Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance abamectin (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/438

of 13 March 2017

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

(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 13(2) thereof,

Whereas:

(1) Commission Directive 2008/107/EC[(2)] included the active substance abamectin as an active substance in Annex I to Council Directive 91/414/EEC[(3)] for uses as an acaricide and as an insecticide. 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)].

(2) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 29 August 2013 the producer of the active substance Syngenta Crop Protection AG submitted an application to the designated rapporteur Member State, the Netherlands, seeking an amendment to the conditions of approval of abamectin in order to provide for its use as a nematicide. In accordance with Article 9(3) of that Regulation, the Netherlands notified the applicant, the other Member States, the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 18 March 2014 that the application was admissible.

(3) The designated rapporteur Member State assessed the new use of the active substance abamectin in relation to potential effects on human and animal health and the environment in accordance with the provisions of Article 4 of Regulation (EC) No 1107/2009, and submitted a draft assessment report to the Commission and to the Authority on 14 April 2015. In accordance with Article 12(3) of that Regulation additional information was requested from the applicant. The Netherlands evaluated the additional information and submitted an updated draft assessment report to the Commission and to the Authority in 15 February 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/438. 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*

(4) On 29 April 2016 the Authority communicated to the Commission its conclusion[5] on whether the new uses of the active substance abamectin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft addendum to the review report for abamectin and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 7 December 2016.

(5) The applicant was invited to submit comments on the review report.

(6) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that, when the plant protection product is used as a nematicide, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to allow the use of the active substance abamectin as a nematicide.

(7) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in light of current scientific and technical knowledge, it is necessary and appropriate to grant approval subject to certain conditions and to require the applicant to provide further confirmatory information.

(8) The approval of abamectin provided that some confirmatory data shall be submitted within two years after the entry into force of Directive 2008/107/EC. The applicant at whose request abamectin was approved submitted the requested information, which was assessed by the Netherlands. A safe use was confirmed for the original approval. Therefore this issue is finalised and there is no need to keep this provision.

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

(10) 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

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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/438. 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*

Done at Brussels, 13 March 2017.

For the Commission

The President

Jean-Claude JUNCKER