



2026/351

19.2.2026

**COMMISSION IMPLEMENTING REGULATION (EU) 2026/351**

**of 18 February 2026**

**renewing the approval of the active substance spinosad 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 <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2007/6/EC <sup>(2)</sup> included spinosad 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 spinosad, 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 spinosad was submitted to the Netherlands, the rapporteur Member State, and France, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> and within the time period provided for in that Article.
- (5) The applicant submitted the supplementary 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 30 March 2017. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of spinosad.

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

<sup>(2)</sup> Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam as active substances (OJ L 43, 15.2.2007, p. 13, ELI: <http://data.europa.eu/eli/dir/2007/6/oj>).

<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, ELI: <http://data.europa.eu/eli/dir/1991/414/oj>).

<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, ELI: [http://data.europa.eu/eli/reg\\_impl/2011/540/oj](http://data.europa.eu/eli/reg_impl/2011/540/oj)).

<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, ELI: [http://data.europa.eu/eli/reg\\_impl/2012/844/oj](http://data.europa.eu/eli/reg_impl/2012/844/oj)).

- (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.
- (8) On 4 April 2018, the Authority communicated to the Commission its conclusion <sup>(6)</sup> on whether spinosad can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) In its conclusion, the Authority proposed that spinosad be classified as toxic for reproduction category 2 according to Regulation (EU) No 1272/2008 of the European Parliament and of the Council <sup>(7)</sup>. Furthermore, adverse effects were observed on multiple organs including endocrine organs. On this basis, the Authority concluded that the interim criteria for the consideration of endocrine disrupting properties concerning human health of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as it stood at that time, may be met, leading to a critical area of concern.
- (10) The Commission presented a draft renewal report for spinosad to the Standing Committee on Plants, Animals, Food and Feed on 24 October 2018.
- (11) Since it was not possible for risk managers to conclude whether spinosad is an endocrine disruptor in accordance with the new scientific criteria for the determination of endocrine disrupting properties set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605 <sup>(8)</sup>, the Commission requested the Authority on 14 January 2019 to re-assess the existing information, to request additional information from the applicant if needed and to update its conclusion on the endocrine disrupting potential of spinosad pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012.
- (12) In July 2024, 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, upon request of the Authority, the additional information regarding the criteria to identify endocrine disrupting properties and proposed renewing the approval of spinosad.
- (13) On 12 December 2024, the Authority communicated to the Commission its updated conclusion <sup>(9)</sup> indicating that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products containing spinosad can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that, based on the scientific evidence, spinosad does not meet the criteria for endocrine disruption.
- (14) The Commission presented an updated renewal report on 11 March 2025 and a draft of this Regulation on 9 July 2025 to the Standing Committee on Plants, Animals, Food and Feed.
- (15) 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.

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<sup>(6)</sup> Conclusion on pesticides peer review of the pesticide risk assessment of the active substance spinosad (*EFSA Journal* 2018;16:e5252, available online: <https://doi.org/10.2903/j.efsa.2018.5252>).

<sup>(7)</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1. ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

<sup>(8)</sup> 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>).

<sup>(9)</sup> Updated conclusion on pesticides peer review of the pesticide risk assessment of the active substance spinosad (*EFSA Journal* 2025;23:e9193, available online: <https://doi.org/10.2903/j.efsa.2025.9193>).

- (16) It has been established with respect to one or more representative uses of at least one plant protection product containing spinosad that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of spinosad.
- (17) Although the risk assessment for the renewal of the approval of the active substance spinosad is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing spinosad may be authorised. It is therefore appropriate not to maintain the restriction to use as an insecticide.
- (18) 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 as well as the outcome of the risk assessment, it is, however, necessary to provide for certain conditions.
- (19) It is, in particular, appropriate that the Member States pay particular attention to the assessment of the consumer intake, taking into account the residues of the metabolites of spinosad and considering the impact of storage and processing; the protection of operators, in particular for hand-held applications in low crops; and the protection of wild mammals, aquatic organisms, bees and non-target arthropods.
- (20) In addition, to increase confidence in the decision, the applicant should submit to the Commission, the Member States and the Authority the following confirmatory information: an *in vitro* interspecies comparative metabolism study; an overall assessment of DNT (developmental neurotoxicity), including the submission of data from an *in vitro* DNT test battery; the toxicity and magnitude of residues in plant and animal matrices of spinosyn B and K, PsA and MET A-Li-4(5b) to confirm the residue definitions for risk assessment; the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water; as well as information regarding the chronic effects on honeybees (adults and larvae).
- (21) Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (22) Commission Implementing Regulation (EU) 2025/99<sup>(10)</sup> extended the approval period of spinosad 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 the renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.
- (23) 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 spinosad, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

<sup>(10)</sup> Commission Implementing Regulation (EU) 2025/99 of 21 January 2025 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), *Bacillus amyloliquefaciens* subsp. *plantarum* D747, benalaxyl-M, cyprodinil, dichlorprop-P, formetanate, fosetyl, halosulfuron-methyl, imazamox, milbemectin, phenmedipham, pirimicarb, *Pseudomonas* sp. strain DSMZ 13134, pyrimethanil, pyriofenone, pyroxsulam, spinosad, sulphur, *Trichoderma harzianum* Rifai strains T-22 and ITEM 908, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T-25 and TV-1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, triticonazole and ziram (OJ L, 2025/99, 22.1.2025, ELI: [http://data.europa.eu/eli/reg\\_impl/2025/99/oj](http://data.europa.eu/eli/reg_impl/2025/99/oj)).

*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 April 2026.

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

Done at Brussels, 18 February 2026.

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

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (%)	Date of approval	Expiration of approval	Specific provisions
<p>Spinosad</p> <p>CAS No: 168316-95-8</p> <p>Spinosad: 131929-60-7</p> <p>Spinosyn A: 131929-63-0</p> <p>Spinosyn D: 131929-63-0</p> <p>CIPAC No: 636</p>	<p>Spinosyn A: (50–95 %) (2R, 3aS, 5aR, 5bS, 9S, 13S, 14R, 16aS, 16bR)- 2-(6-deoxy-2,3,4-tri-O-methyl-<math>\alpha</math>-L-mannopyranosyloxy)- 13-(4-dimethylamino-2,3,4,6-tetra-deoxy-<math>\beta</math>-D- erythro-pyranosyloxy)- 9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b- hexadecahydro-14-methyl-1H-as-indaceno[3,2-d] oxacyclododecine-7,15-dione</p> <p>Spinosyn D: (50–5 %) (2S, 3aR, 5aS, 5bS, 9S, 13S, 14R, 16aS, 16bS)- 2-(6-deoxy-2,3,4-tri-O-methyl-<math>\alpha</math>-L-mannopyranosyloxy)- 13-(4-dimethylamino-2,3,4,6-tetra-deoxy-<math>\beta</math>-D- erythro-pyranosyloxy)- 9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b- hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d] oxacyclododecine-7,15-dione</p>	<p>≥ 850 g/kg</p> <p>with 50–95 % of spinosyn A and 5–50 % of spinosyn D</p>	<p>1 April 2026</p>	<p>1 April 2041</p>	<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 renewal report on spinosad of 11 December 2025, 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"> <li>— the assessment of the consumer intake, taking into account the residues of the metabolites of spinosad and considering the impact of storage and processing;</li> <li>— the protection of operators, in particular for hand-held applications in low crops;</li> <li>— the protection of wild mammals, aquatic organisms, bees and non-target arthropods.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> <li>(1) an <i>in vitro</i> interspecies comparative metabolism study;</li> <li>(2) an overall assessment of DNT (developmental neurotoxicity), including the submission of data from an <i>in vitro</i> DNT test battery;</li> </ol>

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
					<p>(3) the toxicity and magnitude of residues in plant and animal matrices of spinosyn B and K, PsA and MET A-Li-4(5b) to confirm the residue definitions for risk assessment;</p> <p>(4) the effect of water treatment processes on the nature of residues present in drinking water;</p> <p>(5) chronic effects on honeybees (adults and larvae).</p> <p>The applicant shall submit the information referred to in point 1, 3, and 4 to the Commission, the Member States and the Authority by 11 March 2028.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 2 within two years after adoption of a guidance document on assessing DNT. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 5 within two years after the adoption of a guidance document with a revised risk assessment methodology for honeybees.</p>

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

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

- (1) in Part A, entry 139 on spinosad is deleted;
- (2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity (%)	Date of approval	Expiration of approval	Specific provisions
'177	Spinosad CAS No: Spinosad: 168316-95-8 Spinosyn A: 131929-60-7 Spinosyn D: 131929-63-0 CIPAC No: 636	Spinosyn A: (50–95 %) (2R,3aS,5aR,5bS,9S,13S,14-R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl- $\alpha$ -L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy- $\beta$ -D-erythro-pyranosyloxy)-9-ethyl-2,3,3a,5a,5-b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione  Spinosyn D: (50–5 %) (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl- $\alpha$ -L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy- $\beta$ -D-erythro-pyranosyloxy)-9-ethyl-2,3,3a,5a,5-b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione	$\geq$ 850 g/kg  with 50–95 % of spinosyn A and 5–50 % of spinosyn D	1 April 2026	1 April 2041	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 spinosad of 11 December 2025, 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 assessment of the consumer intake, taking into account the residues of the metabolites of spinosad and considering the impact of storage and processing; — the protection of operators, in particular for hand-held applications in low crops; — the protection of wild mammals, aquatic organisms, bees and non-target arthropods.  Conditions of use shall include risk mitigation measures, where appropriate.  The applicant shall submit confirmatory information as regards:  (1) an in vitro interspecies comparative metabolism study;

No	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
						<p>(2) an overall assessment of DNT (developmental neurotoxicity) including the submission of data from an <i>in vitro</i> DNT test battery;</p> <p>(3) the toxicity and magnitude of residues in plant and animal matrices of spinosyn B and K, PsA and MET A-Li-4(5b) to confirm the residue definitions for risk assessment;</p> <p>(4) the effect of water treatment processes on the nature of residues present in drinking water;</p> <p>(5) chronic effects on honeybees (adults and larvae).</p> <p>The applicant shall submit the information referred to in point 1, 3, and 4 to the Commission, the Member States and the Authority by 11 March 2028.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 2 within two years after adoption of a guidance document on assessing DNT. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 5 within two years after the adoption of a guidance document with a revised risk assessment methodology for honeybees.'</p>

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