APPLICATION FOR APPROVAL RENEWAL

Glyphosate & the IPA-,K- and NH_4-salts of Glyphosate

RMS: Germany
Co-RMS: Slovakia

APPLICATION

Notifier(s): Monsanto Europe SA
on behalf of the 'Glyphosate Task Force'
Date: March 24, 2011
(Updated May 9th 2011)

Author: [redacted]

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1 Information concerning the applicant

1.1 Name and address of the applicant including the name of the natural person responsible for the application and further engagements resulting from this Regulation:

Monsanto Europe N.V./S.A.

Haven 627

Scheldelaan 460

B-2040 Antwerp

Belgium

Applying on behalf of the members of the European Glyphosate Task Force[1]. The membership of this task force is further detailed in Addendum-1 to this application and is updated upon change of membership on: www.glyphosatetaskforce.org.

1.2.1

(a) Telephone No: [redacted]

(b) Fax No: [redacted]

(c) E-mail address: [redacted]

1.2.2

(a) Contact:

[redacted]

(same contact details as under 1.2.1)

(b) Alternative:

[redacted]

Telephone No: [redacted]

Fax No: [redacted]

E-mail address: [redacted]

[1] The European Glyphosate Task Force is a consortium of companies joining resources and effort s in order to renew the European glyphosate registration; this consortium is not a legal entity.

2 Information to facilitate identification

2.1 Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer:

Active ingredient: Glyphosate

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

2.2 Chemical name (IUPAC and CAS nomenclature):

Glyphosate:

IUPAC: N-(phosphonomethyl)-glycine

CAS: N-(phosphonomethyl)-glycine

Glyphosate- isopropyl-amine-salt :

IUPAC: N-(phosphonomethyl)glycine - isopropylamine (1:1)

CAS: N-(phosphonomethyl)glycine compound with 2-propanamine (1:1)

Glyphosate-potassium-salt:

IUPAC: potassium *N*-[(hydroxyphosphinato)methyl]glycine

CAS: N-(phosphonomethyl) glycine potassium salt (1:1)

Glyphosate-ammonium-salt:

IUPAC: ammonium N-[(hydroxyphosphinato)methyl]glycine

CAS N-(phosphonomethyl)glycine mono-ammonium salt

2.3 CAS, CIPAC and EEC numbers (if available):

Glyphosate

CAS N°: 1071-83-6

CIPAC N°: 0284

EEC N°: 213-997-4

Glyphosate isopropyl-amine-salt

CAS N°: 38641-94-0

CIPAC N°: 284.105

EEC N°: 254-056-8

Glyphosate potassium-salt

CAS N°: 70901-20-1

CIPAC N°: 284.019

EEC N°: not attributed

Glyphosate ammonium-salt

CAS N°: 40465-66-5

CIPAC N°:284.007

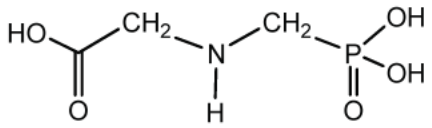
EEC N°: not attributed

2.4 Empirical and structural formula, molecular mass:

Glyphosate

Empirical formula: C3H8NO5P

Structural formula:

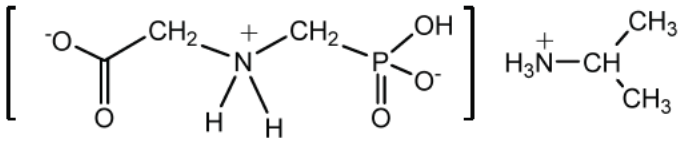


Molecular mass: 169.1 g/mol

Glyphosate isopropyl-amine-salt:

Empirical formula: $C_6H_{17}N_2O_5P$

Structural formula:

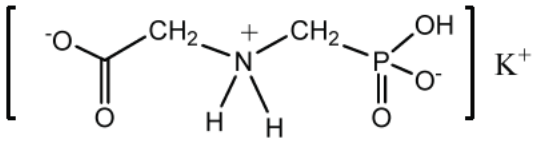


Molecular mass: 228.18 g/mol

Glyphosate potassium-salt

Empirical formula: $C_3H_7KNO_5P$

Structural formula:

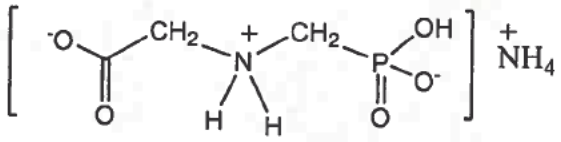


Molecular mass: 207.19 g/mol

Glyphosate ammonium-salt

Empirical formula: $C_3H_{11}N_2O_5P$

Structural formula:



Molecular mass: 186.10 g/mol

2.5 Specification of purity of the active substance in g/kg which should be whenever possible identical or already accepted as equivalent to the one included in Annex I to Directive 91/414/EEC.

Minimum purity: 950 g/kg

2.6 Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[2] (health and environment effects).

Glyphosate:

Classification	Hazard statement codes	Pictogram, Signal word codes
Eye damage 1	H318	GHS05
Aquatic chronic 2	H411	GHS09
		Danger

Salts of Glyphosate (with the exception of those specified elsewhere in Annex IV of Regulation (EC) No 1272/2008) NOTE: glyphosate trimesium is currently the only exception and is not part of this application):

Classification	Hazard statement codes	Pictogram, Signal word codes
Aquatic chronic 2	H411	GHS09

An updating statement, as provided for in Article 5(2), shall be attached as an Annex to the application. The applicant confirms that the above information submitted on March 25, 2011 is correct.

Signature (of the person competent to act for the applicant referred to under 1.1)

[redacted]

MONSANTO EUROPE NV/SA

[2] OJL 353, 31.12.2008, p. 1.

ADDENDUM 1: Glyphosate Task Force Membership (status 24/3/2011)

The membership of this task force is kept updated on: www.glyphosatetaskforce.org.

In alphabetical order:

Agrichem B.V.
Koopvaardijweg 9
4906 CV Oosterhout NB
The Netherlands

Industrias Afrasa S.A.
C/Ciudad de Sevilla Nº53. Pol.Ind.Fuente del Jarro
46988 Paterna (Valencia)
Spain

Agria S.A.
Asenovgradsko Shose
4009 Plodiv
BULGARIA

Albaugh UK Limited
Manor Farm, Eddlethorpe, Malton,
North Yorkshire, YO17 9QT,
United Kingdom

Arysta Lifesciences SAS
Route d' Artix, BP 80,
64150 Nogueres,
France

Barclay Chemicals (R&D) Ltd,
Damastown Way,
Damastown Industrial Park,
Mulhuddart,
Dublin 15,
Ireland

Cheminova A/S
Thyborønvej 78
7673 Harboøre
Denmark

Dow AgroSciences Italia s.r.l.
Viale A. Masini, 36
40126 Bologna
Italia

Excel Industries(Europe) NV
Uitbreidingstraat 84/3 ,2600 Antwerp,
Belgium

Feinchemie Schwebda GmbH
Edmund Rumpler Straße 6
51149 Köln
Germany

Helm AG
Nordkanalstrasse 28
D-20097 Hamburg
Germany

Jingma UK Limited
Aston House, Redburn Road,
Newcastle upon Tyne,NE5 1NB,
United Kingdom

Monsanto Europe S.A./N.V.
Haven 627, Scheldelaan 460
B-2040 Antwerp
Belgium

Nufarm GmbH & Co KG
St.-Peter Str. 25
A-4021 Linz
Austria

Pinus TKI d.d.
Grajski trg 21
SI-2327 Rače,
Slovenia

Rotam Agrochemical Europe Limited
Camrascan House ISIS Way Minerva Busines Park
Lynch Wood; Peterborough
Cambridgeshire
United Kingdom; PE2 6QR

Sabero Organics Gujarat Limited
Plot No.2102, GIDC,
Sarigam 396155,
Dist. Bulsar, State Gujarat,
India

Sapec Agro S.A.
Avenida do Rio Tejo - Herdade das Praias
2910-440 SETÚBAL
Portugal

Sinon Corporation
No. 23, Sec. 1, Mei Chuan W. Rd., West Dist.,
Taichung 403,
Taiwan, R.O.C

Société Financière de Pontarlier
Villa Célony
1175 Montée d'Avignon,
13090 AIX EN PROVENCE
France

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH-4002 Basel,
Switzerland

United Phosphorus Ltd
Chadwick House, Birchwood Park
Warrington, WA3 6AE,
United Kingdom

Wynca UK Limited
32 Threadneedle Street,
London, EC2R 8AY
United Kingdom

The following companies have asked to be included in this application although they are not members of the Task Force. They have applied to join the Task Force and their applications are not yet complete:

AGRO TRADE GmbH
Baerweiler Strasse 55
55568 Lauschied
Germany

Brokden S.L.
Paseo Ribalta, 22 .
12004 . Castellón de la Plana
Spain

Bros Spolka Jawna B.P. Miranowscy
ul. Sokola nr 7, lok. 6
60 - 644 Poznan
Poland

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RMS: Germany

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APPENDIX 1: UPDATING STATEMENT

Notifier(s): Monsanto on behalf of the 'Glyphosate Task Force'

Date: March 24, 2011

(updated May 9th 2011)

Appendix 1: Updating statement

1 Background

Glyphosate is included in Annex I of Council Directive 91/414/EEC since **July 1, 2002** as outlined in Council Directive 2001/99/EC.

Glyphosate was evaluated as part of the first stage of the work-program referred to in Article 8(2) of Council Directive 91/414/EEC and related amendments thereof and according to the rules and procedures as outlined in Commission Regulation (EEC) No 3600/92.

In a period between 10 February, 1993 and 25 April, 1995, thirty five (35) entities notified to the Commission their wish to secure the inclusion of the active substance **glyphosate (isopropylamine-, sodium-, ammonium-salts)** in Annex I to the Directive, in accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92. These entities were:

(1) Feinchemie Schwebda GmbH, (2) Herbex Produtos Quimicos Ltd, (3) Law Offices of Samuel Pisar, (4) Stefes Agro GmbH, (5) United Phosphorus Ltd, (6) Alkaloida Europe, (7) Phytorus SA, (8) Marubeni UK plc (since November 1997 Sinon EU Coorperation), (9) Cequisa, (10) Cheminova Agro A/S, (11) Monsanto S.A., (12) I. Pi. Ci. Industrias Prodotti Chimici, (13) Barclay Chemicals, (14) Chimac-Agriphar SA, (15) SANC, (16) OXON Italia SpA,(17) Makhteshim Agan, (18) Hermoo Belgium NV, (19) Industrial Kern Espag, (20) Tessenderlo, Chemie, (21) Iberotam, (22) Industrias Quimicas del Valles, (23) Aragonesas Agro SA, (24) Stefes Research GmbH, (25) Pilar Iberica SL Juan Amich Gail, (26) AgriChem, (27) Elf Atochem, (28) Portman Agrochemicals, (29) Helm AG, (30) Calliope, (31) Industrias Afrasas, (32) Grower, (33) K.C.S. Products (34) B. V. Luxan and (35) Sanachem GmbH (subsequently Dow AgroScience).

In addition Zeneca Agrochemicals (subsequently Syngenta) notified to the Commission their wish to secure the inclusion of the active substance **glyphosate trimesium-salt** in Annex I to the Directive.
In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, three glyphosate task forces were formed and submitted each a joint dossier to the rapporteur Members State **Germany:** (1) The Tulip task force, comprising AgriChem, Aragonesas Agro SA, Industrias Afrasas, Calliope, Sundat and TKI Pinus Race, (2) Monsanto and Cheminova and (3) Barclay Chemicals and Portman Agrochemicals.

Further individual dossiers were submitted by Feinchemie Schwebda GmbH, Marubeni UK plc (Sinon EU Coorperation), Herbex Produtos, Quimicos Ltd, Luxan, I. Pi. Ci. Industrias Prodotti Chimici, Nufarm Limited, Alkaloida and Sanachem (subsequently Dow AgroScience) all for glyphosate and Zeneca Agrochemicals (Syngenta) for glyphosate trimesium salt.

The submission deadline was 30 April 1995, except for Sanachem (extension till 31 October 1995). Nufarm and Alkaloida officially withdrew their notifications prior to conclusion of the evaluation process.

The task force **Monsanto/Cheminova** as well as Feinchemie Schwebda GmbH were considered ***main data submitters*** for ***glyphosate,*** with a dossier which did not contain substantial data gaps, taking into account the supported uses. Additional information has been submitted by third parties including publications provided by the responsible authorities in other Member States (Denmark, Sweden) and data obtained from the German National Poisoning Information Centre. Sinon EU Corporation (Marubeni), Herbex Produtos, Quimicos Ltd, AgriChem, Aragonesas Agro SA, Industrias Afrasas, Sundat, Calliope, TKI Pinus Race, B. V., Luxan, I. Pi. Ci. Industrias Prodotti Chimici, Nufarm, Barclay Chemicals, Portman Agrochemicals, Alkaloida Europe and Dow AgroScience (Sanachem) did not submit complete dossiers.

Zeneca Agrochemicals (Syngenta) was ***main data submitter*** for ***glyphosate trimesium***, with a dossier which did not contain substantial data gaps, taking into account the supported uses. Additional (published) information was submitted by the Finnish authorities and data on poisoning incidents were provided by the German National Poisoning Information Centre.

On 1 February 1999, Germany submitted its draft assessment report to the Commission, including, as required, a recommendation concerning the possible inclusion of glyphosate in Annex I to the Directive. In addition on 2 March 1999, the Commission and the Member States received also the summary dossier on glyphosate from Feinchemie Schwebda and Monsanto/Cheminova and glyphosate trimesium from Zeneca Agrochemicals (Syngenta).

Subsequently the Commission forwarded for consultation the draft assessment report to all the Member States as well as to Monsanto being the designated representative of the glyphosate task force and to Feinchemie Schwebda and Zeneca Agrochemicals (Syngenta) as the main data submitters.

The Commission organized an intensive consultation of technical experts from a number of Member States, to review the monograph and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties;
- fate and behaviour in the environment;
- ecotoxicology;
- mammalian toxicology;
- residues and analytical methods;
- regulatory questions.

The reports of the peer review on glyphosate and glyphosate trimesium were circulated, for further consultation, to Member States and the main data submitters for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossiers, the draft assessment report, the peer review reports and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from December 1999 to June 2001, and was finalised in the meeting of the Standing Committee on 29 June 2001.

The draft assessment report, the peer review reports and the comments and clarifications submitted after the peer review were also submitted to the Scientific Committee for Plants. No specific questions were addressed to the Committee. Following an exchange of views the Committee noted that there were no issues that it wished to raise regarding the active substances in the context of a possible inclusion in Annex I to the Directive. The Committee reiterated its earlier statements that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

Overall Conclusion:

The overall conclusion (SANCO 6511/VI/99-final) from the evaluation was that it may be expected that plant protection products containing glyphosate will fulfill the safety requirements laid down in Article 5(1) (a) and (b) of Directive 91/414/EEC. This conclusion was however subject to compliance with the following particular conditions:

- The active substance shall comply with the FAO specification
- Member states must pay particular attention to the protection of groundwater in vulnerable areas in particular with respect to non-crop uses.

These conclusions were reached within the framework of the following uses, which were proposed and supported by the main data submitter:

- herbicide against terrestrial annual weeds, perennial weeds and shrubs in fruit, vegetables, forestry, grassland, ornamentals and arable crops as well as non-crop uses.

There was no need for further studies identified related to the inclusion of glyphosate in Annex I of Directive 91/414/EEC.
Regarding the purity and impurity profile of technical glyphosate acid, the EU-review concluded that for the active substances notified by the main data submitters (Feinchemie Schwebda, Monsanto and Syngenta (Zeneca Agrochemicals)), none of the manufacturing impurities considered were of toxicological or environmental concern.

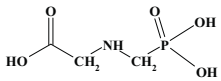
The technical glyphosate from Zeneca Agrochemical (Syngenta) was evaluated by the FAO and the WHO. Equivalence was confirmed by the FAO Group on Specifications at their meeting in June 2001.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Germany also concluded that the technical substances notified by Sinon EU Corporation, Herbex Produtos Quimicos Ltd, AgriChem, Aragonesas Agro SA, Industrias Afrasas, Sundat, TKI Pinus Race, B. V. Luxan, I. Pi. Ci. Industrias Prodotti Chimici, Barclay

Chemicals, Portman Agrochemicals, Alkaloida Europe and Dow AgroScience did not differ significantly in degree of purity and nature of impurities from the composition registered by the main data submitters.

The list of endpoints as stipulated in SANCO 6511/VI/99-final is captured in Table 1-1, with an indication where new endpoint could be proposed based on existing but previously not evaluated studies or based on ongoing studies.

Table 1-1 List of Endpoints for glyphosate acid according to SANCO 6511/VI/99-final

IDENTITY- PHYSICAL AND CHEMICAL PROPERTIES			
PROPERTY	**ENDPOINT**		**COMMENT**
Common name (ISO)	**Glyphosate**		
Chemical name (IUPAC)	*N* (phosphonomethyl) glycin		
Chemical name (CA)	glycin, *N* (phosphonomethyl)		
CIPAC No	0284		
CAS No	1071 83 6		
EEC No	213 997 4		
FAO SPECIFICATION	FAO 284 (2000)		
Minimum Purity	950 g/kg		
Molecular formula	$C_3H_8NO_5P$		
Molecular mass	169		
Structural formula			
Melting point	189.5 °C (999 g/kg)		
Boiling point	Decomposition		
Appearance	colourless crystalls		
Relative density	1.705 (995 g/kg)		
Vapour pressure	$1.31 \cdot 10^{5}$ Pa (25 °C, acid)		
Henry's law constant	$2.1 \cdot 10^{7}$ Pa · m^3 ·mol^{1}		
Solubility in water	pH 2: 10.5 ± 0.2 g/l (20 °C, 995 g/kg)		
Solubility in organic solvents	acetone:	0.078 g/l	
	dichloro methane:	0.233 g/l	
	ethyl acetate:	0.012 g/l	
	hexane:	0.026 g/l	
	methanol:	0.231 g/l	
	n octanol:	0.020 g/l	
	propan 2 ol:	0.020 g/l	
	toluene:	0.036 g/l	
Partition co-efficient (log P_{ow})	pH 5 9: 3.2 at 25 °C (999 g/kg)		
Hydrolytic stability (DT_{50})	pH 5: stable (25 °C)		
	pH 7 : stable (25 °C)		
	pH 9: stable (25 °C)		
Dissociation constant	pKa: 2.34 (20 °C), 5.73 (20 °C), 10.2 (25 °C)		
Quantum yield of direct photo-transformation in water at ε >290 nm	Not determined.		

Flammability	Not highly flammable.	
Explosive properties	Not explosive.	
UV/VIS absorption (max.)	ε: 0.086 (295 nm)	
Photostability in water (DT_{50})	33 d (pH 5), 69 d (pH 7), 77 d (pH 9) (Xenon lamp).	

1. TOXICOLOGY AND METABOLISM		
Absorption, distribution, excretion and metabolism in mammals		
PROPERTY	**ENDPOINT**	**COMMENT**
Rate and extent of absorption:	Rapidly but only to a limited extent (approx. 30%).	
Distribution:	Generally low residues occurring in all tissues.	
Potential for accumulation:	No evidence of accumulation (< 1% after 7 days).	
Rate and extent of excretion:	Rapid and nearly complete (approx. 30% via urine).	
Toxicologically significant compounds:	Parent compound; main plant metabolite, aminomethyl phosphonic acid(AMPA), also detected in rats (< 0.5%).	
Metabolism in animals:	Very limited (< 0.5%) if occurring at all.	
Acute toxicity		
Rat LD_{50} oral:	> 2000 mg/kg bw	A new endpoint may be proposed based on new data and the new GHS classification scheme **(potential refinement of existing endpoint)**
Rat LD_{50} dermal:	> 2000 mg/kg bw	
Rat LC_{50} inhalation:	> 5 mg/l air (4 hour exposure)	
Skin irritation:	Not irritating	
Eye irritation:	Acid: moderately to severely irritating.	
	Salts: slightly or not irritating, no classification	
Skin sensitization (test method used and result):	Not sensitizing (M&K test, Buehler test).	
Short term toxicity		
Target / critical effect:	Liver, gastrointestinal mucosa, salivary glands	
Lowest relevant oral NOAEL / NOEL:	90 days, rat: 2000 ppm (equal to 150 mg/kg bw/d)	A new endpoint may be proposed based on new and existing data **(potential refinement of existing endpoint)**
Lowest relevant dermal NOAEL / NOEL:	21 days, rat: >1000 mg/kg bw/d	
Lowest relevant inhalation NOAEL / NOEL:	2 weeks, rat: >3.8 mg/l	
Genotoxicity		
	Not genotoxic.	

Long term toxicity and carcinogenicity		
Target / critical effect:	Liver (organ weight↑, clinicial chemistry, histology); salivary glands (organ weight↑, histology); stomach mucosa and bladder epithelium (histology); eye (cataracts)	These critical effects will be re assessed in terms of current knowledge in the field of toxicology
Lowest relevant NOAEL:	2 years, rat: 31 mg/kg bw/d	A new NOAEL may be proposed based on new data **(potential refinement of existing endpoint)**
Carcinogenicity:	No evidence of carcinogenicity.	

Reproductive toxicity		
Target / critical effect Reproduction:	Reduced pup weight at parentally toxic doses.	

Lowest relevant reproductive NOAEL / NOEL:	10000 ppm (equal to 700 mg/kg bw/d)	
Target / critical effect Developmental toxicity:	Lower number of viable fetuses and reduced fetal weight; retarded ossification, higher incidence of skeletal and/or visceral anomalies; effects confined to maternally toxic doses.	
Lowest relevant developmental NOAEL / NOEL:	Rat: 300 mg/kg bw/d	
Delayed neurotoxicity	No relevant effects.	
Other toxicological studies		
	Toxicological studies on AMPA revealing the metabolite to be less toxic than the parent compound, no evidence of mutagenicity and teratogenicity; toxicity studies in farm animals: no risk to be expected; mechanistic study on salivary gland findings	
Medical data		
	Comprehensive database, mainly related to accidental or intentional oral intake of glyphosate products.	

	Value	Study	Safety factor	
ADI:	0.3 mg/kg bw	Long term studies in rats	100	A new ADI may be proposed **(potential refinement of existing endpoint)**
AOEL systemic:	0.2 mg/kg bw/day (systemic)	Rabbit teratogenicity study, NOEL for maternal toxicity (30% oral absorption)	100	A new AOEL may be proposed **(potential refinement of existing endpoint)**
ARfD (acute reference dose):	Not allocated (not necessary).			
Dermal absorption	Less than 3%			Data supporting a lower rate of dermal absorption than that used in the initial Annex I Listing will be included in the Annex I Renewal Dossier for the representative formulated product **(refinement of existing endpoint).**

2. FATE AND BEHAVIOUR IN THE ENVIRONMENT

2.1. Fate and Behaviour in soil

PROPERTY	ENDPOINT	COMMENT
Route of degradation		
Aerobic:		
Mineralization after different periods of time (%):	3 soils, 3 different ^{14}C labels: 46.8 55.3 (28 d); 5.8 9.3 (112 d); 34.7 41.4 (84 d) 2 soils: 69.7 80.1 (150 d) 1 soil: 32.7 (112 d) 1 soil: 79.6 (100 d)	New aerobic metabolism and degradation studies for glyphosate will be submitted; these may confirm or refine existing mineralization endpoints **(potential refinement of existing endpoints)**
Non extractable residues after different periods of time (%):	3 soils, 3 different ^{14}C labels: 8.5 40.3 (28 d); 4.6 13.5 (112 d); 16.7 33.9 (84 d) 2 soils: 5.1 8.8 (150 d) 1 soil: 13.9 (112 d) 1 soil: 8.4 (100 d)	
Major metabolites above 10 % of	Aminomethylphosphonic acid (AMPA) 26 29%	

applied, name and/or code, % of applied (range and maximum)	after 14 days	

Supplemental studies		
Anaerobic degradation	Mineralization after different periods of time (%): 3 soils, 3 different ^{14}C labels: 33.5 51.4 (28 d); 1.4 5.0 (112 d); 24.2 38.6 (84 d) 1 soil, < 1 (120 d) Non extractable residues after different periods of time (%): 3 soils, 3 different ^{14}C labels: 12.8 29.7 (28d); 0.4 12.0 (112 d); 15.1 31.6 (84d) 1 soil, 20 (120 d)	An existing (but not previously evaluated) anaerobic metabolism and degradation study for glyphosate will be submitted; this study may confirm or refine the existing mineralization endpoints **(potential refinement of existing endpoints)**
Soil photolysis:	DT_{50}: 96 (90 d dark); 101 d (1236 d dark)	

Rate of degradation		
Laboratory studies		
DT_{50}lab (20 °C, aerobic):	DT_{50lab} (20°C, aerobic): 4 180 d (20°C), mean 49 d, (first order kinetic)	New half lifes in soil based on new and existing studies and based on the most recent guidance regarding degradation kinetics may be proposed **(refinement of existing endpoints)**
DT_{90}lab (20 °C, aerobic):	DT_{90lab} (20°C, aerobic): 40 280 d (20°C), mean 159 d,n 4 (first order kinetic)	
DT_{50}lab (10 °C, aerobic):	DT_{50lab} (10°C, aerobic): not submitted (see field studies)	
DT_{50}lab (20°C, anaerobic):	DT_{50lab} (20°C, anaerobic): comparable to aerobic (study one); (waterphase) 3 d, (system) 1699 d (study two)	
Field studies (country or region)		
DT_{50f} from soil dissipation studies:	DT_{50f} (best fit): Germany 5;12 d; Switzerland7; 21d; USA: 1 d (Texas), 7 d (Ohio), 9 d (Georgia), 12 d (California), 17 d (Arizona), 31 d (Minnesota), 106 d (New York), 130 d (Iowa); Canada: 11 d (Manitoba), 16 d (Ontario), 63 d (Alberta) **AMPA DT_{50f}** (best fit): Germany 218 d (Menslage); Switzerland 135; 139 d; USA: 76 d (Ohio), 93 d (Texas), 103 d (Arizona), 145 d (New York), 170 d (Georgia), d (Minnesota), 240 d (California); Canada: 128 d (Manitoba), 185 d (Ontario)	New half lifes from field dissipation studies will be calculated based on new and existing studies and based on the most recent guidance regarding degradation kinetics**(refinement of existing endpoints)**
DT_{90f} from soil dissipation studies:	not calculated; see DT_{50f}	
Soil accumulation and plateau concentration	Plateau concentration for AMPA: 5.62 mg/kg (mean DT_{50f}: 697 d (first order kinetic))	New PEC calculations in soil will be submitted based on new half lifes
Remarks: e.g. effect of soil pH on degradation rate	None.	
Adsorption/desorption		

K_f / K_{oc}: K_d	soil type	1/n	K_{oc}	K_d	Additional adsorption/desorption studies for glyphosate and AMPA will be submitted. **(potential refinement of existing endpoints)**
	silty clay loam	1.16	60000	900	
	silt loam	0.8	3800	34	
	loamy sand	0.92	22300	245	
	sand	*)	32830	263	
	sand loam	*)	50660	810	
	sandy clay loam	*)	3598	50	
	loamy sand	*)	884	5.3	
	silt loam	*)	3404	47	
	loam (sediment)	*)	17819	510	
	*)The advanced adsorption isotherm test wasn't conducted because in the screening test equilibrium was not reached after 72 hours				
pH dependence:	No pH dependence				
K_f / K_{oc}: K_d	soil type	1/n	K_{oc}	K_d	
	clay loam	0.786	3640	76	
	sand	0.904	8310	1554	
	sand	0.752	1160	15	
	clay loam	0.791	3330	30	
	loamy sand	0.769	6920	111	
	sand	0.788	24800	74	
pH dependence:	No pH dependence				
Mobility					
Column leaching:	1. 0.12 1.45% as of applied in leachate (3 soils) 2. 0.03 6.56% as of applied in leachate (7 soils)				
Aged residue leaching:	1.56, 0.22 and 0.02 % ^{14}C activity in leachates 65.2, 59.0 and 2.1 % evolved as CO_2 30.3, 40.4 and 97.5 % ^{14}C in the upper 2 cm of columns				
Lysimeter/Field leaching studies:	Not submitted.				Supplemental lysimeter study publications will be submitted
Remarks:	None.				

2.2. Fate and behaviour in water		
PROPERTY	**ENDPOINT**	**COMMENT**
Abiotic degradation		
Hydrolytic degradation:	pH__5____: stable (25°C)	
	pH__7____: stable (25°C)	
	pH__8____: stable (25°C)	

Photolytic degradation:	DT_{50}: 33 d (pH 5), 69 d (pH 7), 77 d (pH 9).	

Biological Degradation		
Readily biodegradable:	No	
Water/sediment study:		
DT_{50} water:	1 and 4 days (Möllerfeld and Römbke)	New half lifes in water sediment systems will be calculated based on existing studies (some of which have not previously been reviewed at EU level) and based on the most recent guidance regarding degradation kinetics **(refinement of existing endpoints)**
DT_{90} water:	**not calculated**	
DT_{50} whole system:	27 and 146 days (Möllerfeld and Römbke), 31 and 124 days (Muttzall)	
DT_{90} whole system:	**not calculated**	
Mineralization	18 and 24 % after 100 days (Möllerfeld and Römbke), 6 and 26 % after 91 days (Muttzall)	
Non extractable residues	14 and 22 % after 100 days (Möllerfeld and Römbke), 31 and 35 % after 91 days (Muttzall)	
Distribution in water / sediment systems (active substance)	after 1 day: 47 64% in water, 31 44% in sediment; after 100 days 3% in water, 29 44% in sediment. In sediment: maximum 50 60% after 7 and 14 days, r and 30 50% after 100 days.	
Distribution in water / sediment systems (major metabolites)	AMPA: if found, only in the water phase: maximum after 14 days and 0.5 % after 100 days. Water/sediment studies with ^{14}C **AMPA** (Knoch and Spirlet): 1 st system: waterphase: 101% day 0; 4% day 100; sediment: max. 41% day 59; 20% day 100; 2 nd system waterphase: 100% day 0; 1% day 59; sediment: max. 46% day 14; 32% day 100	
Accumulation in water and/or sediment:	**No accumulation**	
Degradation in the saturated zone	Not submitted.	
Remarks:	None.	

2.3. Fate and behaviour in air		
Volatility		
Vapour pressure:	$1.31 \cdot 10^{5}$ Pa (25 °C, acid)	
Henry's law constant:	$2.1 \cdot 10^{7}$ Pa m^3 mol^{1}	
Photolytic degradation		
Direct photolysis in air:	No absorption for wavelengths > 290 nm. DT_{50} (water):33d (pH 5), 69 d (pH 7), 77 d (pH 9)	
Photochemical oxidative degradation in DT_{50}:	DT_{50}: 1.6 d (Atkinson estimation)	

Volatilisation:	from plant surfaces: no significant volatilization	
	from soil: no significant volatilization	
Remarks:	None.	

3. ECOTOXICOLOGY			
PROPERTY	**ENDPOINT**		**COMMENT**
Terrestrial vertebrates			
Acute toxicity to mammals:	LD_{50} > 2000 mg/kg bw		A new endpoint may be proposed based on existing data **(potential refinement of existing endpoint)**
Acute toxicity to birds:	LD_{50} > 2000 mg/kg bw		A new endpoint may be proposed based on existing data **(potential refinement of existing endpoint)**
Dietary toxicity to birds:	LC_{50} > 4640 ppm		
Reproductive toxicity to birds:	NOEC 200 ppm		A new endpoint may be proposed based on existing data **(potential refinement of existing endpoint)**
Short term oral toxicity to mammals:	NOAEL/NOEL 150 mg/kg bw/d (90 d, rat)		A new endpoint may be proposed based on existing data **(potential refinement of existing endpoint)**
Aquatic Organisms	**glyphosate IPA**	**glyphosate acid**	
Acute toxicity fish: EC_{50}	>1000 mg /L	38 mg/L	
Long term toxicity fish: NOEC	917 mg /L	25 mg/L	
Bioaccumulation fish:	Not relevant	Not relevant	
Acute toxicity invertebrate: EC_{50}	930 mg /L	40 mg/L	
Chronic toxicity invertebrate: NOEC	455 mg /L	30 mg/L	
Chronic toxicity algae EC_{50}	72.9 mg/L	0.64 mg/L	A new endpoint may be proposed for glyphosate acid based on existing data not previously reviewed at EU level **(potential refinement of existing endpoint)**
Chronic toxicity sediment dwelling organism:	Not tested	Not tested	
Long term toxicity aquatic plants: EC_{50}	53.6 mg/L	12 mg/L	Additional aquatic macrophyte studies will be submitted potentially refining existing endpoints **(potential refinement of existing endpoint)**
Honey bees			
Acute oral toxicity:	LD50: 100 µg as/bee		
Acute contact toxicity:	LD50: > 100 µg as/bee		
Other arthropod species			
Test species Test method	% Effect		Additional arthropod studies will be submitted potentially refining existing endpoints
Typhlodromus pyri Lab on inert substrate	Lifecycle: 100 % mortality (3.6 kg as/ha)		
Typhlodromus pyri	Lifecycle: 89 % mortality (7.720 kg as/ha)		

Lab natural substrate on leaves		
Typhlodromus pyri Lab natural substrate on plants	Lifecycle: 30 % mortality; 0 % effect on fertility (3.708 kg as/ha)	
Aphidius rhopalosiphi Lab on inert substrate	Adult: 100 % mortality	
Aphidius rhopalosiphi Lab natural substrate on plants	Adult: 25 % mortality; 6 % effect on fertility (3.720 kg as/ha)	
Chrysoperla carnea Lab on inert substrate	Larval stage: 53 % mortality (0.712 kg as/ha)	
Chrysoperla carnea Lab on inert substrate	Larval stage: 59 % mortality; 20 % effect on fertility (3.708 kg as/ha)	
Aleochara bilineata Lab on inert substrate	Lifecycle: 1% parasitation capacity (1.63 kg as/ha)	
Bembidion lampros Semifield	Adult: 0% mortality (4,890 kg as/ha)	
Poecilus cupreus Lab on inert substrate	Adult: 0% mortality; 31% effect on food uptake (3.6 kg as/ha)	
Trechus quadristriatus Lab on inert substrate	Adult: 14% mortality (3.6 kg as/ha)	
Pardosa spp. Lab on inert substrate	Adult: 56% mortality (3.7 kg as/ha)	
Earthworms		
Acute toxicity:	LC_{50} > 480 mg as/kg	
Reproductive toxicity:	NOEC 28.79 mg/kg (IPA salt)	A new reproduction study will be submitted refining the existing endpoint
Soil micro-organisms		
Nitrogen mineralization:	No effects up to 18 kg as/ha	
Carbon mineralization:	No effects up to 18 kg as/ha	

Note: Additional change proposals of endpoints may arise during the further evaluation of studies and preparation of the dossier. These will be communicated to the Rapporteur and Co-rapporteur.

Notification of renewal

Dr. Richard Garnett (Monsanto) on behalf of the Glyphosate Task Force (GTF) wrote to the European Commission on December 10, 2009 and expressed an intention to renew the approval of glyphosate. Copy of the letter is included in Annex 2 to this document. The minimum 2-year notice required by Directive 91/414/EEC (article 5.5) and by Regulation 1107/2009 (article 80.4) for renewing approval was therefore respected.

A renewal dossier for glyphosate will need to be submitted to rapporteur Member State Germany by **May 31 2012**, as specified in Council Regulation 1141/2010/EEC.

Good agricultural practices (GAP)

The initial GAP that supported the inclusion of glyphosate in Annex I in 2001 is provided in Annex-1a to this summary report.

The GAP proposed as representative for the renewal of the Community approval of glyphosate is provided in Annex-1b to this summary report. This GAP covers the main current general uses of glyphosate in the EU and focuses on the control of annual, perennial and biennial weeds in the following cropping scenarios:

- Pre-emergent use of glyphosate in all crops
- Post-plant pre-emergent uses in all crops
- Pre-harvest uses in cereals and oilseeds
- Orchards and vines (around the base of the trunk and as spot treatment)

The maximum application in any 12-month period for all uses is 4.32 kg a.s./ha. The maximum individual application rate ranges from 2.16 kg a.s./ha to 2.88 kg a.s./ha. The latter only applies for spot treatments in orchards and vines. The application window between subsequent applications in all uses is 28 days. Pre-harvest intervals in cereals and oil-seeds are set at 7 and 14 days respectively.

2 The active substance and the plant protection product

The active substance: glyphosate acid

The active substance's minimum purity specified in the inclusion directive is 950 g glyphosate acid/kg (Monsanto/Cheminova reference specification).

The current new glyphosate task force (GTF) counts 23 members at the time of this notification and represents a total of at least 40 different sources of technical glyphosate relevant to this submission. Taskforce membership of three (3) additional companies is currently under evaluation. Each of these companies could add supplementary sources of technical glyphosate to the submission. These sources of technical glyphosate will be documented and evaluated in company specific confidential parts of the renewal dossier.

The test items discussed in this overview are (1) test items used in studies owned by member companies of the current Glyphosate Task Force (GTF) which were subject to evaluation leading to Annex I inclusion in 2001 (2) studies that were developed after the first Annex I evaluation and (3) test items used in new studies generated by the current glyphosate task force.

The test item overview is limited to technical glyphosate acid and is presented per GTF member, that holds relevant information, in alphabetical order. The compliance of test items relevant in the context of the Annex-I renewal dossier will be documented in the confidential part of the renewal dossier. Purity and impurity profiles of test items that were used in new and previously evaluated studies but relevant in the context of the re-evaluation will be compared against the reference specification. Test items used in studies from GTF members that joined the GTF within 2 months of the submission deadline are not included in this overview. This mainly affects the studies from Jingma Chemical Company Ltd and Sinon. The GTF will provide this information as soon as possible as an addendum to this Application.

Agrichem

Agrichem was part of the 'Tulip task force' that notified and submitted data in the context of the 2001-EU Evaluation. Most of the mammalian tox and ecotox studies were based on technical glyphosate acid: Batches N°:0190A and 22021 with a purity of 98.1% w/w and 96% w/w respectively (Table 2.1):

Table 2.1: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Agrichem

Batch#	Purity (%w/w)
0190A	98.1
22021	96

Arysta Life Sciences

Data from Arysta were not included in the 2001-EU Evaluation for glyphosate. Nevertheless mammalian tox and ecotox studies were developed around 1995-1996 with technical glyphosate acid (purity range 94.6% - 97.6 w/w). Details are listed in Table 2.2.

Table 2.2: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Arysta Life Sciences.

Batch#	Purity (%w/w)
940908-1	95.68
T-941209	97.56
T-950308	94.61

Cheminova

Cheminova (as part of the Monsanto/Cheminova joint submission) was considered one of the main data-submitters in the 2001-EU Evaluation. Technical glyphosate acid was used to conduct mammalian toxicology and ecotoxicology data in a period between 1989 and 1996. The purity of the test items ranges from 98.2 – 99.5% (w/w). Details are presented in Table 2.3. No new mammalian tox or ecotox studies have been developed subsequently.

Table 2.3: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Cheminova.

Batch#	Purity (%w/w)
206-JaK-25-1	98.2
120594	95.2
161-JRJ-131-2	98.5
003-89-A	95.4
206-JaK-59-5	98.7
229-JaK-142-6	99.2
229-JaK-5-1	97.7
206-JaK-119-1	98.5

Batch#	Purity (%w/w)
198-SI-22-1	97.9

Excel

Data from Excel was not included in the 2001-EU Evaluation for glyphosate. Excel developed recent mammalian tox and ecotox studies with technical glyphosate acid with Batch GI-1045 (Table 2.4).

Table 2.4: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Excel.

Batch#	Purity (%w/w)
GI-1045	96.66

Feinchemie Schwebda GmbH

Feinchemie Schwebda GmbH was considered one of the main data-submitters in the 2001-EU Evaluation. Most of the mammalian tox studies were based on technical glyphosate acid batches N° 60 and N° 046. In addition mammalian studies were developed with batches N° F/93/032, N° 01/06/97 and N° 01/12/1997. The batches used in the ecotox studies with technical glyphosate were batches N° 01/06/96 and N° 01/07/95.

Details are presented in Table 2.5.

Table 2.5: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Feinchemie Schwebda GmbH.

Batch#	Purity (%w/w)
60	96.8
046	96.8
F/93/032	>98
01/06/97	95.14
01/12/1997	95.6
01/06/96	96.7

Helm Ag

Helm Ag was a notifier during the 2001-EU Evaluation but did not submit a dossier. Since the first Annex I inclusion Helm Ag has developed new studies that will be included in the GTF Annex I renewal submission.

Technical glyphosate acid was used to conduct mammalian toxicology and ecotoxicology studies in a period between 2007 and 2010. The purity of the test items ranges from 95.1 – 98.8% (w/w). Details are presented in Table 2.6.

Table 2.6: Test item details for studies developed by Helm Ag.

Batch#	Purity (%w/w)
20080801	98.8
2009051501	96.4
37/422/10	97.16
20090506	97.3
080704-1-5	96.71
040205	97.23
20070606	98.05
20090305	98.2
2007091801	98.01

Monsanto

Monsanto (as part of the Monsanto/Cheminova joint submission) was considered one of the main data submitters in the 2001-EU Evaluation. Technical glyphosate acid was used to conduct mammalian toxicology and eco-toxicology data in a period between 1978 and 1995. The purity of the test items ranges from 95.21 – 99.7% (w/w). Details are presented in Table 2.7.

Table 2.7: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Monsanto.

Batch#	Purity (%w/w)
XHI 162	83.00
XLI-55	97.76
XHI 180	98.5
1782608	99.7
XLG-161	95.21
NBP 2472136	96.13
NBP 1992026	98.4
XHJ-46	98.4
XHJ-64	98.7
XLH-264	96.5
XLI-203	97.67
FJGT-07-000	99.2

Batch#	Purity (%w/w)
NBP 1782610	99.7
NBP-3594465	96.6
RUD-9302-4778-T	96.6

The current Glyphosate Task Force (GTF) recently finished/initiated new ecotox studies with technical glyphosate acid sourced from Monsanto (BATCH: GLP-0807-19475-T ; Table 2.8).

Table 2.8: Details for technical glyphosate acid used as test item in new tox/ecotox studies developed by the GTF.

Batch#	Purity (%w/w)
GLP-0807-19475-T	96.22

Nufarm

Nufarm notified and submitted data in the context of the 2001-EU Evaluation but withdrew their notification further on in the process. The EU review report concludes that the impurity profile of the technical substance at that time deviated significantly from the reference (Monsanto/Cheminova).

Nufarm has recently (2007) developed a significant toxicology ecotoxicology data package for technical glyphosate acid using test material with a purity ranging from 94.6 – 97.7% w/w. Details are listed in table 2.9.

Table 2.9: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Nufarm.

Batch#	Purity (%w/w)
H95D161A	95.3
200609062	95.1
H05H016A	95.7
037-919-113	95.49
20060901	97.7
0609-1	95

Zeneca Agrochemicals (Syngenta)

Zeneca Agrochemicals (Syngenta) was considered the main data submitter for glyphosate trimesium salt. Therefore Zeneca Agrochemicals (Syngenta) did not submit mammalian toxicology and ecotoxicology studies relevant for the evaluation of glyphosate acid during the 2001-EU Evaluation. New studies were developed on glyphosate acid over a period from 1996-2002 and cover a purity range from 95.6-99.1% w/w. Details are presented in Table 2.10.

Table 2.10: Details for technical glyphosate acid used as test item in tox/ecotox studies developed by Zeneca Agrochemicals (Syngenta)

Batch#	Purity (%w/w)
P24	95.6
P15	97.4
P18	99.1
P30	97.6
0507	96.1
Bx20070545	99.1

The plant protection product: MON 52276

One of the representative formulations supporting the first Annex I inclusion was Monsanto's MON 52276, a liquid soluble concentrate formulation (SL) containing 360 g glyphosate acid (formulated as isopropylamine salt) per L. This formulation is still registered in Europe and will also be the formulation supporting the joint GTF Annex III dossier for the renewal dossier. The composition of this formulation has not changed.

3 Specific conclusions based on previous evaluation

3.1 Identity, physical/chemical/technical properties and methods of analysis

3.1.1 Identity and physical-chemical properties

Glyphosate acid is a white odourless crystalline solid comprised of one basic amino function and three ionizable acidic sites. It melts at 189.5 °C. The free acid dissociates readily (pKa: 2.34, 5.73, 10.2) resulting in a moderate water solubility of 10 - 12 g/l (20 - 25°C).but its solubility in water increases substantially when converted to monobasic salts by isopropylamine, NaOH and NH_4OH. Glyphosate is generally formulated as water soluble concentrates in the form of the more soluble monobasic salt of isopropylamine (IPA). The n-octanol/water partition coefficient (log P_{OW} = -3.2 at 25°C) indicates no potential for bioaccumulation. Its vapour pressure amounts to 1.31 x 10^{-5} Pa at 25°C. Henry's law constant is 2.1 x 10^{-7} $pa.m^3.mol^{-1}$. Glyphosate is stable to hydrolytic degradations in sterile water in most environmentally relevant pH ranges. The pure active substance does not absorb light significantly at wavelengths longer than 230 nm indicating no sensitivity to direct photolysis. Photochemical oxidative degradation in air is expected to occur fast in 1.6 hours. Its flammability and oxidizing properties are not critical.
During the 2001-EU Evaluation the study results from one notifier showed a positive reaction to shock sensitivity, however thermodynamic and calorimetry data subsequently submitted during the ECCO process clearly demonstrated that glyphosate is not explosive. The latter conclusion is still supported.

MON 52276 is an aqueous based soluble concentrate of isopropylamine salt of glyphosate. It is not flammable or explosive. It is slightly acidic and moderately viscous. Stability testing shows that the product has a shelf-life in excess of two years and is not affected by short periods of low temperature exposure. The product can form persistent foam in certain types of spray equipment; the use of an anti-foam agent may be advisable in certain use conditions.

Additional studies

For glyphosate acid, glyphosate IPA salt and glyphosate NH_4-salt reference will be made to studies submitted in the 2001-EU Evaluation (monograph). In a few cases additional new studies confirming the established endpoints or confirming the conclusions from the previous evaluation will be submitted in order to comply with changes and developments in the technical guidance.

For glyphosate K-salt a complete phys-chem. data package will be submitted.

3.1.2 Analytical methods

According to EU acceptability criteria, adequate **analytical methodology** for glyphosate is available for a wide range of plants and plant products, food of animal origin including milk and eggs, soil, water and air. For the main metabolite AMPA a methodology which fulfils the mentioned criteria has been submitted for various plants products, food of animal origin including milk and eggs, water and air.

The different notifiers submitted different methods for the determination of glyphosate in the active substance as manufactured. The generally used method is the AOAC-CIPAC method. The method is based on HPLC using an anion exchange column, UV detection at 195 nm and evaluation by external standardization. Mobile phase is a buffered solution (pH = 1.9 – 2) of KH_2PO_4 in water/methanol.

In addition a second HPLC method using an amino phase (NH_2) column, UV detection at 210 nm and evaluation by external standardization and acetonitrile/water/phosphoric acid as mobile phase is used.

A third HPLC method quantifying glyphosate as a copper II complex using a Hypersyl-MOS column and UV detection at 230 nm with copper acetate in ammonium carbonate solution as mobile phase was used. Another method is complexometric titration with copper volumetric solution for the determination of glyphosate and the impurity glyphosine together. By titrating with bismuth volumetric solution the glyphosine content can be measured. The difference gives the glyphosate content.

For the determination of glyphosate in formulations the AOAC-CIPAC method (HPLC using an anion exchange column, UV detection) or HPLC using a NH_2 column are applicable. A similar complexometric titration method as described above was also used for the measurement of glyphosate in formulation.

Additional studies

New methods/studies are being developed to generate residue data and for monitoring purposes and will be submitted as part of the renewal dossier. The main reason is the fact that data requirements and method validation criteria with new acceptability requirements have developed since 2001. The following studies are under development:

- Validation of an analytical residue method for crops high in acid content and crops high in oil content
- Validation of an analytical method for residues of glyphosate and AMPA in water matrices (surface water, groundwater and drinking water)
- Inter-laboratory validation study for the analytical method for residues of glyphosate and AMPA in drinking water
- Validation of analytical detection methods for relevant impurities in technical glyphosate (according to the latest guidance) will be submitted in the joint dossier. In addition companies may submit validation methods of impurities relevant to their respective technical sources in the company confidential part of the submission.

3.2 Mammalian toxicology

The mammalian toxicology of glyphosate was reviewed during the 2001 EU evaluation. Since then several toxicology studies were conducted, by several GTF members to support own registrations at EU- Member State level or to support registrations in other world areas. These studies were not evaluated during the glyphosate 2001 EU evaluation. The dossier supporting the approval renewal of glyphosate will include some of these additional studies (as relevant) in addition to a few new GTF studies as outlined below.

3.2.1 Animal metabolism

Following oral administration, glyphosate is absorbed from the gastrointestinal tract rapidly but only to a limited extent of not more than 30 - 40%. Percutaneous absorption of glyphosate at least through the intact skin is confined to a small portion of less than 3%. Elimination via faeces and urine is rapid and nearly complete. Distribution into the organs and tissues is limited with generally low residues occurring. There is no evidence of accumulation in the animal body. After a period of 3 to 7 days following oral administration, total body burden accounted for less than 1% of the applied radioactivity. Elimination from bone is slower than from other tissues. By far, the highest residues were measured in this tissue followed by kidney and liver. This pattern of absorption, distribution and elimination was not significantly changed either by a single high dose or by repeated administration of low doses. Similarly, the sex of the test animals did not affect the results. Metabolism of glyphosate, if occurring, is very limited. Most of the parent glyphosate is eliminated unchanged. To a little extent of less than 0.5%, aminomethylphosphonic acid (AMPA) which is known to be the major plant metabolite of glyphosate may be formed also in mammals. Studies in rabbits, goats and laying hen revealed a similar pattern of toxicokinetics and metabolism.

3.2.2 Acute toxicity

Glyphosate acid and its salts exhibit a low acute toxicity in laboratory animals by the oral and dermal route with LD_{50} values greater than 2000 mg/kg bw. General signs of oral intoxication were breathing difficulties, reduced activity, ataxia and convulsions. The acute inhalation toxicity was also low with LC_{50} values above the limit test dose of 5 mg/L air per 4 hours obtained for the acid and the isopropylammonium salt (IPA). Toxic symptoms after inhalative exposure included irritation of the upper respiratory tract, hyperactivity, loss of hair, ruffled fur and a slight decrease in body weight but were not consistently observed throughout the studies. First death occurred at a concentration of 1.3 mg/L (4-hour exposure) when IPA was tested. Glyphosate acid and the IPA were more toxic by the intraperitoneal route with LD_{50} values down to 134 mg/kg bw. The occurrence of late deaths was assumed to be caused by subsequent peritonitis instead of a direct toxic drug effect. Regarding primary irritation, glyphosate acid and the salts were found to be non-irritant to intact skin and only slightly irritant to abraded skin. Undiluted glyphosate acid was found to be strongly irritating to rabbit eyes requiring classification (R41, severe eye irritant)

and labelling (Xi). There was markedly less eye irritation observed with the salts. Neither glyphosate acid nor the salts have shown sensitizing effects in guinea pigs. However, only the acid and the IPA have been tested under the more stringent conditions of the Magnusson-Kligman test.

3.2.3 Genotoxicity

Glyphosate was examined for mutagenicity in a wide range of test systems covering all relevant endpoints *in vitro* as well as *in vivo*. Against the background of this large database, it can be concluded that the active ingredient does not exhibit a mutagenic risk to humans. In the vast majority of the studies, glyphosate proved clearly negative. One of the two micronucleus tests using the extremely high and already cytotoxic dose of 5000 mg/kg bw/day revealed a weak increase in the incidence of micronuclei but only in one sex. It should be also taken into consideration that there is no evidence of carcinogenic or teratogenic effects in humans although glyphosate products have been in world-wide use for many years.

3.2.4 Sub-chronic, Chronic toxicity and carcinogenicity

Subacute and subchronic toxicity studies also revealed a low oral toxicity of the compound. The lowest NOELs observed were 50 mg/kg bw/day in a subacute and about 100 mg/kg bw/day in a 90-day feeding study in rats with first effects occurring in the range of 250 - 300 mg/kg bw/day. In most studies in rats, mice, and dogs, however, higher NO(A)ELs were established. Some lower values found in dogs were obtained in studies of limited scientific value but these rather equivocal findings were not confirmed in more recent experiments using much higher dosages. Changes in clinical chemistry parameters and liver weight changes might indicate an impact on the liver at least in rats. Soft stools and diarrhea, together with occasionally reduced body weight gain and food consumption, suggest irritation of the gastrointestinal tract. In some oral rat studies and in one experiment with mice, effects on salivary glands were elucidated upon histopathological examination. Repeated dermal exposure of rabbits and rats to glyphosate did not result in any systemic effects. Dermal irritation was observed only at doses as high as 5000 mg/kg bw/day in rabbits or 1000 mg/kg bw/day in rats. Subacute inhalative toxicity of glyphosate active ingredient in rats is low. Up to the highest tested concentration of 3.8 mg/l air, neither local nor systemic toxicity was noted upon repeated exposure. Appendix 2 to the Concise OutlineReport of ECCO 78 Peer Review meeting notes the lowest relevant oral NOAEL/NOEL was 300 mg/kg bw/day based onliver, gastrointestinal mucosa and salivary gland effects in 6 and 12 month dog and 90 day rat studies. The SANCO/6511/VI/99-final document however notes the lowest relevant short term oral NOAEL/NOEL as 200ppm or 150 mg/kg bw/d in a 90-day rat dietary study.

Long-term toxicity and cancerogenicity

In long-term studies in rats and mice, no evidence of cancerogenicity was obtained. The lowest NOELs of 10 mg/kg bw/day and only for female animals 100 ppm (approximately 6 mg/kg bw/day) were established in chronic rat studies with first effects occurring in the range of 60 - 100 mg/kg bw/day; these were non-neoplastic salivary gland effects and mild liver effects. However, the lowest relevant NOEL was considered 31 mg/kg bw/day in rats. Mice appeared less vulnerable. Concerning the non-neoplastic effects upon long-term exposure, considerable differences among the different studies became apparent. In general, there were no adverse effects on survival and no clinical signs of toxicity in any of the chronic studies. Body weight gain was compromized in female Sprague-Dawley rats at the upper dietary level of 20000 ppm, equivalent to a mean daily intake of 1183 mg/kg bw. A lower body weight was also noted in male CD-1 mice receiving the extremely high dietary dose of 30000 ppm (ca 4800 mg/kg bw/day) for two years. A higher activity of alkaline phosphatase and liver weight changes in rats as well as centrilobular hepatocyte hypertrophy in male mice were assumed to reflect a weak effect on the liver. In addition, effects on the eyes and on salivary glands were observed in rats but not consistently seen in all studies. A higher incidence of cataracts was noted in male Wistar rats at 10000 ppm and in male Sprague-Dawley rats at 20000 ppm. In Sprague-Dawley rats, non-neoplastic histological changes accompanied by a higher organ weight occurred in the parotid and mandibular salivary glands in both sexes at 100 mg/kg bw/day and above. Similar microscopic lesions were observed in subchronic studies in rats and mice as well as in multigeneration studies in rats. On the other hand, neither in dogs nor in the long-term mouse studies, effects on salivary glands have been reported. A mechanistic 14-day study in rats suggested the changes to be mediated through an adrenergic mechanism. Local inflammation of gastric mucosa was noted in one study on Sprague-Dawley rats at the high and mid dose levels in both sexes. This finding was most likely due to mucosal irritation and might well correspond to epithelial hyperplasia in the urinary bladder as observed in a long-term mouse study at 5000 ppm and above.

Additional studies

The WHO/FAO Joint Meeting on Pesticide Residues (2004) evaluated glyphosate and selected the salivary gland effects noted in rats as the endpoint to establish, using a NOAEL of 100 mg/kg/day in a rat chronic study to determine an ADI of 1.0 mg/kg. However, the expert reviewers concluded that this endpoint was of "unknown toxicological significance". The JMPR 2004 technical review of glyphosate also suggests that the salivary gland hypertrophy observed in repeat dose feeding studies may be due to local irritation effects of the ingestion of an organic acid rather than a glyphosate specific effect. Therefore, the Glyphosate Task Force designed and contracted a study to address this question posed in the WHO/FAO Joint Meeting on Pesticide Residues (2004) evaluation of glyphosate. In addition, one GTF member company conducted an independent study to evaluate these non-adverse effects in different strains of rats.

3.2.5 Reproductive toxicity

A number of multigeneration studies in rats did not indicate a specific hazard of glyphosate for reproduction. Weak effects on the offspring as evidenced by a reduced pup weight were confined to dose levels as high as 30000 ppm. Compound related effects in the parent animals were similar to those seen in the subchronic and long-term studies and occurred at comparable dose levels. The ECCO 78 review notes the lowest relevant reproductive NOAEL/NOEL as 10000 ppm or 800 mg/kg/bw/day in rats.

Glyphosate does not cause teratogenicity. Adverse effects on the number of viable fetuses and the fetal weight were noted in rats and rabbits at higher dose levels causing also maternal toxicity. A reduced ossification and a higher incidence of skeletal and/or visceral anomalies at these dosages were also indicative of fetotoxicity. The NOEL for developmental effects was 300 mg/kg bw/day in rats and 350 mg/kg bw/day in rabbits. In rabbits, maternal effects occurred at doses lower than those found effective in developmental toxicity, subacute and subchronic studies in rats and might indicate a higher vulnerability of this species. However, in the ECCO 78 review the lowest relevant developmental NOAEL/NOEL of 150 mg/kg bw/day in rabbits was noted for development al endpoints of number of viable fetuses, retarded ossification, higher incidences of skeletal and/or visceral anomalies at maternally toxic doses. The ECCO 78 lowest relevant maternal NOAEL/NOEL in rabbits was considered to be 75 mg/kg bw/day.

Additional studies

In addition to the multiple rabbit teratology studies reviewed in the initial Annex I inclusion of glyphosate, three more rabbit developmental toxicity studies have confirmed that adult rabbits are sensitive to oral gavage dosing with glyphosate. The consistent delayed onset of symptoms, suggest that the effects may be due to repeat dosing of a low pH organic acid via oral gavage to the rabbit. The GTF suggests such route specific dosing effects are not representative of systemic toxicity and therefore considers these endpoints unsuitable to derive an Acceptable Operator Exposure Level. This hypothesis is consistent with the lack of systemic toxicity noted in 21-day rabbit dermal toxicity studies up to 5000 kg/kg bw/d.

3.2.6 Additional toxicity data

Toxicological studies in laboratory animals did not indicate a specific potential for neurotoxicity. Similarly, neurotoxicity studies in hen did not provide clear evidence of such effects. Acute and subacute toxicity studies in goats and cattle confirmed the low toxicity of the compound. Clinical symptoms, however, were somehow different from those observed in laboratory animals. When the IPA had been administered at high doses causing significant overt toxicity, the clinical signs were predominated by CNS dysfunction, reflective not of a neurotoxic agent, but rather an animal in the final stages of death by overt toxicity. In addition, slight renal damage was found upon histopathology. In rats, equivocal evidence of an impact on the kidneys was obtained in one subacute study only. A specific hazard for farm animals *is* not to be expected. The metabolite aminomethyl phosphonic acid (AMPA) was investigated for acute and subchronic effects, mutagenicity and teratogenicity. These studies have shown that AMPA has a lower toxicity than the parent compound and is devoid of any mutagenic or teratogenic potential. Acute toxicity of glyphosate formulations is mediated through an effect on cardiovascular (circulatory) and respiratory functions. A cornmon sign of poisoning is a decrease in arterial blood pressure. There is evidence coming from pharmacological studies that this effect might be rather due to certain surfactants than to the active ingredient itself. This could explain the higher toxicity of some formulations as observed also in cases of human poisoning.

Additional studies
An immunotoxicity study is in progress by a GTF member company in support of the registration review of glyphosate in another world region. Two new subchronic neurotoxicity studies in rats show no subchronic neurotoxicity effects. These studies will be submitted in the Annex I Renewal dossier. In addition, dermal absorption data has been generated using OECD validated *in vitro* methods, establishing lower dermal absorption of glyphosate from the representative formulation over a range of relevant concentrations.

3.2.7 Human risk assessment

The following human reference values were adopted during the initial inclusion of glyphosate in Annex I:

- Acceptable Daily Intake (ADI): 30 mg/kg bw/d on the basis of the chronic rat NOEL and a 100X uncertainty factor.
- Acute Reference Dose (ARfD): was not determined.
- Acceptable Operator Exposure Level (AOEL): 0.2 mg/kg bw based on 75 mg/kg bw NOEL for maternal effects in rabbit teratology studies with a 30% absorption factor and a 100X uncertainty factor

Chronic studies with non-adverse effects were considered relevant in the ADI determination for the initial Annex I inclusion of glyphosate. However, new data presented in Section IIA 5.10 and a more robust chronic data set warrant consideration of a new ADI calculation with a weight of evidence approach using the more comprehensive data set.

Acceptable operator exposure scenarios were identified with standard PPE (coverall and gloves during mixing and loading, coverall during application). The ADI and the ARfD were not exceeded under any scenario for any of the supported crops. Workers and bystanders were considered adequately protected. Dietary risk assessment is summarized in section 3.3.5 below.

Additional studies

In the dossier supporting approval renewal, the operator risk assessment will be revised to take into account the amended GAP. The 3% dermal absorption value previously applied is not reflective of product specific formulation dermal absorption values, which are more appropriate for operator risk assessments.

3.3 Residues

Metabolism and residue studies of glyphosate included in the glyphosate monograph and those studies in the glyphosate-trimesium monograph focused on the glyphosate portion of the molecule are summarized here.

3.3.1 Plant metabolism

3.3.1.1 Studies from the Glyphosate Monograph

Conventional Crop Metabolism
The metabolism and distribution of ^{14}C-glyphosate in more than 20 varieties of conventional crops has been investigated and summarized in the glyphosate monograph. Routes of uptake included root uptake from soil and hydroponic solutions, applications to stems and trunks, and foliar applications of glyphosate to conventional crops.

Uptake and Translocation
Soybeans, cotton, wheat, maize, barley, oats, rice, sorghum, potatoes, sugar beets, and pasture crops were treated with a preemergence application of glyphosate at application rates equivalent to 4.48 kg/ha.

For root uptake from the soil in apple trees, grapes, coffee plants, citrus, and walnut, almond, and pecan trees, glyphosate was applied to the soil surface of pots containing the emerged crops, while shielding the foliage, at glyphosate application rates of between 2.24 kg/ha and 5.07 kg/ha.

In all cases, maximum uptake of radioactivity into plants grown in soil treated with ^{14}C-glyphosate was less than 1 % of the total applied radioactivity, demonstrating that very little of the applied glyphosate is taken up from the soil.

To simulate uptake of glyphosate through trunks and stems following postemergence directed spray applications in orchard and vineyards, a formulated solution of ^{14}C-glyphosate was directly applied to trunks and stems of apple

trees, grapes, and coffee plants. In all cases less than 3 % of the applied radioactivity was incorporated into the plants. These results show that very little of the applied glyphosate will be present as a residue in orchard and vineyard crops as a result of inadvertent applications of glyphosate to trunks and stems following postemergence directed spray treatments.

The distribution and metabolism of glyphosate following foliar applications has been investigated in apple trees, grapes, coffee plants, potatoes, citrus, sugar beets, walnut, almond, and pecan trees by application of subherbicidal levels of a formulated solution of ^{14}C-glyphosate to the surfaces of leaves. In all cases glyphosate was found to be rapidly and extensively translocated throughout the plant.

Metabolic Pathway

The majority of the plant-contained ^{14}C-radioactivity was released by aqueous extraction in almost all cases. Glyphosate was the major ^{14}C-component of the extract, and AMPA was the major ^{14}C-containing metabolite. Glyphosate was almost always present in higher amounts than AMPA, except in corn foliage following hydroponic application of ^{14}C-glyphosate, where glyphosate and AMPA were present at comparable levels. In addition to glyphosate and AMPA several minor metabolites that typically constituted less than 1% of the TRR were also occasionally detected. Several of these minor metabolites were identified, as N-methylaminomethylphosphonic acid (N-methyl-AMPA), methylphosphonic acid, and N-methyl-glyphosate. No significant metabolites other than AMPA were observed.

Glyphosate Tolerant Crop Metabolism

While glyphosate-tolerant crop uses are not being included in the current dossier, the original monograph included four metabolism studies in glyphosate-tolerant crops. Two of the studies were in crops (soyabean and cotton) that included only CP4 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) conferring glyphosate tolerance, and two of the studies were in crops (maize and oilseed rape) that included both CP4 EPSPS and GOX (glyphosate oxidoreductase), which metabolizes glyphosate to AMPA.

The studies on metabolism of glyphosate in tolerant maize and oilseed rape plants reveal a rapid and complete metabolization of glyphosate to AMPA caused by the presence of GOX. In contrast, cotton and soyabean did not contain GOX and thus were more similar to the non-tolerant plants, and metabolized glyphosate only slowly to AMPA.

3.3.1.2 Studies from the Glyphosate-Trimesium Monograph

Studies on the metabolism of ^{14}C-glyphosate (labelled in the glyphosate anion portion of the molecule and applied as the trimesium salt) were summarized in the glyphosate trimesium monograph. The studies included: directed application to soil in citrus, directed application to soil and intentional overspray in grapes, pre-emergence application to soil in soybean, and pre-harvest application in wheat.

The studies demonstrated minimal residues of glyphosate or AMPA in plants following application to soil, either prior to emergence or as a directed application around the crop. When ^{14}C-glyphosate was applied directly to the crop, as the pre-harvest application in wheat or deliberate overspray in grapes, the majority of the residues remained as glyphosate. The only significant metabolite was AMPA. It was usually a minor component of the TRR, but in several of the soybean commodities, AMPA residues exceeded those of glyphosate. No other significant metabolites were identified.

3.3.1.3 Summary

The results of all the numerous plant uptake and metabolism studies demonstrate that glyphosate is slowly metabolized in plants to AMPA. With only a few exceptions (some soybean commodities and hydroponically-grown maize forage where AMPA levels were comparable to or greater than glyphosate levels), glyphosate is the major compound present in plant tissues. In all cases, AMPA accounts for less than 27 % of the radioactive residues, and typically is less than 10 %. With the exception of AMPA, no other metabolites of glyphosate are detected that account for greater than 5% of the total radioactive residues.

Additional Studies

No additional plant metabolism studies will be submitted.

3.3.2 Animal metabolism

3.3.2.1 Studies from the Glyphosate Monograph

Two different sets of studies on lactating goats and laying hens were included in the original glyphosate monograph to determine the absorption, distribution, metabolism and excretion in livestock. In one set of studies animals were

dosed with 9:1 ratio of glyphosate and aminomethylphosphonic acid, AMPA, which is the primary plant metabolite of glyphosate. The goats were dosed at a level corresponding to a total dietary concentration of 120 mg/kg, and the hens at a total dietary concentration of 120 and 400 mg/kg. For the other set of studies both goats and hens were dosed with glyphosate alone at a level corresponding to a total dietary concentration of 200 mg/kg. Glyphosate and AMPA were rapidly excreted mainly in the faeces and urine, primarily as unchanged parent compound, resulting in low residue levels in edible tissues, milk and eggs. There was minimal metabolism of glyphosate to AMPA, as clearly demonstrated in the study conducted with glyphosate alone. Metabolites resulting from the degradation of glyphosate and AMPA in tissues were either insignificant or entirely absent.

3.3.2.2 Studies from the Glyphosate-Trimesium Monograph

Animal metabolism studies in goats and hens were included in the glyphosate trimesium monograph. The animals were dosed with ^{14}C-glyphosate in the form of the trimesium salt at a level equivalent to 62-64 mg/kg of glyphosate acid in the diet.

In goats, the glyphosate portion of glyphosate-trimesium is rapidly excreted mainly in the faeces. Tissue residues were generally low with the relatively highest value reached in the kidneys. The radioactive residues found in tissues consisted mainly of glyphosate itself and the metabolite AMPA. The major radioactive residues in milk were natural products in the form of lactose, triglycerides and protein. Lactose and triglycerides constituted over 45 % TRR in milk, while material associated with post extraction milk solids comprised 20 % TRR, which is consistent with natural incorporation of radiocarbon into proteins. Residues of glyphosate did not accumulate in fat, tissues or milk.

Glyphosate-trimesium radiolabelled in the glyphosate portion was rapidly and nearly completely excreted by hens. The radioactive residues found in tissues and eggs consist mainly of glyphosate and the metabolite AMPA. In addition, a part of the radioactivity was incorporated into naturally occurring products.

3.3.2.3 Summary

Results from all three sets of animal metabolism studies are consistent. Both glyphosate and AMPA were rapidly and extensively excreted after dosing in both goats and hens. Tissue levels were generally low, and AMPA was the only significant metabolite present. Other metabolites resulting from degradation of glyphosate and AMPA were either insignificant or absent.

Additional Studies

No additional animal metabolism studies will be submitted.

3.3.3 Plant unique metabolites

The only significant metabolite of glyphosate present in crops is AMPA. No other metabolites of glyphosate were detected that accounted for greater than 5% of the total radioactive residues. AMPA is a minor metabolite in animals. It was investigated for acute and subchronic effects, mutagenicity and teratogenicity. These studies have shown that AMPA has a lower toxicity than the parent compound and is devoid of any mutagenic or teratogenic potential. There are no plant unique metabolites of concern.

3.3.4 Residue studies and MRLs

3.3.4.1 Field Residue Studies

Field residue studies in many crops were included in the initial glyphosate and glyphosate trimesium dossiers.

EU MRLs were adopted and included in Annex II of Regulation (EC) No 396/2005, which adequately support claimed uses (**Commission regulation No 839/2008 of 31 July 2008 and Commission regulation (EC) No 149/2008 of 29 January 2008**).

Additional Studies

A representative set of residue studies covering the envisaged preplant or pre-emergence GAP uses in representative crops in Northern and Southern Europe will be conducted and included in the submission.

Additional residue studies supporting selected GAP uses and not included in the previous submissions may be submitted to support the existing database.

3.3.4.2 Processing Studies

Processing studies in many crops were included in the initial glyphosate and glyphosate trimesium dossiers. Glyphosate concentrates primarily in processed fractions such as hulls and bran of cereals and citrus peel due to surface residues; in meal after removal of oil fractions; and in concentrated liquid fractions such as molasses. Glyphosate does not partition into oil, and is removed from highly refined fractions such as sugar.

Additional Studies

A study on the nature of the residue in processing was recently completed and will be submitted.

Additional processing studies supporting selected GAP uses and not included in the previous submissions may be submitted to support the existing database.

3.3.4.3 Storage Stability Studies

Studies from the Glyphosate Monograph

The stability of spiked crop samples (exogenous fortifications) has been determined over a period of 0 to 31-32 months while endogenous (plant incorporated) residues have been determined over a period of 2 to 5 years in frozen storage.

Endogenous residues of both glyphosate and AMPA are stable in the seven crop commodities included in the study (corn grain, soy forage, sorghum stover, clover, tomatoes, alfalfa seed and potatoes) after 2-5 years in frozen storage. Although the exogenous AMPA residues show some decline over the course of this stability study, the decline is minimal. Coupled with the high stability of endogenous residues of AMPA, these results show that both glyphosate and AMPA are stable in different crops types (water, oil, protein, and starch containing and dry material) at frozen storage.

Samples of swine, Cow, and chicken fat, muscle, liver and kidney along with cow milk and chicken eggs were fortified with a solution of glyphosate and AMPA and stored frozen at <-20 °C. Samples were stored for up to 13 to 32 months. The data indicate a slight decrease in the glyphosate and AMPA residues for most matrices over the course of the study. However, these results show that losses due to instability have a negligible effect on the results of the feeding studies on swine, dairy cow and laying hens.

Studies from the Glyphosate-Trimesium Monograph

Representative raw agricultural commodities, including sorghum grain, soyabean, soyabean straw, and wheat grain were fortified with glyphosate or AMPA and stored at -20 °C. Samples were removed for analysis at intervals up to 2 years after fortification. In addition, sorghum grain was also analysed at 4 years after fortification. Analysis showed that glyphosate and AMPA were stable in all samples taken.

Storage stability of glyphosate and AMPA has been demonstrated in muscle, liver, kidney, eggs and milk for a minimum of 689 days (1.9 years).

Studies added to the Submission

There are three additional crop storage stability studies that were not included in the glyphosate or glyphosate-trimesium monograph (two of which were submitted prior to ECCO review but after the first draft of the Monograph). These studies cover: soybean commodities; pasture grasses; barley grain and straw, maize (corn), sugar beet root and leaves.

Additional Studies

A storage stability study in an acidic matrix is currently being conducted and will be submitted.

3.3.4.4 Rotational Crop Studies

Studies from the Glyphosate Monograph

A confined rotational crop study was included in the glyphosate monograph. The primary crop, soybeans, received a preplant application of 4.15 kg/ha of ^{14}C-glyphosate. Carrots, lettuce and barley were planted as rotational crops at 30, 119 and 365 days after application.

Total ^{14}C-radioactivity expressed as glyphosate equivalents, was less than 0.2 mg/kg in all rotational crop samples and decreased with time. Release of ^{14}C-radioactivity upon aqueous extraction of rotational crop samples was less than 60 % of the radioactivity in the plants in all cases, and typically less than 40 %. The nonextractable ^{14}C-radioactivity in 30 day rotational barley grain and straw samples harvested 125 days after treatment was characterized as biopolymers of glucose. Aqueous extracts of the rotational crop tissues contained less than 0.02 mg/kg glyphosate in all cases.

The results of this study demonstrate that only very low levels of glyphosate or glyphosate metabolites are present in the soil and plant tissues of rotational crops planted after treatment of a primary crop with glyphosate. The only metabolite of glyphosate found was AMPA. The majority of glyphosate derived radioactivity in the soil and plant tissues has been attributed to natural products derived by incorporation of one carbon compounds such as CO_2 into natural metabolic pools. The distribution of radioactivity in rotational crops was found to be similar to the distribution found in plants exposed to $^{14}CO_2$. The results of these studies show that glyphosate residues in emergency replant and rotational crops will be less than those found in the primary crop.

Studies from the Glyphosate-Trimesium Monograph

A confined rotational crop study was included in the glyphosate-trimesium monograph. ^{14}C-Glyphosate-trimesium (labelled in the glyphosate portion) was applied either as a single or as sequential applications, at a total rate equivalent to 3.9 – 6.6 kg/ha of glyphosate acid. Soybeans were planted as the primary crop. Lettuce, wheat and radishes were planted as the rotational crops, at 35 days, 125 and 370 days after the initial application.

There was minimal uptake of residues in the samples. Glyphosate residue levels were <0.01 mg/kg in all samples, and the maximum AMPA residues were 0.03 mg/kg. All other extractable and unextractable radioactivity was associated with [^{14}C] incorporated or bound to natural products.

These data have been confirmed by two field studies which demonstrate that the residue in following crops are close to or below the limit of determination.

Studies added to the Submission

There is an additional rotational crop study not included in the glyphosate or glyphosate-trimesium monograph but submitted prior to ECCO review. The results are comparable to those included in the monographs.

Summary

These crop rotation studies indicate that there is negligible uptake by the roots, from treated soil, following a regime that is comparable to the maximum single rate and maximum multiple application rates recommended in Europe.

Additional Studies

No additional studies will be submitted.

3.3.4.5 Livestock Feeding Studies

Studies from the Glyphosate Monograph

Animal feeding studies using glyphosate and AMPA have been conducted with lactating cows, poultry, and swine. For these studies, test groups of animals were fed a daily ration containing a nine to one mixture of glyphosate and AMPA at total combined daily dietary levels of 40, 120, and 400 mg/kg for 28 days. The dosing levels are assumed to represent, respectively, lx, 3x, and l0x the maximum expected residue levels of glyphosate and AMPA in the diet. Animals were sacrificed either following the last day of treatment or following a 28 day depuration period. Milk samples were taken in the cow study and eggs were collected in the poultry study at various time points during treatment and depuration. At sacrifice, residue levels were determined in fat, muscle, liver and kidney.

For all three species, glyphosate and AMPA residues were less than 0.05 mg/kg (undetectable) in all fat and muscle samples from all treatment levels following the 28-day dosing period, except muscles samples from swine and fat samples from chickens dosed at the highest level, which had residues of 0.06 to 0.07 mg/kg of glyphosate.

The highest glyphosate and AMPA residues were found in kidneys. At the end of the 28-day dosing period glyphosate residues in kidney of cow, swine and chicken dosed at the 10x level were 3.0, 7.63, and 3.82 mg/kg, respectively. AMPA residue levels in the same tissues were 0.07, 0.29, and 0.96 mg/kg, respectively. Significantly lower levels of glyphosate and AMPA were found in liver tissues collected at the end of the 28-day dosing period. For the l0x dose level liver samples, glyphosate residues were 0.20, 0.60, and 0.61 mg/kg, respectively. AMPA residues in the same tissues were <0.05, 0.12, and 0.39 mg/kg, respectively.

Analysis of tissues following the 28 day depuration period demonstrate that glyphosate and AMPA are rapidly eliminated. Following a 28-day depuration period, AMPA residues were less than 0.05 mg/kg in all samples. Glyphosate residues in the 28-day depurated animal tissues were less than 0.05 mg/kg in all tissues except kidney samples at the 3x and l0x dose levels, which contained average glyphosate residues of 0.08 and 0.18 mg/kg, respectively.

Glyphosate and AMPA residues were less than 0.025 mg/kg (undetectable) in all milk samples collected from cows dose at the l0x level.

Glyphosate residues were undetected in all egg samples collected from hens dosed at the 1x level, and were up to 0.131 mg/kg in eggs of hens dosed at the 10x level. AMPA residues in the same samples were less than 0.025 mg/kg in all cases. All glyphosate residues in eggs collected after a 7-day depuration period were less than 0.025 mg/kg.

Studies from the Glyphosate-Trimesium Monograph

Animal feeding studies were conducted with glyphosate-trimesium in cattle and poultry. Laying hens were fed with glyphosate-trimesium at dose levels of 0.5, 5 and 50 mg glyphosate-trimesium/kg in feed (equivalent to 0.34, 3.4 and 34 mg/kg of glyphosate acid). The hens were dosed for 28 consecutive days. Certain hens were selected for an additional withdrawal period of 7 days in which no glyphosate-trimesium was administered. No treatment-related effects on feed consumption, body weight or egg production were evident throughout the study.

Lactating dairy cattle were dosed daily for 28 days with five rates of glyphosate-trimesium technical, at rates equivalent to 0.5, 5, 50, 300 and 1000 mg/kg in the diet (equivalent to 0.34, 3.4, 34, 207 and 690 mg/kg of glyphosate acid in the diet). Two animals from each group were sacrificed after 28 days and the remainder were sacrificed after 7 days of withdrawal. Feed consumption, milk production and body weights of dairy cows were not affected by daily administration of glyphosate-trimesium at dose levels up to 300 mg/kg in the diet. At a dose level of 1000 mg/kg treatment related effects were observed including lethargy with reduced feed consumption, milk production and bodyweight.

Glyphosate-trimesium, when fed continuously at a level equivalent to 34 mg/kg of glyphosate acid to laying hens, produced low concentrations of residues in eggs and edible tissues. Residues of glyphosate in eggs ranged from <0.01 – 0.015 mg/kg. Residues of glyphosate in kidney were 0.31 mg/kg, and were not detected (<0.05 mg/kg) in liver, fat and muscle. Residues of AMPA were below the limit of determination in all tissues and eggs. All residues were below the limit of determination by 7 days after cessation of dosing.

Glyphosate-trimesium, when fed continuously for 28 days, at a level equivalent to 207 mg/kg of glyphosate acid to dairy cattle, produced low concentrations of residues in milk and edible tissues. One milk sample had glyphosate residues at 0.02 mg/kg, all others were below the limit of determination (<0.02 mg/kg). In kidney, glyphosate residues were 1.8 – 2.6 mg/kg and AMPA residues were 0.47 – 0.58 mg/kg immediately after dosing, and declined to 0.12 mg/kg and <0.05 mg/kg, respectively, 7 days after cessation of dosing. In fat, glyphosate residues were 0.06 mg/kg and AMPA was <0.05 mg/kg. Glyphosate and AMPA levels in liver and muscle were below the limit of determination in all samples.

Summary

Results in both sets of livestock feeding studies are consistent. Glyphosate and AMPA are rapidly excreted. The highest residues are in kidney, with lower residues in the liver. Residues in milk, eggs, tissue and fat were either not detected or were very low. Residues declined quickly after dosing was stopped.

Additional Studies

No additional animal feeding studies will be submitted.

3.3.5 Dietary risk assessment

3.3.5.1 Glyphosate Monograph

For calculation of the TMDI both the FAO/WHO Global Diet and the German BBA Model were used. Predicted TMDI estimates using MRL-level residues for all crops for which glyphosate MRLs were established or proposed were well below the ADI of 0.3 mg/kg bw. The two models provided similar results: Using data from the WHO Global Diet, the TMDI was approximately 16% of the ADI of 0.3 mg/kg bw/day and the BBA model provides a total TMDI estimate equivalent to approximately 23% of the ADI. Since theoretical maximum intake estimates were within the ADI, there was no reason to calculate a more realistic estimate of dietary intake of glyphosate.

3.3.5.2 Glyphosate-trimesium Monograph

The TMDI of glyphosate-trimesium and of the glyphosate portion of the molecule were calculated separately.

The calculations of the TMDI for glyphosate using two methods based on the FAO/WHO global diet and German BBA model lead to values which account for 12 and 22 % of the ADI. The main intake results from residues in cereals grain treated pre-harvest for desiccation but, resulting in an acceptable safety margin for the consumer. Therefore, the obtained TMDI values give no reason to estimate a more realistic intake of glyphosate-trimesium as EMDI.

3.3.5.3 Summary

The TMDI values for glyphosate were determined in each monograph and are slightly different due to some differences in the residue data and proposed MRLs, but were very close. In both cases the results demonstrated an acceptable margin of safety.

The dietary risk assessment will be updated in the dossier to take into account any changes in consumer models, uses and MRLs.

3.4 Environmental fate and behaviour

The environmental fate and behaviour of glyphosate was reviewed during the 2001 EU evaluation. Since then several environmental fate studies were conducted, by several GTF members to support own registrations at EU-Member State level or to support registrations in other world areas. These studies were not evaluated during the glyphosate 2001 EU evaluation. The dossier supporting the approval renewal of glyphosate will include these supplementary studies in addition to new aerobic soil metabolism studies and the updated kinetic analyses (FOCUS 2006) conducted by the GTF in order to address new technical guidance for study design and to refine risk assessment endpoints.

3.4.1 Fate and Behaviour in Soil

3.4.1.1 Aerobic Degradation - Laboratory Studies

The fate and behaviour of glyphosate in soil was evaluated during the 2001 EU evaluation and discussed in detail in the Glyphosate Monograph. Glyphosate degradation studies conducted in the laboratory under aerobic conditions have demonstrated that glyphosate is degraded in soil over time by micro-organisms. The DT_{50} for the degradation of glyphosate in various soils under aerobic conditions in laboratory studies ranged from 4 to 180 days, and were typically less than 25 days; 90% degradation times range from 40 to 280 days. The principal soil metabolite was aminomethylphosphonic acid (AMPA). The degradation rate of AMPA was measured from the glyphosate aerobic degradation studies assuming a bi-phasic degradation of glyphosate. The maximum amount of AMPA detected ranged from 15 to 29% of the total glyphosate applied as reported in the Glyphosate Monograph. These studies also established that AMPA is further degraded by soil micro-flora, although at a slower rate than glyphosate. They also demonstrated that from 6 to 86% of the applied glyphosate is mineralized to carbon dioxide. Several other minor components were also detected but none were present in amount greater than 3% of the applied glyphosate.

Additional Studies

In the 2001 EU evaluation of glyphosate additional information was not required based on the evaluation criteria and guidance in force at that time; however, to refine risk assessment endpoints further additional data on laboratory aerobic soil "rate" and "route" of degradation studies according to the requirements of the new OECD Guideline 307 for aerobic transformation in soil have been generated. Indeed, the joint applicants believe new aerobic soil

studies are needed to comply with current guidelines. The older existing studies have deficiencies which included low mass balance in some studies, the lack of duplicate sampling (FOCUS recommendation) in other studies, concerns about limited pH and soil texture range and the use of non-representative, artificial soils in one study. The renewal dossier will also include several supplementary soil degradation studies conducted by various GTF members which were not evaluated during the 2001 EU evaluation.

In addition, the aerobic degradation half-lives will be recalculated with kinetic approaches reflecting the latest guidance (FOCUS 2006).

3.4.1.2 Anaerobic Degradation- Laboratory Studies

In the 2001 EU evaluation, laboratory studies on anaerobic degradation of glyphosate in soil showed that glyphosate degradation was negligible under anoxic anaerobic conditions as dictated by the old SETAC anaerobic soil test guideline.

Additional Studies

After the EU review a new laboratory anaerobic degradation study with glyphosate has been performed by one GTF member according to the requirements of the new OECD Guideline 307 for anaerobic transformation in soil. The results of the new study show that glyphosate also degrades under anaerobic conditions although at slower rate than the aerobic conditions. The metabolite distribution resulting from the degradation of glyphosate in soil is similar under both aerobic and anaerobic conditions.

3.4.1.3 Field Studies

In the 2001 EU evaluation of glyphosate, field dissipation studies conducted in areas representative for middle-Europe (multiple field locations in Germany and Switzerland) and areas with climate and soil characteristics comparable with those in Southern Europe (USA/ Tennessee, California, Georgia) and northern Europe (Canada) provided glyphosate dissipation DT_{50} values between 1 and 130 days and DT_{90} values between 24 and 326 days. AMPA DT_{50} values from multiple field locations ranged from 13 to 875 days[3]. In the Glyphosate Monograph it was concluded that field soil accumulation studies were not required for glyphosate since the DT_{90} values for glyphosate in field dissipation studies were less than one year. In regard to AMPA, the monograph concluded that AMPA can accumulate in certain soils. The potential for soil accumulation of glyphosate and AMPA was assessed using models proposed by the FOCUS, after multiple applications and using worst case soil degradation input parameters, which concluded that the plateau concentrations of glyphosate and AMPA are of no toxicological concern (Addendum to the monograph-glyphosate, 16 October 2001). The potential soil persistence of AMPA will be further discussed in the renewal dossier.

Additional Studies

No new field dissipation studies will be presented in the renewal dossier although the kinetics used to derive dissipation half-lives will be re-calculated in accordance with the latest guidances (FOCUS 2006, EFSA 2010).

3.4.1.4 Soil Photolysis Study

In the 2001 EU dossier on glyphosate, several soil photolysis studies have been reviewed and summarized. The glyphosate monograph concluded that:

> "Although some differences are found between the various soil photolysis studies, taken together, the results of these soil photolysis studies show that the photolytic degradation of glyphosate on soil surfaces to AMPA is a slow process and is, at most, a very minor pathway for the degradation of glyphosate in soil."

[3] Data from the List of End Points representing both glyphosate and glyphosate trimesium

Additional Studies

No new soil photolysis studies will be presented in the renewal dossier.

3.4.1.5 Mobility studies - Adsorption and Desorption of Glyphosate and AMPA

The mobility of glyphosate in soil was also evaluated during the 2001 EU evaluation. In the studies considered "acceptable" in the Glyphosate Monograph, the K_d and K_{oc} values for glyphosate ranged from 5.3 - 900 and 884 – 60000 mL/g, respectively. K_d and K_{oc} values for AMPA ranged from 15 - 1554 and 1160 - 24800 mL/g, respectively. In general, the pH, % carbon, % clay, % sand, or % silt have minimal effect upon glyphosate and AMPA adsorption to soils. The results of these studies demonstrate that glyphosate and AMPA have very high adsorption and very low desorption values and therefore possess a very low potential for leaching in soil. Based on thin-layer chromatography (TLC) and non-aged and aged column leaching studies, glyphosate and AMPA can be classified as being immobile in soil. Lysimeter and field leaching studies were not required.

Additional Studies

In the renewal dossier, new adsorption-desorption studies with a wide range of soil characteristics will be submitted for both glyphosate and AMPA. These studies will provide a more complete picture of the sorption characteristics of glyphosate and AMPA in soil and will therefore allow a more comprehensive evaluation of the environmental fate and behaviour in soil as required by the guidance document on the assessment of the relevance of metabolites for ground water (SANCO 221/2000, rev10).

Appropriate adsorption/desorption endpoints for glyphosate and AMPA will be derived and presented in the renewal dossier.

3.4.2 Fate and Behaviour in Water

3.4.2.1 Hydrolysis Studies

As demonstrated and concluded in the 2001 EU evaluation dossier, glyphosate is stable to hydrolytic degradation in sterile water in most environmentally relevant pH ranges of 4, 7, and 9; thus, chemical decomposition does not contribute to the degradation of glyphosate in water.

3.4.2.2 Aqueous Photolysis Studies

Glyphosate does not absorb light significantly at wavelengths longer than 230 nm. Thus, in highly purified sterile water, in which direct photolysis is the only mechanism for photo-transformation, glyphosate is expected to be photo-stable.

Several aqueous photolysis studies on glyphosate were evaluated for the 2001 EU evaluation. Studies using artificial light and a solution containing calcium ions reveal slow photodegradation, while some studies using natural or simulated sunlight and sterile water show no photodegradation. At first glance, the results of the first category of studies appear to be ambiguous, and contradictory to the initial conclusions, however, since the initial EU-review, two additional glyphosate aqueous photolysis studies were conducted in natural water using artificial light in one and natural sunlight in the other study. In the Annex I renewal dossier, we will provide evidence that photo-induced degradation of glyphosate can occur in water under certain conditions. Although indirect photodegradation of glyphosate in water can occur, under normal environmental conditions photolysis is expected to be a slow process and compared to microbial degradation is, at most, a very minor pathway for the degradation of glyphosate in the environment.

3.4.2.3 Water/Sediment Studies

Glyphosate easily degrades by microorganisms in non-sterile water and water/sediment systems as demonstrated in the initial EU evaluation dossier. Indeed, degradation of glyphosate in water/sediment systems occurred with whole-system degradation DT_{50} values between 27 to 146 days and water phase dissipation DT_{50} values of 1-4 days. Biological degradation is the primary mechanism of degradation of glyphosate in water and water/sediments systems. In all cases, the results demonstrate the degradation of glyphosate to AMPA and carbon dioxide and the

subsequent degradation of AMPA to carbon dioxide, similar to the pathway in soil. In the existing water/sediment study, evaluated during EU-evaluation, AMPA was seen in the water phase at maximum 16% after 15 days and an additional metabolite, hydroxymethylphosphonic acid (HMPA), was detected in the water phases, with maximum amounts of about 10% of the dose after 61 days. In the sediments no significant metabolites were detected.

Additional Studies

In the Annex I renewal dossier two water/sediment studies from two GTF members will be submitted for both glyphosate and AMPA which provides supplementary/supporting information on the water/sediment behaviour of glyphosate and AMPA. In addition, degradation/dissipation DT_{50} values of all available water/sediment studies will be re-calculated for all relevant compartments in accordance with the kinetic approaches recommended in the latest guidance (FOCUS 2006) to support the aquatic risk assessments.

Impact on water treatment processes

The Glyphosate Monograph concludes:

> "Glyphosate and its metabolite AMPA may be classified as low mobile in soil. Therefore, it is not necessary to consider the impact on water treatment procedures".

However, in the Annex I renewal dossier the impact of glyphosate on the microorganisms in sewage treatment facilities and its removal from surface water sources by treatment processes commonly used for production of drinking water will be discussed.

3.4.3 Fate and Behaviour in Air

Glyphosate has very low vapour pressure (1.31×10^{-5} Pa at 25°C) and significant concentrations are not expected to be found in air following the use of the compound according to the proposed GAP. The fate and behaviour in air of glyphosate was evaluated during Annex I inclusion. The Glyphosate Monograph concludes that:

> "glyphosate can be classified as not volatile substance based on its Henry's law constant and on volatilization experiments from soil and plants with no significant rates. Due to no significant UV-absorption, direct photolysis in air will not occur. Once in the atmosphere rapid photochemical oxidative degradation of glyphosate will occur."

3.4.4 Predicted environmental concentrations (PEC)

For the Annex I registration of glyphosate (6511/VI/99-final, Jan. 2002) PECs in soil, ground water and surface water were generated and reported by a number of different companies and with different formulations. The PECs shown below are an example of the many submitted for glyphosate acid and AMPA from the glyphosate monograph with further supplemental data supplied in Addendum III of the monograph (Addendum to the monograph – volume 3, 11th Dec. 1998, Part A, Glyphosate, 16th October 2000).

3.4.4.1 Soil

A worst-case use-pattern of two times 4320 g/ha was used, assuming a 20 % interception value, resulting in a soil loading of 6912 g/ha. A range of soil half-lives were considered when calculating the PEC values and these are presented in Table 3.4.4-1 below. The PECs were calculated assuming a 5 cm soil depth and a bulk density of 1.5 g/cm^3.

Table 3.4.4-1: Glyphosate PECs (mg/kg) in soil with an application rate of two times 4320 g/ha

Days after last application	DT_{50} (days)				
	5	10	20	100	150
0	4.6	4.7	5.2	7.6	8.1
1	4.0	4.4	5.0	7.6	8.1
2	3.5	4.1	4.8	7.5	8.0
4	2.6	3.5	4.5	7.4	8.0
7	1.7	2.9	4.1	7.3	7.8
28	0.1	0.7	2.0	6.3	7.1
50	0.0	0.1	0.9	5.4	6.4
100	0.0	0.0	0.2	3.8	5.1

In the initial Annex I submission AMPA PECs were not provided; however, PEC data were provided in an addendum to the monograph. A summary of these data are provided in Table 3.4.4-2 generated using two models

proposed and published by FOCUS (Gustin, C., 1999, The potential persistence of glyphosate and AMPA in soil, Final report MLL 31183, Monsanto, BOD2000-594).

Table 3.4.4-2: Summary results of glyphosate and AMPA soil PECs

Output	Glyphosate	AMPA
C_0 initial PEC (mg/kg)	5.76	1.71
C_t plateau PEC (mg/kg)	5.76	5.56
C_{ap} time weighted average PEC (mg/kg)	0.8	4.69
C_{mp} maximum concentration during plateau period (mg/kg)	5.76	5.59
A_{25} amount remaining after initial application as a percentage of yearly application (%)[a]	100	328
C_{25} concentration 25 days after application (mg/kg) [a]	5.76	5.62

[a] Model used did not account for degradation.

3.4.4.2 Ground water

Two scenarios were considered when generating PEC_{GW} for glyphosate, a worst-case approach and a typical case, using the Pesticide Root Zone Model (PRZM) reporting PECs at a soil depth of 1.2 m (Gustafson, D. and Goure, W.F., 1995, BOD96-00590). Input parameters for the model are shown in Table 3.4.4-3 and the results are shown in Table 3.4.4-4.

Table 3.4.4-3: Input parameters for the PRZM model used for calculating PEC_{GW}

Glyphosate Parameter	Modelling scenario	
	Worst-case	Typical case
DT_{50} (days)	122	37.3
K_{OC} (L/kg)	3,144	17,218
Application rate (kg/ha)	4.32	
Soil	Hoerstel (sand)	
Weather	Jutland (high precipitation)	

Table 3.4.4-4: Results from the PRZM ground water simulations

Recurrence interval (years)	Glyphosate soil water concentrations (µg/L)	
	Worst-case	Typical case
10	<0.001	<0.001
3	<0.001	<0.001
2	<0.001	<0.001

In the addendum to the Monograph, PELMO modelling was provided for glyphosate and AMPA (Gustin, C., 1999, Predicted environmental concentrations of glyphosate and its major metabolite AMPA in groundwater recharge based on PELMO, MLL 31044, Monsanto, BOD2000-595). In these scenarios, 4.32 kg glyphosate/ha were applied once annually for ten consecutive years, using conservative input parameters for K_{OC} (lower 80th percentile value) and soil half-life (upper 80th percentile value for glyphosate; mean value for AMPA). The results showed that the average annual concentrations for glyphosate or AMPA in ground water at a depth of 1 m were less than 0.001 µg/L.

3.4.4.3 Surface water

Five routes of entry were considered for surface water: spray drift runoff, drainage, overspray, and atmospheric desposition. No PECs for drainage or atmospheric depoisition were supplied in the original submission, as it was thought that these routes of entry would not be applicable, based on the physical properties of glyphosate. Direct application to water (aquatic use and use across irrigation) were treated as special uses. The results from the spray drift and runoff sections are shown below.

Spray drift

Using the Ganzelmeier spray-drift values, PEC_{SW} were estimated for glyphosate with a range of buffer zone distances, assuming a model pond with 1 m^2 surface area (30 cm deep). Table 3.4.4-5 shows the predicted surface water concentrations for two crops at the highest application rate (4320 g/ha).

Table 3.4.4-5: Initial surface water concentrations of glyphosate from spray-drift

Buffer distance (m)	Initial PEC_{SW} (µg/L)		
	Field crop	Vegetable < 50 cm	Vegetable > 50 cm
0	1440		
5	8.6	8.6	72
10	5.8	5.8	22
15	2.9	2.9	12
20	1.4	1.4	5.8
30	1.4	1.4	2.9
40	0	0	2.9
50	0	0	2.9

The concentration of glyphosate following spray-drift was then calculated using the results from the water-sediment studies (Möllerfeld, J. and Römbke, J., 1993, WAS95-00135). Table 3.4.4-6 shows the concentrations in surface water over time.

Table 3.4.4-6: Glyphosate PEC_{SW} following foliar application at various rates

Days after last application	Glyphosate percentage of applied	PEC_{SW} (µg/L)		
		2160 g/ha	3600 g/ha	4320 g/ha
0	100	720	1200	1440
1	64	461	768	922
2	50	360	600	720
4	37	266	444	533
7	23	166	276	331
14	14	101	168	202
21	11	79	132	158
28	8	58	96	115
42	5	36	60	72

The surface water concentrations for AMPA were calculated to be 3 % of applied at day 1, 5 % at day 2, 11 % at day 7, 16 % at day 14, 12 % at day 30, 5 % at day 61 and 0.5 % at day 100.

Run-off

For the Annex I registration of glyphosate in 2002, data from laboratory studies were provided to demonstrate the potential run-off of glyphosate (Rueppel, M.L. and Brightwell, B.B., 1972, BOD95-00505 and Hensall, A. and Brightwell, B.B., 1972, BOD95-00521). Table 3.4.4-7 shows the results from the first study, whilst Table 3.4.4-8 shows the results from the second study. In both studies three soils were tested: a silt loam, a silty clay loam and a sandy loam.

Table 3.4.4-7: Percentage of applied radioactivity in runoff study

Study	Soil 1	Soil 2	Soil 3
	Percentage of applied radioactivity in runoff (%)		
1st study	15.7	6.0	14.9
2nd study	1.7	1.8	2.0

Table 3.4.4-8: Percentage of applied radioactivity in second runoff study

Soil No.	Day	Artificial rainfall (mins at 19 mm/h)	Supernatant (%AR)	Sediment (%AR)	Total (%AR)
1	1	60	0.0045	0.0019	0.0064
	3	12	0.001	0.0016	0.0026
	7	17	0.0003	0.0008	0.0011
	Total				0.0101
2	1	34	0.0002	0.00004	0.0002
	3	17	0.0013	0.0001	0.0014
	7	24	0.0008	0.00001	0.0008
	Total				0.0042
3	1	73	0.0064	0.0031	0.0095
	3	12	0.0007	0.0002	0.0009
	7	22	0.0002	0.0002	0.0004
	Total				0.0108

Changes to the PECs for the 2012 Annex I renewal dossier

Given the new soil route study and new soil degradation studies for glyphosate and AMPA and given the evolution in technical guidance on degredation kinetics, new half-life values will be calculated using the FOCUS kinetics methodology. FOCUS kinetics will also be used to calculate degradation DT_{50} values in water and sediment for glyphosate. The results from the updated kinetic analyses will be used in the new exposure assessment methodologies that have been developed since the first EU-evaluation of glyphosate (FOCUS ground and surface water scenarios to generate PECs for glyphosate and metabolite(s) in ground water (PEARL and PELMO) and in surface water and sediment). For soil, PECs will be generated for glyphosate and metabolite(s).

3.5 Ecotoxicology

3.5.1 Terrestrial vertebrates, terrestrial invertebrates and terrestrial plants

Terrestrial vertebrates:

Glyphosate has a low toxicity to birds and mammals. A low risk was concluded in the evaluation leading to the 2001-Annex I listing (2001-EU Evaluation). The official EU endpoints are listed below.

Study type	Test Substance	Endpoint	Ref:
Birds:			
Acute	Glyphosate	LD_{50} > 2000 mg/kg bw	SANCO/6511/VI/99-final
5 d dietary	Glyphosate	LC_{50} >4640 ppm diet *	
Repro, 21 w dietary	Glyphosate	NOEL = 200 ppm diet * [1]	
Acute	AMPA	LD50 >2250 mg/kg bw	EU Review Monograph
5 d dietary	AMPA	LC50 >5620 ppm diet	
Mammals:			
Acute toxicity	Glyphosate	LD_{50} > 2000 mg /kg bw	EU Review Monograph
short term oral toxicity to mammals (90 d, rat)	glyphosate	NOEL = 150 mg /kg bw/day	
Reproductive toxicity to mammals (2- gen, rat)	glyphosate	NOEL = 10000 mg /kg diet (700 mg /kg bw/day)	

* Will be converted to value in mg / kg bw/day for purposes of risk assessment.

1 NOEL is for bobwhite quail. The only effect observed at 1000 ppm was a reduced egg-weight (NOEL = 200 ppm). NB Hatchling bodyweight and weight gain, and chick survival were unaffected at 1000 ppm. No effects were observed in the one generation reproduction study with mallard (highest concentration tested: 1000 ppm).

Additional Studies

Several additional acute toxicity studies exist which were not included in the 2001-EU Evaluation (additional studies on quail, mallard and rat). Similarly, an additional reproduction study exists for both bobwhite quail and mallard. These studies will be submitted for completeness; and do not raise concern.

Existing guidance for long term exposure assessment for birds uses conservative generic assumptions of the magnitude of residues on arthropod food items and bird feeding rate. To provide realistic information to enable a refined long term exposure assessment for birds, a new field study on residues (and decline) of glyphosate on arthropods has been conducted (in an arable field in Germany). This will be submitted in the Annex I renewal dossier.

Terrestrial invertebrates:

Earthworms: Glyphosate has a low toxicity to earthworms. A low risk was concluded in the 2001-EU Evaluation. The official EU endpoints are listed below.

Study type	**Test substance**	**Endpoint** **Ref. SANCO/6511/VI/99-final**
Acute toxicity (earthworm *Eisenia fetida*)	glyphosate formulation	14-d LC_{50} > 480 mg as/kg*
Reproductive toxicity (earthworm *Eisenia fetida*)	glyphosate, isopropylamine salt	56-d NOEC = 28.79 mg glyphosate IPA salt/kg (21.31mg glyphosate/kg)

*LC_{50}-values exceed the highest doses tested 1000 and 5000 mg/kg dry weight soil for tests on glyphosate acid and IPA-salt respectively. Acute toxicity for a tested formulation also gave an LC_{50} value greater than highest concentration tested (LC_{50} > 480 mg as/kg).

Additional Studies

A more recent study (from 2009) has indicated a higher 56-d NOEC value based on earthworm growth, reproduction and behaviour for glyphosate of 472.8 mg/kg soil. Also, an acute study and a reproduction study on AMPA (major soil metabolite) are available which give an LC50 of >1000 mg/kg soil and a NOEC of 28.1 mg/kg soil, respectively. These three studies will be submitted; and continue to support a low-risk conclusion.

Other soil non-target macro-invertebrates: Data requirements in this area have changed since the 2001-EU Evaluation. To address the current requirements new studies have been conducted (*Hypoaspis*: glyphosate IPA salt, and AMPA; *Folsomia*: glyphosate IPA salt, and AMPA). The four studies indicate no concern for the risk assessment. They will be submitted for the Annex I renewal.

Terrestrial plants:

Dose-response studies are available for toxicity to non-target (crop) plants (one on seedling emergence; and two on vegetative vigour) which were not part of the 2001-EU Evaluation. These three studies will be submitted. As would be expected, glyphosate has an effect on vegetative vigour. In accordance with Good Agricultural Practice, users of glyphosate should take due care to minimise spray drift onto neighbouring crops or other off-target vegetation.

3.5.2 Aquatic organisms

Glyphosate has a low toxicity to fish and aquatic invertebrates. Green algae and aquatic plants are more sensitive. AMPA is concluded to be less toxic than glyphosate acid. The official EU endpoints are listed below:

Study type	**Test Substance**	**Endpoint**	**Ref:**
Fish:			
Acute; rainbow trout (*Oncorhynchus mykiss*)	Glyphosate acid	96 hr LC50: 38 mg/L	SANCO/6511/VI/99-final
Chronic: fathead minnow*(Pimephales promelas)*; Full Life Cycle	Glyphosate acid	NOEC: 25 mg/L	

Study type	Test Substance	Endpoint	Ref:
Acute; rainbow trout (*Oncorhynchus mykiss*)	AMPA	96 h LC50: 520 mg/L	EU Review Monograph
Aquatic invertebrates:			
Acute; *Daphnia magna*	Glyphosate acid	48 hr EC50: 40mg/L	SANCO/6511/VI/99-final
Chronic; *Daphnia magna*	Glyphosate acid	NOEC: 30 mg/L	
Acute; *Daphnia magna*	AMPA	48 h EC50: 690 mg/L	EU Review Monograph
Algae:			
Saltwater diatom (*Skeletonema costatum)*	Glyphosate acid	168 hr EC50: 0.64 mg/L	SANCO/6511/VI/99-final
Freshwater green (*Scenedesmus subspicatus*)	Glyphosate acid	72 hr EC50: 46 mg/L	EU Review Monograph
Freshwater green (*Pseudokirchneriella subcapitata*)	Glyphosate acid	72 hr EC50: 48 mg/L	
Freshwater green (*Pseudokirchneriella subcapitata*)	AMPA	72 h EC50: 89.8 mg/L	
Aquatic plants:			
Lemna gibba	Glyphosate acid	7 day EC50: 12 mg/L	SANCO/6511/VI/99-final

Additional Studies

Various additional acute toxicity studies exist for fish, *daphnia* and algae which were not part of the 2001-EU Evaluation. These studies will be submitted for completeness, and do not raise additional concerns.

The dossier supporting renewal of the Annex I listing will also include the following new studies (the overall rationale for conducting these studies is to enable completion of the risk assessment under Regulation 1107/2009):

- Fish Early Life Stage (ELS) study on rainbow trout with glyphosate acid.
- Fish ELS study on the fathead minnow with AMPA.
- Chronic toxicity study on *Daphnia magna* with AMPA.
- Growth inhibition study on the rooted aquatic macrophyte *Myriophillum aquaticum* in presence of sediment, with glyphosate acid.
- Growth inhibition study on the rooted aquatic macrophyte *Myriophillum aquaticum* in presence of sediment, with AMPA
- Growth inhibition study on the rooted aquatic macrophyte *Myriophillum aquaticum* in presence of sediment, with the lead formulation (MON 52276)
- Acute toxicity studies on *Daphnia magna*, *Lemna gibba* and green algae with metabolite hydroxy-methyl phosphonic acid (HMPA).

The following studies will be conducted for the US EPA Endocrine Disruptor Screening Program (EDSP) and may be available at the time of the submission of the EU Annex 1 renewal dossier:

- Fish Short Term Reproduction Study on fathead minnow, with glyphosate acid.
- Amphibian Metamorphosis Assay on *Xenopus laevis*, with glyphosate acid.

3.5.3 Bees and other beneficial arthropods

Technical glyphosate and glyphosate formulations were found to be of low toxicity to adult **honeybees** after oral and topical dosing. The conclusion of the 2001-EU Evaluation was low risk to bees.

Additional Studies

Several additional acute toxicity studies exist which were not part of the 2001-EU Evaluation. These studies will be submitted for completeness, and do not raise concern.

The dossier supporting renewal of the Annex I listing will also include the following new study (the rationale for conducting this study is specifically to enable completion of the risk assessment under Regulation 1107/2009; there is no *a priori* concern regarding possible effect of glyphosate on bee brood):

- Bee brood feeding study (Oomen method) with glyphosate acid (or IPA salt).

Existing data on **non-target arthropods** were assessed during the 2001-EU Evaluation, and are summarised in SANCO/6511/VI/99-final; with the conclusion being low risk. To supplement the data set, additional rate response studies with the lead formulation will be submitted in the dossier, for *Aphidius rhopalosiphi* (laboratory; glass plate), *Typhodromus pyri* (laboratory; glass plate), *Aleochara bilineata* (extended lab, soil substrate).

3.5.4 Soil non-target micro-organisms

Laboratory studies demonstrate that there is negligible long-term risk to non-target soil micro-organisms following exposure to glyphosate residues in soil.

Substance	Test design	Ref. SANCO 6511/V1/99 – final
Glyphosate	Carbon and Nitrogen transformation. No significant effects >25%	NOEC 18 kg as/ha

No adverse effects of the test item on nitrogen and carbon transformation in soil were observed up to and including a test concentration of 160 mg/kg soil dry weight, 28 days after application.

Additional Studies

In addition, for the Annex I renewal submission a new study for AMPA will be submitted.

3.6 Definition of the Residues

3.6.1 Glyphosate Monograph

Non-tolerant plants

Plant metabolism studies in non-tolerant crop plants demonstrated that in most cases the residues of AMPA are not significant. AMPA is an animal and soil metabolite, has low acute oral toxicity (LD_{50} >5000 mg/kg), and a mutagenicity study has shown that AMPA is not mutagenic. In addition, due to difficulties with analysis of both glyphosate and AMPA at many analytical laboratories, it was proposed that AMPA should not be included in the MRL expressions to avoid artifacts and mistakes in monitoring programs for supervision of MRLs. As a result, it was concluded in the initial evaluation that the residue definition for monitoring and risk assessment for plants should be: glyphosate.

Animal products:

Radiolabelled studies in lactating goats and laying hens following oral administrations of glyphosate and AMPA, the primary plant metabolite of glyphosate, showed that metabolites resulting from the degradation of these compounds in edible tissues, milk and eggs were either insignificant or entirely absent. Therefore, it was concluded in the initial evaluation that the residue definition for monitoring and risk assessment for animal products should be: glyphosate.

Glvphosate tolerant plants:

In glyphosate tolerant plants, in particular those also containing the GOX enzyme (glyphosate oxidoreductase enzyme), metabolism studies demonstrated that the metabolite AMPA may be present at higher levels than in non-tolerant plants. It was concluded in the initial evaluation that if the use pattern of glyphosate were expanded in the future to cover these tolerant crops, the residue definition for tolerant crops may need to be: AMPA besides glyphosate.

3.6.2 Glyphosate-Trimesium Monograph

The conclusions in the glyphosate-trimesium monograph regarding definition of the residue for the glyphosate portion of the molecule are consistent with those in the glyphosate monograph.

3.7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

3.7.1 Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Glyphosate	Studies have demonstrated that glyphosate is degraded by soil micro organisms and should be non persistent in soil. The DT_{50} for the degradation of glyphosate in various soils under aerobic conditions in laboratory studies ranged from 4 to 180 days, and were typically less than 25 days; 90% degradation times ranged from 40 to 280 days.	Glyphosate has a low toxicity to earthworms and other soil macro organisms. In addition there is negligible long term risk to non target soil micro organisms following exposure to glyphosate residues in soil.
Aminomethyl phosphonic acid (AMPA)	AMPA is further degraded by soil microorganisms, although at a slower rate than glyphosate. The DT_{50} for the degradation of AMPA calculated based on data from a glyphosate aerobic laboratory degradation study ranged from 77 to 155 days. AMPA DT_{50} values from multiple field locations ranged from 13 to 875 days. The potential soil persistence of AMPA will be further discussed in the renewal dossier.	AMPA is concluded to be less toxic than glyphosate acid.

3.7.2 Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Glyphosate	low	none	Herbicide	Low acute short term toxicity; not genotoxic; no evidence of carcinogenicity; no neurotoxic effects	See surface water risk assessment, 3.7.3.

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Aminomethyl phosphonic acid (AMPA)	low	none	none	Less toxic than the parent compound.	See surface water risk assessment, 3.7.3.

3.7.3 Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Glyphosate	Glyphosate has a low toxicity to fish and aquatic invertebrates. Green algae and aquatic plants are more sensitive to this herbicide.
Aminomethyl phosphonic acid (AMPA)	AMPA is concluded to be less toxic than glyphosate acid.

3.8. Information on Classification and labelling

Glyphosate:

Classification	Hazard statement codes	Pictogram, Signal word codes
Eye damage 1	H318	GHS05
Aquatic chronic 2	H411	GHS09
		Danger

Salts of Glyphosate (with the exception of those specified elsewhere in Annex IV of Regulation (EC) No 1272/2008) NOTE: glyphosate trimesium is currently the only exception and is not part of this application):

Classification	Hazard statement codes	Pictogram, Signal word codes
Aquatic chronic 2	H411	GHS09

4 List of studies to be generated, still ongoing but not evaluated and/or peer reviewed

The Glyphosate task force to the best of its knowledge at the time of notification for renewal, expects that the technical dossier supporting the renewal of glyphosate will include the following **non-vertebrate studies** and pieces of information that did not contribute to the initial Annex I inclusion decision.

As indicated in the table below data protection is claimed for confirmatory studies that have not previously been evaluated at EU-level. This claim will be withdrawn if and when these studies are formally confirmed as not essential (and therefore do not need to be submitted) during the Annex-I renewal evaluation process.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 2. Physical and chemical properties of the active substance				**In the different existing phys-chem. studies, test items of different purity are used. This in addition to experimental variability, results sometimes in deviations from the existing endpoints. In general existing endpoints are still supported.**	
	2005	Remnant, V., 2005. Glyphosate technical: Physico chemical properties Huntingdon Life Sciences Ltd. NUF082/043728. GLP, unpublished	Y	NUF	Existing study with no impact on standing endpoints and conclusions from the 2001 EU Evaluation
	2005	Remnant, V., 2005. Glyphosate technical: Physico chemical properties Huntingdon Life Sciences Ltd. NUF081/043684. GLP, unpublished	Y	NUF	Existing study with no impact on standing endpoints and conclusions from the 2001 EU Evaluation
	2006	Comb, AL., 2006. Glyphosate technical acid, NUP 05070 Physico chemical Properties. Huntingdon Life Sciences Ltd. NUF0181/062691. GLP, unpublished	Y	NUF	Existing study with no impact on standing endpoints and conclusions from the 2001 EU Evaluation
	2006	Comb, AL., 2006. Glyphosate technical acid, NUP 05068: Physico chemical properties, TGAI Huntingdon Life Sciences Ltd. NUF0179/062689 GLP, unpublished	Y	NUF	Existing study with no impact on current endpoints and conclusions from the 2001 EU Evaluation
	2002	Woolley, S.M. and Mullee, D.M., 2002. Sinon glyphosate (pure): Determination of general physical chemical properties and spectra, Project No. 1057/013.	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2002	Evans, A.J., 2002. Sinon, Glyphosate (Technical): Determination of Physico Chemical Properties: SPL Project No. 1057/014	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2002	Evans, A.J. and Mullee, D.M., 2002. Sinon Glyphosate (technical) IPA salt: Determination of physical chemical properties, Project No. 1057/018	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2007	Midgley, B. and De Ryckel, B., 2007. Physical chemical properties of glyphosate Potassium salt, Monsanto report MSL 00221012, GLP unpublished	Y	MON	Existing study not previously evaluated and required to support K salt registration

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2011	Complementary phys chem data package for glyphosate potassium salt Experimental Facility : to be decided Status: to be initiated Final report : Expected August 2011 (GLP)	Y	GTF	New study required to support K salt registration
IIA 2.1.1. Melting point	2001	Walter, D., 2002. Melting temperatures of Glyphosate free acid, GAB & IFU, Niefern Öschelbronn, Germany; 20021094/01 PCMP;GLP not published	N	FSG	Existing study with no impact on existing endpoint
	2001	Joshi Chetan, 2001. Melting point of Glyphosate technical, Jai Research Foundation, Vapi, India 3161;GLP, unpublished	N	EXC	Confirmatory study in support of existing endpoints
	1994	Van Helvoirt J.A.M.W., 1994. Determination of the melting temperature of glyphosate technical; Notox report 122333; GLP	N	AGR	Existing study with no impact on existing endpoint
	2002	Bolton A, 2002. Physical properties of Sinon glyphosate. CEMAS Report No. CEMS 1882	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2002	Davidson AJ, 2002.Determination of the physico chemical properties of glyphosate IPA salt; Inveresk 281759	Y	AGR	Existing study with no impact on conclusions from the 2001 EU Evaluation
IIA 2.2. Relative density of purified active substance	2001	Desai, H., 2001. Tap Density of Glyphosate technical Jai Research Foundation, Vapi, India 3162; GLP, unpublished	N	EXC	Study with no impact on existing endpoint
	2008	Remnant, V., 2008. Glyphosate technical acid, NUP 07170, Physical chemical properties Relative Density Huntingdon Life Sciences Ltd. NUF0429; GLP, unpublished	Y	NUF	Confirmatory study in support of the existing endpoint
	2002	Walter D., 2002. Relative density of Glyphosate free acid, GAB & IFU, Niefern Öschelbronn, Germany, 20021094/01 PCRD, GLP, not published	N	FSG	Confirmatory study in support of existing endpoints
	2002	Davidson AJ, 2002.Determination of the physico chemical properties of glyphosate IPA salt; Inveresk 281759; GLP	Y	AGR	Existing study with no impact on conclusions from the 2001 EU Evaluation
	2002	Walter D., 2002. Relative density of Glyphosate Isoprpylamine Salt 62 %; GAB & IFU, Niefern Öschelbronn, Germany; 20021095/01 PCRD; GLP not published;	N	FSG	Existing study with no impact on conclusions from the 2001 EU Evaluation
IIA 2.3.1. Vapour pressure of purified active substance	2003	Srivastav, V.2003. Vapor pressure of Glyphosate technical , Jai Research Foundation, Vapi, India, 4164; GLP, unpublished	Y	EXC	Existing study with no impact on current endpoint (although the result deviates significantly compared to the existing endpoint, the weight of evidence from the other studies confirms the relevance of the current endpoint)
IIA 2.4.2 Appearance	2002	Walter D., 2002. Appearance, colour and odour of Glyphosate free acid, GAB & IFU, Niefern Öschelbronn, Germany; 20021094/01 PCAO; GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2001	Savyad K.A., 2001. Appearance (color, physical state and odor) of Glyphosate technical. Jai Research Foundation, Vapi, India 3160; GLP, unpublished	N	EXC	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2008	Remnant V., 2008. Glyphosate technical acid, NUP 07170, Physico chemical properties Appearance, Huntingdon Life Sciences Ltd., NUF0429; GLP, unpublished	Y	NUF	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	1995	Krips, HJ, 1995.Determination of the appearance of glyphosate; NOTOX 141839 GLP; unpublished	N	AGR	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Walter D., 2002. Appearance, colour and odour of Glyphosate isopropylamine salt 62%. GAB & IFU, Niefern Öschelbronn, Germany; 20021095/01 PCAO; GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Davidson A.J. 2002. Determination of the physico chemical properties of glyphosate IPA salt; Inveresk 281759; GLP, unpublished	Y	AGR	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 2.5.1. 1.	2008	Remnant V., 2008. Glyphosate technical acid, NUP 07170, Physico chemical properties UV / Visible, Huntingdon Life Sciences Ltd, NUF0429 ; GLP, unpublished	Y	NUF	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Woolley S.M. and Mullee D.M., 2002. Sinon glyphosate (technical) IPA salt: Determination of spectra, Project No. 1057/017.	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 2.5.2. Spectra for impurities	2002	Schneider E., 2002. UV/Vis spectrum of N Nitroso Glyphosate. UCL GmbH, Köln, Germany; PR02/010; GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Herling H., 2002. N Nitroso Glyphosate: Synthesis and spectroscopic characterisation. Spectral Servive, Köln, Germany, SSL01602; GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Cuthbert, J.E., 2002.N Nitroso, N (phosphonomethyl)glycine: Determination Spectra: SPL Project No. 1057/016	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 2.6. Solubility in water	2002	Joshi Chetan, 2002. Water solubility of Glyphosate technical Jai Research Foundation, Vapi, India 3763; GLP, unpublished	Y	EXC	Study with no impact on the existing endpoint
IIA 2.7. Solubility in organic solvents	2002	Walter D., 2002. Solubility of Glyphosate free acid in organic solvents, GAB & IFU, Niefern Öschelbronn, Germany; 20021094/01 PSBO; GLP, not published	N	FSG	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1992	Bates, 1992. Glyphosate IPA Salt. Determination of Solubility in Organic Solvents. Hazleton UK; Project No.: 7068 676/7 2. GLP, unpublished report CHA Doc. N°: 98GLY	N	CHE	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 2.8. Partition coefficient	2002	Agarwal M., 2002. Partition coefficient of Glyphosate technical, Jai Research Foundation, Vapi, India, 3164; GLP, unpublished	Y	EXC	Confirmatory study in support of the existing endpoint
IIA 2.9.1. Hydrolysis rate	1996	Kolk, J., 1996. Glyphosate: Determination of the Hydrolysis as a Function of pH in Compliance with OECD Guideline 111: Springborn Report No. 96 115 1020	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 2.9.5. Dissociation in water	2002	Suratwala, 2002. Determination of dissociation constant of Glyphosate technical by titrimetric method, Jai Research Foundation, Vapi, India 3168;GLP, unpublished	Y	EXC	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 2.10 Estimated photochemical oxidative degradation	2001	Schneider E., 2001. Predictive model calculation of the atmospheric oxidation behaviour: Glyphosate , Feinchemie Schwebda GmbH, Eschwege, Germany; non GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2001	Joshi Chetan, 2001. Oxidation / Reduction property of Glyphosate technical, Jai Research Foundation, Vapi, India 3166; GLP, unpublished	N	EXC	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2008	Remnant, V., 2008. Glyphosate technical acid, NUP 07170, Physico chemical properties Oxidation / Reduction; Huntingdon Life Sciences Ltd NUF0429	Y	NUF	Confirmatory study in support of the conclusions from the 2001EU Eevaluation
	2001	Schneider E., 2001. Predictive model calculation of the atmospheric oxidation behaviour: Glyphosate isopropylamine salt 62%. Feinchemie Schwebda GmbH, Eschwege, German;, non GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 2.11.1. Flammability	1999	Walter D. 1999. Flammability (solids) of Glyphosate 95% technical, GAB & IFU, Niefern Öschelbronn, Germany; 99163/01 PCFS; GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2001	Desai H., 2001. Flammability of Glyphosate technical, Jai Research Foundation, Vapi, India 3165; GLP, unpublished	N	EXC	Confirmatory study in support of the conclusions from the 2001 EU Eevaluation
	2002	Walter D. 2002. Flammability (solids) of Glyphosate isopropylamine salt 62%, GAB & IFU, Niefern Öschelbronn, Germany; 20021095/01 PCFS; GLP not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 2.11.2. Auto-flammability	1999	Warncke U., 1999. Determination of the Self Ignition Temperature of the Test Substance Glyphosate Techn., Urania Agrochem GmbH, Christinenthal, Germany U99PCH02; GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2001	Francke J., 2001. Glyphosate Isoprpylamine Salt 62% 170700: Auto flammability (determination of the temperature of self ignition of volatile liquids and of gases); Siemens Axiva GmbH, Frankfurt am Main, Germany; 20020417.01; GLP; not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Jackson W.A., 2002. Determination of Physical and Chemical Properties: 759Salt Syngenta Technology & Projects HT02/074 ;GLP, Not published	Y	AGC	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 2.13.Explosive properties	2002	Jackson W.A., 2002. Thermal stability/ Stability in Air: 759Acid, Syngenta Technology & Projects, HT02/075; GLP, Not published	Y	AGC	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	2002	Jackson W.A., 2002. Determination of Physical and Chemical Properties: 759 Salt; Syngenta Technology & Projects; HT02/074, GLP, not published	Y	AGC	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
	1999	Anonymous, 1999. Glyphosate: Document K, Annex II Point: 2.13, Explosivity, EBRC Consulting GmbH, Hannover, Germany, non GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 evaluation
	2002	Battersby R.V., 2002. Glyphosate technical, Isopropylamine Salt: Document K, Annex II Point: 2.13, Explosivity, EBRC Consulting GmbH, Hannover, Germany, FCS 020501 01; non GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 evaluation
IIA 2.14 Surface tension	1999	Walter D., 1999. Surface tension of Glyphosate 95% techn., GAB & IFU, Niefern Öschelbronn, Germany; 99163/01 PCST; GLP, not published	N	FSG	Existing study with no impact on conclusions from the 2001 EU Evaluation
	2002	Walter D., 2002. Surface Tension of Glyphosate Isopropylamine Salt 62 %, GAB & IFU, Niefern Öschelbronn, Germany, 20021095/01 PCST, GLP, unpublished	N	FSG	Existing study with no impact on conclusions from the 2001 evaluation
IIA 2.15 Oxidizing properties	1999	Anonymous, 1999. Glyphosate technical: Document K, Annex II Point: 2.15, Oxidising properties, EBRC Consulting GmbH, Hannover, Germany, non GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 evaluation
	2002	Battersby R., 2002. Glyphosate technical, Isopropylamine salt: Document K, Annex II Point: 2.15, Oxidising properties; EBRC Consulting GmbH, Hannover, Germany; FCS 020501 02; non GLP, not published	N	FSG	Confirmatory study in support of the conclusions from the 2001 EU Evaluation
IIA 3.6 Information on possible occurrence of the development of resistance or cross resistance	2012	The GTF will provide an update of the state of the art regarding resistance development Experimental Facility : not relevant Status: In progress Final report : Will be available at time of submission (non GLP)	Y	GTF	New report essential to meet a regulatory data requirement

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 4.3. Analytical methods for the determination of residues	2001	Ely S.V., 2001. Analytical Method: Residue Analytical Method for the Determination of PMG and AMPA in Crops. , Report no.: RAM 328/01 GLP: No (see validation report below) Published: Yes method as J. Agric Food Chem. 1994 42, 2751 2759 (Alferness/Iwata)	N	SYN	Existing report, essential to meet a regulatory data requirement
	2001	Anderson, L., 2001. Validation of Analytical Method: PMG and AMPA Validation of a Residue Analytical method for Determination in Various Crops. Report no.: RJ3119B , GLP: Yes, Published: No	N	SYN	Existing report essential to meet a regulatory data requirement
	2001	Schneider V., 2001. Validation of an analytical method for the determination of Glyphosate in foodstuff of animal origin (meet, eggs, milk), Report no.: PR01/005, GLP: Yes; Published: No	N	FSG	Confirmatory study in support of the conclusions from the 2001 evaluation
	2007	Klimmek S., 2007. Validation of the analytical method DFG Method 405 for determination of residues of Glyphosate and its metabolite AMPA in various plant materials., Report No: FCS 0703V (and amendment) , GLP: Yes; Published: No	N	FSG	Analytical method to study Weber H., 2010. Storage stability of residues of Glyphosat and AMPA in various plant materials
	2007	Crook S.J., 2007. ILV: Technical letter justifying published data as a suitable ILV for RAM 328/01. Report no.: Technical letter J6696/01, GLP: No Published: No but refers to published document Alferness P.L. And Weibe L.A. (2001) Determination of Glyphosate and Aminomethylphophonic acid in crops by capillary gas chromatography with mass selective detection: Collaborative Study Journal of AOAC International 84, 3, 824 846	Y	SYN	A new technical report justifying the use of published data as suitable replacement for an ILV for the crop method.
	2004	Norris, D., 2004. Validation of the method for determination of Glyphosate and Aminomethyl Phosphonic Acid residues in Orange and Olive whole fruit, and related specified matrices in compliance with Good Laboratory Practice, Study No. OA01006	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 4.4. Description of methods for analysis of residues in soil	2001	Schneider V., 2001. Validation of an analytical method for the determination of Glyphosate in soil , Report no.: PR01/006, GLP: Yes; Published: No	N	FSG	Confirmatory study in support of the conclusions from the 2001 evaluation
IIA 4.5. Description of methods for analysis of residues in water	2010	Knoch, E., 2010. Validation of an Analytical Method: Determination of Glyphosate and AMPA in Water Matrices Using FMOC Derivatization, Manual SPE Cleanup and LC MS/MS Quantitation Report No. : IF 10/01618859, GLP: Yes; Published: No	Y	GTF	New report required to meet a regulatory data requirement
	2011	ILV for analytical method in drinking water Experimental Facility : GAB Status: In progress Final report: Will be available May 2011(GLP)	Y	GTF	New report required to meet a regulatory data requirement

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 4.7. Description of methods for analysis of residues in air	2001	Schneider V., 2001. Validation of an analytical method for the determination of Glyphosate in air, Report No. : PR01/007 GLP: Yes; Published: No	N	FSG	Existing report required to meet a regulatory data requirement
IIA 5.4 Genotoxicity					
IIA 5.4.1 *In vitro* genotoxicity testing Bacterial assay for gene mutation	1995	Mie, 1995. HR 001: Reverse mutation test IET 94 0142	N	ALS	Confirmatory study in support of the existing endpoint
	2009	Sokolowski A. 2009, *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay with Glyphosate Technical, 1236400, GLP, Unpublished (Harlan, Switzerland).	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	Flügge C., 2009. Mutagenicity Study of Glyphosate TC in the *Salmonella typhimurium* Reverse Mutation Assay (*in vitro)*LPT 23916	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	Sokolowski A., 2010. *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay with Solution of Glyphosate TC spiked with Glyphosine Harlan. 1332300 (C88237)	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	Flügge C., 2010. Mutagenicity Study of Glyphosate TC in the *Salmonella typhimurium* Reverse Mutation Assay (*in vitro*). LPT 24880	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	Wallner B., 2010. Reverse Mutation Assay using Bacteria (*Salmonella typhimurium*) with Glyphosate TC. BSL 101268	Y	HAG	Confirmatory study in support of the existing endpoint
	2007	Ribeiro do Val R., 2007. Bacterial reverse mutation test (Ames Test) for Glifosato Técnico Helm TECAM. 3393/2007 2.0AM B	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	Miyaji, 2008. Evaluation of the mutagenic potential of the test substance Glyphosate Technical by reverse mutation assay in *Salmonella typhimurium* (Ames Test). Bioagri. RF 3996.401.392.07	Y	HAG	Confirmatory study in support of the existing endpoint
	2007	Sokolowski, 2007. *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay with Glyphosate technical (NUP 05068). 1061401	Y	NUF	Confirmatory study in support of the existing endpoint
	2007	Sokolowski, 2007.*Salmonella typhimurium* and *Escherichia coli* reverse mutation assay with Glyphosate technical (NUP 05070). 1061402	Y	NUF	Confirmatory study in support of the existing endpoint
	2007	Sokolowski, 2007. *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay with Glyphosate technical (NUP 05067). 1061403	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	Thompson, 1996 .Technical glyphosate: Reverse mutation assay "Ames test" using *Salmonella typhimurium and Escherichia coli* SPL434 014	Y	NUF	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2000	Ranzani, 2000. Evaluation of the mutagenic potential of the test substance Glifosato IPA Técnico Nufarm by reverse mutation assay in *Salmonella typhimurium* (Ames test)RF G11.040/00	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	Callander RD, 1996. Glyphosate acid: An Evaluation of Mutagenic Potential Using *S.typhimurium* and *E.coli*	N	SYN	Confirmatory study in support of the existing endpoint
	1996	Yang, H.G., 1998. Ames Test of Glyphosate Technical 95%, STCPSE Report No. R9806020S0, unpublished	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2008	Cintia Kaori Miyaji, 2008. Evaluation of the mutagenic potential of the test substance glyphosate technical by reverse mutation assay in *Salmonella typhimurium* (Ames Test). Bioagri Laboratorios report RF 3996.401.392.07, unpublished	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 5.4.2 *In vitro* genotoxicity testing Test for clastogenicity in mammalian cells	1995	Kyomu, 1995. HR 001*: In vitro* cytogenetics Test. IET 94 0143	N	ALS	Confirmatory study in support of the existing endpoint
	1996	Wright, N. P., 1996. Technical glyphosate: chromosome aberration test in CHL (Chinese Hamster Lung) cells *in vitro* SPL434 015	Y	NUF	Confirmatory study in support of the existing endpoint
	1998	Fox V., 1998. Glyphosate acid: *In Vitro* Cytogenetic Assay in Human Lymphocytes	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.4.3 *In vitro* genotoxicity testing Test for gene mutation in mammalian cells	1995	Mie, 1995. HR 001: DNA repair Test (Rec Assay). IET 94 0141	N	ALS	Confirmatory study in support of the existing endpoint
	1996	Clay P, 1996. Glyphosate Acid: L5178Y $TK^{+/}$ Mouse Lymphoma Mutation Assay	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.8 Toxicity studies on metabolites	1996	Mie, 1996. AMPA, Reverse Mutation Test IET 96 0076	N	ALS	Confirmatory study in support of the existing endpoint
	2002	Nesslany, 2002. Measurement of unscheduled DNA synthesis (UDS) in rat hepatocytes *in vitro* procedure with AMPA (Amino methyl phosphonic acid). IPL R 020625	N	ALS	Confirmatory study in support of the existing endpoint
	1998	Callander R. D., 1988. Aminomethyl Phosphonic Acid: An Evaluation of Mutagenic Potential Using *S.typhimurium* and *E.coli*	N	SYN	Confirmatory study in support of the existing endpoint
IIA 6.1.1 Stability during storage of samples	1993	Hubbard, N.S. (1993) Determination of glyphosate in soybean raw agricultural commodities (RAC) stability report Huntingdon Life Sciences Inc. Study No.: 91210, Unpublished report, CHA Doc. No.: 455 GLY (June 1993)	N	CHE	This study provides additional stability information This study was submitted in April 1999, i.e. before the ECCO review but after the 1st draft of the Monograph. Therefore it has been submitted, but may not have been reviewed

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1993	Hubbard, N.S. (1993), Determination of glyphosate in pasture grasses stability report, Huntingdon Life Sciences Inc. Study No.: 91212, Unpublished report, CHA Doc. No.: 456 GLY (June 1993)	N	CHE	This study provides additional stability information This study was submitted in April 1999, i.e. before the ECCO review but after the 1st draft of the Monograph. Therefore it has been submitted, but may not have been reviewed
	2010	Weber H., 2010. Storage stability of residues of Glyphosat and AMPA in various plant materials, Eurofins Dr. Specht GLP GmbH, FCS 0707, GLP, unpublished	Y	FSG	New study providing additional stability information
	2011	Mueth, M. (2011) Storage Stability of Glyphosate and AMPA in Citrus Fruit Experimental Facility : Monsanto ESTC Status: In progress Final report : Will be available early 2012 (GLP)	Y	GTF	This study fills an existing data gap for storage stability in an acidic crop
IIA 6.3. Residue trials	2011	Supervised residue field trials for pre emergent use of MON 52276 in crops representative for all major crop families. Trial initiation: Spring 2011 Final report December 2011 In addition Additional residue studies supporting selected GAP uses and not included in the previous submissions may be submitted to support the existing database.	Y	GTF	Updates database for preemergence uses with GLP trials
IIA 6.5.1. Nature of residue during processing	2010	Tammy Hiler, 2010. Nature of [^{14}C] glyphosate residues in processed commodities High temperature hydrolysis, Monsanto Report Number: MSL0023072, PTRL Report Number: 1925W 001. GLP, unpublished	Y	GTF	This study fills an existing data gap
IIA 7.1. Route of degradation in soil **IIA 7.1.1. Aerobic degradation**	2010	Ponte, 2010. Rate and Route of Degradation of [14C] Glyphosate in One Soil Incubated Under Aerobic Conditions Monsanto Company Report No.: MSL0023070/PTRL1923W 1 GLP: yes Published: No	Y	GTF	This study was conducted by the Glyphosate Task Force to overcome all shortcomings and compliance issues of existing soil metabolism studies. It provides a complete picture of the fate of glyphosate in soil and will allow evaluation of the environmental fate and behaviour of AMPA or any other potential soil metabolites that may occur in soil at concentrations above 5%.to be assessed as required by the guidance document on the assessment of the relevance of metabolites for ground water (SANCO 221/2000, rev10)
	1995	Nakanishi T., Aerobic soil metabolism and route of degradation. Huntingdon Life Sciences Ltd. Report No.: SNY 333	Y	ALS	This study has not been previously reviewed by EU and provides additional information on the fate of glyphosate in soils with wider range of soil characteristics to refine risk assessment endpoints (SANCO 221/2000, rev10)
	1996	Goodyear, A., 14C Glyphosate: Aerobic soil metabolism Corning Hazleton Europe Report No.: CHE 1413/1	Y	NUF	This study has not been previously reviewed by EU and provides additional information on the fate of glyphosate in soils with wider range of soil characteristics to refine risk assessment endpoints (SANCO 221/2000, rev10)

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1996	McLaughing, S., 1996. [^{14}C] Glyphosate: Determination of Soil Degradation, Biotransformation and Metabolism under Aerobic Conditions. Springborn Report No. 96 120 1020	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 7.1.2. anaerobic degradation	2003	Lowrie; M. A. Clayton; and K. Paterson, 2003. The Degradation of [14C] Glyphosate in Soil Under Anaerobic Conditions , Generated by: Monsanto Company, Submitted by : Monsanto Company, Report No.: MSL 18018, GLP: yes, Published: No	Y	MON	This study has not been previously reviewed by the EU and provides additional information on the anaerobic laboratory rate of degradation of glyphosate according to the requirements of the new OECD Guideline 307 for anaerobic transformation in soil
	2004	McEwen, A., 2004. [^{14}C] Glyphosate: Anaerobic Soil Metabolism (Rate and Route of Degradation in a Sandy Loam Soil, BioDynamics Study No. SNN/05	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 7.2.1 Aerobic degradation of the active substance in soils at 20 °C	2010	Ponte, 2010. Rate of Degradation of [14C] Glyphosate in Three Soils Incubated Under Aerobic Conditions, Monsanto Company Report No.: MSL0023071/PTRL1946W 1 GLP yes, Published: No	Y	GTF	This study was conducted by the Glyphosate Task Force to provide additional information on the rate of degradation of glyphosate in soils with wider range of soil characteristics (eg current range in pH was too narrow according to latest guidance) to refine risk assessment endpoints (SANCO 221/2000, rev10)
	2002	Mamouni, A., Amendment (Addendum) to Report RCC 271618: Degradation of 14C Glyphosate in Three Soils incubated under Aerobic Conditions, Unpublished Cheminova A/S report 157 GLY amdt 1	N	CHE	This study has not been previously evaluated at the EU level but the study was submitted to a Member State in support of a national registration. This study provides information on the fate of AMPA under laboratory aerobic soil degradation conditions
IIA 7.4.1 Adsorption and desorption of the active substance	2001	van Noorloos B., Slangen, P.J.. 2001. Adsorption/desorption of Glyphosate on soil. NOTOX 320164, GLP: Yes, Published: No	Y	AGC	This study has not been previously evaluated at the EU level but the study was submitted to a Member State in support of a national registration. The study provides additional adsorption desorption coefficients in various soils with wide range of soil characteristics to refine risk assessment endpoints (SANCO 221/2000, rev10).
	1996	Kolk, J., 1996.Glyphosate: Determination of Adsorption and Desorption Properties Based on the OECD Method 106: Springborn Report No. 95 111 1020	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 7.4.2 Adsorption and desorption of all relevant* metabolites, degradation and reaction products	2002	Knoch, E., 2002. Aminomethylphosphonic acid: Adsorption Desorption. Institut Fresenius Chemische und Biologische Laboratorien GmbH, Herten, Germany. Report No.: IF 02/00005220, GLP: Yes Published: No	N	ALS	This study has not been previously evaluated at the EU level but the study was submitted to a Member State in support of a national registration. The study provides additional adsorption desorption coefficients in various soils with wide range of soil characteristics to refine risk assessment endpoints (SANCO 221/2000, rev10).

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2002	Wittig, A.; Bockholt, K., 2002. Adsorption/desorption behaviour of AMPA on soil according OECD 106 (adopted January 2000), UCL GmbH, Köln, Germany, Report No. PR02/007, GLP: Yes Published: No	N	FSG	This study has not been previously evaluated at the EU level but the study was submitted to a Member State in support of a national registration. The study provides additional adsorption desorption coefficients in various soils with wide range of soil characteristics to refine risk assessment endpoints (SANCO 221/2000, rev10).
	2002	O'Connor, B.J. & Mullee D.M., 2002. Aminomethylphosphonic Acid: Determination of Soil Adsorption Coefficient: SPL. Project No. 1057/015	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 7.4.5 Aged residue column leaching	1996	McLaughin, S., 1996. [^{14}C] Glyphosate: Determination of the Mobility of Aged Residues in One Soil: Springborn Report No. 96 121 1020	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 7.6 Direct phototransformation of relevant metabolites, degradation and reaction products in water	2001	Dean, G.M., Caldwell, E., 2001. Determination of the rate of photolytic degradation in Natural water under laboratory conditions, Report No. ZCA/069, GLP: Yes, Published: No	Y	SYN	This study provides information on the photo induced degradation of glyphosate in water In the dossier this study will be listed under Point 2.9.2 of the Phys chem. section
	2010	Mehrsheikh, A., 2010. Review of Direct and Indirect Photolysis of Glyphosate: MON Internal document	Y	GTF	This review provides information on the photo induced degradation of glyphosate in water In the dossier this study will be listed under Point 2.9.2 of the Phys chem. section
	2005	Ponte, M.., 2005. Degradation Study: Photodegradation of [14C] Glyphosate in Sterilized Pure Water and Natural Water by Artificial Light, Submitted by : Monsanto Company, Report No.: MSL 19889\PTRL 1318W 2, GLP: Yes; Published: No	Y	MON	This study provides information on the photo induced degradation of glyphosate in water In the dossier this study will be listed under Point 2.9.2 of the Phys chem. section
IIA 7.8.3 Water/sediment studies	1999	Bowler D and Johnson J, 1999. Glyphosate Trimesium: Degradation of 14C PMG labelled compound in natural water sediment systems under laboratory conditions, Report No.: RR 99 039B;GLP: Yes, Published: No	N	SYN	This study has not been previously evaluated at the EU level but the study was submitted to a Member State in support of a national registration. This study provides additional/supporting information on the water/sediment behaviour of glyphosate
	2002	Feser Zügner, W., Aminomethylphospho nic acid Fate and behaviour in water sediment: A&M GmbH, Köln, Germany, Report No.: A&M 01 106, GLP: Yes, Published: No	N	FSG	This study has not been previously evaluated at the EU level but the study was submitted to a Member State in support of a national registration. This study provides additional/supporting information on the water/sediment behaviour of AMPA
	2002	McEwen, A., 2002. [^{14}C] AMPA: Degradation and Fate in Water/Sediment Systems, Study No. SNN/03	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2011	GTF, 2011. Deriving parameters for Focus modelling. Experimental Facility : Dr. Knoell Consult Status: In progress Final report : expected April 2011 (non GLP)	Y	GTF	New study needed to address developments in risk assessment; Focus kinetics , and Focus guidance for selecting input parameters for modelling purposes
	2011	GTF, 2011. Glyphosate and AMPA groundwater and surface water modeling Experimental Facility : Dr. Knoell Consult Status: In progress Final report : expected May 2011 (non GLP)	Y	GTF	New study needed to address for developments in risk assessment; Focus modelling;
IIA 8.2.4 Acute toxicity to aquatic invertebrates	1996	Morris DS, Kent SJ, Banner AJ, Wallace SJ, 1996. Glyphosate Acid: Acute Toxicity to *Daphnia magna'*. Zeneca Brixham Environmental Laboratory, Unpublished Report No. BL5551/B, GLP, Syngenta file No ASF71/0198	N	SYN	Confirmatory study in support of the existing endpoint but needed in order to address developments in technical guidance and requirements
	2000	Perina VCF, 2000. Acute toxicity of Glifosate Técnico Nufarm to *Daphnia magna,* RF D51.39/99	N	NUF	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.
	1996	Long KWJ, Shillaber N, Caunter JE, Cornish SK, 1996. Glyphosate Acid: Acute Toxicity to mysid shrimp (*Mysidopsis bahia*). Zeneca Brixham Environmental Laboratory, Unpublished Report No. BL5713/B, GLP, Syngenta file No ASF71/0194	N	SYN	Confirmatory study with a mollusc species conducted to meet international guidelines (EPA) and supporting the existing endpoints for aquatic invertebrates
	1994	Jahnke, M, 1994.Acute toxicity in *Daphnia magna*. Test article: Glyphosate isopropylamine salt, IBR Forschungs GmbH, Report N°83 91 0737 00 93, GLP: yes, Published: no	N	FSG	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.
	2000	Perina, VCF, 2000.Acute toxicity of Glifosate IPA Técnico Nufarm to *Daphnia magna,* RF D51.017/00	N	NUF	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.
	1998	Van de Waart EJ, 1998.Acute toxicity study in *Daphnia magna* with (aminomethyl) phosphonic acid (static), NOTOX, Project 232471, GLP, Unpublished	N	AGR	Confirmatory study confirming the conclusions of the 2001 EU Evaluation
	2010	HMPA; Acute toxicity to *Daphnia magna* Experimental Facility : Wildlife International Status: In progress Final report : expected May 2011 (GLP)	Y	GTF	New study initiated in order to address a new major aquatic metabolite (HMPA) Although this metabolite was identified before it is now quantified in amounts exceeding 10% in an existing (but not previously evaluated) water sediment study from a GTF member.
IIA 8.2.5. Chronic toxicity to aquatic invertebrates	1999	Magor SE, Shillabeer N, 1999. Glyphosate Acid: Chronic Toxicity to *Daphnia magna*'. Zeneca Brixham Environmental Laboratory, Unpublished Report No. BL6535/B, GLP, Syngenta file No ASF71/0204	N	SYN	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.
	2000	Perina VCF, 2000. Chronic toxicity of Glifosate Técnico Nufarm to *Ceriodaphnia*; RF D. 15/99	N	NUF	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1996	Long KWJ, Shillaber N, Caunter JE, Cornish SK, 1996 Glyphosate Acid: Acute Toxicity to larvae of the Pacific oyster (*Crassostrea gigas*). Zeneca Brixham Environmental Laboratory, Unpublished Report No. BL5714/B, GLP, Syngenta file No ASF71/0200	N	SYN	Confirmatory study with a mollusc species conducted to meet international guidelines (EPA) and supporting the existing endpoints for aquatic invertebrates
	1973	Bentley, RE, 1973.Glyphosate: acute toxicity study in Atlantic Oysters; Monsanto No. BN 73 79; non GLP; not published	N	MON	Confirmatory study with a mollusc species conducted to meet international guidelines (EPA) and supporting the existing endpoints for aquatic invertebrates
	2011	21 day aquatic toxicity study of AMPA on *Daphnia magna* Experimental Facility : Wildlife International Status: In progress Final report : expected June 2011 (GLP)	Y	GTF	New study initiated to address the potential long term exposure of aquatic organisms to AMPA (alleged frequent and recurring detections in surface water)
	2003	Palmer S.J., Kendall T.Z. and Krueger H.O., 2003. A 48 hour static acute toxicity test with the Cladoceran *(Daphnia magna)*. Wildlife International report WL 2002 150	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 8.2.6 Effects on algal growth	1996	Smyth DV, Kent SJ, Moris DS, Shearing JM, Shillabeer N, 1996. Glyphosate Acid: Toxicity to the marine alga *Skeltonema costatum*. Brixham Environmental Laboratory, Unpublished Report No. BL5684/B, GLP, Syngenta file No ASF71/0211	N	SYN	The study on which the current endpoint is based is non GLP and has a design that deviates strongly from current guidance. With this study the GTF will present an existing study on the same algal species that does meet current guidance. A new algal endpoint will be proposed.
	1996	Smyth DV, Kent SJ, Moris DS, Johnson PA, Shillabeer N 1996. Glyphosate Acid: Toxicity to the freshwater diatom *Navicula pelliculosa*. Brixham Environmental Laboratory, Unpublished Report No. BL5550/B, GLP, Syngenta file No ASF71/0210	N	SYN	Existing study that will be submitted in support of the new proposed endpoint.
	1996	Smyth DV, Shillabeer N, Moris DS, Wallace, 1996. Glyphosate Acid: Toxicity to the blue green alga *Anabaeena flos-aquae*. Brixham Environmental Laboratory, Unpublished Report No. BL5698/B, GLP, Syngenta file No ASF71/0212	N	SYN	Existing study that will be submitted in support of the new proposed endpoint.
	1996	Smyth DV, Kent SJ, Moris DS, Morgan DJ, Magor SE, 1996. Glyphosate Acid: Toxicity to the Green Alga *Selenastrum carpricornutum*. Brixham Environmental Laboratory, Unpublished Report No. BL5550/B, GLP, Syngenta file No ASF71/0209	N	SYN	Existing study that will be submitted in support of the new proposed endpoint.
	2000	Tavares C., 2000. Acute toxicity of Glifosate Técnico Nufarm to *Selenastrum capricornutum*	N	NUF	Existing study that will be submitted in support of the new proposed endpoint.
	1990	Wüthrich, 1990. Acute Toxicity of Glyphosate to *Scenedesmus subspicatus* (OECD algae growth inhibition test; RCC study No.: 250773; Cheminova Report No.: 23 GLY; fully GLP	N	CHE	Existing study that will be submitted in support of the new proposed endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1996	Scheerbaum, D., 1996. Glyphosate tec.: Alga, growth inhibition test to *Nitzschia palea*, Dr. U. Noack Laboratorium, Report No.: SSO51371, GLP: Yes, Published: No	N	FSG	Existing study that will be submitted in support of the new proposed endpoint
	1998	Van de Waart, 1998. Freshwater algal growth inhibition test with (aminomethyl) phosphonic acid, NOTOX, Project 232458, GLP, Unpublished	N	AGR	Confirmatory study in support of the conclusions of the 2001 EU Evaluation
	2002	Egeler. P and Baumann, J, 2002. A study on the toxicity of Glyphosate isopropylamine salt 62.5% to algae (*Pseudokirchneriella subcapitata*).	N	ALS	Existing study that will be submitted in support of the new proposed endpoint
	2011	*Pseudokirchneriella subcapitata* ; HMPA Wildlife international Experimental Facility : Wildlife International Status: In progress Final report : expected May 2011 (GLP)	Y	GTF	New study initiated in order to address a new major aquatic metabolite (HMPA) Although this metabolite was identified before it is now quantified in amounts exceeding 10% in an existing (but not previously evaluated) water sediment study from a GTF member.
	2003	Desjardin D., Kendall T.Z. and Krueger H.O., 2003. A 72 hour toxicity test with the Freshwater alga *(Selenastrum capricornutum)*. Wildlife International report WL 2002 148, unpublished, GLP	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
	2002	Mallett, M.J.2002. IPA Salt of Glyphosate: Toxicity to the Freshwater Alga *Scenedesmus subspicatus*: CEMAS Report No. CEMR 1874	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 8.2.7. Aquatic macrophytes	1996	Smyth DV, Kent SJ, Morris DS, Cornish SK, Shillabeer N, 1996. Glyphosate Acid: Toxicity to Duckweed (*Lemna gibba*)'. Brixham Environmental Laboratory, Unpublished Report No. BL5662/B, GLP, Syngenta file No ASF71/0213	N	SYN	Confirmatory study in support of the conclusions of the 2001 EU Evaluation
	2002	Turnbull, G., 2002. IPA Salt of Glyphosate: Effects on *Lemna minor*: CEMAS Report No. CEMR 1873	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2011	Wenzel A., 2010. *Myriophyllum aquaticum*, Growth Inhibition Test: Effect of Glyphosate acid on the Growth of Macrophytes in the Presence of Sediment, static conditions. Experimental Facility : Fraunhofer IME Status: In progress Final report : expected May 2011 (GLP)	Y	GTF	New study initiated in order to cover an aquatic macrophyte that in the literature has shown higher sensitivity to glyphosate compared to Lemna In addition glyphosate dissipates rapidly into the sediment which makes the species and design very relevant (study with glyphosate acid).
	2011	Wenzel, A., 2011. *Myriophyllum aquaticum*, Growth Inhibition Test: Effect of AMPA on the Growth of Macrophytes in the Presence of Sediment, static conditions. Experimental Facility : Fraunhofer IME Status: In progress Final report : expected May 2011 (GLP)	Y	GTF	New study initiated in order to cover an aquatic macrophyte that in the literature has shown higher sensitivity to glyphosate compared to Lemna : In addition glyphosate dissipates rapidly into the sediment which makes the species and design very relevant (study with AMPA).

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 8.2.8 Further testing on aquatic organisms	1999	Scheerbaum, D., 1999. Glyphosate 62% IPA salt: Aquatic plant toxicity test using *Lemna gibba*, Dr. U. Noack Laboratorium, Report No.: TLA60871, GLP: Yes, Published: No	N	FSG	Existing study that will be submitted in support of the aquatic macrophyte risk assessment
IIA 8.3.1. Effect on honeybees	1998	Thompson HM, 1998. Glyphosate Acid: Acute Contact and Oral Toxicity to Honey Bees (*Apis mellifera*)'. Central Science Laboratory, Unpublished Report No. FN9700, GLP, Syngenta file No ASF71/0179	N	SYN	Confirmatory study in support of the existing endpoint for exposure through physical contact.
	1995	Van der Steen., 1995. Honeybees (*Apis mellifera* L.), oral toxicity study in the laboratory with glyphosate, NOTOX, Project 141907, GLP, Unpublished	N	AGR/ALS	Confirmatory study in support of the existing endpoint for exposure through oral intake.
	1995	Van der Steen., 1995. Honeybees (*Apis mellifera* L.), contact toxicity study in the laboratory with glyphosate, NOTOX, Project 142335, GLP, Unpublished	N	AGR/ALS	Confirmatory study in support of the existing endpoint for exposure through physical contact.
	1996	Weyman, GS, 1996. Acute contact and oral toxicity to honeybees; glyphosate acid	N	NUF	Confirmatory study in support of the existing endpoints.
	2000	Franco Perina V., 2000. Acute contact toxicity of Glifosato IPA Técnico Nufarm to honeybees (*Apis mellifera*)	N	NUF	Confirmatory study in support of the existing endpoint for exposure through physical contact.
	1995	Kleiner, R., 1995. Testing toxicity to honeybee *Apis mellifera* L. (laboratory) according to EPPO guideline No. 170, BioChem GmbH, Report No.: 95 10 48 065, GLP: Yes, Published: No	N	FSG	Confirmatory study in support of the existing endpoints.
	2012	Bee brood study with MON 52276 Experimental Facility : to be decided Status: planning Final report : expected early 2012 (GLP)	Y	GTF	New study will be initiated to assess the effect of glyphosate on bee brood. This study is necessary to meet proposed regulatory data requirements
	2003	Halsall, N., 2003. Laboratory bioassays to determine acute oral and contact toxicity of MON 78623 to the honeybee *Apis mellifera*. Mambotox report MT 2002 108.	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 8.4.1. Acute toxicity to Earthworms	1991	Thun, S., 1991.Acute Toxicity in Earthworms according to OECD 207; Monsanto No. IB 91 53; GLP; not published	N	MON	Confirmatory study in support of the existing endpoint.
	1992	Hoxter, KA and Smith, GJ, 1992.MON 52276: An Acute toxicity study with the earthworm in an artificial soil substrate; Monsanto No. WL 91 272; GLP; not published	N	MON	Confirmatory study in support of the existing endpoint.
	2002	Mallett, M.J., 2002. Sinon Glyphosate Technical: The Acute Toxicity to the Earthworm *Eisenia foetida*, Report No. CEMR 1875.	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 8.4.2. Earthworms- sublethal effects	2000	Hayward *et al*, 2000.A laboratory investigation of the effects of glyphosate and its breakdown product AMPA on reproduction in the earthworm *Eisenia fetida.*	N	MON	Study submitted during ECCO review; the study was required at that time to fill a data gap on long term toxicity effects on earthworms.
	2009	Friedrich S., 2009. MON 0139 Sublethal toxicity to the earthworm *Eisenia fetida* Biochem agrar report 091048056S; GLP unpublished	Y	GTF	The GTF initiated a new study in order to refine the risk assessments to earthworms. The current endpoint is based on the highest dose tested in Hayward, 2000 (see above).This study will refine the actual endpoint by testing higher doses.
	2002	Servajean, E., 2002. Laboratory determination of the long term toxicity of aminomethyl phosphonic acid (AMPA) as a metabolite of glyphosate to earthworms (*Eisenia foetida*) using artificial soil substrate	N	ALS	Existing study that will be submitted in order to address potential persistence effect of AMPA in soil on terrestrial ecosystems
	2002	Noack, M., 2002. AMPA: Earthworm (*Eisenia fetida*), effects on reproduction, Dr. U. Noack Laboratorium, Report No.: RRR84121, GLP: Yes, Published: No	N	FSG	Existing study that will be submitted in order to address potential persistence effect of AMPA in soil on terrestrial ecosystems
	2002	Mallett, M.J., 2002. Sinon Glyphosate Technical: Sinon Glyphosate Technical and its Breakdown Product AMPA: Effects on Reproduction and Growth in the Earthworm *Elisenia foetida*, Report No. CEMR 1878	Y	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 8.4.2. Effects on non-target soil mesofauna (other than earthworms)	2009	Schulz L., 2009. MON0139 Effects on the reproduction of the predatory mite *Hypoaspis aculeifer;* Biochem agrar report 091048058S; GLP unpublished	Y	GTF	New study essential in order to address potential persistence effect of glyphosate in soil (formulated as IPA salt) on terrestrial ecosystems The GTF initiated studies with structural endpoints (ecosystem) rather than initiating a litterbag study (functional end point) as proposed in new guidance
	2010	Friedrich S., 2010. MON0139 Effects on the reproduction of the collembolans *Folsomia candida.* Biochem agrar report 091048057S; GLP unpublished	Y	GTF	New study essential in order to address potential persistence effect of glyphosate in soil (formulated as IPA salt) on terrestrial ecosystems The GTF initiated studies with structural endpoints (ecosystem) rather than initiating a litterbag study (functional end point) as proposed in new guidance
	2010	Schultz L., 2010. AMPA Effects on the Reproduction of the Predatory Mite *Hypoaspis aculeifer.* Biochem agrar report 101048053S; GLP unpublished	Y	GTF	New study essential in order to address potential persistence effect of AMPA in soil on terrestrial ecosystems (endpoint) The GTF initiated studies with structural endpoints (ecosystem) rather than initiating a litterbag study (functional end point) as proposed in new guidance
	2010	Friedrich S., 2010. AMPA Effects on the reproduction of the collembolans *Folsomia candida* Biochem agrar report 101048054S; GLP unpublished	Y	GTF	New study in order to address long term effect of AMPA on terrestrial ecosystems (composition endpoint) The GTF initiated studies with structural endpoints (ecosystem) rather than initiating a litterbag study (functional end point) as proposed in new guidance

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 8.5 Effects on soil nitrogen transformation	2002	McMurray, 2002. A laboratory assessment of the effects of Glyphosate 360 g/L SL formulation and metabolite AMPA on the soil microflora respiration and nitrogen transformation according to OECD guideline numbers 216 and 217, Chemex, ENV5006, GLP, Syngenta file No ASF71/0260	Y	SYN	Confirmatory study in support of the existing endpoint.
	2000	Perina, VCF, 2000. Side effects of Glifosate Técnico Nufarm on soil microflora: Carbon and Nitrogen cycles	N	NUF	Confirmatory study in support of the existing endpoint.
	2010	Schultz L. AMPA Effects on the Activity of soil microflora (Nitrogen and Carbon transformation test), Biochem agrar report 101048010 C/N; GLP, unpublished	Y	GTF	New study in order to address long term effect of AMPA on terrestrial ecosystems (functional endpoint)
IIA 8.14 Effects on other non-target organisms believed to be at risk	1996	Glyphosate acid: A Tier 2 greenhouse study to assess the effects on seedling emergence of terrestrial non target plants.Zeneca Agrochemicals, Jealott's Hill Research Station, Bracknell Berkshire, UK Report No:RJ2008B, GLP, unpublished	Y	SYN	Confirmatory study in support of the existing endpoint.
	1996	Everett, C.J., Fleming, T.M. and Cole , J.F.H, 1996.Glyphosate acid: A Tier 2 greenhouse study to assess the effects on vegetative vigour of terrestrial non target plants. Zeneca Agrochemicals, Jealott's Hill Research Station, Bracknell Berkshire, UK Report No:RJ2009B GLP, unpublished	Y	SYN	Confirmatory study in support of the existing endpoint.
	1994	Harnish, W.N., 1994. LX1146 02 (Glyphosate Technical) Tier II Non target hazard evaluation Terrestrial vegetative vigor; Landis International, Inc., Valdosta, GA, USA; Report No: 236 GLY GLP, unpublished	Y	CHEM	Confirmatory study in support of the existing endpoint.

The Glyphosate task force to the best of its knowledge **at the time of notification for renewal**, expects that the technical dossier supporting the renewal of glyphosate will include the following **vertebrate studies** and pieces of information that did not contribute to the initial Annex I inclusion decision.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 5 Toxicological and Toxicokinetic Studies on the Active Substance					
IIA 5.1.1 Toxicokinetic studies - Single dose, oral route, in rats	1995	[redacted] 1995. HR 001: Metabolism in the rat. SYN 332/951256	Y	ALS	Confirmatory study in support of the existing endpoint
	1996	[redacted]1996. Glyphosate technical : Pharmacology screening in the rat, SPL 434 021	Y	NUF	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1996	[redacted] 1996. ^{14}C) Glyphosate: Absorption, distribution, metabolism and excretion following oral administration to the rat CHE 1413 2	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate acid: Excretion And Tissue Retention Of A Single Oral Dose (10 mg/kg) In The Rat	N	SYN	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate acid: Excretion and Tissue Retention of a Single Oral Dose (1000 mg/kg) in the Rat	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.1.3 Toxicokinetic studies Repeated dose, oral route, in rats	1996	[redacted] 1996. Glyphosate Acid: Excretion and Tissue Retention of a Single Oral Dose (10 mg/kg) in the Rat Following Repeat Dosing	N	SYN	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate Acid: Whole body autoradiography in the rat (10 mg/kg)	N	SYN	Confirmatory study in support of the existing endpoint
		[redacted] 1996. Glyphosate Acid: Biotransformation in the Rat	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.2 Acute toxicity					
IIA 5.2.1 Acute oral toxicity	1995	[redacted] 1995. HR 001: Acute oral toxicity study in rats. IET 94 0134	N	ALS	Supports new endpoint to align with new GHS classification scheme
	1995	[redacted] 1995. HR 001: Acute oral toxicity study in mice. IET 94 0133	N	ALS	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate Technical: Acute oral Toxicity Study in Rat, C22864, GLP, Unpublished	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	[redacted],2009. Acute Oral Toxicity Study of Glyphosate TC in Rats. LPT 23910	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Oral Toxicity Study of Glyphosate TC in Rats. LPT 24874	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Oral Toxicity Study of Glyphosate TC in Rats. LPT 24602	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate Acute Oral Toxicity Study (UDP) in Rats. Stillmeadow Inc. 12170 08	Y	HAG	Supports new endpoint to align with new GHS classification scheme
	2006	[redacted] 2006. Acute Oral Toxicity of Glyphosate TC in rats (*Rattus norvegicus*) PSL 15274	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted],2008. Acute Oral Toxicity Study in Wistar Hannover Rats for Glyphosate Technical Bioagri. RF 3996.305.475.07	Y	HAG	Confirmatory study in support of the existing endpoint
	2007	[redacted] 2007. GLYPHOSATE TECHNICAL (NUP05068) : Acute oral toxicity study in rats BO2272	Y	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted], 1999. NUP5a99 62% glyphosate MUP: Acute oral toxicity study in rats Limit test	Y	NUF	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1988	[redacted] 1988. Acute Oral Toxicity Study in Rats Glyphosate Technical (Wetcake). Monsanto report BD 88 114.	N	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1988	[redacted] 1988. Acute Oral Toxicity Study of Glyphosate Batch/lot/nbr no. XLI 55 in Sprague Dawley Rats. Monsanto report FD 88 29.	Y	MON	Supports new endpoint to align with new GHS classification scheme Not previously submitted as study was not considered essential.
	1995	[redacted], 1995. Acute Toxicity Study of MON 0139 By Oral Administration In Mice (Study No. B 3101) MONSANTO Study NO.: XX 95 205	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1979	[redacted] WE, 1979. Acute Oral Toxicity Study in Rats. Monsanto report BD 77 428.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1996	[redacted] 1996. Glyphosate Acid: Acute Oral Toxicity Study in Rats	N	SYN	Confirmatory study in support of the existing endpoint
	2008	[redacted] D.V.M., 2008. Acute oral Toxicity Study in Wistar Hannover Rats For Glyphosate Technical, Bioagri Laboratorios report RF 3996.305.475.07, unpublished	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2007	[redacted] 2007. Glyphosate Technical Material: Acute Oral Toxicity Study in the Rat (Up and Down Procedure)	Y	SYN	Confirmatory study in support of the existing endpoint
	2001	[redacted] 2001. An acute oral toxicity study in rats with MON 78623. Springborne Laboratories report Sb 2000 245. GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 5.2.2 Acute percutaneous toxicity	1995	[redacted] 1995. HR 001: Acute dermal toxicity study in rats. IET 94 0154	N	ALS	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate Technical: Acute Dermal Toxicity Study in Rat, C22875, GLP, Unpublished ([redacted])	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Acute Dermal Toxicity Study of Glyphosate TC in CD Rats LPT 23912	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Dermal Toxicity Study of Glyphosate TC in CD Rats LPT 24876	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Dermal Toxicity Study of Glyphosate TC in CD Rats LPT 24604	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate Acute Dermal Toxicity Study in Rats. [redacted] 12171 08	Y	HAG	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2006	[redacted] 2006. Acute Dermal Toxicity of Glyphosate TC in rats (*Rattus norvegicus*) PSL 15275	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Acute Dermal Toxicity in Wistar Hannover Rats for Glyphosate Technical [redacted] RF 3996.310.456.07	Y	HAG	Confirmatory study in support of the existing endpoint
	1988	[redacted] 1988. Acute Dermal Toxicity Study in Rabbits Glyphosate Technical (Wetcake). Monsanto report BD 88 114.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1988	[redacted] 1988. Acute Dermal Toxicity Study of Glyphosate Batch/lot/nbr no. XLI 55 in New Zealand White Rabbits. Monsanto report FD 88 29.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1979	[redacted] WE, 1979. Acute Dermal Toxicity Study in Rabbits. Monsanto report BD 77 428.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	2007	[redacted] GLYPHOSATE TECHNICAL (NUP05068) : Acute dermal toxicity study in rats	Y	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. NUP5a99 62% glyphosate MUP: Acute dermal toxicity study in rats Limit test	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996 Glyphosate Acid: Acute Dermal Toxicity in the Rat	N	SYN	Confirmatory study in support of the existing endpoint
	2007	[redacted] 2007. Glyphosate Technical Material: Acute Dermal Toxicity Study in Rats	Y	SYN	Confirmatory study in support of the existing endpoint
	2008	[redacted] D.V.M., 2008. Acute Dermal Toxicity Study in Wistar Hannover Rats For Glyphosate Technical, [redacted] Laboratorios report RF 3996.310.456.07, unpublished	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2001	[redacted] 2001. An acute dermal toxicity study in rats with MON 78623. [redacted] report SB 2000 246. GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 5.2.3 Acute inhalation toxicity	1995	[redacted] 1995. HR 001: Acute inhalation toxicity study in rats IET 94 0155	N	ALS	Confirmatory study in support of the existing endpoint
	2009	[redacted], 2009. Glyphosate Technical: Acute InhalationToxicity Study in Rat, C22875, GLP, Unpublished ([redacted])	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	[redacted],2009. Acute Inhalation Toxicity Study of Glyphosate TC in Rats LPT 23911	Y	HAG	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2010	[redacted] 2010. Acute Inhalation Toxicity Study of Glyphosate TC in Rats LPT 24875	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Inhalation Toxicity Study of Glyphosate TC in Rats LPT 24603	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted], 2009. Glyphosate Acute Inhalation Toxicity Study in Rats Stillmeadow Inc. 12107 08	Y	HAG	Confirmatory study in support of the existing endpoint
	2006	[redacted] 2006. Acute Inhalation Toxicity of Glyphosate TC in rats (*Rattus norvegicus*) PSL 15276	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Acute Inhalation Toxicity of Glyphosate Technical in Rats Bioagri RF 3996.309.377.07	Y	HAG	Confirmatory study in support of the existing endpoint
	2007	[redacted] 2007. Glyphosate Technical (NUP 05068) : 4 Hour acute inhalation toxicity study in rats B02327	Y	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. NUP5a99 62% glyphosate MUP: Acute inhalation toxicity study in rats Limit test	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate Acid: 4 Hour Acute Inhalation Toxicity Study in the Rat	N	SYN	Confirmatory study in support of the existing endpoint
	1998	[redacted] 1998. Acute Inhalation Toxicity Study of Glyphosate Technical 95% in Rat: [redacted] Report No. R9819110S0	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2008	[redacted] M.Sc., 2008. Acute Inhalation Toxicity Test of Glyphosate Technical in Rats, [redacted] RF 3996.309.377.07	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2004	[redacted] 2004. An acute nose only inhalation toxicity study in rats with MON 78623. [redacted] report SB 2003 116. GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 5.2.4 Skin irritation	1995	[redacted] 1995. HR 001: Primary Dermal irritation study in rabbits. IET 95 0035	N	ALS	Confirmatory study in support of the existing endpoint
	2009	[redacted] (2009). Glyphosate technical: Primary skin irritation study in rat, C22886, GLP, Unpublished (Harlan, Switzerland)	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	[redacted] (2009). Acute Dermal Irritation/Corrosion Test (Patch Test) of Glyphosate TC in Rabbits. LPT 23913	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Acute Dermal Irritation/Corrosion Test (Patch Test) of Glyphosate TC in Rabbits. LPT 24877	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Dermal Irritation/Corrosion Test (Patch Test) of Glyphosate TC in Rabbits. LPT 24605	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted], 2009. Glyphosate Acute Dermal Irritation Study in Rabbits. Stillmeadow Inc. 12173 08	Y	HAG	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2006	[redacted] 2006. Dermal Irritation/Corrosion Effects in rabbits (Oryctolagus cuniculus) of Glyphosate TC PSL 15278	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted]2008. Acute Dermal Irritation/Corrosion Study in Rabbits with Glyphosate Technical. [redacted] RF 3996.311.476.07	Y	HAG	Confirmatory study in support of the existing endpoint
	1988	[redacted] 1988. Primary Dermal Irritation Study in Rabbits for Glyphosate Technical (Wetcake). Monsanto report BD 88 114.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1988	[redacted] 1988. Primary Dermal Irritation Study of Glyphosate Batch/lot/nbr no. XLI 55 in New Zealand White Rabbits. Monsanto report FD 88 29.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1979	[redacted] WE, 1979. Primary Dermal Irritation in Rabbits. Monsanto report BD 77 428.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	2007	[redacted]2007. GLYPHOSATE TECHNICAL (NUP05068): Primary Skin irritation study in rabbits (4 hour semi occlusive application). B02294	Y	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. NUP5a99 62% glyphosate MUP: Primary Skin Irritation study in rabbits	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate Acid: Skin Irritation To The Rabbit	N	SYN	Confirmatory study in support of the existing endpoint
	2007	[redacted] 2007. Glyphosate Technical Material: Primary Skin Irritation Study in Rabbits (4 Hour Semi Occlusive Application)	N	SYN	Confirmatory study in support of the existing endpoint
	1998	[redacted] 1998. Skin Irritation Study of Glyphosate Technical in Rabbits: STCPSE Report No. R9809904S0	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline
	2008	[redacted] 2008. Acute Dermal Irritation/Corrosion Study in Rabbits with Glyphosate technical, [redacted] report RF 3996.311.476.07, unpublished	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2001	[redacted] 2001. A primary skin irritation study in rabbits with MON 78623. [redacted] report SB 2000 249. GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 5.2.5 Eye irritation	1995	[redacted] 1995. HR 001: Primary Eye irritation study in rabbits. IET 95 0034	N	ALS	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate technical: Primary Eye irritation study in rat, C22897, GLP, Unpublished ([redacted])	Y	EXC	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2009	[redacted] 2009. Acute Eye Irritation/Corrosion Test of Glyphosate TC in Rabbits LPT 23914	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Acute Eye Irritation/Corrosion Test of Glyphosate TC in Rabbits LPT 24878	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Acute Eye Irritation/Corrosion Test of Glyphosate TC in Rabbits LPT 24606	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted], 2009. Glyphosate Acute Eye Irritation Study in Rabbits Stillmeadow Inc. 12172 08	Y	HAG	Confirmatory study in support of the existing endpoint
	2006	[redacted] 2006. Eye Irritation/Corrosion Effects in rabbits (Oryctolagus cuniculus) of Glyphosate 95 TC PSL 15277	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Acute Eye Irritation/Corrosion Study in Rabbits with Glyphosate Technical [redacted] RF 3996.312.599.07	Y	HAG	Confirmatory study in support of the existing endpoint
	1988	[redacted] 1988. Eye Irritation Study in Rabbits for Glyphosate Technical (Wetcake). Monsanto report BD 88 114.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1988	[redacted] 1988. Primary Irritation Study of Glyphosate. Monsanto report FD 88 29.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	1979	[redacted] WE, 1979. Rabbit Eye Irritation Study. Monsanto report BD 77 428.	Y	MON	Confirmatory study in support of the existing endpoint. Not previously submitted as study was not considered essential.
	2007	[redacted], 2007. Glyphosate Technical (NUP05068) : Primary Eye irritation study in rabbits B02305	Y	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. NUP5a99 62% glyphosate MUP: Primary eye irritation study in rabbits	Y	NUF	Confirmatory study in support of the existing endpoint
	1997	[redacted] 1997. Glyphosate Acid: Eye Irritation to the Rabbit	N	SYN	Confirmatory study in support of the existing endpoint
	2007	[redacted] 2007. Glyphosate Technical Material: Primary Eye Irritation Study in Rabbits	Y	SYN	Confirmatory study in support of the existing endpoint
	1998	[redacted], 1998. Eye Irritation Study of Glyphosate Technical 95% in Rabbits: STCPSE Report No. R9809403S0	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline
	2008	[redacted] 2008. Acute Eye Irritation/Corrosion Study in Rabbits with Glyphosate Technical , [redacted] report RF 3996.312.599.07, unpublished	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2001	[redacted] 2001. A primary eye irritation study in rabbits with MON 78623. [redacted] report SB 2000 248. GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 5.2.6 Skin sensitization	1995	[redacted] 1995. HR 001: Dermal sensitisation study in Guinea pigs. IET 95 0036	N	ALS	Confirmatory study in support of the existing endpoint
	2009	[redacted], 2009. Glyphosate Technical: Contact Hypersensitivity in albino guinea pig Maximization test, C22908, GLP, Unpublished ([redacted])	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Examination of Glyphosate TC in the Skin Sensitisation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test) LPT 23915	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Examination of Glyphosate TC in the Skin Sensitisation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test) LPT 24879	Y	HAG	Confirmatory study in support of the existing endpoint
	2010	[redacted] 2010. Examination of Glyphosate TC in the Skin Sensitisation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test) LPT 24607	Y	HAG	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate Skin Sensitization Study in Guinea Pigs, Stillmeadow Inc. 12174 08	Y	HAG	Confirmatory study in support of the existing endpoint
	2006	[redacted] 2006. Skin Sensitization in Guinea Pigs (*Cavia porcellus*) of Glyphosate TC. Maximization Test PSL 15279	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Skin Sensitisation Test for Glyphosate Technical in Guinea Pigs [redacted] RF 3996.318.431.07	Y	HAG	Confirmatory study in support of the existing endpoint
	1994	[redacted] 1994. Closed Patch Repeated Insult Dermal Sensitization Study In Guinea Pigs with MON 0139 (Buehler Method)	N	MON	Confirmatory study in support of the existing endpoint
	2007	[redacted] 2007. Glyphosate Technical (NUP05068): Contact hypersensitivity in albino guinea pigs, maximization test. B02316	Y	NUF	Confirmatory study in support of the existing endpoint
	2006	[redacted] 2006. Glyphosate Technical: Skin Sensitisation in the Guinea Pig Magnusson and Kligman Maximisation method. SMK PH 05/2018	Y	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. Dermal Sensitization Study in Guinea pigs (Buehler Method)	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate Acid: Skin Sensitisation to the Guinea Pig	N	SYN	Confirmatory study in support of the existing endpoint
	2007	[redacted] Glyphosate Technical Material Skin Sensitisation (Local Lymph Node Assay in the Mouse)	Y	SYN	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1998	[redacted], 1998. Dermal Sensitization Study of Glyphosate Technical 95% in Guinea Pigs: [redacted] Report No. 9806303S0	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline
	2001	[redacted] 2001. A dermal skin sensitization study in guinea pigs with MON 78623 Standard Buehler design. [redacted] report SB 2000 250. GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 5.3.2 Oral 90-day toxicity (rodents)	1995	[redacted] 1990. HR 001: 13 week Subchronic Oral Toxicity Study in Rats IET 94 0138	N	ALS	Confirmatory study in support of the existing endpoint
	1995	[redacted] 1995. HR 001: 13 week Oral Subchronic Toxicity Study in Mice IET 94 0136	N	ALS	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996 Technical glyphosate : Ninety day subchronic oral (dietary) toxicity study in the rat SPL 434 016	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. First Revision To Glyphosate Acid: 90 Day Feeding Study In Rats.	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.3.3 Oral 90-day toxicity (dog)	1996	[redacted] 1996. HR 001: 13 week Oral Subchronic Toxicity Study in Dogs IET 94 0158	N	ALS	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999: Subchronic (90 day) oral toxicity study with Glyphosate technical in beagle dogs; 1816 AND [redacted] 1997. Test compound stability in experimental diet (dog feed); 1817 R.FST	Y	FSG	Confirmatory study in support of the existing endpoint
	2007	[redacted], 2007 Glyphosate Technical: 13 week toxicity study by oral route (capsule) in Beagle dogs	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. First Revision To Glyphosate Acid: 90 Day Oral Toxicity Study in Dogs.	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.3.4 Oral 1 year toxicity (dog)	1997	[redacted] 1997. HR 001 : 12 Month Oral Chronic Toxicity Study in Dogs IET 94 0157	N	ALS	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Glyphosate Technical: 52 week toxicity study by oral route (capsule) in Beagle dogs 29647	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate Acid: 1 Year Dietary Toxicity Study in Dogs	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.3.7 Percutaneous 28-day toxicity (rodents)	1996	[redacted] 1996. Glyphosate acid: 21 day dermal toxicity study in rats, CTL/P/4985	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.4.4 In vivo genotoxicity testing (somatic cells) - Metaphase analysis in rodent bone marrow, or micronucleus test in rodents	2009	[redacted] 2009. Micronucleus Test of Glyphosate TC in Bone Marrow Cells of the CD Rat by oral administration LPT 23917	Y	HAG	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2007	[redacted] 2007. Mammalian Erythrocyte Micronucleus Test for Glifosato Técnico Helm TECAM 3393/2007 3.0MN B	Y	HAG	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Evaluation of the mutagenic potential of Glyphosate Technical by micronucleus assay in mice Bioagri RF 3996.402.395.07	Y	HAG	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. A micronucleus study in mice for Glyphosate Técnico Nufarm RF G12.79/99	Y	NUF	Confirmatory study in support of the existing endpoint
	2006	[redacted] 2006. Glyphosate Technical: Micronucleus test in the mouse SPL 2060/014	Y	NUF	Confirmatory study in support of the existing endpoint
	2000	[redacted] 2000. Evaluation of the mutagenic potential of the test substance Glifosato IPA Técnico Nufarm by micronucleus assay in mice	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate Acid: Mouse Bone Marrow Micronucleus Test	N	SYN	Confirmatory study in support of the existing endpoint
	2008	[redacted] 2008. Glyphosate Technical Micronucleus Assay in Bone Marrow Cells of the Mouse	Y	SYN	Confirmatory study in support of the existing endpoint
	1997	[redacted] 1997. Bone marrow micronucleus Test of Glyphosate Technical95% in Mouse, STCPSE Report No. R97072100S0	N	SIN	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
	2008	[redacted], 2008. Evaluation of the mutagenic potential of Glyphosate technical by micronucleus assay in mice. Bioagri laboratorios report RF 3996.402.395.07, unpublished	Y	JCC	Existing study that needs further evaluation by the GTF. The study owner joined the GTF within 2 months of the submission deadline.
IIA 5.5.1 Long-term (2 years) oral toxicity in the rat (can be a combined long-term and carcinogenicity study)	1996	[redacted] 1996. Glyphosate acid: One Year Dietary Toxicity Study in Rats.	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.5.2 Carcinogenicity study in the rat (can be a combined long-term and carcinogenicity study)	1997	[redacted] 1997. HR 001: 24 Month Oral Chronic Toxicity and Oncogenicity Study in Rats. IET 94 0150	N	ALS	Existing study not previously evaluated at EU level. May support a new endpoint
	1997	[redacted] 1997. Combined chronic toxicity / carcinogenicity of Glyphosate technical in Sprague dawley rat, Project No 1231, Non GLP, Unpublished	Y	EXC	Existing study not previously evaluated at EU level. May support a new endpoint
	2009	[redacted] 2009. Glyphosate Technical : Dietary combined chronic toxicity / carcinogenicity study in the rat SPL2060 0012	Y	NUF	Existing study not previously evaluated at EU level. May support a new endpoint
	2001	[redacted] 2001. Glyphosate acid: Two year dietary toxicity and oncogenicity study in rats, CTL/PR1111	N	SYN	Existing study not previously evaluated at EU level. May support a new endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 5.5.3 Carcinogenicity study in the mouse	1997	[redacted] 1997. HR 001: 18 Month Oral Oncogenicity Study in Mice IET 940151	N	ALS	Confirmatory study in support of the existing endpoint
	1989	[redacted] 1989. Carcinogenicity and chronic toxicity of Glyphosate technical, AA 50, Non GLP, Unpublished	Y	EXC	Confirmatory study in support of the existing endpoint
	1987	[redacted] 1987. Oncogenicity study of Glyphosate technical, AA 44, Non GLP, Unpublished	Y	EXC	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Carcinogenicity study with Glyphosate technical in Swiss albino mice 1559.CARCI M	Y	FSG	Confirmatory study in support of the existing endpoint
	2009	[redacted] 2009. Glyphosate Technical: Dietary carcinogenicity study in the mouse SPL 2060 0011	Y	NUF	Confirmatory study in support of the existing endpoint
IIA 5.6 Reproductive toxicity					
IIA 5.6.1 Two generation reproductive toxicity in the rat	1997	[redacted] 1997. HR 001: A two generation reproduction study in rats IEP 96 0031	N	ALS	Confirmatory study in support of the existing endpoint
	2007	[redacted], 2007. Glyphosate Technical: Dietary two generation study in the rat SPL 2060/0013	Y	NUF	Confirmatory study in support of an old endpoint, conducted to modern OECD 416 (2001) guideline.
	2000	[redacted] 2000. Glyphosate Acid: Multigeneration Reproduction Toxicity Study In Rats	Y	SYN MON	Confirmatory study in support of an old endpoint, conducted to modern OECD 416 (draft of 2001) guideline.
IIA 5.6.10 Teratogenicity test by the oral route in the rat	1995	[redacted] 1995. HR 001: Teratogenicity Study in Rats. IET 94 0152	N	ALS	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate technical: Oral gavage teratology study in the rat SPL 434/018	Y	NUF	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate acid: Developmental Toxicity Study in the Rat	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.6.11 Teratogenicity test by the oral route in the rabbit	1995	[redacted] 1995. A Teratogenicity Study in Rabbits. IET 94 0153	N	ALS	Existing study not previously evaluated at EU level. May support a new endpoint
	1996	[redacted] 1996. Glyphosate technical: Oral gavage teratology study in the rabbit SPL 434/020	Y	NUF	Existing study not previously evaluated at EU level. May support a new endpoint
	1996	[redacted] 1996. Glyphosate Acid: Developmental Toxicity Study in the Rabbit	N	SYN	Existing study not previously evaluated at EU level. May support a new endpoint. A lower developmental NOAEL of 175 mg/kg was established, but with the maternal NOAEL 100 mg/kg, data are consistent with other studies, that glyphosate is not a selective developmental toxicant

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIA 5.7.1 Acute neurotoxicity - rat	1996	[redacted] 1996. Glyphosate acid: Acute neurotoxicity study in rats, CTL/P/4866	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.7.2 Delayed neurotoxicity following acute exposure	1996	[redacted], 1996. Glyphosate acid: Acute delayed neurotoxicity study in the domestic hen, CTL/C/3122	N	SYN	Confirmatory study in support of the existing endpoint
	2005	[redacted] 2005. Glyphosate Technical: Ninety Day Repeated Dose Oral (Dietary) Neurotoxicity Study in the Rat SPL 2060/010	Y	NUF	Confirmatory study in support of the existing endpoint for subchronic exposure
	1996	[redacted] 1996. Glyphosate acid: Subchronic neurotoxicity study in rats, CTL/P/4867	N	SYN	Confirmatory study in support of an old endpoint for subchronic exposures
IIA 5.8 Toxicity studies on metabolites	1996	[redacted] (1996). AMPA: Acute oral toxicity study in mice. IET 96 0075	Y	ALS	Confirmatory study in support of the existing endpoint
	2002	[redacted] (2002). Acute Toxicity Study of AMPA (Aminomethyl Phosphonic Acid) in CD Rats by Dermal Administration 16168/02	Y	FSG	Confirmatory study in support of the existing endpoint
	2002	[redacted] (2002). Examination of AMPA (Aminomethyl Phosphonic Acid) in the Skin Sensitation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test). 16169/02	Y	FSG	Confirmatory study in support of the existing endpoint
	1988	[redacted] (1988). Aminomethyl phosphonic acid: Acute Oral Toxicity to the Rat	N	SYN	Confirmatory study in support of the existing endpoint
IIA 5.10 Other/special studies	2010	[redacted]. (2010). An 8 week Oral (Diet and Gavage) Toxicity Study of Citric Acid In Male Rats	Y	GTF	This study addresses in part an open point from the 2001 EU Evaluation (salivary gland lesions after repeated dosing in rodents). This study provides evidence of salivary gland effects being adaptive responsive to oral ingestion of an organic acid in diets.
	2001	[redacted] (2001). Glyphosate A 28 Day Oral (Dietary) Immunotoxicity Study in Female B6C3F1 Mice.	Y	MON	Confirmatory study in support of the conclusions of the 2001 EU evaluation of no immunotoxicological effects, following current US EPA OPPTs 870.7800 Guideline
	1996	[redacted] (1996) Glyphosate Acid: Comparison of Salivary Glands effects in Three Strains of Rat (CTL/P/5160)	N	SYN	This study addresses in part an open point form the 2001 EU Evaluation (salivary gland lesions after repeated dosing in rodents). This study provides evidence of salivary gland effects being reversible and not toxicologically relevant.
IIA 8.1.1 Acute oral toxicity to birds	1997	[redacted] 1997 Glyphosate Acid Acute Oral Toxicity (LD_{50}) to Bobwhite Quail. [redacted] Unpublished Report No. ISN 400/963858, GLP, Syngenta file No ASF71/0174	N	SYN	Confirmatory study in support of the existing endpoint
	1996	[redacted] 1996. Glyphosate: Acute oral toxicity to Mallard duck (CHE 1413/5 1011)	N	NUF	Confirmatory study in support of the existing endpoint

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	1996	[redacted], 1996. Glyphosate: Acute oral toxicity to Japanese Quail (CHE 1413/1011)	N	NUF	Confirmatory study in support of the existing endpoint
	2000	[redacted] 2000. Avian single dose acute oral toxicity of Glifosato IPA Técnico Nufarm to Japanese Quail (*Coturnix coturnix japnocá*), RF D81.186/00	N	NUF	Confirmatory study in support of the existing endpoint
	1999	[redacted] 1999. Avian single dose acute oral toxicity in Japanese quail with the chemical product Glifosate Técnico Nufarm. D.8.1 382/99	N	NUF	Confirmatory study in support of the existing endpoint
	2003	[redacted] J.B., 2003. An acute oral toxicity study with the Northern Bobwhite. [redacted] report WL 2002 151, GLP, unpublished.	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 8.1.3 Sub-chronic toxicity and reproduction to birds	1999	[redacted] 1999. Glyphosate Acid: A Reproduction Study in the Northern Bobwhite. [redacted] Unpublished Report No. 123 186, GLP, Syngenta file No ASF71/0178	N	SYN	Confirmatory study in support of the existing endpoint but needed in order to address developments in technical guidance. A new endpoint will proposed based on the results of this study.
	1999	[redacted] 1999. Glyphosate Acid: A Reproduction Study with the Mallard (*Anas platyrhynchos*). [redacted] Unpublished Report No. 123 187, GLP, Syngenta file No ASF71/0177	N	SYN	Confirmatory study in support of the existing and new proposedendpoint but needed in order to address developments in technical guidance and requirements
IIA 8.2.1. Aquatic toxicity to fish	1995	[redacted] 1995. Glyphosate Acid: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*). [redacted] Unpublished Report No. BL5552/B, GLP, Syngenta file No ASF71/0192	N	SYN	Confirmatory study in support of the existing endpoint
	1995	[redacted] PA, 1995. Glyphosate Acid: Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*). [redacted] Laboratory, Unpublished Report No. BL5553/B, GLP, Syngenta file No ASF71/0193	N	SYN	Confirmatory study in support of the existing endpoint.
	1998	[redacted] 1998. 96 Hour acute toxicity study in rainbow trout with (aminomethyl) phosphonic acid (static), [redacted] Project 232469, GLP, Unpublished	N	AGR	Confirmatory study in support of the conclusions from the 2001 EU evaluation.
	2000	[redacted] 2000. Acute toxicity of Glifosate Técnico Nufarm to zebrafish. RF D61.47/99	N	NUF	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.
	2005	[redacted], 2005. Glyphosate Technical: Acute toxicity in common carp (*Cyprinus carpio*). SPL 2060/015	Y	NUF	Confirmatory study in support of/confirming the conservative nature of the existing endpoint.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
	2003	[redacted], 2003. A 96 hour acute toxicity test with the rainbow trout *(Oncorhynchus mykiss)*. [redacted] report WL 2002 149, GLP, unpublished	Y	MON	MON 78623 is the Monsanto code for glyphosate K salt. This existing study is required to support the K salt registration.
IIA 8.2.2. Chronic toxicity to fish	2010	[redacted] 2010, Glyphosate acid:Early life stage toxicity test with rainbow trout (*Oncorhynchus mykiss*) under flow through conditions; Springborn Study No:1005.029.321; Cheminova Report No: not yet assigned.; fully GLP Study conducted at [redacted] Laboratories [redacted] Initiation; April 2009 Final report expected April 2011	Y	GTF	Confirmatory study necessary in order to comply with current 91/414/EC data requirements Although confirms results of an existing (pre 91/414/EC) fish full life cycle study.
	2011	AMPA ELS study with Fathead Minnow Study conducted at Wildlife international Initiation ; January 2011 Final report expected: January 2012	Y	GTF	New study initiated to address the potential long term exposure of aquatic organisms to AMPA (alleged frequent and recurring detections in surface water)
	2000	[redacted], 2000. Chronic toxicity of Glifosate Técnico Nufarm to Zebrafish larvae (*Brachydanio rerio*)	N	NUF	Existing study used to secure registration at national level. Although this study suggests rather sensitive endpoints, the study should have no impact on the current standing endpoints. (design, quality aspects).
		Fish short term reproduction study on fathead minnow with glyphosate acid	Y	Joint Glyphosate Task Force, LLC (a legal entity independent of the EU GTF!)	These studies are under development in the context of the test orders under the US EPA Endocrine Disruptor Screening Program. **See informing statement in section 5** The Glyphosate Task Force (GTF) does not anticipate any adverse endocrine findings from the Tier I EPA screening studies and will make all reasonable effort to obtain and submit study reports
		Amphibian metamorphosis assay on *Xenopus laevis* with glyphosate acid	Y		

The Annex III dossier for the lead formulation (MON 52276) will contain risk assessments (consumer risk, operator exposure risk, environmental risk) that reflects the latest data requirements and risk assessment methodologies. This also involves deriving appropriate endpoints which may be issued as separate reports.

In addition the following non –vertebrate Annex III studies on MON 52276, previously not evaluated in the context of the initial Annex I inclusion, will be presented in the joint dossier:

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIIA 2.7. Storage stability and shelf-life	2001	Bates, C. Long term storage stability at ambient temperature of MON 52276 (glyphosate SL): analysis after 2 years storage at room temperature. Monsanto Company, Report No.: MSL 17439 GLP, Unpublished	N	MON	Existing study that confirms the conclusions of the 2001 EU Evaluation but conducted in order to meet updated data requirements. The study is used to secure registration at member state level.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
III A.7.6 Dermal Absorption	2010	Ward, R.J. 2010. 360 g/L Glyphosate SL Formulation (MON 52276) *In Vitro* Absorption of Glyphosate through Human Epidermis. JV2084 REG	Y	MON	New study required to meet current technical datarequirements for formulated products and in order to allow refinement of the risk assessment operators and bystanders. A new endpoint will be proposed based on this state of the art study.
IIIA 10.1 Effects on birds	2010	Schneider K. and Staedtler T., 2010. Residues of glyphosate in arthropods after spray application in an arable field magnitude and time course of residue decline. Rifcon report 10153, GLP unpublished.	Y	GTF	New study required in order to allow refinement of the risk assessment for insectivorous birds
IIIA 10.4 Effects on bees	2001	Baxter I., 2001. Laboratory Bioassays to determine acute oral and contact toxicity of MON 52276 to the honeybee, *Apis mellifera* Generated by Agrochemical Evaluation Unit Submitted by: Monsanto Company Report No : MT 2000 120	Y	MON	Existing study conducted in order to meet updated data requirements. The study is used to secure registration at member state level.
IIIA 10.5 Effects on arthropods other than bees	1999	Barton, R., 1999, A laboratory evaluation of the effects of MON 52276 on the green lacewing, *Chrysoperla carnea,* Generated by: Agrochemical Evaluation Unit Submitted by: Monsanto Company, Report No. : US 99 093, Date : 16 August 1999	N	MON	Existing study conducted in order to meet updated data requirements. The study is used to secure registration at member state level.
	2010	Stevens, J., 2010. A rate response extended laboratory test to determine the effects of MON 52276 on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae)	Y	GTF	New study addressing the potential non target effects of the formulated product on representative species of beneficial arthropods; this study allows a dose response analysis compared to the limit test available in previous studies.
	1999	Vinall, S., 1999. An extended laboratory test to determine the effects of MON 52276 on the predatory mite, *Typhlodromus pyri* (Phytoseiidae), generated by: Agrochemical Evaluation Unit, Submitted by Monsanto company, report N°.: US 99 092, Date: 30 june 1999	N	MON	Existing Study conducted in order to meet updated data requirements. The study is used to secure registration at memberstate level.
	2010	Fallowfield, L., 2010. A rate response extended laboratory test to determine the effects of MON 52276 on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae)	Y	GTF	New study addressing the potential non target effects of the formulated product on representative species of beneficial arthropods; this study allows a dose response analysis compared to the limit test available in previous studies.
	2010	Spincer, D. 2010. A rate response extended laboratory test to determine the effects of MON 52276 on the ground active beetle, *Aleochara bilineata* (Coleoptera; Staphylinidae)	Y	GTF	New study addressing the potential non target effects of the formulated product on representative species of beneficial arthropods; this study allows a dose response analysis compared to the limit test available in previous studies.
III 10.7 Effects on soil microbial activity	2001	MON 52276 Effects on soil non target micro organisms: nitrogen transformation, carbon transformation, Huntingdon Life Sciences, Monsanto, Report No. HR 2000 244, GLP, Unpublished	N	MON	Existing study conducted in order to meet updated data requirements. The study is used to secure registration at member state level.

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
IIIA 10.8.2. Effects on non-target aquatic plants	2011	Wenzel A., 2010. *Myriophyllum aquaticum*, Growth inhibition test: Effect of MON 52276 on the growth of macrophytes in the presence of sediment, static conditions. Ongoing. Final reports expected spring 2011	Y	GTF	New study initiated in order to cover an aquatic macrophyte that in the literature has shown higher sensitivity to glyphosate compared to *Lemna* (study with formulated product). In addition glyphosate dissipates rapidly into the sediment which makes the species and design very relevant
IIIA 10.8.2. Effects on non-target aquatic plants	2002	Dengler, D., 2002. Assessment of toxic effects of MON 52276 on aquatic plants using the duckweed *Lemna gibba*. Generated by: GAB Biotechnologie GmbH Submitted by: Monsanto Company Monsanto report no. GA 2002 051.	Y	MON	Existing study conducted in order to meet updated data requirements. The study is used to secure registration at member state level.

Also the following vertebrate Annex III study on MON 52276, previously not evaluated in the context of the initial Annex I inclusion, will be presented in the joint dossier:

OECD data point number / Reference number	Year	Authors, Study Report Title Timetable if not yet completed	Data protection claimed	Owner	Justification
III A.7.1.6 Skin sensitization	2001	[redacted] Skin sensitization test in guinea pigs (Modified Buehler test: 9 applications), Monsanto Company, Report No. CI 2001 53, GLP, Unpublished	Y	MON	Existing study used to secure registration at member state level.

List of abbreviations:

Owners :Agrichem B.V. (AGR); Monsanto Europe S.A. (MON); Cheminova S/A (CHE); Syngenta (SYN); Sinon (SIN); Glyphosate Task Force (GTF); Helm Ag (HAG); Feinchemie Schwebda GmbH (FSG); Nufarm GmbH & Co KG (NUF); Arysta LifeSciences SAS (ALS); Excel Industries (Europe) (EXC); Jingma UK Limited (JCC)

Data protection Claimed: Y (Yes) / N (No)

5 Identified areas for which detailed re-evaluation is needed in dossier from notifier in evaluation by RMS/Co-RMS

Commission Directive 2001/99/EC (inclusion directive) states as specific provision for glyphosate that "Member States must pay particular attention to the protection of groundwater in vulnerable areas in particular with respect to non-crop uses. As non-crop use of glyphosate is not part of the representative GAP proposed for the Annex I approval renewal, the renewal dossier will include specific information on groundwater protection in general.

- Predicted environmental concentrations in groundwater according to the latest FOCUS guidance
  - *Supporting information (publication)*: Farenhorst, A. McQueen, D.A.R., Saiyed, I., Hilderbrand, C., Li, S., Lobb, D.A., Messing, P., Schumacher, T.E., Papiernik, S.K., Lindstrom, M.J. (2009) Variations in soil properties and herbicide sorption coefficients with depth in relation to PRZM (pesticide root zone model) calculations. *Geoderma* **150** (3-4): 267-277

- Lysimeter studies (publications)
  - Fomsgaard, I.S., Spliid, N.H., Felding, G. (2003) Leaching of pesticides through normal tillage and low tillage soil – A lysimeter study – II. Glyphosate. *J. Env. Sci. Health B* **B38** (1): 19-35
  - Grundmann, S., Dörfler, U., Ruth, B., Loos, C., Wagner, T., Karl, H., Munch, J.C., Schroll, R. (2008) Mineralization and transfer processes of ^{14}C-labeled pesticides in outdoor lysimeters. *Water Air Soil Pollut: Focus* **8**: 177-185
  - Stadlbauer, H., Fank, J., Lorbeer, G. (2005) Lysimeteruntersuchungen zur Verlagerung von Glyphosate im Lichte der Anwendung von Pflanzenschutzmitteln zur Beseitigung von winterharten Gründecken. 11. Gumpensteiner Lysimetertagung: 131-136

- Review of groundwater monitoring studies
  - Horth, H., Blackmore, K. (2009) Survey of Glyphosate and AMPA in groundwaters and surface waters in Europe, Report WRc UC8073.01

- Groundwater detect investigation (Sweden, The Netherlands, France, Italy, Germany)
  - Carter, A., Pepper, T. (2005) An investigation of reported borehole contamination in the Vemmenhög catchment, Sweden, Contract Research report CCEXXX, ADAS UK Ltd
  - Schmidt, B., Reichert, N. (2006) Clarification of well-related findings of glyphosate and AMPA in groundwater, Study IF-06/00603024, SGS Institut Fresenius, Taunusstein, Germany
  - Franke, A.C., Kempenaar, C., Groeneveld, R.M.W. (2010) Overzicht en evaluatie van glyfosaat en AMPA detecties in grondwater in Nederland. Stichting Dienst Landbouwkundig Onderzoek (DLO) report, unpublished – Follow-up study ongoing – report issued mid-2010
  - Contract research project: SCE Consulting and Engineering Services 'Etude de la contamination des eaux souterraines par le glyphosate/AMPA' - Study ongoing – report expected mid-2011
  - Contract research project: AEIFORIA, Investigation of the potential glyphosate groundwater contamination in Lombardia region (North Italy) – study ongoing – report expected mid- 2011

In addition the dossier supporting the approval renewal will include the following supplementary elements:

Since the first Annex-I inclusion of glyphosate, the GTF members have independently developed a substantial amount of new studies to support their own registrations at EU- Member State level or to support registrations in other world areas. Obviously these **'existing data'** were not evaluated during the first Annex I inclusion. The GTF want to give a full appreciation of all the available data. All studies will be identified but the level of detail submitted on this existing data depends on whether the data addresses new requirements or impact endpoints.

Simple reference to existing studies will be made where studies only support an existing endpoint (confirmatory studies) without addressing any new guidance/requirements. More detailed information on these studies can be obtained upon request.

Existing confirmatory study reports will be submitted and summarized when they are necessary to comply with more recent technical guidance or when the endpoints deviate from the established EU-endpoints.

In addition the GTF developed **new data and risk assessments** especially in the context of the Annex I renewal in order to address new developments in technical guidance for study design and risk assessment approaches. In summary the following will be presented:

- Inclusion of glyphosate K-salt (derived substance) in the renewal dossier (phys-chem, and representative studies for acute tox and ecotox)
- Updated package of analytical methods compliant with the latest data requirements
- Updated residue data package to cover pre-emergence uses of glyphosate. Additional storage stability data and a study on the nature of [^{14}C] Glyphosate residues in processed commodities will be submitted. In addition residue studies supporting selected GAP uses and not included in the previous submissions may be submitted to support the existing database.
- Updated dietary risk assessment to take into account final MRLs, and recent dietary exposure approaches
- Data to address an open point from the previous Annex I-evaluation: salivary gland weight increases and hypertropy of the acinar cells of parotid and sub-maxilliary salivary glands in repeat dose rat studies with glyphosate acid
- Dermal Absorption: Data supporting a lower rate of dermal absorption than that used in the initial Annex I Listing will be included in the Annex I Renewal Dossier for the representative formulated product (refinement of existing endpoint).
- Exposure Assessment: An updated exposure assessment compliant with the latest guidance, addressing the representative GAP, will be included in the Annex I Renewal Dossier.
- Review and potentially proposal of new critical endpoints (such as ADI and AOEL) in the context of risk assessment
- New aerobic metabolism and degradation studies for glyphosate and AMPA
- New half-lifes in environmental compartments based on new and existing studies and based on the most recent guidance regarding degradation kinetics(refinement of existing endpoints)
- New PEC-calculations based on new FOCUS guidance in soil, ground water & surface water
- The relevance of Hydroxy-methyl phosphonic acid (HMPA) as major aquatic metabolite will be assessed
- Updated risk assessment (glyphosate and AMPA) for birds, mammals, soil macrofauna and terrestrial vertebrates based on new studies, new guidance and new trends in risk assessment as per Regulation 1107/2009/EC. Based on the outcome of the new studies it is a possibility that new endpoints could be proposed.
- Refined and updated aquatic risk assessment to address potential concerns on persistence, new guidance, additional tested species, additional ecotoxicity endpoints and revised PEC_{sw} and PEC_{sed}
- In accordance with the requirements of Article 8(5) of EC Regulation 1107/2009, a summary of relevant peer-reviewed open literature on side-effects of glyphosate and its relevant metabolites on health, the environment, and non-target species (published within the last 10 years before the date of submission of the dossier).

The guidance in force on December 28 2010 was used as a base for the data-gap analysis. The GTF, in consultation with the rapporteur Member State, may submit additional studies and risk assessments to address developments in technical guidance or in order to address points that emerge during dossier preparation.

Informing statement

The GTF want to state that glyphosate is currently subject to Test Orders under the US EPA Endocrine Disruptor Screening Program. This program has prioritized substances for screen assays based solely on the criteria of exposure potential. The US EPA has announced in the Federal Register that the substances receiving Test Orders are in no way to be misinterpreted as being on a list of potential endocrine disruptors. "This list should not be construed as a list of known or likely endocrine disruptors. Nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list, these chemicals are suspected to interfere with the endocrine systems of humans or other species, and it would be inappropriate to do so" (Federal Register / Vol. 74,

No. 71 / Wednesday, April 15, 2009 / Notices 17579). In addition, a recently released OECD multi-laboratory validation report on the H295R Steroidogenesis Assay evaluated glyphosate at two laboratories.

No effects from glyphosate in this OECD Level II assay validation were reported:

(http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2010)31&doclanguage=en). This validation report notes that glyphosate "tested negative for E2 effects *in vitro* (H295R) also did not cause any changes in serum E2 concentrations *in vivo*" and "tested negative for changes in Testosterone production in the H295R Steroidogenesis Assay and also reported as not exhibiting significant alterations in concentrations of this hormone *in vivo*" (pages 93 and 94). Given that no endocrine modulating or disruptive effects have been observed across the very extensive toxicology data base for glyphosate including reproductive, developmental, subchronic and chronic apical studies, or in the OECD Level II assay, the Glyphosate Task Force (GTF) does not anticipate any adverse endocrine findings from the Tier I EPA screening studies.

The GTF will make all reasonable effort to obtain and submit study reports but wants to highlight that data-access has yet to be negotiated with the North-American glyphosate task force, a separate legal entity and that study results may not have been generated at the time of EU Annex I renewal submission.

Annex 1a – GAP supporting first inclusion of glyphosate in Annex I of Directive 91/414/EEC

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU												
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
CITRUS FRUIT											
Citrus	Annual weeds, Perennial weeds, shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)	Weeds actively growing. Before, during or immediately after blooming of the crop	1 - 5	-	200-400/ulv	0.72-4.32	Southern Europe	4.32
POME- AND STONE FRUIT											
Orchards	Forestry orchards, non crop and aquatic areas	F	SL SG	spot treatment	actively growing, well developed weeds	1	-	-	33% dilution	United Kingdom, Ireland	
	Couch-grass, Annual weeds, Perennial weeds, Root suckers	F	SL SG	Spraying	14 days before harvest, after harvest, weed height >20cm, trees > 2 years old	1	-	100-400	0.72-4.32	Northern Europe	4.32
	Couch-grass, Annual weeds, Perennial weeds	F	SL SG	spot treatment	trees > 2 years old	1	-	-	2% or 2.94 g/l	Netherlands Luxembourg Belgium	
	Couch-grass	F	SL SG	Spraying	-	1	-	-	1.08	France	1.08
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)	actively growing, well developed weeds. Before, during or immediately after blooming. Trees > 2 years old.	1-3	-	80-400/ulv	0.72-4.32	Southern Europe	4.32

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU											
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
BERRIES AND SMALL FRUIT											
Grapes	Annual weeds, Perennial weeds	F	SL SG	spraying	vine > 4 years old	1	-	100-400	1.44-3.6	Luxembourg	3.6
	Annual weeds, Perennial weeds	F	SL	spraying	vine > 4 years old	1	-	100-400	1.08-4.32	Austria	4.32
	Annual weeds, Perennial weeds	F	SL	spraying	vine > 4 years old	2 (splitting)	-	100-400	1.80+1.80	Germany Luxembourg	3.60
	Annual weeds, Perennial weeds	F	SG	spraying	vine > 4 years old	2 (splitting)	-	100-400	1.68+1.68	Germany	3.36
	Annual weeds, Perennial weeds, Convulvulus	F	SL SG	spraying	vine > 4 years old	1	-	100-400	3.60	Germany	3.60
	Annual weeds, Perennial weeds, Convulvulus	F	SL SG	spraying	vine > 4 years old	1	-	100-400	3.36	Germany	3.36
	Annual weeds, Perennial weeds	F	SL	spraying	well developed weeds	-	-	200-300	1.08-4.32	France	4.32

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU											
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying;+ other (wet rope, drop boom, etc)	Actively growing, well developed weeds. Before, during or immediately after blooming of the crops. Vine > 2 years old.	1-3	-	80-400	0.72-4.32	Southern Europe	4.32
MISCELLANEOUS FRUIT											
Olives	d) Developed weeds e) Perennial weeds f) Growing weeds	F	SL SG	a) spray b) spot c) spray	Trees > 2 years old a) prebloom, postharvest b) immature fruit stage c) preharvest	a) 1 b) 1 c) 1	-	80-600	a) 2.16 b) 4.32 c) 0.54-1.08	Southern Europe	4.32
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)	Weeds actively growing. Before, during or immediately after blooming of the crop	1-3	-	200-400/ulv	4.32 max.	Italy	4.32
Walnuts	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)	any	-	-	200-400/ulv	4.32	Italy	4.32
Hazelnuts	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-3	-	5-400	0.72-2.16	Spain	4.32

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU											
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
Almonds	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-2	-	5-400	0.72-2.16	Spain	4.32
ROOT AND TUBER VEGETABLES											
Beet root	Annual weeds, Wild potato shoots	F	SL	spraying	pre-emergence	1	-	80-250	1.08	Netherlands	1.08
Carrots	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
Witloof (chicory)	Annual weeds, Perennial weeds, Couch-grass	F	SL SG		pre-emergence	-	-	-400	1.44	Netherlands	1.44
BULB VEGETABLES											
Onions	Annual weeds, Wild potato shoots	F	SL SG	spraying	2-4 days before emergence	1	-	80-400	0.7-2.1	Northern Europe	2.1
STEM VEGETABLES											
Asparagus	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	pre-emergence	1	-	80-400	2.16	Netherlands	2.16

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU												
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
FIELD VEGETABLES	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)	pre-emergence according to weed stage, post-harvest	1-3	-	200-400/ulv	1.44-4.32	Italy	4.32
	Annual weeds, Perennial weeds	F	SL	wiping	>10cm height difference	2	-	-	35-50%	Austria	
PULSES											
Pulses	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying and wiping	pre-emergence	1	-	80-400	0.54	Northern Europe	0.54
Beans	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	when ¾ of the pods has changed to black minimum 7 days before harvest (seeds > 30% humidity), full ripening	1	-	80-400	0.7-2.16	Northern Europe	2.16
Broadbeans	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
	Orobanche spp.	F	SL	broadcast spraying	post-emergence of the crop	1-2	-	100-400	0.54-1.08	Spain	1.08
Frenchbeans	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU											
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
Soybeans	Annual weeds, Perennial weeds	F	SL SG	spraying + other (wet rope, drop boom, etc) wiping	pre-plant, post-harvest	1-3	-	200-400/ulv	-	Italy	4.32
Peas	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	when 70-75% of the field has changed to yellow-brown colour min. 7 days before harvest (seeds > 30% humidity), full ripening	1	-	80-400	0.7-2.16	Northern Europe	2.16
	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
OIL SEEDS **Rape seed**	Annual weeds, Perennial weeds	F	SL SG	spraying	<30% moisture content in the seed, 2-3 weeks before harvest	1	-	100-250	1.44-1.47	Northern Europe	2.01
Rape seed		F	SL SG	spraying	pre-emergence	1	-	-	0.54	United Kingdom, Ireland Northern + Southern Europe	2.01

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU												
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
	Harvest management	F	SL SG	spraying	<30% moisture content in the seed, 2-3 weeks before harvest	1	-	-	1.08-1.47	Sweden, United Kingdom, Ireland	2.01
Linseed	Annual weeds, Perennial weeds	F	SL SG	spraying	<30% moisture content in the seed, 2-3 weeks before harvest	1	-	80-250	1.44	United Kingdom, Ireland	1.44
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence	1	-	80-250	0.54	Northern Europe	1.98
	Harvest management	F	SL SG	spraying	-	1	-	-	0.36-0.54	United Kingdom, Ireland	1.08
Mustard seed	Annual weeds, Perennial weeds	F	SL SG	spraying	<30% moisture content in the seed, 8-10 days before harvest	1	-	80-250	1.44	United Kingdom, Ireland	1.44
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence	1	-	80-250	0.54	Northern Europe	1.98
	Harvest management	F	SL SG	spraying	-	1	-	-	1.08	United Kingdom, Ireland	1.08

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
POTATOES											
Potatoes	Annual weeds, Perennial weeds, Couch-grass, Wild potato shoots	F	SL EC GR SG	spraying	pre-drilling, pre-emergence	1	-	50-400	0.54-2.18	Netherlands Sweden	2.1
	Annual weeds, Perennial weeds	F	SL	wiping	>10cm height difference	2	-	-	35-50%	Austria	
	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
	Harvest management (pre-harvest)	F	SL	spraying	1 week before harvest, treatment only if potato tops destroyed or died naturally	1	-	80-250	1.44	Netherlands	1.44
CEREALS											
Cereals	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	full ripening stage (BBCH stage 89), when moisture content of youngest crop grain is < 30%	1	-	40-400	0.7-2.16	Northern Europe	2.16
	Annual weeds, Perennial weeds	F	SL SG	spraying	before drilling	-	-	-	1.08-4.32	France	4.32
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence	1	-	40-250	0.54	United Kingdom, Ireland, Italy, Spain	2.70

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU												
Crop and/or situation	**Pests or Group of pests**	**F or G**	**Type of Form.**	**Application**			**Application rate per treatment**			**Country**	**Appl. max/season kg as/ha**
				method kind	**growth stage**	**number (max.)**	**kg as/hl**	**water l/ha**	**kg as/ha**		
	Annual weeds, Perennial weeds	F	SL SG	spraying; other (wet rope, drop boom, etc)	pre-plant, post-harvest	1-3	-	200-400/ulv		Italy Greece	4.32
Winter wheat and barley	Harvest management (pre-harvest)	F	SL	spraying	1 week before harvest and moisture content of grain is < 25%	1	-	-	2.16	France	2.16
Maize	Annual weeds, Perennial weeds	F	SL	spraying interrow equipment	till growth stage 36	1 or 2 (splitting)	-	100-300 100-300	1.80 or 0.90+0.90	Germany	1.80
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence till 2 days before seeding	1	-	100-300	1.08	Germany	1.08
	Annual weeds, Perennial weeds	F	SL SG	spraying interrow equipment + wiping	any stage	1-3	-	200-400/ulv	-	Italy Greece	4.32
OTHER FOODSTUFF											
Sugar and fodder beet	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	pre-emergence	1	-	100-400	0.7-2.1	Netherlands	2.1

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR GLYPHOSATE USE IN THE EU

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Sugar beet	Annual weeds, Perennial weeds	F	SL SG	spraying; other (wet rope, drop boom, etc)	pre-plant and post-harvest	1-3	-	200-400/ulv	-	Italy Greece	4.32
	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
Sugar beet	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence till 2 days before seeding	1	-	100-300	1.08	Germany United Kingdom	1.08
localized	Thistle, wild beets	F	SL SG	wiping	sufficient height differences between weeds	2	-	-	33-50% concen-tration	Germany United Kingdom	

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Annex 1b – GAP supporting renewal of inclusion of glyphosate in Annex I of Directive 91/414/EEC

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation*		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
All crops**	EU		F	Emerged annual, perennial and biennial weeds	SL	360g/L	Spray	Pre planting of crop	1-2	21d		100-400	0 36-2 16		Spring & autumn after harvest (incl stubble and/or seedbed prep) maximum application rate 4 32 hg/ha in any 12 month period across use categories
All crops**	EU		F	Emerged annual, perennial and biennial weeds	SL	360g/L	Spray	Post planting/ pre emergence of crop	1			100-400	0 36-1 08		
Cereals (pre-harvest)	EU		F	Emerged annual, perennial and biennial weeds	SL	360g/L	Spray	Crop maturity < 30 % grain moisture	1			100-400	0 72-2 16	7	maximum application rate 4 32 hg/ha in any 12 month period across use categories
Oilseeds (pre-harvest)	EU		F	Emerged annual, perennial and biennial weeds	SL	360g/L	Spray	Crop maturity < 30 % grain moisture	1			100-400	0 72-2 16	14	
Orchard crops, vines, including citrus & tree nuts	EU		F	Emerged annual, perennial and biennial weeds	SL	360g/L	Spray	Post emergence of weeds	1-3	28d		100-400	0 72-2 88	N/A	Stone & pome fruit, olives applications made round base of trunk Seasonal application not to exceed 4 32 kg as/ha

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation*		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Orchard crops, vines, including citrus & tree nuts **(spot treatment)**	EU		F	Emerged annual, perennial and biennial weeds	SL	360g/L	Spray Knapsack use	Post emergence of weeds	1 1-3	28d		0-400	0 72-2 88 0 96-2 88	N/A	Stone & pome fruit, olives Applications made round base of trunk Seasonal application not to exceed 4 32 kg as/ha 0 L water/ha covers ULV application of neat (undiluted) product

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e g biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e g wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e g high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e g overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions
* The type and concentration of the lead formulation are used as example

** all seeded or transplanted crops [including but not restricted to: root & tuber vegetables, bulb vegetables, stem vegetables, field vegetables(fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, cereals, and sugar- & fodder beet; before planting fruit crops, ornamentals, trees, nursery plants *etc*]

Annex 2 – Letter from the Glyphosate task force expressing an intention to renew the approval of glyphosate

MONSANTO
imagine

[redacted]

[redacted]

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Dr. Louis Smeets
DG Health and Consumer Protection (SANCO) - Unit E.3
European Commission
B-1049 Brussels

Brussels, 10 December 2009

Dear Dr. Smeets,

Annex I renewal of glyphosate

The Glyphosate Task Force was formed a year ago with the aim of producing a single notification for the renewal of the Annex I inclusion of glyphosate. The task force currently has 9 members with 4 more in the process of application.

We have been discussing potential Rapporteurs. The Rapporteur for the first inclusion of glyphosate, Germany, declined to be RMS for glyphosate renewal. However, we recently met the UK CRD (Richard Davies, Darren Flynn and Rob Mason) which expressed a provisional interest in being the Rapporteur Member State for glyphosate. We understand that a list of potential RMS for the next Annex I renewal substances is being drawn up and would be pleased if you could consider including the UK CRD as the RMS for glyphosate.

The task force is concerned about the progress of the Regulations for the next stage of the renewal process. The expiry date for the inclusion of glyphosate in Annex I is June 30, 2012. However, we understand that the vote on the Regulation for the prolongation of the inclusion of these substances is planned for March. If that is the case, then we trust that there will be no need to submit a dossier to meet the current deadline under Directive 91/414/EC.

Finally, the Glyphosate Task Force would be interested in contacting any other notifiers for the renewal of Annex I inclusion of glyphosate. Therefore, we would appreciate your help in facilitating such contacts should you be aware of other notifiers.

We look forward to further discussions in the coming months.

Your sincerely,

[redacted]

On behalf of the Glyphosate Task Force

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