Commission Regulation (EU) 2016/1389 of 17 August 2016 authorising a health claim made on foods and referring to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1389

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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 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 VAB-nutrition, 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 vitamin D and contribution to the normal function of the immune system (Question No EFSA-Q-2014-00826[(2)]). The claim proposed by the applicant was worded as follows: 'Vitamin D contributes to the normal function of the immune system'.

(6) On 13 May 2015, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a cause and effect relationship had been established between the dietary intake of vitamin D and contribution to the normal

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/1389. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

function of the immune system in children. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(7) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim is to include certain particulars. Accordingly, those particulars should be set out in the Annex to this Regulation as regards the authorised claim and include, as the case may be, the revised wording of the claim, specific conditions of use of the claim, and, where applicable, conditions or restrictions of use of the food and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinion of the Authority.

(8) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation are taken into account in that respect. Therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use as those indicated in the Annex to this Regulation.

(9) 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 claim listed in the Annex to this Regulation may be made on foods placed on the Union market in compliance with the conditions laid down in that Annex.

2 The health claim referred to in paragraph 1 shall 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, 17 August 2016.

For the Commission

The President

Jean-Claude JUNCKER