller andre, herunder besparelser.

Stk. 3. Der kan pålægges selskaber m.v. (juridiske personer) strafansvar efter reglerne i straffelove kapitel.

§ 5. Bekendtgørelsen træder i kraft den 15. december 2015.

Source: The Danish Veterinary and Food Administration

Scope of measure	The scope of the legislation has been to reduce the amount of IP-TFA in food to maximum 2 g per 100 g in eatable oils and fats.
FBOs covered	All
Derogations *(e.g. low fat products, local products)*	The legislation does not cover R-TFA.
Share of SMEs involved *(in case of voluntary measures)*	N/A
Length and characteristics of transition period	The legislation was passed in March 2003, and was fully implemented on 1 January 2004. For transition period, see Order 160 No. of 11 March 2003 Chapter 1, section 3, subsection 2: from 1 June 2003 to 1 January 2004, certain products were allowed to contain 5 g IP-TFA per 100 g oil or fat.

	The Danish industry to a large extent complied with the regulation when this was implemented. The industry had been working towards a reduction of IP/TFA already from the 1990s.[189]
Arrangements for measure enforcement and compliance monitoring	The Danish Veterinary and Food Administration (*Fødevarestyrelsen*) and the National Food Institute at the Technical University of Denmark conducted surveys of the content of TFA in selected foods in 2002-3, 2004-5, 2006-7, 2010 and 2012-13.
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	N/A
Tests used to assess TFA content	The amount of IP-TFA in foods that contain mixed fats, e.g. milk fat and partially hydrogenated soybean oil, can be estimated by: • Estimating the amount of milk fat present in the food based on its butyric acid content (C4:0), butyric acid occurs uniquely in milk fat; • Using this to estimate the amount of naturally occurring TFA in the food based on an assumption about the fraction of milk fat that is TFA; • Subtracting the R-TFA figure form the total amount of TFA to derive an estimate of the IP-TFA content.[190]
Steps taken to raise consumer awareness	Following a *Lancet* article in 1993 and scientific documentation on the effects of a high intake of TFA, there was a lot of media coverage in Denmark about the negative effects of TFA. This, for example, meant that the sale of margarine dropped already from 1993 onwards. When the IP-TFA limit was introduced, the margarine producers largely already complied with the limit.[191] From a Danish perspective, it is considered more efficient that the industry limits limit the level of IP-TFA from products in the market, instead of the costumers having to understand TFA labels

[189] Interview with the Confederation of Danish Industry (13 July 2017)

[190] Danish food institute. 'Analysis of trans fatty acids in Denmark, industrially produced versus ruminant trans fatty acids.'

[191] Traill, Bech-Larsen, Gennaro, Koziol-Kozakowska, Kuhn, and Wills (2012). Reformulation for healthier food: a qualitative assessment of alternative approaches. P. 8. Link: https://www.researchgate.net/publication/254384473_Reformulation_for_healthier_food_a_qualitative_assessment_of_alternative_approaches

	on products.[192] At the time around the introduction of the Order, there was a lot of debate about IP-TFA. This means that the consumers also demanded healthier products.[193] A lot of attention is given to health issues in Denmark; including on the negative effects from e.g. TFA. This could raise the general consumer awareness around TFA (personal view).
Guidance provided to affected businesses	There has been an ongoing dialogue between the industry, the Danish Veterinary and Food Administration (*Fødevarestyrelsen*) and the National Food Institute at the Technical University of Denmark to support the implementation of the Order. Before the implementation of the Order dialogue had been established to encourage a reduction of the IP-TFA level in products on the Danish market. It was mainly just after the introduction of the Order that businesses received guidance and dispensations if they needed more time to adjust to the Order.[194] Denmark has a long term tradition of stakeholder dialogue, which could have had an impact on the process and dialogues around TFA (personal view). Every third year risk-based controls are being conducted to analyse the level of IP-TFA in products which are considered to be at risk of having too high a level of IP-TFA. If the results of the analyses show that the limit of IP-TFA has been exceeded, the business will receive further guidance to avoid sale/production of a product which transgresses the limit. Controls may also be conducted on the background of suspicions for specific products.[195] The branch federations in the Confederation of Danish Industry had already been in dialogue with the Industry before the implementation of the Order, so that the industry largely lived up to the Order when this was introduced.[196] When working to reduce the IP-TFA content, the businesses could enter into dialogue with the suppliers of oils to ensure import of oils with a lower IP-TFA content. Prior to the introduction of the IP-TFA limit, the Danish industry was concerned about the potential costs of this. However, retrospectively seen, the process of limiting the IP-TFA has not been as difficult as expected.[197]
Effectiveness of the measure	The effect of the Danish regulation is clear from the results. Most of the products complied with the regulation already in 2004/5. In the following years (2006/7, 2010 and 2012/13) only occasional transgressions have been found. The surveys demonstrate a

[192] Interview with The Danish Veterinary and Food Administration (5 July 2017)

[193] Interview with the Confederation of Danish Industry (13 July 2017)

[194] Interview with The Danish Veterinary and Food Administration (5 July 2017)

[195] Interview with The Danish Veterinary and Food Administration (5 July 2017)

[196] Interview with the Confederation of Danish Industry (13 July 2017)

[197] Interview with a food procurement company (12 July 2017)

	continual decrease in the number of products that do not comply with the Danish maximum limit for IP-TFA.[198] The limitation of IP-TFA in Denmark has taken place over a number of years, and began before the introduction of the Order 160. In this way the Order supported an ongoing process to limit intake of IP-TFA. Today the health risks of IP-TFA are no longer debated; the industry and authorities agree on and cooperate in the reduction of IP-TFA from products on the Danish market.[199] The Order may have had only a limited effect as the industry was largely compliant with the Order when it was introduced. The Order may mainly have had an effect on imported products and businesses that were not organised via the Confederation of Danish Industry.[200] It is difficult to estimate the actual effectiveness of the measure, as the real process towards a reduction of IP-TFA did not seem to develop in connection with the Order (which was introduced quite late in relation to the process of starting to reduce the TFA content).
Describe (if any) other measures that are currently being considered	The Order has had the desired effects, and the process of introducing the Order has been considered easy and cost-efficient. Apart from ongoing monitoring of the level of IP-TFA, no further measures are currently being considered.[201] Although the Order could be said to have had the desired effects, the actual direct impacts is difficult to estimate. It is more useful to look at the overall process, of which the Order was one component.

TFAs in foods and diets

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	Test results of IP-TFA content in selected foods:[202] Puff pastry: 2 tests of puff pastry. No content of IP_TFA of more than 2 g per 100 g fat was found. Confectionery and caramels: Tests of caramel, candy, chocolate-coated marshmallow, and filled chocolate. No content of IP-TFA of more than 2 g per 100 g fat was found. Croutons: 2 tests of croutons. No content of IP-TFA of more than 2 g per

198 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

199 Interview with The Danish Veterinary and Food Administration (5 July 2017)

200 Interview with the Confederation of Danish Industry (13 July 2017)

201 Interview with The Danish Veterinary and Food Administration (5 July 2017)

202 The National Food Institute (2014). Transfedtsyrer i udvalgte fødevarer 2012. P. 6-8.

100 g fat was found.

Cakes:

16 tests of cakes. No content of IP-TFA of more than 2 g per 100 g fat was found.

Cookies:

25 tests of cookies. 2 tests transgressed the Danish limit of 2 % IP-TFA. Both products were imported.

Chips and frozen potatoes:

10 tests of chips and frozen potatoes. No content of IP-TFA of more than 2 g per 100 g fat was found. 1 test was from a fast food restaurant.

Biscuits:

16 tests of biscuits. 2 tests transgressed the Danish limit of 2 % IP-TFA. Both products were imported.

Crackers (*knækbrød*):

2 tests of crackers. No content of IP-TFA of more than 2 g per 100 g fat was found.

Fast food:

Test of a fried fish filet and a marinated fried chicken for a burger. No content of IP-TFA of more than 2 g per 100 g fat was found.

Margarine:

7 tests of margarine. No content of IP-TFA of more than 2 g per 100 g fat was found.

Fat for microwave popcorn:

4 tests of fat from bags with popcorn for the microwave. No content of IP-TFA of more than 2 g per 100 g fat was found. As the IP-TFA limit was not transgressed, the popcorn have not been microwaved and tested again.

Waffles:

5 tests of waffles. Tests transgressed the Danish limit 2 % IP-TFA. Both products were of foreign origin.

Declarations:

56 of the tests have declared the content of fat and fatty acids. Test results have been compared to the declarations. In 11 tests the declarations do not match with the test results (corresponding to 20 % of the tests); incl. 2 declarations of fat, 4 declarations of SFA, and 5 declarations of both fat and SFA.

These tests have been conducted between October 2012 and June 2013. The total number of tests was 95, and 47 tests were on imported products. 7 tests indicated a higher level of IP-TFA than 2 g per 100 g fat (between 2.7 and 22.7 g IP-TFA per 100 g fat). 4 of these 7 products had declared milk components. In one of the 4 products the TFA could come solely from milk fat, but in the 3

	remaining products there is a level of IP-TFA which is higher than 2 g per 100 g fat. Hence, with the correction for the content of milk fat, the results found more than 2 g IP-TFA per 100 g fat in 6 of the tests (i.e. 6 % of the tests). All these 6 tests are imported products consisting of cookies, biscuits or waffles.
Variation in TFAs content in food after implementation of measure	The test results above can be compared to test results from earlier years:[203] ▪ 2002-3: 25 % of the tests transgressed the Danish limit of 2 g IP-TFA per 100 g fat. ▪ 2004-5: 11 % (17 products) of the tests transgressed the Danish limit of 2 g IP-TFA per 100 g fat. 12 of the 17 tests which transgressed the TFA limit were foreign products. ▪ 2006-7: 9 % (4 products) of the tests transgressed the Danish limit of 2 g IP-TFA per 100 g fat. All 4 products were foreign. ▪ 2010: 7 % (7 products) of the tests transgressed the Danish limit of 2 g IP-TFA per 100 g fat. 6 of the 7 products were foreign. In conclusion, the content of IP-TFA in 2012-3 is the lowest since the first survey in 2002-3, as only 6 % of the products contain more than the IP-TFA limit. All of the 6 products have been selected from ethnical shops, and the products are imported.
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	The survey shows that the small businesses/importers might need extra guidance about the Order 160.[204]
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO*	Despite relative economic equality in Denmark, there is an enduring social inequality when it comes' to citizens' health; i.e. there is a correlation between people's social position in society and their health[205]. Research also suggests that the Danish limit of IP-TFA has decreased the mortality caused by cardiovascular diseases by 14.2 deaths per 100,000 people annually;[206] meaning that the Danish limit on IP-TFA saves around 700 people a year in Denmark.[207]

[203] The National Food Institute (2014). Transfedtsyrer i udvalgte fødevarer 2012. P. 9.

[204] The National Food Institute (2014). Transfedtsyrer i udvalgte fødevarer 2012. P. 9.

[205] Koch, Davidsen og Juel (2012). *Social Ulighed i sundhed, sygelighed og trivsel 2010 og udvikligen siden 1987*. National Institute of Public Health, University of Southern Denmark.

[206] Restrepo and Rieger (2016). Denmark's Policy on Artificial Trans Fat and Cardiovascular Disease. In *American Journal of Preventive Medicine* 50 (1). Pp. 69–76; Martin-Saborido, Mouratidou, Livaniou, Caldeira, and Wollgast (2016). Public health economic evaluation of

contribution)	It has also been suggested that the IP-TFA limit has decreased the health inequality in Denmark with regard to coronary heart disease. Before the introduction of the limit – during the 1990s – health conscious people already largely avoided foods with IP-TFA. By contrast, people who did not spend time on reading declarations on foods in general had a higher intake of IP-TFA. The limit has presumably helped this latter group of people. As doctor and researcher Steen Stender has pointed out: '… it is the lowest social groups which have the highest rate of coronary heart diseases, so one of the advantages is that the ban protects those who need the protection the most.'[208]
Variation in TFAs intake after implementation of measure	See above
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	In general there is a lot of focus on health in the Danish media; including focus on IP-TFA, and the fact that Denmark has a specific rule for this in comparison with other countries. In the national media, IP-TFA has for example been called 'the world's most dangerous fat' (*verdens farligste fedtstof*)[209] and there is attention on imported products which contain too much IP-TFA.[210]

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	All businesses have to comply with the Order, and already before the introduction of the Order – from the 1990s onwards – the industry was working to reduce the level of IP-TFA. Only few businesses received dispensation, in cases where they were not able to comply with the Order at the deadline. There is no known exact number of businesses that reformulated their products.[211]

different European Union–level policy options aimed at reducing population dietary *trans* fat intake. In *The American Journal of Clinical Nutrition.* P. 1219.

[207] http://videnskab.dk/krop-sundhed/dansk-forbud-mod-transfedt-redder-liv-om-dagen

[208] http://videnskab.dk/krop-sundhed/dansk-forbud-mod-transfedt-redder-liv-om-dagen

[209] http://politiken.dk/mad/art5508833/Verdens-farligste-fedtstof-er-p%C3%A5-vej-ud

[210] http://politiken.dk/forbrugogliv/sundhedogmotion/art5508832/Varer-i-indvandrerbutikker-fyldt-med-transfedt

[211] Interview with The Danish Veterinary and Food Administration (5 July 2017)

Evidence of FBO sector facing specific challenges	The adjustments observed in Denmark after introduction of the Danish regulation were made relatively quickly for e.g. frying oils and ready-to-eat French fries from the big burger chains, whereas other French fries and frozen potato products as well as certain baking applications, especially cookies, sometimes needed more time to adjust. The demand for longer time to eliminate IP-TFA from cookies was probably due to difficulties in finding alternative fats with usable properties as well as the existence of many small- and medium-sized baking companies in contrast to the big burger chains.[212] Chocolate producers may not have faced the same challenges as, for example, cookies producers.[213]
For which oils/fats was there a reduction in use and with what were they replaced?	Comparisons of the fatty acid profiles showed that in 68% of the products (e.g. sweets, cakes and cookies as well as fast food such as pie and tortilla), IP-TFA were mainly substituted with saturated fatty acids (SFA). In some cases, the SFA source was coconut fat, whereas in other products, palm oil was added instead of partially hydrogenated oils. However, in important cases like frying fats, healthier fat substitutes with monounsaturated fatty acids were used. The surveys showed that the IP-TFA content has been reduced or removed from most products with originally high IP-TFA content, such as French fries, microwave oven popcorn and various bakery products. IP-TFA levels are now insignificant for the intake of TFA in Denmark.[214]
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	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 IP-TFA limit.[215] Margarine producers already complied with the legislation when this was introduced. At the beginning businesses had to import oils with limited IP-TFA content. These oils could have been more expensive because they were not mainstream products. This may also have increased the prices of products initially – although these prices are thought to have decreased again.[216] Thirdly, the public health focus in Denmark may also support the development of a market in which many consumers demand health friendly products. Businesses might want to comply with this consumer demand.

[212] Bysted, Mikkelsen and Leth (2009). Substitution of trans fatty acids in foods on the Danish market. In *European Journal of Lipid Science and Technology* 111 (6), No. 6. Pp. 574-583.

[213] Interview with a food procurement company (12 July 2017)

[214] Bysted, Mikkelsen and Leth (2009). Substitution of trans fatty acids in foods on the Danish market. In *European Journal of Lipid Science and Technology* 111 (6), No. 6. Pp. 574-583.

[215] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P.8

[216] Interview with a food procurement company (12 July 2017)

	Fourth, it could also be taken into consideration that the Danish state may have a relatively strong societal legitimacy when it comes to regulating businesses' behaviour in society (in comparison to other countries). This could also play a role for businesses' acceptance of the Order, and the industry's willingness to create dialogue about changing their products (personal view).
Cost of understanding/ learning the measure for FBOs	The process of introducing the Order was cost and time efficient, and in some cases it was even easier than expected; for example, not all businesses had to use the entire transition period to achieve compliance.[217] Buying oils with a limited IP-TFA was initially more expensive than ordering the conventional oils hitherto. Also, it took time to reformulate all the products – for example in chocolate production – and implement this reformulation in the entire production process.[218] The Confederation of the Danish Industry did not collect data on the costs, as the industry largely lived up to the Order when this was introduced. Also, how businesses were working to reduce the IP-TFA content could have been commercially confidential.[219]

Consumer prices and choice

Evidence of changes in the price of reformulated products	The effect on product prices is thought to have been limited (see previous section). However, as in the case of chocolate, the import of oils with a limited IP-TFA content for the chocolate production probably initially increased the prices of chocolate initially.[220]
Evidence of price differences between products with iTFAs and alternatives	No evidence found. Mainly imported products seem to transgress the allowed Danish IP-TFA level.
Evidence of changes in the range, quality or taste of products available	No evidence found. The reduced level of IP-TFA in products where crispiness is important seem to have led to an increase of SFA, although the overall fatty acids profile is important to take into consideration to estimate the actual health costs.
Evidence of changes in	The decreased death rates in Denmark caused by coronary diseases are thought to reflect, at least in part, the effects of

[217] Interview with The Danish Veterinary and Food Administration (5 July 2017)

[218] Interview with a food procurement company (12 July 2017)

[219] Interview with the Confederation of Danish Industry (13 July 2017)

[220] Interview with a food procurement company (12 July 2017)

TFAs consumption	changed IP-TFA consumption.
Effect on consumer information and awareness	The general focus on health in the Danish media and the debates about the harmful effects of IP-TFA surrounding the legislation led to an increased awareness of IP-TFA and the negative health consequences of eating too much IP-TFA.

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	Within the European Union, Denmark has the lowest rate of deaths caused by cardiovascular diseases (share of deaths attributed to cardiovascular diseases).[221] Research suggests that the mortality caused by cardiovascular diseases decreased by 14.2 deaths per 100,000 people annually.[222]
Evidence of change in saturated fats intake	As SFA is associated with an increased risk of coronary heart disease, the reduced level of IP-TFA should not lead to an increase of SFA – although SFA has a similar functionality to IP-TFA. If IP-TFA is then replaced with SFA, the level of SFA 'should at least be the same or lower than the combined level of TFA and SFA in the original product.'[223] In margarine and shortening, the IP-TFA level was in general reduced without increasing the level of SFA. Instead, the level of MUFA was increased.[224] In a majority of the products however, IP-TFA was mainly replaced with SFA. These were products where the crispiness is very important, and the fat replacing the IP-TFA must thus have similar functionality.[225] In other products, including chips and frozen potatoes, the level of MUFA was increased when reducing the level of IP-TFA.[226] The adjustments for the TFA level could be made fairly quickly in

[221] See table 1: http://ec.europa.eu/eurostat/statistics-explained/index.php/Cardiovascular_diseases_statistics

[222] Restrepo and Rieger (2016). Denmark's Policy on Artificial Trans Fat and Cardiovascular Disease. In *American Journal of Preventive Medicine* 50 (1). Pp. 69–76

[223] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P. 11.

[224] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P. 9.

[225] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P. 12.

[226] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P. 12.

	frying products. By contrast, the adjustments took longer with baking products given difficulties of finding replacements for TFA.[227]

Competition, innovation and trade

Effect on competition in the domestic market	The Danish IP-TFA level initially led to criticism from the EU because it was said to cause a trade impediment on imported products, as imported products containing too much IP-TFA cannot be sold in the Danish market.[228] In such cases, Danish products could have an advantage over imported products.
Changes in trade of affected goods	For imported products, see above. As the industry quickly complied with the Order, no changes in the trade of affected products have been identified.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	During recent years a number of alternatives have been developed to replace IP-TFA.[229] Examples were provided of suppliers being keen to work with the producer to deliver the right oils, as the suppliers could see the emergence of a market for oils with a limited IP-TFA content.[230]

Administrative burdens

Number of businesses required to provide information	Food business operators are not obliged to notify to the authorities of the marketing of products and/or provide information regarding content before marketing. The decision to regulate the IP-TFA content in foods is considered to have eliminated the need to inform the consumer about TFA on the label.[231]
Evidence of economic burden associated with compliance for FBOs *(obtain cost data*	No particular evidence identified. However, the research identified examples of the producers needing to buy specific fats that complied with the Order from suppliers. These fats were probably more expensive initially, as the requirement for less IP-TFA was new. Also, the changing of product packaging led to extra costs. It also takes a few years to go through all the changes in the entire product chain.[232]

[227] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P. 12.

[228] Interview with The Danish Veterinary and Food Administration (5 July 2017)

[229] Ministry of Food, Agriculture and Fisheries of Denmark and the National Food Institute (2014). Danish data on *trans* fatty acids in foods. P. 12

[230] Interview with a food procurement company (12 July 2017)

[231] Interview with The Danish Veterinary and Food Administration (5 July 2017)

[232] Interview with a food procurement company (12 July 2017)

if possible)	
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	Continuous surveys have been carried out to monitor the development of the IP-TFA level in foods on the Danish market.

Environmental impacts

Evidence of any environmental costs or benefits	No information found.
Evidence of increase in demand for palm oil / other ingredients	If there has been an increase in the use of palm oil, it is not certain whether this is due to the market prices more generally or an increased demand for palm oil as a replacement for hydrogenated oil/fats.[233]
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found.

[233] Interview with The Danish Veterinary and Food Administration (5 July 2017)

Germany

Policy status

	Existing	Proposed/ considered
Legislation		
Voluntary measures	X	
Labelling		Proposed by industry
Consumer information		

Description of existing measure(s)

Type of measure	Voluntary measure
Description of measure *(if legislation paste exact text of legislation)*	Voluntary measure – self-regulation. In a joint initiative the Federal Ministry of Nutrition and Agriculture (BMEL) and the German food industry agreed a voluntary framework guideline for the minimisation of TFA in foods that was issued June 2012. This framework guideline included product-specific guidelines for 1) baking, puff-pastry and cream margarines, 2) deep-frying oils and frying fats, 3) cooking oils and fats, 4) savoury snacks, 5) fine bakery wares, 6) processed potato products ,7) frozen pizzas.
Scope of measure	The food industry in Germany had already been working on reducing TFA from partly hydrogenated fat substantially in many products over the last 20 years. According to data from the National Consumption Study II (NVS II) from 2005 to 2006 and the Food Monitoring Study (2008 to 2009) the average intake of TFA was below the recommendations from the German Association for Nutrition (DGE). One third of men between 14 and 34 years consumed more TFA than recommended, mainly due to consumption of non-ruminant industrial TFA in certain product groups. Against this background the BMEL led a dialogue with economic associations of affected sectors which resulted in a joint initiative between the food industry and the Federal Ministry of Nutrition and Agriculture (BMEL). In close cooperation with a scientific adviser (the Max Rubner Institute (MRI)) the associations developed framework guidelines as well as seven specific guidelines for different product categories. The guidelines are intended to raise awareness among manufacturers and to assist in the transition to TFA-reduced products. Components of the measure include: • Joint Initiative Paper: two-page, short version of general principles, published as a press release and signed by all

stakeholders
- Framework Guideline / General Principles: detailed information on the initiative with backgrounds, aims and strategy
- Product Guidelines: detailed information and recommendations for the implementation in special product categories

The framework guideline describes the joint arrangements for the minimization of TFA in foodstuffs and the initiative. The product guidelines describe in each case which products are involved and in which foodstuffs they are used. Subsequently, the special requirements of the respective product categories are discussed. The TFA content is also described. Finally, recommendations are made on how TFA can be reduced in the respective products, in which context challenges are also addressed. Attention is also drawn to specific areas where research is required.

The guidelines are aimed at food manufacturers and are used to inform them about the subject of TFA. This gives manufacturers the information they need to optimize their processes in order to further reduce TFA. The business associations involved use different channels (e.g. Internet, print media, newsletters, etc.) to inform their members. They provide information about the background and objectives of the initiative and provide links to further literature. The composition of the online offer is quite different depending on the association and the membership structure. This includes: pure specialist information on the topic in the members' areas, question-and-answer catalogs, and other different service offers, which can be used by the various interested parties at any time.

The participating associations are obligated to report regularly on minimization measures. Three reports from the German Federation for Food Law and Food Science (Bund für Lebensmittelrecht und Lebensmittelkunde (BLL)), which is coordinating the industry contributions under the scheme, are now available and are available on the BLL website.[234]

Institutions and associations participating in the agreement:

- Federation of Food Law and Food Science
- Federal Ministry of Food, Agriculture and Consumer Protection
- Federal Association of the German Sweets Industry
- Federal Association of Canteen Tenants
- Federal Association of the Fruit, Vegetable and Potato Processing Industries.
- Federal Association of System Gastronomy
- Federal association of the German food trade

[234] https://www.bll.de/de/lebensmittel/ernaehrung/fett/tfa-trans-fettsaeuren

	• Federal association of German Market Selling Businesses • Federal Association of Fast Food and Snack-Service Companies • The German Association for Baking Ingredients • German Hotel and Catering Association • German Confectioner's Association • Deutscher Schaustellerbund e.V. • German Institute for Frozen Food • OVID Association of the Oilseed Processing Industry in Germany • Association of the German Margarine Industry • Association of Culinary Food Manufacturers • Association of German Bakeries • Central Association of the German Bakery Trade Since the introduction of the measures, relevant sectors have started to change their production conditions for the fats. Data from the state food monitoring show that, for example, the TFA content of hydrogenated fats, fat-rich, sweet spreads and pastry products were significantly reduced.[235]
FBOs covered	This framework guideline includes product-specific guidelines for 1) baking, puff-pastry and cream margarines, 2) deep-frying oils and frying fats, 3) cooking oils and fats, 4) savoury snacks, 5) fine bakery wares, 6) processed potato products ,7) frozen pizzas.
Derogations *(e.g. low fat products, local products)*	N/A
Share of SMEs involved *(in case of voluntary measures)*	Associations representing SMEs were involved in all measures and research activities.
Length and characteristics of transition period	The measure has been in place since June 2012. No transition period was agreed with the participating organisations.

235 http://www.bmel.de/DE/Ernaehrung/SichereLebensmittel/RueckstaendeKontaminanten/_Texte/Transfettsaeuren.html

Arrangements for measure enforcement and compliance monitoring	The German Federation for Food Law and Food Science (Bund für Lebensmittelrecht und Lebensmittelkunde (BLL)) has issued yearly reports on the measures taken by industry from 2013 onwards and informs the Federal Ministry of Food and Agriculture (formerly the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)) regularly about this. The signatory associations provide BLL with the necessary documentation.[236] In the beginning of 2017 the third report on measures on TFA was published.[237]
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	The above listed business associations and their members are participating in the measure. Business has attempted to comply with the guidelines and the levels of TFA were reduced after introduction of the measure. However, it has reported that the implementation of the specific product guidelines is a particular challenge for SMEs. Recipes partly need changing to maintain texture and taste despite substitution of, for example, baking fats.
Tests used to assess TFA content	As an examination method for the determination of the composition of the fatty acids, the gas chromatographic analysis of the fatty acid methylester has been chosen. For the separation, the use of polar capillary columns with a stationary phase of cyanopropyl-polysiloxane having a length of at least 50 m, preferably 100 m has proven useful. A previous enrichment of the TFA via a silver ion chromatography was considered as not required. For the purposes of the guidelines, only those TFAs with a chain length of 18 carbon atoms were considered. TFAs with different chain lengths usually make up a negligible proportion. The three main groups of TFAs are derived from oleic acid, linoleic acid and linolenic acid. TFAs elute on the polar capillary columns described above, respectively before the corresponding cis fatty acids, i.e. between stearic acid methyl ester and oleic acid methyl ester, and also before linoleic acid methyl ester and linolenic acid methyl ester. Fatty acids with conjugated double bonds as characteristic for milk fat, are not included in the assessment. Further information on TFA content data used for the assessment can be found here: TFA-Gehaltsdaten: http://www.bfr.bund.de/cm/343/hoehe-der-derzeitigen-trans-fettsaeureaufnahme-in-deutschland-ist-gesundheitlich-unbedenklich.pdf]

236 http://www.bmel.de/SharedDocs/Downloads/Ernaehrung/Rueckstaende/Trans-Fettsaeuren/TFA_Inhalt.pdf?__blob=publicationFile

237 https://www.bll.de/de/lebensmittel/ernaehrung/fett/tfa-trans-fettsaeuren

Steps taken to raise consumer awareness	For the participating associations, raising awareness within their respective member groups is central to implementing the guidelines. The type of dissemination activities (e.g. Internet, print media, newsletters, working groups, etc.) and content differs depending on the type of association and target industry. The central concern of all participating associations is to reach a broad membership and to elaborate on and enhance possibilities for minimizing non-ruminant TFA. Different media was used including: 1. Information on the homepage of the associations 2. Press releases 3. Circulation 4. (Committee) meetings / working groups / meetings 5. Newsletter 6. Annual reports 7. Specialist events and scientific congresses 8. Trade Journals The participating organisations are reporting on their initiatives in this field to the BLL as part of their yearly reporting obligation.
Guidance provided to affected businesses	• Framework Guideline / General Principles: detailed information on the initiative with backgrounds, aims and strategy • Product Guidelines: detailed information and recommendations for the implementation in special product categories
Effectiveness of the measure	Since signing the guidelines in June 2012, the participating associations have been working on implementation. An assessment of the TFA intake in Germany undertaken one year after the introduction of the measure (2013) by the Federal Institute for Risk Assessment (BfR) confirmed the success of the minimization measures of the German food industry and showed that the current TFA intake in Germany is under the defined limits and not a relevant risk factor for the development of cardiovascular diseases.[238] The German food industry has indicated its commitment to further reduce the content of non-ruminant TFA in foodstuffs, provided this is technically feasible and reasonably achievable. However the BLL indicates that the legal framework for labeling continues to pose a challenge to the implementation of the guidelines, since, according to the provisions of the Food Information Regulation, the TFA content must not be voluntarily marked either on foodstuffs for the final consumer or on raw

[238] http://www.bfr.bund.de/cm/343/hoehe-der-derzeitigen-trans-fettsaeureaufnahme-in-deutschland-ist-gesundheitlich-unbedenklich.pdf

	materials for industrial production.[239]
Describe (if any) other measures that are currently being considered	For the food industry, the clear recognition of low TFA foodstuffs and raw materials through labelling is an important step for the further reduction of non-ruminant TFA. Current legislation does not require this. Against this backdrop, many of the participating associations argue for the possibility of voluntarily providing the non-ruminant TFA content on their products.[240]

TFAs in foods and diets

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	In 2008 the following TFA content was reported for a range of products:[241] • 0.4% to 2% in plant margarine, waffles, baking margarine, fat-rich sweet spreads • 2% to 5% in puff pastry, croissants, pastries, pigs' ears, cream tarts, Stollen • 5% to 10% in *Zieh* margarine, Crème margarine, Fine pastry made of light dough • 10% to 15% in fat pastry from yeast dough, donuts In *Zieh* margarine, Crème margarine, fine baked goods made from light-dough and pastries made from yeast dough, 57% to 65% of all samples had a total content of trans-fatty acids of more than 5 g / 100 g total fat. As part of the monitoring program, it has also been confirmed that industrial margarines contain significantly more trans-fatty acids than plant margarines for the household. Positive results were found for fat-rich sweet spreads (eg peanut cream, nut nougat cream, milk chocolate): the content of trans fatty acids was less than 2 g / 100 g of total fat in 83% to 100% of all samples in this category. In 2011 the following TFA content was reported for ice cream,

[239] https://www.bll.de/de/lebensmittel/ernaehrung/fett/tfa-trans-fettsaeuren (3rd Report issued by the BLL)

[240] 3. Bericht seit der Unterzeichnung der Initiative im Juni 2012 (https://www.bll.de/de/lebensmittel/ernaehrung/fett/tfa-trans-fettsaeuren)

[241] http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/02_BUEp_dokumente/buep_berichte_archiv/BUEp_Bericht_2008.pdf?__blob=publicationFile&v=6

	eggs, soup and sauces (includes rTFA and iTFA)[242]: • Ice-cream = 0.03-2.9 g TFA/100 g fat (Mean/Median: 0.47 g/0.32 g TFA/100 g fat) • Egg = 0.02-1.47 g TFA/100 g fat (Mean/Median: 0.65 g/0.50 TFA/100 g fat) • Soup = 0.01-18.9 g TFA/100 g fat (Mean/Median: 0.86 g/ 0.40 g TFA/100 g fat) • Sauces = 0.02-46.0 g TFA/100 g fat (Mean/Median: 1.63 g /0.51 gTFA/100 g fat) A study published in 2011 indicated the following TFA product content in g per 100 g of total fat[243]: • Doughnuts: 7.3g • Butter: 3.1g • Puff pastries: 2.6g • Chocolate products: 2.1g • Instant products: 2.02g In this study, 96% of the deep-fried potato products, 90% of the confectioneries, 90% of the instant products and 82% of the semi-solid fats contained less than 2% TFA of FAME. The study indicated that the TFA proportion in foods on the German market is declining, especially within the former high risk food groups such as french fries, margarines and shortenings.
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own*	No information found.

[242] Bundesweiter Überwachungsplan 2011. Gemeinsamer Bericht des Bundes und der Länder. Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) (2013)

[243] Kuhnt, K., et al.: Trans fatty acid isomers and the trans-9/ trans-11 index in fat containing foods. Eur. J. Lipid Sci. Technol, 2011. 113: p. 1281-1292.Cited in http://publications.jrc.ec.europa.eu/repository/bitstream/JRC91353/lbna26795enn.pdf

products)	
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	In 2012 (before the initiative was introduced) the average intake of TFA was reported to be below recommendations from German Association for Nutrition (DGE). However, young people (between 14-34 years) were at the time heavy consumers with more than 1% TFA of the daily amount of total energy consumption. This was mainly caused by consumption of non-ruminant industrial TFA in some product groups.[244] The evaluation of the TFA intake in Germany by BfR, which was published in 2013, one year after implementation of the joint initiative, shows that reductions were successfully achieved. The average intake (14-80 y) was estimated as 1.6 g/day or 0.66 E%. For most consumers (including the vast majority of young people between 14-34 years) TFA intake was lower than 1% of their dietary energy intake. It concludes that the current level of TFA intake in Germany does no longer represent a relevant risk factor for the development of cardiovascular disease.
Variation in TFAs intake after implementation of measure	See above.
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	No information found.

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	No information found.

244 http://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/ev20120209_co07_en.pdf (2012)

Evidence of FBO sector facing specific challenges	No information found.
For which oils/fats was there a reduction in use and with what were they replaced?	For each product guideline the alternative oils/fats were identified: For example, for frying oil, new TFA-low oil and fat mixtures were identified that are technologically-feasible and already available on the market. For example, high-oleic acid (HO rapeseed or HO sunflower) oils were recommended. The advantages of these modern TFA-low frying oils are in their nutritionally- and physiologically-favorable composition, with heat and oxidation stability comparable to conventional oils, good sensory results (taste and odor) and markedly reduced TFA contents in the final product (pastry/dumplings). The product guidelines also identify TFA-low margarines as well as the possible exchange of partially hardened vegetable fats and oils (high-TFA content) through non-hardened vegetable fats and oils as technologically feasible for the production of cookies, potato crisps etc. The product guidelines indicate that the transition to TFA-low oils and fats has been practiced in many of the product groups for several years and has shown good results.
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	Research conducted between 2013 and 2015 showed that low-TFA frying fats are less expensive as compared to partially hydrogenated peanut fats.[245]
Cost of understanding/ learning the measure for FBOs	No information found.

Consumer prices and choice

Evidence of changes in the price of	No information found.

[245] http://www.fei-bonn.de/gefoerderte-projekte/projektdatenbank/aif-17875-n.projekt

reformulated products	
Evidence of price differences between products with iTFAs and alternatives	No information found.
Evidence of changes in the range, quality or taste of products available	No information found.
Evidence of changes in TFAs consumption	No information found.
Effect on consumer information and awareness	No information found.

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	No information found.
Evidence of change in saturated fats intake	No information found.

Competition, innovation and trade

Effect on competition in the domestic market	No information found.
Changes in trade of affected goods	No information found.

Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	No information found.

Administrative burdens

Number of businesses required to provide information	No information found.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	Implementation of the specific product guidelines is a particular challenge for SMEs. Recipes partly need changing to maintain texture and taste with the substitution of, for example, baking fats.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	No information found.

Environmental impacts

Evidence of any environmental costs or benefits	No information found.
Evidence of increase in demand for palm oil / other ingredients	No information found.
Effects on deforestation resulting from variation in demand of ingredients	No information found.

(e.g. palm oil, soy)	

Additional references

https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

Hungary

Policy status

	Existing	Proposed/ considered
Legislation	X	
Voluntary measures		
Labelling		
Consumer information	X	

Description of existing measure(s)

Type of measure	Legislation
Description of measure *(if legislation paste exact text of legislation)*	Decree 71/2013 of the Ministry of Human Resources[246] 'It is forbidden to place on the market food products in which the amount of trans fats exceeds 2 g for every 100 g of the total fat content of food products provided or sold to end consumers. This does not include the storage of said products in their finished state in order to place them on the market outside Hungary.' 'For processed food products consisting of multiple ingredients, the above paragraph shall not apply if (a) the total fat content of the food product is lower than 20%; in this case, the amount of trans fats may not exceed 4 g for every 100 g of the total fat content of said food product; (b) the total fat content of the food product is lower than 3%; in this case, the amount of trans fats may not exceed 10 g for every 100 g of the total fat content of said food product.'
Scope of measure	National
FBOs covered	All FBOs involved in food production for the Hungarian market
Derogations *(e.g. low fat products, local products)*	TFAs of animal origin

[246] https://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=a1300071.emm

Share of SMEs involved *(in case of voluntary measures)*	Not applicable, legislation.
Length and characteristics of transition period	The decree came into effect on 18/02/2014, 90 days after its official publication. Nevertheless, foodstuff being at the market on the date of publication of the decree, could still be marketed until their expiration date with a maximum of up to 12 months after the entry into force of the decree.
Arrangements for measure enforcement and compliance monitoring	Quarterly report is being prepared by the territorial government offices which results are sent to the National Food Chain Safety Agency (Nébih). This institution summarises the results received and forwards the report to the National Institute of Pharmacy and Nutrition (OGYÉI).[247]
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	Not applicable, legislation.
Tests used to assess TFA content	Regular laboratory test carried out by the OGYÉI. It examines the amount of TFAs isomers with 14, 16, 18, 20 or 22 carbon atoms in food products. iTFA content of foods marketed in Hungary monitored annually since 2009. Publication on the latest test results from 05/2017 showing the TFA% per type of foodstuff.[248]
Steps taken to raise consumer awareness	As part of a 6 week-long health promotion programme organised in 10 towns around lake Balaton in Hungary in 2013, 1,643 participants (66% males) were asked about TFA. 65% of respondents gave a correct answer regarding the origin of iTFA whereas 18% were knowledgeable of the foods considered to contain iTFA. The number of correct answers showed a positive correlation with education level, and a correlation with the place of residence (city, town, and village) was observed. Targeted information and educational campaigns by the Ministry of Human Resources taking place in hospitals and sanitary institutions, social media, TV spots, web.[249]

[247] http://portal.nebih.gov.hu/elelmiszer-es-takarmanybiztonsagi-igazgatosag

[248] http://www.ogyei.gov.hu/dynamic/tfa_2017-Ine.xlsx

[249] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

Guidance provided to affected businesses	Industry representatives claim that no sufficient guidance was provided by the government in relation to the legislation. They found the transition period short and insufficient. As a recommendation, they would like to have more timely, open and useful communication next time when a measure of such importance gets implemented.[250]
Effectiveness of the measure	National legislation, covering all food products being produced and sold in Hungary. 18 February 2014:The announcement of the Decree 18 February 2015 Sell off period of food products that are already on the market when the regulation entered into force
Describe (if any) other measures that are currently being considered	Measure already in place: **37/2014 decree of Ministry of Human Resources on reforming the public canteens**. The decree aimed to foster healthy, balanced nutrition in all public canteens (i.e. schools) by defining the binding daily intakes per different nutrition groups.[251]

TFAs in foods and diets

TFAs content in food

(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)

A nationwide quarterly monitoring of the TFA content in alimentary products in Hungary. Food samples from different groups are checked with regard to the TFA content.

The results are publicly available, nevertheless the products are selected randomly which makes comparison rather complicated. The table below offers an overview (extracted from the dataset) of the TFA g/100g total fat on different food groups based on the monitoring between 1st quarter 2014 – 1st quarter 2017[252]: According to the data available, the vast majority of products comply with the regulation with only few exceptions.

	2014	2015	2016	2017
Margarines/oils	Min: 0.08 Max: 2.27 Av: 0.68	Min: 0.05 Max: 1.93 Av: 0.59	Min: 0.05 Max: 1.31 Av: 0.73	Only 1 product examined: 0.88
Bakery products, pasta	Min: 0.23 Max: 6.08 Av: 0.90	Min: 0.16 Max: 1.31 Av: 0.66	Min: 0.2 Max: 3.86 Av: 0.86	No product examined

[250] https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf

[251] https://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=a1400037.emm

[252] http://www.ogyei.gov.hu/dynamic/tfa_2017-Ine.xlsx

Sweet biscuits, tea biscuits	Min:0.05 Max:7.53 Av:0.86	Min:0.09 Max:22.15 Av:1.23	Min:0.14 Max:13.00 Av:1.26	Min: 0.2 Max: 0.48 Av: 0.34

Variation in TFAs content in food after implementation of measure	All FBOs needed to reformulate their products in order to comply with the national legislation. The table above gives a good indication of the impact of the Decree.
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	Since the Decree is legally binding, all FBOs must comply with it.
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	The estimated iTFA intake of the Hungarian population is 6.8g/day, taking into account the average consumption data based on the three day dietary questionnaire and the highest iTFA values of the food category. According to the result of a National Nutritional Survey in Kindergartens (OTEF 2009), in 10% of nurseries the daily menu contained more than 2 % TFA.[253]
Variation in TFAs intake after implementation of measure	According to the National Institute of Pharmacy and Nutrition, the daily TFA intake decreased from 6.8 g to less than 1 g two years after the entry into force of the legislation.[254]
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food*	No research on this topic have been carried out, thus no information can be provided here. It can, however, be said that in parallel with the entry into force of the legislation, the vast majority of the Hungarian media (printed, online, TV, radio) raised awareness of the topic, providing consumers with information not only about the Decree but the health risks of high daily TFA intake.

[253] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

[254] http://alimento.blog.hu/2013/11/24/transz-zsirsavak_kulonvelemeny

choice)	

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	The number of SMEs in the affected sectors is particularly high. For them, the obligation to reformulate their products might be particularly demanding (as they often struggle from lack of specialist knowledge, information, financial flexibility and means). Industrial fats with less than 2% TFA content are 13-50% more expensive, what means that there is a close relationship between the price of the industrial fat used and the price of the actual product.[255]
Evidence of FBO sector facing specific challenges	The transition set a number of challenges as follows:[256] - New types of fats to be used - Changing long term contracts of FBOs with subcontractors - Discontinue certain products in order to save on new machinery - New machinery/equipment to be purchased - Carry out laboratory tests on the TFA content of products - Change of wrapping and packaging material
For which oils/fats was there a reduction in use and with what were they replaced?	Only anecdotal evidence was found that claims that the previously used fats have been increasingly replaced by palm.[257]
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	The Federation of Hungarian Food Industries stated that "industrial fats of a TFA content below 2% are by 13-30% more expensive, a fact which means a substantial increase in ingredients' price." When asked about any FBO sector (e.g. SMEs, producers of specific foods) that faced particular challenges, 8 out of 18 confirmed to have corresponding information. According to one SME (referenced in this document), the total cost of transition in the case of a 10 billion HUF (35 Mio EUR) turnover company was approximately 100 mio HUF (300.000 EUR). This source

255 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

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

257 http://alimento.blog.hu/2013/11/24/transz-zsirsavak_kulonvelemeny

	suggests the new types of fats used cost on average 58% more compared to previous one.[258]
Cost of understanding/ learning the measure for FBOs	See above.

Consumer prices and choice

Evidence of changes in the price of reformulated products	No data available on this, however the Hungarian Statistical Office have been publishing consumer price index every year since 1985. The factors for the increase/decrease of prices are not identified here. The table below shows an extract of the food price index, indicating the increase/decrease of prices compared to the year before.

2013	2014	2015	2016
102,8	99,6	100,9	100,7

Evidence of price differences between products with iTFAs and alternatives	Not identified.
Evidence of changes in the range, quality or taste of products available	Not identified.
Evidence of changes in TFAs consumption	The daily intake of TFA decreased from 6.8 g per person/day to less than 1 g per person/day two years after the entry into force of the legislation.
Effect on consumer information and awareness	In parallel with the entry into force of the legislation, the vast majority of the Hungarian media (printed, online, TV, radio) raised awareness of the topic, providing consumers with information not only about the Decree but the health risks of high daily TFA intake. Despite not being measured, it can be concluded that the awareness of Hungarian consumers has significantly increased.

[258] https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	As researches show, a daily intake of TFA of 5 g per person/day increases the risk of cardiovascular diseases by 23%.
Evidence of change in saturated fats intake	No evidence of changes over time

Competition, innovation and trade

Effect on competition in the domestic market	Anecdotal evidence that SMEs were more seriously affected by the legislation, given their more vulnerable financial situation. Production of certain products was discontinued in the absence of financial resources to reconstruct recipes, test the new products and start production. In the meantime, bigger FBOs complied relatively easily with the legislation.
Changes in trade of affected goods	Over the recent years, margarines became synonymous with TFAs and there is expected to have been a decrease in consumption, but no hard data are available on this.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	Suppliers did reformulate their products. A broader impact on innovation at the company level was not identified.

Administrative burdens

Number of businesses required to provide information	According to the national legislation, businesses are not required to provide information.
Evidence of economic burden	According to one SME, the total cost of transition in the case of a 10 billion HUF (35 Mio EUR) turnover company was approximately 100 million HUF (300.000 EUR). This source suggested that the

associated with compliance for FBOs *(obtain cost data if possible)*	new types of fats used cost on average 58% more compared to previous ones.[259] This single report cannot be taken as representative of the typical impact.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	A nationwide quarterly monitoring of the TFA content in alimentary products in Hungary is being conducted by the territorial government offices. Results are sent to the National Food Chain Safety Agency (Nébih).

Environmental impacts

Evidence of any environmental costs or benefits	Not identified
Evidence of increase in demand for palm oil / other ingredients	Only anecdotal evidence, mentioning the increased use of palm oil and its negative environmental effects, mostly deforestation. No statistics are available for Hungary on palm oil import/demand.
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	As above.

[259] https://eu-brusszel.mfa.gov.hu/assets/41/85/91/b3477161e14b1ae5d25a7f3d6f2a9d93b7833546.pdf

Latvia

Policy status

	Existing	Proposed/ considered
Legislation Voluntary measures	X	
Labelling Consumer information		

Description of existing measure(s)

Type of measure	Legislation
Description of measure *(if legislation paste exact text of legislation)*	Cabinet of Ministers Regulation No. 301 on maximally allowed trans fatty acids quantities in food products, adopted on 17 May 2016, in force as of 20 May 2016. The regulation outlines maximally allowed trans fatty acids quantities in food products produced in Latvia, including public catering companies, imported from other European Union member states and countries of European Economic area or third countries, intended for distribution in Latvia. The regulatory requirements apply to food products including trans fatty acids that have been created in the following technological processes of food production: 2.1. by hydrogenating oil; 2.2. by pressing oil at high temperature; 2.3. by frying and heating food products in oil; 2.4. by baking and frying fat-containing food products. 3. The regulatory requirements shall not apply to animal fat and products containing trans fatty acids resulting from natural processes, not being added in the food production process. 4. The maximum amount of trans fat acids in food products shall not exceed 2 g per 100 g of total fat, with the exception of food products mentioned in Articles 5 and 6 of these regulations. 5. The maximum amount of trans fat acids in food products where the total fat content is less than 3%, shall not exceed

	10 g per 100 g of total fat content. 6. The maximum amount of trans fat acids in food products where the total fat content is between 3% and 20%, must not exceed 4 g per 100 g of total fat content. 7. Food products that exceed the maximum quantities of trans fat acids laid down in Articles 4, 5 or 6 of these regulations, can be distributed in Latvia until 1 June 2018. Informative Reference to European Union directive. These regulations contain legal norms arising from the **Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.**
Scope of measure	Food products produced in Latvia, including by public catering companies, and food products imported from other European Union member states and countries of European Economic area or third countries, intended for distribution in Latvia. The regulatory requirements apply to food products including trans fatty acids that have been created in the following technological processes of food production: by hydrogenating oil; by pressing oil at high temperature; by frying and heating food products in oil; by baking and frying fat-containing food products. The regulatory requirements shall not apply to animal fat and products containing trans fatty acids resulting from natural processes, not being added in the food production process.
FBOs covered	It was estimated that the Regulation would affect 7800 food companies, including 6536 public catering companies. At the same time the Ministry of Agriculture did not have precise information on companies that use trans fatty acids in their products.
Derogations *(e.g. low fat products, local products)*	1. The maximum amount of trans fatty acids in food products where the total fat content is less than 3%, shall not exceed 10 g per 100 g of total fat content. 2. The maximum amount of trans fat acids in food products where the total fat content is between 3% and 20%, must not exceed 4 g per 100 g of total fat content.
Share of SMEs involved *(in case of voluntary measures)*	Not applicable.

Length and characteristics of transition period	Transition period until 1 June 2018 for the distribution of products exceeding the maximally allowed quantities of trans fat acids as set out in this regulation. The two year transition period was introduced to limit the negative financial impact of the regulation on food production companies, giving producers enough time to use the existing product packaging and sell the products already produced, as well as change product recipes and production technologies, and create new product packaging to align with the new regulation.
Arrangements for measure enforcement and compliance monitoring	The Food and Veterinary Service (Pārtikas un Veterinārais dienests) is tasked with conducting 1000 additional food controls and 100 laboratory tests of food samples annually, starting from 1 June 2018, when the transition period of the regulation will end. If violations of this regulation are found, the service can issue a written warning, as well as halt or limit the operations of the food production company (including the operations of specific units or plants).
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	Not applicable.
Tests used to assess TFA content	TFA content is analysed using the gas chromatography method in the Institute of Food Safety, Animal Health and Environment (BIOR). The cost of analysing one product is 52.25 EUR (excluding VAT). According to the estimates of the Ministry of Health, each of the 6536 public catering companies will have to test approximately 5 products annually as a self-controlling measure, resulting in the overall financial burden of 1.7 million EUR. In addition, if it is assumed that each of the 1264 food production companies purchase fats with unidentified amount of TFA content, these companies will also have to send these ingredients for tests at BIOR. According to the estimates of the Ministry of Health, the costs of these tests could amount to 198,000 EUR, assuming that each company orders three tests.
Steps taken to raise consumer awareness	Awareness raising was conducted as part of broader educational campaigns, cooperating with municipalities and schools. 'Heart Health' 2014-2015 campaign run by the Ministry of Health included several health promotion activities and public health campaigns to draw attention to the main cardiovascular disease risk factors including TFA. Dietary guidelines developed by the Ministry of Health include recommendations to not use food products which contain partially hydrogenated vegetable oils. Such guidelines have been published for different age groups – children from the age of 2 to 18, adults, as well as people over the age of 60. The Ministry of Health has also published on its website a 1-page fact sheet on TFAs. In 2016 the Centre for Disease

	Prevention and Control published an infographic on fats in nutrition, including information on TFAs and products that most frequently contain TFAs. [260]
Guidance provided to affected businesses	Representatives of food production businesses, including the Latvian Federation of Food Companies, were involved in the legislative process drafting the adopted legislation. In 2014 the Centre for Disease Prevention and Control, in cooperation with the World Health Organisation's representation in Latvia, organized a 2-day seminar on how to decrease salt and TFA content in food, including best practices from Latvia and other European countries on technologies used. The seminar was also attended by representatives of food production and public catering businesses.[261]
Effectiveness of the measure	Effectiveness of the measure cannot be assessed prior to the end of the transition period (1 June 2018).
Describe (if any) other measures that are currently being considered	Since June 2012 the Cabinet of Ministers Regulation No 172, regarding Nutritional Norms for Students of Educational Institutions, Clients of Social Care and Social Rehabilitation Institutions and Patients of Medical Treatment Institutions, prohibits the use of products containing partially hydrogenated vegetable fats (like sugar confectionery, pastries and margarine) in these institutions. The purpose of this Regulation is to ensure the use of healthy and balanced nutrition in pre-schools, general and VET schools, as well as in long-term social care and social rehabilitation institutions, and health care institutions. The main motivation for excluding confectionery containing partially hydrogenated vegetable fats from the meals provided in these institutions was to limit the consumption of foods that are not necessary for the daily consumption requirements of children, patients and social care institution clients (for example food products that contain TFA).
TFAs in foods and diets	
TFAs content in food *(by product, if available please distinguish by TFA*	A study conducted in 2013 by the Institute of Food Safety, Animal Health and Environment (BIOR) on 102 food products from seven food product groups found that the content of TFA was not detected in 37% of analysed food products (the

[260] Links to publicity campaigns online:

http://www.vm.gov.lv/images/userfiles/phoebe/aktualitates_aktualitates_augsas_virsdala_ba89d22083b17edac22575a6002bb060/trans_tauki.pdf

http://www.vm.gov.lv/lv/tava_veseliba/veseligs_uzturs/
https://www.spkc.gov.lv/upload/Infografikas/Informativi%20materiali/infografika_tauki.pdf

[261]

http://www.vm.gov.lv/lv/ministrija/seminars_par_sals_un_transtaukskabju_daudzuma_samazinasana_p/

source – iTFA and rTFA, and PHO)	content of TFA was < 0.1%). At the same time in 22 out of 102 products the content of TFA exceeded 2%. Butter and sour cream products were characterised by the highest risk for TFA content – average TFA content was 6.3% (from 0.2% to 12.3% in sour cream products, and from 3.3% to 9.1% for butter products). Three cheese and cottage cheese/curd products also included considerable TFA content – 5.6%, 6.2% and 6.4% respectively. At the same time almost two-thirds of samples of this product group had a TFA content of 0.7-1%, with the average indicator for the product group at 1.8%. Seven ice cream samples included TFA content from 0.1 to 2%. Out of the 19 tested white bread samples only three contained TFA in the amount of 0.6%, 1.3% and 1.7% of fat content. Out of the 29 tested pastry products (biscuits, waffles), 13 products contained TFA in the amount of less than 0.1% of fat content. The average amount of TFA content for this product group was 0.6%, while 3 products contained 2.4%, 2.7% and 2.9% TFA. 14 pastry products (pastries, cakes) on average included 1% TFA, while the highest values among the samples were 2.2%, 2.9% and 3.3%. TFA concentration was very low in foreign-origin margarine sold in Latvian market (< 0.1%, 0.2% and 0.4%).[262]
Variation in TFAs content in food after implementation of measure	Effects of the adopted legislation are likely to be visible after 1 June 2018 when the transition period ends.
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	Food production companies paid special attention to TFA content in products in 2011, when test results published by Danish professor, Steen Stender (Department of Clinical Biochemistry, Copenhagen County Hospital in Gentofte, University of Copenhagen) revealed high amount of TFA content in some confectionary products (waffles) made by *Laima* and *Staburadze* owned by NP Foods. Following a public uproar, the two food production companies replaced ingredients of these products with vegetable fats, claiming that their products from thereon (September 2011) would have 0% of TFA content. No other major FBOs have made pledges to reduce TFA content in the future beyond what legislation requires.[263]
TFAs intake *(if available please*	No specific data are available on TFAs intake. The only data available are on the consumption of different food products

262 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf
https://www.zm.gov.lv/public/ck/files/ZM/TP%20petijumi/Transtauksk%C4%81bes_p%C4%93t%C4%ABjums.pdf

263 http://www.db.lv/razosana/partika/laima-sak-razot-vafeles-bez-transtaukskabem-danu-profesors-atklaj-jaunus-produktus-grekazus-24406

report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)	among adults and pupils, including those which may contain TFAs like pastry products, sweets and potato chips. According to a 2014 study on the habits affecting health of adults (aged 15-74), pastry products (pastries, biscuits/ cookies, cakes) were frequently consumed (3 and more days per week) by 24.7% men and 24.9% women.[264] The data for 2016 show a slight decrease – 22.5% of men and 22.3% of women consumed pastries, cookies or cakes 3 and more days per week.[265] According to a 2007 study, almost 40% of pupils in the age of 11, 13 and 15 ate sweets at least once a day. Girls consumed sweets more frequently than boys (on average by 11% more frequently). The highest proportion of pupils consuming sweets were in the age of 13. Potato chips were consumed at least once a week by 59% of surveyed pupils, while 7.7% ate potato chips every day at least once a day.[266] According to a 2014 study, almost every third pupil consumed sweets every day (22% boys and 33% girls), with the highest proportion of pupils consuming sweets in the age of 15 (24% of boys and 36% of girls).[267]
Variation in TFAs intake after implementation of measure	Effects of the adopted legislation will be visible after 1 June 2018 when the transition period ends.
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	There are no studies available on this issue, according to the Ministry of Health.

264 https://www.spkc.gov.lv/upload/Petijumi%20un%20zinojumi/FINBALT/finbalt_2014_labotais.pdf

265 https://www.spkc.gov.lv/upload/Petijumi%20un%20zinojumi/FINBALT/finbalt_2016_2.pdf

266 https://www.spkc.gov.lv/upload/Petijumi%20un%20zinojumi/HBSC/uztura_paradumi_kermena_masa_berniem_lv_2007.pdf

267 https://www.spkc.gov.lv/upload/Petijumi%20un%20zinojumi/HBSC/hbsc_2013_2014_aptaujas_rez.pdf

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	The Ministry of Agriculture does not have a precise figure on the number of companies that will need to reformulate their products, as data on companies making products exceeding the TFAs content limited in the regulation are not available. The number of businesses likely to be affected (7800 food companies, including 6536 public catering companies) include all companies, disregarding whether they make products containing TFAs exceeding the limits set in the regulation, or not.
Evidence of FBO sector facing specific challenges	The study on TFAs content reveals that food companies producing butter and sour cream products as well as cheese and cottage cheese/curd products could face most significant challenges, as the study showed that these product groups contained highest TFAs content (specific products with 5.6% - 12.3% TFA content in fat content).
For which oils/fats was there a reduction in use and with what were they replaced?	It is predicted that hydrogenated vegetable oils will be replaced by vegetable oils and butter. For example, the dairy producer *Rīgas Piensaimnieks* will reformulate 4 out of 150 products to align with the requirements of the Regulation. In all of these products hydrogenated vegetable oils are replaced with butter (one reformulated product has been in the market since May 2017, the other will enter the market in August 2017, while the last 2 reformulated products will be produced as of December 2017).
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	This information cannot be obtained until the end of the transition period (1 June 2018), when businesses will have had time to adjust their production processes.
Cost of understanding/learning the measure for FBOs	This information cannot be obtained until the end of the transition period (1 June 2018), when businesses will have had time to adjust their production processes.

Consumer prices and choice

Evidence of changes in the price of reformulated products	Prior to introducing the Regulation the responsible ministries – Ministry of Health and Ministry of Agriculture – did not expect substantial changes in product prices as a result of having to replace TFAs with alternatives such as vegetable oils. However, if the TFA is replaced with butter, the price of the product may increase. Specific data will not be available until the end of transition period (1 June 2018), when businesses have time to reformulate their products.

Evidence of price differences between products with iTFAs and alternatives	No information found.
Evidence of changes in the range, quality or taste of products available	No information found.
Evidence of changes in TFAs consumption	As the transition period of the adopted legislation will only end on 1 June 2018, it is impossible to assess the effect of this measure with regard to changes in TFAs consumption.
Effect on consumer information and awareness	As the transition period of the adopted legislation will only end on 1 June 2018, it is impossible to assess the effect of this measure on consumer information and awareness.

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	According to Eurostat, 16,372 deaths were caused by diseases of the circulatory system, equivalent to 57% of all deaths in Latvia in 2013, which is considerably higher than the EU-28 average of 37.5% for the same year. The effect of the adopted legislation on this indicator can be assessed after the end of the transition period (1 June 2018).
Evidence of change in saturated fats intake	No specific data are available on saturated fats intake.

Competition, innovation and trade

Effect on competition in the domestic market	No information found.
Changes in trade of affected goods	No information found.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	No information found.

Administrative burdens

Number of businesses required to provide information	The chosen measure does not include a requirement for businesses to provide information unless the responsible institution (Food and Veterinary Service) requests this information in the framework of an inspection on site. In this case the company is required to provide information on the

	specification and the recipe of the product.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	TFA content is analysed by using gas chromatography method in the Institute of Food Safety, Animal Health and Environment (BIOR). The cost of analysing one product is 52.25 EUR (excluding VAT). According to the estimates of the Ministry of Health, each of the 6,536 public catering companies will have to test approximately 5 products annually as a self-controlling measure, resulting in a financial burden of 1.7 million EUR. In addition, if one assumes that each of the 1,264 food production companies purchase fats with unidentified amount of TFA content, these companies will also have to send these ingredients for tests at "BIOR". According to the estimates of the Ministry of Health, the costs of these tests could amount to 198,000 EUR (assuming that each of the companies makes 3 tests). The Ministry of Health also estimated that the cost of reformulation of products could be 60,000 EUR (assuming that each of the 1264 food production companies has to reformulate 3 products spending 8 hours on each product).
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	Food and Veterinary Service (Pārtikas un Veterinārais dienests) will need 86,000 EUR to conduct additional controls and order needed laboratory tests in 2018. As of 2019 the cost of this function is estimated at 63,000 EUR annually.

Environmental impacts

Evidence of any environmental costs or benefits	No information found.
Evidence of increase in demand for palm oil / other ingredients	No information found.
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found.

Additional references

https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

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http://www.db.lv/razosana/partika/laima-sak-razot-vafeles-bez-transtaukskabem-danu-profesors-atklaj-jaunus-produktus-grekazus-24406

Netherlands

Policy status

	Existing	Proposed/ considered
Legislation		
Voluntary measures	X (completed/ended)	
Labelling		
Consumer information	X	

Description of existing measure(s)

Type of measure	Voluntary measure
Description of measure *(if legislation paste exact text of legislation)*	**Task Force Verantwoorde Vetzuursamenstelling (Task Force for** **the Improvement of the Fatty Acid Composition).** Members of this voluntary initative include representative organisations of various relevant industries, and the Dutch Ministry for Public Health, Wellbeing and Sport (Volksgezondheid, Welzijn en Sport) as observer. As members, these industries have committed themselves to a continued improvement of the fatty acid composition of the diet. For public health reasons it is desirable that saturated fatty acids and trans fatty acids in the diet are replaced with (cis) unsaturated fatty acids. All affected sectors have committed themselves to a manifesto, which was offered to the Minister of VWS in 2005.[268]
Scope of measure	The measure applied across the various relevant industries (for a specific list, see 'FBOs covered'), which together represent 80% of the food industry that uses oils and fats. The goals of the measure were as follows: • The reduction of the amount of trans fatty acids 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 can be achieved; • The reduction of the amount of saturated fat in food in order to make an important contribution to meeting the Dutch Health Council guideline of a maximum of 10 percent of energy intake originating from saturated fat.

[268] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

	• Over the years (from 2003 to 2010) these were to be achieved through the following activities: • Stimulating innovations. • Supplying information to the professional user. • Supplying information to the consumer. • Monitoring the branches involved in the Task Force.[269]
FBOs covered	**Algemene Kokswaren en Snackproducenten Vereniging (AKSV**: **Association of Producers of Cooked product and Meat Snacks**): The AKSV is the branch organization of Dutch industrial companies that produce convenience foods (snacks, cool meals, salads, soups, sandwiches and sandwiches, etc.). Through mailings, members and committee meetings and annual monitoring, companies are encouraged to reduce trans fatty acids and saturated fatty acids in their products. AKSV has been involved and active since the start of the Task Force (2003). **Koninklijk Horeca Nederland (KHN: Royal Hospitality Netherlands**): KHN is the branch organization for the catering industry in the Netherlands, with around 20,500 companies being affiliated. KHN has been involved since the start of the Task Force (2003). Together with the Information Office on Margarine, Vetten en Oliën (MVO: Margarine, Fats and Oils), it is running the Responsible Frying campaign, with the aim of stimulating the use of liquid frying fat in the catering industry (2004). **Nederlandse Brood- en Banketbakkers Ondernemers Vereniging (NBOV: Dutch Association for the Craft Bakery Industry**): The NBOV represents 1400 artisan bakeries (bread and confectionery). In January 2008, the NBOV officially joined the Task Force, and in the first year it focused on communicating fats towards its members and performing a baseline measurement. **Productschap Margarine Vetten en Oliën (MVO: Margerine, Fats and Oil Industry Association)**: MVO represents the entire chain of vegetable oils and fats, including the producers of consumer margarines, frying fats, bakery margarines and fats and oils for use in foodstuffs. It is the initiator of the Task Force and carries out the secretariat. In addition, MVO together with KHN, promotes the Responsible Frying campaign to stimulate the use of liquid frying fat in the catering industry, and provides information on fat (“Vette Feiten”: "Fat Facts") aimed at the food industry (www.vettefeiten.nl).

[269] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

	Information about fats towards consumers is carried out by the MVO and funded by MVO and BNMF. **Bond van Nederlandse Margarine Fabrikanten (BNMF: Dutch Margarine Producers Association):** BNMF represents the manufacturers of margarine, halvarine and baking products. Information about fats towards consumers is carried out by the MVO and funded by MVO and BNMF. **Vereniging voor de Aardappelverwerkende Industrie (VAVI: Dutch Association for the Potato Processing Industry**): VAVI is the branch organization for Dutch companies of pre-baked, chilled and deep-frozen potato products. The VAVI has been a member of the Task Force since 2003. In addition to activities such as conducting research and communicating recommendations for using better frying fats or less fat for home preparation, among other things, the VAVI has sponsored the Responsible Frying campaign for years. In 2004, 85% of all pre-baked, chilled and deep-frozen potato products came from VAVI companies. **Vereniging voor de Bakkerij- en Zoetwarenindustrie (VBZ: Dutch Association for the Bakery and Sweets Industry) / Nederlandse Vereniging voor de Bakkerij (NVBL Dutch Association for the Bakery Industry):** These two associations together represent the industrial bakery sector. Bakery and confectionery products include all the products belonging to the banquet / biscuit, chocolate, sugar and related products, such as savoury dry snacks, chips, peanuts and nuts, etc. The NVB represents the Dutch medium and large bakery companies. VBZ and NVB have been involved and active since the start of the Task Force (2003). The main activities of VBZ / NVB have been to encourage its members to improve fatty acid composition. They actively communicate with their members and provide practical tools such as the "Healthy Fats in the Bakery" technology research. [270]
Derogations *(e.g. low fat products, local products)*	The self-regulation does not apply to ruminant trans fat. [271]

[270] http://www.vetzuursamenstelling.nl/Partijen/index.html

[271] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

Share of SMEs involved *(in case of voluntary measures)*	Exact share is not available, however the NBOV, which specifically provides representation for SMEs, has around 1400 members. [272]
Length and characteristics of transition period	The task force ran from 2003 to 2010. [273]
Arrangements for measure enforcement and compliance monitoring	The branches involved in the Task Force reported annually on the achieved results. [274]
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	All partners provided information on results. [275] For trans fats the goal was to reduce the amount of trans fatty acids 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 can be achieved. Each partner also had their own goals; AKSV: AKSV aimed for a transfatty acid proportion of less than 2% in 2010. IN 2009 the amount of transfat acids as a proportion of total fat used (i.e. not the proportion of fat in the end product but rather the fat used in the process) was 0.7% opposed to 9.7% in 2002: a reduction of 92.8%. KHN: KHN aimed for an increase in the use of liquid frying fat from the baseline of 30% in 2005 to 75% in 2010 in the hospitality sector. It provided measurements for 2009, in which the proportion was 78%. NBOV: NBOV aim was to limit the amount of trans fat to up to 2% of the total fat content. In addition the reduction in trans fat should not increase the sum of saturated fat and trans fat. The measurement of this included a very small sample of max 10 bakeries. The

[272] http://www.vetzuursamenstelling.nl/Partijen/index.html

[273] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

[274] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

[275] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

	results were subsequently inconclusive and not representative, but did show a wide variety across different products and bakeries. NEBAFA: NEBAFA set a similar aim: to limit the amount of trans fat to up to 2% of the total fat content. In addition the reduction in trans fat should not increase the sum of saturated fat and trans fat. The proportion of trans fat as a share of all fat was 2.8% in 2003 and dropped to 1.7% in 2009. MVO and BNMF: MVO and BNMF set less specific goals regarding trans fat (i.e. to reduce the amount of trans fat), and focused more specifically at reducing the use of solid frying fats. It found from measurements that the amount of trans fat as a proportion of all fat was reduced from 3.4% in 2003, to 1.0% in 2008 in bakery margarines. Trans fat for industrial use and for use on bread was already below 1% and has not been measured. Trans fat for baking products was already below 1% and was measured again in 2009 which showed this was still the case. Measurements also showed a reduction in the use of solid frying fats in favour of liquid frying fats, and a reduction of the proportion of trans fats in solid frying fat from 10% in 2003 to 2% in 2009. VAVI: VAVI's goal was to further reduce the amount of trans fat at product level. This dropped from 1.5% in 2003 to 0.8% in 2009. As a lot of the fat content comes from the consumers' choice of frying fat. An estimate of this has also been added and shows a reduction from 6.4% in 2003 to 1.6% in 2009. VBZ and NVB: No explicit goal, but members were monitored on a yearly basis. It shows a reduction of the amount of trans fat as a proportion of the total fat from 20.1% in 2003 to 1% in 2009. There are concerns about the response rate.
Tests used to assess TFA content	Each partner was responsible for measuring its own progress.[276] AKSV: Sent out a survey to its members and achieved a response rate of 88.9%. Full methodology was not available but respondents were asked (amongst others?) what type of fat they used and in what volume for either frying (e.g. soy oil; liquid frying oil; lard; palm

[276] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

oil; rapeseed oil; sunflower oil) or as ingredient (e.g. rapeseed oil; palm oil; soy oil; margarine; sunflower oil; ruminant fats; baker's fat; olive oil; others).

KHN:

N/A (TFA content not available)

NBOV:

Cast studies/site visits were undertaken to collect data on the use of transfat in 6 particular products but the sample of this was too small to be able to make conclusions.

NEBAFA:

TFA content provided, but there is no information on how test was conducted.

MVO and BNMF:

Wageningen University did the testing for the MVO, based on a sample of 14 margarines from craft bakeries. The report (in Dutch), which includes methods, can be found here: http://edepot.wur.nl/161230 It refers to methods used in previous research available here: http://edepot.wur.nl/45471 Of particular interest is Annex 2 ('Bijlage 2') on page 52 (in English).[277] It sets out the methodology used. Abstract is as follows:

Trans fatty acids in foods are usually analysed by gas-liquid chromatography (GLC) of fatty acid methyl esters (FAME). However, this method may produce erroneously low values because of insufficient separation between cis and trans isomers. Separation can be optimized by preceding silver-ion thin-layer chromatography (Ag-TLC), but this is laborious. We have developed an efficient method for the separation of 18-carbon trans fatty acid isomers by combining GLC of FAME with GLC of fatty acid 4,4-dimethyloxazoline (DMOX) derivatives. We validated this method against conventional GLC of FAME, with and without preceding Ag-TLC. Fatty acid isomers were identified by comparison with standards, based on retention times and mass spectrometry. Analysis of DMOX derivatives allowed the 13t, 14t, and 15t isomers to be separated from the cis isomers. The combination of the GLC analyses of FAME and DMOX derivatives gave results comparable with those obtained by GLC of FAME after preceding Ag-TLC, while saving about 100 h of manpower per 25

[277] Or download here: https://www.researchgate.net/publication/257730530_Analysis_of_C181_cis_and_trans_fatty_acid_isomers_by_the_combination_of_gas-liquid_chromatography_of_44-dimethyloxazoline_derivatives_and_methyl_esters

	samples. It allowed the identification and quantitation of 11 trans and 8 cis isomers and resulted in 25% higher values for total C18:1trans, compared with the analysis of FAME alone. The combination of DMOX and FAME analyses, as applied to the analysis of 14 foods that contained ruminant fat and partially hydrogenated vegetable and fish oils, indicated that the most common isomers were 11t in ruminant fats, 9t in partially hydrogenated fish fats, and either 9t or 10t in partially hydrogenated vegetable fats. The combination of GLC analyses of FAME and DMOX derivatives of fatty acids improves the quantitation of 18-carbon fatty acid isomers and may replace the laborious and time-consuming Ag-TLC. *Analysis of C18:1 cis and trans fatty acid isomers by the combination of gas-liquid chromatography of 4,4-dimethyloxazoline derivatives and methyl esters (PDF Download Available). Available from: https://www.researchgate.net/publication/257730530_Analysis_of_C181_cis_and_trans_fatty_acid_isomers_by_the_combination_of_gas-liquid_chromatography_of_44-dimethyloxazoline_derivatives_and_methyl_esters [accessed Jun 16, 2017].* VAVI: No information is available on methods of VAVI's measurement of trans fat in its member's end products. The estimated additional trans fat consumed as a result of the consumers' choice of frying fats was based on data from the MWO. VBZ and NVB: Annual survey of members (no further information). Concerns about low response rate.
Steps taken to raise consumer awareness	AKSV: None KHN: In cooperation with the Centre for Nutrition the KHN launches the Snackposter, which enables consumers to make informed choices about their food. The poster shows nutritional values of snacks and the number of minutes of cycling required to burn calories NBOV: None NEBAFA: None MVO and BNMF: In addition to product information on products of margarine manufacturers, the MVO Information Centre provides information

	on how margarine, halvarine and baking products fit in healthy, contemporary and tasty food. Through campaigns, the Information Office provides information on fats and health and about products with a favourable fatty acid composition. There are various specific examples of campaigns available, focusing on the use of margarine as healthier alternative and the knowledge platform 'Fat Facts' ('Vette Feiten'). [278] [279] VAVI: Various: information on packaging e.g. type of frying oil to use; support of the Responsible Frying campaign. VBZ and NVB: None
Guidance provided to affected businesses	AKSV: Shared information from the Task Force with its members and also fed back the monitoring results. In its internal policies it has also encouraged its members to use fats with lower trans fat proportions. KHN: KHN has supported businesses in hospitality through making available various information and support on the use of healthy product. The most important one with regards to trans fats is the 'Responsible Frying' campaign during with the KHN and MVO actively engaged with hospitality to promote the use of liquid over solid frying fat. NBOV: Dedicated articles in members' magazine. NEBAFA: Communication in professional magazine about trans fat, NEBAFA has also had direct influence on product development at the business level (not clear how). MVO and BNMF: The campaign Responsible Frying and a Code of Practice for frying fats in the hospitality sector focused on the reduction of use of solid fats (higher in trans fats) and increase in liquid fats (lower in trans fats). VAVI: Coordination of change in use of used ingredients and development of new products. VBZ and NVB: VBZ and NVB engaged TNO (Knowledge and Innovation

[278] http://mvo.nl/vettefeiten

[279] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

	organisation) to run the research project 'Healthy fats in the bakery', aimed at supporting members with reducing the proportion of saturated fats. In addition this topic was often discussed at meetings, newsletters, website, etc. Members were also encouraged to participate in a range of other initiatives aimed at promoting healthy food.[280]
Effectiveness of the measure	Across almost all partners the measures taken were effective against their targets (for concrete numbers refer back to compliance in which details are provided for pre and post project measurements).[281]
Describe (if any) other measures that are currently being considered	The Task Force has officially come to an end. The initiator, MVO, together with BNMF (now IMACE-NL?) are currently looking at how they can further reduce the use of trans fat in a work programme ending in 2020 called 'Herformulering productsamenstelling' (Reformulating product composition). The goal for this project is that as a minimum the average proportion of transfat would stay the same. To achieve this, the action plan for this project focuses on monitoring levels in the sector and working together with other players to gather this information; a continuation of the campaign 'Responsible Frying'; provide information to consumers, intermediaries and businesses and; work together with health professionals.[282]

TFAs in foods and diets

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	See below. This has been extracted from NEVO, an online database, and contains information on trans fat content in many products. The amount of trans fat is presented as a % of all fat in the product and is available broken down by their lipid number: [283]

Voedingsstof	**EuroFIR component code**	**Code NEVO voedingsstof**
Transvetzuren total	**FATRN**	**3136**
C10:1 trans totaal	F10:1TRS	3027
C12:1 trans totaal	F12:1TRS	3055
C14:1 trans totaal	F14:1TRS	3022
C16:1 trans totaal	F16:1TRS	3026

[280] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

[281] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

[282] http://www.mvo.nl/media/gezondheid/20141020_actieplan_mvo_imace_nl___wijzigingen_werkgroep.pdf

[283] http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Tabellen_grafieken/Leefstijl_Voeding/NEVO/Samenstelling_vetzuurclusters_NEVO_online_2016/Download/Samenstelling_vetzuurclusters_NEVO_online_2016.org

C18:1 trans totaal	F18:1TRS	3031
C18:2 n-6 trans	F18:2TTN6	3065
C18:3 n-3 trans	F18:3TTTN3	3131
C20:1 trans totaal	F20:1TRS	3058
C20:2 n-6 trans	F20:2TT	3133
C22:1 trans totaal	F22:1TRS	3059
C24:1 trans totaal	F24:1TRS	3060
Enkelvoudig onverzadigde vetzuren trans rest	FAMSTXR	3116

More recent data are available from NEVO. [284]

Variation in TFAs content in food after implementation of measure[285]

	Reference (2001)		**Most recent (2010)**		**Difference**	
	Avg g /100g	SD	Avg g /100g	SD	g/100g	SD
Mashed potatoes	0.0	0.0	0.0	0.0	-0.0	0.0
Potato products for frying	0.4	0.2	0.1	0.1	-0.3	0.2**
Bread, all types	0.1	0.1	0.0	0.1	-0.0	0.1***
Crackers	0.3	0.3	0.3	0.5	-0.1	0.3
Cake and baked goods	0.7	0.9	0.6	0.8	-0.2	0.5**
Cookies and biscuits	1.4	1.4	0.6	1.0	-0.8	1.1***
(Meat) snacks and salads	1.5	1.4	0.9	1.4	-0.6	0.8**
Fats and margarines	1.1	0.8	0.9	0.5	-0.1	0.4

From: Impact of fatty acid food reformulations on intake of Dutch

[284] http://nevo-online.rivm.nl/Default.aspx

[285] https://www.researchgate.net/profile/Elisabeth_Temme/publication/221800312_Impact_of_fatty_acid_food_reformulations_on_intake_of_Dutch_young_adults/links/0fcfd50ea945d2a3ce000000.pdf

young adults. Elisabeth H.M. TEMME, PhD; Inger L. MILLENAAR, MSc; Gerda VAN DONKERSGOED, MSc; Susanne WESTENBRINK, MSc ; National Institute for Public Health and the Environment (RIVM), the Netherlands

Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*

No information found

TFAs intake

(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)

See below

Intake by socio-economic group is not available in this research, but demographic information is collected and published in the National Food Consumption Survey. For example (from 2003):[286]

	Men		**Women**	
	Avg	**S.E.**	**Avg**	**S.E.**
Age	**P=0.22**		**P=0.002**	
19-24	1.0	0.0	1.0	0.0
25-30	1.0	0.0	1.2	0.0
Family status	**P=0.35**		**P=0.006**	

286 http://www.rivm.nl/dsresource?objectid=f5a9b5c7-a14a-44e1-839b-87cebd52695c&type=org&disposition=inline

Alone	0.9	0.1	1.1	0.1
With partner	1.0	0.0	1.1	0.1
Family with children	1.1	0.1	1.2	0.0
Living with parent(s)	1.0	0.0	1.0	0.0
Education	**P=0.66**		**P=0.99**	
Low	1.0	0.1	1.1	0.0
Middle	1.0	0.0	1.1	0.0
High	1.0	0.0	1.1	0.0
Alcohol use	**P=0.04**		**P=0.16**	
No	1.2	0.1	1.2	0.1
Yes, less than 1 glass p/w	1.1	0.1	1.1	0.0
Yes, 1 glass p/w or more	1.0	0.0	1.0	0.0
Smokes	**P=0.09**		**P=0.51**	
Yes	0.9	0.0	1.1	0.0
No, used to	0.9	0.1	1.0	0.1
No, never	1.1	0.0	1.1	0.0
Activity score	**P=0.28**		**P=0.87**	
Low	1.0	0.0	1.1	0.0
Middle	1.0	0.0	1.1	0.0
High	0.9	0.0	1.1	0.0
Supplement use	**P=0.19**		**P=0.54**	
No	1.0	0.0	1.1	0.0
Yes	0.9	0.1	1.1	0.0

Variation in TFAs intake after implementation of measure

From: Impact of fatty acid food reformulations on

intake of Dutch young adults

Elisabeth H.M. TEMME, PhD; Inger L. MILLENAAR, MSc; Gerda VAN DONKERSGOED, MSc;

Susanne WESTENBRINK, MSc

National Institute for Public Health and the Environment (RIVM), the Netherlands

	Reference scenario	Reformulation scenario

	P50 g/day	95% CI g/day	E% P50	P50 g/day	95% CI g/day	E% P50
Total fat	85	(82.8-87.2)	34.8	84.5	(81.5-87.0)	34.6
SFA	31.4	(30.6-32.6)	12.9	31.3	(30.4-32.1)	12.8
TFA	2.3	(2.2-2.5)	1	1.9	(1.8-2.0)	0.8
MUFA	27.5	(26.6-28.2)	11.3	28.3	(27.5-29.4)	11.6
PUFA	17.2	(16.5-18.0)	7.1	16.1	(15.5-16.7)	6.6

SFA: saturated fatty acids,

TFA: trans fatty acids,

MUFA: monounsaturated fatty acids,

PUFA: polyunsaturated fatty acids.

Newer data are available. Data above are based on the RIVM (Rijksinstituut voor Volksgezondheid en Milieu: State Institute for Public Health and Environment) National Food Consumption Survey 2003. The latest available version is for 2012-2016, although more detailed publications based on this data are not yet available.

Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	There is data on consumers' knowledge and perceived healthfulness of PHVO and FHVO but it is limited to a single population group (women aged 25-65 y, responsible for household shopping). The results showed that consumers have low awareness of FHVO and found them less appealing and far less required in margarine than vegetable oils and fats. In 2003 a study by the National Nutrition Centre (n=500) revealed that 93% had never heard of TFA. Could not find a source on this other than the EC consultation.[287]

Measure impacts

Business responses and costs

Number of business that reformulated their products	No information found

[287] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

(if possible differentiate by large and small companies)	
Evidence of FBO sector facing specific challenges	• Foods serving food based on ruminant meat (out of scope?) • Many artisan bakeries fail to use healthier alternatives to dairy butter which has high contents of naturally occurring trans fat (out of scope?) • For bread and cakes etc producers reformulation of products in practice has proven to be difficult because the consumer has a certain expectation of the product. Many banquet and cake products are traditional products. In practice it turns out that a change in fatty acid composition has consequences for the sensory properties of the product which go against the expectation of the consumer. • Bread, cake etc producers worries about not being able to convey the improvement of lower amounts of trans fats on product labelling (as determined by EC/1924/2006), and therefore being unable to make a return on the investment. [288] From the bakery industry, a combination of regulation pressure (notably the early adoption of the Danish legislation on trans-fatty acids implemented since January 2004) and demands from large customers (supermarkets and producers of bakery products within the Netherlands and in EU) urged a switch in the food industry from partially hydrogenated oil with high levels of iTFA to fully hydrogenated oil with a iTFA content below 2 per cent. Fully hydrogenated oil, although having a iTFA content of less than / equal to 1 percent, 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 meant that bakery suppliers needed to come up with a solution and began to adjust their products so that they would keep their soft texture while containing fully hydrogenated oil. In the Netherlands, this is generally palm oil and is mainly supplied by ADM and Cargill. According to an interview with one bakery supplier, they began this process in 2003 and ended in 2007. This 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).

[288] http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

For which oils/fats was there a reduction in use and with what were they replaced?	Solid frying fat replaced with liquid frying fat For the bakery sector, there was a switch to fully hydrogenised oil, and research was devoted to securing the correct consistency of products at room temperature. For this purpose, two strategies were applied: (a) Reformulation of the product recipes containing fully hydrogenized oil, notably by adding and altering emulsifiers (Monoglycerides; and Calcium Stearoyl Lactylates, CSL); (b) Adjusting the processing of the products (bread improvers, bread and pastry mixes) by heating them to 80 – 90 degrees Celsius and then applying a rapid cooling process (minus 20 degrees Celsius) back to room temperature. This process forces the molecules to form a weaker crystal structure so that the product cannot regain its previous solid texture.
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	Evidence from bakery supplier indicated about 2 to 3 percent price increase of bread improvers, bread and pastry mixes. About 1 to 1.5 man-years (Academic or Higher Vocational Education level), costing rou 120-150k Euros.
Cost of understanding/ learning the measure for FBOs	No information found

Consumer prices and choice

Evidence of changes in the price of reformulated products	According to a bakery supplier, the impact for the baked goods sector was negligible, as bread improvers, bread and pastry mixes represent 2 to 3 percent of the value of the end product (e.g. a bread).
Evidence of price differences between products with	Research from the Vrije Universiteit Amsterdam found a significant negative relationship between the cost of food and its energy density/ saturated fat/ trans fat/ total fat/ carbohydrates. In addition, there was a significant positive relationship between the costs and the percentage of beneficial products in the diet.

iTFAs and alternatives[289]	
Evidence of changes in the range, quality or taste of products available	Not located, but the goal of the Task Force was to lower trans and saturated fats without changing the quality of the product.
Evidence of changes in TFAs consumption	As previously mentioned: From: Impact of fatty acid food reformulations on intake of Dutch young adults Elisabeth H.M. TEMME, PhD; Inger L. MILLENAAR, MSc; Gerda VAN DONKERSGOED, MSc; Susanne WESTENBRINK, MSc National Institute for Public Health and the Environment (RIVM), the Netherlands

	Reference scenario			Reformulation scenario		
	P50 g/day	95% CI g/day	E% P50	P50 g/day	95% CI g/day	E% P50
Total fat	85	(82.8-87.2)	34.8	84.5	(81.5-87.0)	34.6
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TFA	2.3	(2.2-2.5)	1	1.9	(1.8-2.0)	0.8
MUFA	27.5	(26.6-28.2)	11.3	28.3	(27.5-29.4)	11.6
PUFA	17.2	(16.5-18.0)	7.1	16.1	(15.5-16.7)	6.6

SFA: saturated fatty acids,

TFA: trans fatty acids,

MUFA: monounsaturated fatty acids,

PUFA: polyunsaturated fatty acids.

Data above is based on the RIVM (Rijksinstituut voor Volksgezondheid en Milieu: State Institute for Public Health and Environment) National Food Consumption Survey 2003. The latest

[289] https://research.vu.nl/ws/portalfiles/portal/24510456

	available version is for 2012-2016 though more detailed publications based on this data is not yet available.[290]
Effect on consumer information and awareness[291]	The MVO found that a combination of investment of the industry and consumer awareness had led to an increase in the proportion of liquid margarine and baking and bread products (lower % of trans fat) relative to the fixed variants (higher % of trans fat). The share of liquid margarine and baking and baking products on the Dutch market doubled between 2003 and 2009 from 22% to 44%.

Health effects

Evidence of benefits on consumer health

(if possible differentiate by age and socio-economic group)

The below table details death rates by cardiovascular disease.[292]

	2011	2012	2013	2014
M Total	**18,115**	**18,211**	**18,231**	**17,830**
M Younger than 25	42	32	22	25
M 25-49	648	566	502	477
M 50-64	2,362	2,293	2,202	2,026
M 65 and older	15,057	15,313	15,501	15,299
F Total	**20,335**	**20,412**	**20,531**	**20,257**
F Younger than 25	16	18	20	21
F 25-49	313	291	257	238
F 50-64	1,013	1,040	904	903
F 65 and older	18,989	19,060	19,348	19,094
Total	**38,460**	**38,628**	**38,767**	**38,092**

Microsoft Excel Worksheet

See also

Evidence of change in saturated fats intake	Please see above in the table on 'Evidence of changes in TFAs consumption' the amount of SFA (Saturated fatty acids). It has been an explicit goal of the Task Force to not decrease the % of trans fat at the cost of an increase in saturated fats.

290 https://www.researchgate.net/profile/Elisabeth_Temme/publication/221800312_Impact_of_fatty_acid_food_reformulations_on_intake_of_Dutch_young_adults/links/0fcfd50ea945d2a3ce000000.pdf

291291 http://www.vetzuursamenstelling.nl/download/MVO_Taskforce-eindrapportage-2010.pdf

292 http://ec.europa.eu/eurostat/statistics-explained/index.php/Cardiovascular_diseases_statistics

Competition, innovation and trade

Effect on competition in the domestic market	No information found
Changes in trade of affected goods	No information found
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	Part of the mandate of the task force was to examine the reformulation of products. The end report of the task force mentions an increase in healthier liquid frying alternatives as opposed to solid frying fats. Innovation was found to be particularly difficult in bakeries producing sweets (cakes, cookies). The end report specifically mentions a project with Innovation and knowledge company 'TNO' on 'Gezonde vetzuren in de bakkerij' (Healthy fatty acids in the bakery) but a report is not available. The evidence provided of change in TFA amount in food also points to changes in production processes (but no information on the cost of this).

Administrative burdens

Number of businesses required to provide information	No information found
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	No information found
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data*	No enforcement (voluntary), but the RIVM produces and keeps up to date a database with information nutritional values (including TFAs) called NEVO.[293] However, NEVO depends on other parties to supply information. NEVO does set certain criteria for information to be included.[294]

[293] http://nevo-online.rivm.nl/Default.aspx

[294] http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Tabellen_grafieken/Leefstijl_Voeding/NEVO/NEVO_online_2016_achtergrondinformatie/Download/NEVO_online_2016_achtergrondinformatie.org

if possible)	

Environmental impacts

Evidence of any environmental costs or benefits	No information found
Evidence of increase in demand for palm oil / other ingredients	The Netherlands is the largest importer of palm oil in the EU.[295] 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 in 2015, and a much larger increase in use of sustainable palm oil as a proportion of the total amount of palm oil.[296]
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found

[295] https://www.cbs.nl/nl-nl/achtergrond/2014/33/achtergrondinformatie-en-handelsstromen--palmolie--

[296] http://www.taskforceduurzamepalmolie.nl./uploads/media/TaskForceDuurzamePalmolie-FinalReport_2015.pdf

Poland

Policy status

	Existing	Proposed/ considered
Legislation		
Voluntary measures	X	
Labelling		
Consumer information	X	

Description of existing measure(s)

Type of measure	Voluntary measure
Description of measure *(if legislation paste exact text of legislation)*	Self-regulation It is motivated by knowledge of the adverse impact of TFA on human health; prevalence of TFA in different types of Polish foods (according to results from monitoring of TFA levels in foodstuffs); producer awareness of TFA; it is about an encouragement to reduce or eliminate the TFA content in food products.[297] There are no legal obligations for producers in Poland – only an industry initiative to reduce levels.[298] The Ministry Of Health Ordinance from 19/06/2012 sets the Food and Nutrition Institute as a reference laboratory for Poland.[299] The National Health Programme introduced in 2017 assigns the Food and Nutrition Institute with the task of monitoring the TFA content in selected products and to create and maintain a database of TFA levels in

[297] COMMISSION STAFF WORKING DOCUMENT, Results of the Commission's consultations on 'trans fatty acids in foodstuffs in Europe. European Commission 2015 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf; p. 31

[298] Bruce W. et al (2012) Reformulation for healthier food: a qualitative assessment of alternative approaches, https://www.researchgate.net/publication/254384473_Reformulation_for_healthier_food_a_qualitative_assessment_of_alternative_approaches

[299] Dziennik Ustaw 28/06/2012 http://isap.sejm.gov.pl/DetailsServlet?id=WDU20120000728

	food products for the years 2017 - 2020.[300]
Scope of measure	All products potentially containing TFA.
FBOs covered	All FBOs
Derogations *(e.g. low fat products, local products)*	N/A
Share of SMEs involved *(in case of voluntary measures)*	100% potentially covered; industry representatives claim that most companies are aware of issues related to TFA and take action;[301] no hard data is available to verify de facto participation.
Length and characteristics of transition period	N/A
Arrangements for measure enforcement and compliance monitoring	Enforcement not applicable as no legal measures are in place. No information was located on existence of any compliance monitoring – it appears that no such system exists at the level of the whole food sector. However, company-specific measures are in place (e.g. Unilever, Nestle, Sante).
Rate of compliance/ participation and favouring conditions *(in case of voluntary*	Industry representatives claim that most companies are aware of issues related to TFA and take action;[302] no hard data is available to verify de facto participation.

[300] Rozporządzenie Rady Ministrów 4/08/2016 w sprawie Narodowego Programu Zdrowia na lata 2016–2020. http://dziennikustaw.gov.pl/DU/2016/1492/1 p. 13. Interview with representative of the National Food and Nutrition Institute on 29/06/2017

[301] Interview with the Polish Federation of Food Industry (PFPZ)

[302] Interview with the Polish Federation of Food Industry (PFPZ)

measures)	
Tests used to assess TFA content	Rancimat test [303] Fatty acids converted into FAMEs their methyl esters according to ISO standard method [ISO 5509:2000a]. Gas chromatography of the FAMEs was performed according to ISO standard [ISO 5508:2000b].[304]
Steps taken to raise consumer awareness	There are several initiatives aiming to raise consumer awareness. Producers campaigns: The Polish Federation of Food Industry (PFPZ) runs a campaign Good fats, (PL: Dobre tłuszcze, http://dobretluszcze.pl/) with a special subsection of the campaign website focusing on TFA: http://dobretluszcze.pl/unikaj-tluszczow-trans In late 2015, ZT Kruszwica (the largest PL producers of vegetable fats) in partnership with the National Food and Nutrition Institute initiated a campaign *Get to know fats* (PL: *Poznaj sie na tłuszczach*) https://poznajsienatluszczach.pl/.. In 2017, this campaign received a golden award in Power of Content Marketing Awards – Szpalty Roku 2017 in the category „Content Marketing – FMCG". Other similar initiatives initiated by individual producers or groups of food producers include the campaigns on margarines,[305] rapeseed oil,[306] and an initiative created together with The Chief Sanitary Inspectorate.[307]

[303] Żbikowska, Anna et al (2006), Quality of Shortenings Available on the Home Market, Rocz Panstw Zakl Hig 57 (2), pp. 133-142.

[304] Żbikowska, Anna and Krzysztof Krygier (2011), Changes in the Fatty Acids Composition, Especially Trans Isomers, and Heat Stability of Selected Frying Fats Available on the Polish Market in the Years 1997 and 2008, Pol. J. Food Nutr. Sci., Vol. 61, No. 1, pp. 45-49 http://journal.pan.olsztyn.pl/?p=rec&s_rok=2011&s_numer=1

[305] http://www.margaryna.com

[306] http://www.pokochajolejrzepakowy.eu

[307] https://www.jemdrugiesniadanie.pl/

	Some producers take part in the international program *Choices* introduced by Unilever. The *Choices* Programme in Poland started in 2008 under the name *I know what I choose*. The *Choices* logo can be placed on foods and drinks indicating that the products meet qualifying criteria with respect to trans fatty acids, saturated fat, salt and sugar content.[308] More than 100 products received the Choices mark in Poland by 2011.[309] In the same year it run an outdoor marketing campaign to promote the programme, participating firms and products. The programme does not appear to be active at present.
Guidance provided to affected businesses	Sector or product-specific guidance only, e.g. by the European Margarine Association (IMACE).
Effectiveness of the measure	Falling average TFA content in some products and intake and increasing number of firms undertaking measures and/or launching campaigns promoting their products as heathy suggests that the measure is to some extent effective. Similarly, information campaigns may have some impact on rising consumer awareness but no comparable data was identified. Anecdotal evidence, such as the opinion of Beata Michalik (director at Z.T. Bielmar, large producer of vegetable fats) in an interview with food industry portal portalspozywczy.pl suggests that consumers are increasingly able to make a distinction between various fats and their health benefits and risks.[310]
Describe (if any) other measures that are currently being considered	Not identified

TFAs in foods and diets

TFAs content in food	A Nationwide Monitoring of the TFA content in alimentary products in Poland has been in place since 2004. Every year food samples from different groups are checked with regard to the TFA content.

[308] Choices International Foundation (2013), Product Criteria for Poland Ver. 2.5, https://www.choicesprogramme.org/public/criteria/choices_product_criteria_v2-5_poland_130201.pdf

[309] Bruce W. et al (2012) Reformulation for healthier food: a qualitative assessment of alternative approaches, https://www.researchgate.net/publication/254384473_Reformulation_for_healthier_food_a_qualitative_assessment_of_alternative_approaches, p. 14

[310] Portalspozywczy.pl (2017), Bielmar: Polacy coraz częściej przekonują się o walorach tłuszczów roślinnych, http://www.portalspozywczy.pl/zboza/wiadomosci/bielmar-polacy-coraz-czesciej-przekonuja-sie-o-walorach-tluszczow-roslinnych,142324.html

(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)	The results from the monitoring are not publicly available and it is not clear what data have been collected so far. The data have not been shared in response to ICF's request related to this project. Publicly available data comes from different studies covering different sets of products and not necessarily applying the same methodology. The identified results are as follows (organised by the year of a study): 2016: (TFA per total weight of product) • Butter: 1.98-3.01% • Mixed spreads (butter and vegetable oils): 0.17-9.32% • Margarines (hard): 0.33-22.15% • Margarines (soft): 0.13-1.11%[311] 2013: • TFA levels of infant and follow up formula: 0.16%wt/wt (Note: it is unclear from the source whether %wt/wt refers to %TFA per total fat or per total weight of product) • Follow-up formulas (for children): 0.15%wt/wt • Gluten-free food products (31): 2.34%wt/wt 2012: • Chocolate confectionary (31): 2.13%wt/wt • Another 2012 study focused on margarines found that the content of TFA was in the range 0-7.9% for tub and 0-10.9% for stick products. 58% of tub margarines contained below 0.7% TFA.[312] (Note: unclear whether g TFA/100 g refers to g total fat or g product) 2010: • Packed cakes sold as ready to eat (32): 1.19%wt/wt • Among a varied group of products (mostly sweets) analysed in 2009/2010: High heterogeneity of TFA content was found in fat extracted from the products (in short-crust biscuits it

[311] Okręglicka, K, H Mojska, A. Jarosz, M. Jarosz (2017). Fatty acid composition including trans isoforms in selected food fats available on Polish market. Żyw. Człow. Metab. 44 (1), 10-13.

[312] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, p 12

	ranged from 0.3 to 24.8 g TFA/100 g fat) The highest mean content of TFA where found in wafers (1.94 g TFA/100 g of the product).[313] 2008: Frying fats (64): 1.1%wt/wt Including: • Frying fats from fast food restaurants (32): 1.56%wt/wt • Frying fats from other restaurants and outlets (32): 0.59%wt/wt • Liquid frying fats (35): 0.39%wt/wt • Hard frying fats (29): 1.97%wt/wt 2006: • Kebab (13): 0.55%wt/wt • French fries (17): 11.31%wt/wt • Pizza (13): 1.42%wt/wt • Hamburgers (15): 0.55%wt/wt Year unknown: In potato chips manufactured in Poland, the analysis showed low levels – usually below 0.1 g/100 g fried base or final product, max 0.2 g/100 g of the final product.[314]
Variation in TFAs content in food after implementation of measure	A reduction of TFA content of the frying fats was noted from 1997 to 2008. It was found that an average TFA content in frying fats sold in Poland in 1997 was 21.4% (ranging from 0.4 to 57.6%), while in 2008 it was significantly lower and reached 12.2% (ranging from 0 to 54%).[315] The sum of TFA and SFA also declined significantly: from 61.1% in 1997 to and 50.4% in 2008. About 33% of fats analysed in 1997 and about 46% in 2008 were characterised by very small TFA contents (below 1%). TFA levels

313 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, p 12

314 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, p. 36

315 Żbikowska, Anna and Krzysztof Krygier (2011), Changes in the Fatty Acids Composition, Especially Trans Isomers, and Heat Stability of Selected Frying Fats Available on the Polish Market in the Years 1997 and 2008, Pol. J. Food Nutr. Sci., Vol. 61, No. 1, pp. 45-49 http://journal.pan.olsztyn.pl/?p=rec&s_rok=2011&s_numer=1

	of infant and follow up formula remained broadly stable during 2006-2013.[316] Some company specific information is available: PHVO have been replaced in breakfast cereals and in all products based on breakfast cereals (cereal bars) produced by Toruń Pacific Sp. z o.o. The company uses non-hydrogenated vegetable oils. The monitoring results show that TFA content is low (below 0.2%). By 2013 all Nestlé products in Poland have been reformulated according to the Company Policy (CO) on TFA levels (e.g. bars, ice-cream, culinary products, wafers). Non-hydrogenated fats and partly hydrogenated fats have been used which had specific fatty acid profile with TFA levels in line with the CO requirements.
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	No information found.
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	In 2009/2010 relatively low level of average intake of TFA in Poland was reported (approximately 1 E%).[317] Main sources of TFA (rTFA/iTFA): • butter consumption, which contributed 0.359g rTFA/person/day. • products of animal origin (rTFA) were estimated to provide 0.496 g TFA/person/day. Significantly higher consumption of TFA was found in the case of: • Products containing fats of industrial origin: 1.5 g iTFA/person/day) • Margarines and other vegetable fats: 0.988 g iTFA/person/day

316 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, p. 11

317 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, p. 19-20

	• Potato products (N/A) An estimate concerning 2010: TFA consumption (E%) males ≤ 20 years old 1.2 (1.0-1.3) and females 1.2 (1.0-1.4).[318] For the purpose of the model constructed in Martin-Saborido et al. 2016 study it was estimated that the products of natural origin (rTFA) provided 0.496 g/person of TFA per day, and those of industrial origin about 1.5 g (iTFA).[319]
Variation in TFAs intake after implementation of measure	The daily intake of TFA decreased from about 14g per person/day in 1995 to about 2 g per person/day in 2010. Most of the reduction occurred between 1995 and 1999.[320]
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	Of 600 Polish people (>18 y) interviewed as part of a five country survey in 2005, 65% did not know what TFA were and below 50% mentioned that food labelling should include information on TFA (survey conducted on behalf of the European Consumer Organisation – BEUC). From a multi-country student survey carried out in 2012, "most of the students had heard the term 'trans fats' before and were aware of their negative influence on human health. Some of the students could not indicate all of the products constituting a potential source of TFA (around 30%). Polish students were not aware of natural sources of TFA (less than 10%). Polish students from studies not related to food and nutrition sciences had less knowledge in the topic of TFA than respondents in the USA and Canada." At the Warsaw University of Life Sciences (SGGW) more than two

[318] Micha R., Khatibzadeh S., Shi P., Fahimi S., et al., Global, regional, and national consumption levels of dietary fats and oils in 1990 and 2010: A systematic analysis including 266 country-specific nutrition surveys. BMJ 2014, 348, g2272. [PubMed]

[319] Martin-Saborido 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, p. 1218-1226 no. 5 vol. 104 and Online Supplemental Material.

[320] https://www.palmoilandfood.eu/sites/default/files/Anna%20%C5%BBbikowska%20-%20TFA%20in%20Europe%20and%20Poland%20in%20particular.pdf citing http://dx.doi.org/10.1080/07315724.2014.942472

	thirds of the students answered that TFAs have an adverse effect on human health. Most of the Polish students correctly indicated as the main source of TFAs 3 groups of products: shortening, hard margarines and pastry products. The other correct answers related to natural sources of trans fatty acids (milk fat and dairy products) were selected much more often (30% more) by the students from Wageningen University than from SGGW.[321] Information campaigns may have some impact on rising consumer awareness but no comparable data was identified. Anecdotal evidence, such as the opinion of Beata Michalik (director at Z.T. Bielmar, large producer of vegetable fats) in an interview with food industry portal portalspozywczy.pl suggests that consumers are increasingly able to make a distinction between various fats and their health benefits and risks.[322] The Polish Federation of Food Industry (PFPZ) indicates that rules stemming from the 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 are not conducive to helping consumer make informed decisions on TFA content in food, This is because the labelling rules can be confusing and consumers do not understand the difference between partially and fully hydrogenated oils.[323] The Food and Nutrition Institute sets the "Nutrition standards for Polish Population" where it is expressed that the TFA intake should be as low as possible.[324] The Food and Nutrition Institute plans to update the nutrition standards in 2017. The Food and Nutrition Institute intensify its education activities mainly through the newly (beginning of 2017) established National Centre for Nutrition Education that is to organise conferences targeted to FBOs.

Measure impacts

Business responses and costs

Number of business that reformulated their products	Unknown; information available on some large producers (especially multinational companies that changed their company policies)

[321] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf, pp. 24-25

[322] Portalspozywczy.pl (2017), Bielmar: Polacy coraz częściej przekonują się o walorach tłuszczów roślinnych, http://www.portalspozywczy.pl/zboza/wiadomosci/bielmar-polacy-coraz-czesciej-przekonuja-sie-o-walorach-tluszczow-roslinnych,142324.html

[323] Interview with the Polish Federation of Food Industry (PFPZ)

[324] M. Jarosz, Normy żywienia dla populacji polskiej – nowelizacja. IZŻ 2012, http://www.izz.waw.pl/attachments/article/33/NormyZywieniaNowelizacjaIZZ2012.pdf

(if possible differentiate by large and small companies)	
Evidence of FBO sector facing specific challenges	No evidence of specific sectors facing challenges
For which oils/fats was there a reduction in use and with what were they replaced?	Only anecdotal evidence available from specific companies, e.g. Toruń Pacific Sp. z o.o replaced PHVO in breakfast cereals and in all products based on breakfast cereals (cereal bars) with non-hydrogenated vegetable oils. Nestlé Poland reformulated its products switching to non-hydrogenated fats and partly hydrogenated fats have been used which had specific fatty acid profile with TFA levels in line with the Company Policy requirements.
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	No summary data identified. Prices of margarine (CP01152) that are provided by Eurostat for the last 3 years show strong stability, in contrast to butter prices (CP01151) which were very volatile. While the short period of data availability does not allow for drawing any conclusions on the possible impact of actions limiting the trans-fat content, the overall stability of margarine prices relative to the prices of butter suggest that if there is any cost impact of changes in the margarine formulae it is unlikely to be important in cost competition for consumer preferences. The Polish Federation of Food Industry (PFPZ) was not able to provide specific estimates. The situation likely differs between producers depending on the product characteristics, used machinery, etc. For some SMEs costs can be a barrier. The risks of acceptance of modified products by consumers was also highlighted (e.g. due to different taste).[325]
Cost of understanding/ learning the measure for FBOs	See above

Consumer prices and choice

Evidence of changes in the price of	No firm-level data were identified to assess the impact of product changes on costs. Between 2004 and 2017 (the maximum period of Eurostat data availability) the consumer prices of a broad

[325] Interview with the Polish Federation of Food Industry (PFPZ)

reformulated products	category "oils and fats" (CP01115 in the COICOP mnemonics of Eurostat) in Poland increased slower than in the EU28, whereas for the total of "food" (CP011) prices inflation in Poland was higher than in the EU. Also in the case of the category "Sugar, jam, honey, chocolate and confectionery" (CP0118) inflation in Poland was slower than in the EU28. This may partly reflect the fact that improvements in product formulae were not associated with any significant increases of consumer prices, but it is very difficult to draw any strong conclusions given multitude of factors affecting prices. Prices of margarine (CP01152) are only available for the last 3 years and the show strong stability, in contrast to butter prices (CP01151) which were very volatile. While the short period of data availability does not allow for drawing any conclusions on the possible impact of actions limiting the trans-fat content, the overall stability of margarine prices relative to the prices of butter suggest that if there is any cost impact of changes in the margarine formulae it is unlikely to be important in cost competition for consumer preferences.
Evidence of price differences between products with iTFAs and alternatives	Not identified
Evidence of changes in the range, quality or taste of products available	Only firm-specific information available
Evidence of changes in TFAs consumption	The daily intake of TFA decreased from about 14g per person/day in 1995 to about 2 g per person/day in 2010.[326]
Effect on consumer information and awareness	Information campaigns (see above for examples) may have some impact on rising consumer awareness but no comparable data was identified. Anecdotal evidence, such as the opinion of Beata Michalik (director at Z.T. Bielmar, large producer of vegetable fats) in an interview with food industry portal portalspozywczy.pl suggests that consumers are increasingly able to make a distinction between various fats and their health benefits and risks.[327]

[326] https://www.palmoilandfood.eu/sites/default/files/Anna%20%C5%BBbikowska%20-%20TFA%20in%20Europe%20and%20Poland%20in%20particular.pdf

[327] Portalspozywczy.pl (2017), Bielmar: Polacy coraz częściej przekonują się o walorach tłuszczów roślinnych, http://www.portalspozywczy.pl/zboza/wiadomosci/bielmar-polacy-coraz-czesciej-przekonuja-sie-o-walorach-tluszczow-roslinnych,142324.html

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	No direct estimate identified. Indirectly it can be to some extent approximated by the evolution of the share of deaths due to Ischaemic heart diseases in total deaths (Eurostat data – series [hlth_cd_aro). Between 2011 and 2014 the share of such deaths in PL decreased from 12% to 10%. This is a slightly faster decrease (and from a lower level) than in the EU28 (from 14% to 13%). However, the observed changes likely result from a multitude of factors, and the direct implications of possible changes in TFA intake cannot be separated. In general the consumption of fats rose in Poland from 23.6 kg per capita in 1995 to 33.5 kg per capita in 2015 but the share of animal fats consumption decreased from 16 kg in 1995 to 10 kg in 2015 whereas the consumption of vegetable fats rose from 7.5 to 23.4 kg in 2015.[328]
Evidence of change in saturated fats intake	No evidence of changes over time. The daily intake of SFA per person in 2015 was about 52.2 g.[329] SFA contributes to about 11.6 %E.[330] No comparison with past data was available.

Competition, innovation and trade

Effect on competition in the domestic market	Not identified – anecdotal evidence suggests no major impact; promoting healthy aspects of foods is a common strategy in the highly competitive food market in Poland. The overall stability of margarine prices relative to the prices of butter suggests that if there is any cost impact of changes in the margarine formulae it is unlikely to be important in cost competition for consumer preferences.
Changes in trade of affected goods	According to the Central Statistical Office data domestic market supply of margarine fluctuated over the years but remained broadly stable over the last decade (change from 329 thousand tonnes in 2005 to 315 thousand tonnes in 2010 and 320 thousand tonnes in 2015).[331]
Effect on	Suppliers did take decisions to reformulate products. Broader

[328] Rosiak E. (2015), The Consumption of Fats in Poland and the European Union, Scientific Journal Warsaw University of Life Sciences, SGGW, http://www.wne.sggw.pl/czasopisma/pdf/PRS_2016_T16(31)_z2.pdf p. 283

[329] Calculations carried and provided by the Independent Unit of Economics of Food and Nutrition, The National Food and Nutrition Institute based on Central Statistical Office data on consumption patterns and food content data from Kunachowicz H., Nadolna I., Przygoda B., Iwanow K.: Tabele składu i wartości odżywczej żywności. Wydawnictwo Lekarskie PZWL, Warszawa, 2005.

[330] Eliander et al (2015), Intake and sources of dietary fatty acids in Europe: Are current population intakes of fats aligned with dietary recommendations?, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4736684/

[331] GUS, Rynek Wewnętrzny (various annual editions), http://stat.gov.pl/obszary-tematyczne/ceny-handel/handel/rynek-wewnetrzny-w-2015-r-,7,21.html

innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	impact on innovation at the company level was not identified.

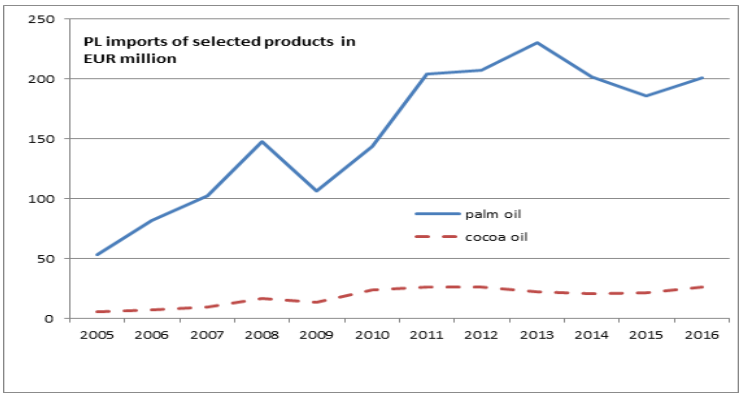
Administrative burdens

Number of businesses required to provide information	Not applicable; Individual companies may impose requirements on their suppliers – data not available
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	Not identified. Likely negligible given the character of the measures.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	N/A

Environmental impacts

Evidence of any environmental costs or benefits	N/A
Evidence of increase in demand for palm oil / other ingredients	Palm oil imports to Poland were on the increasing trend until 2011 and since then appear to have stabilised. Cocoa oil imports to Poland were increasing until around 2010 and have stabilised since then.[332]

[332] Eurostat

	
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	Not identified at the country level – expected to be negligible.

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Mojska H., Gielecińska I., Balas J., Pawlicka M., Szponar L.: Trans fatty acids in foods in Poland: monitoring study. Żyw. Człow. Metab., 2006, 33 (2); 107-122

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Onacik-Gür S et all, Sources of trans fatty acids on the Polish market. Probl Hig Epidemiol 2014, 95(1): p. 120-124
https://www.researchgate.net/publication/283087677_Zrodla_izomerow_trans_kwasow_tluszczowych_na_polskim_rynku

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https://www.choicesprogramme.org/public/criteria/choices_product_criteria_v2-5_poland_130201.pdf

Report from Workshop on 'Trans Fats' held at the European Parliament in Brussels on 5 Nov. 2013
http://www.europarl.europa.eu/RegData/etudes/workshop/join/2014/518744/IPOL-ENVI_AT(2014)518744_EN.pdf

Rosiak, 2016, The Consumption of Fats in Poland and the European Union in The Problems of World Agriculture.
http://www.wne.sggw.pl/czasopisma/pdf/PRS_2016_T16(31)_z2.pdf p. 279

Spożycie tłuszczów na świecie – przegląd badań z 40 krajów, 2014
http://www.pokochajolejrzepakowy.eu/spozycie-tluszczow-na-swiecie-przeglad-badan-z-40-krajow/

Switzerland

Policy status

	Existing	Proposed/ considered
Legislation	X	
Voluntary measures		
Labelling		
Consumer information		

Description of existing measure(s)

Type of measure	Legislation
Description of measure *(if legislation paste exact text of legislation)*	[817.022.105] "**Decree of the Federal Home Office (*Verordnung des EDI ueber Speiseoel, Speisefett und daraus hergestellte Erzeugnisse*) concerning edible oils and fats and all products contained therein"[333]** setting the limit on trans fats in oils and fats at 2%. The above decree was abrogated in May 2017, however relevant elements were incorporated into "[817.022.108] "**Decree of the Federal Home Office on foodstuffs of vegetable origin, mushrooms and edible salt (ODOV)"[334]**, including that the sum of trans fats (cooking oil and cooking fat) has to be limited to 2 grams per 100 grams.
Scope of measure	(Legislative):Federal (national level) Applies only to vegetable oils and fats derived from seeds, spores or fruits: • Vegetable oils are defined as cold pressed, cold washed, virgin, extra-virgin, natural or non-refined; • Olive oils and olive pomace oils are defined as extra virgin

333 https://www.admin.ch/opc/de/classified-compilation/20050165/201401010000/817.022.105.pdf

334 https://www.admin.ch/opc/de/classified-compilation/20143412/201705010000/817.022.17.pdf

	olive oil, refined olive oil, olive oil containing refined olive oil and extra virgin olive oil, crude olive pomace oil, refined olive pomace oil, and olive pomace oil; and • Spreadable fats An amendment to the previous (2005) law seemed to set the limit at 1% for certain oils and fats (i.e. those extracted from krill, the microalga "Schizochytrium" and those with high levels of eicosapentaenoic acid).[335] The provisions concerning the regulation on novel oils contained in the Decree concerning edible oils and fats and all products contained therein were introduced into the novel food regulation (Article 6 (1) (a) and Annex 1). The oils which were placed on the market in accordance with Regulations (EU) No 258/97 and (EU) No 2015/2283 are also commercially viable in Switzerland (with the exception of genetically modified food). The maximum level of 1% for trans fats in certain fats and oils therefore continues to apply.
FBOs covered	Food regulations concerns production, treatment, storage, transport and placing of food on the market (Article 2 of the Federal Law on Food and Consumer Goods (LMG, SR 817.0)). The regulation therefore applies in principle to all foodstuffs which are placed on the market.
Derogations *(e.g. low fat products, local products)*	The Decree on foodstuffs of vegetable origin, mushrooms and edible salt applies to vegetable cooking oils and cooking fats as well as to mixtures of vegetable oils and animal fats, but not for animal fats. The latter are regulated in the regulation on foodstuffs of animal origin (VLtH, SR 817.022.108).
Share of SMEs involved *(in case of voluntary measures)*	No data available
Length and characteristics of transition period	There was a transition period under the original law from 2005 whereby the foodstuffs to which the decree applied could be imported, produced and characterised according to the previous legislation up to 31 December 2007. They could be sold until stocks were exhausted.

[335] https://www.admin.ch/opc/it/official-compilation/2015/3403.pdf

Arrangements for measure enforcement and compliance monitoring	Any person who manufactures, handles, stores, transports, sells, imports or exports food is obliged to implement a self-control system in accordance with Article 26 of the LMG and must ensure that the legal requirements are complied with. The enforcement authorities monitor the compliance with the provisions on foodstuffs and the implementation of a self-control system (Art. 30 LMG). The regulation on the enforcement of food legislation (LMVV, SR 817.042) regulates the official control of foodstuffs
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	Before entry into force of the legislation, Migros and COOP imposed a 2% limit on their products.
Tests used to assess TFA content	Not specified in legislation
Steps taken to raise consumer awareness	The new Swiss Nutrition policy does not mention trans fats, because the limits on TFA are regulated. Nevertheless, reformulation and innovation of products (less sugar, less salt and better fat quality) are one of the priorities in Swiss nutrition policy.
Guidance provided to affected businesses	No guidance provided
Effectiveness of the measure	No information found.
Describe (if any) other measures that are currently being considered	No information found.

TFAs in foods and diets

TFAs content in food	Pre law (2009): A study found that TFA levels were higher than 2%.[336]

[336] Scheeder & Colombani (2009). Trans fatty Acid content of Selected Swiss Products: the TransSwissPilot Study in the Journal of Food Composition and Analysis.

(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)	
Variation in TFAs content in food after implementation of measure	According to a nutritional bulletin by the Federal Office for Food Safety, thanks to the regulation limiting transfats to 2%, there are considerably lower amounts in food in Switzerland.
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	Required by law to be capped at 2% - no reforms foreseen.
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	No specific information on TFA intake, just on diet more generally (so how much fruit/veg are consumed, etc.)
Variation in TFAs intake after implementation of measure	As above.
Information on national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	Interviews undertaken in 2011 by LINK on behalf of COOP (based on a sample of 506 people) demonstrated low knowledge of transfats as well as little preoccupation therewith.[337] Transfats bore very little impact on the interviewees' purchasing choices.

337 http://www.coop.ch/pb/site/common2/get/documents/coop_main/elements/Gesund%20geniessen_2013/_pdf/Studienberichte/Studienbericht_VI_it.pdf

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	No information found.
Evidence of FBO sector facing specific challenges	No information found.
For which oils/fats was there a reduction in use and with what were they replaced?	According to a newspaper article, McDonald's now uses rapeseed oil in order to remain within the 2% boundary.
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	No information found.
Cost of understanding/ learning the measure for FBOs	No information found.

Consumer prices and choice

Evidence of changes in the price of reformulated products	A price increase was not observed. However, no evidence-based studies have been carried out.
Evidence of price differences between	No information found.

products with iTFAs and alternatives	
Evidence of changes in the range, quality or taste of products available	No information found.
Evidence of changes in TFAs consumption	No information found.
Effect on consumer information and awareness	No information found.

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	No information found.
Evidence of change in saturated fats intake	No information found.

Competition, innovation and trade

Effect on competition in the domestic market	No information found.
Changes in trade of affected goods	No information found.
Effect on innovation among suppliers *(i.e. reformulation and/or changes*	No information found.

in production processes)	

Administrative burdens

Number of businesses required to provide information	Does not apply. Decree applies to all.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	No information found.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	Controls are carried out by relevant authorities based on risk assessments.

Environmental impacts

Evidence of any environmental costs or benefits	No information found.
Evidence of increase in demand for palm oil / other ingredients	No information found.
Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found.

United Kingdom

Policy status

	Existing	Proposed/ considered
Legislation		
Voluntary measures	X	
Labelling		
Consumer information		

Description of existing measure(s)

Type of measure	Voluntary measure
Description of measure *(if legislation paste exact text of legislation)*	Voluntary measure – self-regulation and dietary recommendation 1. "Update on TFA and health – Position statement by the Scientific Advisory Committee on Nutrition"[338] 2. England: Public Health Responsibility Deal Food Network: Pledges F3(a) on not using ingredients that contain TFAs and F3(b) on removing artificial TFA from products within 12 months, as well as guidance for small businesses.[339] 3. "Revised Dietary Goals for Scotland" include a goal for the average intake of TFA to remain below 1 E%.[340] [341]
Scope of measure	1. In its report on the "Nutritional Aspects of Cardiovascular Disease (1994)", the Committee on the Medical Aspects for Cardiovascular Disease (COMA) concluded that there was sufficient evidence for an association between TFA intakes and CHD, and for adverse effects on circulating lipoprotein concentrations, to recommend that the average population intake of TFA should not exceed 2% food energy. This recommendation was endorsed by the Scientific Advisory Committee on Nutrition in

[338] https://www.gov.uk/government/publications/sacn-update-on-trans-fatty-acids-2007

[339] https://responsibilitydeal.dh.gov.uk/wp-content/uploads/2012/01/Artificial-trans-fats-advice-Final.pdf

[340] http://www.gov.scot/Resource/0042/00421385.pdf

[341] http://www.gov.scot/Resource/0049/00497558.pdf

	2007. 2. While population average intakes (0.5 E% from TFA in 2010/12) are well within public health recommendations, the possibility that artificial TFA from foods containing PHVO might be consumed at high levels by some vulnerable groups of the population continued to be a concern for some consumers and health groups. For this reason, two voluntary Public Health Responsibility Deal pledges were introduced in England to provide reassurance to consumers and to ensure that intakes of artificial trans fats are reduced to a minimum. The first pledge acknowledged the fact that some organisations had already removed TFA from their products. The second committed companies to remove artificial TFA from their products within the next 12 months. 3. The "Revised Dietary Goals for Scotland" describe, in nutritional terms, the diet that will improve and support the health of the Scottish population. They indicate the direction of travel, and assist policy development to reduce the burden of obesity and diet-related disease in Scotland. They will continue to underpin diet and health policy in Scotland and will be used for scientific monitoring purposes.
FBOs covered	1. UK wide recommendation 2. "All our major supermarkets have committed to removing artificial trans fats from our foods. In total almost 100 companies have signed up to this pledge to date, which includes around 69 per cent of the retail /manufacturing market – Kraft Foods, Heinz, Nestle, Weetabix, Warburtons, Kelloggs and Premier Foods to name but a few – as well as 58 per cent of the major high street and contract catering sector."[342] 3. Scotland wide recommendation
Derogations *(e.g. low fat products, local products)*	Does not apply
Share of SMEs involved *(in case of voluntary measures)*	1. and 3.: Does not apply (UK/Scotland wide) 2. No info
Length and characteristics of transition period	1 and 3: Does not apply (recommendation) 2: Those signed up to F3(a) already have removed trans fat from their offer. Those who signed up to F3(b). Artificial Trans Fat Removal have said they are "(b). We are working to remove

[342] https://responsibilitydeal.dh.gov.uk/progress-to-date/

	artificial trans fats from our products within the next 12 months."
Arrangements for measure enforcement and compliance monitoring	1 and 3: Does not apply (recommendation) 2: Confirmation of pledge delivery for F3(a) Shortly after signing up to F3(a), partners will be asked to provide a delivery plan in which they must confirm when they met this pledge. All delivery plans will be published on this website. There will be no further reporting for these partners once they have confirmed that they have completed this pledge. Partners signing up to F3(b) will participate in the Responsibility Deal's reporting arrangements set out below, until they have completed this work and can transfer to F3(a). Shortly after signing up, partners will be asked to provide pledge delivery plans, laying out how they intend to meet each of the pledges they have signed up to. They will have up to 2,000 characters to describe their plans for each pledge they are signed up to. All delivery plans will be published on this website. Partners will be asked to report on their progress by the end of April each year. For some pledges, partners will be asked to report using pre-defined quantitative measures, while for others they will be asked for a narrative update. Further information on the reporting arrangements for each food pledge for the reporting period 2014/2015 is available.[343] All annual updates will be published on this website.[344]
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	1 and 3: Does not apply (recommendation) 2. No info, though the 11 currently signed for F3(b) signed up more than 12 months ago which could imply they were non-compliant and could not move to F3(a). If this is the case, this means 11 out of a total of 101 who signed up to either a or b were non-compliant.
Tests used to assess TFA content	No specific tests for monitoring any of the above voluntary measures. However, the Department of Health undertakes a rolling programme of nutrient analysis surveys to ensure that reliable, up-to-date information on the nutritional value of foods is available for use in conjunction with food consumption data collected in dietary surveys to monitor the nutritional content of the nation's diet. The following tests have been used for different iterations of this monitoring:

[343] https://responsibilitydeal.dh.gov.uk/wp-content/uploads/2015/02/Food-pledges-annual-update-questions-2014-2015-FINAL.pdf

[344] https://responsibilitydeal.dh.gov.uk/

	I. Department of Health (applies only to England) Nutrient Analysis of Fish and Fish Products (March 2011) and; Department of Health (applies only to England); Nutrient Analysis of Eggs (November 2010 and February 2011)[345] Method: The lipid fractions of the sample are solvent extracted. The isolated fat is transesterified with methanolic sodium methoxide to form fatty acid methyl esters (FAMES). The FAME profile is determined using capillary gas chromatography (GC). Quantification and identification of individual FAMEs in the test material is achieved with reference to calibration standards. Accredited to BS/EN ISO/IEC 17025:2005. UKAS 0680 LOQ 0.01 mg/100g Results: Presented as g TFA/100 g of food II. Department of Health: Analysis of trans and saturated fatty acids (SFA) in fats/oils and takeaway products from areas of deprivation in Scotland (2012)[346] Method: Unknown, performed by the Glasgow Public Analyst Laboratory, which is UKAS accredited for fatty acid analysis, including TFA. Results: Presented as g TFA/100 g of food
Steps taken to raise consumer awareness	No evidence online on campaigns other than from EC report,[347] which lists: • Dissemination through talks in communities and through the use of local media • Skills development programmes and programmes available for lower socio-economic status groups The following organisations have consumer-aimed pages on trans fats (not exhaustive):

345 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167972/Nutrient_analysis_of_eggs_Summary_Report.pdf

346 http://www.foodstandards.gov.scot/sites/default/files/854-1-1588_Report_of_Analysis_of_Trans_fatty_acids_in_fats_FINAL.pdf

347 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

	NHS (National Health Service): http://www.nhs.uk/Livewell/Goodfood/Pages/Fat.aspx#transfats The Association of UK Dietitians: https://www.bda.uk.com/foodfacts/FatFacts.pdf
Guidance provided to affected businesses	The Responsibility Deal gives some basic guidance on how to deliver the pledge.[348] Additionally, the Department of Health has developed guidance to support smaller businesses to deliver the pledge.[349]
Effectiveness of the measure	A study notes that for trans fat even earlier voluntary action by industry (before 2003) had been effective and efficient at reducing intakes to an acceptable level.[350]
Describe (if any) other measures that are currently being considered	No information found.

TFAs in foods and diets

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	From the most comprehensive study (others look at only one or a group of food items (e.g. fish and fish products): 1. Department of 'Health Nutrient analysis of a range of processed foods with particular reference to trans fatty acids', 2013[351] NB: detailed FAMES results available via link[352]

Product	Trans fats (g/100g)
Cheese and tomato pizza, retail, all bases, not stuffed crust	0.11
Garlic and herb baguette, baked	0.31

[348] https://responsibilitydeal.dh.gov.uk/pledges/pledge/?pl=10#_ftn1

[349] https://responsibilitydeal.dh.gov.uk/wp-content/uploads/2012/01/Artificial-trans-fats-advice-Final.pdf

[350] https://www.researchgate.net/publication/254384473_Reformulation_for_healthier_food_a_qualitative_assessment_of_alternative_approaches

[351] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167938/Summary_Report.pdf

[352] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167941/spreadsheet_of_fatty_acid_data.XLS

Crunchy clusters type breakfast cereal without nuts	0.01
Crunchy/crispy muesli type cereal with nuts	0.01
Quiche Lorraine with shortcrust pastry, retail	0.18
Low fat spread (26-39%), not polyunsaturated (including dairy type)	0.12
Low fat spread (26-39%), not polyunsaturated, with olive oil	0.14
Low fat spread (26-39%), polyunsaturated	0.05
Hard block margarine	0.07
Compound cooking fat, not polyunsaturated	0.06
Ghee made from vegetable oil	0.08
Reduced fat spread (41-62%), polyunsaturated	0.13
Reduced fat spread (41-62%), not polyunsaturated	0.15
Reduced fat spread (41-62%), not polyunsaturated, with olive oil	0.11
Reduced fat spread (62-75%), not polyunsaturated	0.14
Takeaway chicken pieces, coated, deep fried	0.11
Coated chicken pieces, takeaway	0.02
Chicken/turkey burger, coated, baked	0.03
Breaded/battered chicken/turkey pieces, cooked	0.02
Chicken breast/steak, coated, baked	0.02
Beef pie, purchased, puff or shortcrust pastry, family size	0.06
Beef pie, purchased, individual, puff or shortcrust pastry	0.13
Cornish pasty, purchased	0.14
Pork pie, individual	0.06
Sausage roll, purchased, ready to eat, flaky pastry	0.03
Chicken/turkey pasties/slices, puff pastry	0.05
Cod in batter, fried in commercial oil, from takeaway fish and chip shops	0.34
Cod in batter, frozen/chilled, baked	0.02
Cod in breadcrumbs, oven baked	0.01
Fish fingers, pollock, grilled	0.01
Coleslaw, purchased, not low calorie	0.02
Chips, fried in commercial oil, from takeaway fish and chip shops	0.16
Chips, fine cut, from fast food outlets	0.02
Potato chips, oven ready, baked	0.00
Potato chips, oven ready, with batter, baked	0.01
Potato crisps, fried in vegetable oil, not Walkers, not premium crisps, not fried in sunflower oil	0.06
Potato crisps, fried in sunflower oil, including premium, not Walkers1	0.03
Potato crisps, fried in high oleic sunflower oil	0.03
Potato rings (e.g. Hula Hoops)	0.02
Withdrawn	N/A
Tortilla chips in Sunseed or high oleic sunflower oil (e.g. Doritos)	0.08
Corn snacks (e.g. Monster Munch, Wotsits)	0.04
Mixed toffees (including liquorice toffees), not premium	0.07
Chew sweets (e.g. Starburst, Chewits, Blackjacks)	0.01

Milk chocolate bar	0.16
Chocolate covered caramels (e.g. Cadburys caramel)	0.10
Dark chocolate with crème or mint fondant centres	0.01
Mars Bars (and own brand equivalents)	0.05
Maltesers (and similar products)	0.07
Milk chocolate covered caramel and biscuit fingers	0.05
Chocolate covered bar with caramel and cereal	0.09
Milky Way bars (and own brand equivalents)	0.06
Snickers bars (and own brand equivalents)	0.03
Chocolate spread	0.03
Cream of tomato soup, canned	0.01
Instant soup, as purchased	0.01
Mayonnaise, retail, standard	0.04
Baby rusks	0.01
Ice cream, non dairy, vanilla, soft scoop	0.04
Ice cream, dairy, vanilla, soft scoop	0.18
Chocolate/choc mint and nut cone (e.g. Cornetto)	0.03
Ice Cream, luxury, dairy, with chocolate/caramel	0.23
Luxury choc ices (e.g. Walls Dream, Bounty, Magnum)	0.11
Butter, spreadable (75-80% fat)	1.38
Butter, spreadable, light (60% fat)	1.01
Coleslaw, purchased, economy products only	0.01

More specific studies:

2. Department of Health Nutrient Analysis of Fish and Fish Products (March 2011)[353]

Product	Trans fats (g/100g)
Cod, chilled/frozen, raw, flesh only	0.00
Cod, chilled/frozen, baked, flesh only	0.00
Cod, chilled/frozen, microwaved, flesh only	0.00
Haddock, chilled/frozen, raw, flesh only	0.00
Haddock, chilled/frozen, grilled, flesh only	0.00
Haddock, chilled/frozen, steamed, flesh only	0.00
Alaskan pollock, chilled/frozen, raw, flesh only	0.01
Sole, chilled/frozen, raw, flesh only	0.00
Sole, chilled/frozen, grilled, flesh only	0.00
Plaice, chilled/frozen, raw, flesh only	0.01
Pangasius, chilled/frozen, raw, flesh only	0.00
Coley, chilled/frozen, raw, flesh only	0.00
Sea bass, chilled/frozen, raw, flesh only	0.02
Sea bass, chilled/frozen, baked, flesh only	0.01
Prawns, cold-water, purchased cooked	0.00

[353] https://www.gov.uk/government/publications/nutrient-analysis-of-fish

Prawns, king, warm-water, raw	0.00
Prawns, king, warm-water, grilled from raw	0.00
Prawns, king, warm-water, purchased cooked	0.00
Mussels, purchased cooked	0.00
Crab, brown meat	0.04
Crab, white meat	0.00
Mackerel, chilled/frozen, raw, flesh only	0.02
Mackerel, chilled/frozen, grilled, flesh only	0.02
Trout, rainbow, chilled/frozen, raw	0.01
Trout, rainbow, chilled/frozen, baked	0.01
Kippers (analysed without butter), grilled	0.01
Kippers, boil in the bag, with butter, cooked	0.02
Tuna, chilled/frozen, raw	0.00
Tuna, chilled/frozen, baked	0.00
Sardines, chilled/frozen, raw	0.01
Haddock, smoked, chilled/frozen, poached	0.00
Plaice, coated in breadcrumbs, baked	0.02
Calamari, coated in batter, baked	0.02
Fish fingers, cod, grilled/baked	0.02
Fish fingers, cod, fried	N/A
Fish fingers, salmon, grilled/baked	0.02
Cod, coated in batter, fried	N/A
Fishcakes, white fish, coated in breadcrumbs, baked	0.02
Fishcakes, salmon, coated in breadcrumbs, baked	0.04
Scampi, coated in breadcrumbs, baked	0.01
Scampi coated in breadcrumbs, fried	N/A
Fish pie, white fish, retail, baked	0.12
Mussels in white wine sauce, cooked	0.04
Salmon, smoked (cold-smoked)	0.01
Salmon, smoked (hot-smoked)	0.01
Mackerel, smoked	0.02
Seafood sticks	0.00
Tuna, canned in brine	0.00
Tuna, canned in sunflower oil	0.00
Salmon, red, canned	0.01
Salmon, red, canned, skinless and boneless	0.01
Salmon, pink, canned	0.01
Mackerel, canned in brine	0.01
Sardines, canned in tomato sauce	0.01
Sardines, canned in brine	0.01
Langoustine, boiled	0.00

3. Department of Health Nutrient Analysis of Eggs (November 2010 – February 2011)[354]

Product	Trans fats

[354] https://www.gov.uk/government/publications/nutrient-analysis-of-eggs

	(g/100g)
Whole egg, raw	0.00
Eggs, chicken, white, raw	N/A
Egg yolk, raw	0.00
Whole egg, boiled	0.00
Eggs, chicken, white, boiled	N/A
Egg yolk, boiled	0.00
Whole egg, poached	0.00
Whole egg, fried	0.00

Product (oils)	Trans fats (g/100g oil)
Beef dripping (new)	4.8 ± 0.3
Animal origin oil (used)	4.6 ± 0.3
Vegetable oil blended (new)	1.4 ± 0.1
Vegetable oil (used)	1.8 ± 0.2

Product (takeaway meals)	Trans fats (g/100g)
Spring rolls	0.14
Chicken pakora	0.18
Vegetable pakora	0.28
Sausage	0.33
Chips	0.35
Fritters	0.73
Fish	0.63

3. A more recent and wider scope study on takeaways than the study above on which more data is available is 'Saturated and trans-fatty acids in UK takeaway food'[355]

Meal type	TFA (g/100 g): median
Chinese (all meals)	**0.03**
Sweet and Sour Chicken with boiled rice	0.02
Chicken Chow Mein	0.10
Char Sin Chow Mein	0.02
Chicken Satay with fried rice	0.01
Kung Po King Prawns with boiled rice	0.04

[355] https://www.researchgate.net/publication/295864106_Saturated_and_trans-fatty_acids_in_UK_takeaway_food

Special Fried Rice	0.1
Indian (all meals)	**0.09**
Chicken Korma with pilau rice	0.09
Lam Rogan Josh with pilau rice	0.10
Vegetable Biryani	0.10
English (all meals)	**0.07**
Chicken and chips	0.1
Fish and chips	0.03
Chips and curry sauce	0.1
Pizzas (all meals)	**0.18**
Ham and Pineapple pizza	0.18
Meat pizza	0.18
Kebabs (all meals)	**0.53**
Donner kebab with chips	0.84
Donner kebab	0.43

Variation in TFAs content in food after implementation of measure	N/A (no 'post' measurement as such and measure is ongoing)
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	"All our major supermarkets have committed to removing artificial trans fats from our foods. In total almost 100 companies have signed up to this pledge to date, which includes around 69 per cent of the retail /manufacturing market – Kraft Foods, Heinz, Nestle, Weetabix, Warburtons, Kelloggs and Premier Foods to name but a few – as well as 58 per cent of the major high street and contract catering sector."[356]
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO*	1. The Diet and nutrition survey of infants and young children, 2011 shows the following results:[357]

Energy, macronutrients	**Age group (months)**			
	4-6	7-9	10-11	12-18
Trans fatty acids g				
Mean	0.1	0.2	0.3	0.6

[356] https://responsibilitydeal.dh.gov.uk/progress-to-date/

[357] https://www.gov.uk/government/publications/diet-and-nutrition-survey-of-infants-and-young-children-2011

contribution)

(=median)
% total energy
Mean (=median) 0.1 0.2 0.3 0.5

2. Derived from: National Diet and Nutrition Survey Results from Years 1, 2, 3 and 4 (combined) of the Rolling Programme (2008/2009 – 2011/2012):[358]

		Average daily trans fatty acid intake g
Boys	4-10	1.1
	11-18	1.4
Total	boys	1.2
Men	19-64	1.5
	65+	1.5
Girls	4-10	1.1
	11-18	1.1
Total	girls	1.1
Women	19-64	1.1
	65+	1.2
Total	1.5-3	0.8
	4-10	1.1
	11-18	1.2
	19-64	1.3
	65+	1.3

*Also available by income group*age group* sex:*

*NB: * p<0.05 and ** p<0.01 denotes a statistical difference between an individual quintile and the highest quintile (reference quintile) of equivalent age group;*

No statistical analysis has been carried out on 65+ due to the cell size of quintile 5 being below 50.

		Trans fat g		Trans fat % food energy	
		Mean	Median	Mean	Median
Boys 4-10 years	Quintile 1	1.1	1.0	0.6	0.6
	Quintile 2	1.1	1.0	0.6	0.6
	Quintile 3	0.9**	0.8	0.5*	0.5
	Quintile 4	1.2	1.1	0.6	0.6

[358] https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012

	Quintile 5	1.1	1.1	0.6	0.6
Boys 11-18 years	Quintile 1	1.5	1.4	0.7	0.6
	Quintile 2	1.2**	1.1	0.6**	0.6
	Quintile 3	1.4	1.2	0.6	0.6
	Quintile 4	1.4	1.3	0.6	0.6
	Quintile 5	1.5	1.4	0.6	0.6
Total boys	Quintile 1	1.3	1.2	0.6	0.6
	Quintile 2	1.1	1.1	0.6*	0.6
	Quintile 3	1.2	1.0	0.6	0.6
	Quintile 4	1.3	1.2	0.6	0.6
	Quintile 5	1.3	1.2	0.6	0.6
Men 19-64 years	Quintile 1	1.2*	1.1	0.6*	0.5
	Quintile 2	1.4	1.2	0.6	0.6
	Quintile 3	1.4	1.3	0.6	0.6
	Quintile 4	1.5	1.5	0.7	0.6
	Quintile 5	1.5	1.4	0.7	0.6
Men 65+	Quintile 1	[1.5]	[1.3]	[0.7]	[0.7]
	Quintile 2	1.5	1.3	0.7	0.6
	Quintile 3	[1.4]	[1.4]	[0.7]	[0.7]
	Quintile 4	1.6	1.5	0.8	0.7
	Quintile 5				
Girls 4-10 years	Quintile 1	1.0	0.9	0.6	0.6
	Quintile 2	1.1	1.1	0.7	0.6
	Quintile 3	1.0	0.9	0.6	0.6
	Quintile 4	1.2*	1.1	0.7	0.7
	Quintile 5	1.0	1.0	0.6	0.6
Girls 11-18	Quintile	1.1	0.9	0.6	0.6

years	1				
	Quintile 2	1.1	1.0	0.6	0.6
	Quintile 3	1.0	1.0	0.6	0.5
	Quintile 4	1.1	1.0	0.6	0.6
	Quintile 5	1.0	0.9	0.6	0.6
Total girls	Quintile 1	1.0	0.9	0.6	0.6
	Quintile 2	1.1	1.0	0.6	0.6
	Quintile 3	1.0	1.0	0.6	0.6
	Quintile 4	1.1	1.1	0.7	0.6
	Quintile 5	1.0	0.9	0.6	0.6
Women 19-64 years	Quintile 1	1.1	1.1	0.6	0.6
	Quintile 2	1.1	1.0	0.7	0.6
	Quintile 3	1.0**	1.0	0.6	0.6
	Quintile 4	1.2	1.1	0.7	0.7
	Quintile 5	1.2	1.1	0.7	0.7
Women 65+	Quintile 1	1.3	1.2	0.8	0.8
	Quintile 2	1.2	1.0	0.7	0.6
	Quintile 3	1.1	0.9	0.7	0.7
	Quintile 4	1.4	1.3	0.8	0.8
	Quintile 5	[1.2]	[1.0]	[0.7]	[0.7]

(also available without the breakdown by sex)

3. The Food Standards Agency Low income diet and nutrition survey Volume 2 Food consumption Nutrient intake found that: 'Mean intakes expressed as a percentage of food energy were 1.3% in men and women and 1.2% in boys and girls. They did not differ significantly between the sexes in any age group, or between adults and children, but were marginally higher in women aged 65 and over (1.4%) compared with other age groups (1.2%).The COMA recommendation2 is that the population average contribution of trans fatty acids to energy should not

exceed 2% and average intakes were below this figure. Over the 24 hour (24h) recall days, intakes by consumers in the upper 2.5 percentile were over double the recommended maximum.'[359] Further data is available breaking results down by age groups (2-10; 11-18; 19-34; 35-49; 50-64; 65+) and sex.

Variation in TFAs intake after implementation of measure

There is no 'post' measurement as such and measure is ongoing but the National Diet and Nutrition Survey Results can be used to look at variation over time:[360]

			Trans fat g		Trans fat % food energy	
			Mean	Median	Mean	Median
Year 1 + 2	Boys	4-10	1.3	1.3	0.8	0.7
		11-18	1.6	1.5	0.7	0.7
	Total	boys	1.5	1.4	0.7	0.7
	Men	19-64	1.8	1.7	0.8	0.8
		65+	1.8	1.6	0.9	0.8
Year 3 + 4	Boys	4-10	0.8**	0.8	0.5**	0.5
		11-18	1.1**	1.0	0.5**	0.5
	Total	boys	1.0**	0.9	0.5**	0.5
	Men	19-64	1.2**	1.1	0.5**	0.5
		65+	1.2**	1.0	0.6**	0.5
Year 1 + 2	Girls	4-10	1.3	1.2	0.8	0.7
		11-18	1.3	1.2	0.7	0.7
	Total	girls	1.3	1.2	0.8	0.7
	Women	19-64	1.3	1.2	0.8	0.7
		65+	1.5	1.4	0.9	0.8
Year 3 + 4	Girls	4-10	0.8**	0.8	0.5**	0.5
		11-18	0.8**	0.8	0.5**	0.5
	Total	girls	0.8**	0.8	0.5**	0.5
	Women	19-64	0.9**	0.8	0.6**	0.5
		65+	1.0**	0.9	0.6**	0.6

(also available without the breakdown by sex)

Information on

Food Standard Agency surveys and research from 2007 showed

359 http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/multimedia/pdfs/lidnsvol02

360 https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012

national consumer awareness of TFAs issues *(e.g. terminology, impact of food choice)*	that consumer concerns remained relatively low in comparison to those about other nutrients and food safety issues.[361] When asked to choose from a list what types of fats it was most important for them to cut down on, just 15% of respondents selected trans fats and hydrogenated vegetable oils. In contrast 45% named saturated fats as the key fat of concern.[362]

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	N/A (but as noted above: "All our major supermarkets have committed to removing artificial trans fats from our foods. In total almost 100 companies have signed up to this pledge to date, which includes around 69 per cent of the retail /manufacturing market – Kraft Foods, Heinz, Nestle, Weetabix, Warburtons, Kelloggs and Premier Foods to name but a few – as well as 58 per cent of the major high street and contract catering sector.")
Evidence of FBO sector facing specific challenges	No information found.
For which oils/fats was there a reduction in use and with what were they replaced?	No information found.
Costs of changes in products and processes *(if possible differentiate by type of cost and include figures)*	No information found.
Cost of understanding/ learning the	No information found.

361 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

362 http://tna.europarchive.org/20120419000433/http://www.food.gov.uk/multimedia/pdfs/board/fsa071207.pdf

measure for FBOs	

Consumer prices and choice

Evidence of changes in the price of reformulated products	No information found.
Evidence of price differences between products with iTFAs and alternatives	No information found.
Evidence of changes in the range, quality or taste of products available	No information found.
Evidence of changes in TFAs consumption	No information found other than information on intake as described above, i.e.: National Diet and Nutrition Survey Results can be used to look at variation over time:[363]

			Trans fat g		Trans fat % food energy	
			Mean	Median	Mean	Median
Year 1 + 2	Boys	4-10	1.3	1.3	0.8	0.7
		11-18	1.6	1.5	0.7	0.7
	Total	boys	1.5	1.4	0.7	0.7
	Men	19-64	1.8	1.7	0.8	0.8
		65+	1.8	1.6	0.9	0.8
Year 3 + 4	Boys	4-10	0.8**	0.8	0.5**	0.5
		11-18	1.1**	1.0	0.5**	0.5
	Total	boys	1.0**	0.9	0.5**	0.5
	Men	19-64	1.2**	1.1	0.5**	0.5
		65+	1.2**	1.0	0.6**	0.5
Year	Girls	4-10	1.3	1.2	0.8	0.7

[363] https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012

1 + 2		11-18	1.3	1.2	0.7	0.7
	Total	girls	1.3	1.2	0.8	0.7
	Women	19-64	1.3	1.2	0.8	0.7
		65+	1.5	1.4	0.9	0.8
Year	Girls	4-10	0.8**	0.8	0.5**	0.5
3 + 4		11-18	0.8**	0.8	0.5**	0.5
	Total	girls	0.8**	0.8	0.5**	0.5
	Women	19-64	0.9**	0.8	0.6**	0.5
		65+	1.0**	0.9	0.6**	0.6

(also available without the breakdown by sex)

Effect on consumer information and awareness

Food Standard Agency surveys and research from 2007 showed that consumer concerns remained relatively low in comparison to those about other nutrients and food safety issues.[364] When asked to choose from a list what types of fats it was most important for them to cut down on, just 15% of respondents selected trans fats and hydrogenated vegetable oils. In contrast 45% named saturated fats as the key fat of concern.[365]

Health effects

Evidence of benefits on consumer health

(if possible differentiate by age and socio-economic group)

From Eurostat[366]

	2011	2012	2013	2014
M Total	**79,085**	**79,334**	**79,722**	**78,222**
M Younger than 25	175	164	143	127
M 25-49	2,975	2,906	2,872	2,860
M 50-64	10,506	9,775	10,056	9,859
M 65 and older	65,429	66,489	66,651	65,376
F Total	**80,171**	**82,637**	**79,514**	**76,689**
F Younger than 25	104	115	111	84
F 25-49	1,192	1,191	1,214	1,208
F 50-64	3,885	3,983	3,930	3,909
F 65 and older	74,990	77,348	74,259	71,488

364 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-oswp_en.pdf

365 http://tna.europarchive.org/20120419000433/http://www.food.gov.uk/multimedia/pdfs/board/fsa071207.pdf

366 http://ec.europa.eu/eurostat/statistics-explained/index.php/Cardiovascular_diseases_statistics

Total	**159,256**	**161,971**	**159,236**	**154,911**

Evidence of change in saturated fats intake

Mean daily saturated fat intakes for all age/sex groups, in line with total fat intakes, also tended to be lower in Y3&4 compared with those in Y1&2, with significant differences observed in boys aged 4 to 10 years (22.1g versus 24.0g), men aged 19 to 64 years (27.4g versus 29.4g), girls aged 11 to 18 years (20.9g versus 22.5g) and women 65 years and over (21.4g versus 24.3g), In line with total fat, mean saturated fat intakes as a percentage of food energy tended to be slightly lower in Y3&4 compared with Y1&2 and were significantly lower in boys aged 4 to 10 years (12.7% versus 13.4%) and women aged 65 years and over (13.2% versus 14.3%).[367]

			Saturated fat g		Saturated fat % food energy	
			Mean	Median	Mean	Median
Year	Boys	4-10	24.0	23.5	13.44	13.11
1 + 2		11-18	28.2	26.8	12.72	12.56
	Total	boys	26.4	25.4	13.02	12.84
	Men	19-64	29.4	27.6	12.89	12.84
		65+	29.5	28.4	14.38	14.35
Year	Boys	4-10	22.1*	21.6	12.74	12.56
3 + 4		11-18	27.4	25.8	12.59	12.5
	Total	boys	24.9	23.9	12.66	12.54
	Men	19-64	27.4*	26.7	12.4	12.37
		65+	27.8	24.3	13.28	13.14
Year	Girls	4-10	22.7	22.2	13.4	13.5
1 + 2		11-18	22.5	21.5	12.5	12.5
	Total	girls	22.6	21.9	12.9	12.9
	Women	19-64	22.6	21.6	12.7	12.5
		65+	24.3	23.4	14.3	14.6
Year	Girls	4-10	21.8	20.7	13.2	13.2
3 + 4		11-18	20.9*	20.5	12.3	12.1
	Total	girls	21.3	20.7	12.6	12.5
	Women	19-64	21.6	20.4	12.6	12.5
		65+	21.4*	21.6	13.2*	13.2

Competition, innovation and trade

Effect on competition in	No information found.

367 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/594361/NDNS_Y1_to_4_UK_report_full_text_revised_February_2017.pdf

the domestic market	
Changes in trade of affected goods	No information found.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	No information found.

Administrative burdens

Number of businesses required to provide information	No information found.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	No information found.
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	No information found.

Environmental impacts

Evidence of any environmental costs or benefits	No information found.
Evidence of increase in demand for palm oil / other ingredients	No information found.

Effects on deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	No information found.

United States

Policy status

	Existing	Proposed/ considered
Legislation	X	
Voluntary measures	X	
Labelling	X	
Consumer information	X	

Description of existing measure(s)

Type of measure	Legislation/voluntary measures/labelling/consumer information
Description of measure *(if legislation paste exact text of legislation)*	**Mandatory ban.** In November 2013 the FDA made a *preliminary determination* that PHOs are not Generally Recognised as Safe (GRAS) for use in foods, followed by a 60 day public comment period. Then, in June 2015, the U.S. Food and Drug Administration (FDA) announced that PHOs were no longer generally recognized as safe and that their use in foods would be phased out of the U.S. market by June 2018.[368] Release of 2005 **Dietary Guidelines** for Americans which included recommendations on trans fat intake. **Mandatory nutrition labelling**. Since 2006, USA manufacturers must list TFA on the nutritional fact panel of foods and certain dietary supplements (FDA issued a final rule on July 11, 2003). [369] More specifically, they must list the quantity of trans fatty acids in a serving of the food product (but not % of daily value as at this time there was no scientific basis for trans fat consumption). On December 1, 2014, the FDA also published a final rule for **menu labelling** requirements which specified that written nutritional information (including trans fat content) for standard menu items be available for consumers who ask to see it, and that on menus and boards, and that a statement regarding the availability of the nutritional information is present on menus and menu boards.[370]

368 https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

369 https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/trans-fatty-acids-europe-where-do-we-stand

370 https://www.federalregister.gov/documents/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food

On May 20, 2016, the FDA announced new Nutrition Facts labels for packaged foods to reflect new scientific information. Among other things, including design changes, calories from fat is being removed (although trans fat content must still be listed).[371]

State level initiatives:

In recognition of the limits of federal regulation and a growing concern regarding the health risks of trans fat consumption, state and local governments began introducing a variety of legislative proposals to restrict the use of artificial trans fats from 2003. California was the first US state to ban restaurants from using trans fats:

California trans fat ban. Approved on July 25, 2008, this requires all food facilities in the state, except public school cafeterias, to stop using artificial trans fats by January 2011.[372] It was expected to affect more than 88,000 restaurants, bakeries, delicatessens, cafeterias and other food service facilities.

Many other states have or are presently considering statewide trans fat bans. Examples are Connecticut, Florida, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, South Carolina, Tennessee, Vermont, and Virginia, among others.[373]

Local level initiatives:

Legislation banning the use of artificial trans fats in restaurants has been passed in New York City, Albany, Nassau and Westchester Counties in New York; King County (Seattle), Washington; Philadelphia, Pennsylvania; Stamford, Connecticut; Boston, Brookline, and Cambridge, Massachusetts; and Baltimore and Montgomery County, Maryland.[374] The New York City ban acted as a catalyst for other jurisdictions. The New York City action was adopted in Dec 2006 and came into effect in July 2008[375]. It restricted all food service establishments from using, storing or serving food that contained PHVO with a total of 0.5g or more TFA per serving.

371 https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

372 Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

373 Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

374 Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

375 https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

	Voluntary agreements In 2004, Tiburon, California (pop. 8,962) became the first community in the US to eliminate the use of artificial trans fats in restaurants pursuant to a voluntary agreement - all restaurants in Tiburon vowed to switch to cooking with trans fat-free oils. In February 2008, San Francisco began implementing a voluntary artificial trans fat elimination programme. In Multnomah County (Portland), Oregon, public health officials and the Oregon Restaurant Association collaborated to create a program to voluntarily phase out artificial trans fat use in restaurants and educate consumers about healthier eating.[376]
Scope of measure	**NYC action** – Any food in a food service establishment that contained PHVO with a total of 0.5g or more TFA per serving. **Labelling measure** – all packaged foods and dietary supplements. **PHO ban** – all food products.
FBOs covered	NYC action is one of the few actions that targets food prepared outside of the home. It covers all food service establishments using, storing or serving food.[377]
Derogations *(e.g. low fat products, local products)*	Foods prepared outside of the home are unaffected by labelling requirements.[378] Some pre-packaged foods and dietary supplements are also exempt if: they come from a retailer with annual gross sales of not more than $500,000, or with annual gross sales of foods or dietary supplements to consumers of not more than $50,000; or if the person claiming the exemption employs fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a 12-month period.[379] In addition, products that have less than 0.5g of trans fats per serving don't have to be labelled as containing trans fats. For menu labelling requirements, chain retail food establishments

[376] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

[377] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

[378] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/trans-fatty-acids-europe-where-do-we-stand

[379] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053857.htm

	with less than 20 locations are exempt. For the PHO ban: • "any interested party may seek food additive approval for one or more specific uses of PHOs with data demonstrating a reasonable certainty of no harm of the proposed use(s)."[380] The Grocery Manufacturer's Association argued in a petition to the FDA (filed on October 1, 2015) that continued low-level use of PHOs (1.5% of energy per day) is safe and should be allowed. Sources of PHO that should be allowed include PHOs manufactured from the following vegetable oils: soy, cottonseed, coconut, canola, palm, palm kernel and sunflower oils, or blends of these oils. Acceptable small-scale usage includes adding PHO as an anti-caking, anti-dusting and free flow agent; a lubricant or release agent; an emulsifier; and a processing aid or solvent for fat soluble ingredients. Arguably submitting such a proposal is a gamble because the GMA estimates that the formal review process for its petition could take two or more years – if it is rejected they will have one year to meet compliance deadline. No response has yet been issued by the FDA.[381] • The use of PHOs as raw materials used to synthesise other ingredients is also outside the scope of the PHO ban, as are ingredients that contain only naturally occurring trans fats. • It also does not include the use of conjugated linoleic acid (CLA) as a food ingredient, or partially hydrogenated methyl ester of rosin as these do not fit the PHO definition.[382]
Share of SMEs involved *(in case of voluntary measures)*	No information found.
Length and characteristics of transition period	After the 2015 announcement that PHOs are not Generally Recognised as Safe (GRAS), the FDA set a compliance period of three years to allow food companies to **either** reformulate products without PHOs and/or petition the FDA to permit specific uses of PHOs.[383] • Food labelling: In May 2016, the U.S. Food and Drug Administration finalized the Nutrition Facts and Supplement

380 https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

381 https://cspinet.org/sites/default/files/attachment/gma_trans_fat_fap_executive_summary_8-5-15.pdf

382

383 https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm449162.htm

Facts Label and Serving Size final rules and set the compliance date for July 26, 2018, with an additional year to comply for manufacturers with annual food sales of less than $10 million. After those rules were finalized, industry and consumer groups provided the FDA with feedback regarding the compliance dates. After careful consideration, the FDA determined that additional time would provide manufacturers covered by the rule with necessary guidance from FDA, and would help them be able to complete and print updated nutrition facts panels for their products before they are expected to be in compliance. On June 13, 2017, the FDA announced its intention to extend the compliance date for the Nutrition Facts Label final rules. The FDA will provide details of the extension through a Federal Register Notice at a later time.[384] The framework for the extension will be guided by the desire to give industry more time and decrease costs, balanced with the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.

- For the menu labelling requirements, the original compliance date was December 2016 (2 years after final rule), however a new final rule in December 2016 changed the compliance date to May 5, 2017. This has subsequently been updated to May 7, 2018.[385]
- California trans fat ban: introduced in July 2008, restaurants are required to use oils, margarine, and shortening with less than half a gram of trans fat per serving by January 1, 2010 for all food items except deep-fried baked goods. Donuts and other deep-fried baked goods will be prohibited from containing artificial trans fat after January 1, 2011.[386]
- New York trans fat ban: the regulation allowed restaurants six month (by July 1, 2007) to switch to oils, margarines, and shortening used for frying and spreading, and eighteen months (by July 1, 2008) to replace artificial trans fat used in baking and deep-frying of bakery goods[387].

384 https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

385 https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm

386 Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

387 Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

Arrangements for measure enforcement and compliance monitoring	California trans fat ban: for enforcement purposes, every food facility must maintain the label of any food that is, or contains, any fat, oil, or shortening, and is stored, distributed, served by, or used in the preparation of food by the facility. Health inspectors then review the labels when they conduct regular food safety inspections. Violation of the law is punishable by a fine of between $25.00 to $1,000.00.[388] New York trans fat ban: violations of the regulation don't count towards an establishment's food service inspection score, but violations will be posted on the health department's website and are subject to re-inspection. Violators are subject to fines of $200.00 to $2,000.00, depending on an establishment's number of prior violations.[389]
Rate of compliance/ participation and favouring conditions *(in case of voluntary measures)*	New York trans fat ban: Based on inspections after the first phase of the ban, the City estimated that 94% of affected food service establishments were in compliance.[390]
Tests used to assess TFA content	There are two methods approved by the FDA for measuring fatty acid composition in the food on food labels (April 2007 article): [391] • Gas chromatography, Association for Official Analytical Chemists method 996.06; and • Attenuated total reflection–Fourier transform infrared spectroscopy (ATR-FTIR), American Oil Chemists' Society method Cd 14d-96.
Steps taken to raise consumer awareness	• A **guidance document** was provided in 2005 to coincide with the labelling legislation. The aim was to help consumers better interpret the new food labelling and make more conscious food choices. The document was produced by the US Department of health and Human Services and the US Department of Agriculture.[392]

[388] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

[389] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

[390] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

[391] file:///C:/Users/32040/Downloads/2231.full.pdf

[392] https://health.gov/dietaryguidelines/dga2005/document/pdf/dga2005.pdf

	• In addition, one report found that reporting on trans fats has been persistent over many years, but sharply peaked about the same time as Federal regulations made it mandatory to label the trans fats content of foods.[393] • Through the labelling regulation, the FDA regulates the statements that food companies are allowed to make on product packages regarding the level of particular nutrients in food. Prior to 2004, such claims were rarely made, but food and beverage products with a "no trans fats" claim showed a marked upward trend beginning in 2004. FDA issued the regulation requiring disclosure of trans fats on the nutrition label in 2003 (to be implemented in 2006). Expressed as a percentage of all food and beverage products introduced, those with a "no trans fats" claim became an increasingly important component of all product introductions, peaking at 10.9 percent in 2009. Compared with the number of other commonly used nutrient claims made on food packages, "no trans fats" claims surpassed low/no/reduced cholesterol claims in 2004 and low/no/reduced sugar claims in 2005. Moreover, in 2008, the percentage of new products with a "no trans fats" claims exceeded those with no/low/reduced fat claims for the first time (see appendix 5 for graph).[394]
Guidance provided to affected businesses	Guidance provided by the FDA for small businesses: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053479.htm. The FDA also have a general food labelling guide for industry: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm And a labelling guide for restaurants and retail establishments selling away-from-home foods: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053455.htm New York trans fat ban: to assist affected restaurants with compliance, the New York City Department of Health and Mental Hygiene created a Trans Fat Help Centre, including a hotline and website. They also held many workshops to teach food preparers how to adapt recipes to substitute trans fat-free oils for partially hydrogenated vegetable oils and vegetable shortening and distributed educational brochures.
Effectiveness of the measure	See section 1.2 below for impact of measures in detail.

[393] https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

[394] https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

Describe (if any) other measures that are currently being considered	No information found.

TFAs in foods and diets

TFAs content in food *(by product, if available please distinguish by TFA source – iTFA and rTFA, and PHO)*	See Appendix 4 for info. on contribution of certain foods to total trans fat intake for Americans (1994-1996).
Variation in TFAs content in food after implementation of measure	Results from multiple studies show **clear decrease in TFA content** of food after measures introduced: • The most recent data on trans-fat intake in the US (2012) suggests that **over two thirds of trans fats** from industrially produced partially hydrogenated oils have already been taken out of the American diet.[395] • Where TFA labelling on packaged foods was mandated in 2006, a **49% reduction** (1.9 to 0.9 g/serving) in the TFA content was reported in an assessment of 360 packaged foods between 2007 and 2011. Some products (e.g., doughnuts, French fries) were reformulated much more rapidly compared with other categories (e.g., popcorn).[396] • Another study found a similar decrease in the trans fat content of food over time.[397] This study looked at the changes in trans fat and saturated fat in major brand name US supermarket and restaurant foods that were reformulated between 1993-2006 and 2008-2009. They identified 83 reformulated products (58 supermarket foods and 25 restaurant foods). **Trans fat content was reduced to less than 0.5 g per serving in 95% of the supermarket products analysed and 80% of the restaurant products analysed**; mean absolute reductions were 1.8 g per serving (84 percentage points) and 3.3 g per serving (92 percentage points), respectively. • Another study looking at the fat contents of US snack foods in response to mandatory trans fat labelling analysed the

[395] D. Doell, D. Folmer, H. Lee, M. Honigfort & S. Carberry. Updated estimate of trans fat intake by the US. Food Additives & Contaminants. 2012. Available online at: http://www.tandfonline.com/doi/abs/10.1080/19440049.2012.664570

[396] Arcand, J., Scourboutakos, M. J., Au, J. T., & L'abbe, M. R. (2014). trans Fatty acids in the Canadian food supply: an updated analysis. *The American journal of clinical nutrition*, ajcn-088732.

[397] http://www.nejm.org/doi/full/10.1056/NEJMc1001841#t=article

composition data of over 5000 chip and cookie products introduced for sale between 2001 (pre-labelling) and 2009 (post-labelling). Results showed that the **shares of chip and cookie introductions containing partially hydrogenated vegetable oil declined by 45 and 42 percentage points, respectively**.[398]

- Another study looked at the average trans fat contents of all new product introductions and for those containing positive levels of trans fats (see Annex 7 for a breakdown) – results showed that it is relatively rare for any new product introductions to contain trans fats and when products do contain trans fat, average trans fat content is a relatively small share of recommended fat intake.[399]
- However, while the evidence collected by FDA show that many foods have been reformulated to remove PHOs, there are two main food categories with PHOs that remain on the market: foods for which consumers have alternatives containing lower levels of trans fat (e.g., cookies, baked goods, microwave popcorn, frozen pizza, frozen pies, shortening) and foods for which consumers have limited or no choice of an alternative containing a lower level of trans fat (e.g., ready-to-use frostings, stick margarine).[400]
- See Additional References: graph shows the decrease in the amount of trans fats found in products with the highest trans fat content (2005-2010).

New York ban:

- Comparison of TFA and SFA content of fast-food customer purchases in NYC restaurants pre-2007 and 2009 (after NYC ban) showed that there was a statistically significant net decrease in combined TFA and SFA content in food purchases ((1.86 g overall mean decrease (13.7 to 11.9 g)) attributed to reformulation and new offerings; mean TFA content per purchase decreased by 2.4 g (from 2.9 to 0.5 g), whereas mean SFA content per purchase increased by 0.55 g (10.8 to 11.4 g) after the implementation of the action. The observed decreases in the TFA content of food purchases benefited similarly customers living in high- and low-income neighbourhoods.[401] In addition, purchases with zero grams of trans fat increased from 32% to 59%.
- In 2008, when the New York City restaurant ban was in full effect, estimated restaurant use of artificial trans fat for frying, baking, or cooking or in spreads had decreased from 50% to less than 2%. Replacement fats also tended to be healthier (in

[398] https://www.ncbi.nlm.nih.gov/pubmed/22314147

[399] https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

[400] https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for

[401] Angell SY, Cobb LK, Curtis CJ, Konty KJ, Silver LD. Change in trans fatty acid content of fast-food purchases associated with New York City's restaurant regulation: a pre-post study. Ann Intern Med 2012; 157: 81-6 pmid: 22801670.

	major restaurant chains total saturate fat plus trans fat in French fries decreased by over 50%).[402]
Future projections of TFAs content in food *(e.g. a major FBO pledged to reduce TFA content in own products)*	No information found.
TFAs intake *(if available please report data by TFA source – iTFA and rTFA, age and socio-economic group, and PHO contribution)*	Mean daily intake of TFAs from intrinsic sources (i.e. meat, milk, dairy and other products), is 1.042 g/day (0.46 %en/day) among the US 2+ y.[403]
Variation in TFAs intake after implementation of measure	Multiple references show clear decrease in TFA intake after measures introduced: • At the time of the 2003 labelling proposed rule, the FDA estimated that the daily mean intake of TFAs from PHOs among adults 20 years of age and older was 4.6g/day (2% energy/day) and total PHO from both animal and PHO sources was 5.8g/day (2.6% energy/day).[404] In 2010, the FDA estimated the mean trans fat intake for the US population aged 2 years or more who consumed one or more of the processed foods identified as containing PHOs to be 1.3g/p/d (0.6% of caloric intake). **This suggests a significant decrease in mean dietary intake of industrially produced trans fats since the July 2003 final rule.** • In 2010, the FDA also prepared an estimate for a high-intake scenario by assuming that trans fat was present at the highest level observed for all foods within a particular food category based on label surveys or analytical data. For this scenario, they estimated the mean intake to be 2.7 g/p/d (1.2 percent of energy) and the 90th percentile intake to be 5.4 g/p/d (2.4

[402] Angell SY, Silver LD, Goldstein GP, Johnson CM, Deitcher DR, Frieden TR, et al., et al. Cholesterol control beyond the clinic: New York City's trans fat restriction. Ann Intern Med 2009; 151: 129-34 pmid: 19620165.

[403] https://cspinet.org/sites/default/files/attachment/gma_trans_fat_fap_executive_summary_8-5-15.pdf

[404] Department of Health and Human Services. Tentative determination regarding partially hydrogenated oils; request for comments and for scientific data and information.

	percent of energy) for the U.S. population aged 2 years or more. • In 2012, the FDA, using survey data, updated the 2010 intake estimate of trans fats from PHOs for those food categories that were identified as major contributors to the dietary intake of trans fat, as well as for those categories where we have noted progress in reformulation. For this most recent estimate, they calculated the mean intake to be 1.0 g/p/d (0.5 percent of energy) and the 90th percentile intake to be 2.0 g/p/d (1.0 percent of energy) for the U.S. population aged 2 years or more. • The FDA also prepared an estimate for a high-intake scenario by assuming that trans fat was present at the highest level observed for all foods within a particular food category based on the label survey. For this scenario, they estimated the mean intake to be 2.1 g/p/d (1.0 percent of energy) and the 90th percentile intake to be 4.2 g/p/d (1.9 percent of energy) for the U.S. population aged 2 years or more. **The change since 2010 is not significant but it does suggest a continued downward trend.** Specifically, there was a **decrease observed in the intake of trans fat in the refrigerated dough, savory snacks, and frozen pizza categories,** consistent with the lower levels of trans fat observed in the label survey. • Although trans fat intake has decreased overall since the 2003 trans fat intake estimate, individuals with certain dietary habits may still consume high levels of trans fat from certain brands or certain types of food products (e.g., refrigerated biscuits, ready-to-use frostings, certain brands of frozen pizzas, and certain brands of microwave popcorn), which could contain several grams trans fat per serving. As noted previously, for those consumers who consistently choose these products, the daily intake of added trans fat is approximately twice as high as that for the consumer who does not choose only the foods containing the highest levels of trans fat within a particular category (2.1 g/p/d vs. 1.0 g/p/d). • Additionally, scientists at the CDC recently studied the change in levels of four major trans fatty acids in the blood of U.S. non-Hispanic white adults from 2000 to 2009, and reported a 58 percent average decrease during that timeframe.[405]
Information on national consumer awareness of TFAs issues *(e.g. terminology,*	The American Heart Association conducted an online consumer research survey in the spring of 2006 with a national sample of 1000 adults 18 to 65 years of age. Results of this market research indicate that when asked if they had heard of the term "trans fats," 84% of the respondents said yes. However, close to half (47%) of the respondents lacked understanding of the health effects of trans fats.[406] Results were even lower for PHOs (68%

[405] https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for

[406] https://www.ncbi.nlm.nih.gov/pubmed/19167956

impact of food choice)	had heard of the term and 67% lacked understanding). Fewer than half of those surveyed could identify any one food as typically containing trans fats, even when asked to choose from a list of foods. The top food identified as containing trans fats was doughnuts (44% of consumers). This compares with the higher knowledge that consumers exhibited regarding foods they thought contained saturated fats. Approximately 70% of consumers surveyed could correctly identify at least 3 foods containing saturated fats from the same list of foods.

Measure impacts

Business responses and costs

Number of business that reformulated their products *(if possible differentiate by large and small companies)*	In New York City, by 2008 an estimated 98 percent of restaurants were not using ingredients containing industrially-produced trans fat, compared with 50 percent in 2005.[407] Many food manufacturers have reformulated their products in the United States to address the need for trans fatty acid reduction. According to the Grocery Manufacturers Association and/or company press releases, as of January 2007, food manufacturers that have made significant efforts to reduce or eliminate partially hydrogenated oils/fats from their product portfolios include Campbell Soup Co, ConAgra Foods, General Mills, The Hershey Company, The J.M. Smucker Co, Johnson & Johnson, Kellogg Co, Kraft Foods, Nestle, PepsiCo, Proctor & Gamble, Sara Lee Corp, The Schwan Food Co, and Unilever.[408]
Evidence of FBO sector facing specific challenges	Some comments as part of the call for comments in response to the 2015 final determination regarding partially hydrogenated oils identified the following challenges: • The **oil industry** will need a minimum of three years to fully commercialise the various oils capable of replacing PHOs in food; and it could take several additional years to reformulate after the development of the new oils. • The **food industry** would prefer to replace PHOs with domestically produced vegetable oils (e.g., high-oleic soybean oil) rather than palm oil, but time is needed to commercialize these options. Some comments stated that sudden demand for palm oil would pose challenges for obtaining sustainably-sourced palm oil, as the current market would likely not be able to meet the demand. • Other comments indicated that the time needed for removal of PHOs is dependent on the product category. A number of comments indicated that the **baking industry** will have difficulty replacing the solid shortenings used in bakery products. Other comments indicated difficulties in the categories of cakes and frostings, fillings for candies, chewing gum, snack

[407] https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for

[408] https://www.ncbi.nlm.nih.gov/pubmed/19167956

bars, and as a component of what the comments termed minor use ingredients, such as for use in coatings, anti-caking agents, encapsulates, emulsifiers, release agents, flavors, and colors.

- Other challenges to PHO removal include the need for new transportation infrastructure (e.g., terminals, rail cars, barges, and storage facilities), packaging changes, and disruption of international trade.
- A number of comments noted challenges faced by **small businesses**, such as 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 comment stated that **small businesses** would need at least 5 years due to their limitations in research and development expertise, inability to command supply of scarce ingredients, and economic pressures of labelling changes.

Comments from the **American Institute of Baking (AIB):**[409]

Challenges faced by the baking sector in moving to trans fatty free solutions:

- Finding substitutes that have the same functionality e.g. extending shelf-life, improving texture. The challenge is particularly large in the manufacture of cakes, cookies, biscuits, pie crusts, pastries and doughnuts.
- In the food service environment, restaurants and bakeries also have to go through extensive recipe reworking and product testing to ensure trans fat free products meet taste, texture and shelf life standards.
- Particular challenge related to finding trans fat-free shortenings without increasing saturated fat. In food manufacturing and food service, many companies that made a switch to trans fatty acid–free alternatives for their baked goods chose shortenings made with palm oil or butter.

The **restaurant industry** raised several objections to trans fat bans including:

- Customers would be dissatisfied with the taste and texture of trans fat free foods;
- National chain restaurants worried that local trans fat bans would interfere with their national product distribution systems or harm their nationwide brand image if products tasted differently in some states;
- The costs of switching to alternative fats were too onerous and would result in higher food costs being passed onto consumers, as well as a disproportionate burden being placed on small, independent restaurants;
- Restaurants would replace trans fats with products high in saturated fat; and
- A rejection was made on philosophical grounds, with the complaint that such laws are paternalistic and it is not the role of government to dictate restaurants' business decisions and

[409] file:///C:/Users/32040/Downloads/2231.full.pdf

	consumers' food choices. However, data shows 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-fat laden fast foods have not decreased significantly in the localities that have implemented trans fat bans; and the costs of switching to trans fat-free alternatives have not resulted in higher restaurant prices. In addition, trans fat-free alternatives have been readily available to restaurants because cooking oil and seed companies anticipated the shift away from hydrogenated oils years before trans fat bans went into effect. Companies began investing in research and accelerating production of trans fat-free alternatives in the 1990s, when the first major studies were released revealing the health risks of trans fat consumption.[410]
For which oils/fats was there a reduction in use and with what were they replaced?	The two most common PHOs currently used by the food industry are partially hydrogenated soybean oil and partially hydrogenated cottonseed oil.[411] It is estimated that roughly 80% of the trans fats Americans consume is from partially hydrogenated vegetable oil.[412] A 2014 study specifically looking at cookies in the US and Canada found that 71% of US cookies contained more than one oil ingredient.[413] In the US, the main fat ingredient was PHVOs in 2006 but by 2012 it was palm oil. By 2012 only 8.3% of cookies in the US used PHVOs as the main oil ingredient. However, many of the shortenings - most of which were made up of hydrogenated fat in combination with another type of oil - included smaller quantities of PHVOs: in the US 31% included PHVOs.[414]
Costs of changes in products and processes *(if possible differentiate by*	**See Additional References for table of costs and benefits for labelling measures.** **PHO removal:** The FDA conducted an economic analysis, reported in the 2015 Final Determination regarding partially hydrogenated oils, which estimated the net present value over 20

[410] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

[411] https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

[412] Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf

[413] https://www.ifama.org/resources/Documents/v17ia/Hooker-Downs.pdf

[414] https://www.ifama.org/resources/Documents/v17ia/Hooker-Downs.pdf

type of cost and include figures)

years of quantified costs to the action will be USD$6.2 billion, with a 90 percent confidence interval of $2.8 billion to $11 billion. They estimate 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) are $130 billion, with a 90 percent confidence interval of $5 billion to $430 billion.[415] **See annex 2 for table of costs and benefits of PHO removal.**

A prior piece of work in 2013 by Bruns placed the total first year costs of eliminating PHOs from the food supply at $8 billion, with several hundred million in costs recurring in out-years.[416] This was made on the assumption that all products containing partially hydrogenated oils will require a reformulation and will also cost 2 percent more as a result of ingredient changes, and that consumers currently using partially hydrogenated oils must also learn new cooking methods and pay more for substitutes. The net present value of these costs over 20 years is about $12 billion at a 7 percent discount rate and $14 billion at a 3 percent discount rate. The document provided a breakdown by type of cost:

Costs for businesses:

- **Reformulation.** A major producer of processed foods reported that reformulating in less than a year cost $25 million for 187 product lines, or $134,000 per product, and after the reformulation the products were fully competitive, with no significant change in price, consumer acceptance, or shelf life. Furthermore, the study estimated that one-time product reformulation cost a total of $2.7 billion. If producers had two years to reformulate rather than one year, the one-time costs of reformulation would fall to $2.3 billion. With three years, the costs would fall to $1.3 billion. This drop in costs is because producers often reformulate products for their own reasons, and required reformulations are less expensive if they can be combined with planned reformulations. However allowing additional time for reformulation was calculated as reducing public health benefits more than reducing industry costs. (These cost estimates only consider processed, packaged foods that bear a Nutrition Facts label. However they estimate that reformulation costs for fast food and food prepared in restaurants, bakeries and other retail food establishments should be lower than for processed, packaged foods).
- **Relabelling.** The average cost of relabelling is about $7,000 per UPC if the change must be made in one year, according to the FDA relabelling model. This means that the one-time relabelling costs would be about $200 million. If producers had two years to relabel rather than one year, the one-time costs of

[415] https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

[416] http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf

relabelling would fall to about $60 million, because many label changes could be coordinated with planned label changes. With three years, the costs would fall to about $40 million.

- **Expected price increases in products because of ingredient substitution.** The 2006 Report of the Trans Fat Conference Planning group lists availability of substitute ingredients as one of the biggest concerns with reformulation. Although the report predicted that supplies of replacements would be readily available at similar prices four years after the report was written, we estimate the costs that would be incurred if substitute ingredients cost 50 percent more, and the PHOs used in packaged food currently account for 4 percent of the price consumers pay for food products, meaning that the total amount spent on these packaged foods would increase by 2 percent. Assuming a 2% increase, the study estimated a total economic cost of $340 million each year. The Net Present Value (NPV) of 20 years of increased product costs, discounted at 7 percent, is $3.6 billion. These costs are likely a low estimate as they do not include food products served in restaurants.

Costs to consumers include:

- **Cost to consumers for changing recipes.** Consumers spend about $120 million each year on vegetable shortening. Assuming that substitute ingredients cost them 50 percent more, consumers would have to spend $60 million more per year for the more expensive ingredients for their recipes. The NPV of 20 years of these increased costs, discounted at 7 percent, is $630 million. Substitute ingredients may require different cooking methods or recipes. If 50 million households currently cook or bake with PHO-containing ingredients, and it takes an average of three hours to learn how to cook with replacement ingredients, then consumers would spend 150 million hours adjusting to the removal of PHO-containing ingredients from the food supply. If this time is valued at the average hourly compensation of $31, then the cost of this adjustment would be $4.7 billion. The total cost to consumers for changing recipes would then be $5.3 billion.
- **Consumers not being able to enjoy products and recipes that cannot be successfully reformulated.** There may be some loss of consumer surplus as a result of their removal from the market. However, producers of vegetable shortening should be able to produce substitute shortenings that contain only fully hydrogenated and non-hydrogenated vegetable oils, because such products have been available in the past at a similar cost. We are unable to estimate a cost for this potential issue.

NPV, $Billions, discounted over 20 years at	7%	3%
1. Reformulation Costs	$2.7	$2.7
2. Relabeling Costs	$0.2	$0.2
3. Ingredient Substitution Costs	$3.6	$5.0
4. Cost to Consumers for Changing Recipes	$5.3	$5.6

	Another study by Cohen in 2014 provided a cost effectiveness value for the trans fat ban, namely the unit cost incurred by the ban per QALY gained.[417] They calculated a cost effectiveness value of between $16,000 to $35,000 per QALY.
Cost of understanding/ learning the measure for FBOs	Information not found.

Consumer prices and choice

Evidence of changes in the price of reformulated products	See section on costs of products and processes above.
Evidence of price differences between products with iTFAs and alternatives	See section on costs of products and processes above. A 2014 study looking at the changing trans fat content and price of cookies in the US and Canada 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.[418] Median price per 100 grams was $US 0.75 (interquartile range: USD 0.46, USD 1.48) in US cookies containing trans fat as compared to USD 1.36 (interquartile range: USD 0.82, USD 2.66) in cookies without trans fat (p<.001).
Evidence of changes in the range, quality or taste of products available	One study looked at the percentage of successful new products with and without trans fats.[419] It found that trans fat-free products were more successful in 9 out of 16 food categories in which comparisons are possible (See Annex 6 for the breakdowns).
Evidence of changes in TFAs consumption	See above
Effect on	See above

[417] Cohen, J. (2014) Commentary: FDA's proposed ban on Trans Fats: How do the costs and benefits stack up? Clinical Therapeutics; volume 36, No.3. Available at: http://www.clinicaltherapeutics.com/article/S0149-2918(14)00016-2/pdf

[418] https://www.ifama.org/resources/Documents/v17ia/Hooker-Downs.pdf

[419] https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

consumer information and awareness	

Health effects

Evidence of benefits on consumer health *(if possible differentiate by age and socio-economic group)*	The reformulation that has occurred because of the labelling rule achieved about 5/7 of the benefit of eliminating industrially produced trans fatty acids from the diet, preventing about 8,000 to 18,000 deaths per year. Elimination of industrially produced trans fatty acids from the diet would save an additional 3,000 to 7,000 lives from coronary heart disease annually according to CDC estimates.[420] Monetizing the lives saved, along with the value of the nonfatal illnesses and medical expenses prevented, yields an estimated benefit of $14.7 billion dollars per year, starting three years after the elimination of partially hydrogenated oils from the food supply. Over a 20-year period, eliminating PHOs from the food supply would generate benefits of about $117 billion discounted at 7 percent, or 242 billion discounted at 3 percent. Subtracting costs from benefits yields an estimated $105 billion in net benefits over 20 years, discounted at 7 percent, or $228 billion discounted at 3 percent:[421] **Expected Annual Benefit** | **Value, 7% discount rate** | **Value, 3% discount rate** 5,000 fatal heart attacks prevented | $8.8 billion | $12.0 billion 15,000 nonfatal attacks prevented | $5.3 billion | $7.3 billion Medical Costs Saved | $0.6 billion | $0.7 billion However, using more recent research (a 2009 article in the European Journal of Clinical Nutrition) which updates the estimate of harm caused by PHOs, the research team updated their estimates as follows: **Expected Annual Benefit** | **Value, 7% discount rate** 15,000 fatal heart attacks prevented | $27.1 billion 58,000 nonfatal attacks prevented | $20.8 billion Medical Costs Saved | $2.2 billion Using this data, the total Net Present Value of 20 years of these benefits is about $399 billion. If only the benefits of the lowest estimate of 3,000 lives saved was counted, with no value placed on nonfatal illnesses prevented, the benefits would be $5.3 billion annually, generating a NPV of $42 billion. The research team

[420] http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf

[421] http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf

	tested the pessimistic assumption that all products would require a critical reformulation, with the extremely pessimistic assumption that the consumer price of packaged food with PHOs would increase by 10 percent. In this case, the total NPV of costs of this action would be $28 billion. Subtracting these high costs from the low benefits of $42 billion gives net benefits of about $14 billion. New York Trans fat ban: a June 2017 study found that between 2002 and 2013, there was an additional 6.2% decline in hospital admissions for myocardial infarction and stroke among populations living in counties with vs without trans-fatty acid restrictions. The decline in events reached statistical significance three or more years after restrictions were implemented.[422]
Evidence of change in saturated fats intake	A study[423] investigating levels of trans fat and saturated fat in major brand-name US supermarket and restaurant foods that were reformulated (83 products: 58 supermarket foods and 25 restaurant foods) showed that **between 1993-2006 and 2008-2009, the amount of trans fat decreased, and 65% of the supermarket products and 90% of the restaurant products had levels of saturated fat that were lower, unchanged, or only slightly higher (<0.5 g per serving) than before reformulation.** The average content of saturated fat in supermarket foods increased slightly owing to increases in one third of the products analyzed; the average content of saturated fat in restaurant foods actually decreased. Reductions in levels of trans fat nearly always exceeded any increase in levels of saturated fat; after reformulation, the overall content of both fats combined was reduced in 90% (52 of 58) of the supermarket products and 96% (24 of 25) of the restaurant products, with average total reductions of 1.2 g and 3.9 g per serving, respectively. A second study also suggested that **products with no trans fats are healthier overall.**[424] Products reformulated to reduce trans fats content may be compensated by an increase in saturated fat to preserve the taste of the product. However, we find that in all categories except sweet spreads, the products with trans fats have more saturated fats and more calories than the products without trans fats. The study concluded that their research suggests that if the labeling regulations led companies to reformulate products to reduce trans fats, they did not compensate with higher levels of saturated fats, sodium, or calories (see Annex 8 for a breakdown). Another study looking at the fat contents of US snack foods in response to mandatory trans fat labelling analysed the composition

[422] Brandt EJ, Myerson R, Perraillon MC, Polonsky TS. Hospital Admissions for Myocardial Infarction and Stroke Before and After the Trans-Fatty Acid Restrictions in New York. JAMA Cardiol. 2017; 2(6): 627-634.

[423] http://www.nejm.org/doi/full/10.1056/NEJMc1001841#t=article

[424] https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

	data of over 5000 chip and cookie products introduced for sale between 2001 (pre-labelling) and 2009 (post-labelling).[425] Despite a decrease in trans fat content, in cookies, there was an increase of 0·49 (98 % CI 0·01, 0·98) g in the average saturated fat content per 30 g serving and an increase of 9 (98 % CI 3, 15) % in the average ratio of saturated to total fat. No statistically significant changes in fat content were observed in chips.[426] New York Trans fat ban: **Preliminary analyses suggest that replacement of artificial trans fat has resulted in products with more healthful fatty acid profiles**. For example, in major restaurant chains, total saturated fat plus trans fat in French fries decreased by more than 50%.[427] Another study also found that a statistically significant decrease in trans fat content of restaurant food was not combined with a commensurate increase in saturated fat. The final sample included 6969 purchases in 2007 and 7885 purchases in 2009. Overall, mean trans fat per purchase decreased by 2.4 g (95% CI, -2.8 to -2.0 g; P < 0.001), whereas saturated fat showed a slight increase of 0.55 g (CI, 0.1 to 1.0 g; P = 0.011). Mean trans plus saturated fat content decreased by 1.9 g overall (CI, -2.5 to -1.2 g; P < 0.001). Mean trans fat per 1000 kcal decreased by 2.7 g per 1000 kcal (CI, -3.1 to -2.3 g per 1000 kcal; P < 0.001). Purchases with zero grams of trans fat increased from 32% to 59%.[428]

Competition, innovation and trade

Effect on competition in the domestic market	No information found.
Changes in trade of affected goods	No information found.
Effect on innovation among suppliers *(i.e. reformulation and/or changes in production processes)*	No information found.

[425] https://www.ncbi.nlm.nih.gov/pubmed/22314147

[426] https://www.ncbi.nlm.nih.gov/pubmed/22314147

[427] Angell, S. Y., Silver, L. D., Goldstein, G. P., Johnson, C. M., Deitcher, D. R., Frieden, T. R., & Bassett, M. T. (2009). Cholesterol control beyond the clinic: New York City's trans fat restriction. Annals of Internal Medicine, 151(2), 129-134.

[428] Angell, S. Y., Cobb, L. K., Curtis, C. J., Konty, K. J., & Silver, L. D. (2012). Change in Trans Fatty Acid Content of Fast-Food Purchases Associated With New York City's Restaurant RegulationA Pre–Post Study. Annals of Internal Medicine, 157(2), 81-86.

Administrative burdens

Number of businesses required to provide information	No information found.
Evidence of economic burden associated with compliance for FBOs *(obtain cost data if possible)*	See section above on costs of processes
Evidence of authorities' effort to enforce/monitor measure *(obtain cost data if possible)*	From the FDA final decision for the trans fat ban: "Although we are mindful of the need to focus our enforcement efforts, those needs do not change the underlying law or FDA's legal authority. Food that is adulterated may be subject to seizure and distributors, manufacturers, and other parties responsible for such food may be subject to injunction. We recognize that manufacturers who have previously added PHO to food, rather than other parties such as distributors who merely receive and sell finished foods, are the members of the food industry who will be most directly affected by this order, and we intend to focus our outreach and enforcement resources accordingly."[429]

Environmental impacts

Evidence of any environmental costs or benefits	From the Final Determination regarding PHOs: "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."[430]
Evidence of increase in demand for palm oil / other ingredients	No information found.
Effects on	No information found.

[429] https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

[430] https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

deforestation resulting from variation in demand of ingredients *(e.g. palm oil, soy)*	

Additional references

https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/trans-fatty-acids-europe-where-do-we-stand

Otite FO, Jacobson MF, Dahmubed A, Mozaffarian D. Trends in trans fatty acids reformulations of US supermarket and brand-name foods from 2007 through 2011. Prev Chronic Dis 2013;10:E85.

Costs and benefits of menu labelling and vending machine rules (in millions)

	Rate	Potential benefits	Estimated costs	Net benefits
Total for Labelling (menu and vending rules) over 20 years*	3	$9,221.3	$1,697.9	$7,523.4
	7	6,752.8	1,333.9	5,418.9
Annualized for Labelling (menu and vending rules) over 20 years*	3	601.9	110.8	491.1
	7	595.5	117.6	477.9
Total for Menu Labelling over 20 years	3	9,221.3	1,166.8	8,054.5
	7	6,752.8	932.8	5,820.0
Annualized for Menu Labelling over 20 years	3	601.9	76.9	525.01
	7	595.5	84.5	510.99

* Benefits for the vending machine labelling rule are not quantified and are not counted in these values.
Source: https://www.federalregister.gov/documents/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food

Costs and benefits of PHO Removal, USD Billions

20-Year net present value of	Low Estimate	Mean	High Estimate
Costs *	$2.8	$6.2	$11

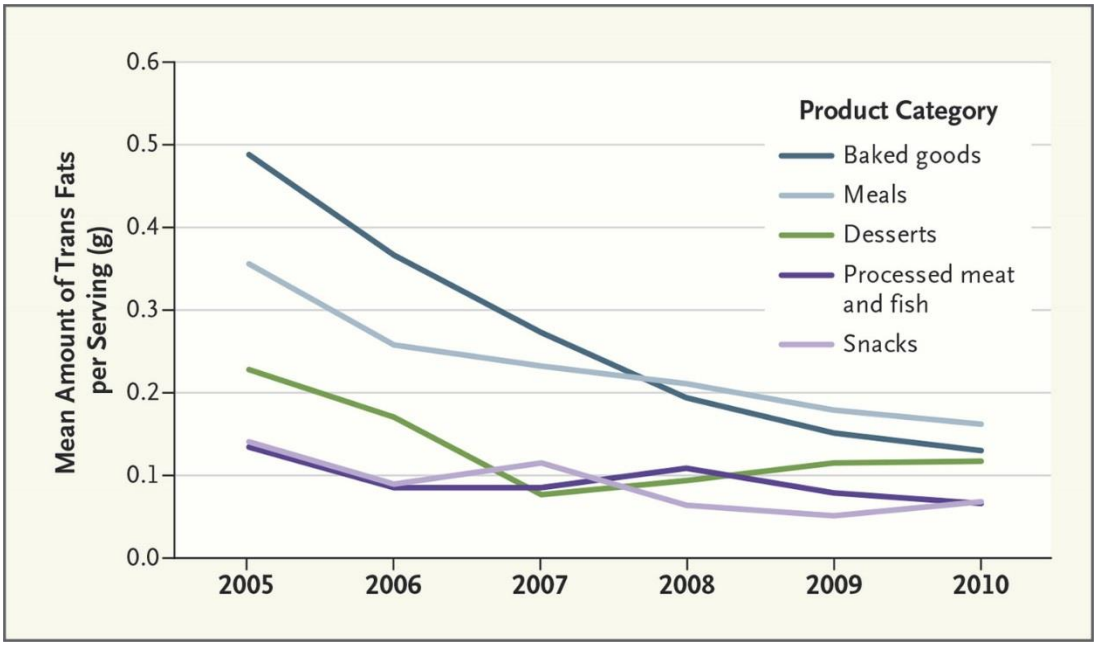
	Rate	Potential benefits	Estimated costs	Net benefits
Benefits		11	140	440
Net Benefits *		5	130	430

* This does not include some unquantified costs, see the economic estimate memo (Ref. 17) for discussion.

Source: https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

	Rate	Potential benefits	Estimated costs	Net benefits

Amount of trans fats found in products with the highest trans fat content (2005-2010)



Data are calculations from the U.S. Department of Agriculture Economic Research Service, which are based on data from the Mintel Global New Products Database.

Source: http://www.nejm.org/doi/full/10.1056/NEJMp1314072#t=article

Contribution of Various Foods to Trans Fat Intake in the American Diet (Mean Intake = 5.84 g) (data collected 1994-1996)

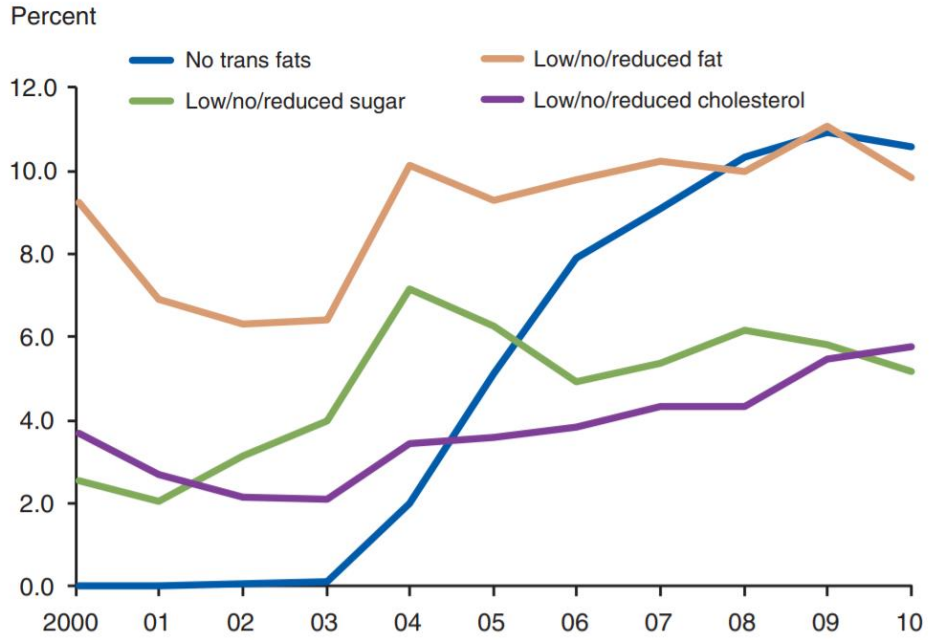
The major dietary sources of *trans* fats listed in decreasing order. Processed foods and oils provide approximately 80 percent of *trans* fats in the diet, compared to 20 percent that occur naturally in food from animal sources. *Trans* fats content of certain processed foods has changed and is likely to continue to change as the industry reformulates products.

Food Group	Contribution (percent of total *trans* fats consumed)
Cakes, cookies, crackers, pies, bread, etc.	40
Animal products	21
Margarine	17
Fried potatoes	8
Potato chips, corn chips, popcorn	5
Household shortening	4
Other[a]	5

[a] Includes breakfast cereal and candy. USDA analysis reported 0 grams of *trans* fats in salad dressing.

Source: Adapted from *Federal Register* notice. *Food Labeling; Trans Fatty Acids in Nutrition Labeling; Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Final Rule and Proposed Rule*. Vol. 68, No. 133, p. 41433-41506, July 11, 2003. Data collected 1994-1996.

Figure 4
Percentage of new products with a "no trans fats" claim compared with other leading nutrient claims, annually, 2000-10



Source: USDA, Economic Research Service calculations based on Mintel Global New Product Database data.

Figure 5
Percentage of new products with a "no trans fats" claim, by product category, 2004-10

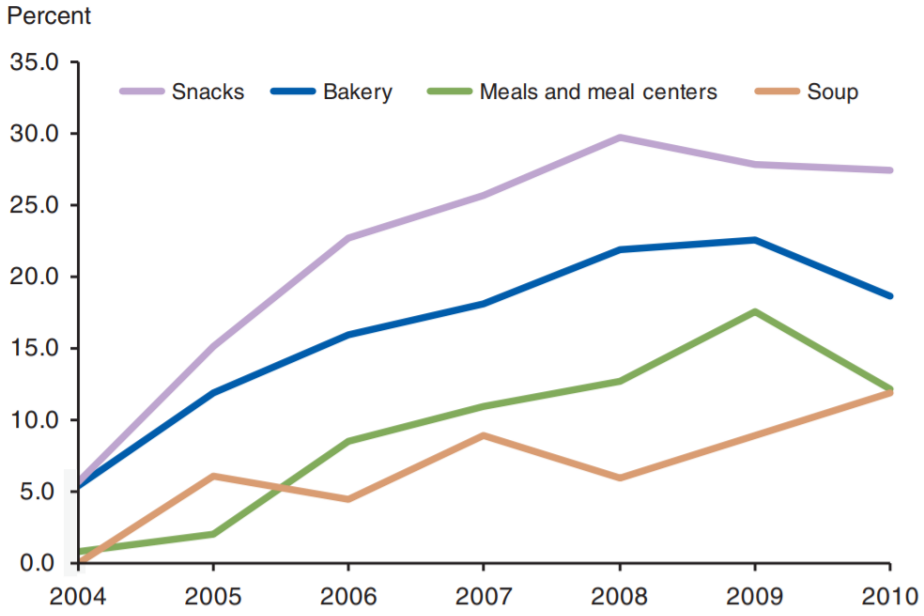
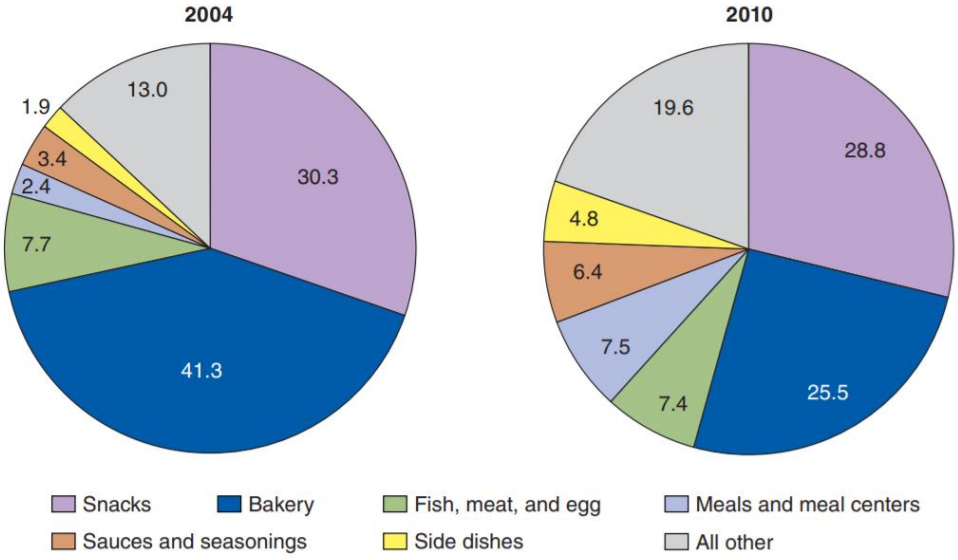


Figure 6
Percentage of all new food product introductions with a "no trans fats" claim accounted for by select product categories, 2004 and 2010



Meals and meal centers = instant noodles, pasta, rice, meal kits, pastry dishes, pizzas, prepared meals, salads, and sandwiches/wraps.

Source: USDA, Economic Research Service calculations based on Mintel Global New Product Database data.

Source:
https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

Success rates of the products with and without trans fats, 2006-10

	Products with trans fats	Products without trans fats	Share of products with trans fats
Category	*Success rates*[1]		
	----------*Percent*----------		
Baby food	na	39.0	0.0
Bakery	23.9	24.3	15.0
Breakfast cereals	0.0	22.2	0.6
Chocolate confectionery	24.4	29.7	3.2
Dairy	12.5	19.8	3.4
Desserts, ice cream	21.9	30.3	8.9
Fruits, vegetables	50.0	15.5	0.3
Meals and meal centers	31.8	26.0	15.1
Nonalcoholic beverages	0.0	27.2	0.9
Processed fish, meat, and egg products	18.6	20.8	7.5
Sauces, seasonings	15.4	18.0	0.6
Savory spreads	20.0	19.6	3.0
Side dishes	26.2	17.8	3.7
Snacks	16.7	29.3	4.1
Soup	15.2	18.9	4.7
Sugar, gum confectionery	31.7	31.1	1.8
Sweet spreads	25.0	12.8	0.5
Sweeteners and sugar	na	14.6	0.0

[1]We define the product to be successful if it is sold in at least 1 percent of the stores tracked by IRI.

Meals and meal centers = instant noodles, pasta, rice, meal kits, pastry dishes, pizzas, prepared meals, salads, and sandwiches/wraps.

na = Shares cannot be calculated due to the absence of products with trans fats.

Source: USDA, Economic Research Service calculations based on Mintel Global New Products Database data and SymphonyIRI Group data.

Table 3
Percentage of new products containing no trans fats that are successful, with and without "no trans fats" labels, 2006-10

	"No trans fats" claimers	"No trans fats" nonclaimers	Share of qualified products with "no trans fats" claim
Category	*Success rates*[1]		
	----------*Percent*----------		
Baby food	60.9	36.7	9.5
Bakery	32.4	21.9	23.1
Breakfast cereals	38.2	20.0	11.9
Chocolate confectionery	41.8	29.4	2.4
Dairy	18.5	19.9	7.9
Desserts, ice cream	35.7	30.0	4.9
Fruits, vegetables	6.1	15.7	2.3
Meals and meal centers	33.6	24.8	13.4
Nonalcoholic beverages	12.5	27.4	1.5
Processed fish, meat, and egg products	31.7	19.3	12.0
Sauces, seasonings	25.6	17.6	4.8
Savory spreads	43.2	17.6	7.6
Side dishes	23.6	17.2	10.2
Snacks	37.1	26.4	27.5
Soup	30.4	17.9	8.4
Sugar, gum confectionery	35.7	31.0	1.9
Sweet spreads	26.3	11.4	9.6
Sweeteners, sugar	0.0	15.0	2.4

[1]We define the product to be successful if it is sold in at least 1 percent of the stores tracked by IRI.

Meals and meal centers = instant noodles, pasta, rice, meal kits, pastry dishes, pizzas, prepared meals, salads, and sandwiches/wraps.

Source: USDA, Economic Research Service calculations based on Mintel Global New Products Database data and SymphonyIRI Group data.

Source:
https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

Table 1
Average trans fats content for all new product introductions and for those containing positive levels of trans fats, by product category, 2006-10

Category	Average trans fats content	Share of products with no trans fats	Average trans fats content for products containing trans fats	Total new product introductions
	Grams per serving	*Percentage*	*Grams per serving*	*Count*
Baby food	0.00	100.0	0.00	231
Bakery	0.22	86.3	1.67	5,289
Breakfast cereals	0.00	99.7	0.88	1,169
Chocolate confectionery	0.05	96.2	1.40	2,169
Dairy	0.04	96.3	1.32	2,349
Desserts and ice cream	0.12	91.7	1.43	1,908
Fruits and vegetables	0.00	99.7	0.50	1,288
Meals and meal centers	0.21	85.3	1.41	2,607
Nonalcoholic beverages	0.01	99.2	1.06	3,684
Processed fish, meat, and egg products	0.08	92.9	1.17	2,945
Sauces, seasonings	0.01	99.4	1.70	4,023
Savory spreads	0.03	97.0	1.07	462
Side dishes	0.05	97.2	1.76	1,469
Snacks	0.08	96.2	2.06	4,294
Soup	0.05	94.8	1.03	638
Sugar, gum confectionery	0.02	98.2	1.14	2,138
Sweet spreads	0.01	99.5	1.13	806
Sweeteners and sugar	0.00	100.0	0.00	159
All new food product introductions	0.08	94.7	1.52	37,628

Meals and meal centers = instant noodles, pasta, rice, meal kits, pastry dishes, pizzas, prepared meals, salads, and sandwiches/wraps.
Source: USDA, Economic Research Service calculations based on Mintel Global New Product Database data.

Source:
https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

Table 4
Nutritional profile of new products containing no trans fats compared with those containing trans fats, 2006-10[1]

Category	With trans fats				Without trans fats			
	Calories	Sugar	Sodium	Saturated fat	Calories	Sugar	Sodium	Saturated fat
		Grams	*Milligrams*	*Grams*		*Grams*	*Milligrams*	*Grams*
Baby food	na	na	na	na	77	6.3	48.9	0.5
Bakery	193.5	13.9	192.2	3.0	149.6	9.2	171.2	2.0
Breakfast cereals	245.0	17.3	213.8	1.1	148.9	9.5	142.0	0.3
Chocolate confectionery	215.0	22.1	44.6	6.8	192.8	18.0	40.6	6.5
Dairy	105.6	4.0	170.6	3.9	101.3	7.5	146.3	3.1
Desserts, ice cream	316.2	24.7	174.0	9.9	144.8	15.8	68.8	3.8
Fruit, vegetables	160.0	8.8	402.5	3.1	72.0	6.9	147.0	0.2
Meals and meal centers	354.9	4.6	839.5	6.6	278.0	5.1	673.8	3.7
Nonalcoholic beverages	131.2	20.0	122.1	1.2	82.9	17.9	54.6	0.7
Processed fish, meat, and egg products	274.4	1.3	516.4	7.7	149.4	1.8	441.2	2.5
Sauces, seasonings	115.8	1.1	305.8	2.4	48.4	3.3	237.2	0.8
Savory spreads	63.9	0.9	176.4	1.4	57.8	1.4	171.7	1.3
Side dishes	210.5	2.5	480.6	3.3	183.3	2.0	268.9	1.0
Snacks	176.8	3.9	331.9	3.0	145.8	6.1	183.1	1.7
Soup	223.9	4.3	795.3	6.7	119.4	3.3	691.4	1.5
Sugar, gum confectionery	145.8	17.9	57.4	1.6	95.4	15.7	22.7	0.9
Sweet spreads	97.5	9.0	67.5	1.2	105.7	13.7	35.6	1.4
Sweeteners, sugar	na	na	na	na	14.9	4.4	0.4	0.0

[1]Table contains average nutrient content per serving size of products containing no trans fats (for both "claimers" and "nonclaimers") and the nutrient content of products containing trans fats. For baby food and sweeteners, there were no products with trans fats introduced in the period studied.
Meals and meal centers = instant noodles, pasta, rice, meal kits, pastry dishes, pizzas, prepared meals, salads, and sandwiches/wraps.
na = No new products containing trans fats.
Source: USDA, Economic Research Service calculations based on Mintel Global New Products Database data.

Source: https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192

Annex 9 Business population data

Annex provided separately in Excel format

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