Commission Implementing Regulation (EU) 2018/1913 of 6 December 2018 renewing the approval of the active substance tribenuron 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1913

of 6 December 2018

renewing the approval of the active substance tribenuron 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 2005/54/EC[(2)] included tribenuron 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 tribenuron, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2019.

(4) An application for the renewal of the approval of tribenuron 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 23 June 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1913. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 dossiers available to the public.

(8) On 29 June 2017 the Authority communicated to the Commission its conclusion[6] on whether tribenuron 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 tribenuron to the Standing Committee on Plants, Animals, Food and Feed on 12 December 2017.

(9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

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

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

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

(13) Commission Implementing Regulation (EU) 2018/1262[7] extended the expiry date of tribenuron to 31 October 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation shall apply from 1 February 2019.

(14) 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 tribenuron 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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1913. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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 February 2019.

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

Done at Brussels, 6 December 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1913. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Tribenuron (parent) CAS No 106040-48-6 CIPAC No 546	2-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-methylcarbamoyl]sulfamoyl]benzoic acid	≥ 960 g/kg (expressed as tribenuron-methyl)	1 February 2019	30 January 2034	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 tribenuron, 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 protection of consumers, in particular to residues on animal products, — the protection of groundwater, — the protection of

a Further details on identity and specification of active substance are provided in the renewal report.