COMMISSION IMPLEMENTING REGULATION (EU) 2024/839

of 8 March 2024

renewing the approval of the low-risk active substance urea 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) in conjunction with Article 22(1) thereof,

Whereas:

(1) Commission Directive 2008/127/EC ([2]) included urea 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 urea, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 November 2026.

(4) An application for the renewal of the approval of the active substance urea was submitted to Greece, the rapporteur Member State, and Finland, 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 applicant 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 July 2020.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal 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.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

([2]) 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, ELI: http://data.europa.eu/eli/dir/2008/127/oj).

([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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).

([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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

([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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

(8) The applicant submitted information as regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([6]), in line with Article 13(3a) of Implementing Regulation (EU) No 844/2012.

(9) The rapporteur Member State, in consultation with the co-rapporteur Member State, prepared an updated draft renewal assessment report in which it considered the additional information as regards the criteria to identify endocrine disrupting properties, and submitted it to the Authority and the Commission on 30 December 2022. In its updated draft renewal assessment report, the rapporteur Member State proposed to renew the approval of urea.

(10) On 18 July 2023, the Authority communicated to the Commission its conclusion ([7]) which indicated that urea can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(11) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 13 October 2023 and 11 December 2023 respectively.

(12) The Commission invited the applicant to submit its 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 applicant submitted its 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 urea that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(14) The Commission further considers that urea is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009, given that urea is not a substance of concern and fulfils the conditions set out in point 5 of Annex II to Regulation (EC) No 1107/2009.

(15) It is therefore appropriate to renew the approval of urea as a low-risk active substance.

(16) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions, including maximum limits for impurities that are considered toxicologically relevant in the technical material as manufactured.

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

(18) Commission Implementing Regulation (EU) 2023/1446 ([8]) extended the approval period of urea to 30 November 2026 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.

(19) 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, ELI: http://data.europa.eu/eli/reg/2018/605/oj).

([7]) EFSA Journal, https://doi.org/10.2903/j.efsa.2023.8112. Available online: www.efsa.europa.eu.

([8]) Commission Implementing Regulation (EU) 2023/1446 of 12 July 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron-methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotrione, tebuconazole and urea (OJ L 178, 13.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/1446/oj).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance urea, as specified in Annex I to this Regulation, 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 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 2024.

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

Done at Brussels, 8 March 2024.

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
Urea CAS No: 57-13-6 CIPAC No: 913	Urea	980 g/kg The following impurities were considered of toxicological concern and a maximum level is established of: Biuret: < 12 g/kg Formaldehyde: < 0,5 g/kg Cadmium: < 1 mg/kg Mercury: < 0,1 mg/kg Lead: < 1 mg/kg Arsenic: < 1 mg/kg	1 May 2024	30 April 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 renewal report on urea, 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 specification of the technical material as commercially manufactured on the basis of an analysis of at least five representative batches. Conditions of use shall include risk mitigation measures, where appropriate.

(1) Further details on the identity and 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 257 on urea is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'48	Urea CAS No: 57-13-6 CIPAC No: 913	Urea	980 g/kg The following impurities were considered of toxicological concern and a maximum level is established of: Biuret: < 12 g/kg Formaldehyde: < 0,5 g/kg Cadmium: < 1 mg/kg Mercury: < 0,1 mg/kg Lead: < 1 mg/kg Arsenic: < 1 mg/kg	1 May 2024	30 April 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 renewal report on urea, 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 specification of the technical material as commercially manufactured on the basis of an analysis of at least five representative batches. Conditions of use shall include risk mitigation measures, where appropriate.'

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