

Literature Review Report

**Scientific peer-reviewed open literature covering the
publication period of January 2020 to June 2020 for the
approval of pesticide active substance glyphosate and
metabolites**

**as under Article 8(5) of Regulation (EC) No 1107/2009
(Ref. EFSA Journal 2011; 9(2) 2092)**

Report number

113898-CA9-1

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Reporting Date

20-October-2020

Date of search(es):

02-July-2020

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1 Summary

A literature search for glyphosate and its metabolites¹ was conducted according to the requirements stated in the EFSA 2092 Guidance Document - EFSA Journal 2011;9(2):2092 “*Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009*”², and the Appendix to the EFSA 2092 Guidance Document “*Further guidance on performing and presenting the literature search*”³, and the EFSA supporting publication from 2019⁴ “*Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances*”.

In addition, a recommendation by the Assessment Group on Glyphosate (AGG)⁵ on how to present the literature search in the dossier has been followed. Please refer to **Appendix 1** (page 63) for more details.

This Literature Review Report summarizes the search and evaluation of glyphosate public literature, covering the publication period of January 2020 to June 2020, as requested by the AGG in their letter dated 10-July-2020, subject “Glyphosate: Check of completeness of the supplementary dossier for renewal of approval under Commission Implementing Regulation (EU) No 844/2012”, section 2: Elements to be submitted in accordance with Article 11(5) of Regulation (EU) No 844/2012, point 23.

The literature search was conducted accessing 11 bibliographic databases via the service provider STN.

852 articles in total were identified upon removal of duplicates within the current search (January 2020 – June 2020) and articles found already in the previous search (January 2010 – December 2019⁶).

All 852 articles were subsequently assessed for their relevance at title/abstract level (“rapid assessment” according to the procedure and requirements stated in the EFSA 2092 Guidance Document).

A total of 774 of the 852 articles were identified as “non-relevant” in the rapid assessment (e.g. publications dealing with chemical synthesis, efficacy, analytical methods or publications which are not related to glyphosate or its metabolites) and excluded from further evaluation. Due to the large quantity of data, and as agreed with the AGG, the list of articles and the justification for their non-relevance is provided in a standalone Literature Review Excel File⁷ (Document ID: 113898_CA9-1_Literature Review Excel File).

For the remaining 78 articles, identified as potentially “relevant” or of “unclear relevance” in the rapid assessment, the full-text documents⁸ were reviewed in detail (“detailed assessment”).

¹ (aminomethyl)phosphonic acid (AMPA), N-acetyl-AMPA, N-acetyl-glyphosate, (hydroxymethyl)phosphonic acid (HMPA), N-methyl-AMPA, N-glyceryl-AMPA, N-malonyl-AMPA, methylphosphonic acid and N-methylglyphosate.

² European Food Safety Authority, 2011: *Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009*. EFSA Journal 2011;9(2):2092. 49 pp, doi:10.2903/j.efsa.2011.2092.

³ Appendix to EFSA Journal 2011;9(2):2092. *Further guidance on performing and presenting the literature search*. Available online: <https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903/j.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf>

⁴ European Food Safety Authority, 2019. *Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances*. EFSA supporting publication 2019:EN-1612. 49 pp., doi:10.2903/sp.efsa.2019.EN-1612.

⁵ On 10th May 2019, the European Commission appointed four Member States (France, Hungary, the Netherlands and Sweden) to act jointly as ‘rapporteurs’ for the AIR5 process assessment of glyphosate. This group of Member States is known as the Assessment Group on Glyphosate (AGG).

⁶ See Literature Review Report 108689-CA9-1 for more details (submitted to the AGG in June 2020).

⁷ Please note that the standalone Literature Review Excel File will be submitted on a separate CD-ROM / DVD.

⁸ All articles used within the glyphosate dossier have been purchased via Copyright Clearance Centre. In some cases, please note that the Copyright Clearance is not overtly visible, and in some instances is part of the article documents. Should the Copyright Clearance proof be required, this can be provided upon request.

A total of 35 articles of the remaining 78 articles were identified as “non-relevant” in the detailed assessment and were excluded from further evaluation. The list of the articles and the justification for their non-relevance is provided in **Table 38** of this Literature Review Report document.

The remaining 43 articles identified as “relevant” in the detailed assessment were classified according to the EFSA 2092 Guidance Document (EFSA Journal 2011;9(2):2092, Point 5.4.1).

Category A Articles which provide data for establishing or refining risk assessment parameters. For all articles of Category A, a reliability assessment was performed as recommended in the EFSA 2092 Guidance Document (GD). Summaries were compiled for Category A articles classified as “reliable” or “reliable with restrictions”. The list of these Category A & reliable / reliable with restrictions articles can be found in **Table 32** and **Table 33** of this Literature Review Report document.

Category B Articles relevant to the data requirement but in the opinion of the applicant providing only supplementary information that does not alter existing risk assessment. A justification for such decision is provided as recommended in the EFSA 2092 Guidance Document (GD). The list of these Category B articles and the justifications can be found in **Table 34** and **Table 35** of this Literature Review Report document.

Category C Articles for which relevance cannot be clearly determined. As recommended in the EFSA 2092 Guidance Document (GD), an explanation is provided why the relevance could not be determined. The list of these Category C articles and the explanations can be found in **Table 36** and **Table 37** of this Literature Review Report document.

The full outcome of the literature evaluation is provided in **Table 1**.

Table 1: Summary of the literature review

Section	Number of articles found	Rapid assessment (title/abstract level)		Detailed assessment (full-text level)	
		non-relevant articles	potentially relevant / unclear relevance	non-relevant articles	relevant articles (Category A+B+C)
Efficacy / Agronomy ^{a)}	360	360	n.a.	n.a.	n.a.
Analytical methods ^{a)}	72	72	n.a.	n.a.	n.a.
Other non-relevant categories ^{b)}	73	73	n.a.	n.a.	n.a.
Ecotoxicology	150	121	29	14	15
E-fate	85	83	2	0	2
Residues	16	15	1	0	1
Toxicology	96	50	46	21	25
Total	852	774	78	35	43

^{a)} Efficacy / Agronomy (e.g. reporting desired effects on organisms to be controlled) and development of analytical methods (artificial measurements) do not provide information useful/required for the environmental or human safety risk assessment.

^{b)} The category "other non-relevant categories" covers a wide range of scientific publications which are not related to glyphosate or its metabolites or are not related to exposure of humans or the environment to glyphosate or its metabolites and thus not relevant for the risk assessments.

The full outcome of the relevant articles after detailed (full-text) assessment is provided in **Table 2**.

Table 2: Relevant articles by full-text classified according to the EFSA 2092 GD, Point 5.4.1

Section	Relevant articles by full-text (EFSA 2092 GD, Point 5.4.1)		
	Category A ^{a)}	Category B ^{b)}	Category C ^{c)}
Ecotoxicology	2	13	0
E-fate	2	0	0
Residues	1	0	0
Toxicology	7	18	0
Total	12	31	0

^{a)} Category A: Articles, which provide data for establishing or refining risk assessment parameters.

^{b)} Category B: Articles relevant to the data requirement but in the opinion of the applicant providing only supplementary information that does not alter existing risk assessment.

^{c)} Category C: Articles for which relevance cannot be clearly determined.

All articles (and their translations) evaluated at full text level (detailed assessment) were submitted to the AGG in a Portable Document Format (PDF).

Please refer to **Appendix 2** (page 64) to see the article selection process in detail.

2 Introduction

A literature search for glyphosate and its metabolites¹ was conducted according to the requirements stated in the EFSA 2092 Guidance Document - EFSA Journal 2011;9(2):2092 “*Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009*”², and the Appendix to the EFSA 2092 Guidance Document “*Further guidance on performing and presenting the literature search*”³, and the EFSA Supporting publication from 2019⁴ “*Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances*”.

In addition, a recommendation by the Assessment Group on Glyphosate (AGG) on how to present the literature search in the dossier has been followed. Please refer to **Appendix 1** (page 63) for more details.

In June 2020, a Literature Review Report (Document ID: 108689-CA9-1), summarizing results of the search and evaluation of the glyphosate scientific peer-reviewed open literature published from January 2010 until end of December 2019 was submitted to the AGG as part of the Glyphosate AIR5 dossier. In July 2020 during the dossier completeness check, the AGG requested a top-up search and evaluation for Glyphosate open literature covering the publication period between December 2019 and June 2020.

This present Literature Review Report 113898-CA9-1 summarizes the top-up search and evaluation of glyphosate public literature, covering the publication period of January 2020 to June 2020. The month of December 2019 was already comprehensively covered by the previously submitted Literature Review Report (108689-CA9-1).

The search has been conducted via the online service provider STN (www.stn-international.de) that provides access to a broad range of databases and to published research, journal literature, patents, structures, sequences, properties, and other data.

To offer a comprehensive literature search covering the requirements of the EFSA 2092 Guidance Document eleven databases have been used: AGRICOLA, BIOSIS, CABA, CAPLUS, EMBASE, ESBIOBASE, MEDLINE, TOXCENTER, FSTA, PQSCITECH, and SCISEARCH.

Please refer to **Table 3** for more details on the literature search.

Table 3: Overview of the search conducted for glyphosate and its metabolites

Performed for	Covering publication period	Conducted on
Glyphosate AMPA N-acetyl-AMPA N-acetyl-glyphosate HMPA N-methyl-AMPA N-glyceryl-AMPA N-malonyl-AMPA methylphosphonic acid N-methylglyphosate	January 2020 – June 2020 (incl. June 2020)	02-July 2020

AMPA = (aminomethyl)phosphonic acid

HMPA = (hydroxymethyl)phosphonic acid

A “focused search for grouped data requirements”⁹ have been performed (a combination of a substance basic input parameters, keywords and “search filters” defined for the four technical sections –toxicology, residues, environmental fate, and ecotoxicology).

Please refer to **Chapter 2.2** and **2.3** (pages 14 and 16) for the input parameters, keywords and search filters used in the literature search.

Regarding details on the bibliographic databases used in the literature search, please refer to **Chapter 2.1 (Table 4)**.

Regarding the number of articles retrieved in the literature search, please refer to **Chapter 2.1 (Table 5)**.

For the relevance and reliability assessment, please refer to **Chapter 2.4** and **2.5** (pages 19 and 22).

For the full outcome of the literature search for the individual technical sections, please refer to **Chapter 3** (page 27).

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⁹ Citation from the EFSA 2092 Guidance Document: *If the number of summary records returned by a single concept search* is extremely large, focused searches for individual or grouped data requirements could be developed. Such searches could combine synonyms for the active substance (one concept) with terms and synonyms for characteristics of the data requirement (second concept).*

*NOTE: Single concept search (as defined in the EFSA 2092 GD document) = using the active substance names and its synonyms.

2.1 Bibliographic databases used in the literature search

Table 4: Overview of the databases used in the literature search

Data requirement(s) captured in the search	Details of the search(es)			
	1. AGRICOLA	2. BIOSIS	3. CABA	4. CAPLUS
Justification for choosing the source:	Provides literature from agriculture and related fields, e.g. biology, biotechnology, botany, ecology etc.	Provides the most comprehensive and largest life science literature, e.g. biosciences, biomedicine etc.	Provides literature from agriculture and related sciences, e.g. biotechnology, forestry, veterinary medicine etc.	Provides literature from chemistry and related fields, e.g. biochemistry, chemical engineering etc.
Number of records in the database at the time of search:	> 6.7 million (09/2019)	> 27.8 million (04/2019)	> 8.9 million (05/2018)	> 50.7 million (08/2019)
Database update:	Monthly	Weekly	Weekly	Daily updates bibliographic data; weekly updates indexing data
Date of the search:	02-July-2020	02-July-2020	02-July-2020	02-July-2020
Database covers records:	1970-present	1926-present	1973-present	1907-present and more than 180,000 pre-1907
Date of the latest database update:	10-June-2020	01-July-2020	01-July-2020	01-July-2020
Language limit:	No	No	No	No
Document types <u>excluded</u> that are not "scientific peer-reviewed open literature":	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release
Search strategy:	Details are summarized in Chapter 2.2 and 2.3 .			
Total number of records retrieved:	258	321	467	364

Table 4: Overview of the databases used in the literature search (continued)

Data requirement(s) captured in the search	Details of the search(es)		
	5. MEDLINE	6. EMBASE	7. TOXCENTER
Justification for choosing the source:	Provides literature from every area of medicine.	Provides literature from biomedical and pharmaceutical fields, e.g. bioscience, biochemistry, human medicine, forensic science, paediatrics, pharmacy, pharmacology, drug therapy, psychiatry, public health, biomedical engineering, environmental science.	Provides literature on pharmacological, biochemical, physiological, and toxicological effects of drugs and other chemicals.
Number of records in the database at the time of search:	> 30 million (08/2019)	> 36.4 million (08/2019)	> 14.4 million (08/2019)
Database update:	Six times each week, with an annual reload	Daily	Weekly
Date of the search:	02-July-2020	02-July-2020	02-July-2020
Database covers records:	1946-present	1974-present	1907-present
Date of the latest database update:	01-July-2020	01-July-2020	30-June-2020
Language limit:	No	No	No
Document types excluded that are not "scientific peer-reviewed open literature":	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release
Search strategy:	Details are summarized in Chapter 2.2 and 2.3 .		
Total number of records retrieved:	207	166	470

Table 4: Overview of the databases used in the literature search (continued)

Data requirement(s) captured in the search	Details of the search(es)			
	8. FSTA	9. PQSCITECH	10. ESBIODBASE	11. SCISEARCH
Justification for choosing the source:	Provides literature on scientific and technological aspects of the processing and manufacture of human food products, e.g. biotechnology, hygiene and toxicology, engineering etc.	Provides a valuable and huge resource of literature (merge of 25 STN databases) from all science areas and technology; from engineering to lifescience.	Provides comprehensive literature on entire spectrum of biological and biosciences research, e.g. microbiology, biotechnology, ecological & environmental sciences, genetics, plant and crop science, toxicology and many more.	Provides one of the largest multidisciplinary scientific literature covering a broad field of sciences, technology, and biomedicine.
Number of records in the database at the time of search:	> 1.4 million (07/2018)	> 32 million (07/2017)	> 7.6 million (07/2018)	> 47.7 million (08/2019)
Database update:	Weekly	Monthly	Weekly	Weekly
Date of the search:	02-July-2020	02-July-2020	02-July-2020	02-July-2020
Database covers records:	1969-present	1962-present	1994-present	1974-present
Date of the latest database update:	25-June-2020	26-June-2020	01-July-2020	29-June-2020
Language limit:	No	No	No	No
Document types <u>excluded</u> that are not "scientific peer-reviewed open literature":	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release	Comments, dissertations, editorials, meetings reports, news, patents, press release
Search strategy:	Details are summarized in Chapter 2.2 and 2.3 .			
Total number of records retrieved:	20	106	206	571

Table 5: Total number of articles retrieved

Scope of the search	After automatic removal of duplicates within the databases in the current search (Jan 2020 – Jun 2020)	After applying search filters ^{a)} within the current search (Jan 2020 – Jun 2020)	After manual removal of duplicates ^{b)} within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019) ^{c)}
January 2020 – June 2020 Glyphosate AMPA N-acetyl-AMPA N-acetyl-glyphosate HMPA N-methyl-AMPA N-glyceryl-AMPA N-malonyl-AMPA methylphosphonic acid N-methylglyphosate	1648	1638	852

^{a)} Search filters applied for the four technical sections (residues, environmental fate, toxicology and ecotoxicology). Please refer to **Chapter 2.3** for more details (page 16).

^{b)} Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{c)} Please refer to the Literature Review Report 108689-CA9-1 submitted to the AGG in June 2020.

2.2 Input parameters used in the literature search

The basic input parameters used in the literature search, e.g. IUPAC, chemical name or CAS number, are provided in **Table 6 - Table 15**.

Table 6: Input parameters – active substance Glyphosate

Substance name	Glyphosate Salts: isopropylamine, potassium, ammonium, methylmethanamine
IUPAC / CA name	2-(phosphonomethylamino)acetic acid
CAS number(s)	1071-83-6 Salts: 38641-94-0, 70901-12-1, 39600-42-5, 69200-57-3, 34494-04-7, 114370-14-8, 40465-66-5, 69254-40-6

Table 7: Input parameters – metabolite AMPA

Substance name	AMPA
IUPAC / CA name	(aminomethyl)phosphonic acid
CAS number(s)	1066-51-9

Table 8: Input parameters – metabolite N-acetyl glyphosate

Substance name	N-acetyl glyphosate
IUPAC / CA name	N-acetyl-N-(phosphonomethyl)glycine
CAS number(s)	129660-96-4

Table 9: Input parameters – metabolite N-acetyl AMPA

Substance name	N-acetyl AMPA
IUPAC / CA name	[(acetylamino)methyl]phosphonic acid
CAS number(s)	57637-97-5

Table 10: Input parameters – metabolite HMPA

Substance name	HMPA
IUPAC / CA name	(hydroxymethyl)phosphonic acid
CAS number(s)	2617-47-2

Table 11: Input parameters – metabolite N-methyl AMPA

Substance name	N-methyl AMPA
IUPAC / CA name	[(methylamino)methyl]phosphonic acid
CAS number(s)	35404-71-8

Table 12: Input parameters – metabolite N-glyceryl AMPA

Substance name	N-glyceryl AMPA
IUPAC / CA name	(2,3-dihydroxypropanoylamino)methylphosphonic acid
CAS number(s)	No data

Table 13: Input parameters – metabolite N-malonyl AMPA

Substance name	N-malonyl AMPA
IUPAC / CA name	3-oxo-3-(phosphonomethylamino)propanoic acid
CAS number(s)	no data

Table 14: Input parameters – metabolite methylphosphonic acid

Substance name	methylphosphonic acid
IUPAC / CA name	methylphosphonic acid
CAS number(s)	993-13-5

Table 15: Input parameters – metabolite N-methylglyphosate

Substance name	N-methylglyphosate
IUPAC / CA name	2-[methyl(phosphonomethyl)amino]acetic acid
CAS number(s)	24569-83-3

2.3 Keywords and search filters used in the literature search

The approach used for the search was the “focused search for grouped data requirements”¹⁰, which combines the active substance and metabolite basic input parameters, keywords and search filters defined for each technical section. Please refer to **Table 16** for more details on the keywords used and to **Table 17 - Table 20** for the search filters.

Table 16: Keywords used for the active substance glyphosate and its metabolites

Gly1: Glyphosate and AMPA	glyphosat? OR glifosat? OR glyfosat? OR 1071-83-6 OR 38641-94-0 OR 70901-12-1 OR 39600-42-5 OR 69200-57-3 OR 34494-04-7 OR 114370-14-8 OR 40465-66-5 OR 69254-40-6 OR aminomethyl phosphonic OR aminomethylphosphonic OR 1066-51-9
Gly2: N-acetyl glyphosate and N-acetyl AMPA	2 acetyl phosphonomethyl amino acetic acid OR n acetyl glyphosate OR n acetyl glyphosate OR n acetyl n phosphonomethyl glycine OR 129660-96-4 OR n acetyl ampa OR acetyl amino methyl phosphonic acid OR acetylaminomethyl phosphonic acid OR 57637-97-5
Gly 3: HMPA	2617-47-2 OR hydroxymethanephosphonic acid OR hydroxymethyl phosphonate OR hydroxymethylphosphonate OR hydroxymethyl phosphonic acid OR hydroxymethylphosphonic acid OR methanhydroxyphosphonic acid OR phosphonic acid(1w)hydroxymethyl OR phosphonomethanol
Gly 4: N-methyl AMPA	35404-71-8 OR methylamino methyl phosphonic acid OR methylaminomethyl phosphonic acid OR methylaminomethylphosphonic acid OR n methyl ampa OR nsc 244826 OR phosphonic acid methylamino methyl OR phosphonic acid p methylamino methyl
Gly 4: N-glyceryl AMPA	2 3 dihydroxy 1 oxopropyl aminomethyl phosphonic acid OR 2 3 dihydroxy 1 oxopropyl aminomethylphosphonic acid OR n glyceryl ampa
Gly 4: N-malonyl AMPA	3 oxo 3 phosphonomethyl amino propanoic acid OR 3 oxo 3 phosphonomethyl aminopropanoic acid OR n malonyl ampa
Gly 4: methylphosphonic acid	993-13-5 OR dihydrogen methylphosphonate OR methanephosphonic acid OR methyl phosphonic acid OR methylphosphonic acid OR nsc 119358 OR phosphonic acid methyl OR phosphonic acid p methyl
Gly 5: N-methylglyphosate (NMG)	24569-83-3 OR 2 methyl phosphonomethyl amino acetic acid OR 2 methyl phosphonomethyl aminoacetic acid OR acetic acid 2 n methyl n phosphonatomethyl amino OR glycine n methyl n phosphonomethyl OR glyphosate n methyl OR methyl glyphosate OR methyl phosphonomethyl amino acetic acid OR methyl phosphonomethyl aminoacetic acid OR n methyl n phosphonomethyl glycine OR n methylglyphosate OR n phosphonomethyl n methyl glycine OR n phosphonomethyl n methylglycine

(1w) = proximity operator (this order, up to 1 word between)

AND / OR / NOT = boolean search operators

? = any character(s)

¹⁰ Citation from the EFSA 2092 GD: *If the number of summary records returned by a single concept search* is extremely large, focused searches for individual or grouped data requirements could be developed. Such searches could combine synonyms for the active substance (one concept) with terms and synonyms for characteristics of the data requirement (second concept).*

*NOTE: Single concept search (as defined in the EFSA 2092 GD document) = using the active substance names and its synonyms.

Table 17: Search filters related to the technical section toxicology

Toxicology
[Gly1] OR [Gly2] OR [Gly3] OR [Gly4] OR [Gly5] AND the following search filters
tox? OR hazard? OR adverse OR health OR NOAEL OR NOEL OR LOAEL OR LOEL OR BMD? OR in vivo OR in vitro OR invivo OR invitro OR mode of action OR skin? OR eye? OR irrit? OR sensi? OR allerg? OR rat OR rats OR dog? OR rabbit? OR guinea pig? OR mouse OR mice OR metabolism OR metabolite? OR metabolic OR distribution OR adsorption OR excretion OR elimination OR kinetic OR cytochrome OR enzym? OR gen? OR muta? OR chromos? OR clastogen? OR DNA OR carcino? OR cancer? OR tumor? OR tumour? OR oncog? OR oncol? OR malign? OR immun? OR neur? OR endocrin? OR hormon? OR gonad? OR disrupt? OR reproduct? OR development? OR malform? OR anomal? OR fertil? OR foet? OR fet? OR matern? OR pregnan? OR embryo? OR epidem? OR medical? OR poison? OR exposure OR operator? OR bystander? OR resident? OR worker? OR occupat? biomonitoring OR human exposure OR microbiome OR oxidative stress OR apoptosis OR necrosis OR cytotoxicity OR Polyoxyethyleneamine OR POEA OR surfactant OR risk assessment?

Table 18: Search filters related to the technical section residues

Residues
[Gly1] OR [Gly2] OR [Gly3] OR [Gly4] OR [Gly5] AND the following search filters
uptake OR translocation OR rumen OR storage stability OR storage OR stability OR metabolic OR metabolism OR breakdown OR nature of residues OR residue? OR magnitude of residues OR process? OR effects of processing OR dessicant OR preharvest OR preemerg? OR ?resistant? OR ?toleran? OR transgenic OR hydroly? OR rotation? OR succeed? OR plant? OR crop? OR feed? OR animal? OR livestock? OR hen OR cattle OR ruminant? OR goat? OR cow? OR pig? OR dietary OR assessment OR risk assessment OR consum? OR exposure

Table 19: Search filters related to the technical section environmental fate

Environmental fate
[Gly1] OR [Gly2] OR [Gly3] OR [Gly4] OR [Gly5] AND the following search filters
soil OR water OR sediment OR degradat? OR photo? OR soil residues OR soil accumulat? OR soil contaminat? OR mobility OR sorption OR column leaching OR aged residue OR leach? OR lysimeter OR groundwater OR contaminat? OR microb? OR exudation OR rhizosphere OR dissipation OR saturated zone OR hydrolysis OR drift OR run-off OR runoff OR drainage OR volat? OR atmosphere OR long-range transport OR short-range transport OR transport OR micronutrient OR phosphate OR iron OR manganese OR half-life OR halflife OR half-lives OR halflives OR DT50 OR kinetics OR off-site movement OR removal OR drinking water OR water treatment processes OR atmospheric deposition OR tile-drains OR surface water OR monitoring data OR disinfectant OR ozone OR tillage OR infiltration OR hard surface OR rainwater OR rain water OR chelat? OR complex? OR mineralization OR persistence OR ligand

Table 20: Search filters related to the technical section ecotoxicology

Ecotoxicology [Gly1] OR [Gly2] OR [Gly3] OR [Gly4] OR [Gly5] AND the following search filters
tox? OR ecotox? OR ?toxic OR ?toxicity OR hazard OR adverse OR endocrine disrupt? OR bioaccumulate? OR biomagnifi? OR bioconcentration OR poison OR effect OR indirect effect? OR direct effect? OR biodivers? OR protection goals OR eco? OR impact OR population OR OR community OR wildlife OR incident OR wildlife OR incident OR pest OR bird? OR acute OR chronic OR long-term OR mallard OR duck OR quail OR bobwhite OR Anas? OR Colinus? OR wild OR dietary OR aquatic OR fish OR daphni? OR alg? OR chiron? OR sediment dwell? OR benthic OR lemna OR marin? OR estuarine OR crusta? OR gastropod? OR insect OR mollusc OR reptile OR amphib? OR plant AND submerge? OR emerge? OR bee? OR apis OR apidae OR bumble? OR colony OR hive OR pollinator OR solitary OR alg? OR aquatic OR freshwater OR vertebrat? OR mammal? OR rat OR mouse OR mice OR rabbit OR hare OR protection OR model? OR vole OR pest OR arthropod? OR beneficials OR typhlodromus OR aphidius OR parasitoid OR predator OR chrysoperla OR Orius OR spider OR worm? OR ?worm OR Eisenia OR soil OR collembol? OR macro organism OR folsomia OR springtail OR decompos? OR micro organisms OR microorganisms OR microbial OR carbon OR nitrogen OR plant? OR vegetative vigo? OR seedling OR germination OR monocot? OR dicot? OR sewage OR activated sludge OR biodegrad? OR bioaccumulation? OR amphib? OR reptile? OR aquatic plant OR beneficial

2.4 Relevance assessment

After removal of duplicates, the remaining articles were assessed for their relevance. First, at “title / abstract level” (so-called “rapid assessment”) and second, at “full-text level” (so called “detailed assessment”).

Articles that were identified as “non-relevant” in the rapid assessment were excluded from further evaluation and a justification for their non-relevance was provided.

For articles that were not excluded in the rapid assessment (potentially relevant articles and articles of an unclear relevance), a detailed relevance assessment of a full-text document was performed.

Articles that were identified as “non-relevant” in the detailed assessment were excluded from further evaluation and a justification for their non-relevance was provided.

For both assessments (rapid and detailed) the same criteria for non-relevance were applied (see **Chapter 2.4.1** and **2.4.2**).

2.4.1 Criteria applied for “non-relevance”

Articles identified as “non-relevant” in the rapid and detailed assessments belong to one of the following categories and were excluded from further evaluation. A justification for their non-relevance was provided.

- Publications related to efficacy (resistance related articles, new uses of control of pest / crops) or to agricultural / biological research (crop science, breeding, fertilization, tillage, fundamental plant physiology / micro- / molecular biology).
- Publications dealing with analytical methods / development.
- Publications describing new methods of synthesis (discovery / developments) or other aspects of basic (organic / inorganic) chemistry.
- Patents.
- Wastewater treatment.
- Abstracts referring to a conference contribution that does not contain sufficient data / information for regulatory risk assessment.
- Publications focusing on genetically modified organisms / transgenic crops; no data directly relevant to glyphosate evaluation (e.g. crop compositional analysis, gene flow, protein characterization).
- Publications where glyphosate or a relevant metabolite were not the focus of the publication.
- Secondary information including scientific and regulatory reviews¹¹.
- Articles dealing with political / socio / economic analysis.
- Observations caused by mixture of compounds / potentially causal factors and thus not attributable to a substance of concern (e.g. mixture toxicity).
- Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes.
- Findings not related to ecotoxicology, toxicology, residues, and environmental fate.
- Publications not dealing with EU representative uses / conditions (e.g. field locations, soil properties, non-EU monitoring etc.).

¹¹ Reviews have been partly evaluated on full text level as well – case by case decision.

- Publications dealing with a Roundup¹² formulation / other glyphosate formulations that is not the representative formulation for the AIR5 dossier and thus not relevant to the EU glyphosate renewal.
- Publications dealing with general pesticide exposures (not glyphosate specific).
- Publications generating endpoints that are not relatable to the EU level regulatory risk assessment (e.g. findings based on enzyme, cellular and molecular level etc.).
- Opinion articles where no new data is provided that can be used for the EU regulatory risk assessment.

2.4.2 Additional criteria for articles on the health and exposure of glyphosate

The scientific literature on the health effects of glyphosate can be subdivided in two main parts:

- Articles containing data on glyphosate acid and salts and on the reference glyphosate formulation MON 52276, and
- Articles only containing data on glyphosate formulations and/or co-formulants that have a composition different from that of the reference formulation MON 52276.

In the case of articles only relating to glyphosate formulations *in vitro* testing with the exception of cell/tissue systems¹³ that are likely to come in direct contact with formulations and glyphosate formulations containing other active ingredients are excluded. The reason for the exclusion of *in vitro* testing of formulations to assess health effects as a result of systemic exposure is the presence of surfactants which produce cell toxicity based on the destabilization of the cell membrane and the mitochondrial membrane thus masking the specific toxicity of glyphosate. The toxicity of the co-formulants in combination with glyphosate is dependent on the concentration and the nature of the co-formulants and can be addressed on a case-by-case basis during the evaluation of formulations on an ad-hoc basis through Zonal and Member State formulation registrations.

In the relevance of glyphosate data, those articles have been considered as not relevant (and reliable) for the assessment for systemic toxicity when only *in vitro* results are presented with glyphosate concentrations above 1 mM. This is because it is physiologically not possible to attain such concentrations in standard regulatory *in vivo* testing due to the limited oral bioavailability (approx. 20%), very low dermal absorption, and rapid systemic elimination of glyphosate in *in vivo* test systems. It thus makes no sense to include such data in the risk assessment of glyphosate. Exceptions can be made in the event of direct contact with formulations resulting in localized effects, but then there is the contribution of the toxicity of the co-formulants which can be better addressed in the evaluation of formulations on an ad-hoc basis through Zonal and Member State formulation registrations.

¹² Roundup is a brand that contains multiple glyphosate-based herbicides, that contain different co-formulants. Of most importance to the toxicity profile associated with a particular product is whether that product contains a surfactant polyethoxylated tallow amine (also polyoxyethyleneamine, POEA) which is not permitted for use in the EU. As the performance / efficacy of herbicidal formulations is dependant on the surfactant system / co-formulants, the findings in articles dealing with POEA based Roundup formulations cannot be related to the representative formulation MON 52276 which is quaternary-ammonium based (and not POEA based).

¹³ Glyphosate-based herbicides (GBH) contain surfactants that destabilize the cell membrane and the mitochondrial membrane and thus produce a toxicity that is not representative for glyphosate (see Levine S. L. et al, *Cell Biol. Toxicol.* (2007) 23:385-400). This has been clearly demonstrated in the scientific literature and also in some papers reviewed for this submission where *in vitro* glyphosate toxicity is compared against that of GBH and surfactants.

The limit of 1 mM has been based on the single dose oral pharmacokinetic data of a formulation containing 71.7% w/w glyphosate where an oral dose of 1,430 mg/kg bw in the rat gives plasma levels of 38.1 µg/mL or 0.225 mM after 2 hours. When extrapolated linearly (which is possible for glyphosate because it is not subject to hepatic metabolism) this gives plasma levels of 53.3 µg/mL or 0.315 mM at 2 hours after oral intake of 2,000 mg/kg bw and 107 µg/mL or 0.630 mM at 2 hours after oral intake of 4,000 mg/kg bw. A systemic concentration of glyphosate of 1 mM would then represent an oral dose of more than 6,000 mg/kg bw which is completely unreasonable for repeat dose experimental *in vivo* testing under today's OECD test guidelines. The ADI for glyphosate of 0.5 mg/kg bw/day corresponds with a daily systemic concentration of 0.17 µg/mL or 1 µM when a 60 kg person with 36 L extracellular fluid is considered with a glyphosate oral bioavailability of 20%. The daily systemic dose of glyphosate on the day of application (i.e. highest exposure day), based on the geometric mean of 3.2 µg/L in urine, of glyphosate applicators in the US is approx. 0.0001 mg/kg bw/day (Acquavella, 2004¹⁴) which is 1000 times less than the systemic dose (0.1 mg/kg bw) corresponding with the ADI oral dose of 0.5 mg/kg bw with 20% oral bioavailability.

Many articles that have been considered relevant for the risk assessment of glyphosate and have been assessed for reliability on full text basis, contain experimental data as well on glyphosate as such as on formulations (different from MON 52276) and co-formulants. In such cases, only the toxicology data pertinent to glyphosate and to the reference formulation (if that can be clearly stated by the author of the article) are summarized and discussed. In the case of articles on exposure monitoring and epidemiology, exposure to glyphosate formulations are considered.

2.4.3 Categorization of “relevant” articles at full-text level

Articles that were not excluded in the detailed assessment (see **Chapter 2.4.1** and **2.4.2**) were categorized as recommended in the EFSA 2092 Guidance Document - EFSA Journal 2011;9(2):2092, Point 5.4.1.

Category A *Studies that provide data for establishing or refining risk assessment parameters. These studies should be summarised in detail following the subsequent steps of the OECD Guidance documents (OECD, 2005; 2006) and should be considered for reliability.*

Category B *Studies that are relevant to the data requirement, but in the opinion of the applicant provide only supplementary information that does not alter existing risk assessment parameters. A justification for such a decision should be provided.*

Category C *Studies for which relevance cannot be clearly determined. For each of these studies the applicants should provide an explanation of why the relevance of such studies could not be definitively determined.*

The list of Category A articles can be found in **Table 32** and **Table 33**. The list of Category B articles and the justifications can be found in **Table 34** and **Table 35**. The list of Category C articles and the explanations can be found in **Table 36** and **Table 37**.

All articles (and their translations) evaluated at full text level (detailed assessment) were submitted to the AGG in a Portable Document Format (PDF).

¹⁴ Acquavella J. F. *et al.* (2004), Environmental Health Perspectives, 112(3), 321-326.

2.5 Reliability assessment

For articles, which were identified, in the detailed assessment, as relevant articles of Category A (see **Chapter 2.4.3**) a reliability assessment was performed. The reliability criteria for each technical section are summarized in **Table 21 - Table 23**.

For relevant articles of Category A that were classified either as reliable or reliable with restrictions, summaries were compiled.

Articles of Category A which were classified as non-reliable were downgraded to articles of Category B and justification for such a decision was provided.

Table 21: Reliability criteria for ecotoxicology, environmental fate and residues

Applied for	Reliability criteria
Ecotoxicology, Environmental Fate, Residues	For guideline-compliant studies (GLP studies): OECD, OPPTS, ISO, and others. The validity/quality criteria listed in the corresponding guidelines are met.
Ecotoxicology, Environmental Fate, Residues	(No) previous exposure to other chemicals is documented (where relevant).
Ecotoxicology	For aquatic studies, the test substance is dissolved in water or where a carrier is required, it is appropriate (non-toxic) and a carrier control / positive control is considered in the test design.
Environmental Fate, Residues	The test substance is dissolved in water or non-toxic solvent.
Ecotoxicology, Environmental Fate, Residues	Test item is sufficiently documented, and reported (i.e. purity, source, content, storage conditions).
Ecotoxicology	For tests including vertebrates, compliance of the batches used in toxicity studies compared to the technical specification.
Ecotoxicology	Species used in the experiment are clearly reported, including source, experimental conditions (where relevant): strain, adequate age/life stage, body weight, acclimatization, temperature, pH, oxygen (dissolved oxygen for aquatic tests) content, housing, light conditions, humidity (terrestrial species) incubation conditions, feeding.
Ecotoxicology	The validity criteria from relevant test guidelines can be extrapolated across different species but not necessarily across different test designs. If different, then the nature of the difference and impact should ideally be discussed.
Ecotoxicology, Environmental Fate, Residues	Only glyphosate or its metabolites is the test substance (excluding mixture), and information on application of the test substance is described.
Ecotoxicology, Environmental Fate, Residues	The endpoint measured can be considered a consequence of glyphosate (or a glyphosate metabolite).
Ecotoxicology, Environmental Fate, Residues	Study design / test system is well described, including when relevant: concentration in exposure media (dose rates, volume applied, etc.), dilution/mixture of test item (solvent, vehicle) where relevant.
Ecotoxicology, Environmental Fate, Residues	Analytical verifications performed in test media (concentration) / collected samples, stability of the test substance in test medium should be documented.

Applied for	Reliability criteria
Ecotoxicology	The test has been performed in several dose levels (at least 3) including a positive / negative control where relevant.
Ecotoxicology	Suitable exposure throughout the whole exposure period was demonstrated and reported.
Ecotoxicology	A clear concentration response relationship is reported – in studies where the dose response test design is employed.
Ecotoxicology	A sufficient number of animals per group to facilitate statistical analysis reported: mortality in control groups reported, observations/findings in positive/negative control clearly reported (where relevant).
Ecotoxicology, Environmental Fate, Residues	Assessment of the statistical power of the assay is possible with reported data.
Ecotoxicology, Environmental Fate, Residues	Statistical methodology is reported (e.g., checking the plots and confidence intervals).
Ecotoxicology	Description of the observations (including time-points), examinations, and analyses performed, with (where relevant) dissections being well documented.
Ecotoxicology	For terrestrial ecotoxicological studies in the laboratory or the field, the substrates used should be adequately described e.g. nature of substrate i.e. species of leaf or soil type.
Ecotoxicology, Environmental Fate, Residues	Field locations relevant / comparable to European conditions.
Ecotoxicology, Environmental Fate, Residues	Characterization of soil: texture (sandy loam, silty loam, loam, loamy sand), pH (5.5-8.0), cation exchange capacity, organic carbon (0.5-2-5%), bulk density, water retention, microbial biomass (~1% of organic carbon).
Ecotoxicology, Environmental Fate	Other soils where information on characterization by the parameters: pH, texture, CEC, organic carbon, bulk density, water holding capacity, microbial biomass.
Ecotoxicology, Environmental Fate, Residues	For tests including agricultural soils, they should not have been treated with test substance or similar substances for a minimum of 1 year.
Ecotoxicology, Environmental Fate	For soil samples, sampling from A-horizon, top 20 cm layers; soils freshly from field preferred (storage max 3 months at 4 +/- 2°C).
Ecotoxicology, Environmental Fate, Residues	Data on precipitation is recorded.
Environmental Fate	The temperature was in the range between 20-25°C and the moisture was reported.
Environmental Fate	The presence of glyphosate identified in samples were collected from European groundwater, soil, surface waters, sediments or air.
Ecotoxicology	For lab terrestrial studies, the temperature was appropriate to the species being tested and generally should fall within the range between 20-25°C and soil moisture / relative humidity was reported.
Ecotoxicology	For bee studies, temperature of the study should be appropriate to species.
Ecotoxicology	For lab aquatic studies:
	The source and / or composition of the media used should be described.
	The temperature of the water should be appropriate to the species being tested and generally fall within the 15-25°C.

Applied for	Reliability criteria
Ecotoxicology, Residues	The residue data can be linked to a clearly described GAP table, appropriate in the context of the renewal of approval of glyphosate (crop, application method, doses, intervals, PHI).
Ecotoxicology, Environmental Fate, Residues	Analytical results present residues measurements which can be correlated with the existing residues definition of glyphosate, and where relevant its metabolites.
Ecotoxicology, Environmental Fate, Residues	Analytical methods are clearly described; and adequate statement of specificity and sensitivity of the analytical methods is included.
Ecotoxicology	Assessment of the ECX for the width of the confidence interval around the median value; and the certainty on the level of protection offered by the median ECX is reported.
Environmental Fate	Radiolabel characterization: purity, specific activity, location of label is reported.
Environmental Fate	If degradation kinetics are included: data tables / model description / statistical parameters for kinetic fit to be provided.
Environmental Fate, Residues	Monitoring data: description of matrix analysed, and analytical methods to be fully described.
Environmental Fate	Clear description of application rate and relevance to approved uses.
Overall assessment: Reliable / Reliable with restrictions / Not reliable	

Table 22: Reliability criteria for toxicology – epidemiology and exposure studies

Reliability criteria – toxicology	
Epidemiology studies	Exposure studies
Guideline-specific	Guideline-specific
Study in accordance to valid internationally accepted testing guidelines/practices	Study in accordance to valid internationally accepted testing guidelines/practices
Study completely described and conducted following scientifically acceptable standards	Study performed according to GLP
	Study completely described and conducted following scientifically acceptable standards
Test substance	Test substance
Exposure to formulations with only glyphosate as a.i.	Exposure to formulations with only glyphosate as a.i.
Exposure to formulations with glyphosate combined with other a.i.	Exposure to formulations with glyphosate combined with other a.i.
Exposure to various formulations of pesticides	Exposure to various formulations of pesticides
Study	Study
Study design – epidemiological method followed	Study design clearly described
Description of population investigated	Population investigated sufficiently described
Description of exposure circumstances	Exposure circumstances sufficiently described
Description of results	Sampling scheme sufficiently documented
Have confounding factors been considered	Analytical method described in detail
Statistical analysis	Validation of analytical method reported
	Monitoring results reported
Overall assessment: Reliable / Reliable with restrictions / Not reliable	

Table 23: Reliability criteria for toxicology – *in vitro* and *in vivo* studies

Reliability criteria – toxicology and metabolism	
<i>In vitro</i> studies	<i>In vivo</i> studies
Guideline-specific	Guideline-specific
Study in accordance to valid internationally accepted testing guidelines	Study in accordance to valid internationally accepted testing guidelines.
Study performed according to GLP	Study performed according to GLP
Study completely described and conducted following scientifically acceptable standards	Study completely described and conducted following scientifically acceptable standards
Test substance	Test substance
Test material (Glyphosate) is sufficiently documented and reported (i.e. purity, source, content, storage conditions)	Test material (Glyphosate) is sufficiently documented and reported (i.e. purity, source, content, storage conditions)
Only glyphosate acid or one of its salts is the tested substance	Only glyphosate acid or one of its salts is the tested substance
AMPA is the tested substance	AMPA is the tested substance
Study	Study
Test system clearly and completely described	Test species clearly and completely described
Test conditions clearly and completely described	Test conditions clearly and completely described
Metabolic activation system clearly and completely described	Route and mode of administration described
Test concentrations in physiologically acceptable range (< 1 mM)	Dose levels reported
Cytotoxicity tests reported	Number of animals used per dose level reported
Positive and negative controls	Method of analysis described for analysis test media
Complete reporting of effects observed	Validation of the analytical method
Statistical methods described	Analytical verifications of test media
Historical negative and positive control data reported	Complete reporting of effects observed
Dose-effect relationship reported	Statistical methods described
	Historical control data of the laboratory reported
	Dose-effect relationship reported
Overall assessment: Reliable / Reliable with restrictions / Not reliable	

3 Search results

The full outcome of the literature search and evaluation is provided below.

Table 24: Summary of the literature search – all technical sections

	Number	Justification
Total number of articles retrieved from the search.	3156	n.a.
Total number of articles after removal of duplicates within all databases.	1648	n.a.
Total number of articles after manual removal of duplicates. ^{a)}	852	n.a.
Number of articles excluded after rapid assessment (title / abstract).	774	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	78	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	35	See Table 38
Number of articles not excluded after detailed assessment. ^{b)}	43	See Table 32-Table 37
Number of summaries presented in the dossier. ^{c)}	12	See Table 32, Table 33

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 25: Results of the article selection process for ecotoxicology

	Number	Justification
Total number of articles after manual removal of duplicates. ^{a)}	150	n.a.
Number of articles excluded after rapid assessment (title / abstract).	121	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	29	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	14	See Table 38
Number of articles not excluded after detailed assessment. ^{b)}	15	See Table 32-Table 37
Number of summaries presented in the dossier. ^{c)}	2	See Table 32, Table 33

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 26: Results of the article selection process for environmental fate

	Number	Justification
Total number of articles after manual removal of duplicates. ^{a)}	85	n.a.
Number of articles excluded after rapid assessment (title / abstract).	83	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	2	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	0	See Table 38
Number of articles not excluded after detailed assessment. ^{b)}	2	See Table 32-Table 37
Number of summaries presented in the dossier. ^{c)}	2	See Table 32, Table 33

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 27: Results of the article selection process for residues

	Number	Justification
Total number of articles after manual removal of duplicates. ^{a)}	16	n.a.
Number of articles excluded after rapid assessment (title / abstract).	15	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	1	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	0	See Table 38
Number of articles not excluded after detailed assessment ^{b)}	1	See Table 32-Table 37
Number of summaries presented in the dossier ^{c)}	1	See Table 32, Table 33

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 28: Results of the article selection process for toxicology

	Number	Justification
Total number of articles after manual removal of duplicates ^{a)}	96	n.a.
Number of articles excluded after rapid assessment (title / abstract).	50	See the Literature Review Excel File.
Total number of full-text documents assessed in detail	46	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	21	See Table 38
Number of articles not excluded after detailed assessment ^{b)}	25	See Table 32-Table 37
Number of summaries presented in the dossier ^{c)}	7	See Table 32, Table 33

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 29: Results of the article selection process for analytical methods

	Number	Justification
Total number of articles after manual removal of duplicates ^{a)}	72	n.a.
Number of articles excluded after rapid assessment (title / abstract).	72	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	n.a.	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	n.a.	n.a.
Number of articles not excluded after detailed assessment ^{b)}	n.a.	n.a.
Number of summaries presented in the dossier ^{c)}	n.a.	n.a.

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 30: Results of the article selection process for efficacy / agronomy

	Number	Justification
Total number of articles after manual removal of duplicates. ^{a)}	360	n.a.
Number of articles excluded after rapid assessment (title / abstract).	360	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	n.a.	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	n.a.	n.a.
Number of articles not excluded after detailed assessment. ^{b)}	n.a.	n.a.
Number of summaries presented in the dossier. ^{c)}	n.a.	n.a.

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 31: Results of the article selection process for “other non-relevant categories”

	Number	Justification
Total number of articles after manual removal of duplicates. ^{a)}	73	n.a.
Number of articles excluded after rapid assessment (title / abstract).	73	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	n.a.	n.a.
Number of articles excluded after detailed assessment (<i>i.e.</i> not relevant).	n.a.	n.a.
Number of articles not excluded after detailed assessment. ^{b)}	n.a.	n.a.
Number of summaries presented in the dossier. ^{c)}	n.a.	n.a.

^{a)} After removal of duplicates within the current search (Jan 2020 – Jun 2020) and entries found already in the previous search (Jan 2010 – Dec 2019). Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

^{b)} All relevant articles by full-text belonging to the relevance Category A, B, C (acc. to the EFSA Journal 2011;9(2):2092, [Point 5.4.1](#)). For details, please refer to Chapter 2.4.3.

^{c)} Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 32: Relevant (category A) & reliable or reliable with restrictions articles after detailed assessment: sorted by data requirement(s)

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
6	CA 5.2.6	Lindberg T. <i>et al.</i>	2020	An integrated transcriptomic- and proteomic-based approach to evaluate the human skin sensitization potential of glyphosate and its commercial agrochemical formulations.	Journal of proteomics, (2020) Vol. 217, Art. No. 103647	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
1	CA 5.5	Crump K. <i>et al.</i>	2020	Accounting for Multiple Comparisons in Statistical Analysis of the Extensive Bioassay Data on Glyphosate.	Toxicological sciences : an official journal of the Society of Toxicology, (2020) Vol. 175, No. 2, pp. 156-167	5.4.1 case a) relevant and provides data for the risk assessment: A summary is presented in the AIR5 dossier under MCA 5.5./026.
8	CA 5.5	Portier C. J. <i>et al.</i>	2020	A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies.	Environmental health : a global access science source, (2020) Vol. 19, No. 1, pp. 18	5.4.1 case a) relevant and provides data for the risk assessment: A summary is presented in the AIR5 dossier under MCA 5.5./027.
3	CA 5.6	Ganesan S. <i>et al.</i>	2020	Absence of glyphosate-induced effects on ovarian folliculogenesis and steroidogenesis.	Reproductive toxicology, (2020) Vol. 96, pp 156-164	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
12	CA 5.8.2	Yahfoufi Z. A. <i>et al.</i>	2020	Glyphosate Induces Metaphase II Oocyte Deterioration and Embryo Damage by Zinc Depletion and Overproduction of Reactive Oxygen Species.	Toxicology, (2020) Vol. 439, Art. No. 152466	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
4	CA 5.8.3	Gastiazoro M. P. <i>et al.</i>	2020	Glyphosate induces epithelial mesenchymal transition-related changes in human endometrial Ishikawa cells via estrogen receptor pathway.	Molecular and cellular endocrinology, (2020) Vol. 510, Art. No. 110841	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
11	CA 5.8.3	Xia Y. <i>et al.</i>	2020	The endoplasmic reticulum stress and related signal pathway mediated the glyphosate-induced testosterone synthesis inhibition in TM3 cells.	Environmental pollution, (2020) Vol. 260, Art. No. 113949	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
7	CA 6.9	Panseri S. <i>et al.</i>	2020	Occurrence of perchlorate, chlorate and polar herbicides in different baby food commodities.	Food chemistry, (2020) Vol. 330, Art. No. 127205	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
5	CA 7.1.4.2	Gros P. <i>et al.</i>	2020	Leaching and degradation of (13)C2-(15)N-glyphosate in field lysimeters.	Environmental monitoring and assessment, (2020) Vol. 192, No. 2, pp. 127	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
2	CA 7.5	De Polo A. <i>et al.</i>	2019	From the traces in the wells of the urban aqueduct network to the subsequent prohibition of the use of glyphosate: the case of an area of high-intensity wine production in the province of Treviso, Veneto.	Igiene e sanità pubblica, (2019) Vol. 75, No. 6, pp. 451-460	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
10	CA 8.1.4	Turhan D. O. <i>et al.</i>	2020	Developmental and lethal effects of glyphosate and a glyphosate-based product on <i>Xenopus laevis</i> embryos and tadpoles.	Bulletin of environmental contamination and toxicology, (2020) Vol. 104, No. 2, pp. 173-179	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
9	CA 8.6.2	Rogacz D. <i>et al.</i>	2020	Ecotoxicological effects of new C-substituted derivatives of N-phosphonomethylglycine (glyphosate) and their preliminary evaluation towards herbicidal application in agriculture.	Ecotoxicology and environmental safety, (2020) Vol. 194, pp. 110331	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.

Table 33: Relevant (category A) & reliable or reliable with restrictions articles after detailed assessment: sorted by author(s)

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
1	Crump K. <i>et al.</i>	CA 5.5	2020	Accounting for Multiple Comparisons in Statistical Analysis of the Extensive Bioassay Data on Glyphosate.	Toxicological sciences : an official journal of the Society of Toxicology, (2020) Vol. 175, No. 2, pp. 156-167	5.4.1 case a) relevant and provides data for the risk assessment: A summary is presented in the AIR5 dossier under MCA 5.5./026.
2	De Polo A. <i>et al.</i>	CA 7.5	2019	From the traces in the wells of the urban aqueduct network to the subsequent prohibition of the use of glyphosate: the case of an area of high-intensity wine production in the province of Treviso, Veneto.	Igiene e sanità pubblica, (2019) Vol. 75, No. 6, pp. 451-460	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3	Ganesan S. <i>et al.</i>	CA 5.6	2020	Absence of glyphosate-induced effects on ovarian folliculogenesis and steroidogenesis.	Reproductive toxicology, (2020) Vol. 96, pp 156-164	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
4	Gastiazoro M. P. <i>et al.</i>	CA 5.8.3	2020	Glyphosate induces epithelial mesenchymal transition-related changes in human endometrial Ishikawa cells via estrogen receptor pathway.	Molecular and cellular endocrinology, (2020) Vol. 510, Art. No. 110841	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
5	Gros P. <i>et al.</i>	CA 7.1.4.2	2020	Leaching and degradation of (13)C2-(15)N-glyphosate in field lysimeters.	Environmental monitoring and assessment, (2020) Vol. 192, No. 2, pp. 127	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
6	Lindberg T. <i>et al.</i>	CA 5.2.6	2020	An integrated transcriptomic- and proteomic-based approach to evaluate the human skin sensitization potential of glyphosate and its commercial agrochemical formulations.	Journal of proteomics, (2020) Vol. 217, Art. No. 103647	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
7	Panseri S. <i>et al.</i>	CA 6.9	2020	Occurrence of perchlorate, chlorate and polar herbicides in different baby food commodities.	Food chemistry, (2020) Vol. 330, Art. No. 127205	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
8	Portier C. J. <i>et al.</i>	CA 5.5	2020	A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies.	Environmental health : a global access science source, (2020) Vol. 19, No. 1, pp. 18	5.4.1 case a) relevant and provides data for the risk assessment: A summary is presented in the AIR5 dossier under MCA 5.5./027.
9	Rogacz D. <i>et al.</i>	CA 8.6.2	2020	Ecotoxicological effects of new C-substituted derivatives of N-phosphonomethylglycine (glyphosate) and their preliminary evaluation towards herbicidal application in agriculture.	Ecotoxicology and environmental safety, (2020) Vol. 194, pp. 110331	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
10	Turhan D. O. <i>et al.</i>	CA 8.1.4	2020	Developmental and lethal effects of glyphosate and a glyphosate-based product on <i>Xenopus laevis</i> embryos and tadpoles.	Bulletin of environmental contamination and toxicology, (2020) Vol. 104, No. 2, pp. 173-179	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
11	Xia Y. <i>et al.</i>	CA 5.8.3	2020	The endoplasmic reticulum stress and related signal pathway mediated the glyphosate-induced testosterone synthesis inhibition in TM3 cells.	Environmental pollution, (2020) Vol. 260, Art. No. 113949	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
12	Yahfoufi Z. A. <i>et al.</i>	CA 5.8.2	2020	Glyphosate Induces Metaphase II Oocyte Deterioration and Embryo Damage by Zinc Depletion and Overproduction of Reactive Oxygen Species.	Toxicology, (2020) Vol. 439, Art. No. 152466	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.

Table 34: Relevant but supplementary (category B) articles after detailed assessment: sorted by data requirement(s)

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
43	CA 5.1	Zoller O. <i>et al.</i>	2020	Urine glyphosate level as a quantitative biomarker of oral exposure.	International journal of hygiene and environmental health, (2020) Vol. 228, Art. No.113526	5.4.1 case b) relevant but supplementary information: This was a study with human volunteers. The trial was designed to ensure comparable exposure levels to glyphosate among participants who consumed diets with low content of glyphosate residue during the 4-day trial, except for the single meal with targeted amount of glyphosate and AMPA corresponding to an intake of 196.8 µg of glyphosate and 1.67 µg of AMPA. Only urine was collected and analysed for glyphosate and AMPA. Blood and faeces were not collected and/or analysed. This goal of the study was to estimate oral glyphosate intake using urinary biomonitoring data. However, the authors recognised that the determination of blood concentrations is necessary to improve human bioavailability data. Comparison of urinary data in humans in this study with those measured in the rat studies suggest that the systemic availability is much lower in humans than in rats and could be about 20-fold lower. However, in the absence of a mass balance, and a very low recovery of glyphosate and AMPA, the data should be considered unreliable. Given the knowledge that orally dosed glyphosate is mostly excreted via the faeces, an appropriate study design to address mass balance could easily have been implemented to make this a robust and informative investigation. Low recovery rates of glyphosate and AMPA suggest a very large capacity for errors. The study design is inadequate to confirm reliability of the findings. The lack of mass balance of analytes, despite common knowledge that orally dosed glyphosate is mostly excreted in faeces, is disappointing, given the ease with which a mass balance could have been assessed. The article was downgraded to Category B due to its non-reliability.
37	CA 5.3	Tang Q. <i>et al.</i>	2020	Glyphosate exposure induces inflammatory responses in the small intestine and alters gut microbial composition in rats.	Environmental pollution, (2020) Vol. 261, Art. No. 114129	5.4.1 case b) relevant but supplementary information: The rats were gavaged with 0, 5, 50, and 500 mg/kg of body weight glyphosate for 35 continuous days. The different segments of the small intestine were sampled to measure indicators of oxidative stress, ion concentrations and inflammatory responses, and fresh feces were collected for microbiota analysis. The investigation of potential effects on the gut microbiome of ruminants is not a data requirement for the approval of pesticides and suitable test protocols to assess these effects are not specified in the form of official guidance documents. No GLP status stated, no HCD provided and no purity of glyphosate stated. Fundamental parameters to understand animal health and toxicology endpoints are not reported. Therefore the context of the study results can not be interpreted with any degree of certainty. The article is not reliable.
16	CA 5.5	Berry C.	2020	Glyphosate and cancer: the importance of the whole picture.	Pest management science, (2020); doi: 10.1002/ps.5834; Online ahead of print.	5.4.1 case b) relevant but supplementary information: The author is providing a general picture of the carcinogenic and genotoxic profile of Glyphosate by commenting the different studies available and the different conclusions made by IARC and Regulatory authorities. There is no evidence in the animals studies to support the IARC conclusion that glyphosate is a probable human carcinogen. The article does not provide any new information.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
24	CA 5.5	Jeon S. <i>et al.</i>	2020	Glyphosate influences cell proliferation in vitro.	Frontiers in Life Science, (2020) Vol. 13, No. 1, pp. 54-65	5.4.1 case b) relevant but supplementary information: Glyphosate was tested in vitro at a range of doses to investigate its effects on cell growth and proliferation in human cells. In conclusion, Glyphosate increases the rate of cell growth in human embryonic kidney 293 (HEK293) cells. Glyphosate promotes cell proliferation by activating gene expression of cell cycle regulators in humans in vitro. Useful information but not altering risk assessment and data requirement and difficult to be used because no HCD provided. No positive control were used, no statistics methods were described. Furthermore, no OECD guideline followed, no GLP status stated. The article is not reliable.
14	CA 5.6	Ait-Bali Y. <i>et al.</i>	2020	Pre- and postnatal exposure to glyphosate-based herbicide causes behavioral and cognitive impairments in adult mice: evidence of cortical ad hippocampal dysfunction.	Archives of toxicology, (2020) Vol. 94, No. 5, pp. 1703-1723	5.4.1 case b) relevant but supplementary information: In vivo study on pre and post natal effects of Roundup on swiss mice at 2 different doses only, no OECD guideline followed, no GLP status stated, no HCD provided. Oral gavage dosing of formulated product is not relevant to real life exposure scenarios. Environmental fate and metabolism for glyphosate active ingredient versus surfactants are different, and oral co-exposures to mammals at the excessively high doses tested in this case are considered irrelevant to human health risk assessment. In addition, insufficient information is provided to determine which formulation was tested and whether it is the glyphosate EU representative formulation.
17	CA 5.6	Cai W. <i>et al.</i>	2020	Low-dose Roundup induces developmental toxicity in bovine preimplantation embryos in vitro.	Environmental science and pollution research international, (2020) Vol. 27, No. 14, pp. 16451-16459	5.4.1 case b) relevant but supplementary information: The effects of Roundup at 3 doses was investigated on the bovine preimplantation embryo. Direct dosing of formulated product to fertilized embryos in vitro is not relevant to real life exposure scenarios. Environmental fate, metabolism and pharmacokinetics for glyphosate active ingredient versus surfactants are very different, and oral co-exposures to mammals at the excessively high doses tested in this case are considered irrelevant to livestock and human health risk assessments. In addition, insufficient information is provided to determine which formulation was tested and whether it is the glyphosate EU representative formulation. No OECD guideline followed, no GLP status stated, no HCD provided and no positive control.
29	CA 5.7	Neto de Silva K. <i>et al.</i>	2020	Glyphosate-based herbicide impairs energy metabolism and increases autophagy in C6 astrogloma cell line.	Journal of toxicology and environmental health. Part A, (2020) Vol. 83, No. 4, pp. 153-167	5.4.1 case b) relevant but supplementary information: In vitro study on the effects of micromolar concentrations of a glyphosate-based herbicide on energy metabolism and mitochondrial mass in astrogloma cell line exposed for 24 h to the herbicide at 3 concentrations below 160 µM. Insufficient information provided to identify which formulation was tested. No positive control was used, no statistics methods were described, no OECD guideline followed, no GLP status stated, no HCD provided. In addition, astrocytes in real life are not co-exposed to the combination of glyphosate + surfactant formulations, based on their very different environmental fates and pharmacokinetics.
26	CA 5.8.2	Levine S. L. <i>et al.</i>	2020	Review and Analysis of the Potential for Glyphosate to Interact with the Estrogen, Androgen, and Thyroid Pathways.	Pest management science, (2020), DOI 10.1002/ps.5983	5.4.1 case b) relevant but supplementary information: A systematic literature review was performed including US EPA EDSP Tier 1 battery assessment, guideline regulatory studies, ESDP including 5 in vitro and 6 in vivo assays to evaluate the EAT pathways. From the available literature, it was concluded that glyphosate does not have an endocrine disrupting potential through estrogenic, androgenic or steroidogenic activity. The review includes relevant literature which has been used for the ED assessment during the current submission process. It can therefore serve as supporting information, however as a review it does not provide new primary data or alter the risk assessment. Therefore, the review has been classified as a relevant but supplementary only (EFSA 2092 GD Point 5.4.1 category B).

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
30	CA 5.8.2	Parks C. G. <i>et al.</i>	2019	Lifetime pesticide use and antinuclear antibodies in male farmers from the agricultural health study	Frontiers in Immunology (2019) Vol. 10, Art. No. 1476	5.4.1 case b) relevant but supplementary information: The development of systemic autoimmunity in response to pesticide exposure was investigated in a retrospective study farmers. Serum antinuclear autoantibodies were measured by immunofluorescence on Hep-2 cells in 668 male farmers. The effect of lifetime use of 46 pesticides (glyphosate among them) on ANA were investigated. The results for glyphosate use demonstrate no increase the risk of farmers developing systemic autoimmunity. This information is useful in a weight of evidence assessment for the measured endpoint, which, however, is not a critical endpoint identified for human health risk assessment of glyphosate.
13	CA 5.9	Abdel-Halim K. Y. <i>et al.</i>	2019	Glyphosate and pendimethalin in breast milk samples from Egyptian rural areas: a pilot study for infant's risk assessment	International Journal of Advanced Research, (2019) Vol. 7, No. 9, pp. 991-1002	5.4.1 case b) relevant but supplementary information: This article claims that glyphosate was detected in breast milk. There are several technical issues with this study: 1st: The solubility of glyphosate in toluene is reported as only 36 PPM. The highest sample values the paper claims is just under 30 PPM. So if we had roughly 30 PPM of glyphosate in milk and took 5 mL for analysis then the toluene would have to be capable of solubilizing 150 PPM of glyphosate! 2nd: And this is a key issue – the HPLC method lists an excitation wavelength that is higher than the emission wavelength! There are several studies evaluating whether glyphosate is detectable in cows milk. A study in human breast milk also was conducted and concluded that glyphosate was not detectable. References: 1. Michelle K McGuire, Mark A McGuire, William J Price, Bahman Shafii, Janae M Carrothers, Kimberly A Lackey, Daniel A Goldstein, Pamela K Jensen, John L Vicini, Glyphosate and aminomethylphosphonic acid are not detectable in human milk, The American Journal of Clinical Nutrition, Volume 103, Issue 5, May 2016, Pages 1285–1290, https://doi.org/10.3945/ajcn.115.126854 2. EFSA. (2018). National summary reports on pesticide residue analysis performed in 2016. EFSA Journal, 16(7), 5348. https://doi.org/org/10.2903/sp.efsa.2018.EN-1454 3. EFSA. (2019). The 2017 European Union report on pesticide residues in food. EFSA Journal, 17(6), 5743. https://doi.org/10.2903/j.efsa.2019.5743 4. EFSA. (2020). The 2018 European Union report on pesticide residues in food. EFSA Journal, 18(4), e06057. https://doi.org/10.2903/j.efsa.2020.6057 5. FDA. (2018). Pesticide residue monitoring program. Fiscal year 2016 pesticide report. FDA. https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm618247.htm 6. FDA. (2019). Pesticide residue monitoring program fiscal year 2017 pesticide report. https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-2017-report-and-data 7. Ehling, S., & Reddy, T. M. (2015). Analysis of glyphosate and aminomethylphosphonic acid in nutritional ingredients and milk by derivatization with fluorenylmethyloxycarbonyl chloride and liquid chromatography-mass spectrometry. Journal of Agricultural and Food Chemistry, 63(48), 10562-10568. https://doi.org/10.1021/acs.jafc.5b04453 8. NZ Ministry for Primary Industries. (2012). Dairy national chemical contaminants programme - raw milk result summary 2011/12. Retrieved 12/15/2015 from http://www.foodsafety.govt.nz/elibrary/industry/dairy-nccp-results-summary.pdf 9. Steinborn, A., Alder, L., Michalski, B., Zomer, P., Bendig, P., Martinez, S. A., Mol, H. G., Class, T. J., & Costa Pinheiro, N. (2016). Determination of glyphosate levels in breast milk

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
						samples from Germany by LC-MS/MS and GC-MS/MS. <i>Journal of Agricultural and Food Chemistry</i>, 64(6), 1414-1421., https://doi.org/10.1021/acs.jafc.5b05852 10. von Soosten, D., Meyer, U., Hütther, L., Dänicke, S., Lahrssen-Wiederholt, M., Schafft, H., Spolders, M., & Breves, G. (2016). Excretion pathways and ruminal disappearance of glyphosate and its degradation product aminomethylphosphonic acid in dairy cows. <i>Journal of Dairy Science</i>, 99(7), 5318-5324. https://doi.org/10.3168/jds.2015-10585 11. Zhao, J., Pacenka, S., Wu, J., Richards, B. K., Steenhuis, T., Simpson, K., & Hay, A. G. (2018). Detection of glyphosate residues in companion animal feeds. <i>Environmental Pollution</i>, 243(Pt B), 1113-1118. https://doi.org/10.1016/j.envpol.2018.08.100 The article is not reliable.
18	CA 5.9	Donato F. <i>et al.</i>	2020	Exposure to glyphosate and risk of non-Hodgkin lymphoma and multiple myeloma: an updated meta-analysis.	La Medicina del lavoro, (2020) Vol. 111, No. 1, pp. 63-73	5.4.1 case b) relevant but supplementary information: The publication is considered not reliable because there is nothing that has been done in this (or other) meta-analysis to address recall bias, selection bias, and failure to control for confounding factors in the NHL case-control studies. The article was downgraded to Category B due to its non-reliability.
19	CA 5.9	Eddleston M.	2020	Poisoning by pesticides.	Medicine, (2020) Vol. 48, No. 3, pp. 214-217	5.4.1 case b) relevant but supplementary information: This is a review article discussing clinical features and management of pesticide overdoses. The article comments that glyphosate has much lower toxicity in acute overdose than older pesticides and discusses the use of supportive care in these overdoses. Since this describes the management of suicidal overdoses it should not impact the risk assessment / re-registration.
31	CA 5.9	Rajput R. <i>et al.</i>	2019	Haemodialysis as an imperative treating modality in severe glyphosate-surfactant poisoning.	Journal, Indian Academy of Clinical Medicine, (2019) Vol. 20, No. 3-4, pp. 224-226	5.4.1 case b) relevant but supplementary information: This is a case report of a patient who developed hyperkalaemia, renal failure and pulmonary edema after a suicidal ingestion of formulated glyphosate. These clinical features are common with large ingestions. Hemodialysis is standard of care in cases such as these. This report raises no new clinical features regarding this type of overdose and should not impact risk assessment / re-registration.
32	CA 5.9	Ren Y. <i>et al.</i>	2020	Cases report of gastrointestinal hemorrhage caused by glyphosate herbicides.	Acta Medica Mediterranea, (2020) Vol. 36, No. 3, pp. 1611-1614	5.4.1 case b) relevant but supplementary information: This article describes two patients with GI hemorrhage after formulated glyphosate ingestion. According to the history, the first patient drank excessive amounts of ethanol for a long time, which in and of itself can contribute to GI ulceration and bleeding. He also ingested triazolone. This patient's course appears to be atypical as the patient appears to have been stable on admission, was in the hospital for weeks, underwent multiple endoscopic procedures for 2 weeks after ingestion and later developed significant GI bleeding necessitating a gastrectomy. In formulated glyphosate overdoses, corrosive injury to the GI tract occurs early due to the surfactant. The second patient in this report also presented with corrosive injury to the GI tract which is not unexpected. Since this paper describes suicidal ingestions it should not impact the risk assessment / re-registration.
36	CA 5.9	Soukup S. T. <i>et al.</i>	2020	Glyphosate and AMPA levels in human urine samples and their correlation with food consumption: results of the	Archives of toxicology, (2020) Vol. 94, No. 5, pp. 1575-1584	5.4.1 case b) relevant but supplementary information: The authors calculated the intake of glyphosate and AMPA based on urinary concentrations and checked this value against the EU acceptable daily intake (ADI) value for glyphosate. The exposure to glyphosate and AMPA was found to be very low. Quantifiable levels of glyphosate and/or AMPA was detected in 8.3% (25 out of 301) of the participants with the highest reported value (0.63 µg/kg BW) being 0.13% of the ADI.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
				cross-sectional KarMeN study in Germany.		24-hr urine samples were collected from 301 adults for analysis of glyphosate. The study subjects were recruited to be healthy and not taking medications. The glyphosate exposures as a percent of the ADI were calculated. However, unlike previous studies, this calculation was not derived using assumptions for body weight or volume of urine. Rather, ADIs were calculated for each study subject using their own body weight and 24-hr urine excretion. Samples were analyzed using an LC-MS/MS that was modified by the procedure of Jensen <i>et al.</i> (1), and 66.5% had neither no detectable glyphosate nor AMPA in urine. Glyphosate and/or AMPA was quantifiable detected in 8.3% of participants with a maximum glyphosate exposure of 0.63 µg/kg BW, which was 0.13% of the ADI. The maximum intake of AMPA + glyphosate corresponded to 0.16% of the ADI. This study also used 24-hr dietary recalls and did rank-order correlations to estimate food sources of glyphosate and AMPA. This was done based solely of the amount of food and not glyphosate content of the food. Nevertheless, they found that consumption of pulses and mushrooms were correlated with glyphosate and AMPA in urine, respectively. Absorbed glyphosate is not metabolized in the body suggesting that ingestion of AMPA per se, not glyphosate, was responsible for urinary AMPA. As a result of their study, the authors concluded that “based on the current risk assessment of glyphosate by EFSA, such exposure levels are not expected to pose any risk to human health. The detected associations with consuming certain foods are in line with reports on glyphosate and AMPA residues in food.” References 1. Jensen, P. K., Wujcik, C. E., McGuire, M. K., and McGuire, M. A. (2016) Validation of reliable and selective methods for direct determination of glyphosate and aminomethylphosphonic acid in milk and urine using LC-MS/MS. <i>Journal of Environmental Science and Health. Part. B, Pesticides, Food Contaminants, and Agricultural Wastes</i> 51, 254-259
38	CA 5.9	Uengchuen K. <i>et al.</i>	2020	Health risk assessment on the glyphosate exposure of knapsack sprayers.	Indian Journal of Public Health Research and Development, (2020) Vol. 11, No. 3, pp. 2088-2093	5.4.1 case b) relevant but supplementary information: This article describes an assessment tool designed by the researchers to evaluate level of exposure based on PPE use, self-reported symptoms 6 months after use and frequency of use. They found that most farmers used PPE and had minimal symptoms such as burning eyes which may be due to the surfactant in formulations. There were no severe symptoms and no description of long-term outcomes. This descriptive article describes self-reported non-specific symptoms (nausea, headache, rash, burning eyes) in glyphosate users and should not affect the risk assessment / re-registration.
39	CA 5.9	Yang F. <i>et al.</i>	2020	Acute obstructive fibrinous laryngotracheobronchitis induced by severe glyphosate surfactant intoxication: A case report.	World journal of emergency medicine, (2020) Vol. 11, No. 2, pp. 125-126	5.4.1 case b) relevant but supplementary information: This is a case report describing a patient who developed fibrinous tracheobronchitis after a suicide attempt with formulated glyphosate. Since the surfactant can cause corrosive injury and the patient had evidence of aspiration, this would be a possible side effect. Since this reflects a suicidal ingestion, it should not impact the risk assessment / re-registration.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
41	CA 5.9	Zhang F. <i>et al.</i>	2020	Concentration Distribution and Analysis of Urinary Glyphosate and Its Metabolites in Occupationally Exposed Workers in Eastern China.	International journal of environmental research and public health, (2020) Vol. 17, No. 8, Art. No. 2943	5.4.1 case b) relevant but supplementary information: This study followed workers who were occupationally exposed to glyphosate in a manufacturing facility. They measured ambient air concentrations and then measured urinary concentrations of glyphosate and AMPA and found that the detection rates of glyphosate (>0.020mg/L) and AMPA (>0.010mg/L) were 86.6% (116/134) and 81.3% (109/134), respectively. The median values were 0.292 mg/L and 0.068 mg/L for urinary glyphosate and AMPA. There was variability in exposure based on where the worker was physically in the plant. This study was looking at biomarkers for exposure and makes no health claims regarding these exposures.
15	CA 8.2.1	Al-Kawaz J. M.	2019	Effect of acute toxicity of glyphosate in gold fish <i>Carassius auratus</i> .	Annals of Tropical Medicine and Public Health, (2019) Vol. 22, No. Special Issue 5, Art No. SP173	5.4.1 case b) relevant but supplementary information: This is a dose-response laboratory study on the 96-h acute toxicity to goldfish (<i>Carassius auratus</i>) with an endpoint of 96-h LC50 = 14.55 ppm. 4 concentrations were tested. Behavioural, morphological and histopathological changes were recorded. No analytical verifications, no control results and no information on origin / any previous exposure of fishes is available. No statistical information provided. In addition, Glyphosate was not sufficiently documented. Fish used in test were collected from fish shops and they were not correctly reported. Previous exposure to pesticides cannot be excluded. The article was downgraded to Category B due to its non-reliability.
20	CA 8.2.1	Erhunmwunse N. O. <i>et al.</i>	2018	Acute toxicity of glyphosate-based Isopropylamine formulation to juvenile African catfish (<i>Clarias gariepinus</i>).	Nigerian Journal of Basic and Applied Sciences (2018) Vol. 26, No. 2, pp. 97-101	5.4.1 case b) relevant but supplementary information: This is a dose-response laboratory study on the 96-h acute toxicity to African catfish (<i>Clarias gariepinus</i>) juveniles with an endpoint of 96-h LC50 = 300 mg/L. However, there is a lack of analytical verifications of the substance concentration in water. No clear origin of the fishes. Unit of the endpoint is unclear (no information whether the endpoint refers to the formulation, glyphosate or its salt). Test item cannot be identified from the article. Test design stated as being based on total residual chlorine in abstract - but it does state in the methods that OECD (1992) procedure was used, which refers to the OECD 203 acute test guideline from July 1992. Concerning fish loading - if the test employed 60 L aquariums - which cannot be confirmed, the loading is too high (approx. 18 g fish/L) compared to OECD 1992 procedure for acute fish testing of approx 1 g fish/L. The article was downgraded to Category B due to its non-reliability.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
25	CA 8.2.1	Kharat T. L. <i>et al.</i>	2016	Effect of glyphosate roundup on oxygen consumption in freshwater fish <i>Rasbora daniconius</i>	Ecscan, (2016) Vol. 9, No., Spec.Iss., pp. 567-571	5.4.1 case b) relevant but supplementary information: This is a dose-response laboratory study on the 96-h acute toxicity to a local fish species (<i>Rasbora daniconius</i>) with an endpoint of 96-h LC50 = 5.66 mg/L. 7 concentrations were tested. Oxygen consumption was measured in a separate test when fishes are exposed to control, lethal and sub-thel concentration of the formulation in water. Behavioural and morphological observations were also made. There is a lack of analytical verifications. No statistical analysis. Glyphosate was not sufficiently documented, No information given about the control. Other relevant methodological information not provided. Wild-caught fish used in test, previous exposure to pesticides cannot be excluded. No test guideline stated. Fitness of test population unknown. Exposure test conditions, test media preparation, environmental controls - all were not defined / no water quality data reported in the results. Fish weights reported, but as test design not presented, the fish loading and influence on outcome of results cannot be determined. Uncertainty in the results based on errors in the results table i.e. 70% mortality stated to have occurred at the 4.6 mg/L rate, when the text and the report table suggest only 30% mortality. The article was downgraded to Category B due to its non-reliability.
33	CA 8.2.1	Sanudi F. <i>et al.</i>	2018	Lethal toxicity of glyphosate herbicide on koi carp, <i>Cyprinus carpio</i> (Linnaeus, 1758) fingerlings.	Toxicology International, (2018) Vol. 25, No. 2, pp. 139-141	5.4.1 case b) relevant but supplementary information: Bioassay experiments were conducted to determine the lethal toxicity of glyphosate herbicide on Koi carp, <i>Cyprinus carpio</i> fingerlings. The fishes were exposed to different concentrations of glyphosate and mortality was recorded after every 6 h for a period of 96 h. The 96 h LC50 concentration for glyphosate on Koi carp fingerlings was found to be 33.2 mg/L. There is no test item information, nor biological observation data presented to corroborate the findings, in addition no chemical analysis and therefore exposure cannot be confirmed. The article was downgraded to Category B due to its non-reliability.
34	CA 8.2.1	Selvarani A. J. <i>et al.</i>	2019	Acute toxicity of glyphosate herbicide on Nile tilapia (<i>Oreochromis niloticus</i>)	International Journal of Current Microbiology and Applied Sciences, (2019) Vol. 8, No. 10, pp. 61-68	5.4.1 case b) relevant but supplementary information: This test was performed in a static renewal regime with Nile tilapia (<i>Oreochromis niloticus</i>) exposed to 5 different concentrations of glyphosate (15.33, 30.67, 61.34, 122.68 and 245.36 mg/L) for 96 hours. Mortality was recorded but also the gill, liver and kidney tissues were dissected out. Lack of analytical verifications of the substance concentration in water but exposure medium was changed every 24 h to maintain the desired concentrations. The test item is not identified. There is no chemical analysis. Water quality measurements have / appear to have only been done at the test start. A table is presented, but whether this is starting or duration derived values is unknown. Fish loading during the 96 hr test is excessive. 10 x 100 g fish in 50 litres = 20 g fish / litre. US EPA requires 0.8 g fish/L; OECD requires 1.0 g/L. This study would be considered invalid in the EU and the US for these reasons. The article was downgraded to Category B due to its non-reliability.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
35	CA 8.2.4.2; CA 8.2.6.2	Solis-Gonzalez G. <i>et al.</i>	2019	Acute toxicity of N-(phosphonomethyl) glycine herbicide on planktonic microorganisms <i>Artemia franciscana</i> and <i>Microcystis aeruginosa</i> .	TIP Revista Especializada en Ciencias Químico-Biológicas, (2019) Vol. 22, pp. 1-8	5.4.1 case b) relevant but supplementary information: The aim of this research was to evaluate the median lethal concentration at 24h in <i>Artemia franciscana</i> , as well as the median population inhibitory concentration and the coefficient of form in the cyanobacterium <i>Microcystis aeruginosa</i> in aquatic ecosystems. The calculated endpoint for <i>A. franciscana</i> was 24-h LC50 = 0.31 mg/L and for <i>M. aeruginosa</i> was 72-h ErC50 = 53.95 mg/L. Lack of analytical verifications during the test. Tested concentrations and dissolved oxygen (for invertebrate species) was not reported. For the additional aquatic invertebrate species, mortality was calculated at 24h (instead of at 48h). As raw data are not provided, it is not possible to check the validity criteria of the tests. The endpoints and the performance of the controls cannot be validated. The article was downgraded to Category B due to its non-reliability.
28	CA 8.2.6	Nagai T.	2019	Sensitivity differences among seven algal species to 12 herbicides with various modes of action.	Journal of Pesticide Science (2019) Vol. 44, No. 4, pp. 225-232	5.4.1 case b) relevant but supplementary information: For glyphosate no data presented that could impact the endpoints used in the risk assessment as they have been achieved using a method that is not recognised at the EU level. Reference to available data is considered a secondary source and therefore not relevant to EU renewal. Validity criteria not reported. ErC50 were calculated at 96h instead of at 72h. The initial green algae biomass concentration was not reported. The test substance was not clearly identified (purity unclear). Control results are missing.
40	CA 8.2.6	Ye J. <i>et al.</i>	2019	The Growth, Apoptosis and Oxidative Stress in <i>Microcystis viridis</i> Exposed to Glyphosate	Bulletin of environmental contamination and toxicology (2019) Vol. 103, No. 4, pp. 585-589	5.4.1 case b) relevant but supplementary information: Provides information on the effects of glyphosate on the growth of <i>Microcystis viridis</i> at 4 different concentrations every 24 h for 10 days but no endpoints are given. The algal growth inhibition test was conducted according to the OECD guideline 201-Freshwater Alga and Cyanobacteria (2011). However, as no raw data and only results in figures were presented, it is not possible to check its validity criteria. No reference substance has been tested. Analytical verifications were performed but it is not clear in the study whether they are only made at the test start or also during the study. Analytically, over a 3 day period, glyphosate is very stable under illuminated conditions. Under 240 hours exposure, it is highly unlikely that the authors could have achieved such high recoveries, hence the thought would be that the measured values presented were initial measured concentrations. The duration of the study is longer than recommended (10 days instead of 3), but growth rate is recorded after 72 h. There is not sufficient information presented to corroborate the findings.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
42	CA 8.2.6.2	Zhang Y. <i>et al.</i>	2016	Inhibitory activity of 26 herbicides against the growth of <i>Scenedesmus obliquus</i>	Anhui Nongye Kexue, (2016) Vol. 44, No. 23, pp. 132-133	5.4.1 case b) relevant but supplementary information: The aim of this research was to determine the inhibitory activities of 26 herbicides against the growth of the microalgae <i>Scenedesmus obliquus</i> using an absorption spectrophotometry method. Among the 26 herbicides, glyphosate was categorized as low toxic (72 h $EyC50 = 73.9$ mg/L) and glyphosate-isopropylammonium (72 h $EyC50 = 2.21$ mg/L) as moderately toxic. Methodology of the test is poorly described and then only final conclusions are reported. The article was published in non-peer reviewed journal. Lack of analytical verifications during the test. pH not reported. Test substance is not clearly identified and tested rates are not reported. The response variable was given as yield, which may be needed to fulfil specific regulatory requirements in some EU countries. However, the data basis of the endpoint is unclear as it was also stated that inhibition concentration based on biomass was calculated. The inhibition rate was calculated using the absorption of the tested solutions and the conversion factor (cell number vs. absorption) is not known. The strain/ origin of the tested organisms is not sufficiently reported. As raw data are not provided, it is not possible to check the validity criteria of the tests. The endpoints and the performance of the controls cannot be validated. The article was downgraded to Category B due to its non-reliability.
22	CA 8.2.8	Gonzalez D. <i>et al.</i>	2019	Freshwater periphyton response to technical-grade and two commercial formulations of glyphosate.	Ecologia Austral, (2019) Vol. 29, No. 1, pp. 20-27	5.4.1 case b) relevant but supplementary information: The effects of a single glyphosate concentration (3 mg/L; 2, 5 and 9 days after application) provided by different means (pure glyphosate and 2 different formulations) on the structure of the microbial community in a freshwater microcosm were investigated. Pigments concentration, dry weight, ash-free dry weight, and algal density were determined. Effects on the control were provided and analytical verifications were made. An increase of Cyanobacteria and a decrease of algae abundances were registered in all treatments with the herbicide. The effect was greater for the formulations and lower with technical-grade glyphosate, suggesting that additives in the commercial formulations may enhance glyphosate effects. The test is not performed according to any OECD guidance, and no endpoints are given. The study is well written and published in an SCI journal. The article presents results for a microcosm type experiment where by 2 Litre treatment units were established with periphyton grown on substrates from a mesocosm. All substrates were pre-exposed to mesocosm water for 36 days, after which time substrates became colonised. Microbial communities were not assessed. Test water was prepared from centrifuged mesocosm water and then 5 pre-grown substrate boards were suspended in each of the three treatments + control. The test does not follow a recognised test design and there is some uncertainties with the methods used for identifying species and for example, how were dead diatoms determined. Despite these substrates being naturally colonised, there is no discussion over the zooplankton community that would also have been present on the substrates including / but not limited to rotifers. The influence of other factors on the periphyton assemblages on the substrates is not discussed.

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
27	CA 8.2.8	Lu T. <i>et al.</i>	2020	Understanding the influence of glyphosate on the structure and function of freshwater microbial community in a microcosm.	Environmental pollution, (2020) Vol. 260, Art. No. 114012	5.4.1 case b) relevant but supplementary information: The effects of single glyphosate concentration (2.5 mg/L, 15 days) on the structure and function of microbial communities in a freshwater microcosm were investigated. This treatment did not significantly alter the physical and chemical condition of the microcosm or the composition of the main species in the community, but the transcriptions of some cyanobacteria were significantly influenced. Under glyphosate stress, the microbial community structure did not change much, but the microbes' function varied a lot. The test is not preformed according to any OECD guidance, but the outcomes on the aquatic microbial community (algae, cyanobacteria) can be relevant for the risk assessment but no endpoints are given. There is a lack of analytical verifications of the product concentration on the artificial medium and that the samples are from a lake and therefore, previous exposure to pesticides cannot be excluded.
23	CA 8.6.	Guo L. <i>et al.</i>	2020	Effects of glyphosate and paraquat on root morphology and aboveground growth of <i>Prunus persica</i> seedlings.	Ying yong sheng tai xue bao = The journal of applied ecology, (2020) Vol. 31, No. 2, pp. 524-532	5.4.1 case b) relevant but supplementary information: The aim of the study is to examine the effects of two herbicides (glyphosate and paraquat) on vegetative growth, root structure, root-tip cell mitosis and photosynthesis in peach (<i>Prunus persica</i>) seedlings. The growth of both shoots and roots of the <i>P. persica</i> seedlings was significantly inhibited by glyphosate applied at 2.5 g/L with a plant height decrease of 31.5% compared to control. Total root length, root surface area, root volume and the number of root tips also decreased compared to the control by 39.5%, 39.5%, 49.8% and 44.6%, respectively. The test does not follow any of the recommended OECD protocols for testing terrestrial plants at the EU level. Furthermore, the test substance is not clearly identified - it is unclear whether it is a product or a technical substance. However, the test item used cannot be related to the EU representative formulation as it was stated that the product used was a 300 g/L formulation - but no other formulation details are presented. Exposure concentrations in the spray were not confirmed. No endpoints nor apical measurements presented that can be related to an EU level risk assessment for renewal purposes. The article is not reliable.
21	CP 10.3.1.1.1	Faita M. R. <i>et al.</i>	2020	Glyphosate-based herbicides and <i>Nosema</i> sp. microsporidia reduce honey bee (<i>Apis mellifera</i> L.) survivability under laboratory conditions	Journal of Apicultural Research, (2020) Vol. 59, pp. 332-342	5.4.1 case b) relevant but supplementary information: This is an acute oral toxicity test on bees performed according to the OECD 213. Collected bees in winter and spring were orally exposed to Roundup alone, <i>Nosema</i> spp. spores and a combination of both. 48-h survival after exposure to Glyphosate only (calculated as 0.08 µg a.s./bee, considering an average food consumption of 30 µL/bee) was above 95% for both winter and spring collected bees. Mortality increased when exposed to the mixture with <i>Nosema</i> spp. spores. One single glyphosate concentration and a control was tested. The study is published in a SCI peer-reviewed journal and provides relevant toxicological information on the acute oral risk to bees but no endpoints are given. There are some lacking information: no RF test conducted, no positive control was used, performance of hive was not reported. In addition, RNA profiling not used as an endpoint is EU Annex I renewal ecotox risk assessment and the outcome of the study is not very useful for the risk assessment because the tested rate is sub-lethal.

Table 35: Relevant but supplementary (category B) articles after detailed assessment: sorted by author(s)

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
13	Abdel-Halim K. Y. <i>et al.</i>	CA 5.9	2019	Glyphosate and pendimethalin in breast milk samples from Egyptian rural areas: a pilot study for infant's risk assessment	International Journal of Advanced Research, (2019) Vol. 7, No. 9, pp. 991-1002	5.4.1 case b) relevant but supplementary information: This article claims that glyphosate was detected in breast milk. There are several technical issues with this study: 1st: The solubility of glyphosate in toluene is reported as only 36 PPM. The highest sample values the paper claims is just under 30 PPM. So if we had roughly 30 PPM of glyphosate in milk and took 5 mL for analysis then the toluene would have to be capable of solubilizing 150 PPM of glyphosate! 2nd: And this is a key issue – the HPLC method lists an excitation wavelength that is higher than the emission wavelength! There are several studies evaluating whether glyphosate is detectable in cows milk. A study in human breast milk also was conducted and concluded that glyphosate was not detectable. References: 1. Michelle K McGuire, Mark A McGuire, William J Price, Bahman Shafii, Janae M Carrothers, Kimberly A Lackey, Daniel A Goldstein, Pamela K Jensen, John L Vicini, Glyphosate and aminomethylphosphonic acid are not detectable in human milk, The American Journal of Clinical Nutrition, Volume 103, Issue 5, May 2016, Pages 1285–1290, https://doi.org/10.3945/ajcn.115.126854 2. EFSA. (2018). National summary reports on pesticide residue analysis performed in 2016. EFSA Journal, 16(7), 5348. https://doi.org/10.2903/sp.efsa.2018.EN-1454 3. EFSA. (2019). The 2017 European Union report on pesticide residues in food. EFSA Journal, 17(6), 5743. https://doi.org/10.2903/j.efsa.2019.5743 4. EFSA. (2020). The 2018 European Union report on pesticide residues in food. EFSA Journal, 18(4), e06057. https://doi.org/10.2903/j.efsa.2020.6057 5. FDA. (2018). Pesticide residue monitoring program. Fiscal year 2016 pesticide report. FDA. https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm618247.htm 6. FDA. (2019). Pesticide residue monitoring program fiscal year 2017 pesticide report. https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-2017-report-and-data 7. Ehling, S., & Reddy, T. M. (2015). Analysis of glyphosate and aminomethylphosphonic acid in nutritional ingredients and milk by derivatization with fluorenylmethyloxycarbonyl chloride and liquid chromatography-mass spectrometry. Journal of Agricultural and Food Chemistry, 63(48), 10562-10568. https://doi.org/10.1021/acs.jafc.5b04453 8. NZ Ministry for Primary Industries. (2012). Dairy national chemical contaminants programme - raw milk result summary 2011/12. Retrieved 12/15/2015 from http://www.foodsafety.govt.nz/elibrary/industry/dairy-nccp-results-summary.pdf 9. Steinborn, A., Alder, L., Michalski, B., Zomer, P., Bendig, P., Martinez, S. A., Mol, H. G., Class, T. J., & Costa Pinheiro, N. (2016). Determination of glyphosate levels in breast milk samples from Germany by LC-MS/MS and GC-MS/MS. Journal of Agricultural and Food Chemistry, 64(6), 1414-1421., https://doi.org/10.1021/acs.jafc.5b05852 10. von Soosten, D., Meyer, U., Hütther, L., Dänicke, S., Lahrssen-Wiederholt, M., Schafft, H., Spolders, M., & Breves, G. (2016). Excretion pathways and ruminal disappearance of glyphosate and its degradation product aminomethylphosphonic acid in dairy cows. Journal of

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
						Dairy Science, 99(7), 5318-5324. https://doi.org/10.3168/jds.2015-10585 11. Zhao, J., Pacenka, S., Wu, J., Richards, B. K., Steenhuis, T., Simpson, K., & Hay, A. G. (2018). Detection of glyphosate residues in companion animal feeds. Environmental Pollution, 243(Pt B), 1113-1118. https://doi.org/10.1016/j.envpol.2018.08.100 The article is not reliable.
14	Ait-Bali Y. <i>et al.</i>	CA 5.6	2020	Pre- and postnatal exposure to glyphosate-based herbicide causes behavioral and cognitive impairments in adult mice: evidence of cortical ad hippocampal dysfunction.	Archives of toxicology, (2020) Vol. 94, No. 5, pp. 1703-1723	5.4.1 case b) relevant but supplementary information: In vivo study on pre and post natal effects of Roundup on swiss mice at 2 different doses only, no OECD guideline followed, no GLP status stated, no HCD provided. Oral gavage dosing of formulated product is not relevant to real life exposure scenarios. Environmental fate and metabolism for glyphosate active ingredient versus surfactants are different, and oral co-exposures to mammals at the excessively high doses tested in this case are considered irrelevant to human health risk assessment. In addition, insufficient information is provided to determine which formulation was tested and whether it is the glyphosate EU representative formulation.
15	Al-Kawaz J. M.	CA 8.2.1	2019	Effect of acute toxicity of glyphosate in gold fish <i>Carassius auratus</i> .	Annals of Tropical Medicine and Public Health, (2019) Vol. 22, No. Special Issue 5, Art No. SP173	5.4.1 case b) relevant but supplementary information: This is a dose-response laboratory study on the 96-h acute toxicity to goldfish (<i>Carassius auratus</i>) with an endpoint of 96-h LC50 = 14.55 ppm. 4 concentrations were tested. Behavioural, morphological and histopathological changes were recorded. No analytical verifications, no control results and no information on origin / any previous exposure of fishes is available. No statistical information provided. In addition, Glyphosate was not sufficiently documented. Fish used in test were collected from fish shops and they were not correctly reported. Previous exposure to pesticides cannot be excluded. The article was downgraded to Category B due to its non-reliability.
16	Berry C.	CA 5.5	2020	Glyphosate and cancer: the importance of the whole picture.	Pest management science, (2020); doi: 10.1002/ps.5834; Online ahead of print.	5.4.1 case b) relevant but supplementary information: The author is providing a general picture of the carcinogenic and genotoxic profile of Glyphosate by commenting the different studies available and the different conclusions made by IARC and Regulatory authorities. There is no evidence in the animals studies to support the IARC conclusion that glyphosate is a probable human carcinogen. The article does not provide any new information.
17	Cai W. <i>et al.</i>	CA 5.6	2020	Low-dose Roundup induces developmental toxicity in bovine preimplantation embryos in vitro.	Environmental science and pollution research international, (2020) Vol. 27, No. 14, pp. 16451-16459	5.4.1 case b) relevant but supplementary information: The effects of Roundup at 3 doses was investigated on the bovine preimplantation embryo. Direct dosing of formulated product to fertilized embryos in vitro, is not relevant to real life exposure scenarios. Environmental fate, metabolism and pharmacokinetics for glyphosate active ingredient versus surfactants are very different, and oral co-exposures to mammals at the excessively high doses tested in this case are considered irrelevant to livestock and human health risk assessments. In addition, insufficient information is provided to determine which formulation was tested and whether it is the glyphosate EU representative formulation. No OECD guideline followed, no GLP status stated, no HCD provided and no positive control.
18	Donato F. <i>et al.</i>	CA 5.9	2020	Exposure to glyphosate and risk of non-Hodgkin lymphoma and multiple myeloma: an updated meta-analysis.	La Medicina del lavoro, (2020) Vol. 111, No. 1, pp. 63-73	5.4.1 case b) relevant but supplementary information: The publication is considered not reliable because there is nothing that has been done in this (or other) meta-analysis to address recall bias, selection bias, and failure to control for confounding factors in the NHL case-control studies. The article was downgraded to Category B due to its non-reliability.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
19	Eddleston M.	CA 5.9	2020	Poisoning by pesticides.	Medicine, (2020) Vol. 48, No. 3, pp. 214-217	5.4.1 case b) relevant but supplementary information: This is a review article discussing clinical features and management of pesticide overdoses. The article comments that glyphosate has much lower toxicity in acute overdose than older pesticides and discusses the use of supportive care in these overdoses. Since this describes the management of suicidal overdoses it should not impact the risk assessment / re-registration.
20	Erhunmwunse N. O. <i>et al.</i>	CA 8.2.1	2018	Acute toxicity of glyphosate-based Isopropylamine formulation to juvenile African catfish (<i>Clarias gariepinus</i>).	Nigerian Journal of Basic and Applied Sciences (2018) Vol. 26, No. 2, pp. 97-101	5.4.1 case b) relevant but supplementary information: This is a dose-response laboratory study on the 96-h acute toxicity to African catfish (<i>Clarias gariepinus</i>) juveniles with an endpoint of 96-h LC50 = 300 mg/L. However, there is a lack of analytical verifications of the substance concentration in water. No clear origin of the fishes. Unit of the endpoint is unclear (no information whether the endpoint refers to the formulation, glyphosate or its salt). Test item cannot be identified from the article. Test design stated as being based on total residual chlorine in abstract - but it does state in the methods that OECD (1992) procedure was used, which refers to the OECD 203 acute test guideline from July 1992. Concerning fish loading - if the test employed 60 L aquariums - which cannot be confirmed, the loading is too high (approx. 18 g fish/L) compared to OECD 1992 procedure for acute fish testing of approx 1 g fish/L. The article was downgraded to Category B due to its non-reliability.
21	Faita M. R. <i>et al.</i>	CP 10.3.1.1.1	2020	Glyphosate-based herbicides and <i>Nosema</i> sp. microsporidia reduce honey bee (<i>Apis mellifera</i> L.) survivability under laboratory conditions	Journal of Apicultural Research, (2020) Vol. 59, pp. 332-342	5.4.1 case b) relevant but supplementary information: This is an acute oral toxicity test on bees performed according to the OECD 213. Collected bees in winter and spring were orally exposed to Roundup alone, <i>Nosema</i> spp. spores and a combination of both. 48-h survival after exposure to Glyphosate only (calculated as 0.08 µg a.s./bee, considering an average food consumption of 30 µL/bee) was above 95% for both winter and spring collected bees. Mortality increased when exposed to the mixture with <i>Nosema</i> spp. spores. One single glyphosate concentration and a control was tested. The study is published in a SCI peer-reviewed journal and provides relevant toxicological information on the acute oral risk to bees but no endpoints are given. There are some lacking information: no RF test conducted, no positive control was used, performance of hive was not reported. In addition, RNA profiling not used as an endpoint is EU Annex I renewal ecotox risk assessment and the outcome of the study is not very useful for the risk assessment because the tested rate is sub-lethal.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
22	Gonzalez D. <i>et al.</i>	CA 8.2.8	2019	Freshwater periphyton response to technical-grade and two commercial formulations of glyphosate.	Ecologia Austral, (2019) Vol. 29, No. 1, pp. 20-27	5.4.1 case b) relevant but supplementary information: The effects of a single glyphosate concentration (3 mg/L; 2, 5 and 9 days after application) provided by different means (pure glyphosate and 2 different formulations) on the structure of the microbial community in a freshwater microcosm were investigated. Pigments concentration, dry weight, ash-free dry weight, and algal density were determined. Effects on the control were provided and analytical verifications were made. An increase of Cyanobacteria and a decrease of algae abundances were registered in all treatments with the herbicide. The effect was greater for the formulations and lower with technical-grade glyphosate, suggesting that additives in the commercial formulations may enhance glyphosate effects. The test is not performed according to any OECD guidance, and no endpoints are given. The study is well written and published in an SCI journal. The article presents results for a microcosm type experiment where by 2 Litre treatment units were established with periphyton grown on substrates from a mesocosm. All substrates were pre-exposed to mesocosm water for 36 days, after which time substrates became colonised. Microbial communities were not assessed. Test water was prepared from centrifuged mesocosm water and then 5 pre-grown substrate boards were suspended in each of the three treatments + control. The test does not follow a recognised test design and there is some uncertainties with the methods used for identifying species and for example, how were dead diatoms determined. Despite these substrates being naturally colonised, there is no discussion over the zooplankton community that would also have been present on the substrates including / but not limited to rotifers. The influence of other factors on the periphyton assemblages on the substrates is not discussed.
23	Guo L. <i>et al.</i>	CA 8.6.	2020	Effects of glyphosate and paraquat on root morphology and aboveground growth of <i>Prunus persica</i> seedlings.	Ying yong sheng tai xue bao = The journal of applied ecology, (2020) Vol. 31, No. 2, pp. 524-532	5.4.1 case b) relevant but supplementary information: The aim of the study is to examine the effects of two herbicides (glyphosate and paraquat) on vegetative growth, root structure, root-tip cell mitosis and photosynthesis in peach (<i>Prunus persica</i>) seedlings. The growth of both shoots and roots of the <i>P. persica</i> seedlings was significantly inhibited by glyphosate applied at 2.5 g/L with a plant height decrease of 31.5% compared to control. Total root length, root surface area, root volume and the number of root tips also decreased compared to the control by 39.5%, 39.5%, 49.8% and 44.6%, respectively. The test does not follow any of the recommended OECD protocols for testing terrestrial plants at the EU level. Furthermore, the test substance is not clearly identified - it is unclear whether it is a product or a technical substance. However, the test item used cannot be related to the EU representative formulation as it was stated that the product used was a 300 g/L formulation - but no other formulation details are presented. Exposure concentrations in the spray were not confirmed. No endpoints nor apical measurements presented that can be related to an EU level risk assessment for renewal purposes. The article is not reliable.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
24	Jeon S. <i>et al.</i>	CA 5.5	2020	Glyphosate influences cell proliferation in vitro.	Frontiers in Life Science, (2020) Vol. 13, No. 1, pp. 54-65	5.4.1 case b) relevant but supplementary information: Glyphosate was tested in vitro at a range of doses to investigate its effects on cell growth and proliferation in human cells. In conclusion, Glyphosate increases the rate of cell growth in human embryonic kidney 293 (HEK293) cells. Glyphosate promotes cell proliferation by activating gene expression of cell cycle regulators in humans in vitro. Useful information but not altering risk assessment and data requirement and difficult to be used because no HCD. No positive control were used, no statistics methods were described. Furthermore, no OECD guideline followed, no GLP status stated. The article is not reliable.
25	Kharat T. L. <i>et al.</i>	CA 8.2.1	2016	Effect of glyphosate roundup on oxygen consumption in freshwater fish <i>Rasbora daniconius</i>	Ecscan, (2016) Vol. 9, No., Spec.Iss., pp. 567-571	5.4.1 case b) relevant but supplementary information: This is a dose-response laboratory study on the 96-h acute toxicity to a local fish species (<i>Rasbora daniconius</i>) with an endpoint of 96-h LC50 = 5.66 mg/L. 7 concentrations were tested. Oxygen consumption was measured in a separate test when fishes are exposed to control, lethal and sub-thel concentration of the formulation in water. Behavioural and morphological observations were also made. There is a lack of analytical verifications. No statistical analysis. Glyphosate was not sufficiently documented, No information given about the control. Other relevant methodological information not provided. Wild-caught fish used in test, previous exposure to pesticides cannot be excluded. No test guideline stated. Fitness of test population unknown. Exposure test conditions, test media preparation, environmental controls - all were not defined / no water quality data reported in the results. Fish weights reported, but as test design not presented, the fish loading and influence on outcome of results cannot be determined. Uncertainty in the results based on errors in the results table i.e. 70% mortality stated to have occurred at the 4.6 mg/L rate, when the text and the report table suggest only 30% mortality. The article was downgraded to Category B due to its non-reliability.
26	Levine S. L. <i>et al.</i>	CA 5.8.2	2020	Review and Analysis of the Potential for Glyphosate to Interact with the Estrogen, Androgen, and Thyroid Pathways.	Pest management science, (2020), DOI 10.1002/ps.5983	5.4.1 case b) relevant but supplementary information: A systematic literature review was performed including US EPA EDSP Tier 1 battery assessment, guideline regulatory studies, ESDP including 5 in vitro and 6 in vivo assays to evaluate the EAT pathways. From the available literature, it was concluded that glyphosate does not have an endocrine disrupting potential through estrogenic, androgenic or steroidogenic activity. The review includes relevant literature which has been used for the ED assessment during the current submission process. It can therefore serve as supporting information, however as a review it does not provide new primary data or alter the risk assessment. Therefore, the review has been classified as a relevant but supplementary only (EFSA 2092 GD Point 5.4.1 category B).

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
27	Lu T. <i>et al.</i>	CA 8.2.8	2020	Understanding the influence of glyphosate on the structure and function of freshwater microbial community in a microcosm.	Environmental pollution, (2020) Vol. 260, Art. No. 114012	5.4.1 case b) relevant but supplementary information: The effects of single glyphosate concentration (2.5 mg/L, 15 days) on the structure and function of microbial communities in a freshwater microcosm were investigated. This treatment did not significantly alter the physical and chemical condition of the microcosm or the composition of the main species in the community, but the transcriptions of some cyanobacteria were significantly influenced. Under glyphosate stress, the microbial community structure did not change much, but the microbes' function varied a lot. The test is not preformed according to any OECD guidance, but the outcomes on the aquatic microbial community (algae, cyanobacteria) can be relevant for the risk assessment but no endpoints are given. There is a lack of analytical verifications of the product concentration on the artificial medium and that the samples are from a lake and therefore, previous exposure to pesticides cannot be excluded.
28	Nagai T.	CA 8.2.6	2019	Sensitivity differences among seven algal species to 12 herbicides with various modes of action.	Journal of Pesticide Science (2019) Vol. 44, No. 4, pp. 225-232	5.4.1 case b) relevant but supplementary information: For glyphosate no data presented that could impact the endpoints used in the risk assessment as they have been achieved using a method that is not recognised at the EU level. Reference to available data is considered a secondary source and therefore not relevant to EU renewal. Validity criteria not reported. ErC50 were calculated at 96h instead of at 72h. The initial green algae biomass concentration was not reported. The test substance was not clearly identified (purity unclear). Control results are missing.
29	Neto de Silva K. <i>et al.</i>	CA 5.7	2020	Glyphosate-based herbicide impairs energy metabolism and increases autophagy in C6 astrogloma cell line.	Journal of toxicology and environmental health. Part A, (2020) Vol. 83, No. 4, pp. 153-167	5.4.1 case b) relevant but supplementary information: In vitro study on the effects of micromolar concentrations of a glyphosate-based herbicide on energy metabolism and mitochondrial mass in astrogloma cell line exposed for 24 h to the herbicide at 3 concentrations below 160 µM. However, insufficient information provided to identify which formulation was tested. No positive control was used, no statistics methods were described, no OECD guideline followed, no GLP status stated, no HCD provided. In addition, astrocytes in real life are not co-exposed to the combination of glyphosate + surfactant formulants, based on their very different environmental fates and pharmaco-kinetics.
30	Parks C. G. <i>et al.</i>	CA 5.8.2	2019	Lifetime pesticide use and antinuclear antibodies in male farmers from the agricultural health study	Frontiers in Immunology (2019) Vol. 10, Art. No. 1476	5.4.1 case b) relevant but supplementary information: The development of systemic autoimmunity in response to pesticide exposure was investigated in a retrospective study farmers. Serum antinuclear autoantibodies were measured by immunofluorescence on Hep-2 cells in 668 male farmers. The effect of lifetime use of 46 pesticides (glyphosate among them) on ANA were investigated. The results for glyphosate use demonstrate no increase the risk of farmers developing systemic autoimmunity. This information is useful in a weight of evidence assessment for the measured endpoint, which, however, is not a critical endpoint identified for human health risk assessment of glyphosate.
31	Rajput R. <i>et al.</i>	CA 5.9	2019	Haemodialysis as an imperative treating modality in severe glyphosate-surfactant poisoning.	Journal, Indian Academy of Clinical Medicine, (2019) Vol. 20, No. 3-4, pp. 224-226	5.4.1 case b) relevant but supplementary information: This is a case report of a patient who developed hyperkalaemia, renal failure and pulmonary edema after a suicidal ingestion of formulated glyphosate. These clinical features are common with large ingestions. Hemodialysis is standard of care in cases such as these. This report raises no new clinical features regarding this type of overdose and should not impact risk assessment / re-registration.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
32	Ren Y. <i>et al.</i>	CA 5.9	2020	Cases report of gastrointestinal hemorrhage caused by glyphosate herbicides.	Acta Medica Mediterranea, (2020) Vol. 36, No. 3, pp. 1611-1614	5.4.1 case b) relevant but supplementary information: This article describes two patients with GI hemorrhage after formulated glyphosate ingestion. According to the history, the first patient drank excessive amounts of ethanol for a long time, which in and of itself can contribute to GI ulceration and bleeding. He also ingested triazolone. This patient's course appears to be atypical as the patient appears to have been stable on admission, was in the hospital for weeks, underwent multiple endoscopic procedures for 2 weeks after ingestion and later developed significant GI bleeding necessitating a gastrectomy. In formulated glyphosate overdoses, corrosive injury to the GI tract occurs early due to the surfactant. The second patient in this report also presented with corrosive injury to the GI tract which is not unexpected. Since this paper describes suicidal ingestions it should not impact the risk assessment / re-registration.
33	Sanudi F. <i>et al.</i>	CA 8.2.1	2018	Lethal toxicity of glyphosate herbicide on koi carp, cyprinus carpio (Linnaeus, 1758) fingerlings.	Toxicology International, (2018) Vol. 25, No. 2, pp. 139-141	5.4.1 case b) relevant but supplementary information: Bioassay experiments were conducted to determine the lethal toxicity of glyphosate herbicide on Koi carp, Cyprinus carpio fingerlings. The fishes were exposed to different concentrations of glyphosate and mortality was recorded after every 6 h for a period of 96 h. The 96 h LC50 concentration for glyphosate on Koi carp fingerlings was found to be 33.2 mg/L. There is no test item information, nor biological observation data presented to corroborate the findings, in addition no chemical analysis and therefore exposure cannot be confirmed. The article was downgraded to Category B due to its non-reliability.
34	Selvarani A. J. <i>et al.</i>	CA 8.2.1	2019	Acute toxicity of glyphosate herbicide on Nile tilapia (Oreochromis niloticus)	International Journal of Current Microbiology and Applied Sciences, (2019) Vol. 8, No. 10, pp. 61-68	5.4.1 case b) relevant but supplementary information: This test was performed in a static renewal regime with Nile tilapia (Oreochromis niloticus) exposed to 5 different concentrations of glyphosate (15.33, 30.67, 61.34, 122.68 and 245.36 mg/L) for 96 hours. Mortality was recorded but also the gill, liver and kidney tissues were dissected out. Lack of analytical verifications of the substance concentration in water but exposure medium was changed every 24 h to maintain the desired concentrations. The test item is not identified. There is no chemical analysis. Water quality measurements have / appear to have only been done at the test start. A table is presented, but whether this is starting or duration derived values is unknown. Fish loading during the 96 hr test is excessive. 10 x 100 g fish in 50 litres = 20 g fish / litre. US EPA requires 0.8 g fish/L; OECD requires 1.0 g/L. This study would be considered invalid in the EU and the US for these reasons. The article was downgraded to Category B due to its non-reliability.
35	Solis-Gonzalez G. <i>et al.</i>	CA 8.2.4.2; CA 8.2.6.2	2019	Acute toxicity of N-(phosphonomethyl) glycine herbicide on planktonic microorganisms Artemia franciscana and Microcystis aeruginosa.	TIP Revista Especializada en Ciencias Químico-Biológicas, (2019) Vol. 22, pp. 1-8	5.4.1 case b) relevant but supplementary information: The aim of this research was to evaluate the median lethal concentration at 24h in Artemia franciscana, as well as the median population inhibitory concentration and the coefficient of form in the cyanobacterium Microcystis aeruginosa in aquatic ecosystems. The calculated endpoint for A. franciscana was 24-h LC50 = 0.31 mg/L and for M. aeruginosa was 72-h ErC50 = 53.95 mg/L. Lack of analytical verifications during the test. Tested concentrations and dissolved oxygen (for invertebrate species) was not reported. For the additional aquatic invertebrate species, mortality was calculated at 24h (instead of at 48h). As raw data are not provided, it is not possible to check the validity criteria of the tests. The endpoints and the performance of the controls cannot be validated. The article was downgraded to Category B due to its non-reliability.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
36	Soukup S. T. <i>et al.</i>	CA 5.9	2020	Glyphosate and AMPA levels in human urine samples and their correlation with food consumption: results of the cross-sectional KarMeN study in Germany.	Archives of toxicology, (2020) Vol. 94, No. 5, pp. 1575-1584	5.4.1 case b) relevant but supplementary information: The authors calculated the intake of glyphosate and AMPA based on urinary concentrations and checked this value against the EU acceptable daily intake (ADI) value for glyphosate. The exposure to glyphosate and AMPA was found to be very low. Quantifiable levels of glyphosate and/or AMPA was detected in 8.3% (25 out of 301) of the participants with the highest reported value (0.63 µg/kg BW) being 0.13% of the ADI. 24-hr urine samples were collected from 301 adults for analysis of glyphosate. The study subjects were recruited to be healthy and not taking medications. The glyphosate exposures as a percent of the ADI were calculated. However, unlike previous studies, this calculation was not derived using assumptions for body weight or volume of urine. Rather, ADIs were calculated for each study subject using their own body weight and 24-hr urine excretion. Samples were analyzed using an LC-MS/MS that was modified by the procedure of Jensen <i>et al.</i> (1), and 66.5% had neither no detectable glyphosate nor AMPA in urine. Glyphosate and/or AMPA was quantifiable detected in 8.3% of participants with a maximum glyphosate exposure of 0.63 µg/kg BW, which was 0.13% of the ADI. The maximum intake of AMPA + glyphosate corresponded to 0.16% of the ADI. This study also used 24-hr dietary recalls and did rank-order correlations to estimate food sources of glyphosate and AMPA. This was done based solely of the amount of food and not glyphosate content of the food. Nevertheless, they found that consumption of pulses and mushrooms were correlated with glyphosate and AMPA in urine, respectively. Absorbed glyphosate is not metabolized in the body suggesting that ingestion of AMPA per se, not glyphosate, was responsible for urinary AMPA. As a result of their study, the authors concluded that “based on the current risk assessment of glyphosate by EFSA, such exposure levels are not expected to pose any risk to human health. The detected associations with consuming certain foods are in line with reports on glyphosate and AMPA residues in food.” References 1. Jensen, P. K., Wujcik, C. E., McGuire, M. K., and McGuire, M. A. (2016) Validation of reliable and selective methods for direct determination of glyphosate and aminomethylphosphonic acid in milk and urine using LC-MS/MS. Journal of Environmental Science and Health. Part. B, Pesticides, Food Contaminants, and Agricultural Wastes 51, 254-259

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
37	Tang Q. <i>et al.</i>	CA 5.3	2020	Glyphosate exposure induces inflammatory responses in the small intestine and alters gut microbial composition in rats.	Environmental pollution, (2020) Vol. 261, Art. No. 114129	5.4.1 case b) relevant but supplementary information: The rats were gavaged with 0, 5, 50, and 500 mg/kg of body weight glyphosate for 35 continuous days. The different segments of the small intestine were sampled to measure indicators of oxidative stress, ion concentrations and inflammatory responses, and fresh feces were collected for microbiota analysis. The investigation of potential effects on the gut microbiome of ruminants is not a data requirement for the approval of pesticides and suitable test protocols to assess these effects are not specified in the form of official guidance documents. No GLP status stated, no HCD provided and no purity of glyphosate stated. Fundamental parameters to understand animal health and toxicology endpoints are not reported. Therefore the context of the study results can not be interpreted with any degree of certainty. The article is not reliable.
38	Uengchuen K. <i>et al.</i>	CA 5.9	2020	Health risk assessment on the glyphosate exposure of knapsack sprayers.	Indian Journal of Public Health Research and Development, (2020) Vol. 11, No. 3, pp. 2088-2093	5.4.1 case b) relevant but supplementary information: This article describes an assessment tool designed by the researchers to evaluate level of exposure based on PPE use, self-reported symptoms 6 months after use and frequency of use. They found that most farmers used PPE and had minimal symptoms such as burning eyes which may be due to the surfactant in formulations. There were no severe symptoms and no description of long-term outcomes. This descriptive article describes self-reported non-specific symptoms (nausea, headache, rash, burning eyes) in glyphosate users and should not affect the risk assessment / re-registration.
39	Yang F. <i>et al.</i>	CA 5.9	2020	Acute obstructive fibrinous laryngotracheobronchitis induced by severe glyphosate surfactant intoxication: A case report.	World journal of emergency medicine, (2020) Vol. 11, No. 2, pp. 125-126	5.4.1 case b) relevant but supplementary information: This is a case report describing a patient who developed fibrinous tracheobronchitis after a suicide attempt with formulated glyphosate. Since the surfactant can cause corrosive injury and the patient had evidence of aspiration, this would be a possible side effect. Since this reflects a suicidal ingestion, it should not impact the risk assessment / re-registration.
40	Ye J. <i>et al.</i>	CA 8.2.6	2019	The Growth, Apoptosis and Oxidative Stress in <i>Microcystis viridis</i> Exposed to Glyphosate	Bulletin of environmental contamination and toxicology (2019) Vol. 103, No. 4, pp. 585-589	5.4.1 case b) relevant but supplementary information: Provides information on the effects of glyphosate on the growth of <i>Microcystis viridis</i> at 4 different concentrations every 24 h for 10 days but no endpoints are given. The algal growth inhibition test was conducted according to the OECD guideline 201-Freshwater Alga and Cyanobacteria (2011). However, as no raw data and only results in figures were presented, it is not possible to check its validity criteria. No reference substance has been tested. Analytical verifications were performed but it is not clear in the study whether they are only made at the test start or also during the study. Analytically, over a 3 day period, glyphosate is very stable under illuminated conditions. Under 240 hours exposure, it is highly unlikely that the authors could have achieved such high recoveries, hence the thought would be that the measured values presented were initial measured concentrations. The duration of the study is longer than recommended (10 days instead of 3), but growth rate is recorded after 72 h. There is not sufficient information presented to corroborate the findings.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
41	Zhang F. <i>et al.</i>	CA 5.9	2020	Concentration Distribution and Analysis of Urinary Glyphosate and Its Metabolites in Occupationally Exposed Workers in Eastern China.	International journal of environmental research and public health, (2020) Vol. 17, No. 8, Art. No. 2943	5.4.1 case b) relevant but supplementary information: This study followed workers who were occupationally exposed to glyphosate in a manufacturing facility. They measured ambient air concentrations and then measured urinary concentrations of glyphosate and AMPA and found that the detection rates of glyphosate (>0.020mg/L) and AMPA (>0.010mg/L) were 86.6% (116/134) and 81.3% (109/134), respectively. The median values were 0.292 mg/L and 0.068 mg/L for urinary glyphosate and AMPA. There was variability in exposure based on where the worker was physically in the plant. This study was looking at biomarkers for exposure and makes no health claims regarding these exposures.
42	Zhang Y. <i>et al.</i>	CA 8.2.6.2	2016	Inhibitory activity of 26 herbicides against the growth of <i>Scenedesmus obliquus</i>	Anhui Nongye Kexue, (2016) Vol. 44, No. 23, pp. 132-133	5.4.1 case b) relevant but supplementary information: The aim of this research was to determine the inhibitory activities of 26 herbicides against the growth of the microalgae <i>Scenedesmus obliquus</i> using an absorption spectrophotometry method. Among the 26 herbicides, glyphosate was categorized as low toxic (72 h EyC50 = 73.9 mg/L) and glyphosate-isopropylammonium (72 h EyC50 = 2.21 mg/L) as moderately toxic. Methodology of the test is poorly described and then only final conclusions are reported. The article was published in non-peer reviewed journal. Lack of analytical verifications during the test. pH not reported. Test substance is not clearly identified and tested rates are not reported. The response variable was given as yield, which may be needed to fulfil specific regulatory requirements in some EU countries. However, the data basis of the endpoint is unclear as it was also stated that inhibition concentration based on biomass was calculated. The inhibition rate was calculated using the absorption of the tested solutions and the conversion factor (cell number vs. absorption) is not known. The strain/ origin of the tested organisms is not sufficiently reported. As raw data are not provided, it is not possible to check the validity criteria of the tests. The endpoints and the performance of the controls cannot be validated. The article was downgraded to Category B due to its non-reliability.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
43	Zoller O. <i>et al.</i>	CA 5.1	2020	Urine glyphosate level as a quantitative biomarker of oral exposure.	International journal of hygiene and environmental health, (2020) Vol. 228, Art. No.113526	5.4.1 case b) relevant but supplementary information: This was a study with human volunteers. The trial was designed to ensure comparable exposure levels to glyphosate among participants who consumed diets with low content of glyphosate residue during the 4-day trial, except for the single meal with targeted amount of glyphosate and AMPA corresponding to an intake of 196.8 µg of glyphosate and 1.67 µg of AMPA. Only urine was collected and analysed for glyphosate and AMPA. Blood and faeces were not collected and/or analysed. This goal of the study was to estimate oral glyphosate intake using urinary biomonitoring data. However, the authors recognised that the determination of blood concentrations is necessary to improve human bioavailability data. Comparison of urinary data in humans in this study with those measured in the rat studies suggest that the systemic availability is much lower in humans than in rats and could be about 20-fold lower. However, in the absence of a mass balance, and a very low recovery of glyphosate and AMPA, the data should be considered unreliable. Given the knowledge that orally dosed glyphosate is mostly excreted via the faeces, an appropriate study design to address mass balance could easily have been implemented to make this a robust and informative investigation. Low recovery rates of glyphosate and AMPA suggest a very large capacity for errors. The study design is inadequate to confirm reliability of the findings. The lack of mass balance of analytes, despite common knowledge that orally dosed glyphosate is mostly excreted in faeces, is disappointing, given the ease with which a mass balance could have been assessed. The article was downgraded to Category B due to its non-reliability.

Table 36: Articles of unclear relevance (category C) after detailed assessment: sorted by data requirement(s)

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Table 37: Articles of unclear relevance (category C) after detailed assessment: sorted by author(s)

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point No.)	Year	Title	Source	Justification
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Table 38: Articles excluded after detailed assessment (i.e. not relevant): sorted by technical section (and by author)

Submission Number	Technical section	Author(s)	Year	Title	Source	Reason for not including publication in dossier (based on relevance and reliability criteria)
44	Ecotoxicology	Almeida P. R. <i>et al.</i>	2019	Acute toxicity (CL50) and behavioral and morphological effects of a commercial formulation with glyphosate active ingredient in tadpoles of <i>Physalaemus cuvieri</i> (Anura, Leptodactylidae) and <i>Rhinella icterica</i> (Anura, Bufonidae).	Engenharia Sanitaria e Ambiental (2019) Vol. 24, No. 6, pp. 1115-1125	The publication is not relevant as in the conclusion, the authors indicated that the product used contains POEA. POEA is not permitted for use in formulated herbicidal products in the EU. As the performance / efficacy of herbicidal formulations is dependant on the surfactant system / co-formulants, the findings in the paper cannot be related to the representative formulation, and are therefore not relevant to the risk assessment for EU renewal. In addition, there is a lack of analytical verifications of the substance concentration in water. Unit of the endpoint is unclear and no information provided whether the endpoint refers to the formulation, glyphosate or its salt.
45	Ecotoxicology	Carpenter D. J. <i>et al.</i>	2020	Effects of Herbicides on Flowering.	Environmental toxicology and chemistry, (2020) Vol. 39, No. 6, pp. 1244-1256	Although Glyphos and Glyphogan are both glyphosate 360 SL formulations, they do contain different surfactant systems. As the performance / efficacy of herbicidal formulations is dependant on the surfactant system / co-formulants, the findings in the paper cannot be related to the representative formulation, and are therefore not relevant to the risk assessment for EU renewal. The surfactant system used in glyphos and glyphogan are respectively - tallow ethoxylate based or oxyethoxylate based, whereas the surfactant used in MON 52276 is ammonium based.
46	Ecotoxicology	Fathi M. A. <i>et al.</i>	2020	Disruption of cytochrome P450 enzymes in the liver and small intestine in chicken embryos in ovo exposed to glyphosate.	Environmental science and pollution research international, (2020) Vol. 27, No. 14, pp. 16865-16875	The publication investigates the effects on antioxidant enzyme activity, histomorphology on the liver and small intestine. Enzyme, cellular and molecular level endpoints are not relevant to EU level ecotoxicology risk assessment.
47	Ecotoxicology	Kalai K. <i>et al.</i>	2019	Effect of induced chronic glyphosate toxicity in liver and kidneys of kuroiler birds.	Indian Journal of Veterinary Pathology (2019) Vol. 43, No. 3, pp. 211-216	The publication investigates biochemical, histopathological and cellular ultrastructural parameters of blood and liver tissues and only findings on cellular/molecular level are reported. Enzyme, cellular and molecular level endpoints are not relevant to EU level ecotoxicology risk assessment.
48	Ecotoxicology	Meshkini S. <i>et al.</i>	2019	acute and chronic effect of Roundup herbicide on histopathology and enzymatic antioxidant system of <i>Oncorhynchus mykiss</i>	International journal of environmental science and technology (2019) Vol. 16, No. 11, pp. 6847-6856	The principal reason for this paper not being relevant is that EPA registration No. 524-529 is a concentrate formulation (50.2%) which contains POEA surfactant. POEA is not permitted for use in formulated herbicidal products in the EU. The article is therefore not relevant to an EU regulatory risk assessment / glyphosate EU renewal.
49	Ecotoxicology	Mestre A. P. <i>et al.</i>	2020	Effects of glyphosate, cypermethrin, and chlorpyrifos on hematological parameters of the tegu lizard (<i>Salvator merianae</i>) in different embryo stages.	Chemosphere, (2020) Vol. 252, Art. No. 126433	The publication investigates haematological parameters on reptiles' embryos and only findings at the cellular/molecular level are reported. Enzyme, cellular and molecular level endpoints are not relevant to EU level ecotoxicology risk assessment.

Submission Number	Technical section	Author(s)	Year	Title	Source	Reason for not including publication in dossier (based on relevance and reliability criteria)
50	Ecotoxicology	Mottier A. <i>et al.</i>	2020	In vitro effects of glyphosate-based herbicides and related adjuvants on primary culture of hemocytes from <i>Haliotis tuberculata</i> .	Fish & shellfish immunology, (2020) Vol. 100, pp. 1-8	The publication investigates in vitro effects on hemocytes and only findings on cellular/molecular level are reported. Enzyme, cellular and molecular level endpoints are not relevant to EU level ecotoxicology risk assessment.
51	Ecotoxicology	Odetti L. M. <i>et al.</i>	2020	Genotoxicity and oxidative stress in <i>Caiman latirostris</i> hatchlings exposed to pesticide formulations and their mixtures during incubation period.	Ecotoxicology and environmental safety, (2020) Vol. 193, Art. No. 110312	In vivo study on the effects of Glyphosate-based herbicides on eggs of <i>Caiman latirostris</i> . The formulation tested (GLY Roundup® Full II (66.2%), water-soluble herbicide (12000 mg/L), containing potassium salt) is not the EU representative formulation for the glyphosate EU renewal and therefore not relevant for the EU risk assessment.
52	Ecotoxicology	Owagboriaye F. <i>et al.</i>	2020	Biochemical response and Vermiremediation assessment of three earthworm species (<i>Alma millsoni</i> , <i>Eudrilus eugeniae</i> and <i>Libyodrilus violaceus</i>) in soil contaminated with a Glyphosate-based herbicide	Ecological indicators (2020) Vol. 108, Art. No. 105678	This study aimed to evaluate the biochemical response and vermiremediation potential of three indigenous earthworm species in glyphosate treated soils. Test design and achieved results are not relateable to an EU level regulatory risk assessment for Annex I renewal.
53	Ecotoxicology	Pontes J. P. <i>et al.</i>	2020	A glyphosate-based herbicide in a free-choice test on parasitism, emergence, and female-biased sex ratio of 10 <i>Trichogrammatidae</i> .	Journal of Plant Diseases and Protection, (2020) Vol. 127, No. 1, pp. 73-79	Roundup Original DI® (a mixture of IPA and diammonium salts) is not the EU representative formulation, therefore the article is not relevant for the glyphosate EU renewal.
54	Ecotoxicology	Ruuskanen S. <i>et al.</i>	2020	Effects of parental exposure to glyphosate-based herbicides on embryonic development and oxidative status: a long-term experiment in a bird model.	Scientific reports, (2020) Vol. 10, No. 1, pp. 6349	Roundup Flex is a potassium salt based formulation and has a different surfactant system compared to the EU representative formulation. Therefore, this publication is not relevant for the EU glyphosate renewal.
55	Ecotoxicology	Shitha C. <i>et al.</i>	2017	Impact of glyphosate and chlorpyrifos on chemical and biological properties of a lateritic soil	Pesticide Research Journal (2017) Vol. 29, pp. 68-74	Roundup SL is commercialized in India and it is not the EU representative formulation thus this article is not relevant for the EU glyphosate renewal. In addition, the study design, the test system and the species tested are not relevant for the European regulatory purposes. The tested soil (even for lab tests) is a local one in India. The tested species (<i>Perionyx excavatus</i> in the case of earthworms) are also native. In addition, the field experiments are not dealing with EU representative conditions. No experiment was performed according to any of the EU recommended testing guidances/designs. No useful endpoint can be derived.
56	Ecotoxicology	Vazquez D. E. <i>et al.</i>	2020	Chronic exposure to glyphosate induces transcriptional changes in honey bee larva: A toxicogenomic study.	Environmental pollution, (2020) Vol. 261, Art. No. 114148	The publication investigates the effects of chronic exposure of a single concentration of pure glyphosate on honey bee larvae regarding their gene expression profile using a transcriptomic approach. However, the study design and the test system are not relevant for the European regulatory purposes. The experiment was not performed according to any of the EU recommended testing guidances/designs. No useful endpoint can be derived. No positive control was tested.

Submission Number	Technical section	Author(s)	Year	Title	Source	Reason for not including publication in dossier (based on relevance and reliability criteria)
57	Ecotoxicology	Villar S. <i>et al.</i>	2019	Measurement of genetic damage in <i>Apis mellifera</i> caused by agrochemicals using comet assay.	Current Topics in Toxicology, (2019) Vol. 15, pp. 133-139	The publication investigates the effects of acute exposure of a glyphosate formulation on adult honey bee DNA. Only findings at the cellular/molecular level are reported. Enzyme, cellular and molecular level endpoints are not relevant to EU level ecotoxicology risk assessment. The experiment was not performed according to any of the EU recommended testing guidances/designs.
58	Toxicology and metabolism	Alarcon R. <i>et al.</i>	2020	Neonatal exposure to a glyphosate-based herbicide alters the uterine differentiation of prepubertal ewe lambs.	Environmental pollution, (2020) Vol. 265, No. Pt B, Art. No. 114874	Roundup FULL II® (Argos SRL, Santa Fe, Argentina), a liquid water-soluble formulation containing 54 g of glyphosate in 100 mL of commercial formulation is not the EU representative formulation for the EU glyphosate renewal and therefore not relevant to the EU glyphosate renewal. In addition, direct injection into the neck of pregnant ewes with formulated product containing surfactant is not relevant to real life exposure scenarios. Environmental fate, metabolism and pharmacokinetics for glyphosate active ingredient versus surfactants are very different. Given the direct systemic exposure, these data are considered irrelevant to livestock and human health risk assessments.
59	Toxicology and metabolism	Barbasz A. <i>et al.</i>	2020	Toxicity of pesticides toward human immune cells U-937 and HL-60.	Journal of environmental science and health. Part. B, Pesticides, food contaminants, and agricultural wastes, (2020) pp. 1-7; Doi: 10.1080/03601234.2020.1777059	Human histiocytic lymphoma cell line (U-937) and human promyelocytic cell line (HL-60) were exposed to glyphosate at a concentrations from 1.3 mM to 21.3 mM. Although the data are accurate, the doses selected are not physiologically relevant to human health risk assessment. Effects are noted well in excess of physiologically relevant doses and therefore, are not applicable to the risk assessment.
60	Toxicology and metabolism	Calvo-Trujillo M. <i>et al.</i>	2019	Exposure to pesticides as a risk factor for Parkinson's disease: A case-control study in San Juan Nepomuceno Town (Bolívar).	Revista de Toxicologia, (2019) Vol. 36, No. 2, pp. 142-147	This publication describes an association between pesticide exposure and Parkinson's disease. The only context in which glyphosate is mentioned is to say that it is a widely used herbicide. There is no claim that glyphosate exposure is associated with PD and therefore this article is not relevant for the glyphosate EU renewal.
61	Toxicology and metabolism	Coppola L. <i>et al.</i>	2020	Integrated approach to evaluate the association between exposure to pesticides and idiopathic premature thelarche in girls: The PEACH project.	International Journal of Molecular Sciences, (2020) Vol. 21, No. 9, Art. No. 3282	No results are provided in the article, only a section with expected results is included. The article does not provide any new information that can be used in the risk assessment.
62	Toxicology and metabolism	de Castilhos Ghisi N. <i>et al.</i>	2020	Glyphosate and its toxicology: A scientometric review.	The Science of the total environment, (2020) Vol. 733, Art. No 139359	This scientometric review does not focus on toxicological endpoints following a glyphosate exposure of any kind. No relevant information or conclusion on the toxicity of glyphosate for the risk assessment can be drawn.
63	Toxicology and metabolism	Devault D. A. <i>et al.</i>	2020	Wastewater-based epidemiology approach to assess population exposure to pesticides: a review of a pesticide pharmacokinetic dataset	Environmental science and pollution research international (2020) Vol. 27, No. 5, pp. 4695-4702	This publication is a literature review and does not contain any toxicological endpoints following the exposure to glyphosate. It rather aims to identify from literature if it is possible to use wastewater based epidemiology to assess human exposure to different pesticides. The article cannot contribute to the risk assessment of glyphosate.

Submission Number	Technical section	Author(s)	Year	Title	Source	Reason for not including publication in dossier (based on relevance and reliability criteria)
64	Toxicology and metabolism	Djaber N. <i>et al.</i>	2020	Roundup-induced biochemical and histopathological changes in the liver and kidney of rats: the ameliorative effects of Linum usitatissimum oil.	Acta Biochimica Polonica, (2020) Vol. 67, No. 1, pp. 53-64	Roundup TURBO (450 g/L) is not the EU representative formulation and therefore not relevant to the EU glyphosate renewal. The Roundup dosing rationale in the study appeared to be to intentionally elicit toxic effects and endorse the administration of Linum usitatissimum oil (LuO) to counter toxicity to liver/kidney tissue (perhaps preventive?). With this approach the dosing regime is a major flaw in the study design as only one dose level was selected and it is unclear what effects may have been seen, if any, at more relevant exposure levels.
65	Toxicology and metabolism	Gallegos C. E. <i>et al.</i>	2020	Intranasal glyphosate-based herbicide administration alters the redox balance and the cholinergic system in the mouse brain.	Neurotoxicology, (2020) Vol. 77, pp. 205-215	Glifloglex®, marketed in Argentina, is not the EU representative formulation and therefore not relevant to the EU glyphosate renewal.
66	Toxicology and metabolism	Gomez A. L. <i>et al.</i>	2020	Exposure to a Glyphosate-based Herbicide Alters the Expression of Key Regulators of Mammary Gland Development on Pre-pubertal Male Rats.	Toxicology, (2020) Vol. 439, Art No. 152477	In vivo study on pre and post natal effects of Glyphosate-based herbicide administered to Wistar female rat at 3.5 and 350 mg/kg/day (8-10 females rat/group). Glyphosate-based herbicide (Glyphosate 66.2% - potassium salt, acid equivalent 54%) was tested, which is not the EU representative formulation and thus article is not relevant for the EU glyphosate renewal.
67	Toxicology and metabolism	Hamdaoui L. <i>et al.</i>	2020	Sub-chronic exposure to Kalach 360 SL, Glyphosate-based Herbicide, induced bone rarefaction in female Wistar rats.	Toxicology, (2020) Vol. 436, Art. No. 152412	In vivo study on effects of Kalach 360 SL on ED parameters on wistar female rat at 2 different doses. Kalach 360 SL is not the EU representative formulation and thus article is not relevant for the EU glyphosate renewal. Kalach 360 SL contains POEA (polyethoxylated tallow amine) which is not permitted for use in formulated herbicidal products in the EU.
68	Toxicology and metabolism	Kass L. <i>et al.</i>	2020	Relationship between agrochemical compounds and mammary gland development and breast cancer.	Molecular and cellular endocrinology, (2020) Vol. 508, Art. No. 110789	This very limited literature review focuses on the endocrine disrupting potential of different agrochemicals with glyphosate among them. Some relevant in vitro, in vivo and epidemiological studies assessing the effects of glyphosate on several factors related to endocrine function, are summarised. The cited monitoring studies highlight that glyphosate-based herbicides were detected in human samples (milk, urine, maternal blood), but contrary scientific papers are not cited. In vitro studies performed with relevant cell lines are presented to be affected by glyphosate. Further, in vivo studies investigating developmental parameters describe effects allegedly induced by glyphosate and are suggested to result from altered endocrine function. The literature review does not provide any new data. It only summarises existing data and states that it is not possible to distinguish if the effects are caused by the active substance glyphosate or additives in the formulation such as surfactants. Due to this statement and no new data the literature review has been classified as not relevant.

Submission Number	Technical section	Author(s)	Year	Title	Source	Reason for not including publication in dossier (based on relevance and reliability criteria)
69	Toxicology and metabolism	McCully K. S.	2020	Environmental Pollution, Oxidative Stress and Thioretinaco Ozonide: Effects of Glyphosate, Fluoride and Electromagnetic Fields on Mitochondrial Dysfunction in Carcinogenesis, Atherogenesis and Aging.	Annals of clinical and laboratory science, (2020) Vol. 50, No. 3, pp. 408-411	No experimental set up is used to investigate glyphosate toxicity. Therefore, it cannot provide new information. A very limited toxicological evaluation of glyphosate fluoride and electromagnetic fields is described based on selected literature, very specific endpoints and not specifying the compound (glyphosate as active ingredient or formulation) which was used in the studies that are cited. This review is considered not relevant.
70	Toxicology and metabolism	Mendler A. <i>et al.</i>	2020	Mucosal-associated invariant T-Cell (MAIT) activation is altered by chlorpyrifos- and glyphosate-treated commensal gut bacteria.	Journal of Immunotoxicology, (2020) Vol. 17, No. 1, pp. 10-20	Gut microbiome (Escherichiacoli, Bifidobacterium adolescentis and Lactobacillus reuteri) were exposed to different concentrations of a glyphosate formulation. Peripheral blood mononuclear cells (PBMCs) obtained from human volunteers were then stimulated with either pesticide-treated or non-treated bacteria (B. adolescentis or L. reuteri). Untreated E. coli were added later. MAIT cells were identified with flow cytometry and riboflavin and folate contents were measured using LC-MS/MS and electroluminescence immunoassay, respectively. A proteomic analysis was performed in E. coli. In conclusion, glyphosate might alter bacterial metabolism potentially leading altered inflammatory immune responses. A formulation of glyphosate is tested in vitro. The article is excluded as in vitro testing of glyphosate formulations produce surfactant induced cytotoxicity that is not representative for glyphosate or relevant of human in vivo exposure scenarios. Further, PBMCs instead of MAIT cells derived from gut were used.
71	Toxicology and metabolism	Namratha M. L. <i>et al.</i>	2019	Effect of glyphosate (GLP) induced toxicity on body weights and gross pathology: ameliorative effect of ascorbic acid (AA) in wistar rats	International Journal of Current Microbiology and Applied Sciences, (2019) Vol. 8, No. 10, pp. 1486-1493	Roundup® (41%) procured in India is not the EU representative formulation (the composition and surfactant system differs from the EU representative formulation), therefore the article is not relevant for the EU glyphosate renewal.
72	Toxicology and metabolism	Ongono J. S. <i>et al.</i>	2020	Pesticides used in Europe and autism spectrum disorder risk: can novel exposure hypotheses be formulated beyond organophosphates, organochlorines, pyrethroids and carbamates? - A systematic review.	Environmental research, (2020) Vol. 187, pp. 109646	Review on potential role of neuro- and thyrotoxic pesticides authorized in Europe other than those widely studied (i.e. OCs, OPs, pyrethroids and carbamates) in the risk of ASD in children or ASD behavioral phenotypes in rodents. This publication is very theoretical and it relies on the interpretation of anxiety like behaviour seen in mice (but not in rats) and the extrapolation of this to humans. Also the paper only identifies a “potential link”, there is no actual exposure driven observations in humans. Therefore the publication is considered as not relevant.
73	Toxicology and metabolism	Onyekachi U. C. <i>et al.</i>	2019	Chemoprotective potentials of selected dietary supplements in glyphosate-based herbicide-induced nephrotoxicity and dyslipidemia in albino wistar rats	Asian Journal of Biological Sciences, (2019) Vol. 12, No. 2, pp. 320-327	Intraperitoneal injection with formulated product containing surfactant is not relevant to real life exposure scenarios. Environmental fate, metabolism and pharmaco-kinetics for glyphosate active ingredient versus sufractants are very different. Given the direct systemic exposure, these data are considered irrelevant to livestock and human health risk assessments.

Submission Number	Technical section	Author(s)	Year	Title	Source	Reason for not including publication in dossier (based on relevance and reliability criteria)
74	Toxicology and metabolism	Pu Y. <i>et al.</i>	2020	Glyphosate exposure exacerbates the dopaminergic neurotoxicity in the mouse brain after repeated administration of MPTP.	Neuroscience letters, (2020) Vol. 730, Art. No. 135032	This in vivo study investigated the potential of Roundup Maxload to cause parkinson's disease. Roundup Maxload (48% w/v, potassium salt), 52% other ingredients such as water and surfactants), is not the EU representative formulation, therefore the article is not relevant for the the EU glyphosate renewal.
75	Toxicology and metabolism	Pu Y. <i>et al.</i>	2020	Maternal glyphosate exposure causes autism-like behaviors in offspring through increased expression of soluble epoxide hydrolase.	Proceedings of the National Academy of Sciences of the United States of America, (2020) Vol. 117, No. 21, pp. 11753-11759	In this in vivo study one concentration of Roundup Maxload was used to dose pregnant mice in drinking water to investigate the risk for autism spectrum disorder in their offspring. Roundup Maxload (48% w/v, potassium salt, 52% other ingredients such as water and surfactants), is not the EU representative formulation, therefore the article is not relevant for the EU glyphosate renewal.
76	Toxicology and metabolism	Schnabel K. <i>et al.</i>	2020	Functionality and DNA-damage properties of blood cells in lactating cows exposed to glyphosate contaminated feed at different feed energy levels.	Archives of animal nutrition, (2020) Vol. 74, No. 2, pp. 87-106	The formulation tested is not the EU representative formulation MON 52276. Roundup Record (007525-60/MOT), Monsanto, Agrar Deutschland GmbH (Düsseldorf, Germany) was used as water-soluble granulate, containing 720 g GL/kg as an active ingredient. Therefore te article is not relevant for the EU glyphosate renewal.
77	Toxicology and metabolism	Turkmen R. <i>et al.</i>	2020	Determination of acute oral toxicity of glyphosate isopropylamine salt in rats.	Environmental science and pollution research international, (2020) Vol. 27, No. 16, pp. 19298-19303	The glyphosate formulation Knockdown 48 SL, which is marketed by Safa Tarım Inc. in Turkey, is not the EU representative formulation therefore the publication is not relevant for the EU glyphosate renewal.
78	Toxicology and metabolism	Zhao J. B. <i>et al.</i>	2020	Clinical analysis of 15 cases of acute glufosinate poisoning.	Zhonghua lao dong wei sheng zhi ye bing za zhi = Zhonghua laodong weisheng zhiyebing zazhi = Chinese journal of industrial hygiene and occupational diseases, (2020) Vol. 38, No. 5, pp. 372-374	This publication discusses acute poisoning cases of glufosinate-ammonium. Glyphosate was mentioned only once in the following context: Glufosinate is a broadspectrum contact herbicide. Its toxicity is between glyphosate and paraquat.

Appendix 1: AGG ADVICE on how to present the literature search in the dossier

ASSESSMENT GROUP ON GLYPHOSATE (AGG)

October 2019

**ADVICE TO GTF2:
HOW TO PRESENT THE LITERATURE SEARCH
IN THE DOSSIER TO BE SUBMITTED JUNE 2020**

The literature search should be carried out and presented as recommended in the EFSA Guidance EFSA Journal 2011;9(2):2092) including its recently published Appendix, available at the EFSA Journal.

**Rapid assessment of
titles/abstracts:**

Articles that are
considered as **not
relevant**:

Not necessary to submit
articles or study
summaries but
justification needed at a
general level, i.e. criteria
used to classify references
as being clearly non-
relevant.

**Detailed assessment of
full text of articles:**

Articles that are
considered as **not
relevant**
or
considered **not reliable**:

Necessary to submit
articles and statement
with the reason of
rejection (no study
summaries).

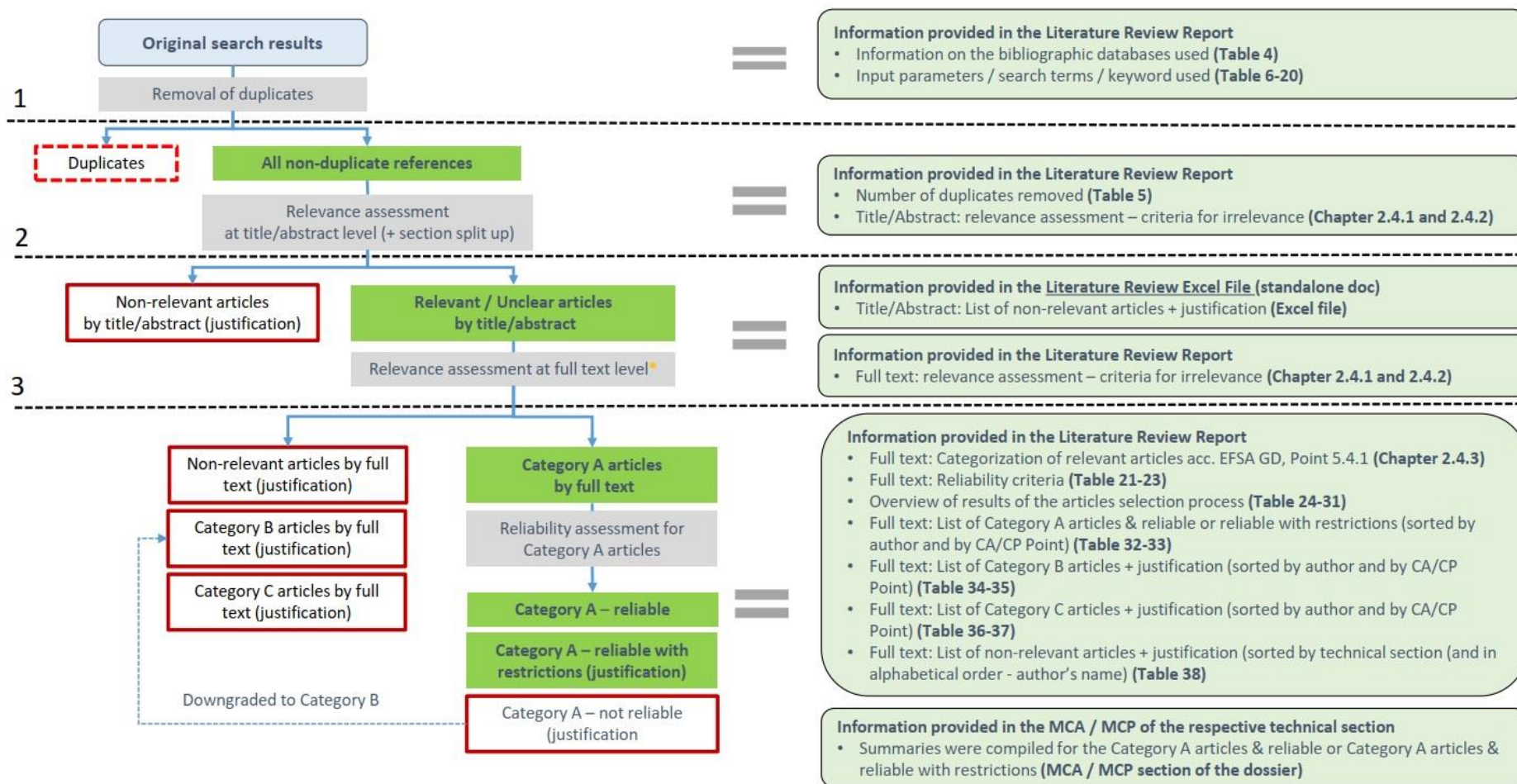
**Detailed assessment of
full text of articles:**

Articles considered as
relevant and reliable:

Necessary to submit
articles. A detailed study
summary should be
provided in the relevant
section of Doc
MCA/MCP.

For presentation of
detailed study summary,
reference is made to
EFSA Administrative
guidance on submission
of dossiers and
assessment reports for
the peer-review of
pesticide active
substances (27 March
2019, doi:
10.2903/sp.efsa.2016.EN
-1612).

Appendix 2: The process of articles selection



* All articles (and their translations) evaluated at full-text level (detailed assessment) are submitted to the AGG.

Appendix 3: ORIGINAL SEARCH QUERY - January 2020 – June 2020

Preparing the search queries on STN:

FILE 'STNGUIDE' ENTERED AT 18:54:53 ON 01 JUL 2020
CHARGED TO COST=113898

L1 QUE SPE=ON ABB=ON PLU=ON GLYPHOSAT? OR GLIFOSAT? OR
GLYFOSAT? OR 1071-83-6 OR 38641-94-0 OR 70901-12-1 OR 39600-42-
5 OR 69200-57-3 OR 34494-04-7 OR 114370-14-8 OR 40465-66-5 OR
69254-40-6 OR AMINOMETHYL PHOSPHONIC OR AMINOMETHYLPHOSPHONIC
OR 1066-51-9
SAVE TEMP L1 GLY1/Q

L2 QUE SPE=ON ABB=ON PLU=ON 2 ACETYL PHOSPHONOMETHYL AMINO
ACETIC ACID OR N ACETYL GLYPHOSATE OR N ACETYLGLYPHOSATE OR N
ACETYL N PHOSPHONOMETHYL GLYCINE OR 129660-96-4 OR N ACETYL
AMPA OR ACETYLAMINO METHYL PHOSPHONIC ACID OR ACETYLAMINOMETHYL
PHOSPHONIC ACID OR 57637-97-5
SAVE TEMP L2 GLY2/Q

L3 QUE SPE=ON ABB=ON PLU=ON 2617-47-2 OR HYDROXYMETHANEPHOSPHON
IC ACID OR HYDROXYMETHYL PHOSPHONATE OR HYDROXYMETHYL PHOSPHONI
C ACID OR METHANEHYDROXYPHOSPHONIC ACID OR PHOSPHONIC ACID(1W)H
YDROXYMETHYL OR PHOSPHONOMETHANOL

L4 QUE SPE=ON ABB=ON PLU=ON HYDROXYMETHYLPHOSPHONATE OR
HYDROXYMETHYLPHOSPHONIC ACID

L5 QUE SPE=ON ABB=ON PLU=ON L3 OR L4
SAVE TEMP L5 GLY3/Q

L6 QUE SPE=ON ABB=ON PLU=ON 35404-71-8 OR METHYLAMINO METHYL
PHOSPHONIC ACID OR METHYLAMINOMETHYL PHOSPHONIC ACID OR
METHYLAMINOMETHYLPHOSPHONIC ACID OR N METHYL AMPA OR NSC
244826 OR PHOSPHONIC ACID METHYLAMINO METHYL OR PHOSPHONIC
ACID P METHYLAMINO METHYL

L7 QUE SPE=ON ABB=ON PLU=ON 2 3 DIHYDROXY 1 OXOPROPYL AMINOMETH
YL PHOSPHONIC ACID OR 2 3 DIHYDROXY 1 OXOPROPYL AMINOMETHYLPHOS
PHONIC ACID OR N GLYCERYL AMPA

L8 QUE SPE=ON ABB=ON PLU=ON 3 OXO 3 PHOSPHONOMETHYL AMINO
PROPANOIC ACID OR 3 OXO 3 PHOSPHONOMETHYL AMINOPROPANOIC ACID
OR N MALONYL AMPA

L9 QUE SPE=ON ABB=ON PLU=ON 993-13-5 OR DIHYDROGEN METHYLPHOSPH
ONATE OR METHANEPHOSPHONIC ACID OR METHYL PHOSPHONIC ACID OR
METHYLPHOSPHONIC ACID OR NSC 119358 OR PHOSPHONIC ACID METHYL
OR PHOSPHONIC ACID P METHYL

L10 QUE SPE=ON ABB=ON PLU=ON (L6 OR L7 OR L8 OR L9)
SAVE TEMP L10 GLY4/Q

L11 QUE SPE=ON ABB=ON PLU=ON 24569-83-3 OR 2 METHYL PHOSPHONOMET
HYL AMINO ACETIC ACID OR 2 METHYL PHOSPHONOMETHYL AMINOACETIC
ACID OR ACETIC ACID 2 N METHYL N PHOSPHONATOMETHYL AMINO OR
GLYCINE N METHYL N PHOSPHONOMETHYL OR GLYPHOSATE N METHYL OR
METHYL GLYPHOSATE

L12 QUE SPE=ON ABB=ON PLU=ON METHYL PHOSPHONOMETHYL AMINO
ACETIC ACID OR METHYL PHOSPHONOMETHYL AMINOACETIC ACID OR N
METHYL N PHOSPHONOMETHYL GLYCINE OR N METHYLGLYPHOSATE OR N
PHOSPHONOMETHYL N METHYL GLYCINE OR N PHOSPHONOMETHYL N
METHYLGLYCINE

L13 QUE SPE=ON ABB=ON PLU=ON (L11 OR L12)
SAVE TEMP L13 GLY5/Q
D COST FUL

L14 QUE SPE=ON ABB=ON PLU=ON TOX? OR HAZARD? OR ADVERSE OR
HEALTH OR NOAEL OR NOEL OR LOAEL OR LOEL OR BMD? OR IN VIVO OR
IN VITRO OR INVIVO OR INVITRO OR MODE OF ACTION OR SKIN? OR
EYE? OR IRRIT? OR SENS? OR ALLERG?

L15 QUE SPE=ON ABB=ON PLU=ON RAT OR RATS OR DOG? OR RABBIT? OR
GUINEA PIG? OR MOUSE OR MICE OR METABOLISM OR METABOLITE? OR
METABOLIC OR DISTRIBUTION OR ADSORPTION OR EXCRETION OR
ELIMINATION OR KINETIC OR CYTOCHROME OR ENZYM?

L16 QUE SPE=ON ABB=ON PLU=ON GEN? OR MUTA? OR CHROMOS? OR
CLASTOGEN? OR DNA OR CARCINO? OR CANCER? OR TUMOR? OR TUMOUR?
OR ONCOG? OR ONCOL? OR MALIGN? OR IMMUN? OR NEUR? OR ENDOCRIN?
OR HORMON? OR GONAD? OR DISRUPT?

L17 QUE SPE=ON ABB=ON PLU=ON REPRODUCT? OR DEVELOPMENT? OR
MALFORM? OR ANOMAL? OR FERTIL? OR FOET? OR FET? OR MATERN? OR
PREGNAN? OR EMBRYO? OR EPIDEM? OR MEDICAL? OR POISON? OR
EXPOSURE OR OPERATOR? OR BYSTANDER? OR RESIDENT? OR WORKER? OR
OCCUPAT?

L18 QUE SPE=ON ABB=ON PLU=ON BIOMONITORING OR HUMAN EXPOSURE OR
MICROBIOME OR OXIDATIVE STRESS OR APOPTOSIS OR NECROSIS OR
CYTOTOXICITY OR POLYOXYETHYLENEAMINE OR POEA OR SURFACTANT OR
RISK ASSESSMENT?

L19 QUE SPE=ON ABB=ON PLU=ON (L14 OR L15 OR L16 OR L17 OR L18)
SAVE TEMP L19 TOX/Q

L20 QUE SPE=ON ABB=ON PLU=ON UPTAKE OR TRANSLOCATION OR RUMEN
OR STORAGE STABILITY OR STORAGE OR STABILITY OR METABOLIC OR
METABOLISM OR BREAKDOWN OR NATURE OF RESIDUES OR RESIDUE? OR
MAGNITUDE OF RESIDUES OR PROCESS? OR EFFECTS OF PROCESSING

L21 QUE SPE=ON ABB=ON PLU=ON DESSICANT OR PREHARVEST OR
PREEMERG? OR ?RESISTANT? OR ?TOLERAN? OR TRANSGENIC OR
HYDROLY? OR ROTATION? OR SUCCEED? OR PLANT? OR CROP? OR FEED?
OR ANIMAL? OR LIVESTOCK? OR HEN OR CATTLE OR RUMINANT?

L22 QUE SPE=ON ABB=ON PLU=ON GOAT? OR COW? OR PIG? OR DIETARY
OR ASSESSMENT OR RISK ASSESSMENT OR CONSUM? OR EXPOSURE

L23 QUE SPE=ON ABB=ON PLU=ON (L20 OR L21 OR L22)
SAVE TEMP L23 RES/Q

L24 QUE SPE=ON ABB=ON PLU=ON SOIL OR WATER OR SEDIMENT OR
DEGRADAT? OR PHOTO? OR SOIL RESIDUES OR SOIL ACCUMULAT? OR
SOIL CONTAMINAT? OR MOBILITY OR SORPTION OR COLUMN LEACHING OR
AGED RESIDUE OR LEACH? OR LYSIMETER OR GROUNDWATER

L25 QUE SPE=ON ABB=ON PLU=ON CONTAMINAT? OR MICROB? OR EXUDATION
OR RHIZOSPHERE OR DISSIPATION OR SATURATED ZONE OR HYDROLYSIS
OR DRIFT OR RUN-OFF OR RUNOFF OR DRAINAGE OR VOLAT? OR
ATMOSPHERE OR LONG-RANGE TRANSPORT OR SHORT-RANGE TRANSPORT

- L26 QUE SPE=ON ABB=ON PLU=ON TRANSPORT OR MICRONUTRIENT OR PHOSPHATE OR IRON OR MANGANESE OR HALF-LIFE OR HALFLIFE OR HALF-LIVES OR HALFLIVES OR DT50 OR KINETICS OR OFF-SITE MOVEMENT OR REMOVAL OR DRINKING WATER OR WATER TREATMENT PROCESSES
- L27 QUE SPE=ON ABB=ON PLU=ON ATMOSPHERIC DEPOSITION OR TILE-DRAINS OR SURFACE WATER OR MONITORING DATA OR DISINFECTANT OR OZONE OR TILLAGE OR INFILTRATION OR HARD SURFACE OR RAINWATER OR RAIN WATER OR CHELAT? OR COMPLEX? OR MINERALIZATION OR PERSISTENCE OR LIGAND
- L28 QUE SPE=ON ABB=ON PLU=ON (L24 OR L25 OR L26 OR L27) SAVE TEMP L28 FATE/Q
- L29 QUE SPE=ON ABB=ON PLU=ON TOX? OR ECOTOX? OR ?TOXIC OR ?TOXICITY OR HAZARD OR ADVERSE OR ENDOCRINE DISRUPT? OR BIOACCUMULATE? OR BIOMAGNIFI? OR BIOCONCENTRATION OR POISON OR EFFECT OR INDIRECT EFFECT? OR DIRECT EFFECT? OR BIODIVERS? OR PROTECTION GOALS OR ECO?
- L30 QUE SPE=ON ABB=ON PLU=ON IMPACT OR POPULATION OR COMMUNITY OR WILDLIFE OR INCIDENT OR PEST OR BIRD? OR ACUTE OR CHRONIC OR LONG-TERM OR MALLARD OR DUCK OR QUAIL OR BOBWHITE OR ANAS? OR COLINUS? OR WILD OR DIETARY OR AQUATIC OR FISH OR DAPHNI? OR ALG? OR CHIRON?
- L31 QUE SPE=ON ABB=ON PLU=ON SEDIMENT DWELL? OR BENTHIC OR LEMNA OR MARIN? OR ESTUARINE OR CRUSTA? OR GASTROPOD? OR INSECT OR MOLLUSC OR REPTILE OR AMPHIB? OR BEE? OR APIS OR APIDAE OR BUMBLE? OR COLONY OR HIVE OR POLLINATOR
- L32 QUE SPE=ON ABB=ON PLU=ON PLANT AND (SUBMERGE? OR EMERGE?)
- L33 QUE SPE=ON ABB=ON PLU=ON SOLITARY OR ALG? OR AQUATIC OR FRESHWATER OR VERTEBRAT? OR MAMMAL? OR RAT OR MOUSE OR MICE OR RABBIT OR HARE OR PROTECTION OR MODEL? OR VOLE OR PEST OR ARTHROPOD? OR BENEFICIALS OR TYPHLODROMUS OR APHIDIUS OR PARASITOID
- L34 QUE SPE=ON ABB=ON PLU=ON PREDATOR OR CHRYSOPERLA OR ORIUUS OR SPIDER OR WORM? OR ?WORM OR EISENIA OR SOIL OR COLLEMBOL? OR MACRO ORGANISM OR FOLSOMIA OR SPRINGTAIL OR DECOMPOS? OR MICRO ORGANISMS OR MICROORGANISMS OR MICROBIAL OR CARBON OR NITROGEN
- L35 QUE SPE=ON ABB=ON PLU=ON PLANT? OR VEGETATIVE VIGO? OR SEEDLING OR GERMINATION OR MONOCOT? OR DICOT? OR SEWAGE OR ACTIVATED SLUDGE OR BIODEGRAD? OR BIOACCUMULATION? OR AMPHIB? OR REPTILE? OR AQUATIC PLANT OR BENEFICIAL
- L36 QUE SPE=ON ABB=ON PLU=ON (L29 OR L30 OR L31 OR L32 OR L33 OR L34 OR L35) SAVE TEMP L36 ECO/Q

SESSION WILL BE HELD FOR 120 MINUTES

STN INTERNATIONAL SESSION SUSPENDED AT 19:51:07 ON 01 JUL 2020

' Final search - update Jul 2020:

FILE 'MEDLINE' ENTERED AT 10:56:11 ON 02 JUL 2020

CHARGED TO COST=113898

- L1 3605 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
- L2 208 SEA SPE=ON ABB=ON PLU=ON L1 AND ED>20200107
- L3 206 SEA SPE=ON ABB=ON PLU=ON L2 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L4 31 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
- L5 0 SEA SPE=ON ABB=ON PLU=ON L4 AND ED>20200224
- L6 583 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
- L7 1 SEA SPE=ON ABB=ON PLU=ON L6 AND ED>20200227
- L8 1 SEA SPE=ON ABB=ON PLU=ON L7 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L9 11 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
- L10 1 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>20200504
- L11 1 SEA SPE=ON ABB=ON PLU=ON L10 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L12 207 SEA SPE=ON ABB=ON PLU=ON L3 OR L8 OR L11 SAVE TEMP L12 GLYMEDL/A

FILE 'AGRICOLA' ENTERED AT 11:20:29 ON 02 JUL 2020

CHARGED TO COST=113898

- L13 7095 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
- L14 248 SEA SPE=ON ABB=ON PLU=ON L13 AND ED>20200107
- L15 248 SEA SPE=ON ABB=ON PLU=ON L14 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L16 6 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
- L17 2 SEA SPE=ON ABB=ON PLU=ON L16 AND ED>20200224
- L18 2 SEA SPE=ON ABB=ON PLU=ON L17 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L19 123 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
- L20 11 SEA SPE=ON ABB=ON PLU=ON L19 AND ED>20200227
- L21 11 SEA SPE=ON ABB=ON PLU=ON L20 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L22 8 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
- L23 1 SEA SPE=ON ABB=ON PLU=ON L22 AND ED>20200504
- L24 1 SEA SPE=ON ABB=ON PLU=ON L23 NOT (COMMENT? OR DISSERTATION OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D T
- L25 258 SEA SPE=ON ABB=ON PLU=ON L15 OR L18 OR L21 OR L24 SAVE TEMP L25 GLYAGRI/A

FILE 'BIOSIS' ENTERED AT 11:32:39 ON 02 JUL 2020

CHARGED TO COST=113898

- L26 10702 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q

L27 364 SEA SPE=ON ABB=ON PLU=ON L26 AND ED>20200107
L28 316 SEA SPE=ON ABB=ON PLU=ON L27 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L29 30 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
L30 1 SEA SPE=ON ABB=ON PLU=ON L29 AND ED>20200224
L31 1 SEA SPE=ON ABB=ON PLU=ON L30 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L32 471 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
L33 8 SEA SPE=ON ABB=ON PLU=ON L32 AND ED>20200227
L34 6 SEA SPE=ON ABB=ON PLU=ON L33 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L35 22 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
L36 0 SEA SPE=ON ABB=ON PLU=ON L35 AND ED>20200504
L37 321 SEA SPE=ON ABB=ON PLU=ON L28 OR L31 OR L34
SAVE TEMP L37 GLYBIOS/A

FILE 'CABA' ENTERED AT 11:39:50 ON 02 JUL 2020

CHARGED TO COST=113898

L38 18563 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
L39 466 SEA SPE=ON ABB=ON PLU=ON L38 AND ED>20200107
L40 466 SEA SPE=ON ABB=ON PLU=ON L39 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L41 5 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
L42 0 SEA SPE=ON ABB=ON PLU=ON L41 AND ED>20200224
L43 71 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
L44 1 SEA SPE=ON ABB=ON PLU=ON L43 AND ED>20200227
L45 1 SEA SPE=ON ABB=ON PLU=ON L44 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L46 41 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
L47 0 SEA SPE=ON ABB=ON PLU=ON L46 AND ED>20200504
L48 467 SEA SPE=ON ABB=ON PLU=ON L40 OR L45
SAVE TEMP L48 GLYCABA/A

FILE 'FSTA' ENTERED AT 11:46:51 ON 02 JUL 2020

CHARGED TO COST=113898

L49 507 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
L50 22 SEA SPE=ON ABB=ON PLU=ON L49 AND ED>20200107
L51 20 SEA SPE=ON ABB=ON PLU=ON L50 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L52 1 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
L53 0 SEA SPE=ON ABB=ON PLU=ON L52 AND ED>20200224
L54 9 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
L55 0 SEA SPE=ON ABB=ON PLU=ON L54 AND ED>20200227
L56 2 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
L57 0 SEA SPE=ON ABB=ON PLU=ON L56 AND ED>20200504
SAVE TEMP L51 GLYFSTA/A

FILE 'PQSCITECH' ENTERED AT 11:51:22 ON 02 JUL 2020

CHARGED TO COST=113898

L58 5130 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
L59 108 SEA SPE=ON ABB=ON PLU=ON L58 AND ED>20200107
L60 105 SEA SPE=ON ABB=ON PLU=ON L59 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L61 24 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
L62 0 SEA SPE=ON ABB=ON PLU=ON L61 AND ED>20200224
L63 294 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
L64 1 SEA SPE=ON ABB=ON PLU=ON L63 AND ED>20200227
L65 1 SEA SPE=ON ABB=ON PLU=ON L64 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L66 12 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
L67 0 SEA SPE=ON ABB=ON PLU=ON L66 AND ED>20200504
L68 106 SEA SPE=ON ABB=ON PLU=ON L60 OR L65
SAVE TEMP L68 GLYPQSCI/A

FILE 'TOXCENTER' ENTERED AT 11:56:52 ON 02 JUL 2020

CHARGED TO COST=113898

L69 15185 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
L70 654 SEA SPE=ON ABB=ON PLU=ON L69 AND ED>20200107
L71 463 SEA SPE=ON ABB=ON PLU=ON L70 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L72 90 SEA SPE=ON ABB=ON PLU=ON GLY3/Q
L73 6 SEA SPE=ON ABB=ON PLU=ON L72 AND ED>20200224
L74 2 SEA SPE=ON ABB=ON PLU=ON L73 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L75 1244 SEA SPE=ON ABB=ON PLU=ON GLY4/Q
L76 12 SEA SPE=ON ABB=ON PLU=ON L75 AND ED>20200227
L77 9 SEA SPE=ON ABB=ON PLU=ON L76 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L78 40 SEA SPE=ON ABB=ON PLU=ON GLY5/Q
L79 1 SEA SPE=ON ABB=ON PLU=ON L78 AND ED>20200504
L80 1 SEA SPE=ON ABB=ON PLU=ON L79 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T
L81 470 SEA SPE=ON ABB=ON PLU=ON L71 OR L74 OR L77 OR L80
SAVE TEMP L81 GLYTOXC/A

FILE 'EMBASE' ENTERED AT 12:11:20 ON 02 JUL 2020

CHARGED TO COST=113898

L82 4354 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q
L83 162 SEA SPE=ON ABB=ON PLU=ON L82 AND ED>20200107

L84 160 SEA SPE=ON ABB=ON PLU=ON L83 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L85 48 SEA SPE=ON ABB=ON PLU=ON GLY3/Q

L86 0 SEA SPE=ON ABB=ON PLU=ON L85 AND ED>20200224

L87 1292 SEA SPE=ON ABB=ON PLU=ON GLY4/Q

L88 6 SEA SPE=ON ABB=ON PLU=ON L87 AND ED>20200227

L89 6 SEA SPE=ON ABB=ON PLU=ON L88 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L90 11 SEA SPE=ON ABB=ON PLU=ON GLY5/Q

L91 0 SEA SPE=ON ABB=ON PLU=ON L90 AND ED>20200504

L92 166 SEA SPE=ON ABB=ON PLU=ON L84 OR L89
SAVE TEMP L92 GLYEMBA/A

FILE 'ESBIOBASE' ENTERED AT 12:18:43 ON 02 JUL 2020
CHARGED TO COST=113898

L93 4837 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q

L94 204 SEA SPE=ON ABB=ON PLU=ON L93 AND ED>20200107

L95 204 SEA SPE=ON ABB=ON PLU=ON L94 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L96 15 SEA SPE=ON ABB=ON PLU=ON GLY3/Q

L97 0 SEA SPE=ON ABB=ON PLU=ON L96 AND ED>20200224

L98 179 SEA SPE=ON ABB=ON PLU=ON GLY4/Q

L99 2 SEA SPE=ON ABB=ON PLU=ON L98 AND ED>20200227

L100 2 SEA SPE=ON ABB=ON PLU=ON L99 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L101 12 SEA SPE=ON ABB=ON PLU=ON GLY5/Q

L102 0 SEA SPE=ON ABB=ON PLU=ON L101 AND ED>20200504

L103 206 SEA SPE=ON ABB=ON PLU=ON L95 OR L100
SAVE TEMP L103 GLYESBIO/A

FILE 'HCAPLUS' ENTERED AT 12:25:03 ON 02 JUL 2020
CHARGED TO COST=113898

L104 24654 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q

L105 743 SEA SPE=ON ABB=ON PLU=ON L104 AND ED>20200107

L106 346 SEA SPE=ON ABB=ON PLU=ON L105 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L107 701 SEA SPE=ON ABB=ON PLU=ON GLY3/Q

L108 8 SEA SPE=ON ABB=ON PLU=ON L107 AND ED>20200224

L109 3 SEA SPE=ON ABB=ON PLU=ON L108 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L110 4029 SEA SPE=ON ABB=ON PLU=ON GLY4/Q

L111 36 SEA SPE=ON ABB=ON PLU=ON L110 AND ED>20200227

L112 15 SEA SPE=ON ABB=ON PLU=ON L111 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L113 120 SEA SPE=ON ABB=ON PLU=ON GLY5/Q

L114 0 SEA SPE=ON ABB=ON PLU=ON L113 AND ED>20200504

L115 364 SEA SPE=ON ABB=ON PLU=ON L106 OR L109 OR L112
SAVE TEMP L115 GLYHCAPI/A

FILE 'SCISEARCH' ENTERED AT 12:30:36 ON 02 JUL 2020
CHARGED TO COST=113898

L116 11035 SEA SPE=ON ABB=ON PLU=ON GLY1/Q OR GLY2/Q

L117 556 SEA SPE=ON ABB=ON PLU=ON L116 AND ED>20200107

L118 553 SEA SPE=ON ABB=ON PLU=ON L117 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L119 69 SEA SPE=ON ABB=ON PLU=ON GLY3/Q

L120 2 SEA SPE=ON ABB=ON PLU=ON L119 AND ED>20200224

L121 2 SEA SPE=ON ABB=ON PLU=ON L120 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L122 876 SEA SPE=ON ABB=ON PLU=ON GLY4/Q

L123 18 SEA SPE=ON ABB=ON PLU=ON L122 AND ED>20200227

L124 18 SEA SPE=ON ABB=ON PLU=ON L123 NOT (COMMENT? OR DISSERTATION
OR EDITORIAL OR MEETING? OR NEWS? OR PATENT OR PRESS RELEASE)/D
T

L125 28 SEA SPE=ON ABB=ON PLU=ON GLY5/Q

L126 0 SEA SPE=ON ABB=ON PLU=ON L125 AND ED>20200504

L127 571 SEA SPE=ON ABB=ON PLU=ON L118 OR L121 OR L124
SAVE TEMP L127 GLYSCIS/A

FILE 'MEDLINE, AGRICOLA, BIOSIS, CABA, FSTA, PQSCITECH, TOXCENTER,
EMBASE, ESBIOBASE, HCAPLUS, SCISEARCH' ENTERED AT 12:38:46 ON 02 JUL 2020
CHARGED TO COST=113898

L128 1648 DUP REM L12 L25 L37 L48 L51 L68 L81 L92 L103 L115... (1508 DUP
ANSWERS '1-207' FROM FILE MEDLINE
ANSWERS '208-430' FROM FILE AGRICOLA
ANSWERS '431-639' FROM FILE BIOSIS
ANSWERS '640-982' FROM FILE CABA
ANSWERS '983-993' FROM FILE FSTA
ANSWERS '994-1051' FROM FILE PQSCITECH
ANSWERS '1052-1205' FROM FILE TOXCENTER
ANSWERS '1206-1276' FROM FILE EMBASE
ANSWERS '1277-1310' FROM FILE ESBIOBASE
ANSWERS '1311-1424' FROM FILE HCAPLUS
ANSWERS '1425-1648' FROM FILE SCISEARCH
SAVE L128 GLY202007/A

L129 1317 SEA SPE=ON ABB=ON PLU=ON L128 AND TOX/Q
SAVE TEMP L129 GLYTOX/A

L130 1432 SEA SPE=ON ABB=ON PLU=ON L128 AND RES/Q
SAVE TEMP L130 GLYRES/A

L131 985 SEA SPE=ON ABB=ON PLU=ON L128 AND FATE/Q
SAVE TEMP L131 GLYFATE/A

L132 1541 SEA SPE=ON ABB=ON PLU=ON L128 AND ECO/Q
SAVE TEMP L132 GLYECO/A
L133 1638 SEA SPE=ON ABB=ON PLU=ON (L129 OR L130 OR L131 OR L132)
SAVE L133 GLY202007FIN/A
D TI 1-1638

SESSION WILL BE HELD FOR 120 MINUTES
STN INTERNATIONAL SESSION SUSPENDED AT 17:01:53 ON 02 JUL 2020