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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, other than those referring to the reduction of disease risk and to children's development and health

Delegations will find attached Commission document D026717/03.

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EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION REGULATION (EU) No …/..

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) No …/..

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 PiLeJe, 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 the effects of a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104 and intestinal discomfort

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

(Question No EFSA-Q-2012-00588)[2]. The claim proposed by the applicant was worded, *inter alia*, as follows: "Improves intestinal comfort".

(6) On 12 February 2013, 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 could not been established between the consumption of a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104 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 PiLeJe, 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 the effects of a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104 and stool frequency **(Question No EFSA-Q-2012-00589)**[3]. The claim proposed by the applicant was worded, *inter alia*, as follows: "Regulates your (intestinal) transit".

(8) On 12 February 2013, 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 could not been established between the consumption of a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophilus* LA 104 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 Nutrilinks Sarl, 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 the effects of ♀EFAX™ and reduction of menstrual discomfort (**Question No EFSA-Q-2012-00591)**[4]. The claim proposed by the applicant was worded, *inter alia*, as follows: "♀EFAX™ contributes to maintain a normal menstruation cycle".

(10) On 12 February 2013, 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 ♀EFAX™ 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) Following an application from Kemin Foods LC, 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 the effects of Slendesta® Potato Extract and reduction of body weight **(Question No EFSA-Q-2012-00704)**[5]. The claim proposed by the applicant was worded as follows: "Slendesta® contributes to the reduction of body weight in overweight individuals".

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2 The EFSA Journal 2013; 11(2):3085.
3 The EFSA Journal 2013; 11(2):3086.
4 The EFSA Journal 2013; 11(2):3081.
5 The EFSA Journal 2013; 11(2):3083.

(12) On 12 February 2013, 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 Slendesta® Potato Extract 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.

(13) Following an application from Zambon 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 the effects of Monurelle® and reduction of bacterial colonisation of the urinary tract **(Question No EFSA-Q-2012-00737)**[6]. The claim proposed by the applicant was worded, *inter alia*, as follows: "Proanthocyanidins from Monurelle® may help to support defence against bacterial pathogens in the lower urinary tract".

(14) On 12 February 2013, 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 Monurelle® 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.

(15) Following an application from S.A. Vichy Catalan, 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 the effects of Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response **(Question No EFSA-Q-2012-00872)**[7]. The claim proposed by the applicant was worded as follows: "Vichy Catalan, a bicarbonated natural mineral water rich in mineral salts, contributes to reduce blood triglycerides rise during digestion".

(16) On 12 February 2013, 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 Vichy Catalan carbonated natural mineral water 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.

(17) The health claim related to Slendesta® Potato Extract is a health claim as referred to in point (c) of Article 13(1) of Regulation (EC) No 1924/2006 and is therefore subject to the transitional period laid down in Article 28(6) of that Regulation. However, as the application was not made before 19 January 2008, the requirement provided for in point (b) of Article 28(6) of that Regulation is not fulfilled, and therefore this claim may not benefit from the transitional period provided for in that Article.

(18) The other health claims subject to this Regulation are health claims as referred to in point (a) of Article 13(1) of Regulation (EC) No 1924/2006, which are subject to the transitional period laid down in Article 28(5) of that Regulation until the adoption of the list of permitted health claims provided that they comply with that Regulation.

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[6] The EFSA Journal 2013; 11(2):3082.

[7] The EFSA Journal 2013; 11(2):3087.

(19) The list of permitted health claims has been established by Commission Regulation (EU) No 432/2012[8] and is applicable since 14 December 2012. As regards claims referred to in Article 13(5) of Regulation (EC) No 1924/2006 for which the evaluation by the Authority or consideration by the Commission has not been completed by 14 December 2012 and which by virtue of this Regulation are not included in the list of permitted health claims, it is appropriate to provide for a transitional period during which they may still be used, in order to allow both food business operators and the competent national authorities to adapt to the prohibition of such claims.

(20) The comments from the applicants and the members of the public 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.

(21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

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.

2. However, the health claims referred to in paragraph 1 used prior to the entry into force of this Regulation, may continue to be used for a maximum period of six months after the entry into force of this Regulation.

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*.

[8] OJ L 136, 25.5.2012, p. 1.

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO