Council of the
European Union

Brussels, 27 March 2017
(OR. en)

7690/17

DENLEG 26
AGRI 163
SAN 122

COVER NOTE

From:	European Commission
date of receipt:	24 March 2017
To:	General Secretariat of the Council
No. Cion doc.:	D049265/01
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 D049265/01.

Encl.: D049265/01

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10967/2016 Rev. 1
(POOL/E1/2016/10967/10967R1-EN.doc) D049265/01
[…](2016) 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, as defined in that Regulation, 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 Ecopharma BVBA, 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 Fabenol® Max, a standardised aqueous extract from *Phaseolus vulgaris* L., and the reduction of the absorption of carbohydrates (Question No EFSA-Q-2015-00123[2]). The claim proposed by the applicant was worded as follows: “Fabenol® Max reduces the absorption of carbohydrates”.

1 OJ L 404, 30.12.2006, p. 9.
2 EFSA Journal 2016;14(2):4401.

(6) On 23 February 2016, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claimed effect was not sufficiently defined and that the applicant did not provide any further information as requested by the Authority. Therefore, on the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Fabenol® Max and the claimed effect. 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 DSM Nutritional Products, 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 docosahexaenoic acid (DHA) and improvement of memory function (Question No EFSA-Q-2015-00456[3]). The claim proposed by the applicant was worded as follows: "DHA contributes to improved memory function".

(8) On 2 May 2016, 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 had not been established between the consumption of DHA and the claimed effect. 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 Tate & Lyle PLC, 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 polydextrose and normal defecation (Question No EFSA-Q-2015-00550[4]). The claim proposed by the applicant was worded as follows: "Polydextrose contributes to an improved bowel function by increasing stool bulk".

(10) On 25 May 2016, 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 had not been established between the consumption of polydextrose and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) 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*.

[3] EFSA Journal 2016;14(5):4455.
[4] EFSA Journal 2016;14(5):4480.

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