

**COMMISSION REGULATION (EU) 2019/649****of 24 April 2019****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****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods <sup>(1)</sup>, and in particular Article 8(2) thereof,

Whereas:

- (1) In accordance with Regulation (EC) No 1925/2006, the Commission may, on its own initiative, take a decision to include a substance, other than a vitamin or mineral, or an ingredient containing such substance in Annex III to that Regulation, listing the substances whose use in foods is prohibited, restricted or under Union scrutiny, if that substance is associated with a potential risk to consumers as provided for in Article 8(1) of that Regulation.
- (2) On 4 December 2009, the European Food Safety Authority (hereinafter 'the Authority') adopted a scientific opinion <sup>(2)</sup> concluding that the intake of trans fatty acids should be as low as possible within the context of a nutritionally adequate diet.
- (3) On 3 December 2015, the Commission adopted a report on trans fats in foods and in the overall diet of the Union population <sup>(3)</sup>. The report recalled that coronary heart disease is the leading cause of death in the Union and a high intake of trans fats seriously increases the risk of heart disease, more than any other nutrient on a per calorie basis.
- (4) The report concluded that establishing a legal limit for industrial trans fats in food appears to be the most effective measure in terms of public health, consumer protection and compatibility with the internal market.
- (5) On 30 April 2018, the Commission asked the Authority to compile the outcomes of scientific advice already provided by the Authority on the health effects of trans fats, in particular on nutrition and health claims, dietary reference values and food additives; and to inform the Commission on how such scientific advice relates to current goals and recommendations on the intake of trans fats to maintain health.
- (6) On 19 June 2018, the Authority provided its conclusion in the form of scientific and technical assistance. It concluded <sup>(4)</sup> based on review of available scientific evidence that according to the latest national and international recommendations, dietary intakes of trans fatty acids should be as low as possible.
- (7) On 15 May 2018, the World Health Organisation called for the elimination of industrially-produced trans fatty acids from global food supply <sup>(5)</sup>.
- (8) Trans fat is a substance other than vitamins and minerals for which harmful effects on health have been identified. The substance should therefore be placed in Part B of Annex III to Regulation (EC) No 1925/2006 and its addition to foods or its use in the manufacture of foods should only be allowed under the conditions specified in that Annex, in view of the current state of scientific and technical knowledge.

<sup>(1)</sup> OJ L 404, 30.12.2006, p. 26.

<sup>(2)</sup> EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); 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.

<sup>(3)</sup> COM(2015)619 final of 3.12.2015.

<sup>(4)</sup> EFSA, 2018. Scientific and technical assistance on trans fatty acids. EFSA supporting publication 2018:EN-1433. 16 pp. doi:10.2903/sp.efsa.2018.EN-1433.

<sup>(5)</sup> REPLACE – an Action package to eliminate industrially-produced trans fatty acids, reference WHO/NMH/NHD/18.4, May 2018.

- (9) The definitions of 'fat' and of 'trans fat' set out in Annex I of Regulation (EC) No 1169/2011 of the European Parliament and of the Council <sup>(6)</sup> and of 'retail' set out in Article 3(7) of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(7)</sup> should apply to the relevant terms in Part B of Annex III to Regulation (EC) No 1925/2006.
- (10) In order to facilitate the application of this Regulation, it is necessary to require from food business operators supplying food to other food business operators with the exception of retailers, to provide them with the information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat.
- (11) In order to enable food business operators to adapt to the new requirements which will result from this Regulation, appropriate transitional measures should be adopted.
- (12) Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

The content of trans fat, other than trans fat naturally occurring in fat of animal origin, in food intended for the final consumer and food intended for supply to retail, shall not exceed 2 grams per 100 grams of fat.

#### *Article 2*

Food business operators supplying other food business operators with food not intended for the final consumer or not intended for supply to retail, shall ensure that supplied food business operators are provided with information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat.

#### *Article 3*

Part B of Annex III to Regulation (EC) No 1925/2006 is amended in accordance with the Annex to this Regulation.

#### *Article 4*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Food which does not comply with this Regulation may continue to be placed on the market until 1 April 2021.

<sup>(6)</sup> 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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

<sup>(7)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 April 2019.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

In Part B of Annex III to Regulation (EC) No 1925/2006 the following table is inserted:

## 'PART B

**Restricted substances**

Restricted substance	Conditions of use	Additional requirements
<b>Trans fat</b> other than trans fat naturally occurring in fat of animal origin	<i>Maximum 2 grams per 100 grams of fat</i> in food intended for the final consumer and food intended for supply to retail	Food business operators supplying other food business operators with food not intended for the final consumer or not intended for supply to retail, shall ensure that supplied food business operators are provided with information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat.'