COMMISSION IMPLEMENTING REGULATION (EU) 2018/1265

of 20 September 2018

approving the active substance fenpicoxamid 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 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 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the United Kingdom received on 2 December 2014 an application from Dow AgroScience GmbH for the approval of the active substance fenpicoxamid.

(2) In accordance with Article 9(3) of that Regulation, the United Kingdom, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 13 January 2015 of the admissibility of the application.

(3) On 13 October 2016 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 31 July 2017.

(5) On 22 December 2017 the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance fenpicoxamid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 23 March 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for fenpicoxamid and a draft Regulation providing that fenpicoxamid is approved.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(8) It is therefore appropriate to approve fenpicoxamid.

(9) 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. In particular, it is appropriate to require further confirmatory information.

(10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]) should be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance fenpicoxamid (XDE-777). EFSA Journal 2018;16(1):5146, 27 pp. https://doi.org/10.2903/j.efsa.2018.5146.
([3]) 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).

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance fenpicoxamid, as specified in Annex I, is approved 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

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991	(3*S*,6*S*,7*R*,8*R*)-8-benzyl-3-{3-[(isobutyryloxy) methoxy]-4-methoxy-pyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate	≥ 750 g/kg	11 October 2018	11 October 2028	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 fenpicoxamid, 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 impact of processing on the consumer risk assessment, — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of fenpicoxamid as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify according to Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 (2), whether the effects observed in the studies submitted for approval are or are not related to a thyroid endocrine disrupting mode of action. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 1 by 11 October 2019, in point 2 within 2 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 and in point 3 by 10 November 2020.

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

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

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'126	Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991	(3*S*,6*S*,7*R*,8*R*)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate	≥ 750 g/kg	11 October 2018	11 October 2028	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 fenpicoxamid, 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 impact of processing on the consumer risk assessment, — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of fenpicoxamid as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify according to Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 (2), whether the effects observed in the studies submitted for approval are or are not related to a thyroid endocrine disrupting mode of action. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 1 by 11 October 2019, in point 2 within 2 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 and in point 3 by 10 November 2020.'

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