EUROPEAN
COMMISSION

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[…](2017) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

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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 582/2012[2] approved bifenthrin as an active substance in accordance with Regulation (EC) No 1107/2009 and required the applicant at whose request bifenthrin was approved to provide *inter alia* confirmatory information on the residual toxicity for non-target arthropods and their potential for recolonization and a monitoring programme to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment.

(2) On 29 July 2013 the applicant submitted the monitoring programme and the results hereof on 31 July 2015. On 29 July 2014 the applicant submitted the additional information to address the other confirmatory data requirements. These three submissions were provided to the Rapporteur Member State France within the time period provided for their submission.

(3) France assessed the additional information and the monitoring programme 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 ('the Authority'), on 17 December 2014, as regards the additional information submitted to address the other confirmatory data requirements, and on 3 November 2015 as regards the monitoring programme.

(4) Those other 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 the technical reports summarising the outcome of the consultation for bifenthrin on 26 March 2015[3] as regards the additional information to address the

[1] OJ L 309, 24.11.2009, p. 1.

[2] Commission Implementing Regulation (EU) No 582/2012 of 2 July 2012 approving the active substance bifenthrin, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 173, 3.7.2012, p. 3).

[3] EFSA (European Food Safety Authority), Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for bifenthrin. EFSA supporting publication 2015:EN-780. 23 pp.

other confirmatory data requirements and on 14 April 2016[4] as regards the monitoring programme.

(5) The draft assessment report, the addendum and the technical reports of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on *[...]* 2017 in the format of the Commission review report for bifenthrin. The Commission invited the applicant to submit its comments on the review report for bifenthrin. The applicant submitted its comments which have been carefully examined.

(6) The Commission has come to the conclusion that the information submitted is insufficient and does not allow to conclude that adequate recolonization of certain species of non-target arthropods in-field takes place while other possibilities of mitigation of such risk cannot realistically be implemented. In addition, the monitoring programme leaves uncertainty on whether its results, based on a superposition of mitigation techniques, are representative for agricultural practise and sufficient to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment.

(7) Therefore, in order to preclude the identified high risk for non-target arthropods and also to take into consideration the potential of bioaccumulation and biomagnification in the aquatic and terrestrial environment, it is appropriate to further restrict the conditions of use of bifenthrin and to only authorise applications in greenhouses with a permanent structure.

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

(9) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing bifenthrin.

(10) For plant protection products containing bifenthrin, where Member States grant any grace period pursuant to Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on *[Office of Publications please insert date 15 months from the date of entry into force]*.

(11) 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.

[4] EFSA (European Food Safety Authority), Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for bifenthrin. EFSA supporting publication 2016:EN-1019. 39 pp.

[5] 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).

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 bifenthrin as active substance by [*Office of Publications please insert date 3 months from the date of entry into force*] at the latest.

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 *[Office of Publications please insert date 15 months from the date of entry into force]* 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,

For the Commission
The President
Jean-Claude JUNCKER