COMMISSION REGULATION (EU) 2022/711

of 6 May 2022

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 ('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 analyze & realize GmbH, 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 GlycoLite™ and the reduction of body weight (Question No EFSA-Q-2018-00611). The claim proposed by the applicant was worded as follows: 'GlycoLite™ helps to reduce body weight'.

(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 evidence provided has been insufficient to establish a cause and effect relationship between the consumption of an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its *in vitro* α-amylase inhibitory activity (GlycoLite™) and a reduction of body weight either under energy restriction or when eating *ad libitum*. 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) Following an application from BioGaia AB, 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 orodispersible lozenges containing a combination of *Lactobacillus reuteri* DSM 17938 and *Lactobacillus reuteri* ATCC PTA 5289 and normal gum function (Question No EFSA-Q-2019-00383). The claim proposed by the applicant was worded as follows: 'Lozenges containing *Lactobacillus reuteri* DSM 17938 and *Lactobacillus reuteri* ATCC PTA 5289 support normal gum function'.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) EFSA Journal 2019;17(6):5715.

(8) The Commission, the Member States and the applicant received the scientific opinion ([3]) on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided has been insufficient to establish a cause and effect relationship between the consumption of orodispersible lozenges containing a combination of *Lactobacillus reuteri* DSM 17938 and *Lactobacillus reuteri* ATCC PTA 5289 and the maintenance of normal gum function. 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.

(9) The comments from analyze & realize GmbH received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when adopting this Regulation.

(10) 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 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, 6 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

([3]) EFSA Journal 2020;18(3):6004.

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	GlycoLite™ – A proprietary standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.)	GlycoLite™ helps to reduce body weight	Q-2018-00611
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Lozenges with two *Lactobacillus reuteri* strains: *Lactobacillus reuteri* DSM 17938 and *Lactobacillus reuteri* ATCC PTA 5289, approximately equal amount of each strain (total minimum amount of 1×10^8 CFU/lozenge of each bacterial strain)	Lozenges containing *Lactobacillus reuteri* DSM 17938 and *Lactobacillus reuteri* ATCC PTA 5289 support normal gum function	Q-2019-00383