

COMMISSION IMPLEMENTING REGULATION (EU) No 365/2013**of 22 April 2013****amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glufosinate****(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 second alternative of Articles 21(3) and 78(2) thereof,

Whereas:

- (1) Commission Directive 2007/25/EC ⁽²⁾ included glufosinate as active substance in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽³⁾, under the condition that the Member States concerned ensure that the notifier at whose request glufosinate was included in that Annex provide further confirmatory information on the risk for mammals and non-target arthropods in apple orchards.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to be approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to 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 ⁽⁴⁾.
- (3) The notifier submitted additional information taking the form of studies with a view to confirm the risk assessment for mammals and non-target arthropods in apple orchards to the rapporteur Member State Sweden within the time period provided for its submission.
- (4) Sweden 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 9 March 2010.

- (5) The Commission consulted the Authority which presented its opinion on the risk assessment of glufosinate on 8 March 2012 ⁽⁵⁾. The draft assessment report, the additional report 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 15 March 2013 in the format of the Commission review report for glufosinate.
- (6) In the light of the additional information provided by the notifier, the Commission considered that the further confirmatory information required had not been provided and that a high risk for mammals and non-target arthropods could not be excluded except by imposing further restrictions.
- (7) The Commission invited the notifier to submit its comments on the review report for glufosinate.
- (8) It is confirmed that the active substance glufosinate is to be deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of mammals and non-target arthropods, 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) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (10) Member States should be provided with time to withdraw authorisations for plant protection products containing glufosinate.
- (11) For plant protection products containing glufosinate, where Member States grant any period of grace in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest one year after the withdrawal of the authorisations.
- (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,

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 106, 24.4.2007, p. 34.

⁽³⁾ OJ L 230, 19.8.1991, p. 1.

⁽⁴⁾ OJ L 153, 11.6.2011, p. 1.

⁽⁵⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance glufosinate. *EFSA Journal* 2012; 10(3):2609. [14 pp.] doi:10.2903/j.efsa.2012.2609. Available online: www.efsa.europa.eu/efsajournal.htm

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

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 glufosinate as active substance by 13 November 2013.

Article 3

Period of grace

Any period of grace granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire 12 months after withdrawal of the respective authorisation 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, 22 April 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

The column 'Specific provisions' of row 151, glufosinate, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

PART A

Only uses as herbicide for band or spot application may be authorised at rates not exceeding 750 g active substance/ha (treated surface) per application and maximum two applications per year.

PART B

In assessing applications to authorise plant protection products containing glufosinate, notably as regards the operator and consumer exposure, 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 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 glufosinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006, shall be taken into account. In this overall assessment Member States shall pay particular attention to:

- (a) the operator, worker and bystander safety; conditions of authorisation shall include protective measures, where appropriate;
- (b) the potential for groundwater contamination, where the active substance is applied in regions with vulnerable soil or climatic conditions;
- (c) the protection of mammals, non-target arthropods and non-target plants.

Conditions of authorisation shall include the application of drift reducing nozzles and spray shields and shall provide for respective labelling of plant protection products. Those conditions shall include further risk mitigation measures, where appropriate.'
