

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/616

of 5 May 2020

renewing the approval of the active substance foramsulfuron 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 2003/23/EC ⁽²⁾ included foramsulfuron 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 foramsulfuron, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2020.
- (4) An application for the renewal of the approval of the active substance foramsulfuron as a herbicide on maize 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.

⁽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) 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 26 March 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 26 February 2016, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether foramsulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial draft renewal report and the draft Regulation for foramsulfuron to the Standing Committee on Plants, Animals, Food and Feed on 11 July 2016 and a revised version on 22 October 2019.
- (9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ⁽⁷⁾, the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that foramsulfuron is an endocrine disrupter via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities. Therefore the Commission concludes that foramsulfuron is not to be considered as having endocrine disrupting properties.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and on the renewal report, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012. The applicant submitted its comments, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance foramsulfuron that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The risk assessment for the renewal of the approval of the active substance foramsulfuron is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing foramsulfuron may be authorised.
- (13) It is therefore appropriate to renew the approval of foramsulfuron.
- (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 provide for certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information as regards the effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface and groundwater, when surface water or groundwater are abstracted for drinking water.
- (15) 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.
- (16) Commission Implementing Regulation (EU) 2019/707 ⁽⁸⁾ extended the approval period of foramsulfuron to 31 July 2020 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation shall apply from 1 June 2020.

⁽⁶⁾ *EFSA Journal* 2016;14(3):4421, 119 pp. Available online: www.efsa.europa.eu

⁽⁷⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

⁽⁸⁾ Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthialdicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole (OJ L 120, 8.5.2019, p. 16).

- (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

The approval of the active substance foramsulfuron 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 June 2020.

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

Done at Brussels, 5 May 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Foramsulfuron CAS No 173159-57-4 CIPAC No 659	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea	≥ 973 g/kg	1 June 2020	31 May 2035	<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 foramsulfuron, and in particular Appendices I and II thereto, 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 risk to consumers and operators, — the risk to aquatic organisms and non-target plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water, within 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.</p>

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

ANNEX II

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

- (1) in Part A, entry 44 on foramsulfuron is deleted;
 (2) in Part B, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'141	Foramsulfuron CAS No 173159-57-4 CIPAC No 659	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea	≥ 973 g/kg	1 June 2020	31 May 2035	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 foramsulfuron, 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 risk to consumers and operators, — the risk to aquatic organisms and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water, within 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 the identity and the specification of the active substance are provided in the renewal report.