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COMMISSION REGULATION (EU) 2025/350

of 21 February 2025

refusing to authorise a health claim 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) Pursuant to Regulation (EC) No 1924/2006, scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and food business operators using those claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

(3) Article 18 of Regulation (EC) No 1924/2006 provides that applications for the inclusion of health claims in the Union list of permitted 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.

(4) Following the receipt of an application, the Authority is to deliver an opinion on the health claim concerned. 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 Greenleaf Medical AB ('the applicant'), submitted pursuant to Article 18(1) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Appethyl® and reduction of body weight (Question No EFSA-Q-2022-00096). The claim proposed by the applicant was worded as follows: 'Appethyl® helps your body weight reduction during mild caloric restriction'.

(6) On 31 August 2023, the Authority adopted the scientific opinion ([2]) on that health claim and forwarded it to the Commission and the Member States on 11 October and 9 November 2023 respectively.

(7) In its opinion, the Authority concluded that, on the basis of the data presented, the food/constituent Appethyl®, an aqueous extract from spinach leaves standardised by the manufacturing process and its lipase/colipase inhibition capacity *in vitro*, which is the subject of the health claim, is sufficiently characterised. However, a cause-and-effect relationship has not been established between the consumption of Appethyl® and a reduction of body weight under the conditions of use proposed by the applicant. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised for the inclusion in the Union list of permitted health claims.

([1]) OJ L 404, 30.12.2006, p. 9, ELI: http://data.europa.eu/eli/reg/2006/1924/oj.
([2]) *EFSA Journal* 2023;21(10):8239.

(8) Upon publication of that opinion, the Commission did not receive any comments pursuant to Article 16(6) of Regulation (EC) No 1924/2006.

(9) The Member States have been consulted in the context of the working group meeting on nutrition and health claims of 17 November 2023.

(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 proposed health claim set out 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, 21 February 2025.

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 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Appethyl®, an aqueous extract from spinach leaves standardised by the manufacturing process and its lipase/colipase inhibition capacity *in vitro*	Appethyl® helps your body weight reduction during mild caloric restriction	*EFSA Journal* 2023;21(10):8239 – Q-2022-00096