Application for Approval Renewal for an Active Substance: Glyphosate & the IPA-, K-, DMA and NH4-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

15th December 2019
22nd January 2020

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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3. Company: Barclay Chemicals Manufacturing Ltd.

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4. Company: CIECH Sarzyna S.A.

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~~8. Company:~~	~~Arysta LifeScience SAS~~[1]
~~Address:~~	~~BP 80 Route d'Artix~~ ~~64150 Nogueres~~ ~~France~~
~~Contact:~~	[redacted]
~~Telephone:~~	[redacted]
~~e-mail:~~	[redacted]

8. Company:	Industrias Afrasa, S.A.[2]
Address:	Ciudad de Sevilla 53 46988-Pol.Ind.Fuente del Jarro Paterna (Valencia) Spain
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Telephone:	[redacted]
Fax:	[redacted]
e-mail:	[redacted]

9. Company:	Syngenta Crop Protection AG
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Contact:	[redacted]
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e-mail:	[redacted]

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] ARYSTA resigned from the Glyphosate Renewal Group on 07 January 2020
[2] AFRASA joined the Glyphosate Renewal Group on 18 December 2019

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

The original ISO names, IUPAC, CA names were taken from Final addendum to RAR_Volume 1 (October 2015).

Common name (ISO): Glyphosate[3]; *N*-(phosphonomethyl)glycine[4]

Active ingredient: Glyphosate

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

N-(phosphonomethyl)glycin isopropylammonium (ISO name according to ECHA[5])

Glyphosate-potassium-salt

Glyphosate-potassium (ISO name according to ECHA[6])

Glyphosate-ammonium-salt

Ammonium salt of *N*-(phosphonomethyl)glycine (ISO name according to ECHA[7])

Glyphosate – dimethylammonium-salt

Glyphosate DMA salt (ISO name according to ECHA[8])

2.2. Chemical name (IUPAC and CAS nomenclature)

	Glyphosate
IUPAC name:	*N*-(phosphonomethyl)glycine
CA name:	*N*-(phosphonomethyl)glycine Glycine, *N*-(phosphonomethyl)- (CA name according to ECHA)

[3] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.012.726
[4] Alternative name provided in the RAR Volume 1 (October 2015)
[5] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.216.627
[6] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.214.061
[7] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.113.866
[8] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.225.339

	Glyphosate-isopropyl-amine-salt Glyphosate-isopropylammonium
IUPAC name:	*N*-(phosphonomethyl)glycine - isopropylamine (1:1) or isopropylammonium N-(phosphonomethyl)glycinate *N*-(phosphonomethyl)glycine isopropylammonium (IUPAC name according to ECHA[9])
CA name:	*N*-(phosphonomethyl)glycine isopropylammonium salt

	Glyphosate-potassium-salt Glyphosate-potassium
IUPAC name:	potassium *N*-[(hydroxyphosphinato)methyl]glycine *N*-(phosphonomethyl)glycine monopotassium salt (IUPAC name according to ECHA[10])
CA name:	*N*-(phosphonomethyl)glycine potassium salt

	Glyphosate-ammonium-salt Ammonium salt of N-(phosphonomethyl)glycine
IUPAC name:	ammonium *N*-[(hydroxyphosphinato)methyl]glycine *N*-(phosphonomethyl)glycine monoammonium salt (IUPAC name according to ECHA[11])
CA name:	*N*-(phosphonomethyl)glycine ammonium salt

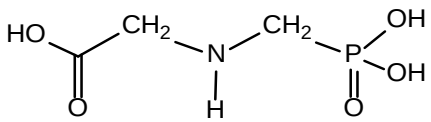
	Glyphosate - dimethylammonium salt Glyphosate DMA salt
IUPAC name:	*N*-(phosphonomethyl)glycine - dimethylamine (1:1) or dimethylammonium *N*-(phosphonomethyl)glycinate Glyphosate DMA Salt (according to ECHA[12])
CA name:	*N*-(phosphonomethyl)glycine dimethyl ammonium salt

[9] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.216.627
[10] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.214.061
[11] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.113.866
[12] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.225.339

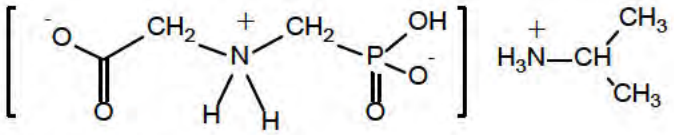
2.3. CAS, CIPAC and EC numbers (if available)

	Glyphosate
CAS No:	1071-83-6
CIPAC No:	284
EC No:	213-997-4
	Glyphosate-isopropyl-amine-salt Glyphosate-isopropylammonium
CAS No:	38641-94-0
CIPAC No:	284.105
EC No:	254-056-8
	Glyphosate-potassium-salt Glyphosate-potassium
CAS No:	39600-42-5
CIPAC No:	284.019
EC No:	687-795-3
	Glyphosate ammonium salt
CAS No:	114370-14-8
CIPAC No:	284.007
EC No:	601-309-9
	Glyphosate - dimethylammonium salt Glyphosate DMA salt
CAS No:	34494-04-7
CIPAC No:	284.102
EC No:	696-134-8

2.4. Empirical and structural formula, molecular mass

	Glyphosate
Empirical formula:	$C_3H_8NO_5P$
Structural formula:	
Molecular mass:	169.1 g/mol
	Glyphosate-isopropyl-amine-salt Glyphosate-isopropylammonium
Empirical formula:	$C_6H_{17}N_2O_5P$

Structural formula:

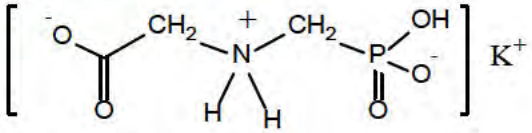


Molecular mass: 228.18 g/mol

Glyphosate-potassium-salt
Glyphosate-potassium

Empirical formula: $C_3H_7KNO_5P$

Structural formula:

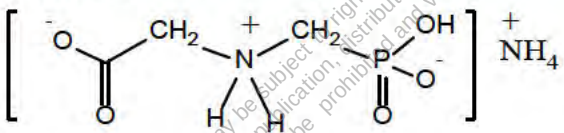


Molecular mass: 207.19 g/mol

Glyphosate-ammonium-salt
Ammonium salt of N-(phosphonomethyl)glycine

Empirical formula: $C_3H_{11}N_2O_5P$

Structural formula:

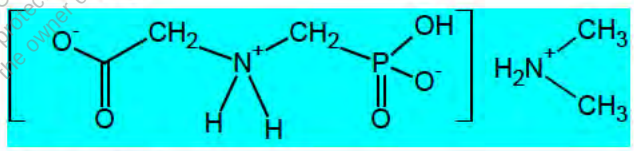


Molecular mass: 186.10 g/mol

Glyphosate - dimethylammonium salt
Glyphosate DMA salt

Empirical formula: $C_5H_{15}N_2O_5P$

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[13] 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 GHS09 Danger
Aquatic chronic 2	H411	

3. New Information

Please refer to **Appendix 1**.

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

[redacted]

22 January 2020

[redacted]

Bayer AG
(On behalf of the Glyphosate Renewal Group)

[13] 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.

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[14]. Glyphosate was renewed (date of approval) on 16th December 2017 with the expiration of approval set up for 15th December 2022.

2. THE ACTIVE SUBSTANCE AND THE PLANT PROTECTION PRODUCT

The lead registrant Bayer Agriculture BVBA[15], 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 ISO name for the active substance and related salts is provided above under point 2 of this application document.

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.

[14] COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324.
[15] 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) 2017/2324 of 2 December 2017 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 Commission Implementing Regulation (EU) No 540/2011
- SANTE/10441/2017 Rev 2 (9 November 2017). Review report for the active substance glyphosate finalized 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 1107/20091

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

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No	Justification/ other remarks	Claim
Section 1					
KCA 1.11	NN	May 2020	5-Batch Material Accountability studies (updated technical specification, relevance of all individual impurities present in the technical specification).	Data requirement.	DC
KCA 1.8	NN	Feb 2020	Safety Data Sheets of the starting materials.	New notifier at EU level	DC

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
Section 2					
KCA 2.4	NN	May 2020	Spectra UV/VIS of glyphosate acid	New study to be used as a weight of evidence refinement, adding additional data to already available dataset.	DP
KCA 2.4	NN	May 2020	Spectra UV/VIS of glyphosate IPA salt	New study to be used as a weight of evidence refinement, adding additional data to already available dataset.	DP
KCA 2.5	[redacted]	Mar 2020	Solubility of glyphosate acid, in water at pH 5, 7 and 9.	New study to be used as a weight of evidence refinement, adding additional data to already available dataset..	DP
KCA 2.5	[redacted]	Mar 2020	Solubility of glyphosate ammonium in water at pH 5, 7 and 9	New study to be used as a weight of evidence refinement, adding additional data to already available dataset.	DP
KCA 2.5	[redacted]	Mar 2020	Solubility of HMPA in water at pH 5, 7 and 9	New study to be used as additional supporting data.	DP
KCA 2.7	[redacted]	Mar 2020	Partition coefficient n-octanol/water: glyphosate acid under neutral, acid and alkaline conditions	New study to be used as a weight of evidence refinement, adding additional data to already available dataset.	DP
KCA 2.7	[redacted]	Mar 2020	Partition coefficient n-octanol/water: compounds in residue definition (AMPA, HMPA and *n*-acetyl glyphosate).	New data requirement according to EC Regulation 283/2013 for all components of the residue definition for risk assessment.	DP
KCA 2.9	[redacted]	2019	Flammability and self-ignition study of glyphosate acid technical (wetcake)	New study to be used as a weight of evidence refinement, adding additional data to already available dataset.	DP
Section 4					
KCA 4.1.2	NN	May 2020	Analytical methods in support of risk assessment. Methods used in support of environmental fate studies: Approx. 20 (1 new study and approx. 19 already available and reviewed regulatory studies). Methods used in support of toxicological studies: Approx. 100 (1 new study and approx. 99 already available and reviewed regulatory studies).	Assessment of the analytical methods used in environmental fate, toxicological, ecotoxicology and residues studies (old and new studies), following current guidance document (SANCO 3029/99 rev 4). The studies already evaluated in the AIR2 process were not evaluated with respective to the analytical methods for data generation. As this is now the data requirement according to EC Regulation 283/2013 all used methods to support the environmental fate,	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
			Methods in support of residues studies: Approx. 15 (3 new studies and approx. 12 already available and reviewed regulatory studies).	toxicological, ecotoxicology and residues studies will be presented.	
			Methods in support of ecotoxicology studies: Approx. 50 (2 new studies and approx. 48 already available and reviewed regulatory studies).		
KCA 4.2	NN	May 2020	Methods for analysis of glyphosate and AMPA in honey (initial validation and ILV).	Triggered study due to new data requirements (SANTE/11956/2016 rev. 9 Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey)	DP
KCA 4.2	[redacted]	2015	Methods for analysis of glyphosate and AMPA in soil.	Study to cover the requested confirmatory method (Peer review of the pesticide risk assessment of the active substance glyphosate; EFSA Journal 2015;13(11):4302). According to SANCO 825/00 rev. 8.1 the confirmation method is required.	DP
KCA 4.2	[redacted]	2016	Methods for analysis of glyphosate and AMPA in body fluids.	New data requirement according to EC Regulation 283/2013.	DP
KCA 4.2	[redacted]	2016	Method for analysis of N-acetyl-glyphosate in plant matrices (dry plant materials and those with high water and high fat content).	Study to cover the requested analytical method (Peer review of the pesticide risk assessment of the active substance glyphosate; EFSA Journal 2015;13(11):4302). According to SANCO 825/00 rev. 8.1 the study is required as N-acetyl-glyphosate is part of the residue definition for monitoring.	DP
KCA 4.2	[redacted]	2016	ILV of the analytical method for N-acetyl-glyphosate in plant matrices (dry plant materials and those with high water and high fat content)	Study to cover the requested independent lab validation (Peer review of the pesticide risk assessment of the active substance glyphosate; EFSA Journal 2015;13(11):4302). According to SANCO 825/00 rev. 8.1 the study is required as N-acetyl-glyphosate is part of the residue definition for monitoring.	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	[redacted]	2016	Methods for analysis of glyphosate in animal fat and kidney/liver.	Study to cover the requested confirmatory method (Peer review of the pesticide risk assessment of the active substance glyphosate; EFSA Journal 2015:13(11):4302). According to SANCO 825/00 rev. 8.1 the confirmation method is required.	DP
KCA 4.2	[redacted]	2016	Methods for analysis of N-acetyl-glyphosate in all animal matrices.	Study to cover the requested confirmatory method (Peer review of the pesticide risk assessment of the active substance glyphosate; EFSA Journal 2015:13(11):4302). According to SANCO 825/00 rev. 8.1 the confirmation method is required.	DP
Section 5					
KCA 5.1.1	[redacted]	Mar 2020	In-vitro: comparative *in vitro* metabolism	Comparative *in vitro* metabolism data are to be performed on animal species (used in pivotal studies) and on human material in order to determine the relevance of the available animal data and in order to establish further testing strategies if relevant.	DP
~~KCA 5.1.1~~	[redacted]	~~May 2020~~	~~Toxicokinetics (detection of active substance in plasma)~~[16]	~~Additional toxicokinetic data are performed in order to fulfil the data requirements and provide essential information on bioavailability relevant for a proper assessment of respective *in vivo* studies. (EC Regulation 283/2013)~~	~~DP~~
KCA 5.2.7	NA	May 2020	Phototoxicity – Expert Statement based on UV/VIS absorption spectra KCA 2.4 regulatory study	New data requirement according to EC Regulation 283/2013.	

[16] This study is a vertebrate study and therefore it was moved to be presented under Table 4.2 1.

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 5.8.3	NA	May 2020	Assessment according to new ED Guidance for identification of endocrine disruptors in the context of EC Regulation 1107/2009 to be performed.	Data requirement for active substance according to EC Regulation 283/2013 to support assessment for potential endocrine disruptor properties. The assessment will compile information of 75 already available and reviewed toxicology regulatory studies.	
Section 6					
KCA 6.1	NN	Feb 2022	Storage stability for the metabolite AMPA in protein rich matrices (study ongoing).	Data requirement according to OECD Test Guideline 506.	DP
KCA 6.1	NN	May 2020	Storage stability for glyphosate and AMPA in honey.	Triggered study due to new data requirements (SANTE/11956/2016 rev. 9 Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey).	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in tree nuts (outdoor) at 2 sites in Southern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in apricots (outdoor) at 4 sites in Southern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in kiwi fruit (outdoor) at 2 sites in Southern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2015	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in bananas (outdoor) at 4 sites in Spain (Canary Islands) 2014	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	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 6.3	[redacted]	2015	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in vine grapes (outdoor) at 4 sites in Northern France and 2 sites in Southern France 2014	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2015	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in vine grapes (outdoor) at 3 sites in Germany and 2 sites in Spain 2014	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2015	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in vine grapes (outdoor) at 4 sites in Southern Europe 2014	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in vine grapes (outdoor) at 2 sites in Germany 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2014	Glyphosate - Residue Study on Mandarin Oranges in Spain in 2013	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2014	Glyphosate - Residue Study on Plum in Italy in 2013	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2014	Glyphosate - Residue Study on Apple in the United Kingdom and Germany in 2013	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2014	Glyphosate - Residue Study on Apple in Spain and Italy in 2013	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2014	Glyphosate - Residue Study on Cherry in Spain and Italy in 2013	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	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 6.3	[redacted]	2013	Determination of Residue of Glyphosate in Stone Fruits Following one Application of Glyphosate SL 360g/L (CA2705) in Northern and Southern France, in 2012	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in bulb onions (outdoor) at 4 sites in Southern and 2 sites in Northern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in courgette (outdoor) at 2 sites in Southern and 2 sites in Northern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in cucumber (outdoor) at 2 sites in Southern and 2 sites in Northern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in tomato (outdoor) at 4 sites in Southern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in head lettuce (outdoor) at 4 sites in Southern and 2 sites in Northern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in parsley (outdoor) at 2 sites in Southern and 2 sites in Northern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	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 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in green beans (outdoor) at 4 sites in Southern and 4 sites in Northern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in carrots (outdoor) at 4 sites in Southern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.3	[redacted]	2016	Determination of residues of glyphosate and its metabolite AMPA after one application of MON 79351 in radish (outdoor) at 2 sites in Southern Europe 2015	Not yet peer-reviewed residue data. Data relevant to support the representative uses listed in the GAP table	DP
KCA 6.5	NN	May 2020	Hydrolysis study to investigate the nature of residues of AMPA and N-acetyl-AMPA in processed commodities.	Data requirement according to EC Regulation 283/2013. AMPA and N-acetyl AMPA are part of the residue definition for risk assessment. Therefore the study is necessary to investigate the nature of residues of AMPA and N-acetyl-AMPA in processed commodities.	DP
KCA 6.7	NN	May 2020	Assessment required according to new EFSA guidance document	Data requirement according to EC Regulation 283/2013, following the EFSA Guidance on the establishment of the residue definition for dietary risk assessment. The assessment will compile information from approx. 20-30 metabolism studies in plant and animal matrices.	
KCA 6.10	NN	May 2020	Residues in honey (tunnel study) and detection of glyphosate in honey (method transfer and validation).	Triggered study due to new data requirements (SANTE/11956/2016 rev. 9 Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey)	DP
Section 7					
KCA 7.1.1.3	NN	May 2020	Update of kinetic evaluation of soil photolysis studies.	Assessment of data according to latest guideline FOCUS Generic Guidance on Degradation Kinetics (Dec. 2014) using latest evaluation tools.	

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 7.1.2.1.1	NN	May 2020	Update of kinetic evaluation of aerobic soil degradation studies.	Assessment of data according to latest guideline FOCUS Generic Guidance on Degradation Kinetics (Dec. 2014) using latest evaluation tools.	
KCA 7.1.2.1.3	NN	May 2020	Update of kinetic evaluation of anaerobic soil degradation studies.	Assessment of data according to latest guideline FOCUS Generic Guidance on Degradation Kinetics (Dec. 2014) using latest evaluation tools.	
KCA 7.1.2.1.2	[redacted]	2017	Aminomethylphosphonic Acid (AMPA): Rate of Degradation of AMPA in one Acidic Soil Incubated under Aerobic Conditions.	To meet requirements of Commission implementing regulation (EU) 2017/2324.	DP
KCA 7.1.2.1.2	NN	May 2020	Rate of degradation of AMPA in acidic soils incubated under aerobic conditions.	To meet requirements of Commission implementing regulation (EU) 2017/2324.	DP
KCA 7.1.2.2.1	NN	May 2020	Update of kinetic evaluation of terrestrial field dissipation studies.	Assessment of data according to latest guideline FOCUS Generic Guidance on Degradation Kinetics (Dec. 2014) & EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values (July 2014) using latest evaluation tools.	
KCA 7.1.3.1.1	NN	May 2020	Glyphosate adsorption to soil according to OECD guideline 106.	Data requirement. To complete dataset in view of OECD 106 evaluators checklist (EFSA, 2017).	DP
KCA 7.1.3.1.1	NN	May 2020	AMPA adsorption to soil according to OECD guideline 106.	Data requirement. To complete dataset in view of OECD 106 evaluators checklist (EFSA, 2017)	DP
KCA 7.2.2.2	NN	March 2020	Aerobic mineralisation in surface water.	New data requirement according to EC Regulation 283/2013.	DP
KCA 7.2.2.3	NN	May 2020	Update of kinetic evaluation of water/sediment studies.	Assessment of data according to latest guideline FOCUS Generic Guidance on Degradation Kinetics (Dec. 2014) using latest evaluation tools.	
KCA 7.3.1	NN	May 2020	Updated calculation of atmospheric half-life.	Update assessment of data using latest evaluation tools.	
KCA 7.5	NN	May 2020	Compilation of European soil, sediment, surface water, groundwater, drinking water, and air - monitoring data.	Data requirement according to EC Regulation 283/2013. Update of existing dataset with most recent monitoring data.	

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
Section 8					
KCA 8.1.1 8.1.2	NN	Dec 2020	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	May 2020	Assessment according to new ED Guidance for identification of endocrine disruptors in the context of EC Regulation 1107/2009 to be performed.	Data requirement for active substance according to EC Regulation 283/2013 to support assessment for potential endocrine disruptor properties. The assessment will compile information from approx. 13 ecotoxicology regulatory studies.	
KCA 8.2.5	NN	May 2020	Chironomus sediment dweller: spiked water test design.	Data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for sediment dweller species.	DP
KCA 8.3.1.1.1	[redacted]	2017	Acute oral study on Bumble bee *(Bombus terrestris)* for Glyphosate IPA salt (MON 0139).	New data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for non-*Apis* pollinator species.	DP
KCA 8.3.1.1.2	[redacted]	2017	Acute contact on Bumble bee *(Bombus terrestris)* for Glyphosate IPA salt (MON 0139).	New data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for non-*Apis* pollinator species.	DP
KCA 8.3.1.1.2	[redacted]	2017	Solitary bee (*Osmia bicornis*) - 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-*Apis* pollinator species.	DP
KCA 8.3.1.2	[redacted]	2017	Honeybee (*Apis mellifera)* 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	May 2020	Honeybee (*Apis mellifera*) chronic larvae (22d).	New data requirement according to EC Regulation 283/2013, to support the honey bee risk assessment (OECD 239).	DP
KCA 8.7	NN	May 2020	Assessment of the impact of Glyphosate on the diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions.	To meet requirements of Commission implementing regulation (EU) 2017/2324	

Table 4.1-3: List of non-vertebrate studies on the chemical product

Annex Point (SANCO)	Author(s)	Year	Study Title (if available) or study type, Report No.	Justification/ other remarks	Claim
Section 5					
KCP 5.1.2	NN	Jun 2020	Analytical methods in support of risk assessment. Methods in support of ecotoxicology studies: Approx. 5 new studies.	Assessment of the analytical methods used in environmental fate, toxicological, ecotoxicology and residues studies (new studies), following current guidance document (SANCO 3029/99 rev 4).	DP
Section 7					
KCP 7.1.7	[redacted]	2000	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
KCP 7.1.7	NN	May 2020	Micronucleus Test in Human Lymphocytes in vitro with MON 52276	New study to be used as a weight of evidence refinement, adding additional data to already available dataset.	DP
Section 10					
KCP 10.4.1	NN	May 2020	Earthworm reproduction study with the representative formulation MON52276	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for sublethal effects to earthworms.	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.

An additional toxicokinetic study was initiated to support global submissions. Since the study is available, it will be submitted. The study will provide essential information on bioavailability relevant for a proper assessment of respective in vivo studies.

~~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
Section 5					
KCA 5.1.1	[redacted]	May 2020	14-Day Oral (Dietary) Toxicokinetic Study of Glyphosate in Sprague Dawley Rats[17]	A 14-day dietary toxicokinetic study in rats at higher doses was initiated to support global submissions where risk assessment endpoints were appropriately selected from repeat dose dietary toxicology studies. Since the study will be available for regulatory purposes outside the EU, it will be submitted with the AIR5 data package for the EU renewal. The one other available dietary repeat dose toxicokinetics glyphosate study ([redacted] 1973) administered glyphosate at 100 ppm in the diet, and this dose was considered too low during the first approval of glyphosate in the EU (2001)"	KCA 5.1.1
~~Section 8~~					
~~KCP 8.1.2~~	~~NN~~	~~Pending~~	~~Semi field enclosure study with common voles~~[18]	~~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.~~

[17] This study is a vertebrate study and therefore moved from Table 4.1 2 since it is appropriate to be presented under Point 4.2: List of new studies intended to be submitted on vertebrate animals

[18] Based on the feedback received from the AGG on the application document sent in Dec 2019, the study will not be considered.