2024/835

13.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/835

of 12 March 2024

renewing the approval of the active substance trinexapac, as trinexapac-ethyl, 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 2006/64/CE ([2]) included trinexapac 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 trinexapac, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2024.

(4) An application for the renewal of the approval of trinexapac, more specifically as the ethyl ester trinexapac-ethyl, was submitted to Lithuania, the rapporteur Member State, and Latvia, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) 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 31 March 2017. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of trinexapac-ethyl.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances (OJ L 206, 27.7.2006, p. 107, ELI: http://data.europa.eu/eli/dir/2006/64/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).

(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 16 March 2018, the Authority communicated to the Commission its conclusion ([6]) on whether trinexapac-ethyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Commission presented a draft renewal report for trinexapac-ethyl to the Standing Committee on Plants, Animals, Food and Feed on 23 October 2018.

(10) In its conclusion, the Authority had concluded that the interim criteria laid down in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, for the determination of endocrine disrupting properties, were not met. However, it had also identified data gaps and therefore could not finalise the assessment of endocrine disrupting properties.

(11) Commission Regulation (EU) 2018/605 ([7]) amended Annex II to Regulation (EC) No 1107/2009 by introducing new scientific criteria for the determination of endocrine disrupting properties. The Commission, thus, requested the Authority, in accordance with Article 14(1a), first subparagraph, of Implementing Regulation (EU) No 844/2012, to update the assessment concerning the endocrine disrupting properties and request additional information from the applicant if needed.

(12) On 8 June 2023, the Authority communicated to the Commission its updated conclusion ([8]) on whether trinexapac-ethyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. In its conclusion, the Authority concluded that trinexapac-ethyl does not meet the criteria to consider a substance as having endocrine disrupting properties.

(13) The Commission presented an updated draft renewal report for trinexapac-ethyl to the Standing Committee on Plants, Animals, Food and Feed on 12 July 2023.

(14) 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.

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

(16) It is therefore appropriate to renew the approval of trinexapac as trinexapac-ethyl.

(17) Although, the risk assessment for the renewal of the approval of trinexapac-ethyl is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing trinexapac-ethyl may be authorised. It is therefore appropriate to remove the restriction for use only as a plant growth regulator.

(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, it is, however, necessary to provide for certain conditions and restrictions. It is, in particular, appropriate to set specific maximum limits for two toxicologically relevant impurities in the technical material and to require confirmatory information on the impact of water treatment processes on the nature of residues of trinexapac-ethyl and its metabolites present in surface water when surface water is abstracted for drinking water, since appropriate guidance was not available at the time of the application for renewal of the approval.

([6]) EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance trinexapac (variant evaluated trinexapac-ethyl). EFSA Journal 2018;16(4):5229. https://doi.org/10.2903/j.efsa.2018.5229.

([7]) 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).

([8]) EFSA (European Food Safety Authority), 2023. Conclusion on updated peer review of the pesticide risk assessment of the active substance trinexapac (variant evaluated trinexapac-ethyl). EFSA Journal 2023;21(6):8082, 26 pp. https://doi.org/10.2903/j.efsa.2023.8082.

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

(20) Commission Implementing Regulation (EU) 2023/689 ([9]) extended the approval period of trinexapac 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 the renewal of the approval of that active substance has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(21) 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 trinexapac, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

Article 2

Amendment 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, 12 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

([9]) Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strain T11, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/689/oj).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Trinexapac-ethyl CAS No 95266-40-3 CIPAC No 732.202	ethyl (1*RS*,4*EZ*)-4-cyclopropyl(hydroxy)methylene-3,5-dioxocyclohexanecarboxylate	≥ 950 g/kg The following impurities shall not exceed the following levels in the technical material: — toluene: 3 g/kg — ethyl (1*RS*)-3-hydroxy-5-oxocyclohex-3-ene-1-carboxylate (CGA158377): 6 g/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 trinexapac-ethyl, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the specification of technical material used in plant protection products, in particular when carrying out assessments of equivalence in accordance with Article 38 of Regulation (EC) No 1107/2009; — the assessment of consumer intake from the diet taking into account the residues of the metabolites of trinexapac-ethyl and the impact of processing; — the levels of residues of the metabolites of trinexapac-ethyl, when straw is used as animal feeding stuff. Conditions of use shall include restrictions for feeding of straw to animals and risk mitigation measures, where appropriate. The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues of trinexapac-ethyl and its metabolites present in surface water, when surface water is abstracted for drinking water, by 1 April 2026.

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

ELI: http://data.europa.eu/eli/reg_impl/2024/835/oj

ANNEX II

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

(1) in Part A, the entry 132 on trinexapac 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
'169	Trinexapac-ethyl CAS No 95266-40-3 CIPAC No 732.202	ethyl (1*RS*,4*EZ*)-4-cyclopropyl(hydroxy) methylene-3,5-dioxocyclohexanecarboxylate	≥ 950 g/kg The following impurities shall not exceed the following levels in the technical material: — toluene: 3 g/kg — ethyl (1*RS*)-3-hydroxy-5-oxocyclohex-3-ene-1-carboxylate (CGA158377): 6 g/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 trinexapac-ethyl, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the specification of technical material used in plant protection products, in particular when carrying out assessments of equivalence in accordance with Article 38 of Regulation (EC) No 1107/2009; — the assessment of consumer intake from the diet taking into account the residues of the metabolites of trinexapac-ethyl and the impact of processing; — the levels of residues of the metabolites of trinexapac-ethyl, when straw is used as animal feeding stuff. Conditions of use shall include restrictions for feeding of straw to animals and risk mitigation measures, where appropriate. The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues of trinexapac-ethyl and its metabolites present in surface water, when surface water is abstracted for drinking water, by 1 April 2026.'

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