Commission Regulation (EU) 2016/1379 of 16 August 2016 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) 2016/1379

of 16 August 2016

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 E-piim production 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 *Lactobacillus plantarum* TENSIA® in the semi-hard Edam-type 'heart cheese' of Harmony™ and maintenance of normal blood pressure (BP) (Question No EFSA-Q-2014-00097[(2)]). The claim proposed by the applicant was worded as follows: 'Regular, at least for eight week consumption of 50 g/day *Lactobacillus plantarum* TENSIA® comprising Südamejuust (English translation: Heart cheese) of the Harmony™ brand helps to maintain the cardio-vascular system/heart health through reduction of blood pressure/Symbol of heart'.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/1379. 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*

(6) On 1 October 2014, 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 *Lactobacillus plantarum* TENSIA® in the semi-hard Edam-type 'heart cheese' of Harmony™ and maintenance of normal blood pressure. 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 British Specialist Nutrition Association 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 carbohydrate solutions and maintenance of physical performance during endurance exercise (Question No EFSA-Q-2014-00058[3]). The claim proposed by the applicant was worded as follows: 'carbohydrate solutions contribute to the maintenance of endurance performance during prolonged endurance exercise'. Upon request of the Authority, the applicant specified that the food that is the subject of this claim relates to carbohydrate solutions that do not include electrolytes and that, as regards the claimed effect, carbohydrate solutions should be compared to water or water-electrolyte solutions.

(8) On 1 October 2014, 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 carbohydrate solutions and maintenance of physical performance during endurance exercise as compared to water or water-electrolyte solutions. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) 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.

(10) 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.

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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2016/1379. 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*

Done at Brussels, 16 August 2016.

For the Commission

The President

Jean-Claude JUNCKER