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Subject: COMMISSION REGULATION (EU) No .../.. of XXX 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

Delegations will find attached Commission document D026731/03.

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COMMISSION REGULATION (EU) No .../..

of **XXX**

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 .../..

of **XXX**

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 foods¹, 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".

¹ OJ L 404, 30.12.2006, p. 9.

² The EFSA Journal 2011; 9(12):2476.

- (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 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.

³ The EFSA Journal 2012; 10(5):2691.

⁴ The EFSA Journal 2012; 10(7):2773.

⁵ The EFSA Journal 2012; 10(7):2801.

- (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-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*_{EFAX}TM and maintenance of normal blood

⁶ The EFSA Journal 2012; 10(7):2807.

⁷ The EFSA Journal 2012; 10(7):2805.

⁸ The EFSA Journal 2012; 10(7):2819.

LDL-cholesterol concentrations (**Question No EFSA-Q-2012-00339**)⁹. The claim proposed by the applicant was worded as follows: “*Opti_{EFAX}*TM 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_{EFAX}*TM 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.
- (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}*TM 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}*TM 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}*TM 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

⁹ The EFSA Journal 2012; 10(7):2802.

¹⁰ The EFSA Journal 2012; 10(7):2803.

¹¹ The EFSA Journal 2012; 10(7):2808.

¹² The EFSA Journal 2012; 10(7):2806.

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 *OptiEFAX*TM 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: “*OptiEFAX*TM 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 *OptiEFAX*TM 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

¹³ The EFSA Journal 2012; 10(7):2804.

¹⁴ The EFSA Journal 2012; 10(9):2887.

¹⁵ The EFSA Journal 2012; 10(9):2888.

¹⁶ The EFSA Journal 2012; 10(9):2890.

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”.
- (36) On 8 November 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 Prolibra® 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.
- (37) 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 *Eff_{EXT}*TM and “Helps to support joint function by maintaining low levels of plasma C-reactive protein” (**Question No EFSA-Q-2012-00386**)¹⁸. The claim proposed by the applicant was worded, *inter alia*, as follows: “Helps to support joint function by maintaining low levels of plasma C-reactive protein”.
- (38) On 27 September 2012, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein and concluded that on the basis of the data presented, a reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of a disease.
- (39) 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 foodstuffs¹⁹. 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 *Eff_{EXT}*TM should not be authorised.

¹⁷ The EFSA Journal 2012; 10(11):2949.

¹⁸ The EFSA Journal 2012; 10(9):2889.

¹⁹ OJ L 109, 6.5.2000, p. 29.

- (40) The health claim related to the effects of *Eff*_{EXT}TM and "Helps to support joint function by maintaining low levels of plasma C-reactive protein", is a health claim attributing medicinal properties to the food subject to the claim and is therefore prohibited for foods.
- (41) The health claim related to Prolibra® and "Helps to reduce body fat while preserving lean muscle" is a health claim 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 application was 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 this claim may not benefit from the transitional period provided for in that Article.
- (42) 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.
- (43) The list of permitted health claims has been established by Commission Regulation (EU) No 432/2012²⁰ 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.
- (44) 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.
- (45) 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.
2. However, the health claims referred to in paragraph 1 used prior to the entry into force of this Regulation, may continue to be used for a maximum period of six months after the entry into force of this Regulation.

²⁰ OJ L 136, 25.5.2012, p. 1.

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,

For the Commission
The President
José Manuel BARROSO

ANNEX

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucosamine	Glucosamine contributes to the protection of joint cartilage exposed to excessive motion or loading and helps to improve the range of motion in joints	Q-2011-00907
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucosamine	Glucosamine contributes to the maintenance of normal joint cartilage	Q-2011-01113
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Wheat polar lipid extract	Contributes to improve skin hydration	Q-2011-01122
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Saccharomyces cerevisiae</i> var. <i>bouardii</i> CNCM I-3799	<i>Saccharomyces cerevisiae</i> var. <i>bouardii</i> CNCM I-3799 helps maintain intestinal comfort	Q-2012-00271
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (<i>Cucurbita pepo</i> L.)	Helps to increase hair number	Q-2012-00334 & Q-2012-00335

Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Rhodiola rosea</i> L. extract	Helps to reduce tiredness in case of stress	Q-2012-00336
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of flaxseed oil and vitamin E	Contributes to maintain skin permeability barrier function	Q-2012-00337
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Opti_{EFAX}</i> TM	<i>Opti_{EFAX}</i> TM helps to maintain healthy blood levels of LDL cholesterol	Q-2012-00339
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Opti_{EFAX}</i> TM	<i>Opti_{EFAX}</i> TM helps to maintain healthy blood levels of HDL cholesterol	Q-2012-00340
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	KF2BL20	Helps to maintain hair strength	Q-2012-00381
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Hyaluronic acid	Helps to maintain good skin hydration	Q-2012-00382

Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Opti</i> _{EFAX} TM	<i>Opti</i> _{EFAX} TM helps to maintain healthy blood levels of triglycerides	Q-2012-00383
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Transitech®	Improves transit and durably regulates it	Q-2012-00296
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Femilub®	Helps to reduce vaginal dryness	Q-2012-00571
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of lycopene, vitamin E, lutein and selenium	Helps to prepare sensitive skin from the inside to improve their tolerance to the sun	Q-2012-00592
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Prolibra®	Helps to reduce body fat while preserving lean muscle	Q-2012-00001
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Eff</i> _{EXT} TM	Helps to support joint function by maintaining low levels of plasma C-reactive protein	Q-2012-00386