Commission Implementing Regulation (EU) 2017/359 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance oxyfluorfen (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/359

of 28 February 2017

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance oxyfluorfen

(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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 798/2011[(2)] approved oxyfluorfen as an active substance in accordance with Regulation (EC) No 1107/2009, under the condition that the Member States concerned ensure that the applicant at whose request oxyfluorfen was approved provides further confirmatory information on five specific aspects, one of which concerned the potential risk to aquatic organisms for the active substance and for the metabolites RH-45469, MW 306, MW 347, MW 274 and the unidentified metabolite Deg 27.

(2) On 29 June and 15 December 2012 the applicant submitted additional information to address the confirmatory data requirements to the rapporteur Member State Spain within the time period provided for its submission.

(3) Spain assessed the additional information submitted by the applicant. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', on 14 July 2014.

(4) The Member States, the applicant and the Authority were consulted and asked to provide comments on the assessment of the rapporteur Member State. The Authority published a Technical Report summarising the outcome of this consultation for oxyfluorfen on 6 November 2014[(3)].

(5) The Commission consulted the Authority in relation to certain areas of the assessment. The Authority presented its conclusion on the risk assessment of oxyfluorfen on 28 July 2015[(4)]. The draft assessment report, the addendum and the conclusion of the Authority were reviewed by the Member States and the Commission within the

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Standing Committee on Plants, Animals, Food and Feed and finalised on 24 January 2017 in the format of the Commission review report for oxyfluorfen.

(6) The Commission invited the applicant to submit its comments on the review report for oxyfluorfen.

(7) The Commission has considered that the additional information provided showed that parent substance and metabolites MW 347 and Deg 27 represent a high risk for aquatic organisms.

(8) The Commission has concluded that the further confirmatory information required has not been fully provided and that a high risk for aquatic organisms resulting from exposure to oxyfluorfen and metabolites MW 347 and Deg 27 cannot be excluded except by imposing further restrictions.

(9) In order to minimise the exposure of aquatic organisms, it is, therefore, appropriate to further restrict the conditions of use of this active substance and to provide for specific risk mitigation measures for the protection of those species.

(10) The Annex to Commission Implementing Regulation (EU) No 540/2011[(5)] should therefore be amended accordingly.

(11) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing oxyfluorfen.

(12) For plant protection products containing oxyfluorfen, 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 21 June 2018.

(13) 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

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing oxyfluorfen as active substance by 21 June 2017 at the latest.

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Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 21 June 2018 at the latest.

Article 4

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, 28 February 2017.

For the Commission

The President

Jean-Claude JUNCKER