COMMISSION IMPLEMENTING REGULATION (EU) 2018/692

of 7 May 2018

renewing the approval of the active substance zoxamide 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 2003/119/EC ([2]) included zoxamide 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 zoxamide, 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 zoxamide 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 5 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 21 August 2017 the Authority communicated to the Commission its conclusion ([6]) on whether zoxamide 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 zoxamide to the Standing Committee on Plants, Animals, Food and Feed on 26 January 2018.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

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

([2]) Commission Directive 2003/119/EC of 5 December 2003 amending Council Directive 91/414/EEC to include mesosulfuron, propoxycarbazone and zoxamide as active substances (OJ L 325, 12.12.2003, p. 41).

([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):4980. Available online: www.efsa.europa.eu

(10) It is therefore appropriate to renew the approval of zoxamide.

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

(12) 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.

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

(14) Commission Implementing Regulation (EU) 2018/84 ([1]) extended the expiry date of zoxamide 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 July 2018.

(15) 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 active substance

The approval of the active substance zoxamide 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 July 2018.

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

Done at Brussels, 7 May 2018.

For the Commission
The President
Jean-Claude JUNCKER

([1]) Commission Implementing Regulation (EU) 2018/84 of 19 January 2018 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
Zoxamide CAS No 156052-68-5 CIPAC No 640	(RS)-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-p-toluamide	≥ 953 g/kg	1 July 2018	30 June 2033	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 zoxamide, 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 protection of groundwater from metabolite RH-141455, — the protection of bees, aquatic organisms and earthworms. 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 the effect of water treatment processes on the nature of residues present in drinking water 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 is made public by the Commission.

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

ANNEX II

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

(1) in Part A, the entry 77 on zoxamide is deleted;

(2) in Part B, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'123	Zoxamide CAS No 156052-68-5 CIPAC No 640	(RS)-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-p-toluamide	≥ 953 g/kg	1 July 2018	30 June 2033	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 zoxamide, 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 protection of groundwater from metabolite RH-141455, — the protection of bees, aquatic organisms and earthworms. 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 the effect of water treatment processes on the nature of residues present in drinking water 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 is made public by the Commission.'

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