EUROPEAN
COMMISSION

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[…](2022) XXX draft

COMMISSION REGULATION (EU) …/…

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) …/…

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 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

[1] OJ L 404, 30.12.2006, p. 9.

[2] EFSA Journal 2021;19(4):6493.

breakfast cereals manufactured by pressure cooking (i.e. either 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

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

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,

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,

For the Commission
The President
Ursula VON DER LEYEN