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## TRANS FATTY ACIDS IN FOOD – CURRENT LEGAL REGULATIONS AS PROTECTIONS FOR CONSUMERS AND FOOD MANUFACTURERS

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It was the goal of this paper to introduce selected regulatory models concerning the legal status of trans fatty acids in connection with the consumer's position and to propose some *de lege ferenda* conclusions.

Legislation, treatises, periodicals, and bulletins have been analysed. Information from portals associated with the European Union and posted on official websites of organizations like the WHO is presented.

As comprehensive descriptions of individual states' approaches to trans fats' presence in the human diet are not available, an attempt was undertaken to obtain as broad a range of positions as possible, of states willing to take part in the study. Alongside research based on responses from Health Ministries of the EU member countries and three states from outside the EU, its conclusions, observable trends, and solutions proposed to minimize content of trans fatty acids are an essential part of this study.

Analysis of legislation and positions on trans fatty acids presence in food submitted by the states demonstrated the need for a consistent, overall regulation of the issue. The authors relied on the information generated to outline such solutions.

**Keywords:** health, trans fatty acids, food safety, hazards, labelling

Due to the hazard posed by trans fatty acids (TFAs) in food, particularly their direct relationship with incidence of coronary artery disease, they have become an object of interest for international and EU law (RESTREPO & RIEGER, 2016; EPRS, 2016; WILKINS et al., 2017).

TFAs, regardless of the source, also contribute to the increase in plasma triacylglycerols. They can also promote weight and fat increase, have an effect on fat metabolism, and can reduce the sensitivity of tissues to insulin (ŻBIKOWSKA et al., 2015). They cause an increase in total cholesterol, an increase in the concentration of LDL, and a lowering of HDL - this increases the risk of atherosclerosis (DHAKA et al., 2011). In addition, they cause excessive release of insulin in response to a glucose load, weakening of the immune response, disturbance of sperm production, and increase in the production of free radicals (DHAKA et al., 2011). TFAs may be responsible for low birth weight, development of pre-eclampsia and pregnancy-induced hypertension, insulin resistance, or allergies (MOURATIDOU et al., 2014).

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The need to develop a comprehensive approach has been noted to minimise presence of these substances in food in the long term. Merely a positive tendency towards lower TFA consumption can be mentioned at the present stage (RITVANEN et al., 2012; MENAA et al., 2013).

Intensive EU legislative efforts can trigger the minimisation of trans fatty acids in food. It also drives internal initiatives by member states. Research, growing interest of national legislators, and increasing responsibility of industry tend to move in a consistent direction – representing a pro-consumer view (KUHNNT et al., 2011; EC, 2015). It is therefore important to determine to what extent trans fats are present in food and whether there are sufficient ways of eliminating or effectively reducing them in food products.

### 1. Materials and methods

Research material consisting of selected international and EU regulations that provide a normative framework for limits of trans fatty acid content in food has been analysed using the dogmatic-exegetical method. The dogmatic-exegetical method, which is suitable for the legal analysis in this study, was used to study the normative material in order to determine the applicable law at a given time in a given territory. The critical interpretation of texts, in particular the legal ones, allowed determining the current trends.

Contents and documents have been analysed in order to highlight the issue's currency and its essential significance from the public viewpoint. Comparative law has been applied in addition, given the specific nature of the study.

Sociological research using interviews has been conducted as part of the empirical section. This method is necessary when exploring the operation of law, that is, not only its formulation but actual practice. It helps to survey law in action.

The project lasted from 11 July 2017 to 30 October 2017. Queries were distributed to all health ministries of the European Union member states, as well as of Switzerland, Russia, the United States, Canada, and China. Responses came from twelve European countries and three states from outside the EU. Countries that responded were: USA, Canada, Switzerland, Ireland, Great Britain, Germany, Hungary, Czech Republic, Lithuania, Latvia, Slovenia, Bulgaria, Finland, Cyprus, and the Netherlands. The interview was sent by e-mail to legal departments of the indicated ministries. The questionnaire contained open-ended questions. The following questions were addressed to each country:

1. are legal regulations for trans fatty acids valid in your country?
2. if yes, when were they introduced?
3. what is their scope?

Our comparative studies were based on the data provided by BATES and co-workers (2011) and DOWNS and co-workers (2013), the scientific report on the status of trans fats in Europe (MOURATIDOU et al., 2014), and the data obtained from the Commission's report for the European Parliament and the Council (EC, 2015).

Interview contacts with Health Ministries in 2017 were another major part of the analysis of states' positions on regulation of trans fats in food. Feedback came from Ireland, Slovenia, Cyprus, Lithuania, Bulgaria, the Czech Republic, and Spain, inter alia.

Analysis of the authors' own research was based on the method of comprehension. The empirical study representing the functional aspect has helped to broaden the cognitive

perspective and indicate recommended legislative solutions in order to enhance legal awareness of consumers and ensure their effective protection.

### *1.1. Definitions of trans fatty acids in the EU legislation*

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

The regulation contains the legal definition of trans fatty acids 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’ (EC, 2011).

The European Parliament Resolution of 26 October 2016 on trans fats (2016/2637(RSP); EP, 2016), based on the sources listed in Table 1, is an important recent EU document in the matter. The table compiles legislation, reports, guidelines, and scientific opinions concerning recommendations on consumption of TFAs and product groups containing them. These are documents helping potential consumers learn about risks and thus make more conscious decisions.

*Table 1.* Legislation, reports, guidelines, regulations related to trans isomer presence in food and providing grounds for the European Parliament Resolution of 26 October 2016 on trans fats (2016/2637(RSP))

• Regulation (EU) No. 1169/2011 of the European Parliament and the Council on the provision of food information to consumers
• ‘Eliminating trans fats in Europe - A policy brief’
• Draft resolution of the Natural Environment Protection, Public Health and Food Safety Commission
• Scientific opinion of the European Food Safety Authority (EFSA) of 2009 including a recommendation for trans fats consumption and WHO’s ‘The effectiveness of policies for reducing dietary trans fats: a systematic review of the evidence’, WHO Bulletin 2013; 91:262–269H.
• Effects of trans fatty acid intake on blood lipids and lipoproteins: a systematic review and meta-regression analysis
• Joint Research Centre (JRC) report entitled ‘Trans Fatty acids in Europe: where do we stand? A synthesis of the evidence: 2003–2013’
• The Commission’s report for the European Parliament and the Council on presence of trans fatty acids in food and overall diet of the EU population dated 3 December 2015 (COM(2015)0619)

## **2. Results**

### *2.1. Existing legal regulations*

The European Parliament Resolution outlines actions intended to restrict TFA consumption. The Commission is also bound to take specific steps within two years of proclaiming the

Resolution. Its recommendations state products containing TFAs can no longer be ‘regarded as generally safe’ to use in human food and will be banned by June 2018. The Parliament additionally obliges the European Commission to establish in the EU compulsory limits for industrial trans fats in food (as components and final products) as soon as possible in order to restrict their consumption by all social groups. The proposal will also be accompanied by an impact assessment including costs of sectoral transformations resulting from introduction of obligatory limits and potential risk of transferring those costs to consumers (EP, 2016).

The European Food Safety Authority has not specified an acceptable content of trans fatty acids in food in numerical terms (EFSA, 2010). The standard adopted by the World Health Organisation recommends no more than 1% of daily energy intake to be consumed as TFAs (Codex Alimentarius, 1963).

It can generally be said that international, EU, and national legislations concerning TFAs are not uniform, varying from advanced systems to voluntary initiatives by industry and lack of any regulations.

Approaches to restricting TFA content in food and their consumption by populations can in principle be divided into legislative and voluntary measures.

Steps available to legislators include:

- Definition of acceptable TFA content in food agents (individual ingredients or final products) or
- Compulsory information on TFA content as part of information about nutrient value (Supplying of nutrient value information is obligatory at the moment).

Voluntary initiatives by industry comprise:

- Changes of product composition or
- Voluntary inclusion of TFA content in information about nutrient value. (EC, 2015).

The European Commission plans to adopt legislation included in the draft “Commission Regulation establishing a legal limit for the industrial trans fats content in foods” that envisages limiting trans fats in food already in 2017 Management Plan (EC, 2017).

Also, governments can issue dietary recommendations on maximum TFA consumption and adequate sources of these trans fatty acids in food. Table 2 illustrates which of these strategies or measures are currently applied in Europe and elsewhere.

Actions to regulate the legal status concerning minimisation of TFA content were to be undertaken promptly not only at the level of EU legislation but also in legal systems of the member states. Interest of the member states has not been observed to rise significantly. Survey of the data in Table 2 shows the trend towards eliminating or minimising the content of trans fatty acids is not significant.

It can be affirmed, however, that the states first addressing trans fat content (i.e. Canada, the United States, Denmark) effectively and dynamically continue to develop both public and private law initiatives to restrict consumption of products containing trans fats (EPRS, 2006).

Canada published a long-term strategy for healthy diet, part of a government vision of healthy Canada, in October 2016. The strategy concentrates on improvement of information about healthy food, more forceful labelling and statements, protection of vulnerable populations, improved availability of nutritious food products, and improvement of food nutrient quality. Policies aimed at eliminating TFA from food are parts of the strategy (ŻBIKOWSKA et al., 2012; ROE et al., 2013).

Table 2. Examples of states' approaches to restricting TFA content in food

Strategy	European Union 2014 details	Globally 2014 details	European Union 2017 details	Globally 2017 details
States with voluntary industry initiatives	Belgium, Germany, The Netherlands, Poland, United Kingdom, Bulgaria, Malta <sup>1</sup> , Slovakia, Finland, Estonia.	Australia, New Zealand, Columbia, Iceland.	Belgium, Germany, The Netherlands, Poland, United Kingdom, Bulgaria, Malta <sup>2</sup> , Slovakia, Finland, Estonia.	Australia, New Zealand, Columbia, Iceland.
States where there is legislation limiting the content of TFA in foodstuffs	Austria, Latvia, Denmark, Hungary, Sweden, Spain.	Switzerland, USA, Canada, China, Ecuador, Hong Kong, Israel, Jamaica, Malaysia, Mexico, Paraguay, South Korea, Taiwan, Uruguay, Brazil, Argentina.	Austria, Latvia, Denmark, Hungary, Sweden, Czech Republic. <sup>3</sup>	Switzerland, USA, Canada, Ecuador, Hong Kong, Israel, Jamaica, Malaysia, Mexico, Paraguay, South Korea Taiwan, Uruguay, Brazil, Argentina.
States with no content regulations			Spain, Cyprus, Ireland, Lithuania, Latvia, Bulgaria, Slovenia. <sup>4</sup>	
States that failed to respond to our queries			France, Romania, Malta, Slovakia, Hungary, Greece, Portugal, Italy.	Russia, China.

Source: The authors' own compilation based on Health Ministry responses and the Commission's report for the European Parliament and the Council on presence of trans fatty acids in food and overall diet of the EU population standard dated 3.12.2015 COM(2015) 619 final.

Legend:

<sup>1</sup>The information based on the *Commission's report for the European Parliament and the Council on presence of trans fatty acids in food and overall diet of the EU population* dated 3.12.2015. COM(2015) 619 final.

<sup>2</sup>The information based on the *Commission's report for the European Parliament and the Council on presence of trans fatty acids in food and overall diet of the EU population* dated 3.12.2015. COM(2015) 619 final.

<sup>3</sup>Only in respect of certain product groups.

<sup>4</sup>At the stage of public consultation.

Positive steps to introduce stable regulations to states like Latvia, Lithuania, or Slovenia have been noted in comparison with 2014. A regulation on limiting trans fatty acid content in food has been prepared in Slovenia. It is in process of implementation. The new regulation envisages a TFA content limit of 2 g/100g.

Interesting feedback also came from Latvia. Information from the Latvian Health Ministry indicates legislation is scheduled for 1 June 2018 by force of which industry will obtain permission to launch food products containing trans fatty acids above maximum acceptable levels. The following TFA content limits are set in the Latvian national legislation:

- Maximum acceptable content of trans fatty acids in food products is 2 g per 100 g of total fat content, with the following exceptions:
- Maximum acceptable content of trans fatty acids in food products with total fat content below 3% is 10 g per 100 g of total fat content.
- Maximum acceptable content of trans fatty acids in food products with total fat content between 3% and 20% is 4 g per 100 g of total fat content.

The above-mentioned limits allow to observe a satisfactory trend of raising the level of acceptable TFA content.

In turn, the Health Ministry of the Lithuanian Republic has prepared a draft ruling of the Health Minister laying down maximum limits for trans fatty acids in food. The Lithuanian authorities notified the European Union of the draft on 29 June 2017 and the three-month interim period ended on 2 October 2017.

The Czech Republic has in place regulations to minimise trans fat levels in such special food products as: infant food formulas and derivatives and products for sale in schools and educational institutions.

Interest in food containing TFAs in Poland is also growing. In spite of the lack of specific public law regulations, research projects by state institutes (e.g. the National Food and Nutrition Institute) and information campaigns ("The National Programme of Counteracting Modern-Age Diseases") are conducted (DoH, 2011).

EU regulations continue to serve as the point of reference for a majority of states (including Bulgaria, Finland, Cyprus – details from states who failed to declare their positions in 2014). The information from the Health Ministry in Germany implies that country has no distinct regulations and relies on EU standards.

The details in Table 2 point to a group of states where obligatory national regulations are absent, yet lively industry initiatives are developing. Regulations of acceptable trans fatty acid levels other than the standards introduced in the European Union do not exist in Ireland. In general, the Irish industry takes initiatives to modify food, reduce quantities of sugar, salt, calories or fats in final food products. That country can be said, therefore, to be open to limiting dietary content of trans fats themselves and to restrict products containing those compounds. The UK food sector successfully minimises use of partly hydrogenated fats (VERGER et al., 2016). Members of the British retail consortium (ASDA, M & S Cooperative, Morrison, Sainsbury, Tesco, and Waitrose) have successfully removed all products containing hydrogenated oils from their brand-name articles (RATNAYAKE et al., 2008; ANSORENA et al., 2013). Contents of trans fatty acids in food are self-regulated by the industry in the Netherlands. These disciplined efforts have produced satisfactory effects as the substances are virtually non-existent in food (WANDERS et al., 2017).

From the above presented positions it appears that the topic of TFA is noticed on the international arena and is gaining importance. In addition to the approach based on EU

solutions, countries are presenting a trend towards tightening the approach to minimise the level of trans fatty acids.

## 2.2. *Potential for limiting trans fats by public and food manufacturers*

There is a range of examples of effective voluntary changes of product composition by food enterprises, also as part of public-private partnerships. Motivation of food enterprises to apply national strategies for restricting TFA content may be limited if such firms must compete in other parts of the EU market against enterprises offering cheaper products with high TFA contents.

Individual actions of member states may lead to cutting of TFA consumption, but it entails the risk of establishing even more inconsistent regulations that may disrupt efficient operation of the common market. One must realise that the final effect on TFA consumption depends above all on some basic factors, primarily:

- Population's knowledge of nutrition;
- Dietary habits of various population groups in Europe (diverse traditions, different sensitivity to price variations, etc.);
- Consumption of TFAs of ruminant origin (dairy and other ruminant products as part of a balanced diet);
- Possible and actual methods of changing composition of food products to decrease content of industrially produced TFAs.

As far as the latter option is concerned, a change of technology, and thus introduction of new replacement products would have to be considered. Products containing partly hydrogenated fats are the most controversial, while also popular. Such products could be substituted by introduction of solid fats, modified by interesterification, or totally hydrogenated fats to final food products. Obviously, the issue requires bold technological changes, acceptance by both consumers and food manufacturers.

The decision of the US Food and Drugs Administration (FDA) of 16 June 2015 saying, based on a detailed analysis of scientific evidence, that partly hydrogenated oils, the major source of industrially produced TFAs in processed food products, are not 'generally considered safe' for human food, is a noteworthy milestone. Food manufacturers will have three years to remove partly hydrogenated oils from products unless a given article is approved by the FDA. It should be stressed that if action is not taken at the EU level, EU manufacturers interested in access to the United States market might encounter difficulties as well.

Introduction of a legally acceptable limit of TFA content should reduce consumption of industrially produced TFAs to the greatest extent, as it would cause products containing substantial quantities of these trans fatty acids, both packaged and not, to be removed from the market.

Combined with appropriate eating habits, this approach could become the most effective way of achieving full compliance with recommendation of the European Food Safety Authority on TFA consumption, which should be 'as low as possible within a diet of adequate nutrient value'.

The solutions and approaches suggested in the conclusion below are evidently subjective proposals of the authors. They are not distant from views of nutrition scientists or those responsible for food supply, however.

Establishing a pan-EU, harmonised, legally acceptable limit of TFA content would minimise or even eliminate the risk of disrupting the community market with national regulatory solutions.

### 3. Conclusions

The need for a consistent, comprehensive legal regulation of the issue of trans fatty acids has been perceived at both international, EU, and national levels. Relying on analyses and experience of the states that have introduced legislation to limit consumption of products containing these substances, guidelines for solutions may be attempted.

Key possible ways of limiting TFA consumption by means of legislation include:

- Introduction of obligatory information about TFA content,
- Determining a legally acceptable (e.g. at the EU level) limit of TFA content in food,
- Voluntary agreements for restricting TFA content in food and diet,
- Guidelines on legally acceptable limits of TFA content in food to be formulated by international authorities, for instance, or more effectively, developed by the EU institutions.

The authors believe that, at this moment, actions can be limited to the national level or voluntary efforts to restrict these contents as alternative solutions. However, it is important in the long-term perspective to introduce coherent legal solutions at the level of the European Union. In addition, it should be remembered though, the burden of conscious choices will remain with the consumer. Appropriate educational campaigns will be of paramount importance, therefore. Public campaigns to inform consumers about TFAs are the right and necessary ways towards cutting their consumption. Insofar as top-down, even highly restrictive solutions will bind manufacturers to place information on packaging, ignorance on the part of consumers will prevent liquidation of the problem anyway. It is therefore the authors' view that frequent and above all effective raising of consumer awareness is an absolute necessity.

Product labelling is in turn connected with the following key factors:

- Role of products to be labelled,
- Consumers' ability to take appropriate advantage of information supplied on labelling,
- Consumers' readiness to pay more for safer food.

The tendencies arising from the positions taken by the states indicate those to have introduced their regulations earlier have abided by their stands. Following them, therefore, it would be recommendable to establish a consistent acceptable limit for industrially produced TFAs in all countries. Policies of these states confirm such actions are feasible and actively functional. In view of the above, the authors remain convinced such regulations would be the most effective means with regard to public health, consumer protection, and compliance with the internal market.

In summary, if the EU member states set clear limits, they will be on the safe side and caring for consumer safety. The authors see another issue that is difficult to determine, namely, what is the daily limit of trans fats in view of the so-called additivity of diet components. Even if a manufacturer properly secures their goods by providing a safe quantity of trans fats, it does not ensure that consumers may safely eat products including trans fats without harming their health. During one meal the consumer can consume several products containing TFAs, accumulating their consumption, and thus exceeding the recommended dose.



The authors are of the opinion that trans fat concentrations resulting from simultaneous consumption of various compounds containing the trans fatty acids continue to be unknown. The only definite solution, therefore, would be to utterly remove products containing trans fatty acids arising in the industrial process. Is such a regulation or solution at all possible though?

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