Council of the
European Union

Brussels, 1 December 2015
(OR. en)

14805/15

DENLEG 156
AGRI 626
SAN 413

COVER NOTE

From:	European Commission
date of receipt:	27 November 2015
To:	General Secretariat of the Council
No. Cion doc.:	D042070/01
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 D042070/01.

Encl.: D042070/01

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10461/2015
(POOL/E4/2015/10461/10461-EN.doc)
D042070/01
[…](2015) 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 the first subparagraph of 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 InQpharm Europe 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 standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight (Question No EFSA-Q-2013-00973[2]). The claim proposed by the applicant was worded as follows: “Helps to reduce body weight”.

(6) On 16 July 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that the evidence provided was

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

[2] EFSA Journal 2014;12(7):3754.

insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight. 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 Natural Alternative International, Inc. (NAI), 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 beta-alanine and increase in physical performance during short-duration, high-intensity exercise (Question No EFSA-Q-2013-00974[3]). The claim proposed by the applicant was worded as follows: "Beta-alanine increases performance during short-duration high intensity exercise".

(8) On 16 July 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of beta-alanine and increase in physical performance during short-duration, high-intensity exercise. 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 Federación Nacional de Industrias Lácteas (FeNIL), 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 fat-free yogurts and fermented milks complying with the specifications "fat free", "low in sugars", "high protein", "source of calcium" and "source of vitamin D" for nutrition claims and reduction of body and visceral fat while maintaining lean body mass in the context of an energy-restricted diet (Question No EFSA-Q-2014-00126[4]). The claim proposed by the applicant was worded as follows: "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to reduce body and visceral fat in the context of an energy-restricted diet".

(10) On 7 January 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications "fat free", "low in sugars", "high protein", "source of calcium" and "source of vitamin D" for nutrition claims and reduction of body and visceral fat while maintaining lean body mass in the context of an energy-restricted diet. In that opinion, the Authority also noted that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. 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 Federación Nacional de Industrias Lácteas (FeNIL), 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 fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications "fat free", "low in sugars", "high protein", "source of calcium" and "source of vitamin D" for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet (Question No EFSA-Q-2014-00127[5]). The claim proposed by the

[3] EFSA Journal 2014;12(7):3755.
[4] EFSA Journal 2015;13(1):3948.
[5] EFSA Journal 2015;13(1):3949.

applicant was worded as follows: “Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to maintain lean body mass (muscle and bone) in the context of an energy-restricted diet”.

(12) On 7 January 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet. In that opinion, the Authority also noted that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. 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 Avesthagen Limited, 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 Teestar™, a fenugreek seed extract standardised by its content of galactomannan, and a reduction of post-prandial glycaemic responses (Question No EFSA-Q-2014-00153[6]). The claim proposed by the applicant was worded as follows: “Teestar™ lowers blood glucose levels”.

(14) On 8 January 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had not been established between the consumption of Teestar™, a fenugreek seed extract standardised by its content of galactomannan, and a reduction of post-prandial glycaemic responses. In that opinion, the Authority also noted that in the absence of evidence for an effect of Teestar™ on post-prandial glycaemic responses in humans, animal studies on potential mechanisms do not provide support for the scientific substantiation of the claim. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) The comments from the applicants 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.

(16) 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.

[6] EFSA Journal 2015;13(1):3952.

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