COMMISSION IMPLEMENTING REGULATION (EU) 2017/407

of 8 March 2017

renewing the approval of the active substance iodosulfuron 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) The approval of the active substance iodosulfuron, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]), expires on 31 October 2017.

(2) An application for the renewal of the approval of iodosulfuron was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([3]) within the time period provided for in that Article.

(3) 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.

(4) 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 (hereinafter 'the Authority') and the Commission on 29 April 2015.

(5) 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.

(6) On 6 April 2016 ([4]), the Authority communicated to the Commission its conclusion on whether iodosulfuron (considered variant iodosulfuron-methyl-sodium) 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 iodosulfuron to the Standing Committee on Plants, Animals, Food and Feed on 11 July 2016.

(7) 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. Those approval criteria are therefore deemed to be satisfied.

(8) It is therefore appropriate to renew the approval of iodosulfuron.

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

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) 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).
([3]) 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).
([4]) EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iodosulfuron-methyl-sodium (approved as iodosulfuron). *EFSA Journal* 2016;14(4):4453. Available online: www.efsa.europa.eu.

(10) 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.

(11) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(12) Commission Implementing Regulation (EU) 2016/950 [1] extended the approval period of iodosulfuron to 31 October 2017 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 that expiry date, this Regulation shall apply from 1 April 2017.

(13) 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 iodosulfuron, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

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 April 2017.

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

Done at Brussels, 8 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin (OJ L 159, 16.6.2016, p. 3).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Iodosulfuron CAS No 185119-76-0 (parent) CAS No 144550-36-7 (iodosulfuron-methyl-sodium) CIPAC No 634 (parent) CIPAC No 634.501 (iodosulfuron-methyl-sodium)	4-iodo-2-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoylsulfamoyl] benzoic acid (iodosulfuron) sodium ({[5-iodo-2-(methoxycarbonyl) phenyl]sulfonyl} carbamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl) azanide (iodosulfuron-methyl-sodium)	≥ 910 g/kg (expressed as iodosulfuron-methyl-sodium)	1 April 2017	31 March 2032	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 iodosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers, — the risk to non-target terrestrial plants, — the risk to aquatic plants. 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 genotoxic potential of the metabolite triazine-amine (IN-A4098), in order to confirm that this metabolite is not genotoxic and not relevant for the risk assessment; (2) the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit the information requested under point (1) by 1 October 2017 and the information requested under point (2) by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

[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 66 on iodosulfuron is deleted;

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'107	Iodosulfuron CAS No 185119-76-0 (parent) CAS No 144550-36-7 (iodosulfuron-methyl-sodium) CIPAC No 634 (parent) CIPAC No 634.501 (iodosulfuron-methyl-sodium)	4-iodo-2-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl) carbamoylsulfamoyl] benzoic acid (iodosulfuron) sodium ({[5-iodo-2-(methoxycarbonyl) phenyl]sulfonyl} carbamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl)azanide (iodosulfuron-methyl-sodium)	≥ 910 g/kg (expressed as iodosulfuron-methyl-sodium)	1 April 2017	31 March 2032	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 iodosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers, — the risk to non-target terrestrial plants, — the risk to aquatic plants. 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 genotoxic potential of the metabolite triazine-amine (IN-A4098), in order to confirm that this metabolite is not genotoxic and not relevant for the risk assessment; (2) the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit the information requested under point (1) 1 October 2017 and the information requested under point (2) by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.'

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