Literature Review Report

Scientific full text assessment of peer-reviewed open literature covering the publication period of 2006 to 2009 the active substance glyphosate (CAS RN® 1071-83-6) for renewal in Japan.

as under Article 8(5) of Regulation (EC) No 1107/2009

(Ref. EFSA Journal 2011; 9(2) 2092)

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1 Summary

A literature search for glyphosate and its metabolites[1] 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 2019[4] "*Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances".*

This Literature Review Report summarizes the the full text assessment glyphosate public literature, covering the publication period 1st July 2006 to 31st December 2009. as requested by Ministry of Agriculture, Forestry and Fisheris.

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

3294 articles in total were identified upon removal of duplicates within the current search (1st July 2006 to 31st December 2009).
All 3294 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 3050 of the 3294 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.

For the remaining 244 articles, identified as potentially "relevant" or of "unclear relevance" in the rapid assessment, the full-text documents[5] were reviewed in detail ("detailed assessment").

A total of 166 articles of the remaining 244 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 29** of this Literature Review Report document.

The remaining 78 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 23** and **Table** 24**24** of this Literature Review Report document.

[1] (aminomethyl)phosphonic acid (AMPA).
[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] 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.

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 25** and **Table 26** 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 27** and **Table** 28**28** 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)
Ecotoxicology	123	24	99	69	30
E-fate	83	18	65	49	16
Residues	13	12	1	0	1
Toxicology	106	30	76	45	31
Efficacy[a)]	2	0	2	2	0
Other non-relevant categories[b)]	2967	2966	1	1	0
Total	**3294**	**3048**	**244**	**166**	**78**

[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

	Relevant articles by full-text (EFSA 2092 GD, Point 5.4.1)		
Section	**Category A**[a)]	**Category B**[b)]	**Category C**[c)]
Ecotoxicology	7	22	1
E-fate	0	16	0
Residues	0	1	0
Toxicology	6	19	6
Efficacy	0	0	0
Total	**13**	**58**	**7**

[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.

2 Introduction

A literature search for glyphosate and its metabolites[1] 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 2019[4] "*Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances".*

This present Literature Review Report summarizes search and evaluation of glyphosate public literature, covering the publication period of 1st July 2006 to 31st December 2009.

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	October 2006 – December 2009	07 September 2021
Glyphosate AMPA	July 2006 – September 2006	14 October 2021

AMPA = (aminomethyl)phosphonic acid

A "focused search for grouped data requirements"[6] 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 13 and 145) 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 17 and 20).

[6] 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.

For the full outcome of the literature search for the individual technical sections, please refer to **Chapter 3** (page 25).

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.	Covers literature from agriculture, food science, biotechnology, crop protection, crop sciences, environment, soils and fertilizers, etc.	Covers literature and patents from Analytical chemistry, Applied chemistry, Biochemistry, Chemical engineering, Macromolecular chemistry, Organic chemistry
Number of records in the database at the time of search:	> 6.7 million (09/2019)	> 27.8 million (04/2019)	> 9.9 million	> 6.7 million (09/2019)
Database update:	Monthly	Weekly	Weekly	Daily updates bibliographic data; weekly updates indexing data
Date of the search:	07-September-2021 14 October 2021	07-September-2021 14 October 2021	07-September-2021 14 October 2021	07-September-2021 14 October 2021
Database covers records:	1970-present	1926-present	1973-present	1907-present and more than 180,000 pre-1907
Date of the latest database update:	04-August-2021 11 October 2021	01-September-2021 13 October 2021	01-September-2021 13 October 2021	06-September-2021 13 October 2021
Language limit:	No	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	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:	906 (07-09-2021) 0 (14-10-2021)	977 (07-09-2021) 51 (14-10-2021)	1908 (07-09-2021) 0 (14-10-2021)	1261 (07-09-2021) 52 (14-10-2021)

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. EMBASE	**6. Esbiobase**	**7. Medline**
Justification for choosing the source:	Covers literature from biological science, biochemistry, drugs, environmetal science, pharmacy, etc.	Covers literature from microbiology, biotechnology, ecological and environmental sciences, plant science, toxicology, etc.	Covers literature from all areas of biomedicine.
Number of records in the database at the time of search:	>36.4 million (08/2019)	>9 million Static file	>33.5 million (01/2022)
Database update:	weekly	weekly	daily
Date of the search:	07-September-2021 14 October 2021	07-September-2021 14 October 2021	07-September-2021 14 October 2021
Database covers records:	1947-present	1994-2021	1946-present
Date of the latest database update:	06-September-2021 13 October 2021	01-September-2021 13 October 2021	06-September-2021 13 October 2021
Language limit:	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
Search strategy:	Details are summarized in **Chapter 2.2** and **2.3**.		
Total number of records retrieved:	246 (07-09-2021) 22 (14-10-2021)	819 (07-09-2021) 0 (14-10-2021)	358 (07-09-2021) 17 (14-10-2021)

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. PQSciTech	**9. SciSearch**	**10. ToxCenter**	**11. FSTA**
Justification for choosing the source:	Covers literature from a wide area of life sciences and engineering	Covers literature from agriculture, biology, biotechnology chemistry, ecology, genetics, plant sciences, etc	Covers literature about adverse drug reactions, chemically induced diseases, environmental pollution, pesticides and herbicides, toxicological analysis, etc.	Covers literature about biotechnology, food sciences, plant pathology etc.
Number of records in the database at the time of search:	>33.6 million (01/2021)	>47.7 million (08/2019)	>16.2 million (01/20222)	>1.59 million (09/2020)
Database update:	monthly	weekly	daily	monthly
Date of the search:	07-September-2021 14 October 2021	07-September-2021 14 October 2021	07-September-2021 14 October 2021	07-September-2021 14 October 2021
Database covers records:	1962-present	1974-present	1907-present	1969-present
Date of the latest database update:	24 August-2021 24 September 2021	06-September-2021 11 October 2021	06-September-2021 11 October 2021	06-September-2021 11 October 2021
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:	1168 (07-09-2021) 0 (14-10-2021)	1211 (07-09-2021) 61 (14-10-2021)	822 (07-09-2021) 29 (14-10-2021)	38 (07-09-2021) 1 (14-10-2021)

Table 5: Total number of articles retrieved

Scope of the search	Total number of hits over all databases within the current search	After applying search filters [a] within the current search	After manual removal of duplicates [b] within the current search
October 2006 – December 2009 Glyphosate AMPA	**9714**	**9458**	**3253**
July 2006 – September 2006 Glyphosate AMPA	**233**	**230**	**41**

[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 14).

[b] Additional duplicates occurred due to different update frequencies within each database and entries of publications ahead of print.

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** - Error! Reference source not found.**7**.

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

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"[7], which combines the active substance and metabolite basic input parameters, keywords and search filters defined for each technical section. Please refer to Error! Reference source not found. for more details on the keywords used and to **Table 9** - **Table 19** for the search filters.

Table 8: Keywords used for the active substance glyphosate.

Gly: 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

(1w) = proximity operator (this order, up to 1 word between)
AND / OR / NOT = boolean search operators
? = any character(s)

Table 9: Search filters related to the technical section toxicology

Toxicology [Gly] 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 108: Search filters related to the technical section residues

Residues [Gly] 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

[7] 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 11: Search filters related to the technical section environmental fate

Environmental fate [Gly] 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 19: Search filters related to the technical section ecotoxicology

Ecotoxicology [Gly] 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 reviews[8].
- 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.).

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

- Publications dealing with a Roundup[9] 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 systems[10] 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.

[9] 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).

[10] 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, 2004[11]) 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 23** and **Table 24**. The list of Category B articles and the justifications can be found in **Table 25** and **Table** 26**26**. The list of Category C articles and the explanations can be found in **Table 27** and **Table** 28**28**.

[11] 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 103 - Table 151115**.

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 103: 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 15-25ºC.

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 14: 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 1511: Reliability criteria for toxicology – *in vitro* and *in vivo* studies

Reliability criteria – toxicology and metabolism	
***In vitro* studies**	***In vivo* 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 16: Summary of the literature search – all technical sections

	Number	Justification
Total number of articles retrieved from the search.	9947	n.a.
Total number of articles after removal of duplicates within all databases.	n.a.	n.a.
Total number of articles after manual removal of duplicates.	3294	n.a.
Number of articles excluded after rapid assessment (title / abstract).	3050	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	244	n.a.
Number of articles excluded after detailed assessment (*i.e.* not relevant).	166	See Table 2929
Number of articles not excluded after detailed assessment. [a)]	78	See Table 23-Table 2828
Number of summaries presented in the dossier. [b)]	13	See Table 23, Table 2424

[a)] 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.

[b)] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 17: Results of the article selection process for ecotoxicology

	Number	Justification
Total number of articles after manual removal of duplicates.	123	n.a.
Number of articles excluded after rapid assessment (title / abstract).	24	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	99	n.a.
Number of articles excluded after detailed assessment (*i.e.* not relevant).	69	See Table 2929
Number of articles not excluded after detailed assessment. [a)]	30	See Table 23-Table 2828
Number of summaries presented in the dossier. [b)]	7	See Table 23, Table 2424

[a)] 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.

[b)] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 18: Results of the article selection process for environmental fate

	Number	Justification
Total number of articles after manual removal of duplicates.	80	n.a.
Number of articles excluded after rapid assessment (title / abstract).	18	See the Literature Review Excel File.
Total number of full-text documents assessed in detail.	65	n.a.
Number of articles excluded after detailed assessment (*i.e.* not relevant).	49	See Table 2929
Number of articles not excluded after detailed assessment. [a)]	16	See Table 23-Table 2828
Number of summaries presented in the dossier. [b)]	0	n.a.

[a)] 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.

[b] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 19: Results of the article selection process for residues

	Number	Justification
Total number of articles after manual removal of duplicates.	13	n.a.
Number of articles excluded after rapid assessment (title / abstract).	12	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.e.* not relevant).	0	See Table 2929
Number of articles not excluded after detailed assessment [a]	1	See Table 23-Table 2828
Number of summaries presented in the dossier [b]	0	n.a.

[a] 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.

[b] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 20: Results of the article selection process for toxicology

	Number	Justification
Total number of articles after manual removal of duplicates	106	n.a.
Number of articles excluded after rapid assessment (title / abstract).	30	See the Literature Review Excel File.
Total number of full-text documents assessed in detail	76	n.a.
Number of articles excluded after detailed assessment (*i.e.* not relevant).	45	See Table 2929
Number of articles not excluded after detailed assessment [a]	31	See Table 23-Table 2828
Number of summaries presented in the dossier [b]	6	See Table 23, Table 2424

[a] 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.

[b] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 21: Results of the article selection process for efficacy

	Number	Justification
Total number of articles after manual removal of duplicates.	2	n.a.
Number of articles excluded after rapid assessment (title / abstract).	0	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.e.* not relevant).	2	See Table 2929
Number of articles not excluded after detailed assessment. [a]	0	n.a.
Number of summaries presented in the dossier. [b]	0	n.a.

[a] 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.

[b] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 22: Results of the article selection process for "other non-relevant categories"

	Number	Justification
Total number of articles after manual removal of duplicates.	2967	n.a.
Number of articles excluded after rapid assessment (title / abstract).	2966	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.e.* not relevant).	1	See Table 2929
Number of articles not excluded after detailed assessment. [a)]	0	n.a.
Number of summaries presented in the dossier. [b)]	n.a.	n.a.

[a)] 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.

[b)] Summaries were compiled for relevant articles of Category A and classified either as reliable or reliable with restrictions.

Table 23: 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	Classification (cat a/b/c) /justification
3031	CA 5.1.1	Anadon et al.	2009	Toxicokinetics of glyphosate and its metabolite aminomethyl phosphonic acid in rats .	Toxicology letters, (2009 Oct 08) Vol. 190, No. 1, pp. 91-5	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
140	CA 5.9.4.	Andreotti et al.	2009	Agricultural pesticide use and pancreatic cancer risk in the Agricultural Health Study Cohort.	International Journal of Cancer, (15 May 2009) Vol. 124, No. 10, pp. 2495-2500	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
2209	CA 5.9.4.	Hoppin et al.	2006	Pesticides and adult respiratory outcomes in the agricultural health study.	Ann. N. Y. Acad. Sci., Vol. 1076, Issue Living in a Chemical World, Page 343-354, Publication Year 2006	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
2206	CA 5.9.4.	Lee et al.	2007	Pesticide use and colorectal cancer risk in the Agricultural Health Study.	Int. J. Cancer, Vol. 121, Issue 2, Page 339-346, Publication Year 2007	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
1697	CA 5.9.4.	Weselak et al.	2007	In utero pesticide exposure and childhood morbidity.	Environmental Research, (JAN 2007) Vol. 103, No. 1, pp. 79-86	5.4.1 case a) relevant and provides data for the risk assessment: This was a retrospective cohort study conducted in Canada as part of the Ontario Farm Family Health Study (OFFHS). A short summary for this article is provided.
2196	CA 5.9.4.	Eriksson et al.	2008	Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis.	International journal of cancer, (2008 Oct 01) Vol. 123, No. 7, pp. 1657-63.	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3084	CA 8.1.4 CA 8.7	Rohr et al.	2008	Understanding the net effects of pesticides on amphibian trematode infections.	Ecological applications : a publication of the Ecological Society of America, (2008 Oct) Vol. 18, No. 7, pp. 1743-53	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3012	CA 8.2.1	Langiano Vivian Do Carmo et al.	2008	Toxicity and effects of a glyphosate -based herbicide on the Neotropical fish Prochilodus lineatus.	Comparative biochemistry and physiology. Toxicology and pharmacology : CBP, (2008 Mar) Vol. 147, No. 2, pp. 222-31	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
1124	CA 8.2.1 CA 8.2.2	Stehr et al.	2009	Evaluating the Effects of Forestry Herbicides on Fish Development Using Rapid Phenotypic Screens	North American Journal of Fisheries Management [N. Am. J. Fish. Manage.]. Vol. 29, no. 4, pp. 975-984. Aug 2009	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3016	CA 8.2.4.1 CA 8.2.6.1	Pereira et al.	2009	Toxicity evaluation of three pesticides on non-target aquatic and soil organisms: commercial formulation versus active ingredient.	Ecotoxicology (London, England), (2009 May) Vol. 18, No. 4, pp. 455-63	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
100	CA 8.2.4.2 CA 8.2.5.2	Bringolf et al.	2007	Acute and chronic toxicity of glyphosate compounds to glochidia and juveniles of Lampsilis siliquoidea (Unionidae).	Environmental toxicology and chemistry, (2007 Oct) Vol. 26, No. 10, pp. 2094-100	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
834	CA 8.2.6.1	Vendrell et al.	2009	Effect of glyphosate on growth of four freshwater species of phytoplankton: a microplate bioassay.	Bulletin of environmental contamination and toxicology, (2009 May) Vol. 82, No. 5, pp. 538-42	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	Classification (cat a/b/c) /justification
413	CP 10.6.2 CA 8.2.7 CA 8.2.6.1	Cedergreen et al.	2007	Combination effects of herbicides on plants and algae: do species and test systems matter?	Pest Management Science (2007), 63(3), 282-295	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.

Table 24: 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	Classification (cat a/b/c) /justification
3031	Anadon et al.	CA 5.1.1	2009	Toxicokinetics of glyphosate and its metabolite aminomethyl phosphonic acid in rats .	Toxicology letters, (2009 Oct 08) Vol. 190, No. 1, pp. 91-5	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
140	Andreotti et al.	CA 5.9.4.	2009	Agricultural pesticide use and pancreatic cancer risk in the Agricultural Health Study Cohort.	International Journal of Cancer, (15 May 2009) Vol. 124, No. 10, pp. 2495-2500	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
100	Bringolf et al.	CA 8.2.4.2 CA 8.2.5.2	2007	Acute and chronic toxicity of glyphosate compounds to glochidia and juveniles of Lampsilis siliquoidea (Unionidae).	Environmental toxicology and chemistry, (2007 Oct) Vol. 26, No. 10, pp. 2094-100	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
413	Cedergreen et al.	CP 10.6.2 CA 8.2.7 CA 8.2.6.1	2007	Combination effects of herbicides on plants and algae: do species and test systems matter?	Pest Management Science (2007), 63(3), 282-295	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
2196	Eriksson et al.	CA 5.9.4.	2008	Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis.	International journal of cancer, (2008 Oct 01) Vol. 123, No. 7, pp. 1657-63.	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
2209	Hoppin et al.	CA 5.9.4.	2006	Pesticides and adult respiratory outcomes in the agricultural health study.	Ann. N. Y. Acad. Sci., Vol. 1076, Issue Living in a Chemical World, Page 343-354, Publication Year 2006	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3012	Langiano Vivian Do Carmo et al.	CA 8.2.1	2008	Toxicity and effects of a glyphosate -based herbicide on the Neotropical fish Prochilodus lineatus.	Comparative biochemistry and physiology. Toxicology and pharmacology : CBP, (2008 Mar) Vol. 147, No. 2, pp. 222-31	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
2206	Lee et al.	CA 5.9.4.	2007	Pesticide use and colorectal cancer risk in the Agricultural Health Study.	Int. J. Cancer, Vol. 121, Issue 2, Page 339-346, Publication Year 2007	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3016	Pereira et al.	CA 8.2.4.1 CA 8.2.6.1	2009	Toxicity evaluation of three pesticides on non-target aquatic and soil organisms: commercial formulation versus active ingredient.	Ecotoxicology (London, England), (2009 May) Vol. 18, No. 4, pp. 455-63	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
3084	Rohr et al.	CA 8.1.4 CA 8.7	2008	Understanding the net effects of pesticides on amphibian trematode infections.	Ecological applications : a publication of the Ecological Society of America, (2008 Oct) Vol. 18, No. 7, pp. 1743-53	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
1124	Stehr et al.	CA 8.2.1 CA 8.2.2	2009	Evaluating the Effects of Forestry Herbicides on Fish Development Using Rapid Phenotypic Screens	North American Journal of Fisheries Management [N. Am. J. Fish. Manage.]. Vol. 29, no. 4, pp. 975-984. Aug 2009	5.4.1 case a) relevant and provides data for the risk assessment: A summary for this article is provided.
834	Vendrell et al.	CA 8.2.6.1	2009	Effect of glyphosate on growth of four freshwater species of phytoplankton: a microplate bioassay.	Bulletin of environmental contamination and toxicology, (2009 May) Vol. 82, No. 5, pp. 538-42	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	Classification (cat a/b/c) /justification
1697	Weselak et al.	CA 5.9.4.	2007	In utero pesticide exposure and childhood morbidity.	Environmental Research, (JAN 2007) Vol. 103, No. 1, pp. 79-86	5.4.1 case a) relevant and provides data for the risk assessment: This was a retrospective cohort study conducted in Canada as part of the Ontario Farm Family Health Study (OFFHS). A short summary for this article is provided.

Table 25: 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
243	CA 5.7	Radio et al.	2008	Assessment of Chemical Effects on Neurite Outgrowth in PC12 cells Using High Content Screening.	Toxicol. Sci., Vol. 105, Issue 1, Page 106-118, Publication Year 2008	5.4.1 case b) relevant but supplementary information: The data presented in this study provide only supportive information for the risk asessment regarding effect of glyphosate on outgrowth of neurites in differentiated Neuroscreen-1 cells.
1336	CA 5.8.1	Manas et al.	2009	Genotoxicity of AMPA, the environmental metabolite of glyphosate , assessed by the Comet assay and cytogenetic tests.	Ecotoxicology and environmental safety, (2009 Mar) Vol. 72, No. 3, pp. 834-7	5.4.1 case b) relevant but supplementary information: The publication is providing genotoxcity information on AMPA via in vitro Comet assay in Hep-2, chromosome aberration test in human lymphocytes and in vivo micronucleus test in mice. The article was downgraded to Category B due to its non-reliability.
174	CA 5.8.2	Abass et al.	2009	An evaluation of the cytochrome P450 inhibition potential of selected pesticides in human hepatic microsomes.	J. Environ. Sci. Health, Part B, Vol. 44, Issue 6, Page 553-563, Publication Year 2009	5.4.1 case b) relevant but supplementary information: The study provides only supplementary information on hepatic CYP interaction in vitro; results do not change the existing risk assessment.
332	CA 5.8.2	Chan et al.	2007	Cardiovascular effects of herbicides and formulated adjuvants on isolated rat aorta and heart.	Toxicol. in Vitro, Vol. 21, Issue 4, Page 595-603, Publication Year 2007	5.4.1 case b) relevant but supplementary information: The article is relevant for the risk assessment since it analyses the effects on cardiovascular cells exposed to glyphosate technical grade. Although only additional information is provided for the risk assessment.
598	CA 5.8.2	Hultberg et al.	2007	Cysteine turnover in human cell lines is influenced by glyphosate .	Environmental Toxicology and Pharmacology, (JUL 2007) Vol. 24, No. 1, pp. 19-22	5.4.1 case b) relevant but supplementary information: The article is providing only supplementary information for the risk assessment regarding the effect of Glyphosate to intra and extra cellular cysteine and glutathione levels.
1296	CA 5.8.2	Mclaughlin et al.	2008	Functional expression and comparative characterization of nine murine cytochromes P 450 by fluorescent inhibition screening	Drug Metabolism and Disposition, (2008) Vol. 36, No. 7, pp. 1322-1331	5.4.1 case b) relevant but supplementary information: The data presented in this study provide only supportive information for the risk asessment regarding potential interaction of glyphosate with mouse and human P450s involved in xenobiotic metabolism.
155	CA 5.8.3	Hokanson et al.	2007	Alteration of estrogen-regulated gene expression in human cells induced by the agricultural and horticultural herbicide glyphosate .	Human and experimental toxicology, (2007 Sep) Vol. 26, No. 9, pp. 747-52	5.4.1 case b) relevant but supplementary information: The toxicity of glyphosate poduct (15%) was examined as a function of its capacity to alter gene expression (29 up and down regulated genes) in the presence or absence of estrogen. Temporal altered gene expression is not a biomarker for toxicity, but rather, may be within the range of normal biological responses of homeostasis. In vitro cytotoxicity of surfactants, however, is a significant confounder in data interpretation. Data do not reflect real in vivo exposure situations, and therefore only provides supporting information for human risk assessment purposes.
297	CA 5.9.4.	Bolognesi et al.	2009	Biomonitoring of genotoxic risk in agricultural workers from five colombian regions: association to occupational exposure to glyphosate .	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 986-97	5.4.1 case b) relevant but supplementary information: This article was downgraded to Category B due to its non-reliability. This publication is considered relevant for the risk assessment of glyphosate, but as supplementary material, and as not reliable. Information necessary to classify health outcome was not collected

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
						at the individual participant level; it is not possible to assess the health outcome in relation to any exposure using the results reported in this study. Additionally, exposure classification was based on self-reported glyphosate exposure, an indirect method by which to estimate exposure status of study participants. No biological evidence is provided to support exposure classification of study participants. Misclassification of either exposure, outcome, or both is possible in this study.
2270	CA 5.9.4.	Caldas et al.	2008	Poisonings with pesticides in the Federal District of Brazil.	Clin. Toxicol., Vol. 46, Issue 10, Page 1058-1063, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
108	CA 5.9.4.	Calvert et al.	2008	Acute pesticide poisoning among agricultural workers in the United States, 1998-2005.	American Journal of Industrial Medicine, (December 2008) Vol. 51, No. 12, pp. 883-898	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
2198	CA 5.9.4.	Dasgupta et al.	2007	Pesticide poisoning of farm workers-implications of blood test results from Vietnam.	Int. J. Hyg. Environ. Health, Vol. 210, Issue 2, Page 121-132, Publication Year 2007	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
377	CA 5.9.4.	Firth et al.	2007	Chemical exposure among NZ farmers.	International journal of environmental health research, (2007 Feb) Vol. 17, No. 1, pp. 33-43	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
2208	CA 5.9.4.	Horiuchi et al.	2008	Pesticide-related dermatitis in Saku district, Japan, 1975-2000.	International journal of occupational and environmental health, (2008 Jan-Mar) Vol. 14, No. 1, pp. 25-34	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
136	CA 5.9.4.	Naidoo et al.	2008	Agricultural activities, pesticide use and occupational hazards among women working in small scale farming in Northern KwaZulu-Natal, South Africa.	Int. J. Occup. Environ. Health, Vol. 14, Issue 3, Page 218-224, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
3281	CA 5.9.4.	Recena et al.	2006	Pesticides exposure in Culturama, Brazil-Knowledge, attitudes, and practices	Environmental Research, (2006) Vol. 102, No. 2, pp. 230-236	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
2416	CA 5.9.4.	Sanin et al.	2009	Regional differences in time to pregnancy among fertile women from five Colombian regions with different use of glyphosate .	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 949-60	5.4.1 case b) relevant but supplementary information: This article was downgraded to Category B due to its non-reliability. This publication is considered relevant for the risk assessment of glyphosate, but as supplementary material, and as not reliable. Information necessary to classify health outcome was not collected at the individual participant level; no biological evidence is provided to support exposure classification of study participants. Misclassification of exposure is possible in this study. It is not possible to assess the health outcome in relation to exposure using the results reported in this study.
1257	CA 5.9.4.	Settimi et al.	2008	Findings from the Italian Program for Surveillance of Acute Pesticide-related Illness, 2005	Clinical Toxicology [Clin. Toxicol.], (20080600) vol. 46, no. 5, p. 388	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
2418	CA 5.9.4.	Sudakin et al.	2009	Regional variation in the severity of pesticide exposure outcomes: applications of geographic information systems and spatial scan statistics	Clinical Toxicology, (2009) Vol. 47, No. 3, pp. 248-252	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
1006	CA 6.5.3	Saka et al.	2008	Effects of processing and cooking on the levels of pesticide residues in soybean samples.	Shokuhin Eiseigaku Zasshi, (JUN 2008) Vol. 49, No. 3, pp. 160-167.	5.4.1 case b) relevant but supplementary information: It provides the information on Pfs that can be used supportive of setting the MRLs. However, in the current Japanese MRL setting system, the MRL for soybean is set for RAC and Pfs for soy bean products are not reflected into the dietary risk assessment.
1231	CA 7.1.2	Simonsen et al.	2008	Fate and availability of glyphosate and AMPA in agricultural soil .	Journal of environmental science and health. Part. B, Pesticides, food contaminants, and agricultural wastes, (2008 Jun) Vol. 43, No. 5, pp. 365-75	5.4.1 case b) relevant but supplementary information: The experimental setup and analytical method are quite well described. The study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Tested soil was not glyphosate free.
623	CA 7.1.2 CA 7.1.3.1	Mamy et al.	2007	Desorption and time-dependent sorption of herbicides in soils	European journal of soil science (2007) , Vol. 58, No. 1, pp. 174-187	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method are quite well described. The study has some deficiencies and results are not presented in detail. Thus, endpoints cannot be verified.
1000	CA 7.1.3.1	Caceres-Jensen et al.	2009	Adsorption of glyphosate on variable-charge, volcanic ash-derived soils .	Journal of environmental quality, (2009 Jul-Aug) Vol. 38, No. 4, pp. 1449-57	5.4.1 case b) relevant but supplementary information: Volcanic ash soils were investigated. These are not relevant for EU but can be relevant for Japan. The experimental setup is quite well described. The study has some deficiencies and results are not presented in detail. Thus, endpoints cannot be verified.
1576	CA 7.1.3.1	Farenhorst et al.	2008	Herbicide sorption coefficients in relation to soil properties and terrain attributes on a cultivated prairie.	Journal of environmental quality, (2008 May-Jun) Vol. 37, No. 3, pp. 1201-8	5.4.1 case b) relevant but supplementary information: The article investigated the adsorption of glyphosate on soil. 287 surface soils (0–15 cm) collected in a 10 × 10 m grid across a heavily eroded, undulating, calcareous prairie landscape in Minnesota (U.S.). Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Adsorption coefficients are only presented a mean values for respective slopes of the sampling location. The study is considered not reliable.
1722	CA 7.1.3.1	Accinelli et al.	2006	Influence of Cry1Ac toxin on mineralization and bioavailability of glyphosate in soil .	Journal of agricultural and food chemistry (2006) , Vol. 54, No. 1, pp. 164-169	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
1896	CA 7.1.3.1	Candela et al.	2007	Laboratory studies on glyphosate transport in soils of the Maresme area near Barcelona, Spain: Transport model parameter estimation.	Geoderma, (JUN 15 2007) Vol. 140, No. 1-2, pp. 8-16	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
2669	CA 7.1.3.1	Sorensen et al.	2006	Sorption , desorption and mineralisation of the herbicides	Environmental pollution (2006) , Vol. 141, No. 1, pp. 184-194	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
				glyphosate and MCPA in samples from two Danish soil and subsurface profiles.		deficiencies and results are not presented in details. One soil site was heavily used for agriculture in the past - the usage of glyphosate is likely. Thus, endpoints cannot be verified. Experiments were performed at 10°C. Additionally, no parental mass balance was established.
2671	CA 7.1.3.1	Al-Rajab et al.	2008	Sorption and leaching of 14 C-glyphosate in agricultural soils	Agronomy for Sustainable Development (Jul 2008) Vol. 28, No. 3, pp. 419-428	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. However, details in the method description are unclear (especially equilibration time). Study has some deficiencies and results are not presented in details. Additionally, no parental mass balance was established. Thus, endpoints cannot be verified.
3128	CA 7.1.3.1	Jacobsen et al.	2008	Variation of MCPA, metribuzine, methyltriazine-amine and glyphosate degradation, sorption, mineralization and leaching in different soil horizons.	Environ. Pollut. (Oxford, U. K.), Vol. 156, Issue 3, Page 794-802, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Experiments were performed at 10°C and only one concentration was used. Additionally, no parental mass balance was established.
3130	CA 7.1.3.1	Farenhorst et al.	2009	Variations in soil properties and herbicide sorption coefficients with depth in relation to PRZM (pesticide root zone model) calculations	Geoderma (2009) , Vol. 150, No. 3-4, pp. 267-277 Source Note: 2009 May 15, v. 150, issue 3-4	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Additionally, no parental mass balance was established. Thus, endpoints cannot be verified.
1010	CA 7.1.3.1	Laitinen et al.	2008	Effects of soil phosphorus status on environmental risk assessment of glyphosate and glufosinate-ammonium.	J. Environ. Qual., Volume 37, Issue 3, Page 830-838, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described, however several details are not reported (e.g. which phase was analysed). Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
2174	CA 7.1.3.1.1 CA 7.1.3.1.2	Gjettermann et al.	2009	Particle-facilitated pesticide leaching from differently structured soil monoliths.	Journal of environmental quality, (2009 Nov-Dec) Vol. 38, No. 6, pp. 2382-93	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described, however several details are not reported (e.g. which phase was analysed). Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
2026	CA 7.1.4.2	Grundmann et al.	2008	Mineralization and Transfer Processes of 14C-labeled Pesticides in Outdoor Lysimeters	Water, air and soil pollution. Focus (2008) , Vol. 8, No. 2, pp. 177-185	5.4.1 case b) relevant but supplementary information: The study has several deficinecies. Furthermore, experimental set-up and analytical results are not described in detail.
1442	CA 7.1.4.3	Laitinen et al.	2009	Glyphosate and phosphorus leaching and residues in boreal sandy soil	PLANT AND SOIL, (OCT 2009) Vol. 323, No. 1-2, Sp. iss. SI, pp. 267-283	5.4.1 case b) relevant but supplementary information: The study does not represent worst case condition. The study period was dry in the whole Southern and Central Finland causing exceptionally low groundwater table levels and droughts in spring 2003. During the whole study the total precipitation was 867 mm in the experimental field, representing 80% of the long-term precipitation. Furthermore, the leaching field was situated in an intensively cultivated region,

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
						where the use of glyphosate is common.
1238	CA 7.2.1.2	Chen et al.	2007	Fe(III)-pyruvate and Fe(III)-citrate induced photodegradation of Glyphosate in aqueous solutions	Journal of Coordination Chemistry, (2007) Vol. 60, No. 22, pp. 2431-2439	5.4.1 case b) relevant but supplementary information: The article shows that glyphosate is stable to photolysis at wavelengths ≥365 nm. According to the guideline, wavermength ≥290 nm should be investigated.
644	CA 7.5	Popp et al.	2008	Determination of glyphosate and AMPA in surface and waste water using high-performance ion chromatography coupled to inductively coupled plasma dynamic reaction cell mass spectrometry (HPIC-ICP-DRC-MS)	Analytical and bioanalytical chemistry (2008) , Vol. 391, No. 2, pp. 695-699	5.4.1 case b) relevant but supplementary information: Details on sampling like exact location, timing, duration and sampling method are not available. Therefore, results cannot be related to the application schedule of glyphosate. Furthermore, available information on the analytical method and its validation does not allow for a full assessment of its acceptability.
23	CA 8.1.4 CA 8.2.8	Relyea et al.	2009	A cocktail of contaminants: how mixtures of pesticides at low concentrations affect aquatic communities .	Oecologia, (2009 Mar) Vol. 159, No. 2, pp. 363-76	5.4.1 case b) relevant but supplementary information: Provides information on the effects of glyphosate on phytoplankton, zooplankton and periphyton and larval development of ambphibians but no risk assessment relevant endpoints are presented.
996	CA 8.1.5	Quassinti et al.	2009	Effects of paraquat and glyphosate on steroidogenesis in gonads of the frog Rana esculenta in vitro	Pesticide biochemistry and physiology (2009) , Vol. 93, No. 2, pp. 91-95	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
1601	CA 8.2.1	Ayoola et al.	2008	Histopathological effects of glyphosate on juvenile African catfish (Clarias gariepinus).	American-Eurasian Journal of Agricultural and Environmental Science (2008) , Vol. 4, No. 3, pp. 362-367	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
3269	CA 8.2.1	Carriquiriborde et al.	2006	Ecotoxicological studies on the pejerrey (Odontesthes bonariensis, Pisces Atherinopsidae).	Biocell, (2006) Vol. 30, No. 1, pp. 97-109	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
3024	CA 8.2.1 / CP 10.2.1	Ayoola et al.	2008	Toxicity of glyphosate herbicide on Nile tilapia (Oreochromis niloticus) juvenile.	African Journal of Agricultural Research (2008) , Vol. 3, No. 12, pp. 825-834	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
197	CA 8.2.4.1 CA 8.2.4.2	Dominguez-Cortinas et al.	2008	Analysis of the toxicity of glyphosate and Faena (R) using the freshwater invertebrates	Toxicological and Environmental Chemistry, (2008) Vol. 90, No. 2, pp. 377-384	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
				Daphnia magna and Lecane quadridentata.		item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
1119	CA 8.2.4.1 CA 8.2.4.2	Melnichuk et al.	2007	Estimation of toxicity of glyphosate -based herbicides by biotesting method using Cladocera.	Hydrobiological Journal, (2007) Vol. 43, No. 3, pp. 80-91	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
3028	CA 8.2.4.2 CA 8.2.5.2	Achiorno et al.	2008	Toxicity of the herbicide glyphosate to Chordodes nobilii (Gordiida, Nematomorpha).	Chemosphere, (2008 May) Vol. 71, No. 10, pp. 1816-22	5.4.1 case b) relevant but supplementary information: Data on adult mortality are not relevant, because the test was conducted with a Roundup formulation. The endpoint for larvae is based on infective capacity (of previously exposed larvae or embryos) for which significant differences compared to control were demonstrated at all tested concentrations. Therefore, a LOEC is the only endpoint that can be established from this study and a LOEC cannot be used in the aquatic RA. Results are considered as only supportive.
939	CA 8.2.4.2 CA 8.2.5.2	Melnichuk et al.	2007	Effects of Fakel herbicide on vital activity of Ceriodaphnia affinis in acute and chronic experiments.	Hydrobiological Journal, (2007) Vol. 43, No. 6, pp. 83-91	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
2945	CA 8.2.5.1	Papchenkova et al.	2009	The parameters of reproduction , sizes, and activities of hydrolases in Daphnia magna straus of successive generations affected by Roundup herbicide.	Inland Water Biology, (JUL 2009) Vol. 2, No. 3, pp. 286-291	5.4.1 case b) relevant but supplementary information: The article shows significant effects compared to the control for some variables and no effects for some other, so no clear endpoint from this study can be used for the risk assessment. Results are considered as only supportive.
751	CA 8.2.6.2	Ruan et al.	2008	Effects of acute glyphosate exposure on the growth and physiology of Nostoc sphaeroides, an edible cyanobacterium of paddy rice fields.	Acta Hydrobiologica Sinica, (JUL 2008) Vol. 32, No. 4, pp. 462-468	5.4.1 case b) relevant but supplementary information: Taking into account that the sampling dates and measured variables do not comply with guidelines, the results of the study are considered only as supportive/supplementary.
698	CA 8.2.7	Nielsen et al.	2007	Direct and indirect effects of the herbicides Glyphosate , Bentazone and MCPA on eelgrass (Zostera marina).	Aquatic toxicology (Amsterdam, Netherlands), (2007 Apr 20) Vol. 82, No. 1, pp. 47-54	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
2915	CA 8.2.7 CP 10.2.1	Turgut et al.	2006	The impact of pesticides toward parrotfeather when applied at the predicted environmental concentration	Chemosphere (2006), Vol. Date 2007, 66(3), 469-473	5.4.1 case b) relevant but supplementary information: The article shows significant effects compared to the control at the only tested rate for some variables and no effects for some other, so no clear endpoint from this study can be used for the risk assessment. Results

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
						are considered as only supportive.
997	CA 8.2.8	Widenfalk et al.	2008	Effects of pesticides on community composition and activity of sediment microbes -- responses at various levels of microbial community organization.	Environmental pollution (Barking, Essex : 1987), (2008 Apr) Vol. 152, No. 3, pp. 576-84	5.4.1 case b) relevant but supplementary information: Detected effects of this study are based on molecular methods that cannot be univocally integrated in the risk assessment. In addition a LOEC cannot be used in the aquatic RA. The article failed to demonstrate effects of glyphosate exposure on community-level endpoints of sediment microorganisms (bacterial activity, fungal and total microbial biomass). Results are considered as only supportive.
251	CA 8.2.8	Bonnet et al.	2007	Assessment of the potential toxicity of herbicides and their degradation products to nontarget cells using two microorganisms , the bacteria Vibrio fischeri and the ciliate Tetrahymena pyriformis.	Environmental toxicology, (2007 Feb) Vol. 22, No. 1, pp. 78-91	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
3017	CA 8.2.8	Hernando et al.	2007	Toxicity evaluation with Vibrio fischeri test of organic chemicals used in aquaculture.	Chemosphere, Vol. 68, Issue 4, Page 724-730, Publication Year 2007	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
2504	CA 8.2.8	Pesce et al.	2009	Response of spring and summer riverine microbial communities following glyphosate exposure .	Ecotoxicology and environmental safety, (2009 Oct) Vol. 72, No. 7, pp. 1905-12	5.4.1 case b) relevant but supplementary information: Although at 10 µg/L no differences between treated and control were detected for chlorophyl content and biomass data (i.e. NOEC), the study does show effects in the community composition at that concentration for the higher temperature. In the treated microcosms, three algal genera (Asterionella, Cyclotella and Oocystis) disappeared between day 0 and day 3. Therefore, a LOEC is the only endpoint that can be established from this microcosm study and a LOEC cannot be used in the aquatic RA. Results are considered as only supportive.
875	CA 8.4	Yasmin et al.	2007	Effect of pesticides on the reproductive output of Eisenia fetida .	Bulletin of environmental contamination and toxicology, (2007 Nov) Vol. 79, No. 5, pp. 529-32	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
1140	CA 8.4.2	Ruan et al.	2009	Evaluation of Pesticide Toxicities with Differing Mechanisms Using Caenorhabditis elegans.	J. Toxicol. Environ. Health, Part A, Vol. 72, Issue 11 and 12, Page 746-751, Publication Year 2009	5.4.1 case b) relevant but supplementary information: No endpoints (NOEC, LOEC, Ecx) are provided, but some findings of the work (generation time, brood size) could serve to investigate sub-lethal effects of glyphosate on non macro-soil organisms as part of a broader discussion.
169	CA 8.5	Przybulewska	2008	An attempt to determine the	Ecol. Chem. Eng. S, Vol. 15, Issue 3,	5.4.1 case b) relevant but supplementary information: No endpoints

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
		et al.		resistance of microorganisms from triazine-contaminated soils to different herbicide groups.	Page 359-374, Publication Year 2008	are provided. Although this publication provides information about effects of high concentrations of Roundup 360 SL formulation (representative EU formulation) in soil on micro-organisms, the results are shown only in form of graphs and no detailed results are presented. Therefore the results of the study are considered only as supportive/supplementary.
3022	CP 10.2.1	Erms et al.	2009	Toxicity of glyphosate and ethoxysulfuron to the green microalgae (Scenedesmus obliquus).	Asian Journal of Chemistry (2009) , Vol. 21, No. 3, pp. 2163-2169	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
978	CP 10.5	Mijangos et al.	2009	Effects of glyphosate on rhizosphere soil microbial communities under two different plant compositions by cultivation-dependent and -independent methodologies	Soil biology and biochemistry (2009) , Vol. 41, No. 3, pp. 505-513	5.4.1 case b) relevant but supplementary information: The article still shows significant effects compared to the control at the lowest tested rate under some of the tested scenarios, so no clear endpoint from this study can be used for the risk assessment. In addition, glyphosate effect is not the only and single tested variable. Results are considered as only supportive.
3090		Curwin et al.	2007	Urinary pesticide concentrations among children, mothers and fathers living in farm and non-farm households in iowa.	The Annals of occupational hygiene, (2007 Jan) Vol. 51, No. 1, pp. 53-65	5.4.1 case b) relevant but supplementary information: Biomonitoring in Urine of farmer children, concentration in urine samples is only reported, likely not relevant or only supportive. Not relevant information for risk assessment but relevant for the dossier.

Table 26: 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
174	Abass et al.	CA 5.8.2	2009	An evaluation of the cytochrome P450 inhibition potential of selected pesticides in human hepatic microsomes.	J. Environ. Sci. Health, Part B, Vol. 44, Issue 6, Page 553-563, Publication Year 2009	5.4.1 case b) relevant but supplementary information: The study provides only supplementary information on hepatic CYP interaction in vitro; results do not change the existing risk assessment.
1722	Accinelli et al.	CA 7.1.3.1	2006	Influence of Cry1Ac toxin on mineralization and bioavailability of glyphosate in soil .	Journal of agricultural and food chemistry (2006) , Vol. 54, No. 1, pp. 164-169	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
3028	Achiorno et al.	CA 8.2.4.2 CA 8.2.5.2	2008	Toxicity of the herbicide glyphosate to Chordodes nobilii (Gordiida, Nematomorpha).	Chemosphere, (2008 May) Vol. 71, No. 10, pp. 1816-22	5.4.1 case b) relevant but supplementary information: Data on adult mortality are not relevant, because the test was conducted with a Roundup formulation. The endpoint for larvae is based on infective capacity (of previously exposed larvae or embryos) for which significant differences compared to control were demonstrated at all tested concentrations. Therefore, a LOEC is the only endpoint that can be established from this study and a LOEC cannot be used in the aquatic RA. Results are considered as only supportive.
2671	Al-Rajab et al.	CA 7.1.3.1	2008	Sorption and leaching of 14 C-glyphosate in agricultural soils	Agronomy for Sustainable Development (Jul 2008) Vol. 28, No. 3, pp. 419-428	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. However, details in the method description are unclear (especially equilibration time). Study has some deficiencies and results are not presented in details. Additionally, no parental mass balance was established. Thus, endpoints cannot be verified.
1601	Ayoola et al.	CA 8.2.1	2008	Histopathological effects of glyphosate on juvenile African catfish (Clarias gariepinus).	American-Eurasian Journal of Agricultural and Environmental	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
					Science (2008) , Vol. 4, No. 3, pp. 362-367	individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
3024	Ayoola et al.	CA 8.2.1 / CP 10.2.1	2008	Toxicity of glyphosate herbicide on Nile tilapia (Oreochromis niloticus) juvenile.	African Journal of Agricultural Research (2008) , Vol. 3, No. 12, pp. 825-834	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
297	Bolognesi et al.	CA 5.9.4.	2009	Biomonitoring of genotoxic risk in agricultural workers from five colombian regions: association to occupational exposure to glyphosate .	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 986-97	5.4.1 case b) relevant but supplementary information: This article was downgraded to Category B due to its non-reliability. This publication is considered relevant for the risk assessment of glyphosate, but as supplementary material, and as not reliable. Information necessary to classify health outcome was not collected at the individual participant level; it is not possible to assess the health outcome in relation to any exposure using the results reported in this study. Additionally, exposure classification was based on self-reported glyphosate exposure, an indirect method by which to estimate exposure status of study participants. No biological evidence is provided to support exposure classification of study participants. Misclassification of either exposure, outcome, or both is possible in this study.
251	Bonnet et al.	CA 8.2.8	2007	Assessment of the potential toxicity of herbicides and their degradation products to nontarget cells using two microorganisms , the bacteria Vibrio fischeri and the ciliate Tetrahymena pyriformis.	Environmental toxicology, (2007 Feb) Vol. 22, No. 1, pp. 78-91	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
1000	Caceres-Jensen et al.	CA 7.1.3.1	2009	Adsorption of glyphosate on variable-charge, volcanic ash-derived soils .	Journal of environmental quality, (2009 Jul-Aug) Vol. 38, No. 4, pp. 1449-57	5.4.1 case b) relevant but supplementary information: Volcanic ash soils were investigated. These are not relevant for EU but can be relevant for Japan. The experimental setup is quite well described. The study has some deficiencies and results are not presented in detail. Thus, endpoints cannot be verified.
2270	Caldas et al.	CA 5.9.4.	2008	Poisonings with pesticides in the Federal District of Brazil.	Clin. Toxicol., Vol. 46, Issue 10, Page 1058-1063, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
108	Calvert et al.	CA 5.9.4.	2008	Acute pesticide poisoning among agricultural workers in the United States, 1998-2005.	American Journal of Industrial Medicine, (December 2008) Vol. 51, No. 12, pp. 883-898	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
1896	Candela et al.	CA 7.1.3.1	2007	Laboratory studies on glyphosate transport in soils of the Maresme area near Barcelona, Spain: Transport model parameter estimation.	Geoderma, (JUN 15 2007) Vol. 140, No. 1-2, pp. 8-16	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
3269	Carriquiriborde et al.	CA 8.2.1	2006	Ecotoxicological studies on the pejerrey (Odontesthes bonariensis, Pisces Atherinopsidae).	Biocell, (2006) Vol. 30, No. 1, pp. 97-109	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
332	Chan et al.	CA 5.8.2	2007	Cardiovascular effects of herbicides and formulated adjuvants on isolated rat aorta and heart.	Toxicol. in Vitro, Vol. 21, Issue 4, Page 595-603, Publication Year 2007	5.4.1 case b) relevant but supplementary information: The article is relevant for the risk assessment since it analyses the effects on cardiovascular cells exposed to glyphosate technical grade. Although only additional information is provided for the risk assessment.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
1238	Chen et al.	CA 7.2.1.2	2007	Fe(III)-pyruvate and Fe(III)-citrate induced photodegradation of Glyphosate in aqueous solutions	Journal of Coordination Chemistry, (2007) Vol. 60, No. 22, pp. 2431-2439	5.4.1 case b) relevant but supplementary information: The article shows that glyphosate is stable to photolysis at wavelengths ≥365 nm. According to the guideline, wavermength ≥290 nm should be investigated.
3090	Curwin et al.		2007	Urinary pesticide concentrations among children, mothers and fathers living in farm and non-farm households in iowa.	The Annals of occupational hygiene, (2007 Jan) Vol. 51, No. 1, pp. 53-65	5.4.1 case b) relevant but supplementary information: Biomonitoring in Urine of farmer children, concentration in urine samples is only reported, likely not relevant or only supportive. Not relevant information for risk assessment but relevant for the dossier.
2198	Dasgupta et al.	CA 5.9.4.	2007	Pesticide poisoning of farm workers-implications of blood test results from Vietnam.	Int. J. Hyg. Environ. Health, Vol. 210, Issue 2, Page 121-132, Publication Year 2007	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
197	Dominguez-Cortinas et al.	CA 8.2.4.1 CA 8.2.4.2	2008	Analysis of the toxicity of glyphosate and Faena (R) using the freshwater invertebrates Daphnia magna and Lecane quadridentata.	Toxicological and Environmental Chemistry, (2008) Vol. 90, No. 2, pp. 377-384	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
3022	Erms et al.	CP 10.2.1	2009	Toxicity of glyphosate and ethoxysulfuron to the green microalgae (Scenedesmus obliquus).	Asian Journal of Chemistry (2009) , Vol. 21, No. 3, pp. 2163-2169	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
1576	Farenhorst et al.	CA 7.1.3.1	2008	Herbicide sorption coefficients in relation to soil properties and terrain attributes on a cultivated prairie.	Journal of environmental quality, (2008 May-Jun) Vol. 37, No. 3, pp. 1201-8	5.4.1 case b) relevant but supplementary information: The article investigated the adsorption of glyphosate on soil. 287 surface soils (0–15 cm) collected in a 10 × 10 m grid across a heavily eroded, undulating, calcareous prairie landscape in Minnesota (U.S.). Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
						verified. Adsorption coefficients are only presented a mean values for respective slopes of the sampling location. The study is considered not reliable.
3130	Farenhorst et al.	CA 7.1.3.1	2009	Variations in soil properties and herbicide sorption coefficients with depth in relation to PRZM (pesticide root zone model) calculations	Geoderma (2009) , Vol. 150, No. 3-4, pp. 267-277 Source Note: 2009 May 15, v. 150, issue 3-4	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Additionally, no parental mass balance was established. Thus, endpoints cannot be verified.
377	Firth et al.	CA 5.9.4.	2007	Chemical exposure among NZ farmers.	International journal of environmental health research, (2007 Feb) Vol. 17, No. 1, pp. 33-43	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
2174	Gjettermann et al.	CA 7.1.3.1.1 CA 7.1.3.1.2	2009	Particle-facilitated pesticide leaching from differently structured soil monoliths.	Journal of environmental quality, (2009 Nov-Dec) Vol. 38, No. 6, pp. 2382-93	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described, however several details are not reported (e.g. which phase was analysed). Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Additionally, no parental mass balance was established.
2026	Grundmann et al.	CA 7.1.4.2	2008	Mineralization and Transfer Processes of 14C-labeled Pesticides in Outdoor Lysimeters	Water, air and soil pollution. Focus (2008) , Vol. 8, No. 2, pp. 177-185	5.4.1 case b) relevant but supplementary information: The study has several deficinecies. Furthermore, experimental set-up and analytical results are not described in detail.
3017	Hernando et al.	CA 8.2.8	2007	Toxicity evaluation with Vibrio fischeri test of organic chemicals used in aquaculture.	Chemosphere, Vol. 68, Issue 4, Page 724-730, Publication Year 2007	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
155	Hokanson et al.	CA 5.8.3	2007	Alteration of estrogen-regulated gene expression in human cells induced by the agricultural and horticultural herbicide glyphosate .	Human and experimental toxicology, (2007 Sep) Vol. 26, No. 9, pp. 747-52	5.4.1 case b) relevant but supplementary information: The toxicity of glyphosate poduct (15%) was examined as a function of its capacity to alter gene expression (29 up and down regulated genes) in the presence or absence of estrogen. Temporal altered gene expression is not a biomarker for toxicity, but rather, may be within the range of normal biological responses of homeostasis. In vitro cytotoxicity of surfactants, however, is a significant confounder in data interpretation. Data do not reflect real in vivo exposure situations, and therefore only provides supporting information for human risk assessment purposes.
2208	Horiuchi et al.	CA 5.9.4.	2008	Pesticide-related dermatitis in Saku district, Japan, 1975-2000.	International journal of occupational and environmental health, (2008 Jan-Mar) Vol. 14, No. 1, pp. 25-34	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
598	Hultberg et al.	CA 5.8.2	2007	Cysteine turnover in human cell lines is influenced by glyphosate .	Environmental Toxicology and Pharmacology, (JUL 2007) Vol. 24, No. 1, pp. 19-22	5.4.1 case b) relevant but supplementary information: The article is providing only supplementary information for the risk assessment regarding the effect of Glyphosate to intra and extra cellular cysteine and glutathione levels.
3128	Jacobsen et al.	CA 7.1.3.1	2008	Variation of MCPA, metribuzine, methyltriazine-amine and glyphosate degradation, sorption, mineralization and leaching in different soil horizons.	Environ. Pollut. (Oxford, U. K.), Vol. 156, Issue 3, Page 794-802, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Experiments were performed at 10°C and only one concentration was used. Additionally, no parental mass balance was established.
1010	Laitinen et al.	CA 7.1.3.1	2008	Effects of soil phosphorus status on environmental risk assessment of glyphosate and glufosinate-ammonium.	J. Environ. Qual., Volume 37, Issue 3, Page 830-838, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described, however several details are not reported (e.g. which phase was analysed). Study has some deficiencies and results are not presented in details. Thus, endpoints

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
						cannot be verified. Additionally, no parental mass balance was established.
1442	Laitinen et al.	CA 7.1.4.3	2009	Glyphosate and phosphorus leaching and residues in boreal sandy soil	PLANT AND SOIL, (OCT 2009) Vol. 323, No. 1-2, Sp. iss. SI, pp. 267-283	5.4.1 case b) relevant but supplementary information: The study does not represent worst case condition. The study period was dry in the whole Southern and Central Finland causing exceptionally low groundwater table levels and droughts in spring 2003. During the whole study the total precipitation was 867 mm in the experimental field, representing 80% of the long-term precipitation. Furthermore, the leaching field was situated in an intensively cultivated region, where the use of glyphosate is common.
623	Mamy et al.	CA 7.1.2 CA 7.1.3.1	2007	Desorption and time-dependent sorption of herbicides in soils	European journal of soil science (2007) , Vol. 58, No. 1, pp. 174-187	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method are quite well described. The study has some deficiencies and results are not presented in detail. Thus, endpoints cannot be verified.
1336	Manas et al.	CA 5.8.1	2009	Genotoxicity of AMPA, the environmental metabolite of glyphosate , assessed by the Comet assay and cytogenetic tests.	Ecotoxicology and environmental safety, (2009 Mar) Vol. 72, No. 3, pp. 834-7	5.4.1 case b) relevant but supplementary information: The publication is providing genotoxcity information on AMPA via in vitro Comet assay in Hep-2, chromosome aberration test in human lymphocytes and in vivo micronucleus test in mice. The article was downgraded to Category B due to its non-reliability.
1296	Mclaughlin et al.	CA 5.8.2	2008	Functional expression and comparative characterization of nine murine cytochromes P 450 by fluorescent inhibition screening	Drug Metabolism and Disposition, (2008) Vol. 36, No. 7, pp. 1322-1331	5.4.1 case b) relevant but supplementary information: The data presented in this study provide only supportive information for the risk asessment regarding potential interaction of glyphosate with mouse and human P450s involved in xenobiotic metabolism.
1119	Melnichuk et al.	CA 8.2.4.1 CA 8.2.4.2	2007	Estimation of toxicity of glyphosate - based herbicides by biotesting method using Cladocera.	Hydrobiological Journal, (2007) Vol. 43, No. 3, pp. 80-91	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
						can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
939	Melnichuk et al.	CA 8.2.4.2 CA 8.2.5.2	2007	Effects of Fakel herbicide on vital activity of Ceriodaphnia affinis in acute and chronic experiments.	Hydrobiological Journal, (2007) Vol. 43, No. 6, pp. 83-91	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
978	Mijangos et al.	CP 10.5	2009	Effects of glyphosate on rhizosphere soil microbial communities under two different plant compositions by cultivation-dependent and -independent methodologies	Soil biology and biochemistry (2009) , Vol. 41, No. 3, pp. 505-513	5.4.1 case b) relevant but supplementary information: The article still shows significant effects compared to the control at the lowest tested rate under some of the tested scenarios, so no clear endpoint from this study can be used for the risk assessment. In addition, glyphosate effect is not the only and single tested variable. Results are considered as only supportive.
136	Naidoo et al.	CA 5.9.4.	2008	Agricultural activities, pesticide use and occupational hazards among women working in small scale farming in Northern KwaZulu-Natal, South Africa.	Int. J. Occup. Environ. Health, Vol. 14, Issue 3, Page 218-224, Publication Year 2008	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
698	Nielsen et al.	CA 8.2.7	2007	Direct and indirect effects of the herbicides Glyphosate , Bentazone and MCPA on eelgrass (Zostera marina).	Aquatic toxicology (Amsterdam, Netherlands), (2007 Apr 20) Vol. 82, No. 1, pp. 47-54	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
2945	Papchenkova et al.	CA 8.2.5.1	2009	The parameters of reproduction , sizes, and activities of hydrolases in Daphnia magna straus of successive generations affected by Roundup herbicide.	Inland Water Biology, (JUL 2009) Vol. 2, No. 3, pp. 286-291	5.4.1 case b) relevant but supplementary information: The article shows significant effects compared to the control for some variables and no effects for some other, so no clear

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
						endpoint from this study can be used for the risk assessment. Results are considered as only supportive.
2504	Pesce et al.	CA 8.2.8	2009	Response of spring and summer riverine microbial communities following glyphosate exposure .	Ecotoxicology and environmental safety, (2009 Oct) Vol. 72, No. 7, pp. 1905-12	5.4.1 case b) relevant but supplementary information: Although at 10 µg/L no differences between treated and control were detected for chlorophyl content and biomass data (i.e. NOEC), the study does show effects in the community composition at that concentration for the higher temperature. In the treated microcosms, three algal genera (Asterionella, Cyclotella and Oocystis) disappeared between day 0 and day 3. Therefore, a LOEC is the only endpoint that can be established from this microcosm study and a LOEC cannot be used in the aquatic RA. Results are considered as only supportive.
644	Popp et al.	CA 7.5	2008	Determination of glyphosate and AMPA in surface and waste water using high-performance ion chromatography coupled to inductively coupled plasma dynamic reaction cell mass spectrometry (HPIC-ICP-DRC-MS)	Analytical and bioanalytical chemistry (2008) , Vol. 391, No. 2, pp. 695-699	5.4.1 case b) relevant but supplementary information: Details on sampling like exact location, timing, duration and sampling method are not available. Therefore, results cannot be related to the application schedule of glyphosate. Furthermore, available information on the analytical method and its validation does not allow for a full assessment of its acceptability.
169	Przybulewska et al.	CA 8.5	2008	An attempt to determine the resistance of microorganisms from triazine-contaminated soils to different herbicide groups.	Ecol. Chem. Eng. S, Vol. 15, Issue 3, Page 359-374, Publication Year 2008	5.4.1 case b) relevant but supplementary information: No endpoints are provided. Although this publication provides information about effects of high concentrations of Roundup 360 SL formulation (representative EU formulation) in soil on micro-organisms, the results are shown only in form of graphs and no detailed results are presented. Therefore the results of the study are considered only as supportive/supplementary.
996	Quassinti et al.	CA 8.1.5	2009	Effects of paraquat and glyphosate on steroidogenesis in gonads of the frog Rana esculenta in vitro	Pesticide biochemistry and physiology (2009) , Vol. 93, No. 2, pp. 91-95	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
						can only be considered as supplementary information that cannot alter the existing risk assessment parameters.
243	Radio et al.	CA 5.7	2008	Assessment of Chemical Effects on Neurite Outgrowth in PC12 cells Using High Content Screening.	Toxicol. Sci., Vol. 105, Issue 1, Page 106-118, Publication Year 2008	5.4.1 case b) relevant but supplementary information: The data presented in this study provide only supportive information for the risk asessment regarding effect of glyphosate on outgrowth of neurites in differentiated Neuroscreen-1 cells.
3281	Recena et al.	CA 5.9.4.	2006	Pesticides exposure in Culturama, Brazil-Knowledge, attitudes, and practices	Environmental Research, (2006) Vol. 102, No. 2, pp. 230-236	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
23	Relyea	CA 8.1.4 CA 8.2.8	2009	A cocktail of contaminants: how mixtures of pesticides at low concentrations affect aquatic communities .	Oecologia, (2009 Mar) Vol. 159, No. 2, pp. 363-76	5.4.1 case b) relevant but supplementary information: Provides information on the effects of glyphosate on phytoplankton, zooplankton and periphyton and larval development of ambphibians but no risk assessment relevant endpoints are presented.
751	Ruan et al.	CA 8.2.6.2	2008	Effects of acute glyphosate exposure on the growth and physiology of Nostoc sphaeroides, an edible cyanobacterium of paddy rice fields.	Acta Hydrobiologica Sinica, (JUL 2008) Vol. 32, No. 4, pp. 462-468	5.4.1 case b) relevant but supplementary information: Taking into account that the sampling dates and measured variables do not comply with guidelines, the results of the study are considered only as supportive/supplementary.
1140	Ruan et al.	CA 8.4.2	2009	Evaluation of Pesticide Toxicities with Differing Mechanisms Using Caenorhabditis elegans.	J. Toxicol. Environ. Health, Part A, Vol. 72, Issue 11 and 12, Page 746-751, Publication Year 2009	5.4.1 case b) relevant but supplementary information: No endpoints (NOEC, LOEC, Ecx) are provided, but some findings of the work (generation time, brood size) could serve to investigate sub-lethal effects of glyphosate on non macro-soil organisms as part of a broader discussion.
1006	Saka et al.	CA 6.5.3	2008	Effects of processing and cooking on the levels of pesticide residues in soybean samples.	Shokuhin Eiseigaku Zasshi, (JUN 2008) Vol. 49, No. 3, pp. 160-167.	5.4.1 case b) relevant but supplementary information: It provides the information on Pfs that can be used supportive of setting the MRLs. However, in the current Japanese MRL setting system, the MRL for soybean is set for RAC and Pfs for soy bean products are not reflected into the dietary risk assessment.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
2416	Sanin et al.	CA 5.9.4.	2009	Regional differences in time to pregnancy among fertile women from five Colombian regions with different use of glyphosate .	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 949-60	5.4.1 case b) relevant but supplementary information: This article was downgraded to Category B due to its non-reliability. This publication is considered relevant for the risk assessment of glyphosate, but as supplementary material, and as not reliable. Information necessary to classify health outcome was not collected at the individual participant level; no biological evidence is provided to support exposure classification of study participants. Misclassification of exposure is possible in this study. It is not possible to assess the health outcome in relation to exposure using the results reported in this study.
1257	Settimi et al.	CA 5.9.4.	2008	Findings from the Italian Program for Surveillance of Acute Pesticide-related Illness, 2005	Clinical Toxicology [Clin. Toxicol.], (20080600) vol. 46, no. 5, p. 388	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome
1231	Simonsen et al.	CA 7.1.2	2008	Fate and availability of glyphosate and AMPA in agricultural soil .	Journal of environmental science and health. Part. B, Pesticides, food contaminants, and agricultural wastes, (2008 Jun) Vol. 43, No. 5, pp. 365-75	5.4.1 case b) relevant but supplementary information: The experimental setup and analytical method are quite well described. The study has some deficiencies and results are not presented in details. Thus, endpoints cannot be verified. Tested soil was not glyphosate free.
2669	Sorensen et al.	CA 7.1.3.1	2006	Sorption , desorption and mineralisation of the herbicides glyphosate and MCPA in samples from two Danish soil and subsurface profiles.	Environmental pollution (2006) , Vol. 141, No. 1, pp. 184-194	5.4.1 case b) relevant but supplementary information: Experimental setup and analytical method quite well described. Study has some deficiencies and results are not presented in details. One soil site was heavily used for agriculture in the past - the usage of glyphosate is likely. Thus, endpoints cannot be verified. Experiments were performed at 10°C. Additionally, no parental mass balance was established.
2418	Sudakin et al.	CA 5.9.4.	2009	Regional variation in the severity of pesticide exposure outcomes: applications of geographic information systems and spatial scan statistics	Clinical Toxicology, (2009) Vol. 47, No. 3, pp. 248-252	5.4.1 case b) relevant but supplementary information: Publication does not report any estimate of association between glyphosate exposure and any health outcome

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
2915	Turgut	CA 8.2.7 CP 10.2.1	2006	The impact of pesticides toward parrotfeather when applied at the predicted environmental concentration	Chemosphere (2006), Vol. Date 2007, 66(3), 469-473	5.4.1 case b) relevant but supplementary information: The article shows significant effects compared to the control at the only tested rate for some variables and no effects for some other, so no clear endpoint from this study can be used for the risk assessment. Results are considered as only supportive.
997	Widenfalk et al.	CA 8.2.8	2008	Effects of pesticides on community composition and activity of sediment microbes --responses at various levels of microbial community organization.	Environmental pollution (Barking, Essex : 1987), (2008 Apr) Vol. 152, No. 3, pp. 576-84	5.4.1 case b) relevant but supplementary information: Detected effects of this study are based on molecular methods that cannot be univocally integrated in the risk assessment. In addition a LOEC cannot be used in the aquatic RA. The article failed to demonstrate effects of glyphosate exposure on community-level endpoints of sediment microorganisms (bacterial activity, fungal and total microbial biomass). Results are considered as only supportive.
875	Yasmin et al.	CA 8.4	2007	Effect of pesticides on the reproductive output of Eisenia fetida .	Bulletin of environmental contamination and toxicology, (2007 Nov) Vol. 79, No. 5, pp. 529-32	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important methodological information is missing (analytical verification of concentrations, test item identification, test individuals and/or substrate source, etc.), so that the results can only be considered as supplementary information that cannot alter the existing risk assessment parameters.

Table 27: 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
601	CA 5.4.1	Sivikova et al.	2006	Cytogenetic effect of technical glyphosate on cultivated bovine peripheral lymphocytes.	International Journal of Hygiene and Environmental Health (2006) , Vol. 209, No. 1, pp. 15-20	5.4.1 case c) unclear relevance for the following reason: The paper is about an in vitro CA and SCE study on bovine lymphocytes exposed to a glyphosate formulation for 2h with metabolic activation and 24h and 48 h without metabolic activation. A glyphosate product (glyphosate , approximate 62% by weight) with 3
2194	CA 5.9.1	Curwin et al.	2007	Pesticide dose estimates for children of Iowa farmers and non-farmers.	Environmental research, (2007 Nov) Vol. 105, No. 3, pp. 307-15	5.4.1 case c) unclear relevance for the following reason: The study is providing only supplementary information for the risk assessment regarding biomonitoring data (urine) for children of farmers and non-farmers.
1545	CA 7.1.7	Malatesta et al.	2008	Hepatoma tissue culture (HTC) cells as a model for investigating the effects of low concentrations of herbicide on cell structure and function.	Toxicology in vitro : an international journal published in association with BIBRA, (2008 Dec) Vol. 22, No. 8, pp. 1853-60	5.4.1 case c) unclear relevance for the following reason: In vitro study with Glyphosate formulation of unknown composition investigating the effects on modifications in mitrochondrial functions and transcription/splicing pathways in hepatocytes. Pure active substance was not tested.
917	CA 8.3.2	Addison et al.	2006	Effect of various pesticides on the non-target species Microctonus hyperodae, a biological control agent of Listronotus bonariensis.	Entomologia Experimentalis et Applicata (2006) Vol. 119, No. 1, pp. 71-79	5.4.1 case c) unclear relevance for the following reason: Study provides information on effects of a Roundup formulation on the parasitoid wasp Microtonus hyperodae. As the exposure situation in the test (exposure via shaking in test solution) is not comparable to the field situation (overspray or exposure to residues) and study condtions are not mentioned the relevance of the study cannot be clearly determined.
430	CP 7.1.7	Dimitrov et al.	2006	Comparative genotoxicity of the herbicides Roundup, Stomp and Reglone in plant and mammalian test systems.	Mutagenesis, (2006 Nov) Vol. 21, No. 6, pp. 375-82. Electronic Publication Date: 23 Sep 2006	5.4.1 case c) unclear relevance for the following reason: The study is providing only supplementary information for the risk assessment. Furthermore, no information on Roundup formulation (batch, adjuvants, expiration date, storage, analytics, purchaser) are given. There are uncertainties whether the test concentrations are in physiologically acceptable range (< 1mM) and the active ingredient content in oral doses is unclear.
1335	CP 7.1.7	Heydens et al.	2008	Genotoxic potential of glyphosate formulations: mode - of - action investigations.	Journal of agricultural and food chemistry, (2008 Feb 27) Vol. 56, No. 4, pp. 1517-23	5.4.1 case c) unclear relevance for the following reason: Genotox data on non-representative glyphosate formulation of unknown composition; relevance uncertain; Publication, no guideline/GLP study/mode of action study: clarifying contradictory results from other genotoxicity studies

Submission Number	Data requirement (indicated by the corresponding CA / CP data point number)	Author(s)	Year	Title	Source	Justification
1182	CP 7.1.7	Holeckova et al.	2006	Evaluation of the in vitro effect of glyphosate -based herbicide on bovine lymphocytes using chromosome painting.	Bulletin of the Veterinary Institute in Puawy (2006) , Vol. 50, No. 4, pp. 533-536	5.4.1 case c) unclear relevance for the following reason: The induction of bovine chromosome 1 aberrations was investigated in cultivated peripheral lymphocytes of cattle after an application of a glyphosate-based herbicide formulation. A glyphosate product (glyphosate , approximate 62% by weight) with 38% inert

Table 28: 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 number)	Year	Title	Source	Justification
917	Addison et al.	CA 8.3.2	2006	Effect of various pesticides on the non-target species Microctonus hyperodae, a biological control agent of Listronotus bonariensis.	Entomologia Experimentalis et Applicata (2006) Vol. 119, No. 1, pp. 71-79	5.4.1 case c) unclear relevance for the following reason: Study provides information on effects of a Roundup formulation on the parasitoid wasp Microtonus hyperodae. As the exposure situation in the test (exposure via shaking in test solution) is not comparable to the field situation (overspray or exposure to residues) and study condtions are not mentioned the relevance of the study cannot be clearly determined.
2194	Curwin et al.	CA 5.9.1	2007	Pesticide dose estimates for children of Iowa farmers and non-farmers.	Environmental research, (2007 Nov) Vol. 105, No. 3, pp. 307-15	5.4.1 case c) unclear relevance for the following reason: The study is providing only supplementary information for the risk assessment regarding biomonitoring data (urine) for children of farmers and non-farmers.
430	Dimitrov et al.	CP 7.1.7	2006	Comparative genotoxicity of the herbicides Roundup, Stomp and Reglone in plant and mammalian test systems.	Mutagenesis, (2006 Nov) Vol. 21, No. 6, pp. 375-82. Electronic Publication Date: 23 Sep 2006	5.4.1 case c) unclear relevance for the following reason: The study is providing only supplementary information for the risk assessment. Furthermore, no information on Roundup formulation (batch, adjuvants, expiration date, storage, analytics, purchaser) are given. There are uncertainties whether the test concentrations are in physiologically acceptable range (< 1mM) and the active ingredient content in oral doses is unclear.
1335	Heydens et al.	CP 7.1.7	2008	Genotoxic potential of glyphosate formulations: mode - of - action investigations.	Journal of agricultural and food chemistry, (2008 Feb 27) Vol. 56, No. 4, pp. 1517-23	5.4.1 case c) unclear relevance for the following reason: Genotox data on non-representative glyphosate formulation of unknown composition; relevance uncertain; Publication, no guideline/GLP study/mode of action study: clarifying contradictory results from other genotoxicity studies
1182	Holeckova et al.	CP 7.1.7	2006	Evaluation of the in vitro effect of glyphosate -based herbicide on bovine lymphocytes using chromosome painting.	Bulletin of the Veterinary Institute in Puawy (2006) , Vol. 50, No. 4, pp. 533-536	5.4.1 case c) unclear relevance for the following reason: The induction of bovine chromosome 1 aberrations was investigated in cultivated peripheral lymphocytes of cattle after an application of a glyphosate-based herbicide formulation. A glyphosate product (glyphosate , approximate 62% by weight) with 38% inert
1545	Malatesta et al.	CA 7.1.7	2008	Hepatoma tissue culture (HTC) cells as a model for investigating the effects of low concentrations of herbicide on cell structure and function.	Toxicology in vitro : an international journal published in association with BIBRA, (2008 Dec) Vol. 22, No. 8, pp. 1853-60	5.4.1 case c) unclear relevance for the following reason: In vitro study with Glyphosate formulation of unknown composition investigating the effects on modifications in mitrochondrial functions and transcription/splicing pathways in hepatocytes. Pure active substance was not tested.

Submission Number	Author(s)	Data requirement (indicated by the corresponding CA / CP data point number)	Year	Title	Source	Justification
601	Sivikova et al.	CA 5.4.1	2006	Cytogenetic effect of technical glyphosate on cultivated bovine peripheral lymphocytes.	International Journal of Hygiene and Environmental Health (2006) , Vol. 209, No. 1, pp. 15-20	5.4.1 case c) unclear relevance for the following reason: The paper is about an in vitro CA and SCE study on bovine lymphocytes exposed to a glyphosate formulation for 2h with metabolic activation and 24h and 48 h without metabolic activation. A glyphosate product (glyphosate , approximate 62% by weight) with 3

Table 29: 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	Justification for non-relevance
2690		Hunter	2008	Spare part nightmare	Farmers Weekly. Vol. 149, no. 8, pp. 59-59. 22 Aug. 2008	Farmers Weekly is not a peer-reviewed journal. No abstract nor full text available. According to the title, it is related to spare parts, not relevant for the risk assessment.
1914	Ecotoxicology (incl. pollen/nectar residue)	Aliferis et al.	2009	Lemna minor L. as a model organism for ecotoxicological studies performing 1H NMR fingerprinting.	Chemosphere, (2009 Aug) Vol. 76, No. 7, pp. 967-73	This study presents findings regarding metabolics and therefore only based on cellular and molecular level that cannot be related to the risk assessment.
253	Ecotoxicology (incl. pollen/nectar residue)	Amoros et al.	2007	Assessment of toxicity of a glyphosate -based formulation using bacterial systems in lake water .	Chemosphere, (2007 May) Vol. 67, No. 11, pp. 2221-8	The Roundup formulation used in the study contains POEA surfactant which is permitted in formulated herbicidal products in the EU / Japan. Analytical verifications of the test item concentrations were conducted but no detailed results were reported. Results are reported in diagrams, but no numerical results are presented for the treatments
69	Ecotoxicology (incl. pollen/nectar residue)	Bautista	2007	A summary of acute risk of four common herbicides to birds and mammals .	U S Forest Service Pacific Northwest Research Station General Technical Report PNW-GTR, (JUN 2007) No. 694, pp. 77-82	In this publication risk assessments for birds and mammals are conducted on the basis of available endpoints from other publications. No new data for the RA is provided.
3020	Ecotoxicology (incl. pollen/nectar residue)	Bernal et al.	2009	Toxicity of formulated glyphosate (glyphos) and cosmo-flux to larval Colombian frogs 1. Laboratory acute toxicity.	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 961-5	In this article the observations were caused by a mixture of compounds (a mixture of formulated glyphosate -Glyphos- and the adjuvant Cosmo-Flux) and thus not attributable to glyphosate alone (e.g. mixture toxicity). In addition, the tested glyphosate formulation is not the representative formulation for the AIR5 dossier and thus not relevant to the EU /Japan glyphosate renewal. It probably contains the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. All tested individuals were taken from natural sources with an unknown history of previous chemical applications.
3021	Ecotoxicology (incl. pollen/nectar residue)	Bernal et al.	2009	Toxicity of formulated glyphosate (glyphos) and cosmo-flux to larval and juvenile colombian frogs 2. Field and laboratory microcosm acute toxicity .	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 966-73	In this article the observations were caused by a mixture of compounds (a mixture of formulated glyphosate -Glyphos- and the adjuvant Cosmo-Flux) and thus not attributable to glyphosate alone (e.g. mixture toxicity). In addition, the tested glyphosate formulation is not the representative formulation for the AIR5 dossier and thus not relevant to the EU /Japan glyphosate renewal. It probably contains the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. All tested individuals were taken from natural sources with an unknown history of previous chemical applications. Furthermore, this field study does not deal with EU / Japan representative uses / conditions (e.g. field locations, water properties, specific climatic conditions, etc.).

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
2205	Ecotoxicology (incl. pollen/nectar residue)	Brausch et al.	2006	Pesticide usage on the Southern High Plains and acute toxicity of four chemicals to the fairy shrimp Thamnocephalus platyurus (crustacea: anostraca).	Tex. J. Sci., Vol. 58, Issue 4, Page 309-324, Publication Year 2006	This publication deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
999	Ecotoxicology (incl. pollen/nectar residue)	Bueno et al.	2008	Effects of pesticides used in soybean crops to the egg parasitoid Trichogramma pretiosum.	Ciencia Rural, (SEP 2008) Vol. 38, No. 6, pp. 1495-1503	This publication is dealing with formulations (Roundup Ready®, Roundup Transorb®, Roundup Original®, Gliz®) that are not the representative formulations for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. They probably contain the surfactant POEA or a similar one, which is not permitted in formulated herbicidal products in the EU / Japan?.
1646	Ecotoxicology (incl. pollen/nectar residue)	Bushaiba et al.	2006	Impact of chemical pesticides on survival and feeding rate of the woodlouse Porcellio scaber (Isopoda, Oniscidea) in Benghazi, Libya.	Jordan Journal of Applied Science (Natural Sciences) (2006) , Vol. 8, No. 2, pp. 43-50	This publication deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan.
775	Ecotoxicology (incl. pollen/nectar residue)	Casabe et al.	2007	Ecotoxicological assessment of the effects of glyphosate and chlorpyrifos in an Argentine soya field	Journal of soils and sediments (2007) , Vol. 7, No. 4, pp. 232-239	The field phase of this publication is not dealing with EU / Japan representative uses / conditions (e.g. the test was conducted in soya fields under open-air conditions in Argentina). In addition, the study was conducted with a Roundup formulation (Roundup FG), probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
1334	Ecotoxicology (incl. pollen/nectar residue)	Cavalcante et al.	2008	Genotoxic effects of Roundup on the fish Prochilodus lineatus.	Mutation research, (2008 Aug-Sep) Vol. 655, No. 1-2, pp. 41-6.	This publication deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, the findings are only based on cellular and molecular level that cannot be related to the risk assessment.
631	Ecotoxicology (incl. pollen/nectar residue)	Cavas et al.	2007	Detection of cytogenetic and DNA damage in peripheral erythrocytes of goldfish (Carassius auratus) exposed to a glyphosate formulation using the micronucleus test and the comet assay.	Mutagenesis, (2007 Jul) Vol. 22, No. 4, pp. 263-8	This publication is dealing with a Roundup formulation containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, the findings are based on cellular and molecular level (analysis of micronuclei and other nuclear abnormalities and a comet assay) that cannot be related to the risk assessment.
2944	Ecotoxicology (incl. pollen/nectar residue)	Cedergreen et al.	2006	The occurrence of hormesis in plants and algae .	Dose-response : a publication of International Hormesis Society, (2006 Oct 17) Vol. 5, No. 2, pp. 150-62	In this publication the frequency, magnitude and dose/concentration range of hormesis of one algal and three plant species after expsoure to glyphosate and other pesticides was investigated. Therefore available dose-response curves from other publications were taken into

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
						account. As no new experimental data was generated and the findings cannot be related to the risk assessment this publication is regarded to be not relevant.
2439	Ecotoxicology (incl. pollen/nectar residue)	Cedergreen et al.	2007	Reproducibility of binary-mixture toxicity studies.	Environmental Toxicology and Chemistry (2007) , Vol. 26, No. 1, pp. 149-156	The observations presented in this study were caused by mixture of different herbicides and thus not attributable to glyphosate itself (e.g. mixture toxicity). Glyphosate alone data (EC50) were also calculated for Lemna minor, but no data/values were given, just graphical representations. For Tripleurospernum indorum, a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan, was used. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
1872	Ecotoxicology (incl. pollen/nectar residue)	Cedergreen et al.	2007	Is mixture toxicity measured on a biomarker indicative of what happens on a population level? A study with Lemna minor.	Ecotoxicology and Environmental Safety, (JUL 2007) Vol. 67, No. 3, pp. 323-332	The observations presented in this study were caused by mixture of different herbicides and thus not attributable to glyphosate itself (e.g. mixture toxicity). Glyphosate alone data were calculated (mean growth and mean pigment EC50 for Lemna minor), but no data/values were given, just graphical representations.
567	Ecotoxicology (incl. pollen/nectar residue)	Cericato et al.	2008	Cortisol response to acute stress in jundia Rhamdia quelen acutely exposed to sub-lethal concentrations of agrichemicals	Comparative Biochemistry and Physiology, Part C: Toxicology and Pharmacology (2008), 148C(3), 281-286	This publication is dealing with a Roundup formulation containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, the findings are based on molecular level (cortisol in plasma) that cannot be related to the risk assessment.
1785	Ecotoxicology (incl. pollen/nectar residue)	Chattopadhyay et al.	2007	Influences of environmental factors and antidote addition on glyphosate toxicity to freshwater fish , Labeo rohita (Hamilton)	Chemistry and Ecology [Chem. Ecol.]. Vol. 23, no. 4, pp. 279-287. Aug 2007	This publication deals with the Glycel® formulation, containing ethoxylated tallow alkyl amines surfactant, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, most observations are addressing the effects of a mixture of potentially causal factors (pH, calcium, salinity) and thus not fully attributable to glyphosate itself. The exposure time of the fish to the fresh or aged residues of glyphosate in water is not given and the applied concentration is not clear (12.3 L a.i/ha/m).
99	Ecotoxicology (incl. pollen/nectar residue)	Comstock et al.	2007	Actue toxic effects of round-up herbicide on wood frog tadpoles (Rana sylvatica).	Journal of Freshwater Ecology, (DEC 2007) Vol. 22, No. 4, pp. 705-708	The Roundup formulation used in the study contains POEA surfactant which is permitted in formulated herbicidal products in the EU / Japan. No analytical verifications of the test item concentrations in the test media were conducted. No replicates were used for the study design and study conditions are not described (pH, temperature, oxygen content, water quality parameters, feeding)
2158	Ecotoxicology (incl. pollen/nectar residue)	Costa et al.	2008	Oxidative stress biomarkers and heart function in bullfrog tadpoles	Ecotoxicology (London, England), (2008 Apr) Vol. 17, No. 3, pp.	This publication deals with a Roundup formulation, containing the surfactant POEA (or any similar), which is

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
				exposed to Roundup Original.	153-63	not permitted in formulated herbicidal products in the EU / Japan.
3019	Ecotoxicology (incl. pollen/nectar residue)	Dinehart et al.	2009	Toxicity of a glufosinate- and several glyphosate-based herbicides to juvenile amphibians from the Southern High Plains, USA.	Sci. Total Environ., Vol. 407, Issue 3, Page 1065-1071, Publication Year 2009	This publication is dealing with Roundup formulations containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan or in a mixture together with pelargonic acid. These are not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, the individuals were taken from natural sources and the specific exposure history of the populations from which animals used in this study were drawn is unknown. These amphibian populations likely experienced previous pesticide exposure because they were inhabiting wetlands surrounded by agriculture.
904	Ecotoxicology (incl. pollen/nectar residue)	Elandalloussi et al.	2008	Effect of the herbicide Roundup on Perkinsus olseni in vitro proliferation and in vivo survival when infecting a permissive host, the clam Ruditapes decussatus.	Bulletin of environmental contamination and toxicology, (2008 Jun) Vol. 80, No. 6, pp. 512-5	In this study the active substance glyphosate and a Roundup formulation containing POEA surfactant is tested. The study results determined for the active substance glyphosate are very limited, i.e. for the parasitic protozoa Perkinsus olseni the in vitro inhibition of growth was tested and one IC50 value without confidence intervals is presented. For the Roundup formulation and the active substance glyphosate no analytical verifcations of test item concentrations were conducted. As the surfactant POEA is not permitted in formulated products in the EU/Japan the determined study results for the Roundup-formulation are not regarded relevant. The study results for the active substance glyphosate are also not regarded relevant, as no analytical verification of the test concentrations were conducted, the results are very limited and the test species and test design is not regarded adequate to assess ecotoxicological relevant endpoints for the risk assessment.
1600	Ecotoxicology (incl. pollen/nectar residue)	El-Shenawy et al.	2009	Histopathologic Biomarker Response of Clam, Ruditapes decussates, to Organophosphorous Pesticides Reldan and Roundup: A Laboratory Study.	Ocean Science Journal, (MAR 2009) Vol. 44, No. 1, pp. 27-34	This publication does not provide any numerical/graphical result, just digital images of histopathological changes without any measure of these changes and no relation with related chronic toxicological effects. In addition, this publication is dealing with a Roundup formulation most probably containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan.
2627	Ecotoxicology (incl. pollen/nectar residue)	Fell et al.	2006	Short-term effects on macroinvertebrates and fishes of herbiciding and mowing Phragmites australis-dominated tidal marsh.	Northeastern Naturalist, (2006) Vol. 13, No. 2, pp. 191-212	This publication is not dealing with EU / Japan representative uses / conditions (e.g. the field survey was conducted in 50 ha of marshland in US). In addition, it deals with a Rodeo formulation in combination with the aquatic surfactant Chem Surf. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. The observations are also caused by a mixture of potentially causal factors and thus not only attributable to glyphosate.

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
342	Ecotoxicology (incl. pollen/nectar residue)	Glazko et al.	2006	Change in the enzyme spectra of soil microorganisms Micrococcus luteus CCM 248 and Stenotrophomonas maltophilia UKM V-257 under the effect of certain pesticides.	Russian Agricultural Sciences (2006) , No. 5, pp. 8-12, translated from Doklady Rossiiskoi Akademii Selskokhozyaistvennykh Nauk (2006) No. 3, 27-30 (Ru)	In this literature article the effect of Roundup and other pesticides on the synthesis of enzymes in M. luteus CCM 248 and S. maltophilia UKM V-257 is examined. As the findings are based on molecular level, they cannot be related to the risk assessment.
104	Ecotoxicology (incl. pollen/nectar residue)	Glusczak et al.	2007	Acute effects of glyphosate herbicide on metabolic and enzymatic parameters of silver catfish (Rhamdia quelen).	Comparative biochemistry and physiology. Toxicology and pharmacology : CBP, (2007 Nov) Vol. 146, No. 4, pp. 519-24	The Roundup formulation used in the study contains POEA surfactant which is permitted in formulated herbicidal products in the EU/Japan. In addition in the study the effects of Roundup on metabolic and enzymatic parameters of silver catfish were assessed. As the findings are only based on molecular level they cannot be related to the risk assessment.
832	Ecotoxicology (incl. pollen/nectar residue)	Glusczak et al.	2006	Effect of glyphosate herbicide on acetylcholinesterase activity and metabolic and hematological parameters in piava (Leporinus obtusidens).	Ecotoxicology and Environmental Safety, (OCT 2006) Vol. 65, No. 2, pp. 237-241	In this literature article the effects of Roundup on acethycholinesterase and hematological parameters in Leporinus obtusidens were assessed. As the findings are only based on molecular level they cannot be related to the risk assessment.
2996	Ecotoxicology (incl. pollen/nectar residue)	Guilherme et al.	2009	Tissue specific DNA damage in the European eel (Anguilla anguilla) following a short-term exposure to a glyphosate -based herbicide	Toxicology Letters [Toxicol. Lett.]. Vol. 189, S212 p. 13 Sep 2009	This abstract refers to the 46th Congress of the European Societies of Toxicology. Tissue specific DNA damage in the European eel following a short-term exposure to a glyphosate based herbicide is the topic under investigation. As no detailed information is provided and the findings are only based on molecular level, they cannot be related to the risk assessment.
2969	Ecotoxicology (incl. pollen/nectar residue)	Guiseppe	2006	The use of glyphosate herbicides in managed forest ecosystems and their effects on non-target organisms with particular reference to ants as bioindicators	(2006) , Electronic Series Title: Technical bulletin (Maine Agricultural and Forest Experiment Station) ; 192	Scientific review of existing literature.
348	Ecotoxicology (incl. pollen/nectar residue)	Gupta et al.	2009	Changes in microbial biomass and phosphatase activity exposed to 2,4-D and glyphosate	Journal of Environmental Research and Development (2009), 3(3), 663-669	The study focuses on the effects of glyphosate on the phosphatase enzyme, biomass carbon and phosphorous in soil. These parameters are not considered relevant for the EU / Japanese risk assessment. In addition, test soils originate from cultivated land from North India and might therefore not be regarded representative for the EU/Japan.
903	Ecotoxicology (incl. pollen/nectar residue)	Jankowska et al.	2007	Effect of the herbicide ROUNDUP 360 SL on the generation time of Aeromonas hydrophila and Pseudomonas fluorescens in lake water .	Polish Journal of Natural Sciences (2007) , Vol. 22, No. 4, pp. 660-669	This publication is dealing with effects of the representative EU formulation (Roundup 360 SL) on the generation time of the aquatic bacteria Aeromonas hydrophila and Pseudomonas fluorescens. No further endpoints were assessed and no anayltical verification of the test item concentrations were conducted. As the evaluated endpoint is is not regarded relatable to the risk assessment, the study was considered as not relevant.
845	Ecotoxicology (incl. pollen/nectar residue)	Kamble et al.	2006	Effect of herbicide glyphosate on DNA , RNA and protein contents of seedlings of Hibiscus cannabinus Linn.	Biosciences Biotechnology Research Asia, (December 2006) Vol. 3, No. 2 A, pp. 431-436	This publication is dealing with effects of glyphosate on macromolecular contents (DNA, RNA and protein) of treated Hibiscus seedlings. As the findings are based on molecular level they cannot be related to the risk

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
						assessment.
418	Ecotoxicology (incl. pollen/nectar residue)	Kramer et al.	2008	Comments on /Evaluation of estrogenic activities of aquatic herbicides and surfactants using a rainbow trout vitellogenin assay/.	Toxicological Sciences, (June 2008) Vol. 104, No. 1, pp. 228-230	This is a letter to the editor (i.e. an opinion article about another different study), where no new data for the RA is provided.
1439	Ecotoxicology (incl. pollen/nectar residue)	Kremer et al.	2009	Glyphosate and glyphosate - resistant crop interactions with rhizosphere microorganisms	European journal of agronomy (2009) , Vol. 31, No. 3, pp. 153-161	This publication is not dealing with EU / Japan representative uses / conditions (e.g. the test was conducted in open-air fields in US under local soil and climate conditions). In addition, glyphosate specifications were not indicated (no details on the used formulation). This work does not present any numerical/tabulated result, just graphical outcomes.
1826	Ecotoxicology (incl. pollen/nectar residue)	Krzysko-Lupicka et al.	2008	Interactions between glyphosate and autochthonous soil fungi surviving in aqueous solution of glyphosate .	Chemosphere, (2008 Apr) Vol. 71, No. 7, pp. 1386-91	The tested material was not identified (just that N-Phosphonomethylglycine used in this study was obtained from commercial formulation by precipitation from its aqueous solution with concentrated hydrochloric acid). In addition, the exposure route (10 grams soil samples were suspended in 90 ml of 1 mM glyphosate solution) is not clear (for how much time?) and seems to not be relevant for EU / Japan regulatory purposes.
1661	Ecotoxicology (incl. pollen/nectar residue)	Kumari et al.	2008	Impact of herbicide (glyphosate) on the biochemical components of the fish , Catla catla	Indian Journal of Environment and Ecoplanning, (2008) Vol. 15, No. 1-2, pp. 434-438	This publication deals with the Glycel® formulation, containing ethoxylated tallow alkyl amines surfactant, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, all findings of this study are based on cellular and molecular level that cannot be related to the risk assessment.
2649	Ecotoxicology (incl. pollen/nectar residue)	Lancaster et al.	2006	Soil Microbial Activity Is Affected by Roundup WeatherMax and Pesticides Applied to Cotton (Gossypium hirsutum)	Journal of agricultural and food chemistry (2006) , Vol. 54, No. 19, pp. 7221-7226, Electronic	The observations presented in this study were caused by mixture of different herbicides and thus not attributable to glyphosate itself (e.g. mixture toxicity). Glyphosate alone data were also provided (only graphically), but a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan, was used. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
429	Ecotoxicology (incl. pollen/nectar residue)	Lee et al.	2009	Comparative effects of the formulation of glyphosate - surfactant herbicides on hemodynamics in swine.	Clinical toxicology (Philadelphia, Pa.), (2009 Aug) Vol. 47, No. 7, pp. 651-8.	Reported results on hemodynamics and death in piglets are according to the publication depending on surfactants (including POEA) and thus not relevant for the risk assessment.
2656	Ecotoxicology (incl. pollen/nectar residue)	Lupwayi et al.	2007	Soil microbial biomass, functional diversity and enzyme activity in glyphosate - resistant wheat-canola rotations under low-disturbance direct seeding and conventional tillage	Soil biology and biochemistry (2007) , Vol. 39, No. 7, pp. 1418-1427	This publication focuses on genetically modified organisms / transgenic crops; no data are directly relevant to glyphosate evaluation. This field study was conducted at six sites on the Canadian prairies and therefore is not dealing with EU / Japan representative uses / conditions (e.g. field locations, soil properties, etc.). Furthermore, the glyphosate

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
						formulation used in this study was not identified (just the application rate) and was mixed with other chemicals and thus the observations are not attributable to glyphosate.
2658	Ecotoxicology (incl. pollen/nectar residue)	Lupwayi et al.	2009	Soil microbial response to herbicides applied to glyphosate - resistant canola	Agriculture, ecosystems and environment (2009) , Vol. 129, No. 1-3, pp. 171-176	This publication is not dealing with EU / Japan representative uses / conditions (e.g. the field survey was conducted on different sites in Canada). In addition, it deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. Some of the treatments are also caused by a mixture of potentially causal factors / chemicals and thus not only attributable to glyphosate. No comparison to control is possible, because there was no control treatment without herbicide application. The study was conducted to compare a glyphosate-resistant canola system with alternative herbicides.
1935	Ecotoxicology (incl. pollen/nectar residue)	Lushchak et al.	2009	Low toxic herbicide Roundup induces mild oxidative stress in goldfish tissues.	Chemosphere, (2009 Aug) Vol. 76, No. 7, pp. 932-7	The glyphosate tested substance in this study is a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. The Roundup formulation is not known. The effects were assessed only at cellular and molecular level that cannot be related to the risk assessment.
109	Ecotoxicology (incl. pollen/nectar residue)	Mccomb et al.	2008	Acute toxic hazard evaluations of glyphosate herbicide on terrestrial vertebrates of the Oregon coast range.	Environmental science and pollution research international, (2008 May) Vol. 15, No. 3, pp. 266-72.	Non relevant route of exposure (i.p.) for mammals.
1612	Ecotoxicology (incl. pollen/nectar residue)	Michalkova et al.	2009	How glyphosate altered the behaviour of agrobiont spiders (Araneae: Lycosidae) and beetles (Coleoptera: Carabidae)	Biological control : theory and application in pest management (2009) , Vol. 51, No. 3, pp. 444-449	This publication deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU/Japan glyphosate renewal. In addition, the study design, test system and exposure routes are not relevant for the EU / Japan regulatory purposes. Tested rate is not clear.
975	Ecotoxicology (incl. pollen/nectar residue)	Nakamura et al.	2008	Effects of glyphosate herbicide on soil and litter macro-arthropods in rainforest: Implications for forest restoration	Ecological management and restoration (2008) , Vol. 9, No. 2, pp. 126-133	This publication is dealing with a "Roundup" formulation (Roundup® Bioactive) probably containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, this field study is not dealing with EU / Japan representative uses / conditions (e.g. the test was conducted in rainforest fields under open-air conditions in Australia).
1602	Ecotoxicology (incl. pollen/nectar residue)	Olurin et al.	2006	Histopathological responses of the gill and liver tissues of Clarias gariepinus fingerlings to the herbicide, glyphosate .	African Journal of Biotechnology, (DEC 18 2006) Vol. 5, No. 24, pp. 2480-2487	This publication does not provide any numerical/graphical result, just digital images of histopathological changes without any measure of these changes and no relation with related chronic toxicological effects. In addition, this

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
						publication does not identify the tested formulation.
755	Ecotoxicology (incl. pollen/nectar residue)	Pelosi et al.	2009	Earthworm community in conventional, organic and direct seeding with living mulch cropping systems.	Agron. Sustainable Dev., Vol. 29, Issue 2, Page 287-295, Publication Year 2009	In this field study comparing different cropping systems for 3 years, the observations in the glyphosate treated plots are caused by a mixture of other compounds/potentially causal factors and thus not attributable to glyphosate itself. In addition, glyphosate specifications and application details and rate were not indicated.
971	Ecotoxicology (incl. pollen/nectar residue)	Pereira et al.	2008	Effects of glyphosate and endosulfan on soil microorganisms in soybean crop .	Planta Daninha (2008) , Vol. 26, No. 4, pp. 825-830	This publication is not dealing with EU / Japan representative uses / conditions (e.g. the test was conducted in open-air field plots in Brazil under local soil and climate conditions). In addition, it only focuses on microbial respiration (CO2 acumulation), which is no longer a variable to consider for the EU / Japan risk assessment
1018	Ecotoxicology (incl. pollen/nectar residue)	Perez et al.	2007	Effects of the herbicide Roundup on freshwater microbial communities : a mesocosm study.	Ecological applications : a publication of the Ecological Society of America, (2007 Dec) Vol. 17, No. 8, pp. 2310-22	This publication is not dealing with EU / Japan representative uses / conditions (e.g. the test was conducted in earthen ponds under open-air conditions in Argentina). In addition, it deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan?. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
3225	Ecotoxicology (incl. pollen/nectar residue)	Quaranta et al.	2009	Why amphibians are more sensitive than mammals to xenobiotics.	PloS one, (2009 Nov 04) Vol. 4, No. 11, pp. e7699. Electronic Publication Date: 4 Nov 2009	Findings of this publication, related to the permeability of frogs and pigs skin to different chemicals including glyphosate are not related to ecotoxicology. In this article glyphosate was not the focus of the study (it deals with general pesticide exposure) and its study design and test system are not relevant for ecotoxicological regulatory purposes
349	Ecotoxicology (incl. pollen/nectar residue)	Ratcliff et al.	2006	Changes in microbial community structure following herbicide (glyphosate) additions to forest soils	Applied soil ecology (2006) , Vol. 34, No. 2-3, pp. 114-124	This study on the effects of glyphosate on the structure of the microbial community in soil is not dealing with EU / Japan representative uses / conditions (e.g. soil was collected from two different ponderosa pine plantations in northern California). In addition, it deals with a Roundup formulation, probably containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
2966	Ecotoxicology (incl. pollen/nectar residue)	Relyea et al.	2009	The toxicity of Roundup Original Max to 13 species of larval amphibians .	Environmental toxicology and chemistry, (2009 Sep) Vol. 28, No. 9, pp. 2004-8	The Roundup Original Max® formulation used in the study probably contains POEA surfactant (or any similar) which is not permitted in formulated herbicidal products in the EU / Japan. In addition no analytical verification of the test item concentration in the test media was conducted.
1654	Ecotoxicology (incl. pollen/nectar residue)	Riaz et al.	2009	Impact of glyphosate and benzo[a]pyrene on the tolerance of mosquito larvae to chemical	Aquat. Toxicol., Vol. 93, Issue 1, Page 61-69, Publication Year 2009	This study investigates the tolerance of mosquito larvae to several insecticides, having been exposed previously to sub-lethal concentrations of glyphosate. The glyphosate tested

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
				insecticides. Role of detoxification genes in response to xenobiotics.		substance is Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. The direct glyphosate effects on mosquitos conferring increased tolerance to insecticides were assessed only at cellular and molecular level that cannot be related to the risk assessment.
2073	Ecotoxicology (incl. pollen/nectar residue)	Rochfort et al.	2009	NMR-based metabolomics using earthworms as potential indicators for soil health	METABOLOMICS, (MAR 2009) Vol. 5, No. 1, pp. 95-107	This study presents findings regarding metabolics and therefore only based on cellular and molecular level that cannot be related to the risk assessment. In addition, the tested material comes from different sites in Australia and therefore not dealing with EU / Japan representative uses / conditions (e.g. field locations, soil properties, etc.). Furthermore, the test item was Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan, and the observations are caused by mixture of compounds / potentially causal factors and thus not attributable to only glyphosate.
1054	Ecotoxicology (incl. pollen/nectar residue)	Saradhamani et al.	2009	Efficacy of herbicide Glyphosate on oxygen consumption of a fresh water fish , Catla catla	Indian Journal of Environment and Ecoplanning (2009), 16(1), 239-243	In this study, assessing the effects of glyphosate exposure on the rate of fish oxygen consumption after 96 hours, the test design and system are not relevant for the EU / Japan regulatory purposes. In addition, the test item was not identified as it was just indicated that it is glyphosate without further content/purity/source indication (it could be a formulation not relevant to the EU / Japan glyphosate renewal). Furthermore, the study seems to be not reliable at all, as shows several inconsistencies in the reported results' table (percent change in the rate of oxygen consumption at 72 h, significant difference detected for the 0.35 ppm concentration at 72 h, etc.) and text. The statistical analysis was not described and it is not possible to determine if it has been conducted or not.
1620	Ecotoxicology (incl. pollen/nectar residue)	Solomon et al.	2009	Human health and environmental risks from the use of glyphosate formulations to control the production of coca in Colombia: overview and conclusions.	Journal of toxicology and environmental health. Part A, (2009) Vol. 72, No. 15-16, pp. 914-20. Ref: 50	This is a scientific review article where no new data, just secondary information, is provided that can be used for risk assessment. In addition, most of the effects reported in this review were caused by mixture of compounds / potentially causal factors and thus not attributable to glyphosate itself.
397	Ecotoxicology (incl. pollen/nectar residue)	Soso et al.	2007	Chronic exposure to sub-lethal concentration of a glyphosate -based herbicide alters hormone profiles and affects reproduction of female Jundia (Rhamdia quelen).	Environmental Toxicology and Pharmacology, (MAY 2007) Vol. 23, No. 3, pp. 308-313	This publication is not dealing with EU / Japan representative uses / conditions (e.g. the test was conducted in earthen ponds under open-air conditions in Brazil). In addition, it deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
3023	Ecotoxicology (incl. pollen/nectar residue)	Sparling et al.	2006	Toxicity of glyphosate as Glypro and LI700 to red-eared slider (trachemys	Environmental toxicology and chemistry, (2006 Oct) Vol. 25, No.	This study presents observations caused by mixture of compounds (the glyphosate formaltion Glypro and a 3%

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				scripta elegans) embryos and early hatchlings.	10, pp. 2768-74	solution of the surfactant LI700) and thus not attributable to only glyphosate.
1642	Ecotoxicology (incl. pollen/nectar residue)	Stachowski-Haberkorn et al.	2008	Impact of Roundup on the marine microbial community , as shown by an in situ microcosm experiment.	Aquatic toxicology (Amsterdam, Netherlands), (2008 Sep 29) Vol. 89, No. 4, pp. 232-41	This publication deals with a Roundup formulation, containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan.
2914	Ecotoxicology (incl. pollen/nectar residue)	Thompson et al.	2005	The impact of insecticides and herbicides on the biodiversity and productivity of aquatic communities.	Ecological applications : a publication of the Ecological Society of America (2006) , Vol. 16, No. 5, pp. 2022-2027	This publication deals with a Roundup formulation, containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, the study design and test system is not fully relevant for regulatory purposes (All tested organisms included in these aquatic mesocosms were brought to the laboratory from natural unidentified sources and distributed into the different aquaria). Year of publication is 2005.
347	Ecotoxicology (incl. pollen/nectar residue)	Tierney et al.	2006	Changes in juvenile coho salmon electro-olfactogram during and after short-term exposure to current-use pesticides.	Environmental toxicology and chemistry, (2006 Oct) Vol. 25, No. 10, pp. 2809-17	In this literature article the effect of glyphosate and other pesticides on the olfaction of juvenile coho-salmons is examined. The assessed study endpoint is not regarded relevant for the EU / Japanese risk assessment.
2423	Ecotoxicology (incl. pollen/nectar residue)	Tierney et al.	2007	Relating olfactory neurotoxicity to altered olfactory-mediated behaviors in rainbow trout exposed to three currently-used pesticides.	Aquatic toxicology (Amsterdam, Netherlands), (2007 Feb 15) Vol. 81, No. 1, pp. 55-64	This publication deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition, the study design and test system (focused on olfactory-mediated behavioral effects) are not relevant for regulatory purposes.
1754	Ecotoxicology (incl. pollen/nectar residue)	Tsui et al.	2006	Influence of glyphosate and its formulation (Roundup super([registered])) on the toxicity and bioavailability of metals to Ceriodaphnia dubia	Environmental Pollution. Vol. 140, no. 2, pp. 59-68. Mar. 2006	In this study, the observations related with glyphosate (IPA salt) were caused by mixture of compounds (metal acute toxicity and accumulation on aquatic invertebrates when previously treated with glyphosate) and thus not attributable to glyphosate itself (e.g. mixture toxicity). The 48-h LC50 was calculated however for Roundup® and therefore dealing with a formulation containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal.
1095	Ecotoxicology (incl. pollen/nectar residue)	Watson et al.	2008	Environmental influences on Acinetobacter sp. strain BD413 transformation in soil	Biology and fertility of soils (2008) , Vol. 45, No. 1, pp. 83-92	In this literature article the effects of Roundup Ready Renew on Acinetobacter sp. strain BD413 transformation in soil were assessed. As the findings are only based on molecular level they cannot be related to the risk assessment.
979	Ecotoxicology (incl. pollen/nectar residue)	Weaver et al.	2007	Effects of glyphosate on soil microbial communities and its mineralization in a Mississippi soil .	Pest management science, (2007 Apr) Vol. 63, No. 4, pp. 388-93	This study consists of two different tests, one field study in USA not dealing with EU / Japan representative uses/conditions (e.g. field locations, soil properties, non-EU monitoring etc.) and one laboratory study with a study

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						design and system that are not relevant for regulatory purposes. Only C-related (and not N-related) mineralization was measured, which is no longer relevant for the risk assessment.
447	Ecotoxicology (incl. pollen/nectar residue)	Whiteside et al.	2008	Comparison of a score-based approach with risk-based ranking of in-use agricultural pesticides in Canada to aquatic receptors.	Integr. Environ. Assess. Manage., Vol. 4, Issue 2, Page 215-236, Publication Year 2008	This article, presenting a new risk-based approach for ranking pesticides and their potential risk to aquatic life, only contains secondary ecotoxicological information from several sources: The Pesticide Manual of the British Crop Protection Council, USEPA pesticide registration data, the French AGRITOX, European Commission pesticide review reports, and the USEPA ECOTOX database. It does not present any new toxicity data. In addition, this publication deals with general pesticide exposures (not glyphosate specific).
2020	Ecotoxicology (incl. pollen/nectar residue)	Zabaloy et al.	2008	Microbial respiration in soils of the Argentine pampas after metsulfuron methyl, 2,4-D, and glyphosate treatments.	Communications in soil science and plant analysis (2008) , Vol. 39, No. 3-4, pp. 370-385	This publication does not deal with EU / Japan representative uses / conditions (e.g. Argentinian field locations with specific soil properties, etc.). In addition, the study focuses on the effects on microbial respiration (CO_2 release) and this is not a data requirement according to EU Regulation 283/2013 anymore. Furthermore, the test item was not fully identified and the test soil had a previous history of pesticide applications that could have altered the diversity and levels of the microbial community.
179	Ecotoxicology (incl. pollen/nectar residue)	Zabaloy et al.	2008	An integrated approach to evaluate the impacts of the herbicides glyphosate, 2,4-D and metsulfuron-methyl on soil microbial communities in the Pampas region, Argentina	Applied soil ecology (2008) , Vol. 40, No. 1, pp. 1-12	This publication is not considered relevant as the used test soils have a reported history of herbicide application. In addition, they originate from agricultural fields of the Pampas region (Argentina) and might therefore not be regarded representative for the EU/Japan.
839	Ecotoxicology (incl. pollen/nectar residue)	Zahra et al.	2006	Effect of glyphosate on various blood parameters of fresh water fishes , Heteropneustes fossilis.	Flora and Fauna (Jhansi) (2006) , Vol. 12, No. 1, pp. 100-104	This publication deals with a Roundup formulation, probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan. In addition, no analytical verification of the test item concentrations in the tested tap water was conducted and the origin/source of the tested fishes is not clear either.
2930	Ecotoxicology (incl. pollen/nectar residue)	Zhidenko et al.	2007	The influence of roundup on the dynamics of histological changes in organs of carps.	Hydrobiological Journal, (2007) Vol. 43, No. 2, pp. 93-99	This publication does provide histological changes after exposure to a Roundup formulation at 0.004 mg/L; no numerical/graphical results are provided. The description of the study design is very limited, the test conditions are poorly described and the effects cannot be related to the risk assessment. Therefore this study is not regarded relevant.
746	Ecotoxicology (incl. pollen/nectar residue)	Zhydenko	2008	Dynamics of the juvenile carps hematological parameters under the impact of herbicides.	Hydrobiological Journal, (2008) Vol. 44, No. 5, pp. 73-80	This publication is dealing with a "Roundup" formulation (no indication of which one) probably containing the surfactant POEA, which is not permitted in formulated herbicidal products in the EU / Japan. This is not the representative formulation for the AIR5 dossier and thus not relevant to the EU / Japan glyphosate renewal. In addition,

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						the findings are all based on cellular and molecular level (changes of the hematological parameters) that cannot be related to the risk assessment.
1092	Ecotoxicology (incl. pollen/nectar residue)/ Efate	Tsui et al.	2008	Environmental fate and non-target impact of glyphosate -based herbicide (Roundup) in a subtropical wetland.	Chemosphere, (2008 Mar) Vol. 71, No. 3, pp. 439-46. Electronic Publication Date: 26 Dec 2007	The Roundup formulation used in the study contains POEA surfactant which is not permitted in formulated herbicidal products in the EU / Japan. The ecotoxicologically relevant findings of this field study (in situ bioassay of fish in a freshwater & estuarine pond) cannot clearly be related to the application of the Roundup formulation as a very open test design was chosen and test species might be exposed to multiple chemicals/stressors. Environmental fate in a subtropical wetland can for various reasons not readily transferred to agricultural conditions considered relevant.
2830	E-fate	Adams et al.	2007	The Absence of Glyphosate Residues in Wet Soil and the Adjacent Watercourse after a Forestry Application in New Brunswick.	Northern journal of applied forestry (2007) , Vol. 24, No. 3, pp. 230-232	Study design is not relevant for the European regulatory purposes and no relevant endpoint was determined. Glyphosate product was applied at a field site in Canada and a water stream and water saturated soil was analysed.
807	E-fate	Adil et al.	2009	Effect of agricultural chemicals on aquatic ecosystem in Guyana	Global Journal of Environmental Research, (2009) Vol. 3, No. 1, pp. 22-25. CODEN: GJERAW.	Publication is reporting on water monitoring under Non-EU conditions which are not relevant for the enviromental risk assessments. Detected residues in algae are considered to be not relevant for the dietary risk assessment as it is neither clear these algal speciel are suitable for human consuption or ever harvested for human consumption, also residues cannot be attributed to a GAP relevant for EU and might be caused by misuse or accidental spillage uncleare exposure.
743	E-fate	Alexa et al.	2009	Dynamic of glyphosate mineralization in different soil types.	Romanian Agricultural Research (2009) , No. 26, pp. 57-60	Study design not relevant for the European regulatory purposes. Different soils from Romania were incubated with glyphosate for 40 days. Only the evolved CO2 was measured. No endpoints can be derived.
2219	E-fate	Barrett et al.	2007	Phosphate and glyphosate mobility in soil columns amended with roundup	Soil science (2007) , Vol. 172, No. 1, pp. 17-26	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. It was investigated whether moderately low glyphosate application rates could mobilize significant PO43- in coarse-textured soils. No endpoints for risk assessment are generated.
2641	E-fate	Bazot et al.	2008	Simultaneous mineralization of glyphosate and diuron by a consortium of three bacteria as free- and/or immobilized-cells formulations.	Applied microbiology and biotechnology, (2008 Jan) Vol. 77, No. 6, pp. 1351-8	Study design is not relevant for the European regulatory purposes. Three isolated bacteria strains were assessed to study the simulaneous mineralisation of glyphosate and diuron.
703	E-fate	Bhaskara et al.	2006	Direct sensitive spectrophotometric determination of glyphosate by using ninhydrin as a chromogenic reagent in formulations and environmental water samples.	Helvetica Chimica Acta (2006) , Vol. 89, No. 11, pp. 2686-2693	Publication dealing with analytical methods / development. Method validation was performed with field water sampled from irrigated land in India.
2189	E-fate	Carpenter et al.	2008	Pesticide Occurrence and Distribution in the Lower Clackamas River Basin, Oregon, 2000-2005	Scientific Investigations Report. U.S. Geological Survey. no. 2008-5027, 99 pp. 2008	Publication not dealing with EU representative uses / conditions (non-EU monitoring).

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2230	E-fate	Chen et al.	2007	Photodegradation of glyphosate in the ferrioxalate system.	Journal of hazardous materials, (2007 Sep 05) Vol. 148, No. 1-2, pp. 360-5	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. Wavelength of the used lamp was > 365 nm and the focus of the article was the photodegradation in a ferrioxalate system.
3145	E-fate	Choquette et al.	2009	Water Quality and Evaluation of Pesticides in Lakes in the Ridge Citrus Region of Central Florida	Scientific Investigations Report. U.S. Geological Survey. no. 2008-5178, 55 pp. 2009	Publication not dealing with Japan/EU representative uses / conditions (non-EU monitoring).
2216	E-fate	Comoretto et al.	2007	Pesticides in the Rhone river delta (France): Basic data for a field-based exposure assessment .	Science of the Total Environment, (JUL 15 2007) Vol. 380, No. 1-3, Sp. Iss. SI, pp. 124-132	Publication where glyphosate or a relevant metabolite were not the focus of the publication.
126	E-fate	Da et al.	2007	Adsorption of glyphosate on clays and soils from Parana state: Effect of pH and phosphate competitive adsorption of phosphate .	Brazilian Archives of Biology and Technology, (MAY 2007) Vol. 50, No. 3, pp. 385-394	No endpoints for risk assessment are generated. Only amout of glyphosate adsorbed reported, no Koc/Kfoc.
2667	E-fate	Damonte et al.	2007	Some aspects of the glyphosate adsorption on montmorillonite and its calcined form. Clay and Health - clays in pharmacy, cosmetics, pelotherapy, and environment protection .	Applied Clay Science (2007) , Vol. 36, No. 1/3, pp. 86-94	Study design is not relevant for the European regulatory purposes. Adsorption to specific mineral, no relevant endpoints were determined.
776	E-fate	De et al.	2006	Effect in glyphosate adsorption on clays and soils heated and characterization by FT-IR spectroscopy.	Geoderma, (DEC 15 2006) Vol. 136, No. 3-4, pp. 738-750	Study design not relevant for the European regulatory purposes. Adsorption of glyphosate was tested on clay minerals and soil. The effect of heating on the clay and soils was investigated. The glyphosate concentration in the supernatant was not determined. No endpoints can be derived.
994	E-fate	Djonova et al.	2008	Effects of mechanical and chemical combating Sorghum halepensis (L.) Pers on soil microflora.	Journal of Balkan Ecology (2008) , Vol. 11, No. 4, pp. 383-390	Findings not related to environmental fate. The effect of glyphosate on the microbial polulation was investigated.
614	E-fate	Doublet et al.	2009	Delayed degradation in soil of foliar herbicides glyphosate and sulcotrione previously absorbed by plants : consequences on herbicide fate and risk assessment .	Chemosphere, (2009 Oct) Vol. 77, No. 4, pp. 582-9	Study design not relevant for the European regulatory purposes. Glyphosate was sprayed on leavea of oilseed rape and maize plants instead of bare soil.
2459	E-fate	Ersilia et al.	2008	Researches regarding the microorganisms influence on glyphosate biodegradation	Journal of Agroalimentary Processes and Technologies (2008), 14(2), 498-502	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. No endpoints for risk assessment are generated. The effect of glyphosate on the soil microbial biomass was investigated.
2899	E-fate	Eser et al.	2007	The effects of glyphosate isopropylamine and trifluralin on the carbon mineralization of olive tree soils . Original Title: Zeytin Topraklarinin Karbon Mineralizasyonuna Glyphosate Isopropylamine ve Trifluralin and apos;in Etkileri.	Turkish Journal of Agriculture and Forestry, (2007) Vol. 31, No. 5, pp. 297-302	Study design and test system that are not relevant for the European regulatory purposes and publications dealing with a Roundup formulation and thus not relevant to the EU glyphosate renewal.

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478	E-fate	Ghanem et al.	2007	Concentrations and specific loads of glyphosate , diuron, atrazine, nonylphenol and metabolites thereof in French urban sewage sludge.	Chemosphere, (2007 Nov) Vol. 69, No. 9, pp. 1368-73	Test system not relevant for the European regulatory purposes. The concentration of glyphosate in sewage sludge was determined.
1235	E-fate	Ghanem et al.	2006	Fate of herbicides and nonylphenol in soil - plant - water systems amended with contaminated sewage sludge	Environmental Chemistry Letters. Vol. 4, no. 2, pp. 63-67. Jun 2006	Study design not relevant for the European regulatory purposes. A mixture of compounds was studied.
2675	E-fate	Gimsing et al.	2007	Sorption of glyphosate and phosphate by variable-charge tropical soils from Tanzania.	Geoderma, (FEB 15 2007) Vol. 138, No. 1-2, pp. 127-132	Study design that is not relevant for the European regulatory purposes and Publication generating endpoints that are not relatable to the EU level risk assessment. Competitive sorption of glyphosate and phosphate was investigated.
1655	E-fate	Gomez et al.	2009	Impact of glyphosate application on microbial biomass and metabolic activity in a Vertic Argiudoll from Argentina.	European Journal of Soil Biology, (MAR-APR 2009) Vol. 45, No. 2, pp. 163-167	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. No endpoints for risk assessment are generated. The effect of glyphosate on the soil microbial biomass was investigated.
2362	E-fate	Goudarzi et al.	2009	QSPR Modeling of Soil Sorption Coefficients (KOC) of Pesticides Using SPA-ANN and SPA-MLR.	J. Agric. Food Chem., Vol. 57, Issue 15, Page 7153-7158, Publication Year 2009	Publication where glyphosate was not the focus of the publication. A QSAR model was developed, glyphosate was among the 124 substances used as input data.
787	E-fate	Hu et al.	2009	Effect of Glyphosate on Soil Enzyme	Journal of Agro-Environment Science [J. Agro-Environ. Sci.]. Vol. 28, no. 4, pp. 680-685. 20 Apr 2009	The article is in Chinese.
2213	E-fate	Hushon	2006	Pesticides in Southwest Florida waterways - A report card.	Florida Scientist, (2006) Vol. 69, No. Suppl. 2, pp. 100-116	Publications not dealing with EU representative uses / conditions (non-EU monitoring).
1276	E-fate	Jankowska et al.	2008	Fluctuations in counts of some microorganisms in lake water caused by the herbicide ROUNDUP 360 SL.	Polish Journal of Natural Sciences (2008) , Vol. 23, No. 1, pp. 121-133	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. The effect of glyphosate concentration on the counts of bacteria in lake water was investigated. No endpoints for risk assessment are generated.
2036	E-fate	Klier et al.	2008	Modelling the Environmental Fate of the Herbicide Glyphosate in Soil Lysimeters	Water, air and soil pollution. Focus (2008) , Vol. 8, No. 2, pp. 187-207	Not relevant, as the focus is on development of a model and transgenic soybeans play a major role. The TSCF was only calculated by a model and no results is given. Additonally, glyphosate was applied to plants by foliar application (not to bare soil).
3089	E-fate	Kolpin et al.	2006	Urban contributions of glyphosate and its degradate AMPA to streams in the United States.	Science of the Total Environment (2006) , Vol. 354, No. 2/3, pp. 191-197	Publication not dealing with Japan/European conditions (field location in the United States).
1493	E-fate	Laitinen et al.	2007	Glyphosate translocation from plants to soil - does this constitute a significant proportion of residues in soil	Plant and soil (2007) , pp. 51-60	Study design not relevant for the European regulatory purposes. Translocation of glyphosate (N-(phosphonomethyl)glycine) to plant roots and its impact on detected herbicide residues in sandy loam soil were studied in a glasshouse pot experiment in Finland. Glyphosate was sprayed on leaves of Quinoa plants.
1236	E-fate	Laitinen et al.	2006	Fate of the herbicides glyphosate, glufosinate-ammonium,	Pest Manage. Sci., Vol. 62, Issue 6, Page 473-491, Publication Year	Study design not relevant for the European regulatory purposes. Glyphosate (Roundup ready) was sprayed on

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				phenmedipham, ethofumesate and metamitron in two Finnish arable soils.	2006	glyphosate resistant sugar beet instead of bare soil.
2652	E-fate	Magga et al.	2008	Soil column experiments used as a means to assess transport , sorption , and biodegradation of pesticides in groundwater .	Journal of environmental science and health. Part. B, Pesticides, food contaminants, and agricultural wastes, (2008 Nov) Vol. 43, No. 8, pp. 732-41	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. Column leaching was performed with artifical groundwater (not artificial rainwater) and over a period of 6.5 months glyphosate was continuously applied to the column.
712	E-fate	Newton et al.	2008	Dissipation of four forest-use herbicides at high latitudes.	Environmental science and pollution research international, (2008 Oct) Vol. 15, No. 7, pp. 573-83	Publications not dealing with Japan/EU representative uses / conditions (e.g. field location) . Dissipation of glyphosate was investigated in forests of Alaska.
1623	E-fate	Ockerman	2008	Hydrologic Conditions and Quality of Rainfall and Storm Runoff for Two Agricultural Areas of the Oso Creek Watershed, Nueces County, Texas, 2005-07	Scientific Investigations Report. U.S. Geological Survey. no. 2008-5103, 67 pp. 2008	Publication not dealing with Japan/EU representative conditions (i.e. monitoring location). The purpose of this report was to characterize hydrologic conditions and the water quality of rainfall and storm runoff for two primarily agricultural subwatersheds in the Oso Creek watershed in Nueces County (Texas, U.S.).
1917	E-fate	Peruzzo et al.	2008	Levels of glyphosate in surface waters , sediments and soils associated with direct sowing soybean cultivation in north pampasic region of Argentina.	Environmental pollution (Barking, Essex : 1987), (2008 Nov) Vol. 156, No. 1, pp. 61-6	Publication not dealing with Japan/EU conditions (field location in Argentina and a transgenic soybean cultivation area).
1451	E-fate	Pessagno et al.	2008	Glyphosate behavior at soil and mineral-water interfaces.	Environmental pollution (Barking, Essex : 1987), (2008 May) Vol. 153, No. 1, pp. 53-9	Study design not relevant for the European regulatory purposes. Adsorption was tested in solutions with adjusted pH. Isotherms were established according to Langmuir. One soil was previously treated with H2O2 to reduce organic matter content.
1476	E-fate	Rampoldi et al.	2008	Glyphosate mineralization : effect of temperature and soybean and corn crop residues .	Chilean Journal of Agricultural Research (2008) , Vol. 68, No. 1, pp. 13-20	Study design not relevant for the European regulatory purposes. The kinetics of mineralization of glyphosate in stubbles of soybean and corn were investigated. No endpoints for risk assessment are generated.
610	E-fate	Sailaja et al.	2006	Degradation of glyphosate in soil and its effect on fungal population .	Journal of environmental science and engineering, (2006 Jul) Vol. 48, No. 3, pp. 189-90	Study design not relevant for the European regulatory purposes. Glyphosate (Glycel, 41% pure) was sprayed on the foliage of weeds instead of bare soil.
261	E-fate	Sandall et al.	2009	Avoiding Glyphosate and Atrazine Runoff and Groundwater Contamination	Crop watch (2009) , No. 18 Source Note: 2009 June 26, no. 18	Opinion article that provides no new data that can be used for risk assessment. Guidance for farmers on how to avoid runoff of glyphosate and atrazine.
284	E-fate	Santos et al.	2009	Biodegradation of glyphosate in rhizospheric soil cultivated with Glycine max, Canavalia ensiformis and Stizolobium aterrimum.	Planta Daninha (2009) , Vol. 27, No. 4, pp. 781-787	Study design not relevant for the European regulatory purposes. Untreated and previously cultivated Brazilian soil (Red-Yellow Argisol) was incubated with glyphosate for 32 days. Only the evolved CO2 was measured. No endpoints for risk assessment are generated.
479	E-fate	Scribner et al.	2007	Concentrations of Glyphosate, Its Degradation Product, Aminomethylphosphonic Acid, and Glufosinate in Ground-and Surface-	Scientific Investigations Report. U.S. Geological Survey. no. 2007-5122, 112 pp. 2007. URL (Document):	Publication not dealing with Japan/EU representative conditions (i.e. monitoring location). The concentration of glyphosate and AMPA was determined in soil, rainfall, ground- and surface water samples collected in the U.S..

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				Water, Rainfall, and Soil Samples Collected in the United States, 2001-06		
2672	E-fate	Shushkova et al.	2009	Sorption and microbial degradation of glyphosate in soil suspensions	Applied biochemistry and microbiology (2009) , pp. 599-603	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. The adsorption of glyphosate was studied after application of a product (Ground Bio) containing the active agent is glyphosate isopropylamine salt. No endpoints for risk assessment are generated.
1488	E-fate	Starrett et al.	2008	Glyphosate runoff when applied to zoysiagrass under golf course fairway conditions	ACS Symposium Series, (2008) Vol. 997, No. Fate of Nutrients and Pesticides in the Urban Environment, pp. 237-253, 1 plate	Publication not dealing with Japan/EU representative conditions (i.e. non-EU field location). Publication dealing with a Roundup formulation that is not representative for AIR5. The objectives of the study were: (1) to measure glyphosate runoff from zoysiagrass fairways on a golf course in Kansas (U.S.) following the application of Roundup herbicide, (2) to determine glyphosate runoff concentrations and their resulting effect on the environment, and (3) to provide up-to-date data of research findings on pesticide transport when applied to turfgrass.
2691	E-fate	Stenrod et al.	2006	Spatial variability of glyphosate mineralization and soil microbial characteristics in two Norwegian sandy loam soils as affected by surface topographical features	Soil biology and biochemistry (2006) , Vol. 38, No. 5, pp. 962-971	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. The effect of glyphosate concentration on soil physical and microbial properties was investigated. Furthermore, the mineralization rate of glyphosate was determined in different activity samples. No endpoints for risk assessment are generated.
121	E-fate	Wang et al.	2009	Adsorption Kinetics of Glyphosate and Copper(II) Alone and Together on Two Types of Soils	Soil Science Society of America journal (2009) , pp. 1995-2001	No endpoints for risk assessment are generated. Adsorption kinetics were investigated in a flow method (column) experiment, but no adsorption coefficient determined.
568	E-fate	Wang et al.	2006	Cosorption of zinc and glyphosate on two soils with different characteristics.	Journal of Hazardous Materials, (SEP 1 2006) Vol. 137, No. 1, pp. 76-82	Study design not relevant for the European regulatory purposes. Adsorption isotherms were determined for glyphosate in absence and presence of Zn. NaNO3 was used as test solution instead of CaCl2. Isotherms are shown graphically but no linear equations are presented. No endpoints can be derived from the study.
1021	E-fate	Warnemuende et al.	2007	Effects of tilling no-till soil on losses of atrazine and glyphosate to runoff water under variable intensity simulated rainfall	Soil and tillage research (2007) , Vol. 95, No. 1-2, pp. 19-26	Publication not dealing with Japan/EU representative conditions (i.e. field location). The runoff of glyphosate and atrazine was tested on field plots in the U.S..
1899	E-fate	Xu et al.	2009	Land use and riparian effects on prairie wetland sediment properties and herbicide sorption coefficients.	Journal of environmental quality, (2009 Jul-Aug) Vol. 38, No. 4, pp. 1757-65	Study design, test system, species tested, exposure routes etc. that are not relevant for the European regulatory purposes. Adsorption study performed with sediment of a wetland. Only mean values (5 sampling points and four cores per point) were reported.
641	E-fate	Yoshioka et al.	2006	Determination of Glyphosate and Its Major Metabolite Aminomethylphosphonic Acid in River Water and Tap Water by High-	Bunseki Kagaku [Bunseki Kaguku]. Vol. 55, no. 3, pp. 177-184. 2006. ISSN: 0525-1931	The article is about the development of analytical method to analyze Glyphosate and AMPA in river water and tap water which is considered not relevant for the submission in Japan.

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				Performance Liquid Chromatography with Postcolumn Derivatization Method		
1781	E-fate	Zablotowicz et al.	2006	Influence of watershed system management on herbicide concentrations in Mississippi Delta oxbow lakes.	The Science of the total environment, (2006 Nov 1) Vol. 370, No. 2-3, pp. 552-60. Electronic Publication: 2006-09-26	Publication where glyphosate or a relevant metabolite were not the focus of the publication. Glyphosate was not among the active substances measured in the article.
1477	E-fate	Zhao et al.	2009	Glyphosate mobility in soils by phosphate application: Laboratory column experiments.	Geoderma, (MAR 15 2009) Vol. 149, No. 3-4, pp. 290-297	Study design not relevant for the European regulatory purposes. Adsorption and column experiments were performed with glyphosate. For the adsorption experiments the soil pH twas adjusted to pH 3–9. The flow direction of the column experiment was from bottom to top. According to the OECD 312 guideline, artificial rain should be applied to the soil columns and the leachate collected. No endpoints were determined in the study.
220	Efficacy	Ransom	2009	Applying Glyphosate Pre-Harvest in Small-Grains	Crop and pest report (2009) , Number 12, pp. 7-8 Source Note: 2009 July 29, issue 12	The article is an application recommendation/suggestion from the North Dakota State University (NDSU) to the farmers. The glyphosate-note is just a small part of it.
37	Efficacy	Service	2007	A growing threat down on the farm.	Science, (25 May 2007) Vol. 316, No. 5828, pp. 1114-1117.	The articles provides an overview about the history and market importance of glyphosate, brief description of a mode of action, first resistance cases, advantages of no-till agriculture, possible replacements/supplements for glyphosate resistant crops.
1209	Human safety (metabolism/toxicology)	Acquavella et al.	2006	Exposure misclassification in studies of agricultural pesticides: Insights from biomonitoring	Epidemiology (Jan 2006) Vol. 17, No. 1, pp. 69-74	A algorithm proposed by Dosemeci and colleagues to estimate lifetime average exposure intensity from questionnaire information. The algorithm was evaluated to measure urinary pesticide concentrations for farmers who applied glyphosate. Statistical analyses included nonparametric correlations, assessment of categorical agreement, and categorical evaluation of exposure distributions.
1698	Human safety (metabolism/toxicology)	Amer et al.	2006	In vitro and in vivo evaluation of the genotoxicity of the herbicide glyphosate in mice .	Bulletin of the National Research Centre (Cairo), (2006) Vol. 31, No. 5, pp. 427-446	Information on concentrations is questionable for in vitro part, as M glyphosate/mL medium is no scientific unit for a concentration. It should be noted, that an ip. injection is not a relevant route of administration and thus considered not relevant to human risk assessment.
2086	Human safety (metabolism/toxicology)	Anadon et al.	2008	Neurotoxicological effects of the herbicide glyphosate	Toxicology Letters [Toxicol. Lett.]. Vol. 180, S164 p. 5 Oct 2008	No full text available (congress abstract only)
1147	Human safety (metabolism/toxicology)	Andre et al.	2007	Evaluation of bulky DNA adduct levels after pesticide use: comparison between open-field farmers and fruit growers.	Toxicol. Environ. Chem., Vol. 89, Issue 1, Page 125-139, Publication Year 2007	Groups of farmers were classified according to the main pesticide sprayed (triazoles or chlorothalonil for open-field farmers n=19; captan for fruit growers n=29). Two blood samples were collected on consecutive days for each farmer, and white blood cell bulky DNA adduct levels were evaluated by 32P-postlabelling method. Glyphosate was only detected in 1/29 farmers. No association between glyphosate exposure and bulky adducts was observed.

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						Farmers were exposed to pesticide mixtures, no further information on exposure and the exposed subtances (batch, manufacturer, analytics, adjuvants) were given.
873	Human safety (metabolism/toxicology)	Astiz et al.	2009	Effect of pesticides on cell survival in liver and brain rat tissues.	Ecotoxicology and environmental safety, (2009 Oct) Vol. 72, No. 7, pp. 2025-32	Non-relevant route of exposure (i.p. injections)
206	Human safety (metabolism/toxicology)	Astiz et al.	2009	Antioxidant defense system in rats simultaneously intoxicated with agrochemicals.	Environmental Toxicology and Pharmacology, (NOV 2009) Vol. 28, No. 3, pp. 465-473	Non-relevant route of exposure (i.p. injections)
1469	Human safety (metabolism/toxicology)	Baucom et al.	2008	Glyphosate induces transient male sterility in Ipomoea purpurea	Botany (2008) , Volume 86, Number 6, pp. 587-594, Electronic ISSN: 1916-2804 Source Note: 2008 June, v. 86, no. 6	The article relates to reproduction and fertility in male Ipomoea purpurea (flower - morning-glory). The test item was not identified in the M&M section (although it seems that they used a Roundup formulation probably containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal products in the EU / Japan). In addition, the study design and test system are not really relevant for the European regulatory purposes (flowering is not a parameter to be used in the RA). Furthermore, an important part of the test was conducted under US field conditions and therefore, not dealing with EU representative uses / conditions (e.g. field locations, soil properties, non-EU monitoring etc.).
2987	Human safety (metabolism/toxicology)	Benachour et al.	2007	Time-and dose-dependent effects of roundup on human embryonic and placental cells.	Archives of environmental contamination and toxicology, (2007 Jul) Vol. 53, No. 1, pp. 126-33	Excessive doses exceed typical in vitro limit doses. In vitro test system is inappropriate for formulations containing surfactants.
1463	Human safety (metabolism/toxicology)	Benachour et al.	2009	Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic , and placental cells.	Chemical research in toxicology, (2009 Jan) Vol. 22, No. 1, pp. 97-105	Excessive doses exceed typical in vitro limit doses. In vitro test system is inappropriate with surfactants
2890	Human safety (metabolism/toxicology)	Caglar et al.	2008	The effect of sub-acute and sub-chronic exposure of rats to the glyphosate -based herbicide Roundup.	Environmental Toxicology and Pharmacology, (JAN 2008) Vol. 25, No. 1, pp. 57-62	The aim of the study was biochemical and histopathological examination of the toxic effects of glyphosate-based herbicide Roundup in rat liver, However the tested Roundup contains POEA which is no longer in the composition of the representative formulation.
2515	Human safety (metabolism/toxicology)	Cericato et al.	2009	Responsiveness of the interrenal tissue of Jundia (Rhamdia quelen) to an in vivo ACTH test following acute exposure to sublethal concentrations of agrochemicals	Comparative Biochemistry and Physiology, Part C: Toxicology and Pharmacology (2009), 149C(3), 363-367	Jundiá (Rhamdia quelen) [catfish]; not relevant species.
1411	Human safety (metabolism/toxicology)	Climent et al.	2008	Glyphosate Poisoning	Clinical Toxicology [Clin. Toxicol.]. Vol. 46, no. 5, p. 419. Jun 2008	The publication is reporting effects after a 39-year-old male patient who consumed intentionally more than 200 ml of glyphosate. This is not relevant for glyphosate dossier and risk assessment.
2294	Human safety (metabolism/toxicology)	Dallegrave et al.	2007	Pre-and postnatal toxicity of the commercial glyphosate formulation in Wistar rats .	Archives of toxicology, (2007 Sep) Vol. 81, No. 9, pp. 665-73	Non-relevant formulation tested

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2159	Human safety (metabolism/toxicology)	El-Shenawy	2009	Oxidative stress responses of rats exposed to Roundup and its active ingredient glyphosate .	Environmental Toxicology and Pharmacology, (NOV 2009) Vol. 28, No. 3, pp. 379-385	The publication is reporting information on oxidative stress responses to rats exposed to Roundup and its active ingredient glyphosate; however using intraperitoneal route of exposure which is not relevant for risk assessment.
2207	Human safety (metabolism/toxicology)	Fisher et al.	2008	Pesticide-associated pemphigus vulgaris.	Cutis, (2008 Jul) Vol. 82, No. 1, pp. 51-4	Case report 40 year old men with pemphigus vulgaris, developed within days of a one-time heavy exposure to fumes of burning glyphosate. No definded information on exposure and the exposed subtance (batch, manufacturer, analytics, adjuvants) were given.
1592	Human safety (metabolism/toxicology)	Gardner et al.	2008	Herbicides, glyphosate resistance and acute mammalian toxicity : simulating an environmental effect of glyphosate - resistant weeds in the USA.	Pest management science, (2008 Apr) Vol. 64, No. 4, pp. 470-8	Usage field-level data to assess glyphosate-resistant (GR) technology with a mammalian toxicity environmental indicator. Use is made of Agricultural Resource Management Survey (ARMS) data collected by the United States Department of Agriculture (USDA) to calculate actual farm-level LD50 doses, and a treatment effect regression model is employed to test the hypotheses. The article is dealing wiht model prediction which is not a toxicological endpoint and then not relevant for risk assessment.
1388	Human safety (metabolism/toxicology)	Gasnier et al.	2009	Glyphosate -based herbicides are toxic and endocrine disruptors in human cell lines.	Toxicology, (2009 Aug 21) Vol. 262, No. 3, pp. 184-91	Excessive doses exceed typical in vitro limit doses. In vitro test system is inappropriate with formulation containing surfactants.
1389	Human safety (metabolism/toxicology)	Gehin et al.	2006	Glyphosate -induced antioxidant imbalance in HaCaT: The protective effect of vitamins C and E.	Environmental Toxicology and Pharmacology, (JUL 2006) Vol. 22, No. 1, pp. 27-34	Roundup 3 plus®, induced significant changes in cellular antioxidant status as a glutathione depletion, enzymatic (catalase, glutathione-peroxidase and superoxide dismutase) disorders, and increased lipid peroxidation. Tested product contains 8% (m/m) polyoxyethylene amine (POEA), which is no longer in the composition of the representative formulation.
1103	Human safety (metabolism/toxicology)	Heras-Mendaza et al.	2008	Erythema multiforme-like eruption due to an irritant contact dermatitis from a glyphosate pesticide.	Contact dermatitis, (2008 Jul) Vol. 59, No. 1, pp. 54-6	Case report 37 year old female gardener noticed redness on her arms which became eczematous on day 2. At 5 day erythemato-purpuric plaques appeared on the skin of the upper extremities as well as target-like lesions on the abdomen, axillae and groin. After recovery, patch tests performed with the Spanish Standard series (True Test and Chemotechnique) and the Pesticide series (Martı´ Tor , Barcelona, Spain) were negative. The observed irritant contact dermatitis (ICD) was developed by sweat or wet conditions. Additionally, she delayed rinsing off the herbicide. Tested product contains polyoxyethylene amine (POEA), which is no longer in the composition of the representative formulation.
2880	Human safety (metabolism/toxicology)	Lee et al.	2008	The early prognostic factors of glyphosate - surfactant intoxication.	The American journal of emergency medicine, (2008 Mar) Vol. 26, No. 3, pp. 275-81	Case study on intoxicated patients (58 patients (19 men and 39 women; age, 48.8 ± 15.8 years)) of Chang Gung Memorial Hospital, Taiwan from April 1996 to March 2003

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						and Taichung Veterans General Hospital, Taiwan from April 2000 to October 2003. No information on substance, administered dose and incidence of intoxication for the patients are given. The intake of the substance was only confirmed via physical examination and statements of patients/witnesses (no analytical analysis was performed).
1083	Human safety (metabolism/toxicology)	Lerda	2009	Endocrine disruptors (ED) and human exposure	Research and Reviews in BioSciences, (2009) Vol. 3, No. 2-3, pp. 106-111	In occupational exposure studies, the exposed and control individuals' blood, urine or sperm samples were used, mainly to determine the level of exposure. No definded information on time and/or way of exposure and the exposed subtance (batch, manufacturer, analytics, adjuvants) were given. The levels of several pollutants were studied as well as other biochemical parameters related to exposure (gentox and mutagenesis, sperm quality, prostate, neurobehaviuor, cancer). The observed effect were not assignable to the reasoning chemical.
709	Human safety (metabolism/toxicology)	Levine et al.	2007	Disrupting mitochondrial function with surfactants inhibits MA-10 Leydig cell steroidogenesis	Cell Biology and Toxicology, (2007) Vol. 23, No. 6, pp. 385-400	The study results demonstrate how perturbation of the mitochondrial membrane by surfactants inhibits import, processing, and cholesterol transfer activity and underscore the importance of including sensitive assays that evaluate mitochondrial function when screening for potential effects on steroidogenesis with in vitro test systems. The roundup product tested contains 16.5% glyphosate-isopropylamine salt (which corresponds to approximately 12.2% glyphosate acid) and 6.1% MON 0818 (POEA). POEA is no longer in the composition of the representative formulation.
1338	Human safety (metabolism/toxicology)	Manas et al.	2009	Genotoxicity of glyphosate assessed by the comet assay and cytogenetic tests.	Environmental Toxicology and Pharmacology (2009) , Vol. 28, No. 1, pp. 37-41	This study applied 3 genotoxicity tests with obvious deviations to current guidelines. The i.p. route of exposure used for the micronucleus assay renders the study irrelevant for human exposure. In the in vitro assays most concentrations used were above 1 mM. 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, the results of the in vitro test are not considered relevant for human health risk assessment of glyphosate. Positive in vitro findings were only observed at concentrations above 1 mM.
2210	Human safety (metabolism/toxicology)	Mink et al.	2008	Pesticides and prostate cancer : A review of epidemiologic studies with specific agricultural exposure information.	European Journal of Cancer Prevention, (April 2008) Vol. 17, No. 2, pp. 97-110	Publication is a Secondary information (e.g. scientific or regulatory reviews) and as such not relevant for the risk assessments. Data of primary research atricles matching search terms of the Glyphosate search are evaluated elsewhere in the Literature review.

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1158	Human safety (metabolism/toxicology)	Mladinic et al.	2009	Evaluation of genome damage and its relation to oxidative stress induced by glyphosate in human lymphocytes in vitro .	Environmental and molecular mutagenesis, (2009 Dec) Vol. 50, No. 9, pp. 800-7	This study is a non-GLP, non-guideline in vitro study although it meets generally accepted scientific principles. However, due to the occurrence of apoptosis, a clear conclusion on the relevance of the positive response cannot be reached.
246	Human safety (metabolism/toxicology)	Mladinic et al.	2008	Assessment of oxidative DNA damage by glyphosate applying hOGG1 modified comet and micronucleus assay	Toxicology Letters [Toxicol. Lett.]. Vol. 180, pp. S170-S171. 5 Oct 2008	Abtract only; data presented refer to Mladinic et al. 2009
600	Human safety (metabolism/toxicology)	Moura et al.	2009	Cytogenetic biomonitoring of Brazilian workers exposed to pesticides: Micronucleus analysis in buccal epithelial cells of soybean growers.	Mutat. Res., Genet. Toxicol. Environ. Mutagen., Vol. 675, Issue 1-2, Page 1-4, Publication Year 2009	MNT analysis of buccal epithelial cells of soybean growers. 29 Brazilian workers exposed to pesticides in soybean fields and in 37 non-exposed individuals. Participants were grouped according theit smoking and drinik habbits. No definded information on exposure and the exposed subtances were given.
2813	Human safety (metabolism/toxicology)	Naydenova et al.	2007	Synthesis, cytotoxicity and clastogenicity of novel alpha-aminophosphonic acids.	Amino acids, (2007 Nov) Vol. 33, No. 4, pp. 695-702	This study is a non-GLP, non-guideline conforming in vivo study. The cytotoxicity, clastogenic and antiproliferative effect of different substances are testes. No informations on test items (batch, expiration date, storage, manufacturer) are given. Characterization of newly synthetized derivates, where glyphosate was used as reference substance fot cytotoxicity.
1019	Human safety (metabolism/toxicology)	Oliveira et al.	2007	Effects of the herbicide Roundup on the epididymal region of drakes Anas platyrhynchos.	Reproductive toxicology (Elmsford, N.Y.), (2007 Feb) Vol. 23, No. 2, pp. 182-91	Study on male ducks (Anas platyrhynchos); non-relevant species for risk assessment.
1082	Human safety (metabolism/toxicology)	Orton et al.	2009	Endocrine Disrupting Effects of Herbicides and Pentachlorophenol: In Vitro and in Vivo Evidence.	Environ. Sci. Technol., Vol. 43, Issue 6, Page 2144-2150, Publication Year 2009	12 environmentally relevant pesticides (11 herbicides and pentachlorophenol (PCP)) were tested for their endocrine disrupting potential in two in vitro assays. Glyphosate was not tested in the study. Xenopus oocytes were used to measure effects on the ovulatory response and ovarian steroidogenesis.
1130	Human safety (metabolism/toxicology)	Paz-Y-Mino et al.	2007	Evaluation of DNA damage in an Ecuadorian population exposed to glyphosate .	Genetics and Molecular Biology, (2007) Vol. 30, No. 2, pp. 456-460	This publication is assessed to be not relevant for human health risk assessment in the EU, as the glyphosate formulation (Roundup Ultra) was applied at much higher dose rates (20x maximum application rate) than recommended for the intended uses in the EU. Potential confounding effects from excess toxicity are thus compromising the relevance of this publication, especially since they were not sufficiently accounted for by the authors. In addition, the herbicide was combined with the adjuvant “Cosmoflux 411F”, which will not be used in the EU, and might influence the results and interpretations drawn from the Comet Assay.
1340	Human safety (metabolism/toxicology)	Poletta et al.	2009	Genotoxicity of the herbicide formulation Roundup (glyphosate) in broad-snouted caiman (Caiman	Mutation research, (2009 Jan 31) Vol. 672, No. 2, pp. 95-102	Comet assay and Micronucleus (MN) test on erythrocytes obtained from blood of hatched broad-snouted caiman (Caiman latirostris); non-relevant species for risk

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
				latirostris) evidenced by the Comet assay and the Micronucleus test.		assessment.
401	Human safety (metabolism/toxicology)	Prasad et al.	2009	Clastogenic Effects of Glyphosate in Bone Marrow Cells of Swiss Albino Mice	Journal of Toxicology [J. Toxicol.]. Vol. 2009, [np]. 2009	This study applied 2 in vivo genotoxicity tests, both with obvious deviations to current guidelines. The i.p. route of exposure used for the micronucleus and chromosomal aberration assay renders the study irrelevant for human exposure.
3011	Human safety (metabolism/toxicology)	Raipulis et al.	2009	Toxicity and Genotoxicity Testing of Roundup	Proceedings of the Latvian Academy of Sciences (2009) , Vol. 63, No. 1-2, pp. 29-32	The tested Roundup BIO formulation (Monsanto, Brussels, Belgium) contains polyoxyethylene amine (POEA), which is no longer in the composition of the representative formulation.
2134	Human safety (metabolism/toxicology)	Remor et al.	2009	Occupational exposure of farm workers to pesticides: Biochemical parameters and evaluation of genotoxicity.	Environ. Int., Vol. 35, Issue 2, Page 273-278, Publication Year 2009	Evaluation of the activities of butyrylcholinesterase (BChE) and -aminolevulinic acid dehydratase (ALA-D) enzymes, hematol., lipid parameters and genotoxicity using Comet assay in peripheral blood leukocytes and a micronucleus (MN) test in oral mucosa cells of agricultural workers. 37 male pesticides appliers (sprayers) exposed since childhood to a mixture of pesticides. No definded information on exposure or subtances were given.
8	Human safety (metabolism/toxicology)	Sakamoto et al.	2007	A 52-week feeding study of genetically modified soybeans in F344 rats .	Shokuhin eiseigaku zasshi. Journal of the Food Hygienic Society of Japan, (2007 Jun) Vol. 48, No. 3, pp. 41-50.	No glyphosate data included in the article.
603	Human safety (metabolism/toxicology)	Simoniello et al.	2008	DNA damage in workers occupationally exposed to pesticide mixtures.	J. Appl. Toxicol., Vol. 28, Issue 8, Page 957-965, Publication Year 2008	Evaluation of 54 subjects occupationally exposed to a large number of pesticides (directly or indirectly) and 30 subjects as a control group using the quantification of DNA damage level by means of the alkaline Comet assay and the evaluation of repair processes. No definded information on time and/or way of exposure and the exposed subtance (batch, manufacturer, analytics, adjuvants) were given.
2057	Human safety (occupational exposure)	Aleguas et al.	2007	Morbidity of Agricultural Chemical Use in Guyana	Clinical Toxicology [Clin. Toxicol.]. Vol. 45, no. 4, p. 361. May 2007	Only an abstract available without details
1716	Human safety (occupational exposure)	Colt et al.	2007	Inferring past pesticide exposures: A matrix of individual active ingredients in home and garden pesticides used in past decades.	Environmental Health Perspectives, (Feb 2007) Vol. 115, No. 2, pp. 248-254	Describes the development of an exposure classification tool to classify pesticide exposure status. Article does not report pesticide exposure status or health outcomes for any study population.
2172	Human safety (occupational exposure)	Monge et al.	2007	Parental occupational exposure to pesticides and the risk of childhood leukemia in Costa Rica.	Scandinavian Journal of Work Environment and Health, (AUG 2007) Vol. 33, No. 4, pp. 293-303	Publication describes general pesticide, exposures, general herbicide exposures, or collective exposures of "paraquat, chlorothalonil, glyphosate, and others."
2452	Human safety (occupational exposure)	Ogg	2008	Research: Pesticide Exposure Extends to Applicators Family	Crop watch (2008) , No. 8 Source Note: 2008 Apr. 25, no. 8	Non peer-reviewed web publication of University of Nebraska.
137	Human safety (occupational exposure)	Spiller et al.	2008	Agricultural chemical exposure in small farmers in Guyana.	Toxicological and Environmental Chemistry, (2008) Vol. 90, No. 2, pp. 361-365.	Publication describes general pesticide exposures (not glyphosate specific)
306	Human safety	Ugaddan et al.	2009	Brain acetylcholinesterase (AChE)	Asia Life Sciences, (JAN-JUN	Study in Oreochromis niloticus L. (tilapia, a cichlid fish);

Submission Number	Technical section	Author(s)	Year	Title	Source	Justification for non-relevance
	(occupational exposure)			activity and liver melanomacrophage centers (MMCs) formation in Nile tilapia (Oreochromis niloticus L.) following exposure to glyphosate herbicide.	2009) Vol. 18, No. 1, pp. 73-85. ISSN: 0117-3375.	not a relevant species for risk assessment. It focuses on the effects of an unidentified formulation of glyphosate on fishes (Nile tilapia), the study only refers to findings based on cellular and molecular level that cannot be related to the Ecotox risk assessment.
2648	Human safety (occupational exposure)	Zhai et al.	2008	Skin decontamination of glyphosate from human skin in vitro .	Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association, (2008 Jun) Vol. 46, No. 6, pp. 2258-60	The article is comparing three model decontaminant solutions for their ability to remove a glyphosate (only used as model herbicide) from an in vitro model. Glyphosate is only used as a control substance (not tested with different doses).
2166	Human safety (toxicology)	Perez-Herrera et al.	2008	PON1Q192R genetic polymorphism modifies organophosphorus pesticide effects on semen quality and DNA integrity in agricultural workers from southern Mexico	Toxicology and Applied Pharmacology, (2008) Vol. 230, No. 2, pp. 261-268	Semen quality of agricultural workers with general high exposure to pesticides (29 different substances), mainly focused on orhanophosphors, was investigated. No definded information on exposure or subtances were given.

Appendix 1: ORIGINAL SEARCH QUERY - July 2006 – December 2009

Preparing the search queries on STN:

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    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
            SAVE TEMP L1 GLY1/Q
L2          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 SENSI? OR ALLERG?
L3          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?
L4          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?
L5          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?
L6          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?
L7          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
L8          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?
L9          QUE SPE=ON  ABB=ON  PLU=ON  GOAT? OR COW? OR PIG? OR DIETARY
            OR ASSESSMENT OR RISK ASSESSMENT OR CONSUM? OR EXPOSURE
L10         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
L11         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
L12         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
L13         QUE SPE=ON  ABB=ON  PLU=ON  ATMOSPHERIC DEPOSITION OR TILE-DRAI
            NS 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
L14         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?
L15         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?
L16         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 QUE PLANT
            AND (SUBMERGE? OR EMERGE?)
L17         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
L18         QUE SPE=ON  ABB=ON  PLU=ON  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
L19         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
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