COMMISSION IMPLEMENTING REGULATION (EU) …/...

of *[OP please insert the next number]*

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specifications of the novel food nicotinamide riboside chloride

(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 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) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes nicotinamide riboside chloride as an authorised novel food.

(4) Commission Implementing Regulation (EU) 2020/16[3] authorised the placing on the market of nicotinamide riboside chloride as a novel food for use in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[4] for adult population.

(5) On 2 March 2020, the company ChromaDex Inc. ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 for an amendment of the conditions of use of the novel food nicotinamide riboside chloride. The applicant requested to extend the use of nicotinamide riboside chloride to

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1 OJ L 327, 11.12.2015, p. 1.

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).

3 Commission Implementing Regulation (EU) 2021/1319 of 9 August 2021 authorising changes in the specifications of the novel food Coriander seed oil from Coriandrum sativum and amending Implementing Regulation (EU) 2017/2470 (OJ L 286, 10.8.2021, p. 12).

4 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).

foods for special medical purposes as defined by Regulation (EU) No 609/2013 of the European Parliament and of the Council[5], total diet replacement for weight control as defined by Regulation (EU) No 609/2013, meal replacement products and nutritional drink mixes intended for the adult population, excluding pregnant and lactating women.

(6) On 2 March 2020, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, a human study evaluating the safety and dose-dependent effects of nicotinamide riboside chloride supplementation[6].

(7) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 8 June 2020, requesting it to provide a scientific opinion by carrying out an assessment of an extension of use of the novel food nicotinamide riboside chloride.

(8) On 14 September 2021, the Authority adopted its scientific opinion on 'Extension of use of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283[7] in accordance with Article 11 of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority concluded that the novel food is safe for use in foods for special medical purposes and total diet replacement for weight control under the proposed conditions of use. In relation to the request for an extension of use in meal replacement products and nutritional drink mixes, the proposed target population is the adult population, excluding pregnant and lactating women. However, as for these two foods, it cannot not be excluded that they would also be consumed by other population groups in accordance with Article 5(6) of Commission Implementing Regulation (EU) 2017/2469[8] the safety assessment by the Authority covered all population groups. On that basis, the Authority concluded that the safety of the novel food has not been established for use in meal replacement products and nutritional drink mixes due to an absence of data that could be used to establish a safe level of intake of nicotinamide riboside chloride in infants, in particular an Upper Level (UL) for nicotinamide for infants.

(10) Therefore, that scientific opinion gives sufficient grounds to establish that nicotinamide riboside chloride, when used at levels of 500 mg per day in foods for special medical purposes and total diet replacement for weight control intended for the adult population, excluding pregnant and lactating women fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283. Furthermore,

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5 Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

6 Clinical Study Safety Report. Safety and Metabolic Effects of Nicotinamide Riboside in a Randomized, Double-blind, Crossover, Placebo-controlled Trial of Men and Women ≥55 Years of Age (Maki et al., 2020). Annex 4 - Study Report Maki.

7 EFSA Journal 2021;19(11):6843.

8 Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 64).

that scientific opinion also gives sufficient grounds to establish that nicotinamide riboside chloride, when used at levels of 300 mg per day in meal replacement products and nutritional drink mixes intended for the adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(11) Safety data and assessment of nicotinamide riboside chloride for use in foods for special medical purposes and total diet replacement for weight control covered only the adult population, excluding pregnant and lactating women. Therefore, a labelling requirement should be provided in order to properly inform the consumers that foods for special medical purposes and total diet replacement for weight control containing nicotinamide riboside chloride should not be consumed by persons under 18 years of age and pregnant and lactating women.

(12) Since the safety of nicotinamide riboside chloride for use in meal replacement products and nutritional drink mixes was established for the adult population, excluding pregnant and lactating women, a labelling requirement should be provided in order to properly inform the consumers that meal replacement products and nutritional drink mixes containing nicotinamide riboside chloride should not be consumed by persons under 18 years of age and pregnant and lactating women.

(13) The Authority in its opinion noted that no maximum levels for heavy metals are established by the relevant legislation for the foods to which an extension of use of the novel food is requested. Therefore, it is appropriate to amend the specifications of the novel food.

(14) Following the conclusion of the Authority's scientific opinion, the human study evaluating the safety and dose-dependent effects of nicotinamide riboside chloride supplementation[9] was not needed for the assessment and reaching the conclusion by the Authority. Therefore, this study should not be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283.

(15) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

[9] Clinical Study Safety Report. Safety and Metabolic Effects of Nicotinamide Riboside in a Randomized, Double-blind, Crossover, Placebo-controlled Trial of Men and Women ≥55 Years of Age (Maki et al., 2020). Annex 4 - Study Report Maki.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2017/2470 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