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Brussels, XXX
SANTE/10026/2016 Rev. 2
[...](2016) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) [...]

of XXX


(Text with EEA relevance)
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COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


Whereas:


(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.

(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.

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(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 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 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 2015 the rapporteur Member State indicated its intention to submit a dossier concerning the harmonised classification of glyphosate under Regulation (EC) No 1272/2008, in accordance with Article 37 of that Regulation, including for the hazard class on carcinogenicity. On 17 March 2016 the rapporteur Member State has submitted that dossier to the relevant EU authority. In view of the time required to assess the dossier, it is 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.

(12) On 30 October 2015 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.

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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.

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)(c)(iii) of Regulation (EC) No 1107/2009.

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.

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.

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.

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.

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.
This draft document does not necessarily represent the views of the European Commission. It incorporates amendments to the text based on comments received from Member States.

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
ANNEXES

to the

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

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**ANNEX I**

<table>
<thead>
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<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
</table>
| Glyphosate                          | N-(phosphonomet hyl)glycine | ≥ 950 g/kg Impurities: Formaldehyde, less than 1 g/kg N-Nitroso-glyphosate, less than 1 mg/kg | 1 July 2016 | 30 June 2024 | 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, and  
  - the risk to, non-target terrestrial plants,  
  - the risk to diversity and abundance of terrestrial vertebrates and invertebrates 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 POET-tallowamine (CAS No 61791-26-2). |

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

Comment [WV(1)]: Based on comments of NL.

Comment [WV(2)]: Based on comments of DE and LU. Also oral comments of AT at SC PAFF.
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:

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| 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 2022 | 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,
— and-to the risk to non-target terrestrial vertebrates,
— the risk to non-target terrestrial plants,
— the risk to diversity and abundance of terrestrial vertebrates and invertebrates 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 |

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