



EUROPEAN
COMMISSION

Brussels, XXX
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[...](2026) XXX draft

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

of XXX

**authorising the placing on the market of beta-nicotinamide mononucleotide (β -NMN) as
a novel food and amending Implementing Regulation (EU) 2017/2470**

(Text with EEA relevance)

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authorising the placing on the market of beta-nicotinamide mononucleotide (β-NMN) as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001¹, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470² has established a Union list of novel foods.
- (3) On 2 August 2023, the company Effepharm (Shanghai) Ltd. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place beta-nicotinamide mononucleotide (β-NMN) on the Union market as a novel food. The applicant requested for the novel food to be used in food supplements as defined in Directive

¹ OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

² Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

2002/46/EC³ intended for the adult population, excluding pregnant and lactating women.

- (4) On 2 August 2023, the applicant also made a request to the Commission for the protection of the following proprietary data: identity of the novel food⁴, compositional data⁵, data on the history of use⁶, Absorption, distribution, metabolism and excretion (ADME)⁷ and toxicological information⁸.
- (5) On 11 April 2024, the Commission requested the European Food Safety Authority ('the Authority') to provide a scientific opinion on beta-nicotinamide mononucleotide (β-NMN) as a novel food.
- (6) On 4 March 2026, the Authority adopted its scientific opinion on the 'Safety of beta-nicotinamide mononucleotide (β-NMN) pursuant the regulation (EU) 2015/2283 and the bioavailability of nicotinamide from this source in the context of Directive 2002/46/EC'⁹ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that the novel food, beta-nicotinamide mononucleotide (β-NMN), is safe under the proposed conditions of use. The Authority also concluded that the novel food is a source from which niacin is bioavailable.
- (8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the proprietary data concerning data on the identity of the novel food, certain compositional data¹⁰, certain data on Absorption, distribution, metabolism and excretion (ADME)¹¹ and toxicological information, without which it could not have assessed the novel food and reached its conclusion.
- (9) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b), of Regulation (EU) 2015/2283.
- (10) The applicant declared that they held proprietary and exclusive rights of reference to the relevant studies, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (11) The Commission assessed all the information provided by the applicant and considers that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data on the identity of the novel food, certain compositional data¹², certain data on Absorption, distribution,

³ 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 supplements (OJ L 183, 12.7.2002, p. 51, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

⁴ Solubility study report (Annex E)

⁵ Certificate of analysis (Annexes D, Annexes H); Method validation (Annex G).

⁶ FDA correspondence (Annexes A).

⁷ Hydrolysis as a function of pH (Annex P); Bidirectional permeability and efflux ration in Caco-2 cells (Annex S); Pharmacokinetic comparison study (Annex T); Human pharmacokinetic study (Annex U).

⁸ Bacterial reverse mutation test (Annex I, Genotoxicity); In vitro micronucleus assay (Annex R, Genotoxicity); In vitro chromosomal aberration assay (Annex J, Genotoxicity); In vivo chromosomal aberration assay (Annex K, Genotoxicity); Acute oral toxicity (Annex L, Acute toxicity); Repeated dose 90-day study (Annex M, Subchronic toxicity); Clinical trial (Annex N, Human Data).

⁹ *EFSA Journal*. 2026;24:e10007.

¹⁰ Certificate of analysis (Annexes D, Annexes H).

¹¹ Human pharmacokinetic study (Annex U).

¹² Certificate of analysis (Annexes D, Annexes H).

metabolism and excretion (ADME)¹³, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place inulin-propionate ester on the market within the Union during a period of five years from the entry into force of this Regulation.

- (12) However, such restriction of the authorisation and the reference to the data contained in the applicant's file for their sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.
- (13) It is appropriate that the inclusion of beta-nicotinamide mononucleotide (β -NMN) as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (14) Beta-nicotinamide mononucleotide (β -NMN) should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (15) 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

1. Beta-nicotinamide mononucleotide (β -NMN) is authorised to be placed on the market within the Union.

Beta-nicotinamide mononucleotide (β -NMN) shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Effepharm (Shanghai) Ltd.¹⁴ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from [*the date of entry into force of this Regulation*] [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for the novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of the company Effepharm (Shanghai) Ltd.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the company Effepharm (Shanghai) Ltd.

¹³ Human pharmacokinetic study (Annex U).

¹⁴ Bld 4, No.1, Mid Wangdong Rd, Shanghai, China.

Article 4

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