II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2022/727

of 11 May 2022

refusing to authorise a health claim made on foods and referring to the reduction of disease risk

(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 17(3) 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 are included in the list of permitted claims.

(2) With regard to health claims on reduction of disease risk, Article 15 of Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims shall 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'.

(3) Following receipt of an application, the Authority is to inform without delay the other Member States and the Commission thereof, and 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 Han-Biotech GmbH submitted via the competent authority of Germany pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Symbiosal® and the lowering of blood pressure and a reduced risk of hypertension (Question No EFSA-Q-2018-00002). The claim proposed by the applicant was worded as follows: '"Symbiosal®" has been shown to lower the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for high blood pressure (hypertension)'.

(6) On 25 July 2018, the Commission and the Member States received the scientific opinion from the Authority ([2]), which concluded that on the basis of the data presented a cause and effect relationship has not been established between the consumption of 'Symbiosal®' and lowering of blood pressure. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) EFSA Journal 2018;16(7):5364.

(7) The comments from the applicant received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting out the measure provided for in this Regulation.

(8) 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 claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) 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, 11 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Rejected health claim

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk.	'Symbiosal®' (a food supplement containing sea salt (97 %) plus chitosan (3 %)).	'Symbiosal®' has been shown to lower the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for high blood pressure (hypertension).	Q-2018-00002