Official Journal
of the European Union

EN
L series

2023/2591

22.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2591

of 21 November 2023

renewing the approval of the active substance ethephon in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending 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 ([1]), and in particular Article 20(1) thereof,

Whereas:

(1) Commission Directive 2006/85/EC ([2]) included ethephon as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(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 ([4]).

(3) The approval of the active substance ethephon, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 November 2024.

(4) On 28 and 30 July 2014, applications for the renewal of the approval of the active substance ethephon were submitted to the Netherlands, the rapporteur Member State, and Poland, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) and within the time period provided for in that Article.

(5) The applicants submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible 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 Authority and the Commission on 2 August 2017.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2006/85/EC of 23 October 2006 amending Council Directive 91/414/EEC to include fenamiphos and ethephon as active substances (OJ L 293, 24.10.2006, p. 3).
([3]) 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).
([4]) 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).
([5]) 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), which continues to apply to the procedure for the renewal of the approval of this active substance pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 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, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

(7) The Authority made the supplementary summary dossier available to the public. The Authority forwarded the draft renewal assessment report to the applicants 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 18 January 2019, the Authority requested the applicants additionnal information on the endocrine disruptive properties of ethephon pursuant to Article 13(3a) of Implementing Regulation (EU) No 844/2012. The applicants submitted information as regards the criteria to identify endocrine disrupting properties set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605 ([6]).

(9) In September 2022, the rapporteur Member State made an updated draft renewal assesment report available to the Authority, the Member States and the Commission. In its updated draft renewal assessment report, the rapporteur Member State considered the additional information regarding the criteria to identify endocrine disrupting properties and proposed renewing the approval of ethephon.

(10) On 7 December 2022, the Authority communicated to the Commission its conclusion ([7]) which indicated that ethephon can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(11) The Commission presented a draft renewal report and a draft Regulation regarding ethephon to the Standing Committee on Plants, Animals, Food and Feed on 24 May 2023 and on 11 July 2023, respectively.

(12) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicants submitted their comments, which have been carefully examined and taken into consideration.

(13) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance ethephon that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(14) The risk assessment for the renewal of the approval of the active substance ethephon is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing ethephon may be authorised. It is therefore appropriate not to maintain the restriction to use as a plant growth regulator.

(15) It is therefore appropriate to renew the approval of ethephon.

(16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(17) Commission Implementing Regulation (EU) 2023/918 ([8]) extended the approval period of ethephon to 15 November 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([6]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

([7]) *EFSA Journal* 2023;21(1):7742. Available online: www.efsa.europa.eu

([8]) Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, Helicoverpa armigera nucleopolyhedrovirus, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum strain T34 and Trichoderma atroviride strain I-1237 (OJ L 119, 5.5.2023, p. 160).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance ethephon, as specified in Annex I, is renewed, subject to the conditions laid down in that Annex.

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 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 February 2024.

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

Done at Brussels, 21 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Ethephon CAS No: 16672-87-0 CIPAC No: 373	2-chloroethylphosphonic acid	≥ 692 g/kg (TK) ≥ 910 g/kg (TC, theoretical) The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: TK: 1,2-dichloroethane < 0,3 g/kg 2-chloroethanol < 0,3 g/kg TC (theoretical): 1,2-dichloroethane < 0,5 g/kg 2-chloroethanol < 0,3 g/kg	1 February 2024	31 January 2039	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethephon, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of bystanders and residents, ensuring that conditions of use include the use of drift reduction equipment during application. Conditions of use shall include risk mitigation measures, where appropriate.

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

ELI: http://data.europa.eu/eli/reg_impl/2023/2591/oj

ANNEX II

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

(1) in Part A, entry 142 on ethephon is deleted;

(2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'168	Ethephon CAS No: 16672-87-0 CIPAC No: 373	2-chloroethylphosphonic acid	≥ 692 g/kg (TK) ≥ 910 g/kg (TC, theoretical) The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: TK: 1,2-dichloroethane < 0,3 g/kg 2-chloroethanol < 0,3 g/kg TC (theoretical): 1,2-dichloroethane < 0,5 g/kg 2-chloroethanol < 0,3 g/kg	1 February 2024	31 January 2039	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethephon, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of bystanders and residents, ensuring that conditions of use include the use of drift reduction equipment during application. Conditions of use shall include risk mitigation measures, where appropriate.'

[1] Further details on identity and specification of active substance are provided in the review report.