



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10819/2018
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[...] (2018) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**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 animal
fat, in foods intended for the final consumer**

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) .../...

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(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 foods¹, 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 opinion² 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 population³. 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.

¹ OJ L 404, 30.12.2006, p. 26.

² 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.

³ COM(2015)619 final of 3.12.2015.

- (6) On 19 June 2018, the Authority provided its conclusion in the form of scientific and technical assistance. It concluded⁴ 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 supply⁵.
- (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.
- (9) Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (10) The definitions of "fat" and of "trans fat" set out in Annex I to Regulation (EC) No 1169/2011 of 25 October 2011 of the European Parliament and of the Council⁶ should apply to the relevant terms in Part B of Annex III to Regulation (EC) No 1925/2006.
- (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) 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

In Part B of Annex III to Regulation (EC) No 1925/2006, the following entry is added:

"Trans fat

The following conditions shall apply:

- a. The content of trans fat, other than trans fat naturally occurring in animal fat, in food which is intended for the final consumer, shall not exceed 2 grams per 100 grams of fat.
- b. The definitions of "fat" and of "trans fat" set out respectively in points (2) and (4) of Annex I to Regulation (EC) No 1169/2011 shall apply.

Article 2

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.

⁴ 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.

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

⁶ OJ L 304, 22.11.2011, p. 18.

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

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