COMMISSION IMPLEMENTING REGULATION (EU) 2022/1160

of 5 July 2022

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 the 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: foods for special medical purposes and total diet replacement for weight control, as defined by Regulation (EU) No 609/2013 of the European Parliament and of the Council ([5]), at 500 mg per day, and meal replacements, at 300 mg per day; all of those categories 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 study submitted in support of the application, namely, a human study evaluating the safety and dose-dependent effects of nicotinamide riboside chloride supplementation ([6]).

([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) 2020/16 of 10 January 2020 authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 7, 13.1.2020, p. 6).

([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).

([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) 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 the '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 nicotinamide riboside chloride, when used at levels of 500 mg per day in foods for special medical purposes and in total diet replacement for weight control intended for the adult population, excluding pregnant and lactating women, is safe. Therefore, it is appropriate to change the conditions of use of nicotinamide riboside chloride and to authorise use of nicotinamide riboside chloride in those foods.

(10) In the same opinion, the Authority assessed the safety of meal replacements for the general population, and not only for adults, as according to Article 5(6) of Commission Implementing Regulation (EU) 2017/2469 ([8]) it cannot be excluded that meal replacements containing the novel food would be consumed by other groups of the population. In its opinion, the Authority also indicated that, with the exception of infants, the intake of 300 mg per day of nicotinamide riboside chloride from meal replacements for the adult population, excluding pregnant and lactating women, would be below the established nicotinamide Upper Level ([9]) ('UL') and thus would be considered to be safe. However, in light of the assessment of the Authority on the use of the novel food in meal replacements for all population groups, except infants, demonstrating that the intake of the novel food from meal replacements will be well below the UL for nicotinamide, and in light of the fact that meal replacements are a category of food that is essentially exclusively sought after and used by adults, the Commission is of the view that the novel food may be authorised only for use in meal replacements for the adult population, excluding pregnant and lactating women, at the use level of 300 mg day, as proposed by the applicant.

(11) 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 Articles 9 and 12(1) of Regulation (EU) 2015/2283. Furthermore, that scientific opinion also gives sufficient grounds to establish that nicotinamide riboside chloride, when used at levels of 300 mg per day in meal replacements 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.

(12) Safety data and assessment of nicotinamide riboside chloride for use in foods for special medical purposes, total diet replacement for weight control and meal replacements 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, total diet replacement for weight control and meal replacements containing nicotinamide riboside chloride should only be consumed by persons above 18 years of age excluding pregnant and lactating women.

(13) In its scientific opinion, the Authority included maximum levels for mercury, cadmium and lead in the specifications of the novel food. These levels are applicable only to foods for special medical purposes, total diet replacement for weight control and meal replacements as for these foods no maximum levels for mercury, cadmium and lead have been established by Commission Regulation (EC) No 1881/2006 ([10]). Therefore, the specification of the novel food should be amended accordingly by setting up maximum levels for these heavy metals applicable only to new uses. As no maximum level have been set for arsenic by the same Regulation, the level set by the present Regulation shall be applicable to all authorised uses.

([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).

([9]) EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Committee on Food on the tolerable upper intake level of nicotinic acid and nicotinamide (Niacin): expressed on 17 April 2002. In: SCF (Scientific Committee on Food) and EFSA NDA Panel (Scientific Panel on Dietetic Products, Nutrition and Allergies). Tolerable upper intake levels for vitamins and minerals. EFSA, s.l. 121–134. pp.

([10]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

(14) In its scientific opinion, the Authority indicated that the human study evaluating the safety and dose-dependent effects of nicotinamide riboside chloride supplementation ([11]) was not needed for the assessment and reaching the conclusion by the Authority. Therefore, that 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,

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, 5 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

([11]) 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.

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the entry for 'nicotinamide riboside chloride' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Specified food category	*Maximum levels*			
'**Nicotinamide riboside chloride**	Food supplements as defined in Directive 2002/46/EC	300 mg/day for the adult population, excluding pregnant and lactating women 230 mg/day for pregnant and lactating women	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'nicotinamide riboside chloride'.		Authorised on 20 February 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: ChromaDex Inc., 10900 Wilshire Boulevard Suite 600, Los Angeles, CA 90024 USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by ChromaDex Inc. unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of ChromaDex Inc. End date of the data protection: 20 February 2025.'
	Foods for special medical purposes as defined by Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	In accordance with the particular nutritional requirements of the persons for whom the products are intended	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'nicotinamide riboside chloride' 2. The labelling of foodstuffs containing the novel food shall bear a statement that those foods should only be consumed by persons above 18 years of age excluding pregnant and lactating women.		
	Total diet replacement for weight control as defined by Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	500 mg/day			
	Meal replacements for the adult population, excluding pregnant and lactating women	150 mg/meal (maximum 2 meals/day up to a maximum of 300 mg/day)			

(2) in Table 2 (Specifications), the entry for 'nicotinamide riboside chloride' is replaced by the following:

Authorised Novel Food	Specification
'**Nicotinamide riboside chloride**	**Description/Definition:** The novel food is a synthetic form of nicotinamide riboside. The novel food contains ≥ 90 % nicotinamide riboside chloride, predominantly in its β form, the remaining components being residual solvents, reaction by-products and degradation products. Nicotinamide riboside chloride: CAS number: 23111-00-4 EC number: 807-820-5 IUPAC name: 1-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]pyridin-1-ium-3-carboxamide;chloride Chemical formula: C11H15N2O5Cl Molecular weight: 290,7 g/mol **Characteristics/Composition:** Colour: White to light brown Form: Powder Identification: Conforms by NMR (nuclear magnetic resonance) Nicotinamide riboside chloride: ≥ 90 % Water content: ≤ 2 % **Residual solvents:** Acetone: ≤ 5 000 mg/kg Methanol: ≤ 1 000 mg/kg Acetonitrile: ≤ 50 mg/kg Methyl tert-butyl ether: ≤ 500 mg/kg **Reaction by-products:** Methyl acetate: ≤ 1 000 mg/kg Acetamide: ≤ 27 mg/kg Acetic acid: ≤ 5 000 mg/kg **Heavy metals:** Arsenic: ≤ 1 mg/kg Mercury*: ≤ 0,1 mg/kg Cadmium*: ≤ 1 mg/kg Lead*: ≤ 0,5 mg/kg **Microbiological criteria:** Total Plate Count: ≤ 1 000 CFU/g Yeast and Mould: ≤ 100 CFU/g *Escherichia coli*: Absence in 10 g CFU: colony forming units (*) only for foods for special medical purposes, total diet replacement for weight control and meal replacements'