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Delegations will find attached document D039049/02.

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EUROPEAN
COMMISSION

Brussels, XXX
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[…](2015) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise certain health claims made on foods and referring to children's development and health

(Text with EEA relevance)

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of XXX

refusing to authorise certain health claims made on foods and referring 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 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 Specialised Nutrition Europe (formerly European Dietetic Food Industry Association), submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to 'non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin' and 'increase in calcium absorption' (Question No EFSA-Q-2008-140[2]). The claim proposed by the applicant

[1] OJ L 404, 30.12.2006, p. 9.
[2] EFSA Journal 2014;12(11):3889.

was worded, *inter alia*, as follows: 'With non-digestible oligo- and/or polysaccharides to stimulate calcium absorption'.

(6) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 19 November 2014, that a cause and effect relationship cannot be established between the consumption of 'non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin' and a beneficial physiological effect. In particular, the Authority considered that the food constituents 'non-digestible oligo- and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin' were not sufficiently characterised. 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 Specialised Nutrition Europe, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort (Question No EFSA-Q-2008-148[3]). The claim proposed by the applicant was worded, *inter alia*, as follows: 'Lactase for comfortable digestion'.

(8) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 9 October 2014, that a cause and effect relationship had not been established between the consumption of beta-galactosidase, which is produced by *Streptococcus thermophilus* (subsequently inactivated) during fermentation of an infant formula, and reduction of gastrointestinal discomfort. 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 Specialised Nutrition Europe, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to prunes and contribution to normal bowel function (Question No EFSA-Q-2008-193[4]). The claim proposed by the applicant was worded, *inter alia*, as follows: 'dried plums/prunes can contribute to normal bowel function'.

(10) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 19 November 2014, that a cause and effect relationship had not been established between the consumption of prunes and contribution to normal bowel function without the occurrence of diarrhoea for infants and young children from six months to three years of age. In particular, the Authority noted that no studies investigating the effect of prunes on bowel function in infants and young children 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) In accordance with Article 28(6) of Regulation (EC) No 1924/2006, health claims referred to in Article 14(1)(b) of that Regulation and not authorised by a decision pursuant to Article 17(3) of that Regulation may continue to be used for six months after the adoption of that decision, provided that the application for authorisation was

[3] EFSA Journal 2014;12(10):3841.
[4] EFSA Journal 2014;12(11):3892.

made before 19 January 2008. Accordingly, as the health claims listed in the Annex to this Regulation fulfil those conditions, the transitional period laid down in Article 28(6) of Regulation (EC) No 1924/2006 should apply.

(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

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.

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*.

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