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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	17 July 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D(2025) 105783
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 D(2025) 105783.

Encl.: D(2025) 105783

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2024/2178 Rev.1
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[…](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 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) Regulation (EC) No 1924/2006 also 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 Edge Pharma Sp. z o.o. ('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 citicoline and support of the memory (Question No EFSA-Q-2022-00411). The claim proposed by the applicant was worded as follows: 'Citicoline intake supports memory function in healthy middle-aged and elderly persons encountering age-related memory impairment'.

(6) On 4 July 2024, the Authority published a scientific opinion[2] 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 the consumption of citicoline (CDP-Choline) inner salt and improvement, maintenance or reduced loss of memory in healthy middle-aged or elderly adults encountering age-associated subjective memory impairment. Accordingly, as the health claim does not

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

[2] EFSA Journal 2024;22(7) :e8861.

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.

(8) 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.

(9) 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