Commission Implementing Regulation (EU) 2017/375 of 2 March 2017 renewing the approval of the active substance prosulfuron, 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/375

of 2 March 2017

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(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) The approval of the active substance prosulfuron, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(2)], expires on 30 June 2017.

(2) An application for the renewal of the inclusion of prosulfuron in Annex I to Council Directive 91/414/EEC[(3)] was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[(4)] within the time period provided for in that Article.

(3) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. 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 15 July 2013.

(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 25 August 2014 the Authority communicated to the Commission its conclusion[(5)] on whether prosulfuron can be expected to meet the approval criteria provided for in

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/375. 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 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for prosulfuron to the Standing Committee on Plants, Animals, Food and Feed on 29 May 2015.

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

(8) 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 restrict the use of plant protection products containing prosulfuron in order to minimise the exposure for groundwater by setting a maximum dose of 20 g of active substance per hectare, every third year on the same field and to require further confirmatory information.

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

(10) The Commission however considers that prosulfuron is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Prosulfuron 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 is greater than 40 days and the long-term no-observed effect concentration for freshwater organisms is less than 0,01 mg/L. Prosulfuron therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

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

(12) 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.

(13) Commission Implementing Regulation (EU) 2016/549[(6)] extended the expiry date of prosulfuron 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 the extended expiry date, this Regulation should apply from 1 May 2017.

(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:

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Article 1

Renewal of the approval of the active substance as a candidate for substitution

The approval of the active substance prosulfuron, 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 May 2017.

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

Done at Brussels, 2 March 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Prosulfuron CAS No 94125-34-5 CIPAC No 579	1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea	950 g/kg The impurity 2-(3,3,3-trifluoro-propyl)-benzene sulphonamide shall not exceed 10 g/kg in the technical material	1 May 2017	30 April 2024	PART A Use shall be limited to one application every three years on the same field at a maximum dose of 20 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No1107/2009, the conclusions of the review report on prosulfuron, 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 groundwater, when

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

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					— the substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (CGA150829) to confirm that this metabolite is not genotoxic and not relevant for risk assessment. The applicant shall submit that information

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