



2023/2589

22.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2589

of 21 November 2023

renewing the approval of the active substance aluminium ammonium sulfate 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 2008/127/EC ⁽²⁾ included aluminium ammonium sulfate as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) According 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 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 aluminium ammonium sulfate, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2024.
- (4) On 24 August 2016, an application for the renewal of the approval of the active substance aluminium ammonium sulfate was submitted to Ireland, the rapporteur Member State, and Portugal, 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 pursuant to Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). 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 25 June 2019. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of aluminium ammonium sulfate.
- (7) The Authority forwarded 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. The Authority also made the supplementary summary dossier available to the public.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽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).

⁽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).

- (8) On 13 April 2022, the Authority communicated to the Commission its conclusion ⁽⁶⁾ which indicated that aluminium ammonium sulfate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding aluminium ammonium sulfate and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 24 May 2023 and 11 July 2023, respectively.
- (10) 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.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance aluminium ammonium sulfate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The risk assessment for the renewal of the approval of the active substance aluminium ammonium sulfate is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing aluminium ammonium sulfate may be authorised. It is therefore appropriate not to maintain the restriction to use as a repellent.
- (13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions.
- (14) It is therefore appropriate to renew the approval of aluminium ammonium sulfate.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2023/1446 ⁽⁷⁾ extended the approval period of aluminium ammonium sulfate to 15 December 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.
- (17) 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 aluminium ammonium sulfate, as specified in Annex I, is renewed, subject to the conditions laid down in that Annex.

⁽⁶⁾ EFSA (European Food Safety Authority). Peer review of the pesticide risk assessment of the active substance aluminium ammonium sulfate EFSA Journal 2022;20(5):7319. Available online: www.efsa.europa.eu.

⁽⁷⁾ 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).

*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

ANNEX I

| Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--|----------------------------|--|------------------|------------------------|--|
| Aluminium ammonium sulfate (dodecahydrate) CAS No: 7784-26-1 CIPAC No: 840 | Aluminium ammonium sulfate | <ul style="list-style-type: none"> — 975 g/kg — Anhydrous - Not less than 510 g/kg — No relevant impurities | 1.2.2024 | 31.1.2039 | <p>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 Aluminium ammonium sulfate, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers where relevant, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms when the substance is applied in regions with acidic or basic soil conditions; — the protection of bees from spray applications during the flowering period of adjacent fields or when flowering weeds are present in the treated field; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions (i.e. situations when soil pH is lower than 5,5, e.g. grassland in upland areas, areas of coniferous forestry and areas of ericaceous ornamental plant growing); — the authorisation, for use on row and combinable crops, as a barrier treatment only on field edges. <p>Conditions of use shall include risk mitigation measures where relevant.</p> |

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

ANNEX II

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

- (1) in Part A, entry 219 on aluminium ammonium sulphate 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 |
|-----|--|----------------------------|--|------------------|------------------------|---|
| 167 | Aluminium ammonium sulfate (dodecahydrate) CAS No: 7784-26-1 CIPAC No: 840 | Aluminium ammonium sulfate | — 975 g/kg — Anhydrous - Not less than 510 g/kg — No relevant impurities | 1.2.2024 | 31.1.2039 | 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 Aluminium ammonium sulfate, 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 where relevant, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms when the substance is applied in regions with acidic or basic soil conditions; — the protection of bees from spray applications during the flowering period of adjacent fields or when flowering weeds are present in the treated field; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions (i.e. situations when soil pH is lower than 5,5, e.g. grassland in upland areas, areas of coniferous forestry and areas of ericaceous ornamental plant growing); — the authorisation, for use on row and combinable crops, as a barrier treatment only on field edges. Conditions of use shall include risk mitigation measures where relevant.' |

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