Commission Implementing Regulation (EU) 2015/2233 of 2 December 2015 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance haloxyfop-P (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/2233

of 2 December 2015

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

(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 Directive 2010/86/EU[(2)] included haloxyfop-P as active substance in Annex I to Council Directive 91/414/EEC[(3)] under the condition that the Member States concerned ensure that the notifier at whose request haloxyfop-P was included in that Annex provides further confirmatory information on the risk for groundwater contamination by its soil metabolites.

(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 notifier submitted additional information taking the form of studies with a view to confirm the risk assessment for groundwater to the rapporteur Member State Austria within the time period provided for its submission.

(4) Austria assessed the additional information submitted by the notifier. 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 15 October 2013.

(5) The Commission consulted the Authority which presented its opinion on the risk assessment of haloxyfop-P on 28 November 2014[(5)].

(6) The Commission considered that the additional information provided by the notifier demonstrated that metabolite DE-535 pyridinone must be considered to be toxicologically relevant and, as a consequence, should not occur in concentrations above the regulatory limit for groundwater of 0,1 μg/l.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/2233. 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 Commission invited the notifier to submit its comments on the review report for haloxyfop-P.

(8) The Commission has concluded that the further confirmatory information required has not fully been provided and that an unacceptable risk for groundwater cannot be excluded except by imposing further restrictions.

(9) It is confirmed that the active substance haloxyfop-P is to be deemed to have been approved under Regulation (EC) No 1107/2009. In order to preclude the occurrence of that metabolite in groundwater in excess of the above limit referred to in recital 6, it is, however, appropriate to amend the conditions of use of this active substance, in particular by setting limits to the rates and frequency of its application.

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

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

(12) For plant protection products containing haloxyfop-P, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months after the entry into force of this Regulation.

(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 haloxyfop-P as active substance by 23 June 2016.

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 23 June 2017 at the latest.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/2233. 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

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, 2 December 2015.

For the Commission

The President

Jean-Claude JUNCKER