COMMISSION IMPLEMENTING REGULATION (EU) 2016/370

of 15 March 2016

approving the active substance pinoxaden, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and allowing the Member States to extend provisional authorisations granted for that active substance

(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 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For pinoxaden the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2005/459/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC, the United Kingdom received on 31 March 2004 an application from Syngenta Crop Protection AG for the inclusion of the active substance pinoxaden in Annex I to Directive 91/414/EEC. Decision 2005/459/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State, the United Kingdom, submitted a draft assessment report on 30 November 2005. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant on 6 June 2011. The evaluation of the additional data by the United Kingdom was submitted in the format of addenda to the draft assessment report on 30 January 2012.

(4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion ([5]) on the peer review of the pesticide risk assessment of the active substance pinoxaden on 14 June 2013. The draft assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 29 January 2016 in the format of the Commission review report for pinoxaden.

(5) It has appeared from the various examinations made that plant protection products containing pinoxaden may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve pinoxaden.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) 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).
([3]) Commission Decision 2005/459/EC of 22 June 2005 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pinoxaden in Annex I to Council Directive 91/414/EEC (OJ L 160, 23.6.2005, p. 32).
([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).
([5]) European Food Safety Authority, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden. EFSA Journal 2013;11(6):3269, 112 pp. doi:10.2903/j.efsa.2013.3269.

(6) In accordance with Article 13(2) 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 include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.

(8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing pinoxaden. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.

(9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

(10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [2] should be amended accordingly.

(11) It is also appropriate to allow Member States to extend provisional authorisations granted for plant protection products containing pinoxaden in order to provide them with the time necessary to fulfil the obligations set out in this Regulation as regards those provisional authorisations.

(12) 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

Approval of active substance

The active substance pinoxaden, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing pinoxaden as an active substance by 31 December 2016.

[1] Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

[2] 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).

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing pinoxaden as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 June 2016 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing pinoxaden as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2017 at the latest; or

(b) in the case of a product containing pinoxaden as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2017 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4

Extension of existing provisional authorisations

Member States may extend existing provisional authorisations for plant protection products containing pinoxaden for a period ending on 31 December 2017 at the latest.

Article 5

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 July 2016 with the exception of Article 4 which shall apply as of the entry into force of this Regulation.

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

Done at Brussels, 15 March 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Pinoxaden CAS No 243973-20-8 CIPAC No 776	8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate	≥ 970 g/kg Toluene max. content 1 g/kg	1 July 2016	30 June 2026	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 pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate. The applicant shall submit confirmatory information as regards: (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; (b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (2) concerning pinoxaden.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) 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).

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'97	Pinoxaden CAS No 243973-20-8 CIPAC No 776	8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate	≥ 970 g/kg Toluene max. content 1 g/kg	1 July 2016	30 June 2026	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 pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate. The applicant shall submit confirmatory information as regards: (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; (b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 concerning pinoxaden.'

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