COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EU) 2017/2470 as regards the labelling requirements of the novel foods α-cyclodextrin and γ-cyclodextrin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[[1]](#footnote-1), and in particular Article 12 thereof,

Whereas:

1. Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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[[2]](#footnote-2) has established a Union list of novel foods.
3. Novel food α-cyclodextrin is included in the Union list of authorised novel foods set out in the Annex to Implementing Regulation (EU) 2017/2470.
4. Commission Decision 2008/413/EC[[3]](#footnote-3) authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[[4]](#footnote-4), the placing on the market of α-cyclodextrin as a novel food ingredient (CAS No 10016-20-3). That Decision included in the specifications the term “α-dextrin” as a synonym for α-cyclodextrin.
5. On 23 December 2021, the company Wacker Chemie AG (‘the applicant’) submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the labelling requirements of the novel food α-cyclodextrin (*NF/2021/1876*). The applicant requested to include “alpha-dextrin” and “α-dextrin” to the specific labelling requirements for the already authorised novel food α-cyclodextrin, in addition to the currently permitted terms “Alpha-cyclodextrin” and “α-cyclodextrin”.
6. The applicant justified the request by indicating that the terms ‘alpha-dextrin’ and ‘alpha-cyclodextrin’ have been used interchangeably for a number of years in the market place and have become synonymous. The Commission understands that including the term alpha dextrin in the labelling requirements will more accurately reflect the prevailing understanding and practice in the market place and will clarify the designation of the product for consumers.
7. Commission Implementing Decision 2012/288/EU[[5]](#footnote-5) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of γ-cyclodextrin as a novel food ingredient (CAS No 17465-86-0). That Decision included in the specifications the term “γ-dextrin” as a synonym for γ-cyclodextrin.
8. The Commission considers that the specific labelling requirements for gamma-cyclodextrin, which was authorised by Commission Implementing Decision 2012/288/EU[[6]](#footnote-6), should also be amended to include the term ‘gamma-dextrin’ for the same reasons justifying the inclusion of alpha dextrin in the specific labelling of alpha-cyclodextrin.
9. The Commission considers that the update of the Union list is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The changes in the labelling requirements only concern the addition of synonyms for α-cyclodextrin and γ-cyclodextrin with the aim to allow the applicant and economic operators to use the term that they consider more appropriate.
10. The information provided in the application gives sufficient grounds to establish that the changes of the labelling requirements of the novel foods α-cyclodextrin and γ-cyclodextrin are in accordance with the conditions of Article 12(2) of Regulation (EU) 2015/2283.
11. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
12. 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

The Annex to Implementing Regulation (EU) 2017/2470 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

1. OJ L 327, 11.12.2015, p. 1. [↑](#footnote-ref-1)
2. 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). [↑](#footnote-ref-2)
3. Commission Decision 2008/413/EC of 26 May 2008 authorising the placing on the market of alpha-cyclodextrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council*.* (OJ L 146, 5.6.2008, p. 12). [↑](#footnote-ref-3)
4. Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1). [↑](#footnote-ref-4)
5. [↑](#footnote-ref-5)
6. 5 Commission Implementing Decision 2012/288/EU of 1 June 2012 authorising the placing on the market of Gamma-cyclodextrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 144, 5.6.2012, p. 41). [↑](#footnote-ref-6)