II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2023/1141

of 1 June 2023

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 the Union list of permitted health claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisation 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 ('the Authority').

(3) Following the receipt of an application, the Authority is to inform without delay the other Member States and the Commission, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of the health claim taking into account the opinion delivered by the Authority.

(5) Following an application from Nestlé S.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to beta-glucans sourced from oats and/or barley in ready-to-eat breakfast cereals manufactured via pressure cooking and to the reduction of blood glucose rise after consumption (Question No EFSA-Q-2020-000447). The claim proposed by the applicant was worded as follows: 'Consumption of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contributes to a reduction of the blood glucose rise after that meal'.

(6) On 8 April 2021, the Commission and the Member States received the scientific opinion ([2]) on that claim from the Authority, which concluded that, on the basis of the data presented, the effect of beta-glucans in reducing post-prandial blood glucose responses is well established. However, the evidence provided had been insufficient to establish an effect on reduction of post-prandial glycaemic responses at doses of 1,3 g beta-glucans per 25 g of available carbohydrate incorporated into ready-to-eat breakfast cereals manufactured by pressure cooking (i.e. either

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2021;19(4):6493.

batch cooking or extrusion), as requested by the applicant. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.

(7) Following an application from Pharmactive Biotech Products, S.L., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Affron® and the contribution to the maintenance of a healthy mood (Question No EFSA-Q-2020-00617). The claim proposed by the applicant was worded as follows: 'Affron® contributes to maintain a healthy mood by reducing the negative traits of depressive and anxiety feelings'.

(8) On 6 July 2021, the Commission and the Member States received the scientific opinion ([3]) on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided had been insufficient to establish a cause and effect relationship between the consumption of Affron® and increase in positive mood. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.

(9) Following an application from Praline i Cokolada j.d.o.o., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to MegaNatural®-BP grape seed extract and the maintenance of normal blood pressure (Question No EFSA-Q-2020-00718). The claim proposed by the applicant was worded as follows: 'MegaNatural®-BP helps maintain healthy blood pressure'.

(10) On 9 August 2021, the Commission and the Member States received the scientific opinion ([4]) on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided had been insufficient to establish a cause and effect relationship between the consumption of MegaNatural®-BP, a grape seed extract standardised for total phenolics, gallic acid and the sum of catechin and epicatechin content, and maintenance of normal blood pressure. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.

(11) Following an application from Sensus B.V. (Royal Cosun), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Frutalose® and the maintenance of normal defecation (Question No EFSA-Q-2020-00631). The claim proposed by the applicant was worded as follows: 'Frutalose® chicory oligofructose contributes to regular bowel function by increasing stool frequency'. The applicant also provided three alternative wordings for the claim.

(12) On 12 August 2021, the Commission and the Member States received the scientific opinion ([5]) on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided was insufficient to establish a cause and effect relationship between the consumption of Frutalose® and the maintenance of normal defecation under the proposed conditions of use. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.

(13) The comments by Nestlé S.A. on the Authority's opinion on the health claim relating to beta-glucans sourced from oats and/or barley in ready-to-eat breakfast cereals manufactured via pressure cooking and to the reduction of blood glucose rise after consumption (Question No EFSA-Q-2020-000447), received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when adopting this Regulation.

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

([3]) *EFSA Journal* 2021;19(7):6669.
([4]) *EFSA Journal* 2021;19(8):6776.
([5]) *EFSA Journal* 2021;19(8):6775.

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 health 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, 1 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

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	Beta-glucans sourced from oats and/or barley, incorporated into ready-to-eat breakfast cereals manufactured via pressure cooking (i.e. either by batch cooking or extrusion), and present at a level of at least 1,3 g per 25 g available carbohydrate in the ready-to-eat cereal	Consumption of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contributes to a reduction of the blood glucose rise after that meal	Q-2020-000447
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Affron®, aqueous saffron extract, with the sum of crocins and safranal concentration > 3,5 % and dextrin as inert carrier	Affron® contributes to maintain a healthy mood by reducing the negative traits of depressive and anxiety feelings	Q-2020-00617
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	MegaNatural®-BP grape seed extract made entirely of California-grown grapes containing biologically active constituents: total phenolics (90–93 %), gallic acid (≥ 2 %) and catechin and epicatechin (≥ 5 %). The distribution of phenolic compounds in the MegaNatural®-BP is on average 9 % monomers, 69 % oligomers and 22 % polymers	MegaNatural®-BP helps maintain healthy blood pressure	Q-2020-00718
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Frutalose® chicory oligofructose	Frutalose® chicory oligofructose contributes to regular bowel function by increasing stool frequency (And three other alternative wordings)	Q-2020-00631