Commission Regulation (EU) No 155/2014 of 19 February 2014 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 155/2014

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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 Vitabiotics 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 L-tyrosine and contribution to normal synthesis of dopamine (Question No EFSA-Q-2011-00319)[(2)]. The claim proposed by the applicant was worded as follows: 'L-tyrosine is essential for the natural formation of dopamine'.

(6) On 20 July 2011, the Commission and the Member States received the scientific opinion from the Authority, which noted that the role of L-tyrosine in the normal synthesis of catecholamines for the general population has already been addressed with a favourable outcome in a previous opinion[(3)] in the context of evaluation of claims referred to in Article 13(1) of Regulation (EC) No 1924/2006 and that L-tyrosine is the

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starting point for the synthesis of all catecholamines, including dopamine. Thus, the Authority concluded that a cause and effect relationship had been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of dopamine and proposed as appropriate conditions of use that 'a food should be at least a source of protein *as per* Annex to Regulation (EC) No 1924/2006'.

(7) The Commission and the Member States have considered whether the health claim reflecting those conclusions should be authorised under the proposed conditions of use, since 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. In the Authority's response of 9 November 2012 to the request of the Commission, *inter alia*, for clarification in relation to the evidence submitted for the health claim on L-tyrosine and the proposed conditions of use, the Authority noted that its conclusions for this claim were based on the well established biochemical role of L-tyrosine, as contained in protein. It added that, on the basis of the evidence submitted, it could not provide a quantitative indication of the necessary daily intake of L-tyrosine per se to produce the beneficial physiological effect. Therefore, it is not possible to establish specific conditions for the use of this claim to ensure that L-tyrosine is contained in the final product in a quantity that will produce the beneficial physiological effect in accordance with point (i) of Article 5(1)(b) of Regulation (EC) No 1924/2006. In the absence of such specific conditions of use, the beneficial effect of the substance to which the claim relates cannot be assured and thus this claim could be misleading to the consumer. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(8) Following an application from Pierre Fabre Dermo-Cosmétique, 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 iron and maintenance of normal hair growth (Question No EFSA-Q-2012-00059)[(4)]. The claim proposed by the applicant was worded as follows: 'Excessive hair loss in non-menopausal women'.

(9) On 15 March 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 intake of iron and maintenance of normal hair growth. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(10) Following an application from Biocodex, 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 citrulline-malate and faster recovery from muscle fatigue after exercise (Question No EFSA-Q-2011-00931)[(5)]. The claim proposed by the applicant was worded as follows: 'Maintenance of adenosine triphosphate (ATP) levels through reduction of lactates in excess for recovery from muscle fatigue'.

(11) 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

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and effect relationship had not been established between the consumption of citrulline-malate 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.

(12) 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 E*ff*$_{EXT}$™ and maintenance of normal joint mobility (Question No EFSA-Q-2012-00384)[6]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Contributes to support joint flexibility'.

(13) On 14 December 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 E*ff*$_{EXT}$™ 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.

(14) 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 krill oil and maintenance of joint comfort (Question No EFSA-Q-2012-00385)[7]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to improve the comfort of sensitive joints'.

(15) On 14 December 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 krill oil 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.

(16) 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 *Vitis vinifera* L. seeds extract and normal venous blood flow (Question No EFSA-Q-2012-00387)[8]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Contributes to promote venous circulation in the legs'.

(17) On 14 December 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 *Vitis vinifera* L. seeds 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.

(18) 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 *Vitis vinifera* L. seeds extract and 'Helps to decrease swollen legs' (Question No EFSA-Q-2012-00388)[9]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to decrease swollen legs'.

(19) On 14 December 2012, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claim refers to the reduction of

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peripheral oedema in the context of chronic clinical conditions (e.g. chronic venous insufficiency) and concluded that on the basis of the data presented, such reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for their treatment.

(20) 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[10]. 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 *Vitis vinifera* L. seeds extract and 'Helps to decrease swollen legs' should not be authorised.

(21) Following an application from Roxlor Nutra LLC, 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 Cynatine® and maintenance of normal joint mobility (Question No EFSA-Q-2012-00570)[11]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Daily consumption of 500 mg of Cynatine® helps to support joint flexibility'.

(22) On 14 December 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 Cynatine® 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 Actina, 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 OXY 280 and reduction of body weight (Question No EFSA-Q-2012-00572)[12]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'OXY 280 helps to lose weight'.

(24) On 14 December 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 OXY 280 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 *Vitis vinifera* L. seeds extract and 'Helps to drain the body in case of water accumulation' (Question No EFSA-Q-2012-00574)[13]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to drain the body in case of water accumulation'.

(26) On 14 December 2012, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claimed effect refers to the maintenance of normal venous blood flow. The Authority noted also that the same

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health relationship was already subject to its assessment in a previous opinion[14] with an unfavourable outcome and that the reference provided for the scientific substantiation of this claim was already considered in the previous opinion. 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 a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and reduction of body weight (Question No EFSA-Q-2012-00590)[15]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to burn fat'.

(28) On 14 December 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 *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts 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 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 'Helps to prepare and activate tanning' (Question No EFSA-Q-2012-00593)[16]. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to prepare and activate tanning'.

(30) On 14 December 2012, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claimed effect refers to increasing the pigmentation of the skin (i.e. tanning) which may contribute to the protection of the skin against UV-induced damage. The Authority noted also that the same health relationship was already subject to its assessment in a previous opinion[17] with an unfavourable outcome and that the reference provided for the scientific substantiation of this claim was the same as in the previous opinion. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(31) The health claim related to the effects of *Vitis vinifera* L. seeds extract and 'Helps to decrease swollen legs' is a health claim that attributes medicinal properties to the food that is the subject of the claim, which is prohibited for foods.

(32) The health claims related to OXY 280 and to the combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts are health claims as referred to in point (c) of Article 13(1) of Regulation (EC) No 1924/2006 and are therefore 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.