Application for Approval Renewal for an Active Substance: Glyphosate ~~& the IPA , K , DMA and NH4 salts of Glyphosate (hereafter Glyphosate)~~[1]

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
24th April 2020
1st July 2020

Applicant

Notifier(s): ~~Bayer Agriculture BVBA~~

Bayer Agriculture BV[2]

on behalf of the Glyphosate Renewal Group

[1] Details of the salts are included in this document, please see point 2.1.
[2] In accordance with the new Belgian Code on Companies and Associations, Bayer Agriculture BVBA's legal form will be formally converted into Bayer Agriculture BV in the beginning of August 2020. Other than legal form change, all other details of the company as well as its address will remain unchanged.

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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

1. Company:	~~Bayer Agriculture BVBA~~ Bayer Agriculture BV[2] Lead registrant on behalf of the Glyphosate Renewal Group
Address:	Haven 627 Scheldelaan 460 B-2040 Antwerp Belgium
Contact:	[redacted] Bayer AG, Crop Science Division Alfred Nobel Str. 50 40789 Monheim am Rhein Germany
Telephone:	[redacted]
Fax:	[redacted]
e-mail:	[redacted]
2. ~~Company:~~	~~ADAMA Agan Ltd.~~[3]
~~Address:~~	~~Edmund-Rumpler-Str. 6~~ ~~51149 Koeln (Cologne)~~ ~~Germany~~
~~Contact:~~	[redacted]
~~Telephone:~~	[redacted]
~~Fax:~~	[redacted]
~~e-mail:~~	[redacted]

[3] ADAMA Agan Ltd. resigned from the Glyphosate Renewal Group on 25 March 2020.

~~3.~~ 2. Company	Barclay Chemicals Manufacturing Ltd.
Address:	Damastown Way Damastown Industrial Park Mulhuddart Dublin 15 Ireland
Contact:	[redacted]
Telephone:	[redacted]
Fax:	[redacted]
e-mail:	[redacted]
~~4.~~ 3. Company:	CIECH Sarzyna S.A.
Address:	ul. Wspólna 62 00-684 Warschau Poland
Contact:	[redacted]
Telephone:	[redacted]
e-mail:	[redacted]
~~5.~~ 4. Company:	Albaugh Europe SARL
Address:	World Trade Center Lausanne Avenue Gratta-Paille 2 1018 Lausanne Switzerland
Contact:	[redacted]
Telephone:	[redacted]
e-mail:	[redacted]
~~6.~~ 5. Company:	Nufarm GmbH & Co KG
Address:	St.-Peter-Str. 25 A-4021 Linz Austria
Contact:	[redacted]
Telephone:	[redacted]
e-mail:	[redacted]

~~7.~~ 6. Company:	SINON Corporation
Address:	No. 101, Nanrong Road Dadu District Taichung City 43245 Taiwan (R.O.C.)
Contact:	[redacted]
Telephone:	[redacted]
e-mail:	[redacted]
~~8.~~ Company:	~~Arysta LifeScience SAS~~[4]
Address:	~~BP 80 Route d'Artix~~ ~~64150 Nogueres~~ ~~France~~
Contact:	[redacted]
Telephone:	[redacted]
e-mail:	[redacted]
~~8.~~ 7. Company:	Industrias Afrasa, S.A.[5]
Address:	Ciudad de Sevilla 53 46988-Pol.Ind.Fuente del Jarro Paterna (Valencia) Spain
Contact:	[redacted]
Telephone:	[redacted]
Fax:	[redacted]
e-mail:	[redacted]
~~9.~~ 8. Company:	Syngenta Crop Protection AG
Address:	Rosentalstrasse 67 CH-4002 Basel Switzerland
Contact:	[redacted]
Telephone:	[redacted]
e-mail:	[redacted]

[4] ARYSTA resigned from the Glyphosate Renewal Group on 04 February 2020.
[5] AFRASA joined the Glyphosate Renewal Group on 18 December 2019.

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

The original ISO names, IUPAC, CA names for glyphosate and its related salts (variants), were taken from Final addendum to RAR_Volume 1 (October 2015).

Common name (ISO):	Glyphosate[6]; *N*-(phosphonomethyl)glycine[7]
Active ingredient:	Glyphosate
Related salt-types:	Glyphosate- isopropyl-amine-salt
	N-(phosphonomethyl)glycin isopropylammonium (ISO name according to ECHA[8])
	Glyphosate-potassium-salt
	Glyphosate-potassium (ISO name according to ECHA[9])
	Glyphosate-ammonium-salt
	Ammonium salt of *N*-(phosphonomethyl)glycine (ISO name according to ECHA[10])
	Glyphosate – dimethylammonium-salt
	Glyphosate DMA salt (ISO name according to ECHA[11])

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)

[6] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.012.726
[7] Alternative name provided in the RAR Volume 1 (October 2015)
[8] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.216.627
[9] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.214.061
[10] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.113.866
[11] 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[12])
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[13])
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[14])
CA name:	*N*-(phosphonomethyl)glycine ammonium salt

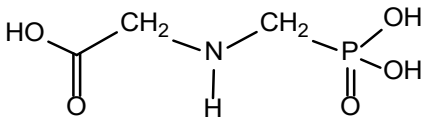
	Glyphosate - dimethylammonium salt Glyphosate DMA salt
IUPAC name:	*N*-(phosphonomethyl)glycine - dimethylamine (1:1) or dimethylammonium *N*-(phosphonomethyl)glycinate Glyphosate DMA Salt (according to ECHA[15])
CA name:	*N*-(phosphonomethyl)glycine dimethyl ammonium salt

[12] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.216.627
[13] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.214.061
[14] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.113.866
[15] ECHA website: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.225.339

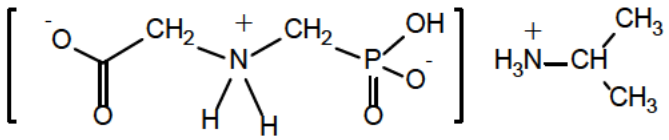
2.3. CAS, CIPAC and EC numbers (if available)

	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:

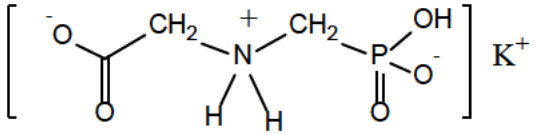


Molecular mass: 228.18 g/mol

Glyphosate-potassium-salt
Glyphosate-potassium

Empirical formula: $C_3H_7KNO_5P$

Structural formula:

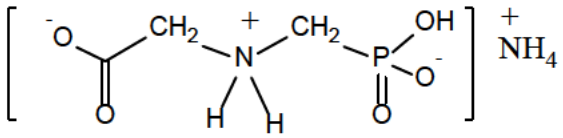


Molecular mass: 207.19 g/mol

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

Empirical formula: $C_3H_{11}N_2O_5P$

Structural formula:

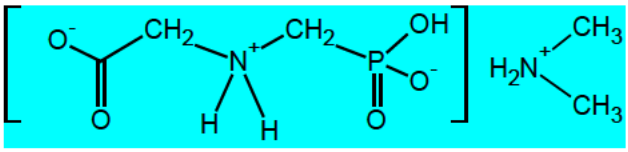


Molecular mass: 186.10 g/mol

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[16] 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]

01 July 2020

[redacted]

Bayer AG
(On behalf of the Glyphosate Renewal Group)

[16] 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[17]. 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 BV~~BA~~[18], 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.

[17] COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324.
[18] 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. In accordance with the new Belgian Code on Companies and Associations, Bayer Agriculture BVBA's legal form will be formally converted into Bayer Agriculture BV in the beginning of August 2020. Other than legal form change, all other details of the company as well as its address will remain unchanged.

The sources of technical glyphosate will be documented and evaluated in company specific J document(s) of the renewal dossier.
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~~ [redacted]	~~May~~ Feb 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~~ [redacted]	~~May~~ Feb 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~~ Feb 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~~ Feb 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~~ Feb 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~~ Feb 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~~ Feb 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 2.7	[redacted]	Feb 2020	Partition coefficient n-octanol/water: compounds in residue definition (HMPA).	New data requirement according to EC Regulation 283/2013, relevant for all components of the residue definition for risk assessment.	DP
KCA 2.9	[redacted]	Oct 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	Jun 2020	Analytical methods in support of risk assessment Methods used in support of identified valid studies environmental fate studies: ~~Approx. 20~~ 23 (~~1~~ 3 new study and ~~approx. 19~~ 20 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	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 used in support of toxicological studies: ~~Approx. 100~~ 89 (~~1~~ 11 new study and ~~approx. 99~~ 78 already available and reviewed regulatory studies).	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, toxicological, ecotoxicology and residues studies will be presented.	
			Methods in support of residues studies: ~~Approx. 15~~ 34(~~3~~ 14 new studies and ~~approx. 12~~ 20 already available and reviewed regulatory studies).		
			Methods in support of ecotoxicology studies: ~~Approx. 50~~ 68 (~~2~~ 6 new studies and ~~approx. 48~~ 62 already available and reviewed regulatory studies).		
			Methods in support of physical and chemical studies: 8 (7 new studies and 1 already available and reviewed regulatory study).		
KCA 4.2	~~NN~~ [redacted]	~~May 2020~~ Jun 2019	~~Methods for analysis of glyphosate and AMPA in honey (initial validation and ILV).~~ Validation of Monsanto ME-2220 Analytical Method for the Determination of Glyphosate and AMPA Residues 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 4.2	[redacted]	Mar 2020	ILV of method ME-2220-01 and short term storage stability of glyphosate and its metabolite 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

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]	Nov 2015	~~Methods for analysis of glyphosate and AMPA in soil.~~ Validation of an Analytical Method for the Determination of Glyphosate and AMPA in Soil Using LC/MS/MS	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]	Dec 2016	~~Methods for analysis of glyphosate and AMPA in body fluids.~~ Analytical Method for Determination of Glyphosate and AMPA in Urine	New data requirement according to EC Regulation 283/2013.	DP
KCA 4.2	[redacted]	Jun 2016	~~Method for analysis of N-acetyl-glyphosate in plant matrices (dry plant materials and those with high water and high fat content).~~ Analytical Method for the Determination of N-Acetyl Glyphosate in Matrices of Plant Origin	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]	Aug 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)~~ Independent Laboratory Validation of an Analytical Method for the Determination of N-Acetyl glyphosate in Matrices of Plant Origin	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
KCA 4.2	[redacted]	Mar 2016	~~Methods for analysis of glyphosate in animal fat and kidney/liver.~~ Analytical Method for the Determination of Glyphosate and AMPA in Matrices of Animal Origin	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

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]	Jun 2016	~~Methods for analysis of N-acetyl-glyphosate in all animal matrices.~~ Analytical Method for the Determination of N-Acetyl Glyphosate in Matrices of Animal Origin	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]	Sep 2016	Independent Laboratory Validation of analytical methods for the determination of glyphosate and its metabolites N-acetyl glyphosate and AMPA in matrices of animal origin	Not yet peer-reviewed data. The study is required as N-acetyl-glyphosate is part of the residue definition for monitoring.	DP
KCA 4.2	[redacted]	Mar 2016	Analytical Method for the Determination of Glyphosate and AMPA in Matrices of Plant Origin	Not yet peer-reviewed data. New study to address method for post-approval control and monitoring purposes.	DP
KCA 4.2	[redacted]	Jun 2015	Independent Laboratory Validation of an Analytical Method for the Determination of Glyphosate and AMPA in Different Matrices of Plant Origin	Not yet peer-reviewed data. New study to address method for post-approval control and monitoring purposes.	DP
KCA 4.1.2 KCA 4.2	[redacted]	Aug 2018	Validation of Monsanto ME-2015 Analytical Method for the Determination of Glyphosate and AMPA Residues in Crop Matrices	Not yet peer-reviewed method for data generation. The data will not be presented during the submission in June 2020, as no data was generated using the described method in the submitted studies yet. Nevertheless it will be used in planned EU pre-emergence and rotational crop trials. It may also be proposed as monitoring method. Therefore, it is listed.	DP
KCA 4.2	NN	2022	ILV of Monsanto ME-2015 Analytical Method for the Determination of Glyphosate and AMPA Residues in Crop Matrices	New method validation conducted in the context of planned EU pre-emergence and rotational crop trials. The validation will be run as an ILV since the method will be proposed 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
Section 5					
KCA 5.1.1	[redacted]	~~Mar~~ Apr 2020	~~In vitro: comparative *in vitro* metabolism~~ Metabolic stability and profiling of [^{14}C]-Glyphosate in hepatocytes from human, rat, mouse, dog and rabbit for inter-species comparison	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. No applicable OECD or US EPA OCSPP Guideline is available	DP
~~KCA 5.1.1~~	[redacted]	~~May 2020~~	~~Toxicokinetics (detection of active substance in plasma)~~[19]	~~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.	DP
KCA 5.4	[redacted]	Aug 2020	Glyphosate: V79 HPRT Gene Mutation Assay	Triggered study. New study to comply with current guideline(s). New study to comply with OECD Test Guideline 476.	DP
KCA 5.4	[redacted]	Aug 2020	Glyphosate: Micronucleus Test in Human Lymphocytes in vitro	Triggered study. New study to comply with current guideline(s). New study to comply with OECD Test Guideline 487.	DP
KCA 5.8.1	[redacted]	Aug 2020	Aminomethylphosphonic acid: Reverse Mutation Assay 'Ames Test' using *Salmonella typhimurium* and *Escherichia coli*	Triggered study. New study to comply with current guideline(s). New study to comply with OECD Test Guideline 471.	DP
KCA 5.8.1	[redacted]	Aug 2020	Aminomethylphosphonic acid: V79 HPRT Gene Mutation Assay	Triggered study. New study to comply with current guideline(s). New study to comply with OECD Test Guideline 476.	DP
KCA 5.8.1	[redacted]	Aug 2020	Aminomethylphosphonic acid: Micronucleus Test in Human Lymphocytes in vitro	Triggered study. New study to comply with current guideline(s). New study to comply with OECD Test Guideline 487.	DP

[19] 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 5.8.1	[redacted]	Dec 2004	*Salmonella-Escherichia coli* / Mammalian-Microsome reverse mutation assay with a confirmatory assay with N-acetyl-glyphosate	Not yet peer-reviewed data. New study with N-acetyl glyphosate to comply with OECD Test Guideline 471.	DP
KCA 5.8.1	[redacted]	Sep 2006	IN-MCX20: In Vitro Mammalian Cell Gene Mutation Test (CHO/HGPRT)	Not yet peer-reviewed data. New study with N-acetyl glyphosate [study code: IN-MCX20] to comply with OECD Test Guideline 476.	DP
KCA 5.8.1	[redacted]	Sep 2004	Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells	Not yet peer-reviewed data New study with N-acetyl glyphosate to comply with OECD Test Guideline 473.	DP
KCA 5.8.1	[redacted]	Jul 2007	IN-EY252: Bacterial reverse mutation assay.	Not yet peer-reviewed data. New study with N-acetyl AMPA [study code: IN-EY252] to comply with OECD Test Guideline 471.	DP
KCA 5.8.1	[redacted]	Sep 2007	IN-EY252: In vitro mammalian cell gene mutation test (CHO/HGPRT test)	Not yet peer-reviewed data. New study with N-acetyl AMPA [study code: IN-EY252] to comply with OECD Test Guideline 476.	DP
KCA 5.8.1	[redacted]	Jun 2007	IN-EY252: In vitro mammalian chromosome aberration study in human peripheral blood lymphocytes	Not yet peer-reviewed data. New study with N-acetyl AMPA [study code: IN-EY252] to comply with OECD Test Guideline 473.	DP
KCA 5.8.3	[redacted]	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 79 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~~ [redacted]	~~May~~ Mar 2020	~~Storage stability for glyphosate and AMPA in honey.~~ ILV of method ME-2220-01 and short term storage stability of glyphosate and its metabolite 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

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 6.2	[redacted]	Oct 2000	Metabolism of Glyphosate in Roundup Ready® Wheat	Data requirement according to OECD Test Guideline 501.	DP
KCA 6.3	[redacted]	Feb 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]	Mar 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]	Feb 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]	Nov 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
KCA 6.3	[redacted]	Nov 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]	Nov 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

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]	Nov 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]	May 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]	Apr 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]	Apr 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]	Feb 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]	Mar 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]	Apr 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
KCA 6.3	[redacted]	Jan 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]	Mar 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

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]	Apr 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]	Apr 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]	Mar 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]	Apr 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]	Mar 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
KCA 6.3	[redacted]	Apr 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]	Apr 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

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]	Apr 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~~ [redacted]	~~May~~ Feb 2020	~~Hydrolysis study to investigate the nature of residues of AMPA and N-acetyl AMPA in processed commodities.~~ AMPA and N-Acetyl AMPA: Hydrolysis under Typical Conditions (pH, Temperature and Time) of Processing	Data requirement for active substance according to EC Regulation 283/2013 OECD Test Guideline 507	DP
KCA 6.6.2	NN	Q4 2022	Determination of glyphosate and AMPA in field rotational crops.	Data requirement according to EC Regulation 283/2013 and also considering the OECD Guidance ENV/JM/MONO(2018)9. The investigations will be conducted according to OECD Test Guideline 504 with two locations, three crops and three plant back intervals. For practical reasons the work may be divided in two or several GLP studies.	DP
KCA 6.6.2	NN	2022	Determination of glyphosate and AMPA after pre-emergence application in cereals, oilseed rape and pulses	Supportive information for rotational crop data. Studies will be conducted according to OECD Test Guideline 509. The package will include a total of 12 trials (4 trials per crop, i.e. per residue zone). For practical reasons the work may be divided in three or more GLP studies.	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 6.7~~	~~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.~~ The assessment of the residue definition for risk assessment and monitoring according to EC Regulation 283/2013 will be part of the MCA chapter 6.7.1. Therefore, a separate report is not needed.	
KCA 6.7.1	[redacted] knoell Germany GmbH	May 2020	(Q)SAR and read-across genotoxicity evaluation of Glyphosate and seven metabolites, using VEGA v1.1.5b22, DEREK Nexus v6.0.1, Toxtree v3.1.0 and OECD QSAR Toolbox v4.4	Data requirement according to EC Regulation 283/2013 to derive a residue definition for dietary risk assessment.	
KCA 6.10	~~NN~~ [redacted]	May 2020	~~Residues in honey (tunnel study) and detection of glyphosate in honey (method transfer and validation).~~ Determination of Residues of Glyphosate in Honey after one Application in *Phacelia tanacetifolia* at 4 Sites in Germany 2019	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~~ [redacted]	May 2020	~~Update of kinetic evaluation of soil photolysis studies.~~ Estimation of kinetic endpoints for glyphosate and its metabolite AMPA from a soil photolysis study	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~~ [redacted]	May 2020	~~Update of kinetic evaluation of aerobic soil degradation studies.~~ Estimation of kinetic endpoints for glyphosate and its metabolite AMPA from aerobic laboratory 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~~ [redacted]	May 2020	~~Update of kinetic evaluation of anaerobic soil degradation studies.~~ Estimation of kinetic endpoints for glyphosate and its metabolite AMPA from an anaerobic laboratory soil degradation study	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]	Jun 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~~ [redacted]	~~May~~ ~~Jul~~ June 2020	~~Rate of degradation of AMPA in acidic soils incubated under aerobic conditions.~~ AMPA – Rate of Degradation of Aminomethylphosphonic Acid (AMPA) in Aerobic Soil	To meet requirements of Commission implementing regulation (EU) 2017/2324. Study up to DAT 92.	DP
KCA 7.1.2.1.2	[redacted]	Jul 2020	Amendment to Simmonds 2020: AMPA – Rate of Degradation of Aminomethylphosphonic Acid (AMPA) in Aerobic Soil	To meet requirements of Commission implementing regulation (EU) 2017/2324. Amendment contains DAT 120 plus additional information (microbial activity)	
KCA 7.1.2.2.1	~~NN~~ [redacted]	May 2020	~~Update of kinetic evaluation of terrestrial field dissipation studies.~~ Estimation of kinetic endpoints for glyphosate and its metabolite AMPA from terrestrial field dissipation studies in Europe	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.	

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 7.1.2.2.1	[redacted]	April 2020	Glyphosate: Ecoregion Crosswalk for Nineteen Terrestrial Field Dissipation Study Locations in North America	Evaluation of terrestrial field dissipation studies in US and Canada for representativeness throughout Europe based on climate and soil similarity using the OECD ENASGIPS tool (Europe – North American Soil Geographic Information for Pesticide Studies)	
KCA 7.1.2.2.1	[redacted]	May 2020	Estimation of kinetic endpoints for glyphosate and its metabolite AMPA from terrestrial field dissipation studies in the USA and Canada	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~~ [redacted]	May 2020	~~Glyphosate adsorption to soil according to OECD guideline 106.~~ Glyphosate – Adsorption/Desorption of [^{14}C]-Glyphosate in Ten Soils	Data requirement. To complete dataset in view of OECD 106 evaluators checklist (EFSA, 2017).	DP
KCA 7.1.3.1.1	[redacted]	Aug 2020	Amendment to [redacted] 2020: Glyphosate – Adsorption/Desorption of [^{14}C]-Glyphosate in Ten Soils	Repetition of analytics for some concentrations and soils. Additional information in order to fulfil requirements of Evaluators Checklist.	
KCA 7.1.3.1.2	~~NN~~ [redacted]	~~May~~ Aug 2020	~~AMPA adsorption to soil according to OECD guideline 106.~~ Adsorption/Desorption of ^{14}C-AMPA in Six Soils	Data requirement. To complete dataset in view of OECD 106 evaluators checklist (EFSA, 2017)	DP
KCA 7.2.2.2	~~NN~~ [redacted]	~~March~~ Apr 2020	~~Aerobic mineralisation in surface water.~~ Glyphosate – Aerobic Mineralisation of [^{14}C]-Glyphosate in Surface Water	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 7.2.2.2	[redacted]	Jul 2020	Characterization of the material in unidentified peak from study CRO-2019-0268, Glyphosate - Aerobic Mineralisation of [^{14}C]Glyphosate in Surface Water	The confirmatory method showed the presence of a peak that exceeded levels requiring further characterization in the original study [redacted] April 2020: "Glyphosate – Aerobic Mineralisation of [^{14}C] Glyphosate in Surface Water". Efforts to characterize were undertaken in the original study, but time did not permit adequate characterization.	
KCA 7.2.2.3	~~NN~~ [redacted]	May 2020	~~Update of kinetic evaluation of water/sediment studies.~~ Estimation of kinetic endpoints for glyphosate and its metabolites AMPA and HMPA from laboratory 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~~ [redacted]	~~May~~ Apr 2020	~~Updated calculation of atmospheric half-life.~~ Glyphosate: Calculation of the Chemical Half-Life in the Troposphere	Update assessment of data using latest evaluation tools.	
KCA 7.5	~~NN~~ [redacted]	~~May~~ Mar 2020	~~Compilation of European soil, sediment, surface water, groundwater, drinking water, and air monitoring data.~~ Collection of public monitoring data for European countries for the compartments soil, water, sediment and air for Glyphosate, AMPA and HMPA	Data requirement according to EC Regulation 283/2013. Update of existing dataset with most recent monitoring data.	
KCA 7.5	[redacted]	May 2020	Glyphosate (GLY) and the primary metabolites Aminomethyl Phosphonic Acid (AMPA) and Hydroxymethyl Phosphonic Acid (HMPA): Public monitoring data assessment and interpretation.	Data requirement according to EC Regulation 283/2013. Update of existing dataset with most recent monitoring data.	
KCA 7.5	[redacted]	Nov 2015	Survey of glyphosate and AMPA in drinking water supplies in Europe - 2015 update report	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
KCA 7.5	[redacted]	May 2016	Survey of glyphosate and AMPA in ground waters and surface waters in Europe - 2015/16 update review – final report	Data requirement according to EC Regulation 283/2013. Update of existing dataset with most recent monitoring data.	
KCA 7.5	[redacted]	Jul 2016	Analyse des données de suivi du glyphosate et de l'AMPA dans les eaux de France Période 1997-2013[20]	Data requirement according to EC Regulation 283/2013. Update with most recent monitoring data.	
KCA 7.5	[redacted]	Feb 2019	Etude environnementale du Glyphosate et de l'AMPA à l'échelle des 10 points de surveillance les plus préoccupants pour le Glyphosate et pour l'AMPA Analyse des suivis du Glyphosate et de l'AMPA en lien avec les bassins versants drainés par les stations de mesures et l'occupation des sols - Etudes des stations sur l'AMPA[21]	Data requirement according to EC Regulation 283/2013. Update with most recent monitoring data.	
KCA 7.5	[redacted]	Feb 2019	Etude environnementale du Glyphosate et de l'AMPA à l'échelle des 10 points de surveillance les plus préoccupants pour le Glyphosate et pour l'AMPA Analyse des suivis du Glyphosate et de l'AMPA en lien avec les bassins versants drainés par les stations de mesures et l'occupation des sols - Etudes des stations sur le glyphosate[22]	Data requirement according to EC Regulation 283/2013. Update with most recent monitoring data.	

[20] Suggested translation: "*Analysis of glyphosate and AMPA monitoring data in French waters Period 1997-2013*"
[21] Suggested translation: "*Environmental study of glyphosate and AMPA at the scale of the 10 most concerning monitoring points for glyphosate and AMPA. Analysis of glyphosate and AMPA monitoring data in connection with the upstream catchments of the monitoring stations and land use – Study of monitoring stations on AMPA.*"
[22] Suggested translation: "*Environmental study of glyphosate and AMPA at the scale of the 10 most concerning monitoring points for glyphosate and AMPA. Analysis of glyphosate and AMPA monitoring data in connection with the upstream catchments of the monitoring stations and land use – Study of monitoring stations on glyphosate.*"

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 7.5	[redacted]	Feb 2019	PHASE 1: TRAITEMENTS ET ANALYSES STATISTIQUES SUR LES DONNÉES SOES UIPP 2008-2014 - Analyse des données de suivi de glyphosate et de l'AMPA dans les eaux de France Période 2008 -2014[23]	Data requirement according to EC Regulation 283/2013. Update with most recent monitoring data.	
KCA 7.5	[redacted]	Feb 2019	PHASE 3 ET 4:TRAITEMENTS ET ANALYSES STATISTIQUES SUR LES DONNÉES SOES UIPP 2008–2014 ANALYSES DES DONNÉES DE SURVEILLANCES SUR 6 TERRITOIRES TÉMOINS SYNTHÈSE DES DONNÉES SUR L'ENSEMBLE DES TERRITOIRES VITICOLES - Analyse des données de suivi de glyphosate et de l'AMPA dans les eaux de France Période 2008 -2014[24]	Data requirement according to EC Regulation 283/2013. Update with most recent monitoring data.	
KCA 7.5	[redacted]	May 2019	Mitigating glyphosate levels in surface waters: Pilot catchment details and monitoring results	Data requirement according to EC Regulation 283/2013. Update with most recent monitoring data.	
Section 8					
~~KCA 8.1.1 8.1.2~~	~~NN~~	~~Dec 2020~~	~~Broad leaf residue decline.~~[25]	~~New study to be used as a weight of evidence refinement to the chronic wild mammal risk assessment~~	~~DP~~

[23] Suggested translation: "*Phase 1: Processing and statistical analyses of the data SOES UIPP 2008-2014 – Analysis of glyphosate and AMPA monitoring data in French waters. Period 2008-2014.*"
[24] Suggested translation: "*Phase 3 and 4: Processing and statistical analyses of the data SOES UIPP 2008-2014 – Analysis of monitoring data for 6 control areas. Synthesis of the data for the whole of wine-growing areas. Analysis of glyphosate and AMPA monitoring data in French waters. Period 2008-2014.*"
[25] The study will not be submitted as a decline value (DT50) for glyphosate following foliar application to surrogate broadleaf weed plants (pea plants) could not be determined due to technical issues encountered during the residues analysis phase of the study. The application rate applied was 2.88 kg/ha, which was too high and resulted in pea plants (surrogate broadleaf weed) mortality within 2-3 days following application. This resulted in insufficient time point data being available on which to conduct an appropriate kinetics analysis. The study was stopped and kinetics analysis was not conducted.

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 8.1.1 8.1.2	NN	2021	Broad-leaf residue decline [26]	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 8.2.5.3	[redacted]	May 2020	MON 77973: A study on the toxicity to the sediment dweller *Chironomus riparius* using spiked water.	Data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for sediment dweller species.	DP
KCA 8.2.5.4	[redacted]	May 2020	MON 77973: A study on the toxicity to the sediment dweller Chironomus riparius using spiked sediment.	Range-finding test Data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for sediment dweller species.	DP
KCA 8.2.5.4	NN	May 2021	MON 77973: A study on the toxicity to the sediment dweller Chironomus riparius using spiked sediment.	Trigger study, considering outcome of study performed by [redacted] (higher test concentration to be added to complete risk assessment) Data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for sediment dweller species.	DP
KCA 8.2.6	NN	Jul 2020	Algae study (freshwater green) with the metabolite AMPA	Data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for algal species.	DP
KCA 8.3.1.1.1	[redacted]	Sep 2017	~~Acute oral study on Bumble bee *(Bombus terrestris)* for Glyphosate IPA salt (MON 0139).~~ Acute Oral and Contact Toxicity to the Bumble Bee, *Bombus terrestris* L. under Laboratory Conditions	New data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for non-*Apis* pollinator species.	DP

[26] Due to the cancellation of the 2020 planned study (see above footnote 24), the GRG is planning to conduct a further decline study before the renewal dossier evaluation is complete, to support the June 2020 submitted risk assessment, once a modified test design has been worked out.

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 8.3.1.1.2	[redacted]	Sep 2017	~~Acute oral study on Bumble bee *(Bombus terrestris)* for Glyphosate IPA salt (MON 0139).~~ Acute Oral and Contact Toxicity to the Bumble Bee, *Bombus terrestris* L. under Laboratory Conditions	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]	Sep 2017	~~Solitary bee (*Osmia bicornis*) - Acute contact on Glyphosate IPA salt (MON 0139).~~ Acute Contact Toxicity to the Solitary Bee, *Osmia bicornis* under Laboratory Conditions	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]	Nov 2017	~~Honeybee (*Apis mellifera*) chronic adult (10d) Glyphosate IPA salt (MON 0139).~~ MON 0139: Chronic Oral Toxicity Test on the Honey Bee (*Apis mellifera* L.) in the Laboratory	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~~ [redacted]	Feb 2020	~~Honeybee (*Apis mellifera*) chronic larvae (22d).~~ AMENDED REPORT FOR MSL0031012: MON 0139 - Repeated exposure of honey bee larvae (*Apis mellifera* L.) under laboratory conditions	New data requirement according to EC Regulation 283/2013, to support the honey bee risk assessment (OECD 239).	DP
KCA 8.7	[redacted]	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 2					
KCP 2.7	[redacted]	Mar 2016	Accelerated Storage Stability to Support the Registration of MON 52276 as an End-Use Herbicide.	Study available, not yet peer reviewed at EU level. Study evaluated during Art 43 product authorization process (EC Regulation 1107/2009)	
KCP 2.7	[redacted]	May 2018	Two Year Storage Stability Study to Support the Registration of MON 52276 as an End-Use Herbicide	Study available, not yet peer reviewed at EU level. Study evaluated during Art 43 product authorization process (EC Regulation 1107/2009)	
KCP 2.7	[redacted]	Sep 2018	Shelf-life and stability of MON 52276 after storage for 5 years.	Study available, not yet peer reviewed at EU level. Study evaluated during Art 43 product authorization process (EC Regulation 1107/2009)	
KCP 2.8.4	[redacted]	Apr 2016	Persistent foam and dilution stability of several glyphosate formulations.	Study available, not yet peer reviewed at EU level. Study evaluated during Art 43 product authorization process (EC Regulation 1107/2009)	
Section 5					
KCP 5.1.1	[redacted]	Mar 2019	N-Nitrosoglyphosate method validation in MON 52276, MON 76610, MON 79351, MON 79545 and MON 79991	Study available, not yet peer reviewed at EU level. Study evaluated during Art 43 product authorization process (EC Regulation 1107/2009)	
KCP 5.1.2	NN	Jun 2020	Analytical methods in support of risk assessment. Methods in support of ecotoxicology studies: ~~Approx. 5 new studies.~~ 9 (1 new study and 7 already available and reviewed regulatory 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
KCP ~~5.2~~ 5.1.1	[redacted]	Feb 2020	Validation of the Analytical Method ME-1137 for Formaldehyde in MON 52276	New study to be used to comply with new guidance document SANCO 3030/99, rev. 5	DP
KCP 5.2	[redacted]	Apr 2020	Validation of the Analytical Method for the analysis of N-nitrosoglyphsoate (NNG) in MON 52276	New study to be used to comply with new guidance document SANCO 3030/99, rev. 5	DP

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
KCP ~~5.2~~ 5.1.1	[redacted]	Apr 2020	Position Paper supporting the Approval Renewal Dossier for an Active Substance: Glyphosate & the IPA-, K-, DMA and NH4-salts of Glyphosate (hereafter Glyphosate)	Justification for the FAO Maximum Allowable Limit (MAL) for the Relevant Impurity *N*-Nitrosoglyphosate (NNG) in Glyphosate TK and Glyphosate based PPP	DP
Section 7					
KCP 7.1.7	[redacted]	Oct 2016	MON 52276: Bacterial Reverse Mutation Assay	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	[redacted]	~~2000~~ Oct 2016	~~Micronucleus Test in Human Lymphocytes in vitro with MON 52276~~ In Vitro Mammalian Cell Micronucleus Assay in Human Peripheral Blood Lymphocytes (HPBL)	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~~ [redacted]	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 9					
KCP 9.1.3	[redacted]	May 2020	Predicted environmental concentrations of glyphosate and its metabolite AMPA in soil following application to various crops – a modelling assessment for Europe using ESCAPE	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment	
KCP 9.2.4.1	[redacted]	May 2020	Predicted environmental concentrations of glyphosate and its metabolite AMPA in groundwater following application to various crops – a modelling assessment for Europe using FOCUS PEARL, FOCUS PELMO and FOCUS MACRO	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment	
KCP 9.2.4.1; KCP 9.2.5	[redacted]	May 2020	Predicted environmental concentrations of glyphosate and its metabolites AMPA and HMPA in groundwater and surface water following application to railways – a modelling assessment using HardSPEC	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment	

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
KCP 9.2.5	[redacted]	May 2020	Predicted environmental concentrations of glyphosate and its metabolites AMPA and HMPA in surface water and sediment following application to various crops – a modelling assessment for Europe using the FOCUS surface water scenarios at Steps 1 - 3	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment	
Section 10					
KCP 10.4.1.1	[redacted]	May 2020	~~Earthworm reproduction study with the representative formulation MON52276~~ MON 52276: Effects on survival, growth and reproduction of the earthworm *Eisenia andrei* tested in artificial soil	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for sublethal effects to earthworms.	DP
KCP 10.4.2.1	NN	Jul 2020	*Folsomia candida* with the representative formulation MON52276	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for sublethal effects to additional soil organisms.	DP
KCP 10.4.2.1	NN	Jul 2020	*Hypoaspis aculeifer* 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 additional soil organisms.	DP
KCP 10.6.2	[redacted]	Oct 2019	MON52276: Effects on the Seedling Emergence and Growth of Ten Non-Target Terrestrial Plant Species under Greenhouse Conditions	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for non-target terrestrial plants	DP
KCP 10.6.2	NN	Oct 2020	Vegetative vigour study with MON 52276	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for non-target terrestrial plants	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 0-1: 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~~ Mar 2020	14-Day Oral (Dietary) Toxicokinetic Study of Glyphosate in Sprague Dawley Rats[27]	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)"	DP
KCA 5.7.1	[redacted]	Sep 2006	Glyphosate technical: ninety day repeated dose oral (dietary) neurotoxicity study in rat	Not yet peer-reviewed data. Supporting information for the evaluation of data requirement(s). OECD Guidelines for Testing of Chemicals No. 424 "Neurotoxicity Study in Rodents" (Adopted 21 July 1997).	DP
KCA 5.8.1	[redacted]	Dec 2004	Mass Balance, Metabolism, and Pharmacokinetics of [14C]N-acetylglyphosate Following Administration of a Single Oral Dose to Rats	Not yet peer-reviewed data with N-acetyl glyphosate. Supporting information for the evaluation of data requirement(s). Conducted according to 40 CFR 160, Guideline OPPTS 870.7485	DP
KCA 5.8.1	[redacted]	Dec 2004	Acute oral toxicity study in rats with N-acetyl-glyphosate, Sodium salt (Acute toxic class method)	Not yet peer-reviewed data with N-acetyl glyphosate. Supporting information for the evaluation of data requirement(s). Conducted according to OECD Test Guideline No. 423 (Acute Toxic Class Method)	DP

[27] 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

Table 0-1: 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
KCA 5.8.1	[redacted]	Feb 2007	IN-MCX20: Sub-chronic Toxicity 90-Day Feeding Study in Rats	Not yet peer-reviewed data with N-acetyl glyphosate [study code: IN-MCX20]. Supporting information for the evaluation of data requirement(s). Conducted according to OECD Test Guideline No. 408 and OPPTS 870.3100 (1998)	DP
KCA 5.8.1	[redacted]	Aug 2006	IN-MCX20: Mouse Bone Marrow Micronucleus Test	Not yet peer-reviewed data with N-acetyl glyphosate [study code: IN-MCX20]. Supporting information for the evaluation of data requirement(s). Conducted according to OECD Test Guideline No. 474 (1998) and OPPTS 870.5395 (1998)	DP
KCA 5.8.1	[redacted]	Oct 2007	IN-EY252: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure	Not yet peer-reviewed data with N-acetyl AMPA [study code: IN-EY252]. Supporting information for the evaluation of data requirement(s). Conducted according to OECD Test Guideline No. 425 (2001) and OPPTS 870.1100 (2002)	DP
KCA 5.8.1	[redacted]	May 2008	IN-EY252 Technical: Sub-chronic toxicity 90-day feeding study in rats	Not yet peer-reviewed data with N-acetyl AMPA [study code: IN-EY252]. Supporting information for the evaluation of data requirement(s). Conducted according to OECD Test Guideline No. 408 and OPPTS 870.3100	DP
KCA 5.8.1	[redacted]	Sep 2007	IN-EY252: Mouse bone marrow micronucleus assay	Not yet peer-reviewed data with N-acetyl AMPA [study code: IN-EY252]. Supporting information for the evaluation of data requirement(s). Conducted according to OECD Test Guideline No. 474 (1998) and OPPTS 870.5395 (1998)	DP
~~Section 8~~					

Table 0-1: 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
~~KCP 8.1.2~~	~~NN~~	~~Pending~~	~~Semi-field enclosure study with common voles~~[28]	~~New study to be used as a weight of evidence refinement to the chronic wild mammal risk assessment~~	~~DP~~

Table 0-2: List of 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 7					
KCP 7.1.3	[redacted]	Jul 2015	MON 52276: Acute Inhalation Toxicity in Rats	Study available, not yet peer-reviewed at EU level. Study requested during Art 43 product authorization process (EC Regulation 1107/2009).	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.~~

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