II

(Non-legislative acts)

REGULATIONS

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular Article 4(5) thereof,

Whereas:

(1) Annexes I and II to Directive 2002/46/EC list the vitamins and minerals and their forms, which may be used in the manufacture of food supplements.

(2) Pursuant to Article 14 of Directive 2002/46/EC, provisions on vitamin and mineral substances in food supplements that may have an effect upon public health are to be adopted after consultation with the European Food Safety Authority ('the Authority').

(3) Pursuant to Article 14(1) and 14(3)(a) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([2]) food shall not be placed on the market if it is unsafe with regard to the normal conditions of use of the food by the consumer.

(4) Following a request from the European Commission to deliver an opinion on nicotinamide riboside chloride as a novel food including the safety of its use in food supplements as a source of niacin and the bioavailability of nicotinamide, a form of niacin, from this source, in the context of Directive 2002/46/EC, on 4 July 2019 the Authority adopted a scientific opinion on the safety of nicotinamide riboside chloride as a novel food ingredient for use as a source of niacin in food supplements ([3]).

(5) It follows from that opinion that the use of nicotinamide riboside chloride in food supplements is not of safety concern provided that certain limitations are respected which are set out in the approval of this substance by Commission Regulation (EU) 2020/16 ([4]).

([1]) OJ L 183, 12.7.2002, p. 51.

([2]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([3]) EFSA Journal 2019;17(8):5775.

([4]) 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).

(6) Based on the Authority's favourable opinion and on the authorisation as a novel food ingredient as set out in Regulation (EU) 2020/16, nicotinamide riboside chloride should be included in the list set out in Annex II to Directive 2002/46/EC.

(7) Pursuant to Article 8 of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([5]), magnesium citrate malate was included in the Union list of authorised novel foods provided for in the Annex to Commission Implementing Regulation (EU) 2017/2470 ([6]). This listing provides that magnesium citrate malate is authorised exclusively as a novel food ingredient for the use in food supplements as defined in Directive 2002/46/EC. This listing does not include a maximum daily limit for its use in food supplements.

(8) Following a request from the European Commission to deliver an opinion on the nutrient source, magnesium citrate malate, the Authority adopted a scientific opinion on the bioavailability of magnesium from magnesium citrate malate when added for nutritional purposes to food supplements ([7]). The Authority concluded that magnesium citrate malate is a source from which magnesium is bioavailable. The assessment of the bioavailability of a nutrient source is of relevance to its safety assessment as explained by the Authority in its guidance document 'Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources' ([8]). The Authority explains that its approach to evaluating the bioavailability of a nutrient source is by using comparative studies that consider the bioavailability of the chemical forms of the nutrient that are already on the positive lists in the relevant legislation. The Authority further explains that the classification of the bioavailability of a nutrient source as being equivalent, higher or lower than a reference source has implications for the safety of the source at the proposed uses and use levels and with respect to relevant health-based guidance values, such as the tolerable upper intake level (UL) for the nutrient itself.

(9) The Authority in its above-mentioned guidance document, explains that the evaluation of the safety of a nutrient source does not include an assessment of the nutritional, physiological function or safety of the nutrient *per se*, in line with the relevant legal basis for this evaluation. The Authority, however explained that if the proposed uses and use levels of the source were likely to reach the UL for that nutrient, it would consider this in its safety assessment. The Authority, in its scientific opinion on the bioavailability of magnesium citrate malate, noted that at the proposed maximum use levels for magnesium citrate malate, the existing UL for magnesium in food supplements, water, or added to food and beverages (250 mg per day) was exceeded. Directive 2002/46/EC recognises that excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those maximum levels should be set taking into account the UL of the vitamin or mineral, as established by scientific risk assessment based on generally acceptable scientific data, and on intakes of the nutrient from the normal diet. It is to be noted that in 2001, the Scientific Committee on Food ([9]) set the UL for magnesium based on a mild, transient laxative effect which is easily reversible and to which the body can easily adapt within days. On the basis of generally acceptable scientific data, the reported adverse effects from the intake of magnesium when used in the manufacture of food supplements are not considered to be of a severe nature that would necessitate the setting of a maximum safe level for the use of magnesium citrate malate at the proposed use levels in food supplements. However, this situation could be revised as scientific information becomes available that would demonstrate the need to establish a harmonised maximum safe level for magnesium. Furthermore, until such limits are set at EU level, national rules governing the use of magnesium in the manufacture of food supplements may be applied on the basis of the criteria laid down in Article 5 of Directive 2002/46/EC.

(10) Based on the Authority's favourable opinion on the bioavailability of magnesium from magnesium citrate malate, and on its authorisation as a novel food ingredient as set out in Implementing Regulation (EU) 2017/2470, magnesium citrate malate should be included in the list set out in Annex II to Directive 2002/46/EC.

([5]) Regulation (EU) 2015/2283 of the 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]) 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).

([7]) EFSA Journal 2018;16(12):5484.

([8]) EFSA Journal 2018;16(6):5294.

([9]) http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

(11) Pursuant to Article 8(1) and (3) of Directive 2002/46/EC, the amount of copper present in a food supplement is to be declared on the labelling in numerical form using the units of measurement specified in Annex I to Directive 2002/46/EC. Pursuant to Article 8(3) of Directive 2002/46/EC, the information on this substance is also to be expressed as a percentage of the references values set out in Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council [10]. Pursuant to Annex I to Directive 2002/46/EC, the units of measurement for copper required for labelling purposes for food supplements are 'µg', whereas those required for copper pursuant to Regulation (EU) No 1169/2011 are 'mg'. For reasons of consistency and clarity, the units of measurement for copper in Annex I to Directive 2002/46/EC should also be 'mg'. Since the modification of the units of measurement for copper is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.

(12) The Advisory Group on the Food Chain and Animal and Plant Health was consulted and its comments were taken into consideration.

(13) In order to avoid disruptions in trade, sufficient time should be given to allow producers to comply with the new units of measurement for copper. Moreover, in the absence of safety concerns, the marketing of existing stocks of copper-containing food supplements should be allowed after the date of application of Article 1 of this Regulation, until those stocks are exhausted.

(14) Directive 2002/46/EC should therefore be amended accordingly.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 2

Annex II to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 3

Products placed on the market or labelled prior to 30 September 2022 and that do not comply with point 1 of the Annex to this Regulation may be marketed after that date until the existing stocks run out.

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*.

Article 1 shall apply from 30 September 2022.

[10] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Directive 2002/46/EC is amended as follows:

(1) in point 2 of Annex I to Directive 2002/46/EC the entry 'Copper (µg)' is replaced by the following:

'Copper (mg)';

(2) Annex II is amended as follows:

(a) in point A.7. NIACIN the following entry is added after the entry for 'inositol hexanicotinate (inositol hexaniacinate)':

'(d) nicotinamide riboside chloride';

(b) in point B the following entry is added after the entry 'magnesium chloride':

'magnesium citrate malate'.