

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/962****of 15 May 2023****amending Implementing Regulation (EU) 2021/1448 as regards the conditions of approval of the low-risk active substance calcium carbonate and limestone, and amending Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 13(2)(c) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC <sup>(2)</sup> included the approval of calcium carbonate and limestone as active substances in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) Pursuant to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009. The approval of the active substance calcium carbonate, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>, was initially set to expire on 31 August 2022. The approval of the active substance limestone, as set out in Part A of the Annex to the same Regulation was set to expire on 31 August 2019.
- (3) Commission Implementing Regulation (EU) 2021/1448 <sup>(5)</sup> renewed the approval of the low-risk active substance calcium carbonate until 31 October 2036 and amended the Annex to Implementing Regulation (EU) No 540/2011 accordingly.
- (4) On 11 August 2017, AgroRadomysl a.s. submitted to Czechia, as rapporteur Member State, an application for the approval of the active substance limestone in accordance with Article 7(1) of Regulation (EC) No 1107/2009.
- (5) On 26 July 2019, the rapporteur Member State notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application, in accordance with Article 9(3) of Regulation (EC) No 1107/2009.
- (6) The rapporteur Member State finalised its assessment, in the form of a draft assessment report, and sent it to the Commission and the Authority on 11 September 2020. The draft assessment report included a recommendation concerning the decision to be taken with regard to the approval of limestone for the representative uses supported by the applicant.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) 2021/1448 of 3 September 2021 renewing the approval of the low-risk active substance calcium carbonate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 313, 6.9.2021, p. 15).

- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 8 April 2022 <sup>(6)</sup>, the Authority communicated to the Commission its conclusion <sup>(7)</sup> on whether limestone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) In its conclusion, the Authority stated that the two substances, calcium carbonate and limestone, are chemically the same substance.
- (10) The Commission presented a draft review report on limestone (as an additional specification of calcium carbonate) on 8 December 2022 and a draft of this Regulation amending the renewal of approval of calcium carbonate to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2023.
- (11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the draft review report. The applicant submitted its comments, which have been carefully examined.
- (12) Pursuant to Regulation (EC) No 1107/2009, 'substances' should be understood as chemical elements and their compounds, as they occur naturally or by manufacture. Since limestone is composed of calcium carbonate and is chemically the same substance, it is appropriate to include limestone under the same entry as 'calcium carbonate'.
- (13) Calcium carbonate and limestone being chemically the same substance, the Commission considers that the low-risk criteria for calcium carbonate under Article 22 and point 5.1 of Annex II to Regulation (EC) No 1107/2009 are also fully applicable to limestone.
- (14) It is therefore necessary to amend the conditions of approval of calcium carbonate so as to include the specification of limestone. Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) 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*

### **Amendment to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

#### *Article 2*

### **Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

<sup>(6)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance limestone. *EFSA Journal* 2022;20(5):7315.

<sup>(7)</sup> *EFSA Journal* 2021;19(4):6500. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

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

Done at Brussels, 15 May 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Entry 31 in Part D of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'31	Calcium carbonate CAS No 471-34-1 CIPAC No 843 Limestone CAS No 1317-65-3 CIPAC No 852	IUPAC name: Calcium carbonate	950 g/kg	1 November 2021	31 October 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on calcium carbonate and the review report on limestone, and in particular Appendices I and II thereto, shall be taken into account.'

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.