

COMMISSION IMPLEMENTING REGULATION (EU) 2017/805**of 11 May 2017****renewing the approval of the active substance flazasulfuron 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 2004/30/EC ⁽²⁾ included flazasulfuron 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 flazasulfuron, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2018.
- (4) An application for the renewal of the approval of flazasulfuron 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 14 August 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 10 August 2016 ⁽⁶⁾ the Authority communicated to the Commission its conclusion on whether flazasulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the renewal report for flazasulfuron to the Standing Committee on Plants, Animals, Food and Feed on 6 October 2016.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2004/30/EC of 10 March 2004 amending Council Directive 91/414/EEC to include benzoic acid, flazasulfuron and pyraclostrobin as active substances (OJ L 77, 13.3.2004, p. 50).

⁽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(9):4575, 24 pp. Available online: www.efsa.europa.eu

- (9) It has been established with respect to one or more representative uses of at least one plant protection product containing flazasulfuron 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 flazasulfuron.
- (10) The risk assessment for the renewal of the approval of flazasulfuron is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing flazasulfuron may be authorised. It is therefore appropriate not to maintain the restriction to use only as a herbicide.
- (11) 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.
- (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) 2016/2016 ⁽¹⁾ extended the approval period of flazasulfuron to 31 January 2018 in order to allow the renewal process to be completed before the expiry date of the approval of that substance. However, given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation shall apply from 1 August 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:

Article 1

Renewal of the approval of active substance

The approval of the active substance flazasulfuron, 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 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 August 2017.

⁽¹⁾ Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flazasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, Pseudomonas chlororaphis Strain: MA 342, pyraclostrobin, quinoxifen, thiacloprid, thiram, ziram, zoxamide (OJ L 312, 18.11.2016, p. 21).

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

Done at Brussels, 11 May 2017.

For the Commission

The President

Jean-Claude JUNKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Flazasulfuron CAS No 104040-78-0 CIPAC No 595	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulphonyl)urea	≥ 960 g/kg	1 August 2017	31 July 2032	<p>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 flazasulfuron, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic plants, — the protection of non-target terrestrial plants, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p>

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

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 80 on flazasulfuron is deleted;

(2) in Part B, the following entry 108 is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'108	Flazasulfuron CAS No 104040-78-0 CIPAC No 595	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulphonyl)urea	≥ 960 g/kg	1 August 2017	31 July 2032	<p>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 flazasulfuron, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic plants, — the protection of non-target terrestrial plants, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.'</p>

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