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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) No …/.. of XXX refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

Delegations will find attached document D038040/01.

Encl.: D038040/01

EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) No …/..

of XXX

refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

of XXX

refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

(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 17(3) 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'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and 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 SANOFI-AVENTIS FRANCE submitted pursuant to Article 19(1) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on the modification of the authorisation of a health claim related to plant sterol esters and lowering blood LDL-cholesterol. That health claim has been authorised, pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, by Commission Regulations (EC)

[1] OJ L 404, 30.12.2006, p. 9.

No 983/2009[2] and (EU) No 384/2010[3]. The applicant requested an extension of the conditions of use, as provided for in Regulation (EC) No 983/2009 as amended by Regulation (EU) No 376/2010[4] and in Regulation (EU) No 384/2010 in its original version, to powder supplements to be diluted in water at a dose of 2 g per day, which would lower blood LDL-cholesterol concentrations by "5,4-8,1 %" after six weeks of daily consumption.

(6) On 21 February 2014, the Commission and the Member States received a scientific opinion from the Authority (Question No EFSA-Q-2013-00595)[5] which concluded that while plant sterols added to foods such as margarine-type spreads, mayonnaise, salad dressings, and dairy products such as milk, yoghurts, including low-fat yoghurts, and cheese have been shown consistently to lower blood LDL-cholesterol concentrations in a large number of studies, the effective dose of plant sterols (as powder diluted in water) needed to achieve a given magnitude of effect in a given timeframe, as requested by the applicant, cannot be established with the data provided.

(7) In accordance with the second paragraph of Article 16(6) of Regulation (EC) No 1924/2006, the applicant or members of the public may make comments to the Commission on opinions published by the Authority pursuant to the first paragraph of Article 16(6) of that Regulation. On 14 April 2014, the Commission requested the Authority to respond to the scientific comments received from the applicant according to Article 16(6) of Regulation (EC) No 1924/2006. The comments were related to the scientific evaluation of the Authority on the extension of the conditions of use to plant sterol esters in powder, in particular to the intervention study on which the conclusion of the adopted scientific opinion was based and to a new published meta-analysis which was submitted with the comments.

(8) On 21 May 2014, the Commission received the Authority's response to the comments on the scientific opinion (Question No EFSA-Q-2014-00310)[6] in which the Authority reiterated the conclusion of its scientific opinion (Question No EFSA-Q-2013-00595) with respect to the intervention study. The Authority added that the new published meta-analysis does not provide additional information for the scientific substantiation of the extension of the conditions of use to plant sterol esters in powder. Accordingly, as under the requested conditions of use the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Jemo-pharm A/S submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of CranMax® and reduction of the risk of urinary tract infection by inhibiting the

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2 Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (OJ L 277, 22.10.2009, p. 3).

3 Commission Regulation (EU) No 384/2010 of 5 May 2010 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health (OJ L 113, 6.5.2010, p. 6).

4 Commission Regulation (EU) No 376/2010 of 3 May 2010 amending Regulation (EC) No 983/2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (OJ L 111, 4.5.2010, p. 3).

5 EFSA Journal 2014;12(2):3577.

6 EFSA supporting publication 2014:EN-596.

adhesion of certain bacteria in the urinary tract (Question No EFSA-Q-2013-00649)[7]. The claim proposed by the applicant was worded as follows: "Prevent adhesion of E. coli to the uroepithelial cells in women which is a risk factor for developing urinary tract infections".

(10) On 5 May 2014, the Commission and the Member States received the scientific opinion 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 CranMax® and reduction of the risk of urinary tract infection by inhibiting the adhesion of certain bacteria in the urinary tract. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) The comments received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(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

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 14(1) 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
Jean-Claude JUNCKER

[7] EFSA Journal 2014;12(5):3657.