

**Application for Approval Renewal for an Active Substance:  
Glyphosate & the IPA-, K-, DMA and NH<sub>4</sub>-salts of Glyphosate  
(hereafter Glyphosate)**

**Commission Regulation (EU) No 844/2012,  
Articles 1 & 2 and Annex**

**Rapporteur Member States:  
Assessment Group on Glyphosate (AGG)  
France, Hungary, Sweden, and The Netherlands**

**Date**

**15<sup>th</sup> December 2019**

**Applicant**

**Notifier(s): Bayer Agriculture BVBA  
on behalf of the Glyphosate Renewal Group**

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The present document is prepared following the Regulation (EU) No 844/2012 as well as SANCO/2012/11251 rev. 5 (22 Mar 2019).

## 1. Information concerning the applicant

### 1.1. Name and address of the applicant including the name of the natural person responsible for the application and further engagements resulting from this regulation

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Applying on behalf of the members of the Glyphosate Renewal Group

**1.2. Primary contact Glyphosate Renewal Group**

Contact: [REDACTED]  
Telephone No: [REDACTED]  
E-mail address: [REDACTED]

**1.3. Alternative contact Glyphosate Renewal Group**

Alternative contact: [REDACTED]

Telephone No: [REDACTED]

E-mail address: [REDACTED]

**2. Information to facilitate identification****2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines manufactured by the producer**

Common name (ISO): glyphosate (ISO); N-(phosphonomethyl)glycine

Active ingredient: Glyphosate

Related salt-types: Glyphosate- isopropyl-amine-salt

Glyphosate-potassium-salt

Glyphosate-ammonium-salt

Glyphosate - dimethylammonium salt

**2.2. Chemical name (IUPAC and CAS nomenclature)**

Glyphosate

IUPAC name: *N*-(phosphonomethyl)-glycine

CA name: *N*-(phosphonomethyl)-glycine

Glyphosate-isopropyl-amine-salt

IUPAC name: *N*-(phosphonomethyl)glycine - isopropylamine (1:1)

CA name: *N*-(phosphonomethyl)glycine compound with 2-propanamine (1:1)

Glyphosate-potassium-salt

IUPAC name: potassium *N*-[(hydroxyphosphinato)methyl]glycine

CA name: *N*-(phosphonomethyl) glycine potassium salt (1:1)

Glyphosate-ammonium-salt

IUPAC name: ammonium *N*-[(hydroxyphosphinato)methyl]glycine

CA name: *N*-(phosphonomethyl)glycine mono-ammonium salt

Glyphosate - dimethylammonium salt:

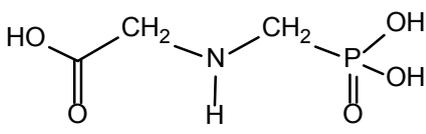
IUPAC name: *N*-(phosphonomethyl)glycine - dimethylamine (1:1)  
or dimethylammonium *N*-(phosphonomethyl)glycinate

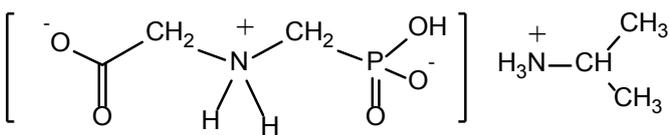
CA name: *N*-(phosphonomethyl)glycine - dimethylamine (1:1)  
or dimethylammonium *N*-(phosphonomethyl)glycinate

**2.3. CAS, CIPAC and EC numbers (if available)**

	<u>Glyphosate</u>
CAS No:	1071-83-6
CIPAC No:	0284
EC No:	213-997-4
	<u>Glyphosate isopropyl-amine-salt</u>
CAS No:	38641-94-0
CIPAC No:	284.105
EC No:	254-056-8
	<u>Glyphosate potassium-salt</u>
CAS No:	70901-20-1
CIPAC No:	284.019
EC No:	not attributed
	<u>Glyphosate ammonium-salt</u>
CAS No:	40465-66-5
CIPAC No:	284.007
EC No:	not attributed
	<u>Glyphosate - dimethylammonium salt:</u>
CAS No:	34494-04-7
CIPAC No:	284.102
EC No:	not attributed

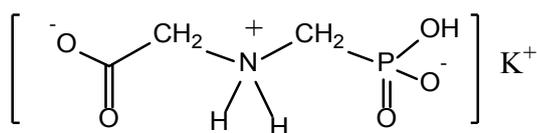
**2.4. Empirical and structural formula, molecular mass**

	<u>Glyphosate</u>
Empirical formula:	C <sub>3</sub> H <sub>8</sub> NO <sub>5</sub> P
Structural formula:	
Molecular mass:	169.1 g/mol

	<u>Glyphosate isopropyl-amine-salt</u>
Empirical formula:	C <sub>6</sub> H <sub>17</sub> N <sub>2</sub> O <sub>5</sub> P
Structural formula:	
Molecular mass:	228.18 g/mol

	<u>Glyphosate potassium-salt:</u>
Empirical formula:	C <sub>3</sub> H <sub>7</sub> KNO <sub>5</sub> P

Structural formula:



Molecular mass:

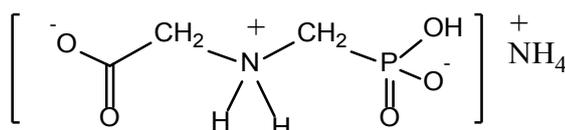
207.19 g/mol

Glyphosate ammonium-salt

Empirical formula:

C<sub>3</sub>H<sub>11</sub>N<sub>2</sub>O<sub>5</sub>P

Structural formula:



Molecular mass:

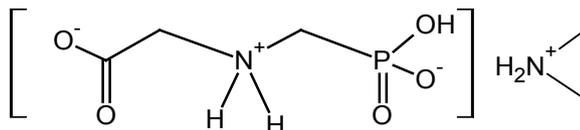
186.10 g/mol

Glyphosate - dimethylammonium salt

Empirical formula:

C<sub>5</sub>H<sub>15</sub>N<sub>2</sub>O<sub>5</sub>P

Structural formula:



Molecular mass:

214.15 g/mol

**2.5. Specification of purity of the active substance in g/kg**

Minimum purity: 950 g/kg

**2.6. Classification and labelling of the active substance in accordance with the provisions of the Regulation (EC) No 1272/2008**

According to the harmonised classification and labelling RAC opinion<sup>1</sup> approved by the European Union, glyphosate presents the harmonized classification presented in the table below. In this opinion, all classification and labelling elements are given in accordance with the CLP Regulation. The RAC opinion on the proposed harmonised classification and labelling was adopted on 15 March 2017 by consensus.

CLP Classification		
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictograms, Signal Word Code(s)
Eye damage 1	H318	GHS05
Aquatic chronic 2	H411	GHS09 Danger

<sup>1</sup> RAC Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N (phosphono-methyl)glycine. CLH-O-0000001412-86-149/F. Adopted 15 Mar 2017.

### **3. New Information**

Please refer to [Appendix 1](#).

15 December 2019



Bayer AG

(On behalf of the Glyphosate Renewal Group)

## APPENDIX 1: NEW INFORMATION

### 1. BACKGROUND

Commission Directive 2001/99/EC included glyphosate as an active substance in Annex I to Council Directive 91/414/EEC. Following a peer review organised by the European Commission, glyphosate was included in Annex I of Council Directive 91/414/EEC with Commission Directive 2001/99/EC, entering into force on 1 July 2002. According to Regulation (EU) No 540/2011 glyphosate was deemed for approval under Regulation (EC) No 1107/2009 as well.

In agreement with Article 4 of Regulation (EC) No 1141/2010 Monsanto Europe S.A./N.V. on behalf of the European Glyphosate Task Force submitted an application to Germany as RMS and Slovakia as Co-RMS notifying the intention to renew the existing approval of glyphosate on 24 March 2011 during the AIR 2 process. A collective supplementary dossier from the Glyphosate Task Force comprising 24 applicants was submitted on 25 May 2012.

The AIR 2 process at EU level, concluded that it has been established with respect to one or more representative uses of at least one plant protection product containing the active substance glyphosate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Thus the approval criteria of demonstrating a safe use were deemed to be satisfied. It was therefore appropriate to renew the active substance glyphosate<sup>1</sup>. Glyphosate was renewed (date of approval) on 16<sup>th</sup> December 2017 with the expiration of approval set up for 15<sup>th</sup> December 2022.

### 2. THE ACTIVE SUBSTANCE AND THE PLANT PROTECTION PRODUCT

The lead registrant Bayer Agriculture BVBA<sup>2</sup>, submitting this application on behalf of the Glyphosate Renewal Group, was also the lead registrant of the Glyphosate Dossier submitted during the AIR 2 renewal process in 2012, and previous process in 2002.

#### Active substance

Glyphosate is the ISO common name for N-(phosphonomethyl)glycine (IUPAC).

The salts glyphosate-isopropylammonium, glyphosate-potassium, glyphosate-monoammonium, glyphosate-dimethylammonium are the modified ISO common names for isopropylammonium N-(phosphonomethyl)glycinate, potassium N-[(hydroxyphosphinato)methyl]glycine, ammonium N-[(hydroxylphosphinato)methyl]glycine and dimethylammonium N-(phosphonomethyl)glycinate (IUPAC), respectively. These salts are derivatives of the active substance glyphosate.

The active substance's minimum purity to be supported during the AIR 5 process remains at 950 g glyphosate acid/kg (Bayer reference specification), as previously approved at EU level.

The sources of technical glyphosate will be documented and evaluated in company specific J document(s) of the renewal dossier.

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<sup>1</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324.

<sup>2</sup> Due to the Bayer-Monsanto acquisition in 2018, the legal entity name Monsanto Europe S.A. / N.V. has been changed to Bayer Agriculture BVBA.

The compliance of test items relevant in the context of the AIR renewal dossier will be documented in the J document of the renewal dossier. Purity and impurity profiles of test items that were used in new and previously evaluated studies but relevant in the context of the re-evaluation will be compared against the reference specification (based on the batch profiles of all members). Test items used in studies from the Glyphosate Renewal Group members that might join the Glyphosate Renewal Group within 3 months of the submission deadline are not included in this overview. If that is the case, then the Glyphosate Renewal Group will provide this information as soon as possible as an addendum to this Application.

### **Plant protection product MON 52276**

The representative formulations supporting the renewal of the active substance glyphosate is MON 52276, a soluble concentrate (SL) containing 360 g/L glyphosate as isopropylammonium salt (486 g/L).

This formulation is registered in Europe and will also be the representative chemical product supporting the joint Glyphosate Renewal Group dossier for the renewal dossier. The composition of this formulation has not changed.

The chemical product MON 52276 has been already peer reviewed during the previous AIR 2 process at EU level.

### **3. SPECIFIC CONCLUSIONS BASED ON PREVIOUS EVALUATION**

Please refer to the following regulatory documents:

- EFSA Journal 2015; 13(11): 4302. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. doi:10.2903/j.efsa.2015.4302.
- EFSA Journal 2017. Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate. EFSA Journal 2017;15(9):4979, 20 pp. <https://doi.org/10.2903/j.efsa.2017.4979>
- Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ L 208, 2.8.2016, p. 1).
- SANTE/10441/2017 Rev 2 (9 November 2017). Review report for the active substance glyphosate finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 9 November 2017 in view of the renewal of the approval of glyphosate as active substance in accordance with Regulation (EC) No 1107/2009

#### **4. LIST OF STUDIES TO BE GENERATED, STILL ON-GOING BUT NOT EVALUATED AND/OR PEER REVIEWED**

The Glyphosate Renewal Group claims data confidentiality for all studies marked with “DC” in the column labelled “Claims”. The Glyphosate Renewal Group claims data protection for all studies marked with “DP”.

**DISCLAIMER:** The lists below were prepared to the best of our knowledge. Further studies not appearing necessary at this stage may need to be submitted, depending on the outcome of the planned/on-going studies, on the outcome of the risk assessment, or based on new requests from the relevant authorities.

The Glyphosate Renewal Group to the best of its knowledge at the time of application for renewal, expects that the technical dossier supporting the renewal of glyphosate will include the following non-vertebrate studies and pieces of information.

**4.1. Additional studies****Table 4.1-1: List of confidential studies**

<b>Annex Point (SANCO)</b>	<b>Author(s)</b>	<b>Year</b>	<b>Study Title (if available) or study type, Report No</b>	<b>Justification/ other remarks</b>	<b>Claim</b>
<b>Section 1</b>					
KCA 1.11	NN	pending	5-Batch Material Accountability studies (updated technical specification, relevance of all individual impurities present in the technical specification).	Data requirement.	DC, DP
KCA 1.8	NN	pending	Safety Data Sheets of the starting materials.	New notifier at EU level	DC, DP

**Table 4.1-2: List of non-vertebrate studies on the chemical active**

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No.	Justification/ other remarks	Claim
<b>Section 2</b>					
KCA 2.4	NN	pending	Spectra UV/VIS of glyphosate acid	Data requirement. New study following current guidance documents	DP
KCA 2.4	NN	pending	Spectra UV/VIS of glyphosate IPA salt	Data requirement. New study following current guidance documents	DP
KCA 2.5	NN	pending	Solubility of glyphosate acid, in water at pH 5, 7 and 9.	Data requirement. New study following current guidance documents	DP
KCA 2.5	NN	pending	Solubility of glyphosate ammonium in water at pH 5, 7 and 9	Data requirement. New study following current guidance documents	DP
KCA 2.5	NN	pending	Solubility of HMPA in water at pH 5, 7 and 9	Data requirement. New study following current guidance documents	DP
KCA 2.7	NN	pending	Partition coefficient n-octanol/water: glyphosate acid under neutral, acid and alkaline conditions	Data requirement. New study following current guidance documents	DP
KCA 2.7	NN	pending	Partition coefficient n-octanol/water: compounds in residue definition (AMPA, HMPA and <i>n</i> -acetyl glyphosate).	Data requirement. New study following current guidance documents	DP
KCA 2.9	NN	pending	Flammability and self-ignition study of glyphosate acid technical (wetcake)	Data requirement. New study following current guidance documents	DP
<b>Section 4</b>					
KCA 4.1.2	NN	pending	Analytical methods in support of risk assessment.	State of the art assessment. New study following current guidance documents.	DP
KCA 4.2	NN	pending	Methods for analysis of glyphosate and AMPA in honey (initial validation and ILV).	Triggered study due to new data requirements.	DP
KCA 4.2	NN	pending	Methods for analysis of glyphosate and AMPA in soil.	Triggered study. Linked to KCA 7 and 8 – Residue definition for monitoring.	DP
KCA 4.2	NN	pending	Methods for analysis of glyphosate and AMPA in body fluids.	New data requirement according to EC Regulation 283/2013.	DP

**Table 4.1-2: List of non-vertebrate studies on the chemical active**

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No.	Justification/ other remarks	Claim
KCA 4.2	NN	pending	Methods for analysis of glyphosate in animal fat and kidney/liver, for N-acetyl-glyphosate in plant matrices (dry plant materials and those with high water and high fat content) and N-acetyl-glyphosate in all animal matrices.	Triggered study. New study following current guidance documents	DP
<b>Section 5</b>					
KCA 5.1.1	NN	pending	In-vitro: comparative <i>in vitro</i> metabolism	Data requirement.	DP
KCA 5.1.1	NN	pending	Toxicokinetics (detection of active substance in plasma).	Data requirement.	DP
KCA 5.2.7	NN	pending	Phototoxicity	New data requirement according to EC Regulation 283/2013.	DP
KCA 5.4.1	NN	pending	Micronucleus Test in Human Lymphocytes in vitro with MON 52276	Study available, not yet peer-reviewed at EU level. Study requested during Art 43 product authorization process (EC Regulation 1107/2009).	DP
KCA 5.8.3	NN	pending	Assessment according to new ED Guidance for identification of endocrine disruptors in the context of EC Regulation 1107/2009 to be performed.	New data requirement.	DP
<b>Section 6</b>					
KCA 6.1	NN	pending	Storage stability for the metabolite AMPA in protein rich matrices (study ongoing).	Data requirement.	DP
KCA 6.1	NN	pending	Storage stability for glyphosate and AMPA in honey.	Data requirement.	DP
KCA 6.3	NN	pending	Field residue trials grapes & top fruits.	Study available, not yet peer-reviewed at EU level.	DP
KCA 6.5	NN	pending	Hydrolysis study to investigate the nature of residues of AMPA and N-acetyl-AMPA in processed commodities.	Data requirement.	DP
KCA 6.7	NN	pending	Assessment required according to new EFSA guidance document	New data requirement.	DP

**Table 4.1-2: List of non-vertebrate studies on the chemical active**

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No.	Justification/ other remarks	Claim
KCA 6.10	NN	pending	Residues in honey (tunnel study) and detection of glyphosate in honey (method transfer and validation).	Data requirement.	DP
<b>Section 7</b>					
KCA 7.1.1.3	NN	pending	Update of kinetic evaluation of soil photolysis studies.	State of the art assessment of data.	DP
KCA 7.1.2.1.1	NN	pending	Update of kinetic evaluation of aerobic soil degradation studies.	State of the art assessment of data.	DP
KCA 7.1.2.1.3	NN	pending	Update of kinetic evaluation of anaerobic soil degradation studies.	State of the art assessment of data.	DP
KCA 7.1.2.1.2	Göcer, M.	2017	Aminomethylphosphonic Acid (AMPA): Rate of Degradation of AMPA in one Acidic Soil Incubated under Aerobic Conditions.	Data requirement.	DP
KCA 7.1.2.1.2	NN	pending	Rate of degradation of AMPA in acidic soils incubated under aerobic conditions.	Data requirement.	DP
KCA 7.1.2.2.1	NN	pending	Update of kinetic evaluation of terrestrial field dissipation studies.	State of the art assessment of data.	DP
KCA 7.1.3.1.1	NN	pending	Glyphosate adsorption to soil according to OECD guideline 106.	Data requirement.	DP
KCA 7.1.3.1.1	NN	pending	AMPA adsorption to soil according to OECD guideline 106.	Data requirement.	DP
KCA 7.2.2.2	NN	pending	Aerobic mineralisation in surface water.	New data requirement according to EC Regulation 283/2013.	DP
KCA 7.2.2.3	NN	pending	Update of kinetic evaluation of water/sediment studies.	State of the art assessment of data.	DP
KCA 7.3.1	NN	pending	Updated calculation of atmospheric half-life.	State of the art assessment of data.	DP
KCA 7.5	NN	pending	Compilation of European soil, sediment, surface water, groundwater, drinking water, and air - monitoring data.	Data requirement.	DP

**Table 4.1-2: List of non-vertebrate studies on the chemical active**

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No.	Justification/ other remarks	Claim
<b>Section 8</b>					
KCA 8.1.1 8.1.2	NN	Pending	Broad-leaf residue decline.	New study to be used as a weight of evidence refinement to the chronic wild mammal risk assessment	DP
KCA 8.1.5 KCA 8.2.3	NN	Pending	Assessment according to new ED Guidance for identification of endocrine disruptors in the context of EC Regulations 1107/2009 to be performed.	New data requirement.	DP
KCA 8.2.5	NN	Pending	Chironomus sediment dweller: spiked water test design.	Data requirement.	DP
KCA 8.3.1.1.1	Molitor	2017	Acute oral study on Bumble bee ( <i>Bombus terrestris</i> ) for Glyphosate IPA salt (MON 0139).	New data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for non- <i>Apis</i> pollinator species.	DP
KCA 8.3.1.1.2	Molitor	2017	Acute contact on Bumble bee ( <i>Bombus terrestris</i> ) for Glyphosate IPA salt (MON 0139).	New data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for non- <i>Apis</i> pollinator species.	DP
KCA 8.3.1.1.2	Molitor	2017	Solitary bee ( <i>Osmia bicornis</i> ) - Acute contact on Glyphosate IPA salt (MON 0139).	New data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for non- <i>Apis</i> pollinator species.	DP
KCA 8.3.1.2	Schmitzer & Eichler	2017	Honeybee ( <i>Apis mellifera</i> ) chronic adult (10d) Glyphosate IPA salt (MON 0139).	New data requirement according to EC Regulation 283/2013, to support the honey bee risk assessment (OECD 245).	DP
KCA 8.3.1.3	NN	Pending	Honeybee ( <i>Apis mellifera</i> ) chronic larvae (22d).	New data requirement according to EC Regulation 283/2013, to support the honey bee risk assessment (OECD 239).	DP
KCA 8.4.1	NN	Pending	Earthworm reproduction study with the representative formulation MON52276	Data requirement.	DP

**4.2. List of new studies intended to be submitted on vertebrate animals**

Discussion for data sharing for vertebrate data, if any, will be **compulsory discussed with original notifiers before submission of any new vertebrate study**. Further discussion with the RMS representatives, in conjunction with EFSA would be scheduled.

A new higher tier study is being conducted with common voles to support the wild mammal data package, and to be used as a weight of evidence refinement to the chronic wild mammal risk assessment (see below).

**Table 4.2-1: List of vertebrate studies on the chemical active**

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No.	Justification/ other remarks	Claim
<b>Section 2</b>					
KCA 8.1.2	NN	Pending	Semi-field enclosure study with common voles.	New study to be used as a weight of evidence refinement to the chronic wild mammal risk assessment	DP

**5. IDENTIFIED AREAS FOR WHICH DETAILED RE-EVALUATION IS NEEDED IN DOSSIER FROM NOTIFIER AND IN EVALUATION BY RMS/CO-RMS**

The dossier supporting the approval renewal and its evaluation will/should focus on the main following areas:

The applicant confirms that the above information submitted included in the application is correct.