

COMMISSION IMPLEMENTING REGULATION (EU) No 1124/2013**of 8 November 2013****amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance bifenox****(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 first alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2008/66/EC ⁽²⁾ included bifenox as active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.

(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) In accordance with the first subparagraph of Article 21(1) of Regulation (EC) No 1107/2009 Belgium submitted a request to the Commission to review the approval of bifenox in the light of new scientific and technical knowledge resulting from information submitted to that Member State by the notifier pursuant to Article 56(1) of that Regulation. That information concerned formation of nitrofen resulting from the application of bifenox.

(4) Belgium assessed the 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 21 March 2013.

(5) In the light of that information the Commission considered that there are indications that bifenox no longer satisfies the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(6) The Commission invited the notifier to submit its comments.

(7) The Commission has come to the conclusion that, given the fact that under certain environmental conditions the use of bifenox has the potential to form nitrofen a risk for the environment cannot be excluded except by imposing further restrictions.

(8) It is confirmed that the active substance bifenox is to be deemed to have been approved under Regulation (EC) No 1107/2009. When assessing applications for authorisation of plant protection products, Member States should pay particular attention to the potential of bifenox to form nitrofen and impose restrictions as regards the conditions of use, where appropriate.

(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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*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***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*.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/66/EC of 30 June 2008 amending Council Directive 91/414/EEC to include bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinclamine as active substances (OJ L 171, 1.7.2008, p. 9).

⁽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).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 November 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

The column 'Specific provisions' of row 180, bifenox, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

PART A

Only uses as herbicide may be authorised.

PART B

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 bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.

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

- (a) the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;
- (b) the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops;
- (c) the environmental conditions leading to the potential formation of nitrofen.

Member States shall impose restrictions as regards the conditions of use, where appropriate in view of point (c).'
