



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10158/2022
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[...] (2022) **XXX** draft

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

of **XXX**

**refusing to authorise a health claim made on foods and referring 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 and referring 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 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 authorisation 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 the health claim taking into account the opinion delivered by the Authority.
- (5) Following an application from the Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology, submitted pursuant to Article 14(1), point (b), of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to organic foods and their contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage, and whose target population are healthy children 3 to 15 years old (Question No EFSA-Q-2021-00055). The claim proposed by the applicant was worded as follows: 'Organic food (lower levels of pesticide residues than those in conventional food) contributes to the protection of body cells and molecules (lipids and DNA) from oxidative damage'.
- (6) On 20 October 2021, the Commission and the Member States received the Authority's scientific opinion² on that claim. In that opinion, the Authority noted that the level of pesticide residues required to characterise foods as 'organic' has not been specified either in the application or in the human studies submitted for the substantiation of the

¹ OJ L 404, 30.12.2006, p. 9.

² EFSA Journal 2021;19(10):6847.

health claim, and concluded that, on the basis of the data presented, the food/constituent 'organic foods', which is the subject of the health claim, is not sufficiently characterised and therefore a cause and effect relationship cannot be established between the consumption of organic foods and the protection of body cells and molecules (lipids and DNA) from oxidative damage. 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 health claims, it should not be authorised.

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

For the Commission
The President
Ursula VON DER LEYEN