COMMISSION IMPLEMENTING REGULATION (EU) 2017/1531

of 7 September 2017

renewing the approval of the active substance imazamox, 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 2003/23/EC ([2]) included imazamox 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 imazamox, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 31 July 2018.

(4) An application for the renewal of the approval of imazamox 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 13 April 2015.

(7) The Authority communicated the renewal assessment report to the applicant and to the other 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 15 March 2016 the Authority communicated to the Commission its conclusion ([6]) on whether imazamox 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 imazamox to the Standing Committee on Plants, Animals, Food and Feed on 11 July 2016.

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

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

([2]) Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances (OJ L 81, 28.3.2003, p. 39).

([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 2016;14(4):4432. Available online: www.efsa.europa.eu.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing imazamox 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 imazamox.

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

(12) The Commission, however, considers that imazamox is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Imazamox 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 fresh water and sediment is higher than 120 days and the long term no-observed effect concentration for aquatic plants is 0,0045 mg/l. Imazamox 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 imazamox 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.

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

(16) Commission Implementing Regulation (EU) 2017/841 ([1]) extended the approval period of imazamox to 31 July 2018 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 November 2017.

(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 imazamox, 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 November 2017.

([1]) Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, Ampelomyces quisqualis strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, Gliocladium catenulatum strain: j1446, imazamox, imazosulfuron, isoxaflutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin (OJ L 125, 18.5.2017, p. 12).

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

Done at Brussels, 7 September 2017.

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
imazamox CAS No 114311-32-9 CIPAC No 619	2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid	≥ 950 g/kg The impurity cyanide ion (CN^-) shall not exceed 5 mg/kg in the technical material.	1 November 2017	31 October 2024	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 imazamox, 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 consumers; — the protection of aquatic plants and of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from imazamox and metabolites CL 312622 and CL 354825 in vulnerable zones, where appropriate.

(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 41 on imazamox is deleted;

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'8	imazamox CAS No 114311-32-9 CIPAC No 619	2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid	≥ 950 g/kg The impurity cyanide ion (CN^-) shall not exceed 5 mg/kg in the technical material.	1 November 2017	31 October 2024	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 imazamox, 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 consumers; — the protection of aquatic plants and of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from imazamox and metabolites CL 312622 and CL 354825 in vulnerable zones, where appropriate.'

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