有効成分グリホサートおよびその代謝物に関する 公表文献の収集、選択等の実施報告書

検索対象期間: 2006 年 7 月 1 日~2009 年 12 月 31 日

検 索 日 : 2021 年 9 月 7 日 2021 年 10 月 14 日

報告日:2022年6月28日一部改定:2022年11月21日

ニューファム株式会社

1. 検索に用いたデータベース

表 1 文献検索に用いたデータベースの概要 (報告書原文 p.9-11 Table 4)

データベース名	データベースの特徴 収集分野、等	収集範囲、文献検索時 の文献数	更新頻度	検索日	検索対象期間
AGRICOLA	農業関連分野を後半に 収集、生物学、生物工学、 生態学、植物学等	1970~現在 670万論文以上 (2019/9月現在)	月1回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
BIOSIS	生物学、生物医学関連の 最大のデータベース 生物化学、免疫、病理、 生理学、毒性学、薬学等	1926~現在 2,780 万論文以上 (2019/4 月現在)	週1回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
CABA	農業関連 生物学、生物工学、林学、 植物学、食品工学、栄 養学、土壌、肥料学等	1973~現在 990 万論文以上	週1回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
CAPLUS	化学関連 分析化学、生化学、化学 工 学、有機化学等	1907~現在 670万論文以上 (2019/9月現在)	毎日	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
EMBASE	生物医学、薬学関連 生化学、医学、法医学、 薬 学、公衆衛生、環境 科学等	1947~現在 3,640 万論文以上 (2019/8 月現在)	毎日	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
ESBIOBASE	生物学、生化学全般 応用微生物学、細胞生物学、 生態学、環境科学、臨床医 学、分子生物学、毒性学、神 経科学、毒性学、植物学等	1994~現在 900 万論文以上	週 1 回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
MEDLINE	米国国立医学図書館が 提供する医学、看護、歯 学、獣医学、保健医療分 野から前臨床領域の文 献を収載	1946~現在 3,350 万論文 (2022/1 月現在)	週 6 回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
PQSCITECH	科学、技術全般を収載 25 のデータベースを統 合	1962~現在 3,360 万論文以上 (2021/1 月現在)	月 1 回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
SCISEARCH	科学、工学、生物医学の 広範 な文献を収載	1974~現在 4,770 万論文以上 (2019/8 月現在)	週 1 回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
TOXCENTER	薬学、生化学、生理学、 医薬や一般化学物質の 毒性等	1907~現在 1,620 万論文以上 (2022/1月現在)	週 1 回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31
FSTA	食品製造に関する科学、 技術生化学、衛生学、毒 性学、発酵学、生理学、 植物病理学等	1969~現在 159 万論文以上 (2020/9 月現在)	週 1 回	2021/09/07 2021/10/14	2006/01/01 ~ 2009/12/31

2. 検索に使用したキーワード、検索の条件

(1) 対象とする農薬

表 2 検索に用いたキーワード:有効成分グリホサート (報告書原文 p.13 Table 6)

一般名	Glyphosate
	Salts: isopropylamine, potassium, ammonium, methylmethanamine
IUPAC/CAS 名	2-(phosphonomethylamino)acetic acid
CAS 番号	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
その他の名称	-

表 3 検索に用いたキーワード: 代謝物 AMPA (報告書原文 p.13 Table 7)

一般名	AMPA
IUPAC/CAS 名	(aminomethyl)phosphonic acid
CAS 番号	1066-51-9
その他の名称	_

表 4 検索に用いたキーワード: グリホサートおよび代謝物 (報告書原文 p.14 Table 8)

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)

表 14 4分野に関連する文献の検索に用いたキーワード (報告書原文 p.14-15 Table 9-12) [Gly] AND 下記キーワード を用いた。

[GIY] AND THE	ピキーワード を用いた。
ヒトに対する毒性	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?
農作物及び畜産物	uptake OR translocation OR rumen OR storage stability OR storage OR stability
 への残留	OR metabolic OR metabolism OR breakdown OR nature of residues OR residue?
7- 1-4	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
生活環境動植物及び	tox? OR ecotox? OR ?toxic OR ?toxicity OR hazard OR adverse OR endocrine
家畜に対する毒性	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
環境動態	soil OR water OR sediment OR degradat? OR photo? OR soil residues OR soil
·水·元·沙/心	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 half-life OR half-lives OR half-lives 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

表 15 評価対象となる生物種等に関するキーワード

ヒトに対する毒性	rat OR rats OR dog? OR rabbit? OR guinea pig? OR mouse OR mice OR	
	operator? OR bystander? OR resident? OR worker? OR human exposure	
農作物及び畜産物	plant? OR crop? OR animal? OR livestock? OR hen OR cattle OR ruminant?	
への残留	OR goat? OR cow? OR pig?	
生活環境動植物及び	bird? OR mallard OR duck OR quail OR bobwhite OR Colinus? OR aquatic OR	
家畜に対する毒性	fish OR daphni? OR alg? OR benthic OR lemna OR marin? OR crusta? OR	
	gastropod? OR insect OR mollusc OR reptile OR amphib? OR bee? OR apis OR	
	apidae OR bumble? 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	
	arthropod? 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 micro organisms OR	
	microorganisms OR microbial OR sewage OR activated sludge OR amphib?	
環境動態	soil OR water OR sediment OR groundwater OR drinking water OR surface water	
	OR rainwater OR rain water	

なお、検索キーワードは製剤に関するものが入っていないが、欧州委員会に提出した公表文献検索と同様であり、その検索キーワードを用いて多くのグリホサート製剤に関する文献が検索されている。また、当社の代表的な製剤である「Credit Xtreme」についてデータベース Web of Science を用いて検索したところ、「Credit Xtreme」および「Credit-Xtreme」ではヒットはなく、「Credit and Xtreme」で3件のヒットがあったがいずれも関係のない文献であった(添付資料)。

以上のことから問題はないと考える(これは「2006 年 7 月 \sim 2009 年 12 月」のみの公表文献検索についてだけではなく、「2021 年 8 月」までの検索についても同様である)。

- 3. 評価目的との適合性評価(第1段階、第2段階)及び信頼性評価で設定した判断基準 評価目的との適合性(第1及び第2段階)で設定した判断基準
 - 第1段階:文献の表題及び概要に基づく適合性評価 (RA)
 - 第1段階として、文献の表題及び要約に基づき、下記の①から®に該当するものは明らかに評価の目的 と適合しない文献と見なした。
 - ①有効性(耐性関連の記事、害虫/作物の防除の新しい使用法)または農業/生物学研究(作物科学、育種、施肥、耕作、基本的な植物生理学/ミクロ/分子生物学)に関連する論文
 - ②分析方法/開発を扱った論文
 - ③新しい合成方法の発見や開発または有機化学・無機化学の基礎的な部分を記述した論文
 - ④特許に関するもの
 - ⑤廃水処理に関するもの
 - ⑥規制リスク評価のための十分なデータ/情報を含まない会議の貢献に言及する要約
 - ⑦遺伝子組み換え生物/トランスジェニック作物に焦点を当てた出版物。 グリホサートの評価に直接関連するデータはありません(作物の組成分析、遺伝子流動、タンパク質の特性評価など)
 - ⑧グリホサートまたは関連する代謝物が焦点ではなかった論文
 - ⑨科学的および規制上のレビューを含む二次情報
 - ⑩政治的/社会的/経済的分析を扱った記事

- ①化合物の混合物/潜在的に原因となる要因によって引き起こされ、したがって懸念物質(混合物の毒性など)に起因しない観察
- ②欧州の規制目的に関係のない試験デザイン、試験システム、試験種、暴露経路など
- ③生態毒性学、毒物学、残留物、および環境運命に関連しない所見
- ④欧州の代表的な用途/条件を扱っていない出版物(例:圃場の場所、土壌の特性、欧州以外のモニタリングなど)
- ⑤AIR5 ドシエの代表的な処方ではなく、したがって欧州でのグリホサートの更新に関連しないラウンドアップ処方/その他のグリホサート処方を扱っている出版物
- (b)一般的な農薬曝露を扱った出版物 (グリホサートに固有ではないもの)
- ①欧州レベルの規制リスク評価に関連しないエンドポイントを生成する出版物(例:酵素、細胞および分子レベルなどに基づく所見)
- ®欧州の規制リスク評価に使用できる新しいデータが提供されていない意見記事

評価目的との適合性(第2段階)で設定した判断基準

第2段階:文献の全文に基づく適合性評価(DA)

第1段階で除外した以外の公表文献については、文献全文の内容に基づいて、以下の手順に従って評価目的との適合性を検証し、その結果により分類した。

(ア) 評価の目的と適合しない文献の除外

文献全文の内容に基づき、第1段階と同様に下記の①から®に該当するものは評価の目的と適合しない 文献と見なし、その論文リストと判断理由を英文報告書 p.55-77 の Table 29 に示した。

- ①有効性(耐性関連の記事、害虫/作物の防除の新しい使用法)または農業/生物学研究(作物科学、育種、施肥、耕作、基本的な植物生理学/ミクロ/分子生物学)に関連する出版物
- ②分析方法/開発を扱った出版物
- ③新しい合成方法(発見/開発)または基本的な(有機/無機)化学の他の側面を説明する出版物
- ④特許に関するもの
- ⑤廃水処理に関するもの
- ⑥規制リスク評価のための十分なデータ/情報を含まない会議の貢献に言及する要約
- ⑦遺伝子組み換え生物/トランスジェニック作物に焦点を当てた出版物。 グリホサートの評価に直接関連するデータはありません(作物の組成分析、遺伝子流動、タンパク質の特性評価など)
- ⑧グリホサートまたは関連する代謝物が出版物の焦点ではなかった出版物
- ⑨科学的および規制上のレビューを含む二次情報
- ⑩政治的/社会的/経済的分析を扱った記事
- ①化合物の混合物/潜在的に原因となる要因によって引き起こされ、したがって懸念物質(混合物の毒性など)に起因しない観察
- ②欧州の規制目的に関係のない試験デザイン、試験システム、試験種、暴露経路など
- ③生態毒性学、毒物学、残留物、および環境運命に関連しない所見
- ④欧州の代表的な用途/条件を扱っていない出版物(例:圃場の場所、土壌の特性、欧州以外のモニタリングなど)
- ⑤AIR5 ドシエの代表的な処方ではなく、したがって欧州でのグリホサートの更新に関連しないラウンドアップ処方/その他のグリホサート処方を扱っている出版物
- ⑥一般的な農薬曝露を扱った出版物(グリホサートに固有ではないもの)
- ①欧州レベルの規制リスク評価に関連しないエンドポイントを生成する出版物 (例:酵素、細胞および分子レベルなどに基づく所見)
- ⑧欧州の規制リスク評価に使用できる新しいデータが提供されていない意見記事

グリホサートによる健康被害と曝露に関する論文に対する追加基準

グリホサートの健康影響に関する科学文献は、大きく2つに分けられる。

- グリホサート酸と塩および基準グリホサート製剤 MON 52276 に関するデータを含む論文、

および

- 基準製剤 MON 52276 とは異なる組成を持つグリホサート製剤および/または共配合剤に関するデータのみを含む論文。

グリホサート製剤にのみ関連する論文の場合、全身曝露の結果としての健康影響を評価するための 製剤の in vitro 試験は、細胞膜とミトコンドリア膜の不安定化に基づく細胞毒性を生み出す界面活性 剤が存在することによりグリホサート特有の毒性を覆い隠してしまうため、除外した。

また、グリホサート濃度が 1 mM を超える in vitro の結果のみが提示されている場合、これらの論文は全身毒性に関する評価には関連性がなく、信頼性がないと判断された。これは、in vivo 試験系におけるグリホサートの経口バイオアベイラビリティが限られており(約 20%)、経皮吸収が非常に低く、全身への排泄が速いため、標準的な規制対象の in vivo 試験でその濃度を達成することは生理学的に不可能であるためです。

1 mM の限界値は、グリホサート 71.7%w/w を含む製剤の単回経口薬物動態データに基づいており、ラットに 1,430 mg/kg bw を経口投与すると、2 時間後の血漿濃度は $38.1\,\mu g/mL$ あるいは $0.225\,m$ となる。線形に外挿すると(グリホサートは肝代謝を受けないので可能)、2,000 mg/kg bw を経口摂取後 2 時間で $53.3\,\mu g/mL$ または $0.315\,m$ M、4,000 mg/kg bw を経口摂取後 2 時間で $107\,\mu g/mL$ または $0.630\,m$ M という血漿濃度となる。グリホサートの全身濃度 1 mM は $6,000\,m g/kg$ bw を超える経口投与に相当し、現在の OECD 試験ガイドラインに基づく反復投与実験 in vivo 試験には全く不適当です。グリホサートの ADI $0.5\,m g/kg$ bw/day は、グリホサートの経口バイオアベイラビリティを 20%として、体重 $60\,k g$ 、細胞外液 $36\,L$ のヒトの一日全身濃度を $0.17\,\mu g/mL$ または $1\,\mu$ M と見なすことができる。米国におけるグリホサート施用者の尿中幾何平均値 $3.2\,\mu g/L$ に基づく施用日(すなわち最高暴露日)のグリホサートの一日全身量は約 $0.0001\,m g/kg$ bw/day であり(Acquavella, 2004)、経口バイオアベイラビリティ 20%の ADI $0.5\,m g/kg$ bw の全身量($0.1\,m g/kg$ bw)より $1000\,m g/kg$ とのから。

グリホサートのリスク評価に関連すると考えられ、全文ベースで信頼性が評価された多くの論文には、グリホサートに加え、(MON 52276 とは異なる)製剤や共配合剤に関する実験データも含まれている。このような場合、グリホサートと参照製剤(論文の著者が明確に述べている場合)に関連する毒性データのみを要約し、議論している。曝露モニタリングと疫学に関する論文の場合は、グリホサート製剤への曝露を考慮する。

(イ) 評価の目的と適合した文献の分類

(ア)で除外した以外の文献については、適合性があると判断した文献とし、EFSA2092 ガイダンス文書-EFSA ジャーナル 2011;9(2): 2092、ポイント 5.4.1 で推奨されているように分類された。 分類区分

区分	該当する文献
A	リスク評価パラメータの設定または精緻化のためのデータを提供する研究。
D	データ要件に関連するが、申請者の意見では、既存のリスク評価パラメータを変更しない
D	補足情報のみ を提供する研究
С	関連性が明確に判断できない研究。

結果の信頼性に基づく分類

評価目的への適合性評価において「区分 A」に分類した文献については表 16 - 18 に示した判断基準に従って信頼性を評価した。信頼できないと分類されたカテゴリーA の文献は、カテゴリーB に格下げされた。

表 16:生態毒性、環境運命、残留に関する信頼性基準(英文報告書 p.19-21 Table 13)

適用	信頼性基準
Ecotoxicology, Environmental Fate, Residues	ガイドラインに準拠した試験(GLP試験)の場合:OECD、OPPTS、ISO、その他。 対応するガイドラインに記載されている妥当性・品質基準を満たす。
Ecotoxicology, Environmental Fate, Residues	他の化学物質への以前の暴露の有無が記録されている(関連する場合)
Ecotoxicology	水生試験においては、被験物質を水に溶かすか、溶媒が必要な場合は適切なもの(非 毒性)で、溶媒対照/陽性対照を試験計画に考慮する。
Environmental Fate, Residues	試験物質は水または無毒の溶媒に溶解する。
Ecotoxicology, Environmental Fate, Residues	被験物質について十分に文書化され、報告されていること(純度、供給源、含有量、 保管条件など)。
Ecotoxicology	脊椎動物を含む試験については、毒性試験に使用されたバッチの原体規格との適合性。
Ecotoxicology	実験に供した種については、入手源、実験条件(関連する場合):系統、齢/ライフステージ、体重、順化、温度、pH、酸素(水生実験では溶存酸素)含有量、飼育環境、光条件、湿度(陸生種)、培養条件、餌を含めて明確に報告されていること。 関連する試験ガイドラインの妥当性基準は、異なる種間で外挿することができる
Ecotoxicology	が、必ずしも 異なる試験デザイン間で外挿する必要はない。異なる場合、その違いの性質と影響について議論することが理想的である。
Ecotoxicology, Environmental Fate, Residues	グリホサートまたはその代謝物のみを被験物質とし(混合物を除く)、被験物質の適 用に関する情報が記載されている。
Ecotoxicology, Environmental Fate, Residues	測定されたエンドポイントは、グリホサート(またはグリホサート代謝物)の影響と 考えることができる。
Ecotoxicology, Environmental Fate, Residues	試験計画/試験系がよく記述されており、関連する場合は、曝露媒体中の濃度(投与率、適用量など)、被験物質(溶媒、ビヒクル)の希釈/混合が含まれています。
Ecotoxicology, Environmental Fate, Residues	試験媒体(濃度)/採取した試料で実施した分析の検証、試験媒体中の被験物質の安 定性を記載すること。
Ecotoxicology	試験は、関連する場合は陽性/陰性対照を含むいくつかの用量レベル (少なくとも3つ) で実施されています。
Ecotoxicology	全期間を通して適切な露出が実証され、報告された。
Ecotoxicology	用量反応試験デザインを採用した試験において、明確な濃度反応関係が報告 されている。
Ecotoxicology	統計解析を容易にするために、1群につき十分な数の動物が報告されている:対照群における死亡率、陽性/陰性対照における観察/所見を明確に報告されている(関連する場合)。
Ecotoxicology, Environmental Fate, Residues	報告されたデータにより、アッセイの統計的検出力を評価することが可能である。
Ecotoxicology, Environmental Fate, Residues	統計手法が報告されている(プロットや信頼区間の確認など)
Ecotoxicology	観察(時間を含む)、検査、解析の実施内容、(関連する場合)解剖が十分軌 陸されている
Ecotoxicology	実験室や野外での陸上生態毒性試験では、使用する基質(葉の種類や土壌の 種類など)を適切に説明する必要がある。
Ecotoxicology, Environmental Fate, Residues	欧州の状況に関連する/比較可能なフィールドロケーション。

適用	信頼性基準
Ecotoxicology, Environmental Fate, Residues	土壌の特性: テクスチャー(砂質ローム、シルト質ローム、ローム、ローム 状砂)、pH (5.5-8.0)、陽イオン交換容量、有機炭素 (0.5-2-5%)、かさ密度、 保水性、微生物バイオマス (有機炭素 1%以下)。
Ecotoxicology, Environmental Fate	その他の土壌については、pH、テクスチャー、CEC、有機炭素、かさ密度、 保水力、微生物バイオマスなどのパラメータによる特性評価に関する情報が 提供されている。
Ecotoxicology, Environmental Fate, Residues	農地土壌を含む試験の場合、最低1年間は被験物質または類似の物質で処理 されていないことが望ましい。
Ecotoxicology, Environmental Fate	土壌サンプルは、A-horizon の最上部 20 cm の層から採取し、現場からの 新鮮な土壌が望ましい(4 +/- 2℃で最大 3 ヶ月保管)。
Ecotoxicology, Environmental Fate, Residues	降水量に関するデータを記録
Environmental Fate	温度は 20~25℃の範囲で、水分は報告されている。
Environmental Fate	欧州の地下水、土壌、地表水、堆積物、大気から採取されたサンプルにグリ ホサートの存在が確認された。
Ecotoxicology	実験室での陸上試験では、温度は試験対象種に適したもので、一般に 20~ 25°Cの範囲に収まるべきであり、土壌水分/相対湿度が報告されている。
Ecotoxicology	蜂の試験については、試験の温度は種に適したものであるべきである。
Ecotoxicology	実験室での水生生物試験: 使用され媒体の入手元や組成が記載されていること。 水温はテストする生物種に適したもので、一般的に 15~25℃の範囲に収まるようにします。
Ecotoxicology, Residues	残留データは、グリホサートの承認更新の状況に応じて文脈で適切な、明確に記述された GAP 表(作物、適用方法、投与量、間隔、PHI)にリンクさせることができる。
Ecotoxicology, Environmental Fate, Residues	分析結果は、グリホサートおよびその代謝物に関する既存の残留性定義と関連づけることができる残留物の測定値を示す。
Ecotoxicology, Environmental Fate, Residues	分析方法が明確に記述されており、分析方法の特異性、感度が適切に記述されている。
Ecotoxicology	中央値付近の信頼区間の幅に対する ECX の評価と、ECX の中央値が提供する保護レベルの確実性が報告される。
Environmental Fate	放射性標識の特性:純度、比活性、標識の位置が報告されている。
Environmental Fate	分解キネティクスが含まれる場合: データテーブル/モデル説明/動態適合のための統計パラメータを提供すること。
Environmental Fate, Residues	モニタリングデータ:分析されたマトリックスの説明、および分析方法を完全に記述すること。
Environmental Fate	適用量および承認された用途との関連性を明確に記述すること。

総合評価: 信頼できる / 制約があるが信頼できる / 信頼できない

表 17:毒性学 - 疫学と暴露試験に関する信頼性基準(英文報告書 p.22 Table 14)

疫学試験	暴露試験
ガイドラインに準拠	ガイドラインに準拠
国際的に認められた有効な試験ガイドライン/プラクティスに従った試験	国際的に認められた有効な試験ガイドライン/プラクティスに従った試験
試験は完全に記述され、科学的に許容される基準に従っ て実施された。	GLP に準拠して実施された試験
	試験は完全に記述され、科学的に許容される基準に 従って実施された。
被験物質	被験物質
グリホサートのみをa.i.とした製剤への曝露。	グリホサートのみを a.i.とした製剤への曝露。
グリホサートと他のa.i.を併用した製剤への曝露。	グリホサートと他の a.i.を併用した製剤への曝露。
様々な製剤の農薬に暴露される。	様々な製剤の農薬に暴露される。
試験	試験
試験デザイン - 疫学的手法に準拠	試験デザインの明確な記述
調査対象者(集団)を記述	調査した母集団が十分に記述されている
暴露状況について記述	暴露の状況を十分に説明する
結果の記述	サンプリングスキームが十分に文書化されている
交絡因子は考慮されているか	分析方法の詳細が記述されている
統計解析	報告された分析法の妥当性確認
	モニタリング結果の報告

総合評価: 信頼できる / 制約があるが信頼できる / 信頼できない

表 18:毒性学 - in vitro and in vivo 試験に関する信頼性基準(英文報告書 p.23 Table 15)

信賴性基準	- 毒性・代謝
in vitro 試験	in vivo 試験
ガイドラインに準拠	ガイドラインに準拠
国際的に認められた有効な試験ガイドラインに従った試験	国際的に認められた有効な試験ガイドラインに従った試験
GLPに準拠して実施された試験	GLP に準拠して実施された試験
研究は完全に記述され、科学的に許容される基準に従っ て実施された。	研究は完全に記述され、科学的に許容される基準に従って 実施された。
被験物質	被験物質
被験物質 (グリホサート) について十分に記述され、報告されていること (純度、供給源、含有量、保管条件など)。	被験物質(グリホサート)について十分に記述され、報告 されていること(純度、供給源、含有量、保管条件など)。
グリホサート酸またはその塩のみが被検物質である	グリホサート酸またはその塩のみが被検物質である
AMPA は被検物質	AMPA は被検物質
試験	試験
試験系が明確かつ完全に記述されている	試験系が明確かつ完全に記述されている
試験条件が明確かつ完全に記述されている	試験条件が明確かつ完全に記述されている
代謝活性化システムが明確に完全に記述されている	投与経路・投与方法が記載されている
生理額的に許容される範囲の試験濃度(< 1 mM)である	投与量が報告されている
細胞毒性試験の報告	用量レベルごとに使用した動物数の報告
陽性及び陰性対照	分析試験媒体の分析方法について記載
観察された影響の完全な報告	分析法の妥当性確認
統計手法の記述	試験媒体の分析検証
陰性及び陽性対照の背景データの報告	観察された影響の完全な報告
用量相関の報告	統計手法の記述
	試験施設の背景データの報告

総合評価: 信頼できる / 制約があるが信頼できる / 信頼できない

4. 検索結果のまとめ

表 19 検索結果のまとめ — すべての論文 (英文報告書 p.24 Table 16)

	論文数
対象とする農薬名で検索抽出した総論文数(全データベースの合計)	9947
手動で重複を削除した後の総論文数	3294
迅速な評価(タイトル・要旨)の結果、除外された論文の数	3050
詳細な評価を行った総論文数	244
詳細な評価の結果、除外された論文数(例:関連性がない)	166
詳細な評価の結果、除外されなかった論文の数 a)	78

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

表 20 適合性評価第 2 段階で適合性ありとされた文献と分類結果 (英文報告書 p.6 Table 2)

分野	該当する論文数		
	区分 A	区分 B	区分 C
毒性	6	19	6
残留	0	1	0
環境毒性	7	22	1
環境動態	0	16	0
薬効/農学	0	0	0
nH nH	13	58	7

表 21 検索結果のまとめ― 環境毒性に関する論文(英文報告書 p.24 Table 17 から抜粋)

	論文数
手動で重複を削除した後の総論文数	123
迅速な評価(タイトル・要旨)の結果、除外された論文の数	24
詳細な評価を行った総論文数	99
詳細な評価の結果、除外された論文数(例:関連性がない)	69
詳細な評価の結果、除外されなかった論文の数 ^{a)}	30

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

表 22 検索結果のまとめ― 環境動態に関する論文 (英文報告書 p.24 Table 18 から抜粋)

	論文数
手動で重複を削除した後の総論文数	80
迅速な評価(タイトル・要旨)の結果、除外された論文の数	18
詳細な評価を行った総論文数	65
詳細な評価の結果、除外された論文数(例:関連性がない)	49
詳細な評価の結果、除外されなかった論文の数®	16

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

表 23 検索結果のまとめ一 残留に関する論文 (英文報告書 p.25 Table 19 から抜粋)

	論文数
手動で重複を削除した後の総論文数	13
迅速な評価(タイトル・要旨)の結果、除外された論文の数	12
詳細な評価を行った総論文数	1
詳細な評価の結果、除外された論文数(例:関連性がない)	0
詳細な評価の結果、除外されなかった論文の数	1

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

表 24 検索結果のまとめ― 毒性に関する論文 (英文報告書 p.25 Table 20 から抜粋)

	論文数
手動で重複を削除した後の総論文数	106
迅速な評価(タイトル・要旨)の結果、除外された論文の数	30
詳細な評価を行った総論文数	76
詳細な評価の結果、除外された論文数(例:関連性がない)	45
詳細な評価の結果、除外されなかった論文の数®	31

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

表 25 検索結果のまとめ― 薬効/農学に関する論文 (英文報告書 p.25 Table 21 から抜粋)

	論文数
手動で重複を削除した後の総論文数	2
迅速な評価(タイトル・要旨)の結果、除外された論文の数	0
詳細な評価を行った総論文数	2
詳細な評価の結果、除外された論文数(例:関連性がない)	2
詳細な評価の結果、除外されなかった論文の数 a)	0

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

表 26 検索結果のまとめ― その他の関連性のないカテゴリーに関する論文

(英文報告書 p.26 Table 22 から抜粋)

	論文数
手動で重複を削除した後の総論文数	2967
迅速な評価(タイトル・要旨)の結果、除外された論文の数	2966
詳細な評価を行った総論文数	1
詳細な評価の結果、除外された論文数(例:関連性がない)	1
詳細な評価の結果、除外されなかった論文の数 a)	0

a :関連性カテゴリーA、B、C(EFSA Journal 2011;9(2):2092, Point 5.4.1 による)に属する全文関連論文

5. 適合性評価の第2段階で「適合しない」と判断した論文リストとその理由

表 27 適合性評価の第2段階で「適合しない」と判断した論文とその理由 (英文報告書 p.55-77 の Table 29)

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
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

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						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.).
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.

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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 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.

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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 exposed to Roundup Original.	Ecotoxicology (London, England), (2008 Apr) Vol. 17, No. 3, pp. 153-63	This publication deals with a Roundup formulation, containing the surfactant POEA (or any similar), which is not permitted in formulated herbicidal

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						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 verifications 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

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						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.
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.	Guiseppe	2006	The use of glyphosate herbicides in	(2006) , Electronic Series Title:	Scientific review of existing literature.

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	pollen/nectar residue)			managed forest ecosystems and their effects on non-target organisms with particular reference to ants as bioindicators	Technical bulletin (Maine Agricultural and Forest Experiment Station) ; 192	
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 analytical 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 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

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						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 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.

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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

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						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 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

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						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 insecticides. Role of detoxification genes in response to xenobiotics.	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 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),

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						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 scripta elegans) embryos and early hatchlings.	Environmental toxicology and chemistry, (2006 Oct) Vol. 25, No. 10, pp. 2768-74	This study presents observations caused by mixture of compounds (the glyphosate formaltion Glypro and a 3% solution of the surfactant LI700) and thus not attributable to only glyphosate.
1642	Ecotoxicology (incl.	Stachowski-	2008	Impact of Roundup on the marine	Aquatic toxicology (Amsterdam,	This publication deals with a Roundup formulation,

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	pollen/nectar residue)	Haberkorn et al.		microbial community, as shown by an in situ microcosm experiment.	Netherlands), (2008 Sep 29) Vol. 89, No. 4, pp. 232-41	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 cohosalmons 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

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						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 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 (CO2 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	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

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				microbial communities in the Pampas region, Argentina		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, 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.

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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 environmental 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).
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

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						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	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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				Mineralizasyonuna Glyphosate Isopropylamine ve Trifluralin and apos;in Etkileri.		
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. Additionally, glyphosate was applied to plants by foliar application (not to bare soil).

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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, phenmedipham, ethofumesate and metamitron in two Finnish arable soils.	Pest Manage. Sci., Vol. 62, Issue 6, Page 473-491, Publication Year 2006	Study design not relevant for the European regulatory purposes. Glyphosate (Roundup ready) was sprayed on 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.

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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- Water, Rainfall, and Soil Samples Collected in the United States, 2001-06	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
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

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						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- Performance Liquid Chromatography with Postcolumn Derivatization Method	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.
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-	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.

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
					26	
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	Toxicol. Environ. Chem., Vol. 89, Issue 1, Page 125-139,	Groups of farmers were classified according to the main pesticide sprayed (triazoles or chlorothalonil

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
				open-field farmers and fruit growers.	Publication Year 2007	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. 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	Caglar et al.	2008	The effect of sub-acute and sub-chronic	Environmental Toxicology and	The aim of the study was biochemical and

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
	(metabolism/toxicology)			exposure of rats to the glyphosate -based herbicide Roundup.	Pharmacology, (JAN 2008) Vol. 25, No. 1, pp. 57-62	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
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	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

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
				lines.		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 (Marti 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 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.

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						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

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						Literature review.
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

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						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 latirostris) evidenced by the Comet assay and the Micronucleus test.	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 broadsnouted caiman (Caiman latirostris); non-relevant species for risk 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.

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						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 (occupational exposure)	Ugaddan et al.	2009	Brain acetylcholinesterase (AChE) activity and liver melanomacrophage centers (MMCs) formation in Nile tilapia (Oreochromis niloticus L.) following exposure to glyphosate herbicide.	Asia Life Sciences, (JAN-JUN 2009) Vol. 18, No. 1, pp. 73-85. ISSN: 0117-3375.	Study in Oreochromis niloticus L. (tilapia, a cichlid fish); 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.

6. 適合性評価の第2段階で「区分b」「区分c」へ分類された論文リストとその理由

表 28 適合性評価の第 2 段階で「区分 b」と判断した論文とその理由 (英文報告書 p.31-38 の Table 25 及び p.39-50 の Table 26)

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
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 assessment 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 assessment 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.

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
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 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.

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						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
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.

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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 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.
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	Gjettermann et	2009	Particle-facilitated pesticide leaching	Journal of environmental quality,	5.4.1 case b) relevant but supplementary information:

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	CA 7.1.3.1.2	al.		from differently structured soil monoliths.	(2009 Nov-Dec) Vol. 38, No. 6, pp. 2382-93	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, 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		5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important

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				gariepinus).	Science (2008) , Vol. 4, No. 3, pp. 362-367	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 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.
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

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
						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 are considered as only supportive.
997	CA 8.2.8	Widenfalk et al.	2008	Effects of pesticides on community composition and activity of sediment microbesresponses 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	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

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				fischeri and the ciliate Tetrahymena pyriformis.		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 $10~\mu g/L$ 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 et al.	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 microorganisms, 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	Asian Journal of Chemistry (2009), Vol. 21, No. 3, pp. 2163-	5.4.1 case b) relevant but supplementary information: Although the study is relevant for the data requirement, important

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
				obliquus).	2169	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.

表 29 適合性評価の第 2 段階で「区分 c」と判断した論文とその理由 (英文報告書 p.51-52 の Table 27 及び p.53-54 の Table 28)

Submission Number	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	判断理由
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	CP 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
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

7. 適合性評価の第2段階で「区分a」と判断した論文リスト及び信頼性を評価した結果

表 30 適合性評価の第 2 段階で「区分 a」と判断した論文リスト及び信頼性を評価した結果 (英文報告書 p.27-28 の Table 23 及び p.29-30 の Table 24)

Submission Number	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	信頼性 分類	判断理由
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	1	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	1	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	1	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	1	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	1	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.	1	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	1	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	1	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	1	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	Pereira et al.	2009	Toxicity evaluation of three pesticides on	Ecotoxicology (London,	1	5.4.1 case a) relevant and provides data for the risk

Submission Number	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	信頼性 分類	判断理由
	CA 8.2.6.1			non-target aquatic and soil organisms:	England), (2009 May) Vol. 18,		assessment: A summary for this article is provided.
				commercial formulation versus active	No. 4, pp. 455-63		
				ingredient.			
100	CA 8.2.4.2	Bringolf et al.	2007	Acute and chronic toxicity of glyphosate	Environmental toxicology and	1	5.4.1 case a) relevant and provides data for the risk
	CA 8.2.5.2			compounds to glochidia and juveniles of	chemistry, (2007 Oct) Vol. 26,		assessment: A summary for this article is provided.
				Lampsilis siliquoidea (Unionidae).	No. 10, pp. 2094-100		
834	CA 8.2.6.1	Vendrell et al.	2009	Effect of glyphosate on growth of four	Bulletin of environmental	1	5.4.1 case a) relevant and provides data for the risk
				freshwater species of phytoplankton: a	contamination and toxicology,		assessment: A summary for this article is provided.
				microplate bioassay.	(2009 May) Vol. 82, No. 5, pp.		
					538-42		
413	CP 10.6.2	Cedergreen et	2007	Combination effects of herbicides on	Pest Management Science	1	5.4.1 case a) relevant and provides data for the risk
	CA 8.2.7	al.		plants and algae: do species and test	(2007), 63(3), 282-295		assessment: A summary for this article is provided.
	CA 8.2.6.1			systems matter?			

8. EFSA, USEPA, JMPR の評価において評価書に結果が引用されている場合は、引用した機関、引用された評価書名、発行年等の情報表 31 EFSA, USEPA, JMPR の評価書に引用されている論文

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	評価 機関	評価書情報 (発行年等)	備考
FE 001	II 5	Ackermann W, et al.	2015	The influence of glyphosate on the microbiota and production of botulinum neurotoxin during ruminal fermentation.	Curr Microbiol 70(3):374–82	JMPR	2016, Part II	
FE 002	II 5	Acquavella JF, et al.	1999	Human ocular effects from self-reported exposure to Roundup herbicides.	Hum Exp Toxicol. 18: 479–86.	JMPR	2016, Part II	
FE 003	II 5	Acquavella JF, et al.	2004	Glyphosate biomonitoring for farmers and their families: results from the Farm Family Exposure Study.	Environ Health Perspec.112:321-6.	JMPR	2016, Part II	
FE 004	II 5	Akcha, F., et al.	2012	Genotoxicity of diuron and glyphosate in oyster spermatozoa and embryos.	Aquatic Toxicol. 106-107: 104-113.	USEPA	2015, 417701	
FE 005	II 5	Alavanja MC, et al.	2004	Pesticides and lung cancer risk in the agricultural health study cohort.	Am J Epidemiol. 160(9):876–85.	JMPR	2016, Part II	
FE 006	II 5	Alavanja MC, et al.	2014	Non-Hodgkin lymphoma risk and insecticide, fungicide and fumigant use in the agricultural health study.	PLoS ONE. 9:e109332. doi:10.1371/journal.pone.0109332	JMPR	2016, Part II	
FE 007	II 5	Alavanja, M. C., et al.	2003	Use of agricultural pesticides and prostate cancer risk in the Agricultural Health Study cohort.	Am J Epidemiol, 157(9), 800-814.	USEPA	2014, D417808	
FE 008	II 5	Alavanja, M. C., et al.	2004	Pesticides and lung cancer risk in the agricultural health study cohort.	Am J Epidemiol, 160(9), 876-885. doi: 160/9/876 [pii]10.1093/aje/kwh290	USEPA	2014, D417808	
FE 009	II 5	Alison RH, et al.	1994	Neoplastic lesions of questionable significance to humans.	Toxicol Pathol. 22;179–86.	JMPR	2016, Part II	
FE 010	II 7	Al-Rajab, Abdul Jabbar and Michael Schiavon	2010	Degradation of 14C-glyphosate and aminomethylphosphonic acid (AMPA) in three agricultural soils.	Journal of Agricultural Sciences. 22(9):1374-1380.	USEPA	2015, 417701	
FE 011	II 5	Alvarez-Moya C, et al.	2014	Comparison of the in vivo and in vitro genotoxicity of glyphosate isopropylamine salt in three different organisms.	Genetics and Molecular Biology, 37, 1, 105- 110	JMPR USEPA	2016, Part II 2017, D444689	
FE 012	II 5	Amer SM, et al.	2006	In vitro and in vivo evaluation of the genotoxicity of the herbicide glyphosate in mice.	B Natl Res Cent (Cairo). 31:427–46.	JMPR	2016, Part II	
FE 013	II 5	Amerio, P., et al.	2004	Skin toxicity from glyphosate-surfactant formulation.	J Toxicol Clin Toxicol, 42(3), 317-319.	USEPA	2014, D417808	
FE 014	II 8	Amy Blankinship	2018	Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate	EPA-HQ-OPP-2009-0361-2341 dated November 21, 2018	USEPA	2020 ID	
FE	II 5	Anadón A, et al	2009	Toxicokinetics of glyphosate and its metabolite	Toxicology letters, (2009 Oct 08) Vol. 190, No. 1, pp. 91-5.	JMPR	2016, Part II	

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	評価 機関	評価書情報 (発行年等)	備考
015				aminomethyl phosphonic acid in rats.	Electronic Publication Date: 14 Jul 2009			
FE	II 5	Andreotti, G., et	2009	Agricultural pesticide use and pancreatic cancer	Int J Cancer, 124(10), 2495-2500. doi: 10.1002/ijc.24185	USEPA	2014, D417808	
016		al.		risk in the Agricultural Health Study Cohort.			2017, D444689	
FE	II 5	Andreotti, G., et	2018	Glyphosate use and cancer incidence in the	JNCI: Journal of the National Cancer Institute. 110(5): 509-	USEPA	2017, D444689	
017		al.		Agricultural Health Study.	516. doi:10.1093/ jnci/djx233. https://academic.oup.com/jnci/article/110/5/509/4590280		2020, D455531	
FE	II 5	Arbuckle, T. E., et	2001	An exploratory analysis of the effect of pesticide	Environmental Health Perspectives, 109(8), 851-857.	USEPA	2014, D417808	
018		al.		exposure on the risk of spontaneous abortion in an Ontario farm population.				
FE	II 5	Ashby J, et al.	1989	Classification according to chemical structure,	Mutat Res. 223(2):73–103.	JMPR	2016, Part II	
019				mutagenicity to Salmonella and level of				
				carcinogenicity of a further 42 chemicals tested				
				for carcinogenicity by the U.S. National Toxicology Program.				
FE	II 5	Axelrad JC, et al.	2003	The effects of acute pesticide exposure on	Toxicology. 185:67–78.	JMPR	2016, Part II	
020				neuroblastoma cells chronically exposed to				
		D. N. T I	0000	diazinon.		LIGEDA	0015 417701	
FE 021	II 7	Baker, N.T., et al.	2006	Occurrence and Transport of Agricultural Chemicals in Leary Weber Ditch Basin, Hancock	U.S. Department of the Interior, U.S. Geological Survey, Scientific Investigations Report, 2006	USEPA	2015, 417701	
021				County, Indiana, 2003- 2004. 2005 National Water	Scientific investigations Neport, 2000			
				Quality Assessment Program.				
FE	II 5	Baldrick P, Reeve	2007	Carcinogenicity evaluation: comparison of tumor	Toxicol Pathol. 35(4):562–9.	JMPR	2016, Part II	
022		L		data from dual control groups in the CD-1 mouse.				
FE	II 7	Balthazor TM,	1986	Glyphosate-degrading microorganisms from	Appl Environ Microbiol. 51(2):432–4.	JMPR	2016, Part II	
023		Hallas LE		industrial activated sludge.				
FE	II 5	Band, P. R., et al.	2011	Prostate cancer risk and exposure to pesticides	Prostate, 71(2), 168-183.	JMPR	2016, Part II	
024				in British Columbia farmers.	doi: 10.1002/pros.21232	USEPA	2014, D417808	
							2017, D444689	
FE	II 5	Bando, H., et al.	2010	[Extreme hyperkalemia in a patient with a new	Chudoku Kenkyu, 23(3), 246-249.	USEPA	2014, D417808	
025				glyphosate potassium herbicide poisoning: report of a case].				
FE 026	II 5	Baris, D, et al.	2001	Cohort mortality study of Philadelphia firefighters	American Journal of Industrial Medicine. 39: 463-476. doi: 10.1002/ajim.1040.	USEPA	2017, D444689	
FE	II 8	Barky, F. A. et al.	2012	Influence of Atrazine and Roundup Pesticides on	Pesticide Biochem Physio. 104(1): 9-18	USEPA	2015, 417701	
027				Biochemical and Molecular Aspects of				
				Biomphalaria alexandrina Snails.				
FE	II 7	Battaglin,W.A., et	2005	GLYPHOSATE, OTHER HERBICIDES, AND	Journal of the American Water Resources Association (JAWRA),	USEPA	2015, 417701	1

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	評価 機関	評価書情報 (発行年等)	備考
028		al.		TRANSFORMATION PRODUCTS IN MIDWESTERN STREAMS, 2002	April, pp. 323-332 <a cgi="" digitalcommons.unl.edu="" href="https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=" https:="" td="" vi<="" viewcontent.cgi="" viewcontent.cgi?article="https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article="><td></td><td></td><td></td>			
FE 029	II 5	Beane Freeman LE, et al.	2005	Cancer incidence among male pesticide applicators in the Agricultural Health Study cohort exposed to diazinon.	Am J Epidemiol. 162:1070–9.	JMPR	2016, Part II	
FE 030	II 5	Benachour N, et al.	2007	Time- and dose-dependent effects of Roundup on human embryonic and placental cells.	Arch Environ Contam Toxicol. 53(1):126–33. doi:10.1007/s00244-006-0154-8.	JMPR	2016, Part II	
FE 031	116/117	Benbrook.	2016	Trends in glyphosate herbicide use in the United States and globally.	Environmental Sciences Europe. 28(3).	USEPA	2017, D444689	
FE 032	II 5	Benjamini, Y. et al.	1995	Controlling the false discovery rate: a practical and powerful approach to multiple testing.	Journal of the Royal Statistical Society B. 57: 289-300.	USEPA	2017, D444689	
FE 033	II 8	Bernal, M. H. et al.	2009	Toxicity of Formulated Glyphosate (Glyphos) and Cosmo-Flux to Larval and Juvenile Colombian Frogs 2. Field and Laboratory Microcosm Acute Toxicity.	J. Toxicol. Environ. Health, Part A. 72(15): 966- 973	USEPA	2015, 417701	
FE 034	II 5	BfR (Bundesinstitut für Risikobewertung)	2015	Does glyphosate cause cancer?	BfR Communication No 007/2015, 23 March 2015. Available at: http://www.bfr.bund.de/cm/349/does-glyphosatecause-cancer.pdf	EFSA	2015, Conclusion	
FE 035	II 5	Blair A, et al.	2011	Impact of pesticide exposure misclassification on estimates of relative risks in the Agricultural Health Study.	Occup Environ Med. 68(7):537–41. doi:10.1136/oem.2010.059469.	JMPR	2016, Part II	
FE 036	II 5	Blakley BR	1997	Effect of roundup and tordon 202C herbicides on antibody production in mice.	Vet Hum Toxicol. 39(4):204-6.	JMPR	2016, Part II	
FE 037	II 5	Bolognesi C, et al.	1997	Genotoxic activity of glyphosate and its technical formulation roundup.	J Agric Food Chem. 45(5):1957–62.	JMPR USEPA	2016, Part II 2017, D444689	
FE 038	II 5	Bolognesi C, et al.	2009	Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: association to occupational exposure to glyphosate.	J Toxicol Environ Health A. 72(15–16):986–97.	JMPR	2016, Part II	
FE 039	II 5	Bonassi S, et al.	2001	Human MicroNucleus project: international database comparison for results with the cytokinesis-block micronucleus assay in human lymphocytes: I. Effect of laboratory protocol, scoring criteria, and host factors on the frequency of micronuclei.	Environ Mol Mutagen. 37(1):31-45.	JMPR	2016, Part II	
FE	II 5	Borenstein, M., et	2008	Introduction to Meta-Analysis.	John Wiley and Sons: London.	USEPA	2020, D455531	

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	評価機関	評価書情報 (発行年等)	備考
040		al.						
FE	II 5	Borenstein, M., et	2010	A basic introduction to fixed effect and random	Res. Syn. Meth. 1(2):97-111.	USEPA	2020, D455531	
041		al.		effects models for meta-analysis.	doi: 10.1002/jrsm.12. Epub 2010 Nov 21.			
FE 042	II 5	Borenstein, Michael.	2019	Common Mistakes in Meta-analysis and How to Avoid Them.	Biostat, Inc: Englewood, NJ.	USEPA	2020, D455531	
FE 043	11 8	Boutin, C., et al.	2004	Toxicity testing of fifteen non-crop plant species with six herbicides in a greenhouse experiment: implications for risk assessment.	Ecotoxicology. 13: 349-369	USEPA	2015, 417701	
FE 044	II 8	Boutin, C., et al.	2010	Measuring variability in phytotoxicity testing using crop and wild plant species.	Environ. Toxicol. Chem. 29(2): 327-337.	USEPA	2015, 417701	
FE 045	11 8	Boutin, C., et al.	2012	Phytotoxicity testing for herbicide regulation: Shortcomings in relation to biodiversity and ecosystem services in agrarian systems.	Sci. Total Environ. 415:79-92	USEPA	2015, 417701	
FE 046	II 5	Bradberry SM, et al.	2004	Glyphosate poisoning	Toxicol Rev. 23(3):159-67	JMPR USEPA	2016, Part II 2014, D417808	
FE 047	11 8	Brausch J M, et al.	2006	Pesticide usage on the southern high plains and acute toxicity of four chemicals to the fairy shrimp Thamnocephalus platyurus Crustacea: Anostraca).	Texas J Sci. 58(4):309-324.	USEPA	2015, 417701	
FE 048	II 8	Brausch JM, Beall B, Smith PN	2007	Acute and Sub-Lethal Toxicity of Three POEA Surfactant Formulations to Daphnia magna.	Bull Environ Contam Toxicol, 78, 510-514.	USEPA	2015, 417701	
FE 049	118	Brausch JM, Smith PN	2007	Toxicity of Three Polyethoxylated Tallowamine Surfactant Formulations to Laboratory and Field Collected Fairy Shrimp, Thamnocephalus platyurus.	Archives of Environmental Contamination and Toxicology, 52(2), 217-221.	USEPA	2015, 417701	
FE 050	II 5	Brayton et al.	2012	Pathology of aging mice and GEM background strains and experimental design.	Vet Path. 49 (1): 85-105.	USEPA	2017, D444689	
FE 051	II 5	Brewster DW, et al.	1991	Metabolism of glyphosate in Sprague-Dawley rats: Tissue distribution, identification, and quantitation of glyphosate-derived materials following a single oral dose.	Fundam Appl Toxicol. 17(1):43-51.	JMPR	2016, Part II	
FE 052	II 8	Bringolf RB, et al.	2007	Acute and Chronic Toxicity of Glyphosate Compounds to Glochidia and Juveniles of Lampsilis siliquoidea (Unionidae).	Environ Toxicol Chem. 26(10):2094-100	USEPA	2015, 417701	
FE 053	II 5	Brown LM, et al.	1990	Pesticide exposures and other agricultural risk factors for leukemia among men in Iowa and Minnesota.	Cancer Res, 50(20), 6585-6591.	JMPR USEPA	2016, Part II 2014, D417808 2017, D444689	

ID	データ要求 (項目番号)	著者	出版年	論文表題	掲載詩名、号、ページ等	評価 機関	評価書情報 (発行年等)	備考
FE 054	II 5	Brown, L. M., et al.	1993	Pesticide exposures and multiple myeloma in lowa men.	Cancer Causes Control, 4(2), 153-156.	USEPA	2014, D417808 2017, D444689	
FE 055	II 5	Cantor KP, et al.	1992	Pesticides and other agricultural risk factors for non-Hodgkin's lymphoma among men in lowa and Minnesota.	Cancer Res, 52(9), 2447-2455.	JMPR USEPA	2016, Part II 2014, D417808	
FE 056	II 5	Cantor, K.P., et al.	1993	Pesticides and Other Agricultural Risk Factors for Non-Hodgkin's Lymphoma among Men in Iowa and Minnesota.	Cancer Research 53, 2421-2421.	USEPA	2017, D444689	
FE 057	II 5	Carreon, T., et al.	2005	Gliomas and farm pesticide exposure in women: The Upper Midwest Health Study.	Environmental Health Perspectives, 113(5), 546-551. doi: 10.1289/ehp.7456	USEPA	2014, D417808 2017, D444689	
FE 058	11 6 / 17 / 11 8	Casabe, N. et al.	2007	Ecotoxicological Assessment of the Effects of Glyphosate and Chlorpyrifos in an Argentine Soya Field.	Argentine Soya Field. 7 (4): 232-239	USEPA	2015, 417701	
FE 059	6 / 7 / 8	Cerdeira A, Duke S	2006	The current status and environmental impacts of glyphosate-resistant crops: a review.	J Environ Qual. 35(5):1633–58.	JMPR	2016, Part II	
FE 060	11 5	Chan PO, Mahler JF	1992	NTP technical report on toxicity studies of glyphosate (CAS No. 1071-83-6) administered in dosed feed to F344/N rats and B6C3F1 mice.	National Toxicology Program, Research Triangle Park, NC, USA. NTP Toxicity Report Series No. 16, NIH Publication 92-3135, dated July 1992. Submitted to WHO by Monsanto Int. Services SA, Brussels, Belgium.	JMPR	2016, Part II	
FE 061	II 5	Chandra M, et al.	1992	Spontaneous neoplasms in aged Sprague- Dawley rats.	Arch Toxicol. 66:496–502.	JMPR	2016, Part II	
FE 062	II 5	Chandra M, Frith CH	1994	Spontaneous renal lesions in CD-1 and B6C3F1 mice.	Exp Toxicol Pathol. 46:189–98	JMPR	2016, Part II	
FE 063	II 5	Chang, C. B., & Chang, C. C.	2009	Refractory cardiopulmonary failure after glyphosate surfactant intoxication: a case report.	J Occup Med Toxicol, 4, 2. doi: 10.1186/1745- 6673-4-2	USEPA	2014, D417808	
FE 064	II 5	Chang, C. Y., et al.	1999	Clinical impact of upper gastrointestinal tract injuries in glyphosate-surfactant oral intoxication.	Hum Exp Toxicol, 18(8), 475-478.	USEPA	2014, D417808	
FE 065	II 5	Chang, E.T., et al.	2016	Systematic review and meta-analysis of glyphosate exposure and risk of lymphohematopoietic cancers.	Journal of environmental science and health Part B, Pesticides, food contaminants, and agricultural wastes 51, 402-434.	USEPA	2017, D444689	
FE 066	11 8	Chen L, et al.	2012	The combined effects of UV-B radiation and herbicides on photosynthesis, antioxidant enzymes and DNA damage in two bloom-forming cyanobacteria.	Ecotoxicol Environ Saf. 80:224–30.	JMPR	2016, Part II	
FE 067	II 5	Chen, H. H., et al.	2013	Spectrum of corrosive esophageal injury after intentional paraquat or glyphosatesurfactant	Int J Gen Med, 6, 677-683. doi: 10.2147/ijgm.s48273	USEPA	2014, D417808	

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FE 069	II 5	Chester G, et al.	1986	Biological monitoring of a herbicide applied through backpack and vehicle sprayers.	Toxicol Lett. 33:137–49.	JMPR	2016, Part II	
FE 070	II 5	Chhabra et al	1990	An over view of prechronic and chronic toxicity/carcinogenicity experimental study designs and criteria used by the National Toxicology Program.	Environ Health Perspect. 86: 313-321.	USEPA	2017, D444689	
FE 071	II 5	Chirn-Bin Chang, Chia-Chu Chang	2009	Refractory cardiopulmonary failure after glyphosate surfactant intoxication: a case report.	J Occup Med Toxicol. 2009 Jan 30;4:2.	USEPA	2014, D417808	
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FE 073	11 5	Chruscielska K, et al.	2000b	Glyphosate: Evaluation of chronic activity and possible far-reaching effects. Part 2. Studies on mutagenic activity.	Pestycydy (Warsaw). 3–4: 21–25.	JMPR USEPA	2016, Part II 2017, D444689	
FE 074	II 5	Cimino, M.C.	2006	Comparative overview of current international strategies and guidelines for genetic toxicology testing for regulatory purposes.	Environmental and Molecular Mutagenesis 47 (9): 362-390.	USEPA	2017, D444689	
FE 075	II 6	Clair E, et al.	2012	Effects of Roundup and glyphosate on three food microorganisms: Geotrichum candidum, Lactococcus lactis subsp. cremoris and Lactobacillus delbrueckii subsp. bulgaricus.	Curr Microbiol. 64:486–91.	JMPR	2016, Part II	
FE 076	6 / 7 / 8	Claire Paisley- Jones	2020	Glyphosate Case (103601,103604, 103605, 103607, 103608, 103613, 417300) National and State Summary Use and Usage Matrix	EPA-HQ-OPP-2020-0585-0003. MEMORANDUM	USEPA	2020 ID	
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FE 078	II 5	Clewell HJ, et al.	2005	Quantitative estimates of risk for noncancer endpoints.	Risk Anal. 25:285–9.	JMPR	2016, Part II	
FE 079	115/116	Coble J, et al.	2005	The validation of a pesticide exposure algorithm using biological monitoring results.	J Occup Environ Hyg. 2:194–201.	JMPR	2016, Part II	
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FE 084	II 8	Contardo-Jara, V. et al.	2009	Bioaccumulation of Glyphosate and Its Formulation Roundup Ultra in Lumbriculus variegatus and Its Effects on Biotransformation and Antioxidant Enzymes.	Environ. Poll. 157(1): 57-63	USEPA	2015, 417701	
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FE 096	II 5	Dennis, L. K., et al.	2010	Pesticide use and cutaneous melanoma in pesticide applicators in the agricultural heath study.	Environ Health Perspect, 118(6), 812-817. doi: 10.1289/ehp.0901518	USEPA	2014, D417808 2017, D444689	
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FE 104	5 6 	EFSA	2015a	Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance glyphosate.	Available at www.efsa.europa.eu	EFSA	2015, Conclusion	
FE 105	5 6 	EFSA	2015b	Statement of EFSA on the request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine.	Available at www.efsa.europa.eu	EFSA	2015, Conclusion	
FE	115/116/11	EFSA (European	2015	Conclusion on the peer review of the pesticide	EFSA Journal 2015;13(11):4302, 107 pp.	EFSA	2017, PR	

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FE 108	11 7	EFSA PPR Panel	2013	Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of lower tiers.	EFSA Journal 2013;11(2):3114. 29 pp. doi:10.2903/j.efsa.2013.3114	EFSA	2015, Conclusion	
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FE 115	II 5	Evans N, et al.	2012	Validation of T47D-KBluc cell assay for detection of estrogen receptor agonists and antagonists.	Society of Toxicology (SOT) Annual Meeting, San Francisco, CA, USA. 11–15 March 2012	JMPR	2016, Part II	
FE 116	II 5	Fisher, K. R., et al.	2008	Pesticide-associated pemphigus vulgaris.	Cutis, 82(1), 51-54.	USEPA	2014, D417808	
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FE 118	II 7	FOCUS	2001	FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC.	Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2.	EFSA	2015, Conclusion	

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FE 120	II 5	Fontana et al	1990	Incidence rates of lymphomas and environmental measurements of phenoxy herbicides: ecological analysis and case-control study.	Archives of Environmental Health: An International Journal. 53: 384-387.	USEPA	2017, D444689	
FE 121	II 5	Forgacs AL, et al.	2012	BLTK1 murine Leydig cells: a novel steroidogenic model for evaluating the effects of reproductive and developmental toxicants.	Toxicol Sci. 127(2):391–402. doi:10.1093/toxsci/kfs121.	JMPR USEPA	2016, Part II 2017, D444689	
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FE 124	II 5	Garcia, A., et al.	1998	Paternal exposure to pesticides and congenital malformations.	Scandinavian Journal of Work Environment & Health, 24(6), 473-480.	USEPA	2014, D417808	
FE 125	II 5	Garry, V. F., et al.	2002	Birth defects, season of conception, and sex of children born to pesticide Page 47 of 127 applicators living in the Red River Valley of Minnesota, USA.	Environ Health Perspect, 110 Suppl 3, 441-449.	USEPA	2014, D417808	
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FE 127	II 5	George J, et al.	2010	Studies on glyphosate-induced carcinogenicity in mouse skin: A proteomic approach.	J Proteomics 73(5): 951-964.	JMPR USEPA	2016, Part II 2017, D444689	
FE 128		Germany	1998	Draft assessment report (DAR) on the active substance glyphosate prepared by the rapporteur Member State Germany in the framework of Directive No 91/414/EEC		EFSA	2015, Conclusion	
FE 129		Germany	2013	Renewal assessment report (RAR) on the active substance glyphosate prepared by the rapporteur Member State Germany in the framework of Regulation (EU) No 1141/2010	Available at www.efsa.europa.eu	EFSA	2015, Conclusion	
FE 130		Germany	2015	Final addendum to the renewal assessment report (RAR) on the active substance glyphosate prepared by the rapporteur Member State	Available online: www.efsa.europa.eu	EFSA	2017, PR	

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FE 132	11 5	Germany	2017a	Addendum 2 to the renewal assessment report (RAR): Assessment of potential endocrine disrupting properties of glyphosate. 30 March 2017.	Available online: www.efsa.europa.eu	EFSA	2017, PR	
FE 133	11 5	Germany	2017b	Addendum 2 to the renewal assessment report (RAR): Assessment of potential endocrine disrupting properties of glyphosate. Revised on 22 May 2017 (rev 1) and 4 July 2017 (rev 2).	Available online: www.efsa.europa.eu	EFSA	2017, PR	
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FE 135	II 5	Giknis, M. L. A., et al.	2005	Spontaneous Neoplastic Lesions in the Crl:CD1 (ICR) Mouse in Control Groups from 18 Month to 2 Year Studies.	Charles River. http://www.criver.com/files/pdfs/rms/cd1/rm_rm_r_lesions_crlcd_1_icr_mouse.aspx	USEPA	2017, D444689	
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FE 138	II 5	Greim, H., et al.	2015	Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies.	Crit Rev Toxicol 45(3): 185-208.	USEPA	2017, D444689	
FE 139	115/118	Grisolia CK	2002	A comparison between mouse and fish micronucleus test using cyclophosphamide, mitomycin C and various pesticides.	Mutat Res. 518(2):145–50.	JMPR	2016, Part II	
FE 140	II 8	Guilherme S, et al.	2012	DNA damage in fish (<i>Anguilla anguilla</i>) exposed to a glyphosate-based herbicide – elucidation of organ-specificity and the role of oxidative stress.	Mutat Res. 743(1-2):1-9	JMPR	2016, Part II	
FE 141	II 5	Guyatt GH, et al.	2008	GRADE: an emerging consensus on rating quality of evidence and strength of recommendations.	BMJ. 336:924–6.	JMPR	2016, Part II	
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FE 146	II 5	Haseman, JK.	1995	Data analysis: Statistical analysis and use of historical control data.	Regul Toxicol Pharmacol 21:52–59.	USEPA	2017, D444689	
FE	II 5	Hecker M,	2011	The OECD validation program of the H295R	Environ Sci Pollut Res. 18:503–15.	JMPR	2016, Part II	
147				steroidogenesis assay: phase 3. Final interlaboratory validation study.				
FE	II 5	Heras-Mendaza,	2008	Erythema multiforme-like eruption due to an	Contact Dermatitis, 59(1), 54-56.	USEPA	2014, D417808	
148		F., et al.		irritant contact dermatitis from a glyphosate	doi: 10.1111/j.1600-0536.2007.01307.x			
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FE	II 5	Higgins JP, Green	2011	Cochrane handbook for systematic reviews of	(www.cochrane-handbook.org.	JMPR	2016, Part II	
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FE	115/116/11	Hill AB	1965	The Environment and Disease: Association or	Proc R Soc Med. May 1965; 58(5): 295–300.	USEPA	2017, D444689	
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FE	II 5	Hines CJ, et al.	2008	Captan exposure and evaluation of a pesticide	Ann Occup Hyg. 52:153–66.	JMPR	2016, Part II	
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153				and soft-tissue sarcoma.	doi:10.1001/jama.1986.03380090081023.	USEPA	2017, D444689	
FE	II 5	Hohenadel, K., et	2011	Exposure to multiple pesticides and risk of non-	Int J Environ Res Public Health, 8(6), 2320-2330.	USEPA	2014, D417808	
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FE	II 5	Hoppin, J. A., et	2002	Chemical predictors of wheeze among farmer	American Journal of Respiratory and Critical Care Medicine,	USEPA	2014, D417808	
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FE 160	II 5	Hori, Y., et al.	2003	Determination of the herbicide glyphosate and its metabolite in biological specimens by gas chromatography-mass spectrometry. A case of poisoning by roundup herbicide.	J Anal Toxicol, 27(3), 162-166.	USEPA	2014, D417808	
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(EFSA)

(1) Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, EFSA, EFSA Journal 2015;13(11):4302 (「EFSA (2015, Conclusion)」と表記した)

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(「USEPA (2017, D444689)」と表記した)

(2) MEMORANDUM Date: February 6, 2014

SUBJECT: Glyphosate: Tier II Incident Repor

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(3) MEMORANDUM Date: January 6, 2020

SUBJECT: Glyphosate: Epidemiology Review of Zhang et al. (2019) and Leon et al. (2019) publications for Response to Comments on the Proposed

Interim Decision

DP Barcode: D455531

(「USEPA (2020, D455531)」と表記した)

(4) MEMORANDUM Date: September 8, 2015

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SUBJECT: Registration Review – Preliminary Ecological Risk Assessment for Glyphosate and Its Salts DP Barcode: 417701
(「USEPA(2020, 417701)」と表記した))
(5) Glyphosate Interim Registration Review Decision Case Number 0178, DATE: January 22, 2020
(「USEPA(2020, ID)」と表記した))

(JMPR)
Pesticide residues in food - 2016, Part II - Toxicological evaluations
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以上