COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX


(TEXT with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list 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 establishing a Union list of authorised novel foods was adopted.

(3) On 16 May 2018, the company DSM Nutritional Products Ltd. ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 to place calcidiol monohydrate on the Union market as a novel food. The applicant requested calcidiol monohydrate to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council, for the general population above 3 years of age.


In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 14 December 2018, requesting it to provide a scientific opinion by carrying out an assessment of calcidiol monohydrate as a novel food.

On 25 May 2021, the Authority adopted its scientific opinions on the ‘Safety of calcidiol monohydrate produced by chemical synthesis as a novel food pursuant to Regulation (EU) 2015/2283’. This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

In that opinion, the Authority concluded that the novel food, calcidiol monohydrate (25-hydroxycholecalciferol monohydrate), is safe under the proposed conditions of use and use levels, (up to 10 µg/day) for children ≥ 11 years old and adults. The Authority also concluded that the novel food is a bioavailable source of the biologically active metabolite of vitamin D, i.e. 1,25-dihydroxyvitamin D. Therefore, the opinion of the Authority gives sufficient grounds to establish that calcidiol monohydrate when used in food supplements for the general population, excluding food supplements for infants and children under 11 years of age under the specific conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

The Authority also noted that for children combined intake of the novel food (5 µg/day) and of calcidiol from the background diet, added to the background intake of vitamin D, would approach the UL for vitamin D (D2 and D3) in children of age 3 to 10 years of age. Furthermore, the applicant proposes to add the novel food to food supplements a preparation containing 0.25% to 0.275% w/w of calcidiol monohydrate. This could result in the Tolerable Upper Intake Level (UL) for children of this age being exceeded. Given the uncertainties, the Authority could not conclude on the safety of consumption of the novel food in children of 3 to 10 years of age at the proposed daily intake. Therefore, the opinion of the Authority does not give sufficient grounds to establish that calcidiol monohydrate when used in food supplements for children from 3 to 10 years of age under the specific conditions of use, complies with Article 12(1) of Regulation (EU) 2015/2283.

In its opinion, the Authority considered that the master data and product specifications, ADME studies, toxicity studies, human studies and the analytical reports including the annexes served as a basis to establish the safety of the novel food. On this basis, the Commission considers that the conclusions on the safety of calcium fructoborate could not have been reached without the data from the reports of those studies.

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A labelling requirement should be provided in order to properly inform the consumers that the food supplements containing calcidiol monohydrate should not be consumed by infants and children under 11 years of age.

Following the authority’s opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the data concerning the production process and compositional data, and to clarify their claim to an exclusive right of reference to that data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.

The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to that data under national law, and that therefore third parties cannot lawfully access or use those studies or refer to that data.

The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data concerning the…… contained in the applicant’s file should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of calcidiol monohydrate should be restricted to the applicant for that period.

However, restricting the authorisation of calcidiol monohydrate and of the reference to the data contained in the applicant’s file for the sole use of the applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.

Regulation (EU) 2017/2470 should therefore be amended accordingly.

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

1. Calcidiol as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the initial applicant:
   - Company: DSM Nutritional Products Ltd.,
   - Address: Wurmisweg 576, 4303 Kaiseraugst, Switzerland,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of DSM Nutritional Products Ltd.
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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

**Article 2**

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

**Article 3**

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*