



2025/352

24.2.2025

COMMISSION REGULATION (EU) 2025/352

of 21 February 2025

amending Directive 2002/46/EC of the European Parliament and of the Council as regards calcidiol monohydrate used in the manufacture of food supplements

(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 establish the lists of vitamins and minerals, and for each of them the forms, which may be used in the manufacture of food supplements.
- (2) Pursuant to Article 14 of Directive 2002/46/EC, provisions on vitamins and minerals 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) Following a request from the Commission to deliver an opinion on calcidiol monohydrate as a novel food pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽²⁾ and as a source of vitamin D in the context of Directive 2002/46/EC, on 25 May 2021, the Authority has adopted a scientific opinion on the matter ⁽³⁾.
- (4) It follows from that opinion that there are no safety concerns about the use of calcidiol monohydrate in food supplements, provided that the conditions for its authorisation set out in Commission Implementing Regulation (EU) 2024/1052 ⁽⁴⁾ are met. Based on the Authority's favourable opinion and on its authorisation as a novel food ingredient in Implementing Regulation (EU) 2024/1052, calcidiol monohydrate should be included in the list of vitamin and mineral substances set out in Annex II to Directive 2002/46/EC, in order to allow its use as a source of vitamin D in food supplements.
- (5) Directive 2002/46/EC should therefore be amended accordingly.
- (6) 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 Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 183, 12.7.2002, p. 51, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>.

⁽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, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>).

⁽³⁾ EFSA NDA Panel. Safety of calcidiol monohydrate produced by chemical synthesis as a novel food pursuant to Regulation (EU) 2015/2283, *EFSA Journal* 2021;19(6):6660.

⁽⁴⁾ Commission Implementing Regulation (EU) 2024/1052 of 10 April 2024 authorising the placing on the market of calcidiol monohydrate as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 2024/1052, 11.4.2024, ELI: http://data.europa.eu/eli/reg_imp/2024/1052/oj).

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, 21 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In point A.2. (VITAMIN D) of Annex II to Directive 2002/46/EC, the following entry is added after the entry for '(b) ergocalciferol':

'(c) calcidiol monohydrate ^(4*)

^(4*) As listed in the Union list of novel foods in 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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).'
