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.

(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.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances (OJ L 316, 26.11.2008, p. 4).
([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]) *EFSA Journal* 2014;12(5):3692. Available online: www.efsa.europa.eu

(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.

Done at Brussels, 13 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The column 'Specific provisions' of row 210, abamectin, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'PART A

Only uses as insecticide, acaricide and nematicide may be authorised.

PART B

In assessing applications to authorise plant protection products containing abamectin for uses other than citrus, lettuce and tomatoes, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information are provided before such an authorisation is granted.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on abamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 and of the addendum to the review report on abamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed dated 24 January 2017 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,

— the residues in food of plant origin and evaluate the dietary exposure of consumers,

— the protection of bees, non-target arthropods, soil organisms, birds, mammals and aquatic organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones and waiting periods, should be applied where appropriate.

The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water by 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.'