



Brussels, **XXX**  
SANTE/10026/2016 ANNEX Rev. 1  
(POOL/E3/2016/10026/10026R1-EN  
ANNEX.doc)  
[...] (2016) **XXX** draft

ANNEXES 1 to 2

## **ANNEXES**

**to the**

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

**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**

## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>1</sup>	Date of approval	Expiration of approval	Specific provisions
Glyphosate CAS No 1071-83-6 CIPAC No 284	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 2034 <del>26</del>	<p><b>PART A</b></p> <p>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.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and to the risk to non-target terrestrial vertebrates and non-target terrestrial plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>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.</p> <p>The applicant shall submit confirmatory information as regards the <u>absence of endocrine disrupting properties that may cause adverse effect in humans potential for an endocrine mediated mode of action</u> to the Commission, the Member States and the Authority by 1 August 2016.</p> <p><b>PART B</b></p> <p>Member States shall ensure that <u>plant protection products containing glyphosate-based formulations</u> do not contain the co-formulant POE-tallowamine (<u>CAS No 61791-26-2</u>).</p>

<sup>1</sup> Further 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 <sup>2</sup>	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 203426	<p><b>PART A</b></p> <p>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.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and to the risk to non-target terrestrial vertebrates and non-target terrestrial plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>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.</p> <p>The applicant shall submit confirmatory information as regards the <u>absence of endocrine disrupting properties that may cause adverse effect in humans</u><del>potential for an endocrine mediated mode of action</del> to the Commission, the Member States and the Authority by 1 August 2016.</p> <p><b>PART B</b></p> <p>Member States shall ensure that <u>plant protection products containing</u> glyphosate<del>-based formulations</del> do not contain the co-formulant POE-tallowamine <u>(CAS No 61791-26-2)</u>.'</p>

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

