Commission Regulation (EU) 2015/8 of 6 January 2015 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) 2015/8

of 6 January 2015

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(4) thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that 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 are to 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 Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority. In some cases, the scientific risk assessment alone cannot provide all the information on which a risk management decision should be based and therefore other legitimate factors relevant to the matter under consideration should also be taken into account.

(4) Following an application from Dextro Energy GmbH & Co. KG, 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 glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266)[(2)]. The claim proposed by the applicant was worded as follows: ‘Glucose is metabolised within body's normal energy metabolism’.

(5) On 11 May 2012, 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 been established between the consumption of glucose

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and contribution to energy-yielding metabolism. The target population is the general population.

(6) Following an application from Dextro Energy GmbH & Co. KG, 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 glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00267)[(3)]. The claim proposed by the applicant was worded as follows: 'Glucose supports normal physical activity'.

(7) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(8) Following an application from Dextro Energy GmbH & Co. KG, 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 glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00268)[(4)]. The claim proposed by the applicant was worded as follows: 'Glucose contributes to normal energy-yielding metabolism'.

(9) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(10) Following an application from Dextro Energy GmbH & Co. KG, 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 glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00269)[(5)]. The claim proposed by the applicant was worded as follows: 'Glucose contributes to normal energy-yielding metabolism during exercise'.

(11) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(12) Following an application from Dextro Energy GmbH & Co. KG, 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 glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00270)[(6)]. The claim proposed by the applicant was worded as follows: 'Glucose contributes to normal muscle function'.

(13) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred

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to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(14) Pursuant to Articles 6(1) and 13(1) of Regulation (EC) No 1924/2006 health claims need to be based on generally accepted scientific evidence. Authorisation may also legitimately be withheld if health claims do not comply with other general and specific requirements of Regulation (EC) No 1924/2006, even in the case of a favourable scientific assessment by the Authority. Health claims inconsistent with generally accepted nutrition and health principles should not be made. The Authority concluded that a cause and effect relationship has been established between the consumption of glucose and contribution to energy-yielding metabolism. However, the use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced. Therefore, such a health claim does not comply with point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006 which foresees that the use of claims should not be ambiguous or misleading. Furthermore, even if the concerned health claim was to be authorised only under specific conditions of use and/or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently the claim should not be authorised.

(15) The health claims covered by this Regulation are health claims as referred to in Article 13(1)(a) of Regulation (EC) No 1924/2006, which, provided that they comply with that Regulation, 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.

(16) The list of permitted health claims has been established by Commission Regulation (EU) No 432/2012[7] 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.

(17) The comments from the applicant 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.

(18) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

1 The health claims set out 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.