

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/437****of 16 March 2022****renewing the approval of the active substance carbon dioxide 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****(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 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC <sup>(2)</sup> included carbon dioxide as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance carbon dioxide, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2022.
- (4) An application for the renewal of the approval of the active substance carbon dioxide was submitted, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup>, within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 17 December 2019.

<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) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 4 May 2021, the Authority communicated to the Commission its conclusion <sup>(6)</sup> on whether carbon dioxide can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report to the Standing Committee on Plants, Animals, Food and Feed on 6 July 2021 and a draft of this Regulation on 1 December 2021.
- (9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance carbon dioxide that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) In accordance with Article 14(1) of Regulation (EC) No 1107/2009, read in conjunction with Article 6 thereof, and in the light of current scientific and technical knowledge, it is, however, necessary to provide for certain conditions and restrictions.
- (12) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (13) Commission Implementing Regulation (EU) 2021/745 <sup>(7)</sup> extended the approval period of carbon dioxide to 31 August 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that the decision on its renewal is being taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.
- (14) 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*

### **Renewal of the approval of the active substance**

The approval of the active substance carbon dioxide is renewed, subject to the conditions set out in Annex I to this Regulation.

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<sup>(6)</sup> EFSA (European Food Safety Authority) Journal 2021;19(5): 6605, 44 pp. doi:10.2903/j.efsa.2021.6605. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu).

<sup>(7)</sup> Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, bentiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxylglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 160, 7.5.2021, p. 89).

*Article 2***Amendments to Implementing Regulation (EU) No 540/2011**

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

*Article 3***Entry into force and date of application**

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

It shall apply from 1 May 2022.

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

Done at Brussels, 16 March 2022.

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

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## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
Carbon dioxide CAS No: 124-38-9 CIPAC No: 844	Carbon dioxide	999 g/kg  The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: phosphane max. 0,3 ppm v/v benzene max. 0,02 ppm v/v carbon monoxide max. 10 ppm v/v methanol max. 10 ppm v/v hydrogen cyanide max. 0,5 ppm v/v	1 May 2022	30 April 2037	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 carbon dioxide, and in particular Appendices I and II thereof, shall be taken into account.  In this overall assessment Member States shall pay particular attention to: — adequate ventilation (e.g. with a ‘certificate of gas clearance’) before humans can re-enter treated and/or surrounding areas (i.e. chambers, buildings and silos). — the need of buffer zones for residents (subjected to revision considering the wind-speeds in the different Member States).  Conditions of use shall include risk mitigation measures, where appropriate.

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

## ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 225 on carbon dioxide is deleted;  
 (2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'150	Carbon dioxide CAS No: 124-38-9 CIPAC No: 844	Carbon dioxide	999 g/kg  The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: phosphane max. 0,3 ppm v/v benzene max. 0,02 ppm v/v carbon monoxide max. 10 ppm v/v methanol max. 10 ppm v/v hydrogen cyanide max. 0,5 ppm v/vv	1 May 2022	30 April 2037	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 carbon dioxide, and in particular Appendices I and II thereof, shall be taken into account.  In this overall assessment Member States shall pay particular attention to: — adequate ventilation (e.g. with a “certificate of gas clearance”) before humans can re-enter treated and/or surrounding areas (i.e. chambers, buildings and silos). — the need of buffer zones for residents (subjected to revision considering the wind-speeds in the different Member States).  Conditions of use shall include risk mitigation measures, where appropriate.’

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