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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2313

of 17 November 2025

renewing the approval of the active substance gibberellic acid as a low-risk active substance 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 gibberellic acid 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 gibberellic acid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2026.

(4) An application for the renewal of the approval of the active substance gibberellic acid was submitted to Slovenia, the rapporteur Member State, and Slovakia, 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 renewal dossier 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 27 February 2019. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of gibberellic acid.

(7) The Authority 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 and made the supplementary summary dossier available to the public.

([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) On 13 July 2020, the Authority requested additional information from the applicant on the endocrine disrupting properties of gibberellic acid pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012. The applicant submitted information to allow the Authority to conclude the assessment as regards whether the scientific criteria for the determination of endocrine disrupting properties set out in point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605 ([6]), are met.

(9) In April 2023, the rapporteur Member State made an updated draft renewal assessment 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 gibberellic acid.

(10) On 16 October 2024, the Authority communicated to the Commission its conclusion ([7]) indicating that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products containing gibberellic acid 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 14 May 2025 and 9 July 2025, 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 gibberellic acid that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

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

(15) The Commission further considers that gibberellic acid is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Gibberellic acid is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009 and, considering its intended uses, it is expected that plant protection products containing gibberellic acid will pose only a low risk to human and animal health and the environment.

(16) It is therefore appropriate to renew the approval of gibberellic acid as a low-risk active substance.

(17) 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.

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

([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]) Conclusion on pesticides peer review of the pesticide risk assessment of the active substance gibberellic acid (GA3); *EFSA Journal* 2024;22:e9065. Available online: https://doi.org/10.2903/j.efsa.2024.9065.

(19) Commission Implementing Regulation (EU) 2025/787 ([8]) extended the approval period of gibberellic acid to 31 October 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.

(20) 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 gibberellic acid, 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 January 2026.

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

Done at Brussels, 17 November 2025.

For the Commission
The President
Ursula VON DER LEYEN

([8]) Commission Implementing Regulation (EU) 2025/787 of 24 April 2025 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1,4-dimethylnaphthalene, amidosulfuron, bentazone, bixafen, clomazone, fenoxaprop-P, fludioxonil, fluoxastrobin, flutolanil, fluxapyroxad, gibberellic acid, gibberellins, halauxifen-methyl, mecoprop-P, paraffin oil, penthiopyrad, pirimiphos-methyl, propamocarb, propyzamide, prothioconazole, rimsulfuron, sedaxane and sulfoxaflor (OJ L, 2025/787, 25.4.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/787/oj).

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Gibberellic acid CAS No: 77-06-5 CIPAC No: 307	(3S,3aS,4S,4aS,7-S,9aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid or (3S,3aR,4S,4aS,6-S,8aR,8bR,11S)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-ethano-3,8b-prop-1-enoperhydroindeno[1,2-b]furan-4-carboxylic acid	≥ 850 g/kg The impurities Fumonisins B1 and B2; The sum of fumonisin B1 + fumonisin B2 shall not exceed 200 µg/kg in the technical material.	1 January 2026	31 December 2040	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 gibberellic acid, 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 non-target terrestrial plants in the off-crop area. 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.

ELI: http://data.europa.eu/eli/reg_impl/2025/2313/oj

ANNEX II

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

(1) in Part A, entry 232 on Gibberellic acid 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
‘55	Gibberellic acid CAS No: 77-06-5 CIPAC No: 307	(3S,3aS,4S,4aS,7S,9aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid or (3S,3aR,4S,4aS,6S,8aR,8bR,11S)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-ethano-3,8b-prop-1-enoperhydroindeno[1,2-b]furan-4-carboxylic acid	≥ 850 g/kg The impurities Fumonisins B1 and B2; The sum of fumonisin B1 + fumonisin B2 shall not exceed 200 µg/kg in the technical material.	1 January 2026	31 December 2040	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 gibberellic acid, 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 non-target terrestrial plants in the off-crop area. 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.