EUROPEAN
COMMISSION

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[…](2022) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of nicotinamide riboside chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 15 of 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[1] provides that certain types of substances may be added to one or more of those categories of food only if those substances are included in the Union list that is set out in the Annex.

In order to take into account the technical progress, scientific developments or the protection of consumers' health, and subject to the general requirements set out in Articles 6 and 9 of Regulation (EU) No 609/2013, Article 16(1) of the Regulation empowers the Commission to amend the Annex by means of delegated acts with respect to the addition of substances to the Union list.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the European Food Safety Authority ('the Authority') on the matter. The Authority's Scientific Opinion on the extension of use of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283[2] constitutes the scientific basis for this delegated Regulation.

Member States' experts were consulted in writing in the context of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[3] between 22 April 2022 and 13 May 2022.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Union list of substances that may be added to the specific categories of food covered by the scope of Regulation (EU) No 609/2013 as set out in its Article 1(1) is updated in accordance with Article 16 of that Regulation and on the basis of the above-mentioned Authority's opinion to authorise the addition of nicotinamide riboside chloride as a source of niacin to those categories of food aimed at the adult population, namely total diet replacement for weight control and food for special medical purposes.

1 OJ L 181, 29.6.2013, p. 35.
2 EFSA Journal 2021;19(11):6843.
3 Reference E02893 in the Register of Commission Expert Groups and other similar entities.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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

[1], and in particular Article 16(1) thereof,

Whereas:

(1) The Annex to Regulation (EU) No 609/2013 establishes a Union list of substances that may be added to one or more of the categories of food referred to in Article 1(1) of that Regulation.

(2) In accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council[2], 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.

(3) Following an application for extension of the use of nicotinamide riboside chloride as a novel food to cover also its use for nutritional purposes as a source of niacin, in particular, in food for special medical purposes and total diet replacement for weight control, the Commission requested the European Food Safety Authority ('the Authority') to deliver an opinion on such extension of use in accordance with Regulation (EU) 2015/2283 and, following the outcome of that assessment, to evaluate in the context of Regulation (EU) No 609/2013 the safety and bioavailability of that substance when added to the foods in question. On 14 September 2021, the Authority adopted a scientific opinion on the extension of use of nicotinamide riboside chloride as a novel food[5]. In that opinion, the Authority concluded that nicotinamide riboside chloride is as safe as pure nicotinamide, for use in food for special medical purposes and total diet replacement for weight control. Furthermore, the Authority confirmed the bioavailability of nicotinamide, a form of niacin, from nicotinamide riboside chloride.

(4) Commission Implementing Regulation (EU) 2022/1160[6] authorised the use of nicotinamide riboside chloride in, among other products, foods for special medical purposes and total diet replacement for weight control for the adult population, excluding pregnant and lactating women, subject to certain conditions.

(5) The Commission considers that the Authority's opinion also gives sufficient grounds to establish that nicotinamide riboside chloride is not of safety concern as a source of niacin when used in food for special medical purposes and total diet replacement for weight control, under the conditions set out in Commission Implementing Regulation (EU) 2022/1160. Therefore, it is appropriate to allow the use of nicotinamide riboside

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1 OJ L 181, 29.6.2013, p. 35.

2 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 (OJ L 327, 11.12.2015, p. 1)

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 Scientific opinion on the extension of use of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283, EFSA Journal 2021;19(11):6843.

6 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 (OJ L 179, 6.7.2022, p. 25).

chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control. That substance should therefore be included in the Union list of substances that may be added to certain categories of food, set out in the Annex to Regulation (EU) No 609/2013.

(6) The Annex to Regulation (EU) No 609/2013 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 609/2013 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