# Commission Regulation (EU) No 1017/2013 of 23 October 2013 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) No 1017/2013

## of 23 October 2013

## 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'.

(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 Ceprodi KOT, 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 the effects of 'hypo-caloric snacks (KOT products)' on reduction of adipocyte size at the abdominal level in the context of a low-calorie diet (Question No EFSA-Q-2011-00016)[(2)]. The claim proposed by the applicant was worded as follows: 'Contributes to reduce the adipocytes size at the abdominal level, in the context of a low-calorie diet'.

(6) On 30 September 2011, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented,

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a cause and effect relationship had not been established between the consumption of 'hypo-caloric snacks (KOT products)' and a beneficial physiological effect related to the reduction of subcutaneous adipocyte size at the abdominal level. 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 Valio 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 the effects of isoleucyl-prolyl-proline (IPP) and valyl-prolyl-proline (VPP) on maintenance of normal blood pressure (Question No EFSA-Q-2011-00121)[(3)]. The claim proposed by the applicant was worded as follows: 'Peptides IPP and VPP help to maintain normal blood pressure'.

(8) On 30 September 2011, 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 IPP and VPP and the claimed effect. 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 Diana Naturals, 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 the effects of Appl'In® polyphenolic apple extract powder (*Malus domestica*) on reduction of post-prandial glycaemic responses (Question No EFSA-Q-2011-00190)[(4)]. The claim proposed by the applicant was worded as follows: 'Appl'In® contributes to decrease glycaemic response in women'.

(10) On 5 October 2011, 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 Appl'In® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from Tchibo GmbH, 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 the consumption of coffee C21 and reduction of spontaneous DNA strand breaks (Question No EFSA-Q-2011-00783)[(5)]. The claim proposed by the applicant was worded as follows: 'Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body'.

(12) On 5 December 2011, 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 coffee C21 and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from Kao Corporation, 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 the effects of diacylglycerol (DAG) oil and reduction of body weight (Question No EFSA-Q-2011-00751)[(6)]. The claim proposed by the applicant was

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worded as follows: 'Substituting your usual vegetable oil with DAG oil helps in the management of body weight through weight loss'

(14) On 5 December 2011, 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 DAG oil (as a replacement of triacylglycerol oils) and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) Following an application from Giuliani S.p.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effects of spermidine and prolongation of the growing phase (anagen) of the hair cycle (Question No EFSA-Q-2011-00896)[(7)]. The claim proposed by the applicant was worded as follows: 'Spermidine prolongs the growing phase (anagen) of the hair cycle'.

(16) On 7 December 2011, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, the claimed effect is related to pathological conditions leading to the shortening of the anagen phase of hair growth and relates thus to the treatment of a disease.

(17) Regulation (EC) No 1924/2006 complements the general principles of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[(8)]. Article 2(1)(b) of Directive 2000/13/EC provides that the labelling shall not attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties. Accordingly, as the attribution of medicinal properties to foods is prohibited, the claim related to the effects of spermidine should not be authorised.

(18) Following an application from Clasado 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 the effects of galacto-oligosaccharides from Bimuno® (Bimuno® GOS) and reducing gastro-intestinal discomfort (Question No EFSA-Q-2011-00401)[(9)]. The claim proposed by the applicant was worded as follows: 'Regular daily consumption of 1,37 g galacto-oligosaccharides from Bimuno® may reduce intestinal discomfort'.

(19) On 8 December 2011, 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 Bimuno® GOS and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(20) Following an application from Nordic Sugar A/S., 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 the effects of sugar beet fibre and decreasing intestinal transit

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time (Question No EFSA-Q-2011-00971)[10]. The claim proposed by the applicant was worded as follows: 'Sugar beet fibre decreases intestinal transit time'.

(21) On 8 December 2011, 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 sugar beet fibre and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(22) The health claim related to the effects of spermidine and prolongation of the growing phase (anagen) of the hair cycle, is a health claim attributing medicinal properties to the food subject to the claim and is therefore prohibited for foods.

(23) The health claims related to 'hypo-caloric snacks (KOT products)' and to diacylglycerol (DAG) oil are health claims as those referred to in point (c) of Article 13(1) of Regulation (EC) No 1924/2006 which are subject to the transitional period laid down in Article 28(6) of that Regulation. However, as the applications were not made before 19 January 2008, the requirement provided for in point (b) of Article 28(6) of that Regulation is not fulfilled, and therefore those claims may not benefit from the transitional period provided for in that Article.

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

(25) The list of permitted health claims has been established by Commission Regulation (EU) No 432/2012[11] 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.

(26) The comments from the applicants 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.

(27) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

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 13(3) of Regulation (EC) No 1924/2006.