Commission Regulation (EU) 2018/1556 of 17 October 2018 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) 2018/1556

of 17 October 2018

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 Laboratoires Nutrition et Cardiométabolisme, 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 Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (tryptophan to neutral amino acids ratio) and decrease in visceral fat while preserving lean mass (Question No EFSA- Q-2016-00319[(2)]). The claim proposed by the applicant was worded as follows: ‘In the context of a well-balanced diet and a mild caloric restriction, the addition of Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors’.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2018/1556. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(6) On 28 February 2017, 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 has not been established between the consumption of Stablor® and reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet. 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 Suomen Terveysravinto Oy, 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 curcumin and normal functioning of joints (Question No EFSA- Q-2016-00856[(3)]). The claim proposed by the applicant was worded as follows: 'Curcumin contributes to the normal functioning of joints'.

(8) On 8 May 2017, 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 has not been established between the consumption of curcumin and the maintenance of joint function. 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 Marks and Spencer 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 a carbohydrate:protein (CHO:P) ratio ≤ 1.8 on an energy basis in the context of an energy-restricted diet and body weight (Question No EFSA-Q-2016-00436[(4)]). The claim proposed by the applicant was worded as follows: 'Helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet (< 8,368 kJ/2,000 kcal/day) for a minimum of 12 weeks'.

(10) On 13 June 2017, 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 has not been established between the consumption of a CHO:P ratio ≤ 1.8 on an energy basis consumed in the context of an energy-restricted diet and the reduction of body weight. 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 Loc Troi group, 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 Vibigaba (germinated brown rice) and reduction of body weight in the context of an energy-restricted diet (Question No EFSA- Q-2017-00032[(5)]). The claim proposed by the applicant was worded as follows: 'In the context of an energy-restricted diet contributes to weight loss'.

(12) On 21 July 2017, 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 has not been established between the consumption of Vibigaba (germinated brown rice) and the reduction of body weight in the context of an energy-restricted diet. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2018/1556. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(13) Following an application from Loc Troi group, 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 Vibigaba (germinated brown rice) and maintenance of long-term normal blood glucose concentration (Question No EFSA- Q-2017-00033[6]). The claim proposed by the applicant was worded as follows: 'Contributes to the maintenance of normal blood glucose levels'.

(14) On 21 July 2017, 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 has not been established between the consumption of Vibigaba (germinated brown rice) and the maintenance of long-term normal blood glucose concentration. 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 Loc Troi group, 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 Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood pressure (Question No EFSA- Q-2017-00031[7]). The claim proposed by the applicant was worded as follows: 'Contributes to the maintenance of normal blood pressure'.

(16) On 21 July 2017, 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 has not been established between the consumption of Vibigaba (germinated brown rice) and the maintenance of normal BP. 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 Loc Troi group, 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 Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood cholesterol concentration (Question No EFSA-Q-2017-00030[8]). The claim proposed by the applicant was worded as follows: 'Contributes to the maintenance of normal blood cholesterol levels'.

(18) On 21 July 2017, 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 has not been established between the consumption of Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(19) 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:

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2018/1556. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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.

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, 17 October 2018.

For the Commission

The President

Jean-Claude JUNCKER