



EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

renewing the approval of the active substance glyphosate 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 Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

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(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/EEC¹, and in particular Article 20(1) thereof,

Whereas:

- (1) The approval of the active substance glyphosate, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011², expires on 30 June 2016.
- (2) An application for the renewal of the inclusion of glyphosate in Annex I to Council Directive 91/414/EEC³ was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010⁴ within the time period provided for in that Article.
- (3) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.
- (4) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter ‘the Authority’) and the Commission on 20 December 2013.
- (5) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the

¹ OJ L 309, 24.11.2009, p. 1.

² 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).

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 Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

Commission. The Authority also made the supplementary summary dossier available to the public.

- (6) Following the findings of the International Agency for Research on Cancer as regards the carcinogenic potential of glyphosate, the Commission on 29 April 2015 mandated the Authority to review the underlying information and to include those findings in its conclusion.
- (7) To allow for an appropriate evaluation of the information⁵ from the International Agency for Research on Cancer and the extraordinarily high number of comments received from Member States and the public, the Commission extended the deadline for the submission of the Authority's conclusion.
- (8) On 30 October 2015⁶ the Authority communicated to the Commission its conclusion on whether glyphosate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for glyphosate to the Standing Committee on Plants, Animals, Food and Feed on 28 January 2016.
- (9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied.
- (10) It is therefore appropriate to renew the approval of glyphosate.
- (11) On 22 July 2015⁷ the rapporteur Member State indicated its intention to submit a dossier concerning the harmonised classification of glyphosate under Regulation (EC) No 1272/2008⁸, in accordance with Article 37 of that Regulation, including for the hazard class on carcinogenicity. If that procedure would lead to a change in the harmonised classification of glyphosate that is relevant for its approval based on the criteria set out in Regulation (EC) No 1107/2009, the Commission will review the approval in accordance with Article 21 of that Regulation.
- (12) On 30 October 2015⁹ the Authority communicated to the Commission its statement on the toxicological assessment of POE-tallowamine (CAS No 61791-26-2), a substance frequently used as a co-formulant in plant protection products containing glyphosate. It concluded that compared to glyphosate, a significant toxicity of POE-tallowamine

⁵ IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112 (2015). Available online: www.iarc.fr.

⁶ EFSA Journal 2015; 13(11): 4302. Available online: www.efsa.europa.eu.

⁷ ECHA Registry of Intentions. Available online: echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions.

⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁹ EFSA Journal 2015; 13(11): 4303. Available online: www.efsa.europa.eu.

was observed on all endpoints investigated. Additional concerns were highlighted as regards the potential of POE-tallowamine to negatively affect human health.

- (13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information and to exclude POE-tallowamine (CAS No 61791-26-2) from the use in plant protection products containing glyphosate.
- (14) In accordance with Article 27(2) of Regulation (EC) No 1107/2009, a list of co-formulants not accepted for inclusion in plant protection products shall be established. The Commission, the Authority and Member States have started work in view of establishing that list. In carrying out that work, the Commission will pay particular attention to potentially harmful co-formulants used in plant protection products containing glyphosate. The list of unacceptable co-formulants will be established in future in a separate act, in accordance with the procedural requirements set out in Article 27(2) of Regulation (EC) No 1107/2009.
- (15) The risk assessment for the renewal of the approval of glyphosate is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing glyphosate may be authorised. It is therefore appropriate not to maintain the restriction to uses as a herbicide.
- (16) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (17) This Regulation should apply from the day after the date of expiry of the approval of the active substance glyphosate, as referred to in recital 1.
- (18) 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

Renewal of the approval of active substance

The approval of the active substance glyphosate, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2016.

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