Commission Regulation (EU) No 1066/2013 of 30 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 1066/2013

of 30 October 2013

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(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 Béres Pharmaceuticals 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 glucosamine and maintenance of joints (Question No EFSA-Q-2011-00907)[(2)]. The claim proposed by the applicant was worded as follows: 'Glucosamine contributes to the protection of joint cartilage exposed to excessive motion or loading and helps to improve the range of motion in joints'.

(6) 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

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glucosamine 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.

(7) Following an application from Merck Consumer Healthcare, 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 glucosamine and maintenance of normal joint cartilage (Question No EFSA-Q-2011-01113)[(3)]. The claim proposed by the applicant was worded, inter alia, as follows: 'Glucosamine contributes to the maintenance of normal joint cartilage'.

(8) On 16 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 not been established between the consumption of glucosamine 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 Extraction Purification Innovation France, 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 wheat polar lipid extract and protection of the skin against dehydration (Question No EFSA-Q-2011-01122)[(4)]. The claim proposed by the applicant was worded, inter alia, as follows: 'Contributes to improve skin hydration'.

(10) On 5 July 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 not been established between the consumption of wheat polar lipid extract 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 Lesaffre International/Lesaffre Human Care, 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 *Saccharomyces cerevisiae* var. *boulardii* CNCM I-3799 and reducing gastro-intestinal discomfort (Question No EFSA-Q-2012-00271)[(5)]. The claim proposed by the applicant was worded as follows: 'Saccharomyces cerevisiae var. boulardii CNCM I-3799 helps maintain intestinal comfort'.

(12) On 17 July 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 could not be established between the consumption of *Saccharomyces cerevisiae* var. *boulardii* CNCM I-3799 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 two applications from Nutrilinks Sarl, 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 a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair (Question No EFSA-Q-2012-00334 and EFSA-

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Q-2012-00335)[6]. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to increase hair number'.

(14) On 17 July 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 not been established between the consumption of a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) 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 Nutrilinks Sarl, 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 *Rhodiola rosea* L. extract and reduction of mental fatigue (Question No EFSA-Q-2012-00336)[7]. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to reduce tiredness in case of stress'.

(16) On 17 July 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 not been established between the consumption of *Rhodiola rosea* L. extract 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.

(17) Following an application from Nutrilinks Sarl, 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 a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function (Question No EFSA-Q-2012-00337)[8]. The claim proposed by the applicant was worded, inter alia, as follows: 'Contributes to maintain skin permeability barrier function'.

(18) On 17 July 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 not been established between the consumption of a combination of flaxseed oil and vitamin E 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.

(19) Following an application from Nutrilinks Sarl, 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 *Opti*$_{\text{EFAX}}$™ and maintenance of normal blood LDL-cholesterol concentrations (Question No EFSA-Q-2012-00339)[9]. The claim proposed by the applicant was worded as follows: '*Opti*$_{\text{EFAX}}$™ helps to maintain healthy blood levels of LDL cholesterol'.

(20) On 17 July 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 not been established between the consumption of *Opti*$_{\text{EFAX}}$™ 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.

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(21) Following an application from Nutrilinks Sarl, 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 *Opti*$_{EFAX}$™ and maintenance of normal blood HDL-cholesterol concentrations (Question No EFSA-Q-2012-00340)[10]. The claim proposed by the applicant was worded as follows: '*Opti*$_{EFAX}$™ helps to maintain healthy blood levels of HDL cholesterol'.

(22) On 17 July 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 not been established between the consumption of *Opti*$_{EFAX}$™ 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.

(23) Following an application from Nutrilinks Sarl, 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 KF2BL20, which is a combination of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin, and maintenance of normal hair (Question No EFSA-Q-2012-00381)[11]. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to maintain hair strength'.

(24) On 17 July 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 not been established between the consumption of KF2BL20 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.

(25) Following an application from Nutrilinks Sarl, 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 hyaluronic acid and protection of the skin against dehydration (Question No EFSA-Q-2012-00382)[12]. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to maintain good skin hydration'.

(26) On 17 July 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 not been established between the consumption of hyaluronic acid 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.

(27) Following an application from Nutrilinks Sarl, 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 *Opti*$_{EFAX}$™ and maintenance of normal blood concentrations of triglycerides (Question No EFSA-Q-2012-00383)[13]. The claim proposed by the applicant was worded as follows: '*Opti*$_{EFAX}$™ helps to maintain healthy blood levels of triglycerides.'

(28) On 17 July 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 not been established between the consumption of *Opti*$_{EFAX}$™

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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.

(29) Following an application from Vivatech, 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 Transitech® and 'improves transit and durably regulates it' (Question No EFSA-Q-2012-00296)[(14)]. The claim proposed by the applicant was worded as follows: 'Improves transit and durably regulates it'.

(30) On 26 September 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 could not be established between the consumption of Transitech® 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.

(31) Following an application from Nutrilinks Sarl, 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 Femilub® and maintenance of vaginal moisture (Question No EFSA-Q-2012-00571)[(15)]. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to reduce vaginal dryness'.

(32) On 26 September 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 not been established between the consumption of Femilub® 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.

(33) Following an application from Nutrilinks Sarl, 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 a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced damage (Question No EFSA-Q-2012-00592)[(16)]. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to prepare sensitive skin from the inside to improve their tolerance to the sun'.

(34) On 27 September 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 not been established between the consumption of a combination of lycopene, vitamin E, lutein and selenium 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.

(35) Following an application from Glanbia Nutritionals plc, 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 Prolibra® and 'Helps to reduce body fat while preserving lean muscle' (Question No EFSA-Q-2012-00001)[(17)]. The claim proposed by the applicant was worded as follows: 'Helps to reduce body fat while preserving lean muscle'.