COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of magnesium L-threonate 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 1852/2001[1], 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) 2017/2470[2] has established a Union list of novel foods.

(3) On 24 March 2021, the company AIDP Inc. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place magnesium L-threonate 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 2002/46/EC of the European Parliament and of the Council[3] intended for adults, excluding pregnant and lactating women.

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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).

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) On 24 March 2021, the applicant also made a request to the Commission for the protection of the following proprietary data: bioavailability study in rats[4], toxicological studies (*in vitro* bacterial reverse mutation assay[5], *in vivo* micronucleus test[6] and toxicity studies[7]) and a randomised, placebo-controlled human study[8].

(5) On 28 June 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of magnesium L-threonate as a novel food. Furthermore, the Commission considered that the novel food, magnesium L-threonate, should be considered as a source of magnesium in the context of Directive 2002/46/EC of the European Parliament and of the Council. Therefore, the Commission requested the Authority to evaluate, following the outcome of the novel food assessment, the safety and bioavailability of the novel food when added for nutritional purposes as a source of magnesium to food supplements.

(6) On 30 January 2024, the Authority adopted its scientific opinion on the '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'[9] in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that the novel food, magnesium L-threonate, is safe under the proposed conditions of use. The Authority also considers that the novel food is a source from which magnesium is bioavailable. Therefore, that scientific opinion gives sufficient grounds to establish that magnesium L-threonate, when used under the proposed conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the bioavailability study in rats, the *in vitro* bacterial reverse mutation assay, the *in vivo* micronucleus test, and the randomised, placebo-controlled human study, 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)(b) of Regulation (EU) 2015/2283.

(10) The applicant declared that it held proprietary and exclusive rights of reference to the bioavailability study in rats, the *in vitro* bacterial reverse mutation assay, the *in vivo* micronucleus test, and the randomised, placebo-controlled human study, at the time it 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 considered that it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the bioavailability study in rats, the *in vitro* bacterial reverse mutation assay, the *in vivo* micronucleus test, and the randomised, placebo-controlled human study should be protected in

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4 Annex 37 – Bioavailability study.
5 Annex 38 – OECD 471 study.
6 Annex 39 – OECD 474 study.
7 Annexes 41 and 42 – OECD 408 study.
8 Annexes 43 and 44 – clinical trial study.
9 EFSA Journal. 2024;22:e8656.

accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place magnesium L-threonate on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, restricting the authorisation of monosodium salt of L-5-methyltetrahydrofolic acid 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 magnesium L-threonate 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) Magnesium L-threonate 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) Magnesium L-threonate is authorised to be placed on the market within the Union.

Magnesium L-threonate 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 AIDP Inc.[10] 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 that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of AIDP Inc.

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 AIDP Inc.

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.*

[10] 19535 East Walnut Drive South City of Industry, CA 91748, the United States.

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