REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/755

of 23 May 2018

renewing the approval of the active substance propyzamide, as a candidate for substitution, 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 24 in conjunction with Article 20(1) thereof,

Whereas:

(1) Commission Directive 2003/39/EC ([2]) included propyzamide 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 propyzamide, 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 propyzamide 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 July 2015.

(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 12 July 2016 the Authority communicated to the Commission its conclusion ([6]) on whether propyzamide 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 propyzamide to the Standing Committee on Plants, Animals, Food and Feed on 22 March 2018.

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

([2]) Commission Directive 2003/39/EC of 15 May 2003 amending Council Directive 91/414/EEC to include propineb and propyzamide as active substances (OJ L 124, 20.5.2003, p. 30).

([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 (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance propyzamide. *EFSA Journal* 2016;14(7):4554, 103 pp. doi:10.2903/j.efsa.2016.4554; Available online: www.efsa.europa.eu

(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 propyzamide that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of propyzamide.

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

(12) The Commission however considers that propyzamide is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Propyzamide is a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in freshwater is greater than 40 days and the long-term no-observed effect concentration for freshwater organisms is less than 0,01 mg/L. Propyzamide therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(13) It is therefore appropriate to renew the approval of propyzamide as a candidate for substitution.

(14) 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.

(15) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

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

(17) 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 as a candidate for substitution

The approval of the active substance propyzamide, as a candidate for substitution, 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.

[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).

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

Done at Brussels, 23 May 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
Propyzamide CAS No 23950-58-5 CIPAC No 315	3,5-dichloro-N-(1,1-dimethylprop-2-ynyl) benzamide	920 g/kg	1 July 2018	30 June 2025	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 propyzamide 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 protection of operators, — the protection of groundwater in vulnerable areas, — the protection of birds, mammals, non-target plants, soil and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. In particular, personal protective equipment such as gloves, coverall and sturdy footwear has to be worn to ensure that the AOEL is not exceeded for the operator. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the completion of assessment of toxicological profile of metabolites identified in significant concentration in primary and rotational crops; 2. the soil degradation of major metabolite RH- 24580; 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit the information mentioned under point (1) by 31 October 2018 and the information mentioned under point (2) by 30 April 2019. The applicant shall submit the confirmatory information mentioned in point (3) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater be 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, entry 55 on propyzamide is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'9	Propyzamide CAS No 23950-58-5 CIPAC No 315	3,5-dichloro-*N*-(1,1-dimethyl-prop-2-ynyl) benzamide	920 g/kg	1 July 2018	30 June 2025	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 propyzamide 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 protection of operators, — the protection of groundwater in vulnerable areas, — the protection of birds, mammals, non-target plants, soil and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. In particular, personal protective equipment such as gloves, coverall and sturdy footwear has to be worn to ensure that the AOEL is not exceeded for the operator. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the completion of assessment of toxicological profile of metabolites identified in significant concentration in primary and rotational crops; 2. the soil degradation of major metabolite RH- 24580; 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit the information mentioned under point (1) by 31 October 2018 and the information mentioned under point (2) by 30 April 2019. The applicant shall submit the confirmatory information mentioned in point (3) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater be made public by the Commission.'

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