EUROPEAN
COMMISSION

Brussels, XXX
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[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise a health claim made on foods and referring to children's development and health

(Text with EEA relevance)

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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 are 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 H.J. Heinz Supply Chain Europe B.V., 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 'Nutrimune®' and immune defence against pathogens in the gastrointestinal tract and upper respiratory tract (Question No EFSA-Q-2016-00008[2]). The claim proposed by the applicant was worded as follows: "'Nutrimune®' supports the immune defence in the gastrointestinal and upper respiratory tract of young children".

(6) On 30 January 2017, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, the scientific evidence is insufficient to establish a cause and effect relationship between the consumption of 'Nutrimune®' (a pasteurised cow's skim milk fermented with *Lactobacillus paracasei* CBA L74) and the immune defence against pathogens in the gastrointestinal and upper respiratory tracts. Accordingly, as the claim does not

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

[2] EFSA Journal 2017;15(1):4679.

comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

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

(8) 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 claim 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