COMMISSION REGULATION (EU) 2022/710

of 6 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 included in the Union 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 ('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 health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Anxiofit Ltd., submitted pursuant to Article 14(1), point (a), of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Anxiofit-1 and the reduction of subthreshold and mild anxiety (Question No EFSA-Q-2020-00032). The claim proposed by the applicant was worded as follows: 'Anxiofit-1 has been shown to ameliorate subthreshold and mild anxiety. Subthreshold and mild anxiety are risk factors in the development of anxiety disorders and depression'.

(6) The Commission, the Member States and the applicant received the scientific opinion ([2]) on that claim from the Authority, which concluded that, on the basis of the data presented, the scientific evidence had been insufficient to establish a cause and effect relationship between the consumption of Anxiofit-1 and the reduction of subthreshold and mild anxiety. 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 claims, it should not be authorised.

(7) 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 set out 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.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) EFSA Journal 2020;18(10):6264.

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, 6 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), point (a), health claim referring to the reduction of disease risk	Anxiofit-1, a food ingredient that contains an *Echinacea angustifolia* hydro-alcoholic root dry extract standardised for the specific alkamide profile	Anxiofit-1 has been shown to ameliorate subthreshold and mild anxiety. Subthreshold and mild anxiety are risk factors in the development of anxiety disorders and depression	EFSA-Q-2020-00032