EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10026/2016 Rev. 2
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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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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)

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 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 540/2011[2], expires on 30 June 2016.

2 An application for the renewal of the inclusion of glyphosate in Annex I to Council Directive 91/414/EEC[3] was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[4] 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.

1OJ L 309, 24.11.2009, p. 1.

2Commission 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).

3Council 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).

4Commission 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).

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 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 information[5] 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 2015[6] 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 However, several Member States expressed in the Standing Committee on Plants, Animals, Food and Feed on 7 March 2016 the view that from the risk management perspective an approval period shorter than the maximum period provided for in Article 14(2) of Regulation (EC) No 1107/2009 would be appropriate for the renewal of approval of glyphosate, and other Member States pointed to additional circumstances specific to glyphosate which should be taken into account.

12 In particular, while a large amount of information on the active substance glyphosate already exists and has been assessed, additional information on glyphosate is published at an exceptionally high rate compared to other active substances. The possibilities of rapid developments in science and technology should be taken into account when deciding on the length of the approval period of glyphosate, also bearing in mind the fact that the International Agency for Research on Cancer and the Authority have each made distinct findings as regards the carcinogenic potential of glyphosate and that glyphosate is one of the most widely used herbicides in the Union.

13 In light of the above factors, and bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection that is sought within the Union, it is appropriate to provide for a renewal of the approval of glyphosate for a period of nine years that ensures a priority re-assessment of glyphosate over other active substances.

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

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

14 On 13 April 2016 the European Parliament adopted its Resolution P8_TA-PROV(2016)0119 on the previous draft of the Commission Implementing Regulation renewing the approval of the active substance glyphosate made available to the European Parliament on 23 February 2016.

15 On 22 July 2015[7] the rapporteur Member State indicated its intention to submit a dossier concerning the harmonised classification of glyphosate, including for the hazard class on carcinogenicity, in accordance with Article 37 of Regulation (EC) No 1272/2008[8]. On 17 March 2016 the rapporteur Member State has submitted that dossier to the European Chemicals Agency. In view of the time required to assess the dossier, it was not possible to finalise the classification procedure before the expiration of the approval. 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, including the criterion on classification as carcinogen, the Commission will without delay review and, if appropriate, amend or withdraw, the approval in accordance with Article 21 of that Regulation.

16 On 30 October 2015[9] 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 was observed on all endpoints investigated. Additional concerns were highlighted as regards the potential of POE-tallowamine to negatively affect human health.

17 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 the co-formulant POE-tallowamine (CAS No 61791-26-2) from the use in plant protection products containing glyphosate.

18 In its renewal assessment report, the rapporteur Member State indicated that the use of glyphosate may affect populations of non-target terrestrial arthropod and vertebrate species via trophic interactions. Taking into account that report, it is appropriate to require Member States to pay particular attention to this issue in accordance with Article 4(3)(e)(iii) of Regulation (EC) No 1107/2009 when granting authorisations for plant protection products.

19 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

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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).

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

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.

20 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.

21 It should be recalled that in accordance with Directive 2009/128/EC[10] in conjunction with Article 55 of Regulation (EC) No 1107/2009, Member States should encourage the development and implementation of integrated pest management and of alternative approaches or techniques in order to reduce their dependency on the use of pesticides. Member States should also ensure that the use of pesticides is minimised or prohibited in areas such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities.

22 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.

23 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.

24 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.

10 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p.71).

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

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10026/2016 ANNEX Rev. 2
(POOL/E3/2016/10026/10026R2-EN
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ANNEXES 1 to 2

ANNEXES

to the

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonomethyl)glycine	≥ 950 g/kg Impurities: Formaldehyde, less than 1 g/kg *N*-Nitroso-glyphosate, less than 1 mg/kg	1 July 2016	30 June 2025	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 glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, — the risk to non-target terrestrial vertebrates, — the risk to non-target terrestrial plants, — the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions. Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies. The applicant shall submit confirmatory information as regards the absence of endocrine disrupting properties that may cause adverse effect in humans to the Commission, the Member States and the Authority by 1 August 2016. Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).

1Further details on identity and specification of active substance are provided in the review report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 25 on glyphosate is deleted;

(2) in Part B, the following entry is added:

	Common Name, Identification Numbers	IUPAC Name	Purity[2]	Date of approval	Expiration of approval	Specific provisions
'XX	Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonomethyl)glycine	≥ 950 g/kg Impurities: Formaldehyde, less than 1 g/kg *N*-Nitroso-glyphosate, less than 1 mg/kg	1 July 2016	30 June 2025	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 glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, — the risk to non-target terrestrial vertebrates, — the risk to non-target terrestrial plants, — the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions. Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies. The applicant shall submit confirmatory information as regards the absence of endocrine disrupting properties that may cause adverse effect in humans to the Commission, the Member States and the Authority by 1 August 2016.

2Further details on identity and specification of active substance are provided in the review report.

	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
						Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).'