



EUROPEAN COMMISSION

Brussels, 18.06.2018
SEC(2019) 187 final

REGULATORY SCRUTINY BOARD OPINION

**COMMISSION REGULATION amending Annex III to Regulation (EC)
No 1925/2006 of the European Parliament and of the Council as regards
trans fat, other than trans fat naturally occurring in fat of animal origin**

{C(2019) 2902 final}
{SWD(2019) 161 final}
{SWD(2019) 162 final}



EUROPEAN COMMISSION

Regulatory Scrutiny Board

Brussels,

Ares(2018)

Opinion

Title: Impact Assessment / Limiting trans fats intake in the EU

(version of 16 May 2018)*

Overall opinion: POSITIVE

(A) Context

Trans fats (TFAs) are a type of unsaturated fat used in food to improve e.g. its stability or texture. TFAs are present naturally in ruminant and dairy products and can also be made synthetically in the case of industrial trans fats. Evidence suggests that TFA intake raises the risk of, in particular, coronary heart and artery diseases and cardio vascular disease. Seven EU Member States have legislation that restricts industrial trans fats. Some third countries, including the United States and Canada, have banned industrial trans fats. Calls for EU action have come from the European Parliament and the Council, Member States and stakeholders. There is reportedly also support from industry and consumers.

This impact assessment explores options to reduce industrial TFA use in the EU. It examines economic, social and environmental consequences of alternative measures.

(B) Main considerations

The Board takes note of additional written information provided by the lead DG ahead of the meeting and the commitment to amend the report to address the Board's earlier written comments.

The Board gives a positive opinion, with a recommendation to further improve the report with respect to the following key aspects:

- (1) The need for alternative baselines is not well justified.**
- (2) The report does not clearly explain how limiting trans fats content in foods would lead to better outcomes than banning partly hydrogenated oils.**
- (3) Implications of the proposed measure for the food sector and for SMEs remain unclear.**

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted.

(C) Further considerations and recommendations for improvement

(1) The report should further justify the use of alternative baseline scenarios. It would be preferable to select the most likely scenario as baseline and to include the others in the impacts section as sensitivity analysis. The report should elaborate on the reasons for questioning the validity of the JRC projections and provide additional evidence of the levelling-off of the downward trend in TFA intake across Europe. It should also further acknowledge uncertainties surrounding this trend, and stress the reasons for increase of TFA intake in some regions. It could better indicate the distribution and size of population subgroups at risk of excessive TFA intake. The report could better explain that existing instruments (such as voluntary industry initiatives) have reached their limits. The introduction could also better reflect the ongoing global trend in terms of adopting legal measures to limit TFA intakes. Building on these elements, the description of the need to act could better reflect potential reputational risks for the EU in case of inaction.

(2) The report should better explain the differences between the option to set an upper limit on TFA content and the option to ban partly hydrogenated oils. The impacts section should more clearly explain why the two options have identical expected health benefits. The report could explain why a more ambitious option in terms of health benefits was not envisaged. The report should also better justify the proposed threshold and explain why it does not consider alternative options such as a limit below 2% of total fat content as feasible. It should more clearly compare them in terms of scope, approach, potential implementation issues and impacts on health as well as for businesses.

(3) The report could refine its analysis of the impacts of the proposed measures on the food sector, including the costs for SMEs. It could better describe the market structure of the relevant food sector(s) and describe how the measures might impact different actors in the food value chain. A revised intervention logic could support such an explanation by illustrating the channels through which trans fats enter the food chain and the stages at which different measures propose to intervene. The report could also expand on planned mitigation measures, e.g. in terms of transition periods.

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

The Board takes note of the quantification of the various costs and benefits associated to the preferred option of this initiative, as assessed in the report considered by the Board and summarised in the attached quantification tables.

Some more technical comments have been transmitted directly to the author DG.

(D) RSB scrutiny process

The lead DG shall ensure that the recommendations of the Board are taken into account in the report prior to launching the interservice consultation.

The attached quantification tables may need to be adjusted to reflect any changes in the choice or the design of the preferred option in the final version of the report.

Full title	Initiative to limit industrial trans fats intake in the EU
Reference number	2016/SANTE/143
Date of RSB meeting	13/06/2018

ANNEX: Quantification tables extracted from the draft impact assessment report submitted to the Board on 16/05/2018

(N.B. The following tables present information on the costs and benefits of the initiative in question. These tables have been extracted from the draft impact assessment report submitted to the Regulatory Scrutiny Board on which the Board has given the opinion presented above. It is possible, therefore, that the content of the tables presented below are different from those in the final version of the impact assessment report published by the Commission as the draft report may have been revised in line with the Board's recommendations.)

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

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

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