

COMMISSION REGULATION (EU) 2023/1065**of 1 June 2023****amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council
as regards nicotinamide riboside chloride added to foods****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ⁽¹⁾, and in particular Article 3(3) thereof,

Whereas:

- (1) Annexes I and II to Regulation (EC) No 1925/2006 establish the list of vitamin and mineral substances, and for each of them the forms, which may be added to foods.
- (2) Commission Implementing Regulation (EU) 2020/16 ⁽²⁾ authorised the placing on the market of nicotinamide riboside chloride as a novel food for use in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾, for the adult population.
- (3) As the initial authorisation of this substance as a novel food as set out in Implementing Regulation (EU) 2020/16 concerned only food supplements, the substance has been included in the list set out in Annex II to Directive 2002/46/EC by Commission Regulation (EU) 2021/418 ⁽⁴⁾. 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 meal replacements, 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 of the European Parliament and of the Council ⁽⁵⁾ and, following the outcome of that assessment, to evaluate in the context of Regulation (EC) No 1925/2006, the safety and bio-availability 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 ⁽⁶⁾.
- (4) It follows from that opinion that the use of nicotinamide riboside chloride in foods is not of safety concern as a source of niacin provided that certain conditions are fulfilled. Those conditions are set out in the authorisation of this substance by Commission Implementing Regulation (EU) 2022/1160 ⁽⁷⁾.

⁽¹⁾ OJ L 404, 30.12.2006, p. 26.

⁽²⁾ 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).

⁽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).

⁽⁴⁾ Commission Regulation (EU) 2021/418 of 9 March 2021 amending Directive 2002/46/EC of the European Parliament and of the Council as regards nicotinamide riboside chloride and magnesium citrate malate used in the manufacture of food supplements and as regards the units of measurement used for copper (OJ L 83, 10.3.2021, p. 1).

⁽⁵⁾ 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).

⁽⁶⁾ EFSA Journal 2021;19(11):6843.

⁽⁷⁾ 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).

- (5) In accordance with Article 3(1) of Regulation (EC) No 1925/2006, only vitamins and/or minerals listed in Annex I, in the form listed in Annex II to that act may be added to foods. Based on the Authority's favourable opinion and on the authorisation as a novel food as set out in Implementing Regulation (EU) 2022/1160, nicotinamide riboside chloride should be included in Annex II to Regulation (EC) No 1925/2006 as a form of niacin.
- (6) The Advisory Group on the Food Chain and Animal and Plant Health was consulted and its comments were taken into consideration.
- (7) Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (8) 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

Annex II to Regulation (EC) No 1925/2006 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, 1 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II to Regulation (EC) No 1925/2006, within Point 1 on 'Vitamin formulations', under 'NIACIN', the following entry is added after the entry for 'nicotinamide':

'nicotinamide riboside chloride'.
