

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

EN EN

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- (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 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).

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

	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- (phosphonometh yl)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.

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

Common Name, Identification Numbers	IUPAC Name	Purity ²	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).'

