COMMISSION IMPLEMENTING REGULATION (EU) 2018/1264

of 20 September 2018

renewing the approval of the active substance pethoxamid 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, and amending the Annex to 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 2006/41/EC ([2]) included pethoxamid 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 pethoxamid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2019.

(4) An application for the renewal of the approval of pethoxamid was submitted 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 in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 31 August 2016.

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 30 August 2017 the Authority communicated to the Commission its conclusion ([6]) on whether pethoxamid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for pethoxamid to the Standing Committee on Plants, Animals, Food and Feed on 6 October 2017.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

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

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2006/41/EC of 7 July 2006 amending Council Directive 91/414/EEC to include clothianidin and pethoxamid as active substances (OJ L 187, 8.7.2006, p. 24).

([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).

([6]) EFSA Journal 2017;15(9):4981 [22 pp.] Available online: www.efsa.europa.eu.

(11) It is therefore appropriate to renew the approval of pethoxamid.

(12) The risk assessment for the renewal of the approval of pethoxamid is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing pethoxamid may be authorised. It is therefore appropriate to remove the restriction for use only as an herbicide.

(13) 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 include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

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

(15) Commission Implementing Regulation (EU) 2018/84 [1] extended the expiry date of pethoxamid to 31 January 2019 in order to allow the renewal process to be completed before the expiry of the approval of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply from 1 December 2018.

(16) 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 pethoxamid is renewed as set out in Annex I.

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 December 2018.

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) 2018/84 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, clothianidin, copper compounds, dimoxystrobin, mancozeb, mecoprop-p, metiram, oxamyl, pethoxamid, propiconazole, propineb, propyzamide, pyraclostrobin and zoxamide (OJ L 16, 20.1.2018, p. 8).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Pethoxamid CAS No 106700-29-2 CIPAC No 665	2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl) acetamide	≥ 940 g/kg Impurities: Toluene: max 3 g/kg.	1 December 2018	30 November 2033	PART A Use shall be limited to one application every two years in the same field at a maximum dose of 1 200 g active substance per hectare. PART B 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 pethoxamid, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk of groundwater metabolites when pethoxamid is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms and earthworms; — the risk to consumers from residues in the succeeding crops or in case of crop failure. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the relevance of the metabolites that may occur in groundwater, taking into account any relevant classification for pethoxamid in accordance with Regulation (EC) No 1272/2008 of the Parliament and of the Council [2], in particular as carcinogen category 2; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of pethoxamid as regards the thyroid modality/pathway as a minimum providing mechanistic data to clarify whether there is a thyroid endocrine disrupting mode of action. The applicant shall submit the information requested under point 1 within one year after the publication of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council with respect to pethoxamid and the information requested.

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					The applicant shall submit the information requested under point 2 within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission. The applicant shall submit the information requested under point 3 by 10 November 2020 in accordance with Commission Regulation (EU) 2018/605 (3) amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.

(1) Further details on identity and specification of active substance are provided in the renewal 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).
(3) 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).

ANNEX II

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

(1) in Part A, entry 122 on pethoxamid 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
'127	Pethoxamid CAS No 106700-29-2 CIPAC No 665	2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl) acetamide	≥ 940 g/kg Impurities: Toluene: max 3 g/kg.	1 December 2018	30 November 2033	PART A Use shall be limited to one application every two years in the same field at a maximum dose of 1 200 g active substance per hectare. PART B 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 pethoxamid, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk of groundwater metabolites when pethoxamid is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms and earthworms; — the risk to consumers from residues in the succeeding crops or in case of crop failure. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the relevance of the metabolites that may occur in groundwater, taking into account any relevant classification for pethoxamid in accordance with Regulation (EC) No 1272/2008 of the Parliament and of the Council (2), in particular as carcinogen category 2;

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of pethoxamid as regards the thyroid modality/pathway as a minimum providing mechanistic data to clarify whether there is a thyroid endocrine disrupting mode of action. The applicant shall submit the information requested under point 1 within one year after the publication of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council with respect to pethoxamid and the information requested. The applicant shall submit the information requested under point 2 within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission. The applicant shall submit the information requested under point 3 by 10 November 2020 in accordance with Commission Regulation (EU) 2018/605 (3) amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.'

(1) Further details on identity and specification of active substance are provided in the renewal 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).
(3) 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).