



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/967/2023
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[...] (2023) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

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)

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 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 foods¹, 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) Article 18 of the Regulation (EC) No 1924/2006 also provides that applications for authorisation of health claims must 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 other Member States for information.
- (3) Following the receipt of an application, the Authority is to deliver an opinion on the health claim concerned within five months.
- (4) The Commission is to decide on the authorisation of the health claim taking into account the opinion delivered by the Authority. However, in accordance with Article 17 of the Regulation (EC) No 1924/2006, in that consideration the Commission must take into account also other legitimate factors relevant to the matter.
- (5) Following an application from BENEIO GmbH, submitted pursuant to Article 18(1) of Regulation (EC) No 1924/2006 for a health claim within the meaning of Article 13(5), the Authority was required to deliver an opinion on a health claim related to isomaltulose and its contribution to the normal energy-yielding metabolism (Question No EFSA-Q-2021-00073). The claim proposed by the applicant was worded as follows: 'Consumption of foods/drinks containing isomaltulose (Palatinose™) replacing other sugars contributes to normal energy-yielding metabolism yet via a slower hydrolysis'. Upon a request from the Authority according to which the contribution of glycaemic carbohydrates (including isomaltulose) to energy-yielding metabolism does not depend on the rate of hydrolysis to glucose, the scope of the scientific evaluation was restricted to the contribution of isomaltulose as a source of

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¹ OJ L 404, 30.12.2006, p. 9.

glucose to normal energy-yielding metabolism with the agreement of the applicant. The target population is the general population.

- (6) On 15 September 2021, the Authority adopted a scientific opinion² on that claim, in which the Authority concluded that, on the basis of the data presented, a cause-and-effect relationship has been established between the consumption of isomaltulose and the contribution to normal energy-yielding metabolism. However, since the contribution to energy-yielding metabolism is not specific to isomaltulose but applies to all energy containing macronutrients (i.e. carbohydrates, proteins, and lipids) which supply the body with metabolisable energy and that any amount of those macronutrients would contribute to the claimed effect, the Authority could not set conditions of use for this claim.
- (7) Pursuant to Articles 6(1) and 13(1) of Regulation (EC) No 1924/2006, health claims shall be based on generally accepted scientific evidence. According to Regulation (EC) No 1924/2006, health claims must also be truthful, clear, reliable and useful to the consumer in choosing a healthy diet. In this respect also Article 5(2) requires that the health claim can only be made if the average consumer can be expected to understand the beneficial effects as expressed in the claim. Authorisation may legitimately be withheld if health claims do not comply with other general and specific requirements of Regulation (EC) No 1924/2006, even in the case of a favourable scientific assessment by the Authority. Health claims inconsistent with generally accepted nutrition and health principles should not be made. In this particular case, the use of such a health claim would convey a conflicting and confusing message to consumers. Isomaltulose is a disaccharide that consists of one glucose and one fructose molecule and therefore such health claim would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced.
- (8) Therefore, a health claim as described above does not comply with point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006, which provides that the use of nutrition and health claims should not be ambiguous or misleading. Furthermore, even if the concerned health claim was to be authorised only under specific conditions of use and/or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently it should not be authorised for inclusion in the Union list of permitted health claims. That conclusion is also in line with Commission Regulation (EU) 2015/8³, which contains the same finding concerning glucose and the contribution to energy yielding metabolism.
- (9) The comments of the applicant received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when adopting this Regulation.
- (10) The Member States have been consulted in the context of the working group meeting on nutrition and health claims of 11 July 2022.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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² EFSA Journal 2021;19(10):6849.

³ Commission Regulation (EU) 2015/8 of 6 January 2015 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 ([OJ L 3, 7.1.2015, p. 6](#)).

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 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