Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018 concerning the non-renewal of approval of the active substance oxasulfuron, 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 Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1019

of 18 July 2018

concerning the non-renewal of approval of the active substance oxasulfuron, 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 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)(b) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2003/23/EC[(2)] included oxasulfuron 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 oxasulfuron, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2019.

(4) An application for the renewal of the approval of oxasulfuron 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 29 January 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1019. 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 dossier available to the public.

(8) On 2 February 2017 the Authority communicated to the Commission its conclusion[6] on whether oxasulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority identified a large number of data gaps resulting in the inability to finalise the risk assessment in several areas. In particular, the available information on oxasulfuron and its metabolites did not allow finalising the assessment of the overall consumer exposure, the groundwater exposure, the risk to aquatic organisms, earthworms, soil macro- and microorganisms and non-target terrestrial plants.

(10) The Commission presented the draft renewal report and a draft Regulation for oxasulfuron to the Standing Committee on Plants, Animals, Food and Feed on 19 July 2017.

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

(12) However, despite the arguments put forward by the applicant, the concerns referred to in recital 9 could not be eliminated.

(13) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The approval of the active substance oxasulfuron should therefore not be renewed.

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

(15) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing oxasulfuron.

(16) For plant protection products containing oxasulfuron, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 8 November 2019.

(17) Commission Implementing Regulation (EU) 2018/917[7] extended the expiry date of oxasulfuron to 31 July 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Given that a decision is taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(18) This Regulation does not prejudice the submission of a further application for the approval of oxasulfuron in accordance with Article 7 of Regulation (EC) No 1107/2009.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1019. 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*

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance oxasulfuron is not renewed.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 42 on oxasulfuron, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing oxasulfuron as active substance by 8 November 2018 at the latest.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 20 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 8 November 2019 at the latest.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 18 July 2018.

For the Commission

The President

Jean-Claude JUNCKER