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To:	General Secretariat of the Council
No. Cion doc.:	D067444/03
Subject:	COMMISSION REGULATION (EU) …/… of XXX refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

Delegations will find attached document D067444/03.

Encl.: D067444/03

EUROPEAN
COMMISSION

Brussels, XXX
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D067444/03
[…](2020) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[1], and in particular Article 18(5) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims, taking into account the opinion delivered by the Authority.

(5) Following an application from Lonza Ltd, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to L-carnitine and normal lipid metabolism (Question No EFSA-Q-2017-00564). The claim proposed by the applicant was worded as follows: 'L-carnitine contributes to normal lipid metabolism'.

(6) On 16 January 2018, the Commission and the Member States received the scientific opinion[2] from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of L-carnitine and contribution to normal lipid metabolism in the target population. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Unilever N.V., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to black tea and maintenance of normal endothelium-dependent

[1] OJ L 404, 30.12.2006, p. 9.
[2] EFSA Journal 2018;16(1):5137.

vasodilation (Question No EFSA-Q-2017-00419). The claim proposed by the applicant was worded as follows: 'improves endothelium-dependent vasodilation which contributes to healthy blood flow'.

(8) On 16 January 2018, the Commission and the Member States received the scientific opinion[3] from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of black tea and maintenance of normal endothelium-dependent vasodilation. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Newtricious R&D B.V., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to NWT-02, a fixed combination of lutein, zeaxanthin and docosahexaenoic acid in egg yolk, and a reduction of the loss of vision (Question No EFSA-Q-2017-00539). The claim proposed by the applicant was worded as follows: 'Consumption of NWT-02 reduces loss of vision'.

(10) On 18 January 2018, the Commission and the Member States received the scientific opinion[4] from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of NWT-02, a fixed combination of lutein, zeaxanthin and DHA in egg yolk and a reduction of the loss of vision. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from TA-XAN AG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to xanthohumol in XERME®, a xanthohumol-enriched roasted malt extract, and protection of DNA from oxidative damage (Question No EFSA-Q-2017-00663). The claim proposed by the applicant was worded as follows: 'helps to maintain the integrity of DNA and protects against oxidative damage in the cells of the body'.

(12) On 13 March 2018, the Commission and the Member States received the scientific opinion[5] from the Authority which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of xanthohumol in XERME®, a xanthohumol-enriched roasted malt extract, and protection of DNA from oxidative damage. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from Essential Sterolin Products (Pty) Ltd., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to a combination of beta-sitosterol and beta- sitosterol glucoside and normal function of the immune system (Question No EFSA-Q-2018-00701). The claim proposed by the applicant was worded as follows: 'contributes to the normal function of the immune system by restoring balance between T_H1- and T_H2- mediated immunity'.

(14) On 24 July 2019, the Commission and the Member States received the scientific opinion[6] from the Authority, which concluded that, on the basis of the data presented,

[3] EFSA Journal 2018;16(1):5138.
[4] EFSA Journal 2018;16(1):5139.
[5] EFSA Journal 2018;16(3):5192.
[6] EFSA Journal 2019;17(7):5776.

a cause and effect relationship cannot be established between the consumption of a combination of beta- sitosterol and beta- sitosterol glucoside in a ratio 100:1 and a beneficial physiological effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) 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 health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

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*.

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

Done at Brussels,

For the Commission
The President
Ursula von der Leyen