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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 18 July 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards magnesium L-threonate as a source of magnesium used in the manufacture of food supplements

Delegations will find attached document D(2025) 106539.



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2805/2024 Rev.1
(POOL/A1/2024/2805/2805R1-
EN.docx) D106539/02
[...](2025) **XXX** draft

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

of **XXX**

amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards magnesium L-threonate as a source of magnesium used in the manufacture of food supplements

(Text with EEA relevance)

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

of **XXX**

amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards magnesium L-threonate as a source of magnesium used in the manufacture of food supplements

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements¹, and in particular Article 4(5) thereof,

Whereas:

- (1) Annexes I and II to Directive 2002/46/EC establish the lists of vitamin and mineral substances, and for each of them the forms, which may be used in the manufacture of food supplements.
- (2) Following a request from the European Commission, the European Food Safety Authority ('the Authority') was asked to deliver an opinion on the safety of magnesium L-threonate as a novel food pursuant to Regulation (EU) 2015/2283 and to address the bioavailability of magnesium from this source in the context of Directive 2002/46/EC.
- (3) On 30 January 2024, the Authority adopted a scientific opinion², where it concluded that magnesium L-threonate is safe under the proposed conditions of use and that it is a source from which magnesium is bioavailable.
- (4) Commission Implementing Regulation (EU) 2024/2694³ authorised, based on the Authority's scientific opinion, the placing on the market of magnesium L-threonate as a novel food for use in food supplements, subject to specific conditions.
- (5) The Commission considers that the Authority's scientific opinion of 2024 gives sufficient grounds to establish that magnesium L-threonate used in food supplements as authorized by Implementing Regulation (EU) 2024/2694 is not of safety concern as a source of magnesium.

¹ OJ L 183, 12.7.2002, p. 51, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>.

² EFSA NDA Panel. Safety of magnesium L-threonate as a novel food pursuant to regulation (EU) 2015/2283 and bioavailability of magnesium from this source in the context of Directive 2002/46/EC, <https://doi.org/10.2903/j.efsa.2024.8656>

³ Commission Implementing Regulation (EU) 2024/2694 of 17 October 2024 authorising the placing on the market of magnesium L-threonate as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L, 2024/2694, 18.10.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2694/oj).

- (6) Therefore, magnesium L-threonate should be included in the list of vitamin and mineral substances set out in Annex II to Directive 2002/46/EC, in order to allow its use as a source of magnesium in food supplements.
- (7) Directive 2002/46/EC should therefore be amended accordingly.
- (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

Annex II to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

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