II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2016/1411

of 24 August 2016

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', 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 SmithKline Beecham Limited, 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 caffeine and increased alertness (Question No EFSA-Q-2013-00399 ([2])). The claim proposed by the applicant was worded as follows: 'caffeine helps to increase alertness'.

(6) On 21 February 2014, the Commission and the Member States received the scientific opinion from the Authority. In its opinion, the Authority recalled that a claim on caffeine and increased alertness in the general adult population for products containing at least 75 mg of caffeine per serving had already been assessed by the Authority with a favourable outcome ([3]). In the present application, the applicant proposed that, in order to bear

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2014; 12(2):3574.
([3]) *EFSA Journal* 2011; 9(4):2054.

the claim, a product should contain a dose of caffeine of at least 40 mg per serving. The Authority considered that the scientific substantiation of this claim related to doses of caffeine between 40 mg per serving ([1]) and 75 mg per serving ([2]), and concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of caffeine and increased alertness under the conditions of use proposed by the applicant. Further, the Authority reiterated its previous conclusion that, in order to bear the claim, a product should contain at least 75 mg caffeine per serving. Accordingly, as the claim, under the proposed conditions of use, does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from BASF SE and Stepan Lipid Nutrition, 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 an equimolar mixture (marketed under the trade names Clarinol® and Tonalin®) of the two conjugated linoleic acid (CLA) isomers c9,t11 and t10,c12, and contribution to a reduction in body fat mass (Question No EFSA-Q-2014-00580 ([3])). The claim proposed by the applicant was worded as follows: 'Consumption of Clarinol® or Tonalin® contributes to a reduction in body fat mass'.

(8) On 8 January 2015, 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 an equimolar mixture of the CLA isomers c9,t11 and t10,c12, marketed under the trade names of Clarinol® and Tonalin®, 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 Synbiotec S.r.l., 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 SYNBIO®, a combination of *Lactobacillus rhamnosus* IMC 501® and *Lactobacillus paracasei* IMC 502®, and maintenance of normal defecation (Question No EFSA-Q-2014-00567 ([4])). The claim proposed by the applicant was worded as follows: 'SYNBIO® persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being'.

(10) On 13 May 2015, 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 SYNBIO® and maintenance of normal defecation. 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 WILD-Valencia SAU, 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 a FRUIT UP®, a carbohydrate extract from carob pods (*Ceratonia siliqua* L.), and a reduction of post-prandial blood glucose responses (Question No EFSA-Q-2014-00405 ([5])). The claim proposed by the applicant was worded as follows: 'FRUIT UP® reduces post-prandial blood glucose responses compared to high-glycaemic carbohydrates'.

(12) On 13 May 2015, 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 FRUIT UP® and a reduction of post-prandial glycaemic responses over and above the well-established effect of fructose ([6]) on reducing post-prandial glycaemic responses when replacing glucose in foods. The Authority also stated that no effect had been observed when FRUIT UP® was compared with sucrose. 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 Nerthus ApS, 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 a combination of pomegranate pomace extract (standardised by its content of punicalagins) and greater galangal rhizome powder

([1]) Minimum effective dose proposed by the applicant.
([2]) Minimum effective dose proposed by EFSA.
([3]) *EFSA Journal* 2015; 13(1):3953.
([4]) *EFSA Journal* 2015; 13(5):4095.
([5]) *EFSA Journal* 2015; 13(5):4098.
([6]) *EFSA Journal* 2011; 9(6):2223. A health claim relating to fructose was authorised by Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health (OJ L 160, 12.6.2013, p. 4).

(standardised by its content of acetoxychavicol acetate) and an increase in the number of motile spermatozoa in semen (Question No EFSA-Q-2014-00566 ([1])). The claim proposed by the applicant was worded as follows: 'A combination of standardised pomegranate pomace extract and greater galangal rhizome powder increases the number of motile spermatozoa in semen'.

(14) On 13 May 2015, 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 the combination of pomegranate pomace extract (standardised by its content of punicalagins) and greater galangal rhizome powder (standardised by its content of acetoxychavicol acetate) 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 Lallemand Health Solutions, 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 *Bifidobacterium bifidum* CNCM I-3426 and defence against pathogens in the upper respiratory tract (Question No EFSA-Q-2014-00673 ([2])). The claim proposed by the applicant was worded as follows: '*Bifidobacterium bifidum* CNCM I-3426 increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress'.

(16) On 13 May 2015, 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 *B. bifidum* CNCM I-3426 and defence against pathogens in the upper respiratory tract. 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 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 coffee C21, a coffee standardised by its content of caffeoylquinic acids, trigonelline and N-methylpyridinium, and reduction of DNA damage by decreasing spontaneous DNA strand breaks (Question No EFSA-Q-2014-00624 ([3])). 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'.

(18) On 13 May 2015, 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.

(19) The comments from the applicants 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.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 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.

([1]) *EFSA Journal* 2015; 13(5):4097.
([2]) *EFSA Journal* 2015; 13(5):4094.
([3]) *EFSA Journal* 2015; 13(5):4099.

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, 24 August 2016.

For the Commission

The President

Jean-Claude JUNCKER

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	Caffeine	Caffeine helps to increase alertness * * *For intakes of caffeine between 40 mg per serving and 75 mg per serving*.	Q-2013-00399
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Clarinol® and Tonalin®	The consumption of Clarinol® or Tonalin® contributes to a reduction in body fat mass.	Q-2014-00580
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	SYNBIO®	SYNBIO® persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being'.	Q-2014-00567
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	FRUIT UP®	FRUIT UP® reduces post-prandial blood glucose responses compared to high-glycaemic carbohydrates.	Q-2014-00405
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 pomegranate pomace extract and greater galangal rhizome powder	A combination of standardised pomegranate pomace extract and greater galangal rhizome powder increases the number of motile spermatozoa in semen.	Q-2014-00566
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	*Bifidobacterium bifidum* CNCM I-3426	*Bifidobacterium bifidum* CNCM I-3426 increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress.	Q-2014-00673
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Coffee C21 (coffee standardised by its content of caffeoylquinic acids, trigonelline and *N*-methylpyridinium)	Regular consumption of coffee C21 contributes to the maintenance of DNA integrity in cells of the body.	Q-2014-00624