

## COMMISSION IMPLEMENTING REGULATION (EU) No 1178/2013

of 20 November 2013

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

(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<sup>(1)</sup>, and in particular the second alternative of Articles 21(3) and 78(2) thereof,

Whereas:

- (1) Commission Directive 2007/52/EC<sup>(2)</sup> included ethoprophos as active substance in Annex I to Council Directive 91/414/EEC<sup>(3)</sup>, under the condition that the Member States concerned ensure that the notifier at whose request ethoprophos was included in that Annex provides further confirmatory information in the form of studies on the risk for birds and earthworm eating mammals.
- (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<sup>(4)</sup>.
- (3) The notifier submitted additional information taking the form of studies concerning the risk for birds and earthworm eating mammals to the rapporteur Member State United Kingdom within the time period provided for its submission.
- (4) The United Kingdom 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 5 September 2011.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.<sup>(2)</sup> Commission Directive 2007/52/EC of 16 August 2007 amending Council Directive 91/414/EEC to include ethoprophos, pirimiphos-methyl and fipronil as active substances (OJ L 214, 17.8.2007, p. 3).<sup>(3)</sup> 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).<sup>(4)</sup> 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) The Commission consulted the Authority which presented its opinion on the risk assessment of ethoprophos on 30 January 2013<sup>(5)</sup>. The draft assessment report, the addendum and the opinion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 3 October 2013 in the format of the Commission review report for ethoprophos.
- (6) The Commission invited the notifier to submit its comments on the review report for ethoprophos.
- (7) The Commission has come to the conclusion that the further confirmatory information showed that a high risk for birds and earthworm eating mammals cannot be excluded except by imposing further restrictions.
- (8) It is confirmed that the active substance ethoprophos is to be deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of birds and earthworm eating mammals, it is, however, appropriate to further restrict the uses of this active substance and to provide for specific risk mitigation measures for the protection of those species.
- (9) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (10) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing ethoprophos.
- (11) For plant protection products containing ethoprophos, 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 the Regulation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

<sup>(5)</sup> Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance ethoprophos. EFSA Journal 2013; 11(2):3089. [27 pp.] doi:10.2903/j.efsa.2013.3089. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

HAS ADOPTED THIS REGULATION:

authorisations for plant protection products containing ethoprophos as active substance by 11 June 2014.

*Article 1*

**Amendment to Implementing Regulation (EU)  
No 540/2011**

Part A of 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

*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 11 June 2015 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, 20 November 2013.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

The column 'Specific provisions' of row 155, ethoprophos, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

**PART A**

Only uses as nematicide and insecticide in soil application may be authorised. Only one application per season may be authorised, at a rate not exceeding 6 kg active substance/ha.

Authorisations shall be limited to professional users.

**PART B**

In assessing applications to authorise plant protection products containing ethoprophos for uses other than potatoes not cultivated for human or animal consumption, Member States shall pay particular attention to the criteria in Article 29(1) of Regulation (EC) No 1107/2009 and shall ensure that any necessary data and information is 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 ethoprophos, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 March 2007, shall be taken into account.

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

- (a) the dietary exposure of consumers;
- (b) the operator safety, ensuring that the conditions of use prescribe the application of adequate personal and respiratory protective equipment and other risk mitigation measures such as the use of a closed transfer system for the distribution of the product;
- (c) the protection of birds, mammals, aquatic organisms, surface and groundwater under vulnerable conditions.

Conditions of authorisation shall include risk mitigation measures, such as buffer zones and the achievement of complete incorporation of granules in the soil.'

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