



Brussels, 13 January 2026
(OR. en)

5235/26

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FOOD 3
SAN 19

COVER NOTE

From:	European Commission
date of receipt:	12 January 2026
To:	General Secretariat of the Council

No. Cion doc.:	D109784/02
Subject:	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

Delegations will find attached document D109784/02.

Encl.: D109784/02



Brussels, **XXX**
PLAN/2025/1081
(POOL/E1/2025/1081/1081-EN.docx)
D109784/02
[...](2025) **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)

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 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.
- (3) Following the receipt of an application, the Authority is 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 Alzchem Trostberg GmbH ('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 creatine and improvement in cognitive function (Question No EFSA-Q-2024-00106). The claim proposed by the applicant was worded as follows: 'Daily creatine supplementation can contribute to improved cognitive function'.
- (6) On 19 November 2024, the Authority published its scientific opinion² on that health claim.
- (7) In its scientific opinion, the Authority concluded that, on the basis of the data presented, a cause and effect relationship has not been established between creatine supplementation and an improvement in cognitive function in one or more of its domains, such as memory, verbal fluency, attention, alertness, processing speed,

¹ OJ L 404, 30.12.2006, p. 9., ELI: data.europa.eu/eli/reg/2006/1924/oj.

² EFSA Journal 2024;22 :e9100. <https://doi.org/10.2903/j.efsa.2024.9100>

psychomotor speed, executive function and general cognitive ability or flexibility and fluid intelligence.

- (8) 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.
- (9) The Authority forwarded its scientific opinion to the Commission, the applicant and the Member States. Upon publication of that opinion, the Commission did not receive any comments from the applicant or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.
- (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 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