REGISTRATION REPORT
Part A

Risk Management

Product code: HAG 500 02 H
Active Substance: Glyphosate 450 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Helm AG
Date: 15/03/2013

Table of Contents

PART A – Risk Management		**4**
1	**Details of the application**	**4**
1.1	**Application background**	**4**
1.2	**Annex I inclusion**	**5**
1.3	**Regulatory approach**	**5**
1.4	**Data protection claims**	**6**
1.5	**Letters of Access**	**6**
2	**Details of the authorisation**	**6**
2.1	**Product identity**	**6**
2.2	**Classification and labelling**	**7**
2.2.1	**Classification and labelling under Directive 1999/45/EC**	**7**
2.2.2	**Classification and labelling under Regulation (EC) No 1272/2008**	**7**
2.2.3	**Standard phrases under regulation (EU)No 547/2011**	**7**
2.2.4	**Other phrases, conditions and restrictions**	**8**
2.2.4.1	**Specific restrictions linked to the PPP**	**8**
2.2.4.1	**Restrictions linked to the PPP**	**8**
2.2.4.2	**Specific restrictions linked to intendes uses**	**8**
2.3	**Product uses**	**10**
3	**Risk management**	**13**
3.1	**Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles**	**13**
3.1.1	**Physical and chemical properties (Part B, Section 1, Points 2 and 4)**	**13**
3.1.2	**Methods of analysis (Part B, Section 2, Point 5)**	**13**
3.1.2.1	**Analytical method for the formulation (Part B, Section 2, Point 5.2)**	**13**
3.1.2.2	**Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)**	**13**
3.1.3	**Mammalian Toxicology (Part B, Section 3, Point 7)**	**14**
3.1.3.1	**Acute Toxicity (Part B, Section 3, Point 7.1)**	**14**
3.1.3.2	**Operator Exposure (Part B, Section 3, Point 7.3)**	**14**
3.1.3.3	**Bystander Exposure (Part B, Section 3, Point 7.4)**	**14**
3.1.3.4	**Worker Exposure (Part B, Section 3, Point 7.5)**	**14**
3.1.3.5	**Conclusion of Exposure Estimation and Risk Assessment**	**14**
3.1.4	**Residues and Consumer Exposure (Part B, Section 4, Point 8)**	**16**
3.1.4.1	**Residues (Part B, Section 4, Points 8.3 and 8.7)**	**16**
3.1.4.2	**Consumer exposure (Part B, Section 4, Point 8.10)**	**16**

3.1.5	**Environmental fate and behaviour (Part B, Section 5, Point 9)**	**17**
3.1.6	**Ecotoxicology (Part B, Section 6, Point 10)**	**20**
3.1.6.1	**Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)**	**20**
3.1.6.2	**Effects on Aquatic Species (Part B, Section 6, Point 10.2)**	**20**
3.1.6.3	**Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)**	**21**
3.1.6.4	**Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)**	**22**
3.1.6.5	**Effects on Soil Organic matter breakdown(Part B, Section 6, Point 10.6)**	**23**
3.1.6.6	**Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)**	**23**
3.1.6.7	**Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)**	**23**
3.1.7	**Efficacy (Part B, Section 7, Point 8)**	**24**
3.2	**Conclusions**	**27**
3.3	**Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation**	**27**
Appendix 1 – Copy of the product authorisation		**28**
Appendix 2 – Copy of the product label		**28**
Appendix 3 – Letter of Access		**28**

PART A – Risk Management

This document describes the acceptable use conditions required for the authorisation of HAG 500 02 H containing glyphosate in Germany. This evaluation is required subsequent to the inclusion of glyphosate on Annex I.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national authorisation by the EU review. It also includes assessment of data and information relating to HAG 500 02 H where that data has not been considered in the EU review. Otherwise assessments for the safe use of HAG 500 02 H have been made using endpoints agreed in the EU review of glyphosate.

This document describes the specific conditions of use and labelling required for Germany for the authorisation of HAG 500 02 H.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.

Appendix 2 of this document is a copy of the product label for Germany.

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 Letter of access.

Letters of access are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by HELM AG on 29.04.2011. Although the application was submitted under Directive 91/414/EEC and the authorisation will be granted according to § 15 Plant Protection Act of 1998, last amended on 2 November 2011, it has been evaluated as voluntary worksharing in line with the requirements of the zonal assessment under Regulation (EC) No. 1107/2009.

The application was for approval of HAG 500 02 H, an SL formulation containing 450g/L glyphosate for use as a herbicide. A trade name has not yet been allocated to the formulated product. The provisional designation Glyphosate 450 SL AE was used in study reports.

According to the GAP, HAG 500 02 H is intended to be applied only once per season with a maximum application rate of 3.6 kg a.s./ha (acid equivalent) (range 0.675 to 3.6 kg a.s./ha) for all uses. It will be used against monocotyledonous and dicotyledonous weeds on the following crops: BEAVA (*Beta vulgaris*), BRSNW (*Brassica napus*, winter), HORVS and HORVW (spring and winter *Hordeum* *vulgare)*, MABSS (Apple), PIBSA (Field pea), PYUSS (Pear), TRZAS and TRZAW (spring and winter *Triticum aestivum*), TTLSO and TTLWI (spring and winter Triticale), and YACKR (Arable land). The product is intended to be applied on BRSNW, HORVW, HORVS, PIBSA, TRZAS, TRZAW, TTLSO and TTLWI pre-harvest for desiccation.

Besides the zonal Rapporteur Germany, authorisations are applied for in Austria, Belgium, the Czech Republic, Hungary, Ireland, The Netherlands, Poland, Romania, Slovakia and the United Kingdom.

1.2 Annex I inclusion

Glyphosate has been included in Annex I of the EU Directive 91/414/EEC with entry into force by 1 July 2002. The corresponding EU Commission Directive 2001/99/EC has been published in the Official Journal of the European Communities on 20 November 2001.

Glyphosate has been completely and sufficiently assessed in the review of the dossier for inclusion into Annex I (Review report for the active substance glyphosate, finalised on 29 June 2001 in view of the inclusion of glyphosate in Annex I of Directive 91/414/EEC). The overall conclusion was that plant protection products containing glyphosate will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. These conclusions were reached within the framework of the following uses:

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

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29/06/2001, shall be taken into account. In this overall assessment:

Member States must pay particular attention to the:

- protection of the groundwater in vulnerable areas, in particular with respect to non-crops uses

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain approval the product HAG 500 02 H must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in Germany in order to allow the first approval of this product/use in the Central Zone in accordance with the above.

1.4 Data protection claims

Helm AG claims data protection for all study reports which are submitted in support of the authorisation of HAG 500 02 H. The data protection claims are correctly provided in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 7 and Part C.

1.5 Letters of Access

Data access has been proven. A letter of access dated 2nd April 2012 was submitted by Syngenta Crop Protection; a letter of access dated 26. November 2012 was submitted by Feinchemie Schwebda and a letter of access dated 30. November 2012 was submitted by DuPont Crop Protection. Further study reports and data submitted are the property of Helm AG.

2 Details of the authorisation

2.1 Product identity

Product Name	HAG 500 02 H
Authorization Number (for re-registration)	007385-00
Function	herbicide
Applicant	Helm AG, Hamburg, Germany
Composition	450 g/L Glyphosate in the formulation as isopropylamine-salt
Formulation type	soluble concentrate [Code: SL]
Packaging	1000 ml HDPE bottle, 5L, 20 L HDPE canister, 120 L, 220L HDPE drum, 640 L - 1250 L HDPE intermediate bulk container

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 1999/45/EC

The following labelling is proposed in accordance with Directive 1999/45/EC:

Symbol(s)/Indication(s) of danger:	
N	Dangerous for the environment
Risk phrases:	
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases:	
S35	This material and its container must be disposed of in a safe way.
S57	Use appropriate container to avoid environmental contamination.
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories: (kein Labelling-Requirement!)	
Aquatic Acute1 Aquatic Chronic 1	Hazardous to the aquatic environment
Hazard pictograms:	
GHS 09	
Signal words:	
None.	
Hazard statements:	
H411	Toxic to aquatic life with long lasting effects
Precautionary statemtents:	
P273	Avoid release to the environment.
P391	Collect spillage.
P501	Dispose of contents/container to ….
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Supplemental labelling information	

2.2.3 Standard phrases under regulation (EU)No 547/2011

None.

2.2.4 Other phrases, conditions and restrictions

2.2.4.1 Specific restrictions linked to the PPP

2.2.4.1 Restrictions linked to the PPP

Labelling phrases for human health protection

SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB010	Keep out of the reach of children.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.

Labelling phrases for efficacy and sustainable use

WMG	Mode of action (HRAC-group): G
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.

Labelling phrases for ecosystem protection

NW262	The product is toxic for algae.
NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals

2.2.4.2 Specific restrictions linked to intendes uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

WH914	The instructions for use must include a summary of weeds, and if applicable woody plants, which can be controlled well, less well and insufficiently by the product.
WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.
NW642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.
NT102	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

2.3 Product uses

GAP rev. (No), date: 2012-09-17 (1)

PPP (product name/code)	**HAG 500 02 H**	**Formulation type:**	**SL**
active substance 1	**glyphosate**	**Conc. of as 1:**	**450 g/L**
Applicant:	**HELM AG**	**professional use**	☒
Zone(s):	**Central Zone**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha
		(crop destination / purpose of crop)		(additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. recommended or mandatory tank mixtures
001	DE	Field crops	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD	spraying	stubble treatment; after harvest, up to 4 days before sowing	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400	F	WH914 NW642-1 NT102
002	DE	Pome fruit	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD	spraying	spring to summer	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400	42	WH9161 NW642-1 NT102
003	DE	Pome fruit	F	CONAR	spraying	spring to summer	a) 1 b) 1	a) 8.0 b) 8.0	a) 3.6 b) 3.6	100 - 400	42	No authorization in Germany
004	DE	Grape vine	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD	spraying	utilisation as wine and table grape from 4th year after planting of the vine onwards;	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400	30	WH9161 NW642-1 NT102

						spring to summer						
005	DE	Grape vine	F	CONAR	spraying	utilisation as wine and table grape from 4th year after planting of the vine onwards; spring to summer	a) 1 b) 1	a) 8.0 b) 8.0	a) 3.6 b) 3.6	100 - 400	30	No authorization in Germany
006	DE	Cereals (barley, oats, rye, triticale, wheat)	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD, siccation YELSI	spraying	except for seed production and brewing purposes; 89 - 89; up to 7 days before harvest, during late treatment	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400	7	WH914 NW642-1 NT102 YELSI only requested for laid crops in DE
007	DE	Grassland, pasture, meadow	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD,	spraying	5-7 days before sowing, during vegetative period	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400	F (grass and hay)	WH914 NW642-1 NT102
008	DE	Winter rape	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD, siccation YELSI	spraying	except for seed production; 87 - 89; up to 14 days before harvest, during late treatment	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400	14	WH914 NW642-1 NT102 YELSI not requested in DE
009	DE	Winter rape	F	monocotyledonous weeds TTTMM, dicotyledonous weeds TTTDD	spraying	except for seed production; 00 - 08; Before emergence, after emergence of weeds	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400	F	use will not be pursued in DE

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, develeopmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(9) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g.g or kg / ha)
(12) The range (min/max) of water volumn under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:
The appearance of the product is that of a yellowish homogenous liquid, with a characteristic odour. It is not explosive, has no oxidising properties. It shows no flash point up to 250 °C where decomposition starts. In aqueous solution, it has a pH value around 4.6. The stability data at 54 °C indicate a shelf life of at least 2 years at ambient temperature, but the final results are not available yet. Its technical characteristics are acceptable for a soluble concentrate formulation.

Implications for labelling: none

Compliance with FAO specifications:
The product HAG 500 02 H complies with FAO specifications.

Compatibility of mixtures:
No tank mixtures are recommended.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment (coverall, protective glasses, gloves can be washed with water) for the safe handling of HAG 500 02 H has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

The active substance glyphosate can be quantified in the formulation using a HPLC method.
The relevant impurities formaldehyde and N-Nitrosoglyphosate can be quantified in the formulation using HPLC methods.
All analytical methods are sufficiently validated.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

New analytical methods for the monitoring of glyphosate residues have not been submitted by the applicant. The assessment according to the guidance document SANCO/825/00 rev. 8.1 has shown that not all of the analytical methods for monitoring which were found acceptable for the Annex I inclusion are still in compliance with the current data requirements. However, adequate analytical methods are available to monitor all compounds given in the respective residue definition in food of plant and animal origin, soil, water and air.

As several validated studies are still subject to data protection in Germany, Letters of Access were provided by the applicant. These Letters of Access cover the requirements for the determination of residues in food of animal origin, soil and water, and include a necessary ILV for plant matrices, as well. Furthermore, as the applicant is a member of the Task Force for the renewal of the approval of glyphosate and has access to the Annex II dossier, sufficient confirmatory methods for the determination of residues in food of plant origin are also available.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Acute toxicity studies for HAG 500 02 H were not evaluated as part of the EU review of the glyphosate. Therefore, all relevant data were provided and are considered adequate.
HAG 500 02 H, containing 450 g/L glyphosate, has a very low toxicity by the oral, percutaneous and inhalation route. It is neither a skin nor an eye irritant nor possesses a sensitising potential according to the results of the Magnusson and Kligman test. According to Directive 67/548/EEC or Reg. 1272/2008, HAG 500 02 H needs not to be classified.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure to HAG 500 02 H was not evaluated as part of the EU review of glyphosate for this submitted rates/crops. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.
Operator exposure was assessed against the systemic AOEL agreed in the EU review (glyphosate: 0.2 mg/kg bw/day). Data on dermal absorption of HAG 500 02 H was provided and considered acceptable. Operator exposure was modelled using UK OPEX and German models.

According to the model calculations, it can be concluded that the risk for the operator using HAG 500 02 H on the critical uses in vineyards and pome fruit orchards is acceptable with the use of personal protective equipment. During mixing/loading and application gloves and an impermeable coverall should be worn.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

Since safe use could be demonstrated, no bystander or resident exposure studies are necessary and were therefore not performed.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Since safe use could be demonstrated, no worker exposure studies are necessary and were therefore not performed.

3.1.3.5 Conclusion of Exposure Estimation and Risk Assessment

The risk assessment has shown that according to the German model the estimated exposure towards glyphosate in HAG 500 02 H will not exceed the systemic AOEL for operators, workers, bystanders and residents if prescribed PPE is worn by operators.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.
However, according to the UK POEM estimated operator exposure will exceed the AOEL-S in the case hand-held equipment is assumed for application under grape vine or pome, even if gloves are used during mixing/loading and application. If HAG 500 02 H is applied by tractor mounted equipment under these plants safe use can be demonstrated in the case gloves are considered during mixing/loading and application.

Implications for labelling resulting from operator, worker, bystander assessments:

Hazard Symbol:	None.
Indication of danger:	None.
Risk Phrases:	None.
Safety Phrases:	None.

R and S phrases under Directive 2003/82/EC (Annex IV and V): None.

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

The residue behaviour of the active substance glyphosate was evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended uses.

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

No new data has been provided and full reference has been made to the DAR. Available data are sufficient for the evaluation of the uses applied for.
Existing MRLs as established in Regulation (EC) No 396/2005 are sufficient to cover residues arising from the intended uses.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

A further assessment of consumer intake levels was conducted. TMDI calculations using the EFSA model PRIMo and the German VELS model were performed to take account of all crops to which glyphosate may be applied.
The estimated consumer intake levels do not exceed the EU agreed ADI of 0.3 mg/kg bw/day for glyphosate. It can therefore be concluded that acceptable margins of safety exist for consumers. With the current EFSA model and the German VELS model the chronic risk assessment ranges from 44 % (based on WHO cluster diet B) to 21 % of ADI
The long-term and short-term intake of glyphosate residues is unlikely to present a public health concern.
As far as consumer health protection is concerned, the zRMS agrees with the authorisation of the intended uses.
As no acute reference dose has been set for the active substance, there is no need to evaluate the acute risk for this active substance.
Based on the different calculations made to estimate the risk for consumer though diet and other means it can be concluded that the use of product HAG 500 02 H does not lead to unacceptable risk for consumer when applied according to the recommendations.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product HAG 500 02 H in its intended uses in various crops is documented in detail in the core assessment of the plant protection product HAG 500 02 H dated from July 2012 performed by Germany.

The following chapters summarises specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of HAG 500 02 H in Germany according to its intended uses.

For reasons of better readability the intended uses in of the plant protection product HAG 500 02 H in Germany are summarised as follows:

Metabolites

No new study on the fate and behaviour of glyphosate or HAG 500 02 H has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites has already been performed for EU approval (see SANCO/6511/VI/99-final, 21 January 2002). AMPA is considered ecotoxicologically not relevant and did not penetrate into groundwater. Therefore no new risk assessment hence no exposure assessment is necessary.

For details see Part B, core assessment, section 5, chapter 5.3.1.3.

The risk assessment for groundwater by direct leaching for the application of the plant protection product and its intended uses includes the soil metabolite AMPA.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product HAG 500 02 H according to use 002/004 (4 L/ha) and 003/005 (8 L/ha), covering all other uses, PECsoil was calculated for the active substance glyphosate considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance glyphosate in soil the accumulation potential of glyphosate was not considered.

The PECsoil-values calculated for glyphosate and the metabolite AMPA are shown in the following table. Details are given in Part B National Addendum-Germany, Section5, chapter 5.5.

Use no.	**active substance/ formulation**	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**
003/005	glyphosate	3600	2.5	9.600
	AMPA	100 % formation fraction from as	2.5	3.890 on day 14
	HAG 500 02 H	8000	2.5	21.333
002/004	glyphosate	1800	2.5	4.800
	AMPA	100 % formation fraction from as	2.5	1.945 on day 14
	HAG 500 02 H	4000	2.5	10.677

The results for PEC soil for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Direct leaching into groundwater

Results of modelling with FOCUS PELMO 4.4.3 show that the active substance glyphosate is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L. For the metabolite AMPA concentrations of ≥ 0.1 µg/L in groundwater can be excluded.

For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.1.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance glyphosate due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can only be excluded in case risk mitigation measures depending on the use are applied.

The following input parameters for glyphosate were used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0:

Parameter	**Glyphosate**	**Reference to Part B, Section 5, Core assessment**
$K_{foc, Runoff}$	21616	arithmetic mean, Table 5.4-5 of core assessment
$K_{foc, mobility\ class}$	21616	arithmetic mean, Table 5.4-5 of core assessment
DT_{50} soil (d)	113.6	90^{th} percentile lab studies, see Table 5.4-1 of core assessment, field studies not considered due to application timing
Solubility in water (mg/L)	18800	see core assessment chapter 5.3.1.2
Mobility class	1	-
Reduction by bank filtration	23.5 %	measured values, see Schmidt, 2005 (TZW Karlsruhe)

Using these parameters, the following PECgw-values were calculated for glyphosate after surface run-off and drainage with subsequent bank filtration:

Active substance		**glyphosate**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001, 00-002, 00-004, 00-007*	1800 g/ha 0 %	0	0.058	autumn/winter/ early spring	0.052
		5	0.050		
		10	0.043	spring/summer	0.017

		20	0.030		
00-003, 00-005	3600 g/ha 0 %	0	**0.116**	autumn/winter/ early spring	not relevant for use
		5	**0.101**		
		10	0.087	spring/summer	0.034
		20	0.061		
required labelling		NG 402			

* also covering the remaining uses 00-006, 00-008, 00-009

For the authorization of the plant protection product HAG 500 02 H the following risk mitigation is assigned:

Use No. 00-003, 00-005 NG 402

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product HAG 500 02 H in pome fruit and vineyards according to use No 00-003 and 00-005 (covering all other uses) PECsw was calculated for the active substance glyphosate considering the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately.

The vapour pressure at 20 °C of the active substance glyphosate is between 10^{-5} und 10^{-4} Pa. Hence the active substance glyphosate is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of surface water by the active substance glyphosate due to deposition following volatilization was considered.

Details are given in Part B, National Addendum-Germany, Section5, chapter 5.6.

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance glyphosate is between 10^{-5} und 10^{-4} Pa, hence the active is regarded as semivolatile. In volitilisation trials, volatilisation only from plant surfaces was mearsured. The photochemical oxidative degradation in air (calculation according to Atkinson) 1,6 d, therefore a long-range transport is not to be considered.

Implications for labelling resulting from environmental fate assessment:

None

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

The intended use of HAG 500 02 H in Germany is generally covered by the uses evaluated in the course of the core assessment.

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Please refer to the core dossier for the central zone.

Based on the presumptions of Tier 1, the calculated TER values for acute and long-term risk resulting from an exposure of mammals to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H up to 3600 g glyphosate/ha achieve the acceptability criteria TER ≥ 10 (for mouse and vole ≥ 5) and TER ≥ 5 (for mouse and vole ≥ 2), respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals from the intended uses.

Implications for labelling:
None

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Risk assessments for aquatic organisms were conducted based on the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 final).

Predicted environmemtal concentrations in surface water have been calculated in accordance with German national requirements for drift, run-off and drainage entry into surface water.

Based on the calculated concentrations of glyphosate the calculated TER-values for the acute and long-term risk resulting from an exposure of aquatic organisms to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10. The results of the assessment indicate an acceptable risk for aquatic organisms for all intended uses of HAG 500 02 H applying up to 3600 g glyphosate/ha without specific risk mitigation measures.

However, due to the toxicity to algae (EyC50 = 1.6 mg Prod./L, *Pseudokirchneriella subcapitata), t*he product may not be applied in or in the immediate vicinity of surface or coastal waters. The labelling NW641-1 is assigned to all uses.

Implications for labelling:
Because of the toxicity of the active ingredient the following labels are assigned:

NW 262	The product is toxic for algae (EC_{50}: 0,64 mg glyphosate/L (*Skeletonema costatum)*
NW 468:	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NW642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.

According to directives 67/548/EEC, 78/631/EEC and 1999/45/EEC, using the relevant toxicity of HAG 500 02 H (EyC50 = 1.6 mg/L, *Pseudokirchneriella subcapitata*), the following classification & labelling is assigned:

Danger Symbol	N, dangerous for the environment
Risk Phrases	R 51/53 (Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)
C&L according directive 1272/2008	
Danger Symbol	GHS 09
Hazard Statements	H 411

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Toxicity
The results of laboratory bee toxicity studies with the active substance glyphosate and the formulation HAG 500 02 H are presented in table below:

Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	GLP	Guideline	Reference
Glyphosate 450 SL AE (= HAG 500 02 H)	oral 48 h	>> 217.2 µg product/bee	yes	OECD 213/214	Sekine, T., 2010; project 50354035
	contact 48 h	>> 200 µg product/bee			
Glyphosate tech.	oral 48 h	= 100 µg /bee	*	*	*
	contact 48 h	> 100 µg /bee			

* EU agreed endpoints for bees (SANCO/6511/VI/99-final, 2002)

Hazard quotients for bees
Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

Hazard Quotient = max. application rate [g test substance/ha] / LD_{50} [µg test substance/bee]

Hazard quotients for honeybees

Test substance	Exposure route	LD_{50}	Max. single application rate	Hazard quotient (HQ)	HQ assessment trigger
HAG 500 02 H	oral	>> 217.2 µg product/bee	9568 g product/ha	< 45	50
	contact	>> 200 µg product/bee		< 48	50

Risk assessment
Due to the results of laboratory tests both technical glyphosate and the formulation HAG 500 02 H containing 450 g/L glyphosate are considered practically non toxic to bees. All hazard quotients are well below the trigger of 50, indicating a low risk to bees in the field. Bee brood testing is not required since HAG 500 02 H is not an IGR and not deemed to cause a significant exposure of larvae or hive bees.

Overall conclusion:
It is concluded that HAG 500 02 H will not adversely affect bees or bee colonies when used as recommended.

Label applied:
NB6641 The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

Other non-target arthropods

For details of the risk assessment see National Addendum Germany.

The lowest dose tested (35.6 g a.s./ha) with effects on reproduction of *T. pyri* was used in the risk assessment (surrogate endpoint reproduction = 35.6 g a.s./ha), since sublethal endpoints are considered to be relevant for a Tier 2 risk assessment step,

The off-field TER values *T. pyri* are below the trigger value, indicating that HAG 500 02H does pose an unacceptable risk to non-target arthropods in off-field areas. Risk mitigation via 50 % drift reduction (NT101) or 5m buffer zone for an application rate of 1x 1800 g a.i /ha is needed.

The off-field TER values T. pyri are below the trigger value, indicating that HAG 500 02H does pose an unacceptable risk to non-target arthropods in off-field areas. Risk mitigation via 75 % drift reduction (NT102) or 5m buffer zone for an application rate of 1x 3600 g a.i /ha is needed.

Since non-target arthropods are not the most sensitive group of terrestrial organisms, the risk mitigation measures for non-target plants will also cover the protection of non-target arthropods (see 3.1.6.7).

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

Risk assessments for earthworms and other soil non-target macro-organisms were conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final). The assessments for acute and chronic exposure have been conducted based on the formulated product HAG 500 02 H.

Predicted environmental concentrations in soil were calculated based on German national requirements; i.e. for a soil penetration depth of 2.5 cm for substances with KOC < 500 L/kg.

Based on the worst-case scenarios vineyard and orchard the acceptability criteria TER ≥ 10 for acute effects, according to Annex VI to directive 1107/2009 (EG), uniform principles, point 2.5.2.5 is reached, indicating that HAG 500 02 H poses low acute risk to earthworms when applied at the maximum application rate of 8 L/ha (3600 g glyphosate / ha).

The reduced application rate of 4 L/ha (1800 g glyphosate / ha) covering all other uses except Group C pose, according to the TER values, low chronic risk to earthworms.

Based on the worst-case scenario, the acceptability criteria TER ≥ 5 for long-term effects, according to directive 1107/2009 (EG), Annex VI. uniform principles, point 2.5.2.5 is not reached for the formulation HAG 500 02 H at the maximum application rate of 8 L/ha (3600 g glyphosate / ha) for earthworms. The TER values below the acceptability criteria for use 00-003 and 00-005 (3600 g glyphosate / ha), indicate an unacceptable long term risk for earthworms.

Implications for authorization:
No authorisation for uses 00-003, 00-005

3.1.6.5 Effects on Soil Organic matter breakdown(Part B, Section 6, Point 10.6)

Not relevant. None of the criteria mentioned in the Guidance Document on Terrestrial Ecotoxicology is met for Glyphosate, since DT90field value is less than 365 days and no risk was identified for soil fauna and soil micro-organisms.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

The risk assessment for soil microflora functions was conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final) based on data for the formulated product HAG 500 02 H.

All effects on soil microflora carbon respiration and nitrogen transformation) caused by HAG 500 02 H were below the trigger value < 25% after 28d exposure, indicating that the proposed uses pose acceptable risk. No specific risk mitigation measures are assigned.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Non-Target Plants

Based on the most sensitive endpoints for vegetative vigour (ER_{50} *Brassica oleracea:* 125 ml prod./ha), the TER of 5 is not met for all uses.

For the rates of 2,5 or 4 L/ha (all uses except 00-003 and 00-005), an acceptable risk to terrestrial non-target plants is only achieved with a drift reduction of 75 % and 1 m buffer or 5 m buffer without drift reduction. In Germany, the risk mitigation NT102 is assigned.

For the rate of 8 L/ha (uses 00-003 and 00-005), a low and acceptable risk to terrestrial non-target plants is only achieved with a drift reduction of 90 % and 1 m buffer or 5 m buffer with a drift reduction of 50 %. In Germany, the risk mitigation measure NT103 should be assigned. However, these uses will not be authorized in Germany due to the high risk to earthworms (see 3.1.6.4).

Implications for labelling:
NT 102 for all uses except 00-003 and 00-005

3.1.7 Efficacy (Part B, Section 7, Point 8)

All the data regarding the efficacy of the product have been submitted. These data demonstrate that HAG 500 02 H fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC).

Summary and assessment of data according to points 6.1 to 6.5

Glyphosate is an organic phosphorus compound, belonging to the chemical class of glycines, with no or low soil residual activity. Herbicides containing glyphosate differ in the salt formulation. Glyphosate may present as glyphosate-ammonium-salt, as glyphosate-isopropylammonium-salt or as glyphosate-potassium-salt. Glyphosate is a non-selective herbicidal active substance. Glyphosate is taken up by the leaves and other green parts of the plant and is translocated systemically (apoplastic and symplastic) in the whole plant, also in underground parts like roots, rhizomes or stolons. Glyphosate uptake through the roots is negligible because the active substance is strongly adsorbed in the soil. The extensive adsorption of glyphosate together with a ready degradation in soil, are the principal deactivation and dissipation mechanisms in the soil environment.

In plants, glyphosate inhibits the shikimic acid pathway. Glyphosate binds to and blocks the activity of its target enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), an enzyme of the aromatic amino acid biosynthetic pathway (HRAC classification G). The inhibition of the enzyme prevents the plant from synthesizing the essential aromatic amino acids (e.g. phenylalanine, tyrosine, and tryptophane) needed for protein biosynthesis. This reduces the production of protein in the plant, and inhibits plant growth. EPSPS is present in all plants. It leads to an accumulation of the amino acids glutamine, glutamic acid, shikimic acid and ammonia. As a consequence of missing aromatic amino acids the formation of phenolic compounds is inhibited (e.g. lignin, flavanoids).

Label applied:

WMG Mode of Action (HRAC-Group): G

The product HAG 500 02 H formulated as 450 g/L glyphosate SL formulation is intended to be used as non-selective herbicide against monocotyledonous and dicotyledonous weeds in on a number of field crops as well as in vineyards and orchards (pome fruit) and for desiccation. The active substance glyphosate is a commonly used herbicide in agriculture worldwide.

The submission of the present draft Registration Report (dRR) serves the core registration of HAG 500 02 H (glyphosate) in the central registration zone (B) of the European Union. A national addendum for Germany was not submitted. The national label for Germany is available. A master label for the central zone (B) is also available. In the master label some uses are named which are not requested by the applicant in Germany: Sugar beet and field peas.

The applicant applies for a herbicide containing the active ingredient glyphosate. The evaluation of the test compound is based on results of field trials conducted in Germany, the United Kingdom, France and Poland (north east zone) during the years 2009 to 2010. Weed occurrence and cropping systems are comparable between Germany and Poland. Therefore the results from Poland can be considered for the assessment. No trials were carried out in the EPPO south-east climate zone. Due to the different climatic conditions an extrapolation of the data to the countries of the south-east EPPO zone is not possible. The trials satisfy the requirements for registration with regard to comprehension and quality of the studies. The GEP-requirement is taken care of.

Minimum effective dose tests were conducted in a variety of crops in the maritime EPPO climate zone and in Poland regarding the control of mono- and dicotyledonous weeds. The trials demonstrate that for all intended uses the requested dose rate is needed. No usable data were submitted for the intended use 009 and the intended use in sugar beet. No minimum effective dose trials were submitted for the south-

east climate zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible
Efficacy tests were conducted in a variety of crops in the maritime EPPO climate zone and in Poland regarding the control of mono- and dicotyledonous weeds. HAG 500 02 H was tested in all trials in comparison to the commercial standard reference products relevant in the different countries. In the trials HAG 500 02 H demonstrated a level of efficacy against the different weed species present in the trials similar to that of the commercial country specific standard reference products. No usable data were submitted for the intended use 009 and for some intended uses only one-year result were submitted. No efficacy tests were submitted for the south-east climate zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Efficacy tests in woody plants for the control of *Convolvulus arvensis* (CONAR) as well as other mono- and dicotyledonous weeds were conducted in grape and pome fruits. For the control of mono- and dicotyledonous weeds in grape a total of four trials was conducted in 2009 and 2010. For example for 7 weed species (CAPBP, CIRAR, LAMPU, FUMOF, GERMO, VERPE and PICHI) a control level of 98-100 % was achieved using a dosage of 1800 g as/ha HAG 500 02 H. Furthermore, the effectiveness of HAG 500 02 H for the control of mono- and dicotyledonous weeds using a target dose of 1800 g as/ha was tested in 7 trials in pome fruit orchards. In these trials HAG 500 02 H showed a good control effect on 27 weed species. A partial, moderate or useful level of control (60-80 %) or a reduction (40-60 %) of weed species respectively was observed for some weed species like LOLMU, ERIAN, URTDI, EPIAD, GERDI and CUCLA. In the case of *Convolvulus arvensis* (CONAR) two trials were conducted in grape and two trials in pome fruit orchards in 2009. The results have shown that the overall control effect in woody plants regarding the control of *Convolvulus arvensis* (CONAR) was sufficiently. The results can be transferred to stone fruits.

Regarding efficacy of weed control in grassland re-sowing and grassland renewal six trials were conducted in the years 2009 and 2010. In these 4 trials HAG 500 02 H showed a level of efficacy against the different weed species present in the trials similar to that of the standard reference product Roundup Ultra Max.

For the efficacy of HAG 500 02 H for desiccation in the absence of weeds in TRZAS, HORVS, TTLSO, HORVW and TTLWI 17 trials were conducted considering the requested dose rate.

To test the efficacy of HAG 500 02 H for desiccation in winter oilseed rape four trials were conducted in 2009. HAG 500 02 H applied at 1125 g as/ha, equivalent to 2.5 L product/ha showed the same accelerated crop desiccation and ripening process than the double dose of HAG 500 02 H applied at 2250 g as/ha, equivalent to 5.0 L product/ha.

In stubbles the efficacy of HAG 500 02 H against various weed species was tested in 26 trials in 2009 and 2010. In these trials HAG 500 02 H demonstrated a level of efficacy against the different weed species present in the trials similar to that of the commercial country specific standard reference products.

The efficacy of HAG 500 02 H against *Elytrigia repens* (AGRRE) in winter cereals (TRZAW, HORVW, TTLWI) regarding desiccation and harvest facilitation was tested in 16 trials in 2009 and 2010.
HAG 500 02 H demonstrated a level of efficacy against the different weed species present in the trials similar to that of the commercial country-specific standard reference products in the first crop and the following crop.

In 2009 four trials were conducted to test the efficacy of HAG 500 02 H for the control of *Elytrigia repens* (AGRRE) and other weeds in oilseed rape (BRSNW). The trials have shown, that in general HAG 500 02 H had a level of efficacy against the different weed species present in the trials similar to that of the commercial country specific standard reference products in the first crop and the following crop.

In sugar beet the efficacy is demonstrated with an application rate of 1.6 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south-east EPPO zone.

HAG 500 02 H was tested in various field trials for its effects on yield and quality of plants and plant products. The test product HAG 500 02 H applied at the requested dose rate showed comparable results than the commercial standard reference product.

Adverse effects such as phytotoxicity to host crop were tested for example in grape. For this crop no specific crop selectivity trials are available for HAG 500 02 H. The crop selectivity of HAG 500 02 H was determined in all 4 trials in grape which have been conducted at the target dose rate of 1800 g as/ha, equivalent to 4.0 L product/ha and the following doses 1080 g as/ha, equivalent to 2.4 L product/ha, 1440 g as/ha, equivalent to 3.2 L product/ha and 2160 g as/ha, equivalent to 4.8 L product/ha. All different grape varieties showed a good product tolerance and no phytotoxicity were observed.

In none of the trials negative effects on beneficial or non-target organisms were observed. At the highest proposed application rate of 3600 g a.s./ha, the product HAG 500 02 H is harmless for the parasitoid Aphidius rhopalosiphi and the ground beetle Poecilus cupreus with both lethal and sublethal effects < 25% under extended laboratory conditions.

The product was harmful for the predatory mite Typhlodromus pyri at the highest proposed rate which caused 100% mortality under extended laboratory conditions. Although the exposure of predatory mites in orchards and vineyards is diminished by the proposed ground directed strip application, the product is still considered harmful, since already 1% of the highest proposed rate caused a sublethal effect of 90%.

Labels applied:

NN1001 The product is classified as non-harmful for populations of relevant beneficial insects.

NN3002 The product is classified as harmful for populations of relevant beneficial predatory mites and spider.

There were no special studies conducted concerning the influence of the product HAG 500 02 H on plants used for propagating purposes. In literature information on inhibition of seed germination in crops treated with glyphosate is given. Because of this, the treatment of cereals to desiccate is excluded according to the GAP for example.

Also no additional studies were conducted on the impact of the product HAG 500 02 H on succeeding crops. Because glyphosate has no potential for a build-up or an accumulation in soil under field conditions it can be assumed that there is no negative impact on succeeding crops.

As HAG 500 02 H is non selective herbicide the product should be used with care and in line with good plant protection practice. Directions for use for example in regard to uncontrolled spay drift to neighbouring fields, weather conditions or water volumes have to be observed. If requirements of good plant protection practice are observed it can be assumed that there are no negative impacts on other plants, including adjacent crops.

Despite the intensive use of glyphosate in many important crops on a worldwide scale, the number of documented cases of resistance is still comparatively low. However, the increasing use of glyphosate in many cropping systems in the Central Zone of Europe constitutes an increasing risk of resistance. The general resistance risk of HAG 500 02 H is therefore assessed as being low to medium. The applicant has not provided any information on the individual resistance risk within the different member states in the Central zone.

3.2 Conclusions

Based on efficacy/sustainable use data an authorisation can be granted.

The long-term and short-term intake of possible residues of glyphosate following treatment of crops according to the intended conditions of use is unlikely to present a public health concern for consumers. If used properly and according to these conditions adverse health effects for operators, workers, bystanders and residents will not be expected. As far as human health protection is concerned, the zRMS agrees with the authorisation of the uses applied for the product HAG 500 02 H.

Regarding analytical methods for residues an authorisation can be granted.

Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended for the intended uses 00-001, 00-002, 00-004, 00-006, 00-007, 00-008 and 00-009. Risk mitigation measures are assigned to minimise risk to non-target terrestrial plants and terrestrial arthropods other than bees.

For the intended uses 00-003 and 00-005 no authorization is possible in Germany due to the risk of unacceptable long term effects on earthworms.

An authorisation can be granted.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

The applicant needs to submit following confirmatory data :

AIIIA 2.7.5	shelf life study showing stability of the formulation for two years at ambient temperature.

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Dr. Dietmar Gottschild
Referent

TELEFON +49 (0)531 299-3512
TELEFAX +49 (0)531 299-3002
E-MAIL dietmar.gottschild@bvl.bund.de
INTERNET www.bvl.bund.de

Mit Zustellungsurkunde

HELM AG
Nordkanalstr. 28
20097 Hamburg

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.007385-00/00.53590

DATUM 4. April 2013

ZV1 007385-00/00

HAG 500 02 H

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	450 g/l	Glyphosat
Zulassungsnummer:	007385-00	
Versuchsbezeichnung:	HEL-50002-H-0-SL	
Antrag vom:	29. April 2011	

wird auf der Grundlage § 15 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 1527, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I S. 2162), in Verbindung mit Artikel 80 Absatz 5 Buchstabe a der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S.1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. Dezember 2023.

Festgesetzte Anwendungsgebiete

Es werden folgende Anwendungsgebiete gemäß § 15 Abs. 2 Nr. 1 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162) festgesetzt (siehe Anlage 1):

Schadorganismus/ Zweckbestimmung	**Pflanzen/-erzeugnisse/Objekte**	**Anwendungsnummer**
Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter	Wiesen, Weiden	007385-00/00-007
Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter	Winterraps	007385-00/00-008
Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter	Ackerbaukulturen	007385-00/00-001
Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter	Kernobst	007385-00/00-002
Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter	Weinrebe	007385-00/00-004
Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter, Sikkation	Getreide (Gerste, Hafer, Roggen, Triticale, Weizen)	007385-00/00-006

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 15 Abs. 2 Nr. 2 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162) festgesetzt:

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Aufgrund der Auswirkungen des Wirkstoffs Glyphosat gegenüber Algen (Skeletonema costatum EbC50 = 0,64 mg a.s./L) besitzt das o. g. Pflanzenschutzmittel einen den Naturhaushalt

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schädigenden Charakter, so dass jeder weitergehende, d. h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des Pflanzenschutzmittels "HAG 500 02 H" übersteigende Eintrag von Rückständen in Gewässer zu einer erheblichen Gefährdung des Naturhaushaltes führen würde. Angesichts der Umstände, dass ein erheblicher Anteil an Pflanzenschutzmittelfrachten im einzelnen Gewässer auf Einträge aus kommunalen Kläranlagen zurückzuführen ist (vgl. Umweltpolitik - Wasserwirtschaft in Deutschland, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlussbericht zum DBU-Projekt 09931, April 1998), ist es unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar zu begegnen.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 4.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 15 Abs. 4 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162) verbunden:

Kennzeichnungsauflagen gemäß § 20 Abs. 2 Nr. 6 PflSchG in Verbindung mit § 15 Abs. 4 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162):

(NN3002)
Das Mittel wird als schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW262)
Das Mittel ist giftig für Algen.

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz

"Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(WMG)
Wirkungsmechanismus (HRAC-Gruppe): G

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 3.

Sonstige Auflagen:

(VH368)
Der Gehalt an N-Nitrosoglyphosat im technischen Konzentrat von Glyphosat oder Glyphosatsalzen darf 1mg/kg nicht überschreiten. Der Gehalt an Formaldehyd darf 1,3 g/kg bezogen auf die Äquivalenzmasse der Glyphosatsäure nicht überschreiten.

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs.1 Verwaltungsverfahrensgesetz verbunden:

- keine -

Vorbehalt

Der Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß § 4 Gefahrstoffverordnung

Gefahrensymbole:	N
Gefahrenbezeichnungen:	Umweltgefährlich

Gefahrenhinweise (R-Sätze):

R 51/53: Giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben.

Sicherheitshinweise (S-Sätze):

S 35: Abfälle und Behälter müssen in gesicherter Weise beseitigt werden

S 57 : Zur Vermeidung einer Kontamination der Umwelt geeigneten Behälter verwenden

Zur Vermeidung von Risiken für Mensch und Umwelt ist die Gebrauchsanleitung einzuhalten.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

- keine -

Gefahrenpiktogramme:

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

(H411)

Giftig für Wasserorganismen, mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):

- keine -

Nicht festgesetzte Anwendungsgebiete und nicht vorgesehene Anwendungen

Folgende Anwendungsgebiete werden bei der Zulassung nicht festgesetzt (siehe Anlage 2):

Anwendungsnummer	**Schadorganismus/ Zweckbestimmung**	**Pflanzen/-erzeugnisse/Objekte**
007385-00/00-003	Acker-Winde	Kernobst
007385-00/00-005	Acker-Winde	Weinrebe

Folgende Anwendungen werden bei der Zulassung nicht vorgesehen (siehe Anlage 2):

- keine -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

(NN1001)

Das Mittel wird als nicht schädigend für Populationen relevanter Nutzinsekten eingestuft.

Weitere Hinweise und Bemerkungen

Zur Etikettierung:

Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:

Enthält ca. 8 g /L Natriumchlorid als Bestandteil eines Beistoffes.

Zu KIIIA1 6.2.8:

Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus (WMG: Glyphosat):

Die HRAC-Klassifizierung ist als neutrale Information direkt dem Wirkstoff zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Herbiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Für folgende Anwendungen ist die Bearbeitung noch nicht abgeschlossen:

- keine -

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Hans-Gerd Nolting
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 007385-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Ackerbaukulturen

2 Einsatzgebiet

Einsatzgebiet:	Ackerbau

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	Stoppelbehandlung
Stadium der Kultur:	
- Erläuterungen:	
Anwendungszeitpunkt:	Nach der Ernte, bis 4 Tage vor der Saat
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	4 l/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH914)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter und ggf. Holzgewächse aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden können.

3.3 Wartezeiten

(F)	Freiland: Ackerbaukulturen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

4 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

Begründung:
Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 125 ml/ha (Vegetative Vigour Test). Ausgehend von den geltenden Modellen zur Abdrift ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestri-

schen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels "HAG 500 02 H" zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 1 zugelassene Anwendung: 007385-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Kernobst

2 Einsatzgebiet

Einsatzgebiet:	Obstbau

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	Behandlung bei 15-20 cm Unkrauthöhe
Erläuterung zur Kultur:	
Stadium der Kultur:	
- Erläuterungen:	
Anwendungszeitpunkt:	Frühjahr bis Sommer
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	Reihenbehandlung
Aufwand:	
-	4 l/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

3.3 Wartezeiten

42 Tage	Freiland: Kernobst

4 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

<u>Begründung:</u>
Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 125 ml/ha (Vegetative Vigour Test). Ausgehend von den geltenden Modellen zur Abdrift ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels "HAG 500 02 H" zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 1 zugelassene Anwendung: 007385-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Weinrebe

2 Einsatzgebiet

Einsatzgebiet:	Weinbau

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	Behandlung bei 10-20 cm Unkrauthöhe
Erläuterung zur Kultur:	Nutzung als Kelter- und Tafeltraube ab 4. Standjahr der Weinrebe
Stadium der Kultur:	
- Erläuterungen:	
Anwendungszeitpunkt:	Frühjahr bis Sommer
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	Reihenbehandlung
Aufwand:	
-	4 l/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

3.3 Wartezeiten

30 Tage	Freiland: Weinrebe (Tafel- und Keltertrauben)

4 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

<u>Begründung:</u>
Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 125 ml/ha (Vegetative Vigour Test). Ausgehend von den geltenden Modellen zur Abdrift ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels "HAG 500 02 H" zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 1 zugelassene Anwendung: 007385-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Zweikeimblättrige Unkräuter, Einkeimblättrige Unkräuter, Sikkation
Pflanzen/-erzeugnisse/Objekte:	Getreide (Gerste, Hafer, Roggen, Triticale, Weizen)

2 Einsatzgebiet

Einsatzgebiet:	Ackerbau

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	Lagergetreide, ausgenommen Saat- und Braugetreide
Stadium der Kultur:	89
- Erläuterungen:	
Anwendungszeitpunkt:	Bis 7 Tage vor der Ernte, zur Spätbehandlung
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	4 l/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(VV835)
Stroh von behandeltem Getreide nicht für Kultursubstrate verwenden.

(WH914)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter und ggf. Holzgewächse aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden können.

3.3 Wartezeiten

7 Tage	Freiland: Getreide (Gerste, Hafer, Roggen, Triticale, Weizen)

4 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

<u>Begründung:</u>
Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 125 ml/ha (Vegetative Vigour Test). Ausgehend von den geltenden Modellen zur Abdrift ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels "HAG 500 02 H" zu

gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 1 zugelassene Anwendung: 007385-00/00-007

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Wiesen, Weiden

2 Einsatzgebiet

Einsatzgebiet: Grünland

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich: Freiland

- Erläuterungen:

Erläuterung zum Schadorganismus:

Stadium des Schadorganismus:

- Erläuterungen:

Erläuterung zur Kultur: Grünlanderneuerung

Stadium der Kultur:

- Erläuterungen:

Anwendungszeitpunkt: 5-7 Tage vor der Aussaat, während der Vegetationsperiode

- Erläuterungen:

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1
- für die Kultur bzw. je Jahr: 1
- Abstand:
- Erläuterungen Anzahl Behandlungen:

Mischungspartner:

- Erläuterungen:

Anwendungstechnik: spritzen

- Erläuterungen:

Aufwand:

- 4 l/ha in 100 bis 400 l Wasser/ha

- Erläuterungen:

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(VV549)
Behandelten Aufwuchs (Abraum vor der Neueinsaat) nicht zur Heugewinnung verwenden, er kann der direkten Verfütterung oder der Silierung dienen.

(WH914)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter und ggf. Holzgewächse aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden können.

3.3 Wartezeiten

(F)	Freiland: Wiesen, Weiden (Gras und Heu) Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

4 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

<u>Begründung:</u>
Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat

weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 125 ml/ha (Vegetative Vigour Test). Ausgehend von den geltenden Modellen zur Abdrift ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels "HAG 500 02 H" zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 1 zugelassene Anwendung: 007385-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Winterraps

2 Einsatzgebiet

Einsatzgebiet:	Ackerbau

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	Ausgenommen zur Saatguterzeugung
Stadium der Kultur:	87 bis 89
- Erläuterungen:	
Anwendungszeitpunkt:	Bis 14 Tage vor der Ernte, zur Spätbehandlung
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	2,5 l/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH914)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter und ggf. Holzgewächse aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden können.

3.3 Wartezeiten

14 Tage	Freiland: Winterraps

4 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

Begründung:
Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 125 ml/ha (Vegetative Vigour Test). Ausgehend von den geltenden Modellen zur Abdrift ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels "HAG 500 02 H" zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 2 nicht zugelassene Anwendung: 007385-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Acker-Winde

Pflanzen/-erzeugnisse/Objekte: Kernobst

2 Einsatzgebiet

Einsatzgebiet: Obstbau

3 Angaben zur sachgerechten Anwendung

Anwendungsbereich: Freiland

- Erläuterungen:

Erläuterung zum Schadorganismus:

Stadium des Schadorganismus:

- Erläuterungen:

Erläuterung zur Kultur:

Stadium der Kultur:

- Erläuterungen:

Anwendungszeitpunkt: Frühjahr bis Sommer

- Erläuterungen:

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1
- für die Kultur bzw. je Jahr: 1
- Abstand:
- Erläuterungen Anzahl Behandlungen:

Mischungspartner:

- Erläuterungen:

Anwendungstechnik: spritzen

- Erläuterungen: Reihenbehandlung

Aufwand:

- 8 l/ha in 100 bis 400 l Wasser/ha

- Erläuterungen:

Sonstige Ergänzungen und Hinweise: - keine -

4 Begründung

Naturhaushalt
Die Prüfung der zum o.g. Antrag vorliegenden Untersuchungsergebnisse hat ergeben, dass die Zulassungsvoraussetzungen für die Indikationen 00-003 und 00-005 nicht erfüllt sind. Das Pflanzenschutzmittel "HAG 500 02 H" bzw. der darin enthaltene Wirkstoff Glyphosat besitzt langfristig ein hohes Gefährdungspotenzial für Regenwürmer. Das Akzeptabilitätskriterium TER >= 5 für langfristige Effekte wird unter den worst-case-Annahmen nicht erreicht. Bewertungsbestimmend sind hier die NOEC von 21,31 mg/kg (Glyphosate Acid) und PEC-soil. 9,6 mg/kg. Unvertretbare langfristige Auswirkungen auf Regenwürmer infolge der bestimmungsgemäßen und sachgerechten Anwendung von "HAG 500 02 H" sind somit nicht auszuschließen. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 2 nicht zugelassene Anwendung: 007385-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Acker-Winde
Pflanzen/-erzeugnisse/Objekte:	Weinrebe

2 Einsatzgebiet

Einsatzgebiet:	Weinbau

3 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	Nutzung als Kelter- und Tafeltraube ab 4. Standjahr der Weinrebe
Stadium der Kultur:	
- Erläuterungen:	
Anwendungszeitpunkt:	Frühjahr bis Sommer
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	Reihenbehandlung
Aufwand:	
-	8 l/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

4 Begründung

Siehe Anwendung 00/00-003.

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information
Detailed summary of the risk assessment

Product code: HAG 500 02 H

Active Substance: Glyphosate 450 g/L

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Helm AG
Date: 15/03/2013

Table of Contents

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT 8
IIIA 1.1 Applicant 8
IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s) 8
IIIA 1.2.1 Manufacturer(s) of the preparation 8
IIIA 1.2.2 Manufacturer(s) of the active substance(s) 8
IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s) 8
IIIA 1.3 Trade Names and Manufacturer’s Code Numbers for the Preparation 8
IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation 9
IIIA 1.4.1 Content of active substance and formulants 9
IIIA 1.4.2 Certified limits of each component 9
IIIA 1.4.3 Common names and code numbers for the active substance(s) 10
IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function. 10
IIIA 1.4.5 Formulation process 10
IIIA 1.4.5.1 Description of formulation process 10
IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern 10
IIIA 1.5 Type of Preparation and Code 10
IIIA 1.6 Function 10
IIIA 1.7 Other/Special Studies 11
IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT 12
IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15 19

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT 19

IIIA 3.1 Field of Use 19

IIIA 3.2 Nature of the Effects on Harmful Organisms 19

IIIA 3.3 Details of Intended Use 19

IIIA 3.3.1 Details of existing and intended uses 19

For further details please refer to Part B Section 7: Efficacy Data and Information 19

IIIA 3.3.2 Details of harmful organisms against which protection is afforded 20

IIIA 3.3.3 Effects achieved 20

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation) 20

IIIA 3.5 Concentration of the Active Substance in the Material Used 20

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent 20

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection 20

IIIA 3.7.1 Maximum number of applications and their timings 20

IIIA 3.7.2 Growth stages of crops or plants to be protected 20

IIIA 3.7.3 Development stages of the harmful organism concerned 20

IIIA 3.7.4 Duration of protection afforded by each application 20

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications 20

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops 20

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops 20

IIIA 3.8.2 Limitations on choice of succeeding crops 20

IIIA 3.8.3 Description of damage to rotational crops 20

IIIA 3.9 Proposed Instructions for Use as Printed on Labels 21

IIIA 3.10 Other/Special Studies 21

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT 22

IIIA 4.1 Packaging and Compatibility with the Preparation 22

IIIA 4.1.1 Description and specification of the packaging 22

IIIA 4.1.2 Suitability of the packaging and closures 25

IIIA 4.1.3 Resistance of the packaging material to its contents 25

IIIA 4.2 Procedures for Cleaning Application Equipment 25

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing 25

IIIA 4.2.2 Effectiveness of the cleaning procedures 26

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment 26

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop 26

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed 26

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated 26

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs 26

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products 26

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops 27

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used 27

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks 27

IIIA 4.4.1 Warehouse storage 27

IIIA 4.4.2 User level storage 27

IIIA 4.4.3 Transport 28

IIIA 4.4.4 Fire 28

IIIA 4.4.5 Nature of protective clothing proposed 28

IIIA 4.4.6 Characteristics of protective clothing proposed 29

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment 29

IIIA 4.4.8 Procedures to minimise the generation of waste 29

IIIA 4.4.9 Combustion products likely to be generated in the event of fire 30

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use 30

IIIA 4.5.1 Containment of spillages... 30

IIIA 4.5.2 Decontamination of areas, vehicles and buildings... 30

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials.................. 32

IIIA 4.5.4 Protection of emergency workers and bystanders 32

IIIA 4.5.5 First aid measures 32

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage........... 33

IIIA 4.6.1 Details of proposed procedures for small quantities....................................... 33

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)............................ 33

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste 33

IIIA 4.6.4 Details of proposed procedures for large quantities 33

IIIA 4.6.5 Evaluation of products of neutralization (large quantities) 33

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste.................... 34

IIIA 4.7 Pyrolytic Behaviour of the Active Substance.. 34

IIIA 4.8 Disposal Procedures for the Plant Protection Product................................... 34

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging 34

IIIA 4.8.2 Methods other than controlled incineration for disposal 34

IIIA 4.9 Other/Special Studies.. 34

IIIA 11 FURTHER INFORMATION... 34

IIIA 11.1 Information of Authorisations in Other Countries... 34

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries 34

IIIA 11.3 Justified Proposals for Classification and Labelling....................................... 35

IIIA 11.4 Proposals for Risk and Safety Phrases 35

IIIA 11.5 Proposed Label 35

IIIA 11.6 Specimens of Proposed Packaging 35

Appendix 1: List of data used in support of the evaluation 36

Appendix 2: Critical Uses – justification and GAP tables 37

Appendix 3: Experimental testing of the product's physico-chemical and technical characteristics: 43

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product HAG 500 02 H containing the active substance glyphosate which is approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**glyphosate** (Reg. (EU) No. 540/2011)
Purity of active substance	min 950 g/kg

Appendix 1 of this document contains the list of references included in this document for support of the evaluation. Appendix 2 of this document is the table of intended uses for HAG 500 02 H.

Information on the detailed composition of HAG 500 02 H can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Company
Helm AG
Nordkanalstr. 28
D – 20097 Hamburg

Contact person
Dr. Nikolaus Wilhelm
Telephone: + 49 – 40 – 2375 1387
Telefax: + 49 – 40 – 2375 1845
e-mail: N.Wilhelm@helmag.com

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

The minimum content of pure glyphosate in the technical grade active substance is 950 g/kg.

The information on impurities is provided separately in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name:	Not yet allocated for most countries Agenor 450 SL (intended for Poland)
Provisional designation	Glyphosate 450 SL AE (used in the studies reported in this dossier)
Company codes:	HAG 500 02 H

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

content of pure glyphosate:	450 g/L
limits glyphosate:	no limits stated by the applicant, according to FAO/WHO manual the appropriate limits are: 427.5 – 472.5 g/L

Technical active substance:

content of technical glyphosate at minimum purity (95.0 %):	473.7 g/L

Isopropylamine is added in the formulation process, so in the final product the active substance is present as the isopropylamine salt.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 545/2011.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Glyphosate (BSI, E-ISO, (m) F-ISO, ANSI, WSSA, JMAF)
1.4.3.2	CAS No.	1071-83-6
1.4.3.2	EINECS No.	213-997-4
1.4.3.2	CIPAC No.	284
1.4.3.2	ELINCS	213-997-4
1.4.3.3	Salt, ester anion or cation present	Glyphosate is formulated in HAG 500 02 H as salt. The cation is isopropylammonium

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Glyphosate may contain two impurities of toxicological concern, formaldehyde and N-nitrosoglyphosate. Both impurities originate from the manufacturing process of the technical active substance. Therefore the impurities are included in the product specification and will not occur at unacceptable levels in formulations containing glyphosate.

IIIA 1.5 Type of Preparation and Code

Type : Soluble Concentrate Code : SL

IIIA 1.6 Function

The product will be used as herbicide.

IIIA 1.7 Other/Special Studies

None.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is that of a yellowish homogenous liquid, with a characteristic odour. It is not explosive, has no oxidising properties. It shows no flash point up to 250 °C where decomposition starts. In aqueous solution, it has a pH value around 4.6. The stability data at 54 °C indicate a shelf life of at least 2 years at ambient temperature, but the final results are not available yet. Its technical characteristics are acceptable for a soluble concentrate formulation.

Tabelle 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	**Method used / deviations**	**Test material purity and specification**	**Findings**	**GLP Y/N**	**Reference**	**Acceptability / comments**
Colour, odour and physical state (IIIA 2.1)	Visual assessment and organoleptic determination	Batch Be 1988 07 10	Yellowish homogeneous liquid with a characteristic odour.	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable
Explosive properties (IIIA 2.2.1)	DSC and Expert Statement Manual of Tests and Criteria, Fourth revised edition, 2003, Appendix 6, “Orange Book”	-	Total decomposition energy is about 236 J/g (UN limit: 500 J/g). Non-explosive	N	Kühne, M. 2010a	Acceptable
Oxidizing properties (IIIA 2.2.2)	Expert statement Manual of Tests and Criteria, Fourth revised edition, 2003, Appendix 6, “Orange Book”	--	No oxidising properties	N	Kühne, M. 2010b	Acceptable
Flash point	EEC A9	Batch Be 1988 07 10 (Helm Sample No.	No flash point could be observed	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.3.1)		37/530/10) content a.s.: 450.4 g/L				
Flammability (IIIA 2.3.2)	-	-	not required for SL formulations	-	-	Acceptable.
Auto-flammability (IIIA 2.3.3)	EEC A15	Batch 3342/R content a.s.: 461 g/L	475 °C	Y	Nau, M. (2009)	Acceptable
Acidity or alkalinity and pH (IIIA 2.4.1)	-	-	not required, for the pH of undiluted formulation is 4.4	-	-	Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3	Batch Be 1988 07 10	before storage: pH 4.6 at 20 ± 1 °C after storage: pH 4.5 undiluted formulation: pH 4.4 (before and after storage)	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable
Kinematic viscosity (IIIA 2.5.1)	-	-	Not required, HAG 500 02 H is not intended for ultra low volume (ULV) use.	-	-	Acceptable.
Dynamic viscosity (IIIA 2.5.2)	CIPAC MT 192 OECD 114	Batch Be 1988 07 10	52.2 mPa.s at 20.0 ± 0.2 °C 27.3 mPa.s at 40.0 ± 0.2 °C at a constant shear rate of 1000 [1/s] 59 - 73 mPa.s at a shear rate from 20 - 100 [1/s]	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (IIIA 2.5.3)	EEC A5 OECD 115 DIN EN 14370	Batch Be 1988 07 10	25.2 mN/m at 20 ± 0.5 °C	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable
Relative density (IIIA 2.6.1)	EEC A3 OECD 109 OPPTS 830.7300	Batch Be 1988 07 10	1.196 g/cm³ (20.0 °C)	Yes	Meinerling, M.; Herrmann, S. (2010a)	Acceptable
Bulk or tap density (IIIA 2.6.2)	-	-	not required for liquid formulations	-	-	Acceptable.
Storage Stability after 14 days at 54º C (IIIA 2.7.1)	CIPAC MT 46.3	Batch Be 1988 07 10	storage in 1 L PE bottles: Stable under test conditions, no significant change of the physical properties. Content of a.s. glyphosate: 446.8 g/l before storage 443.4 g/L after storage The packaging material showed no cracking, fogging, discoloration or distortion or change in weight.	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	-	-	not required, for the formulation is stable after 14 d at 54 °C.	-	-	Acceptable.
Minimum content after heat stability	-	-	see IIIA 2.7.1	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
testing (IIIA 2.7.3)						
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	Batch Be 0030609-907 I (Helm Sample No. 37/219/09) content a.s.: 453.6 g/L	After storage period of 7 days at 0 °C the test item is a yellowish homogeneous liquid. No separated material on the bottom and the top occurs in the pure test item.	Y	Meinerling, M.; Herrmann, S. (2010b)	Acceptable
Ambient temperature shelf life (IIIA 2.7.5)	-	-	The shelf life study is ongoing. The results from the accelerated storage stability study indicate that HAG 500 02 H will be stable for 2 years. Package material: PE bottles	-	-	Not acceptable. Finalisation expected in December 2012. Study not submitted yet.
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-	-	Please refer to MIIIA1 2.7.5.	-	-	Acceptable.
Wettability (IIIA 2.8.1)	-	-	not required for liquid formulations	-	-	Acceptable.
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Batch Be 1988 07 10	at a concentration of 8 % (v/v): 68 mL foam after 10 s 5 mL foam after 1 min 3 mL foam after 3 min 1 mL foam after 12 min	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (IIIA 2.8.3.1)	-	-	not required for SL formulations	-	-	Acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)	-	-	not required for SL formulations	-	-	Acceptable.
Dilution stability (IIIA 2.8.4)	CIPAC MT 41	Batch Be 1988 07 10	No separated material occurred (before and after storage)	Y	Meinerling, M.; Herrmann, S. (2010a)	Acceptable
Dry sieve test (IIIA 2.8.5.1)	-	-	not required for SL formulations	-	-	Acceptable.
Wet sieve test (IIIA 2.8.5.2)	-	-	not required for SL formulations	-	-	Acceptable.
Particle size distribution (IIIA 2.8.6.1)	-	-	not required for SL formulations	-	-	Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)	-	-	not required for liquid formulations	-	-	Acceptable.
Dust content (IIIA 2.8.6.3)	-	-	not required for liquid formulations	-	-	Acceptable.
Particle size of dust	-	-	not required for liquid formulations	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.8.6.4)						
Friability and attrition (IIIA 2.8.6.5)	-	-	not required for liquid formulations	-	-	Acceptable.
Emulsifiability (IIIA 2.8.7.1)	-	-	not required for SL formulations	-	-	Acceptable.
Dispersibility (IIIA 2.8.7.1)	-	-	not required for SL formulations	-	-	Acceptable.
Flowability (IIIA 2.8.8.1)	-	-	not required for liquid formulations	-	-	Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)	-	-	not required for SL formulations	-	-	Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)	-	-	not required for liquid formulations	-	-	Acceptable.
Physical compatibility of tank mixes (IIIA 2.9.1)	-	-	no tank mixes are intended	-	-	Acceptable.
Chemical compatibility of tank mixes	-	-	no tank mixes are intended	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.9.2)						
Adhesion to seeds (IIIA 2.10.1)	-	-	not required, for HAG 500 02 H is not intended for seed treatment	-	-	Acceptable
Distribution to seed (IIIA 2.10.2)	-	-	not required, for HAG 500 02 H is not intended for seed treatment	-	-	Acceptable
Miscibility (IIIA 2.11)	-	-	Not required by regulation (EU) 2011/545.	-	-	
Dielectric breakdown (IIIA 2.12)	-	-	Not required by regulation (EU) 2011/545.	-	-	
Corrosion characteristics (IIIA 2.13)	-	-	Not required by regulation (EU) 2011/545.	-	-	
Container material (IIIA 2.14)	-	-	Not required by regulation (EU) 2011/545.	-	-	
Other/special studies (IIIA 2.15)	-	-	Not required by regulation (EU) 2011/545.	-	-	

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

The appearance of the product is that of a yellowish homogenous liquid, with a characteristic odour. It is not explosive, has no oxidising properties. It shows no flash point up to 250 °C where decomposition starts. In aqueous solution, it has a pH value around 4.6. The stability data at 54 °C indicate a shelf life of at least 2 years at ambient temperature, but the final results are not available yet. Its technical characteristics are acceptable for a soluble concentrate formulation.

Experimental testing of the product's physico-chemical and technical characteristics:

See Appendix 3

Implications for labelling:

No labelling necessary due to physical or chemical properties described above.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

The product HAG 500 02 H formulated as 450 g/L glyphosate SL formulation is intended to be used as non-selective herbicide against monocotyledonous and dicotyledonous weeds in on a number of field crops as well as in vineyards and orchards (pome fruit) and for desiccation. The active substance glyphosate is a commonly used herbicide in agriculture worldwide.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Glyphosate is a non-selective herbicidal active substance. Glyphosate is taken up by the leaves and other green parts of the plant and is translocated systemically (apoplastic and symplastic) in the whole plant, also in underground parts like roots, rhizomes or stolons. Glyphosate uptake through the roots is negligible because the active substance is strongly adsorbed in the soil. The extensive adsorption of glyphosate together with a ready degradation in soil, are the principal deactivation and dissipation mechanisms in the soil environment.

In plants, glyphosate inhibits the shikimic acid pathway. Glyphosate binds to and blocks the activity of its target enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), an enzyme of the aromatic amino acid biosynthetic pathway (HRAC classification G). The inhibition of the enzyme prevents the plant from synthesizing the essential aromatic amino acids (e.g. phenylalanine, tyrosine, and tryptophane) needed for protein biosynthesis. This reduces the production of protein in the plant, and inhibits plant growth. EPSPS is present in all plants. It leads to an accumulation of the amino acids glutamine, glutamic acid, shikimic acid and ammonia. As a consequence of missing aromatic amino acids the formation of phenolic compounds is inhibited (e.g. lignin, flavanoids).

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

For further details please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.3.3 Effects achieved

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7: Efficacy Data and Information

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

HAG 500 02 H is to be marketed in bottles, canisters, drums and intermediate bulk containers with volumes from 1000 mL up to 1250 L.

1000 mL bottle	Material:	Plastic bottles: HDPE or HDPE + LDPE	
	Opening	Diameter:	40 mm
	Type of closure:	Screw caps	
	Dimensions:	Total height of the bottle:	240 mm
		Diameter:	88.5 mm
		Minimum wall thickness :	0,50 mm
	Volume :	1000 mL	
	Weight:	80 g	
5 L canister	Material:	Plastic canister: HDPE or HDPE + LDPE	
	Opening:	Diameter:	56 mm
	Type of closure:	Screw caps	
	Dimension:	Size:	186 x 135 x 336 mm
		Minimum wall thickness:	0,75 mm
	Volume :	5000 mL	
	Weight:	280 g	
10 L canister	Material:	Plastic canister: HDPE or HDPE + LDPE	
	Opening:	Diameter:	54 mm
	Type of closure:	Screw caps	

	Dimension:	Size:	230 x 165 x 375 mm
		Minimum wall thickness bottom:	0,6 mm
		Minimum wall thickness side:	1,2 mm
	Volume :	10000 mL	
	Weight:	400 g	
20 L canister	Material:	Plastic canister: HDPE or HDPE + LDPE	
	Opening:	Diameter:	53,7 mm
	Type of closure:	Screw caps	
	Dimension:	Size:	290 x 259 x 386 mm
	Volume :	20000 mL	
	Weight:	900 g +/- 4 %	
120 L drum	Material:	Plastic canister: HDPE or HDPE + LDPE	
	Type of closure:	- Sealing caps - Bung combination BCS70 x 6/BCS56 x4	
	Dimension:	Total height of the drum:	745 mm
		Diameter:	493 mm
	Volume :	120000 mL	
	Weight:	5500 g	
220 L drum	Material:	Plastic canister: HDPE or HDPE + LDPE	
	Type of closure:	- Sealing caps - Bung combination BCS70 x 6/BCS56 x4	
	Dimension:	Total height of the drum:	935 mm
		Diameter:	581 mm
	Volume :	220000 mL	
	Weight:	8500 g	

640 L intermediate bulk container	Material:	Inner bottle: HDPE Outer container: Welded tubular steel grid, galvanized	
	Type of closure:	Filling opening: DN 150 and DN 225 with screw cap Outlet valves: - Integrated butterfly valve DN 50 - Screwable butterfly valve DN 50, DN 80, DN 150 - Screwable ball valve DN 50	
	Dimension:	Size:	1200 x 800 x 1000 mm
	Volume :	640000 mL	
	Weight:	46000 g steel, 50000 g plastic	
820 L intermediate bulk container	Material:	Inner bottle: HDPE Outer container: Welded tubular steel grid, galvanized	
	Type of closure:	Filling opening: DN 150 and DN 225 with screw cap Outlet valves: - Integrated butterfly valve DN 50 - Screwable butterfly valve DN 50, DN 80, DN 150 - Screwable ball valve DN 50	
	Dimension:	Size:	1200 x 1000 x 1000 mm
	Volume :	820000 mL	
	Weight:	53000 g steel, 56000 g plastic	
1000 L intermediate bulk container	Material:	Inner bottle: HDPE Outer container: Welded tubular steel grid, galvanized	
	Type of closure:	Filling opening: DN 150 and DN 225 with screw cap Outlet valves: - Integrated butterfly valve DN 50 - Screwable butterfly valve DN 50, DN 80, DN 150 - Screwable ball valve DN 50	
	Dimension:	Size:	1200 x 1000 x 1160 mm
	Volume :	1000000 mL	

	Weight:	58000 g steel, 61000 g plastic	
1250 L intermediate bulk container	Material:	Inner bottle: HDPE Outer container: Welded tubular steel grid, galvanized	
	Type of closure:	Filling opening: DN 150 and DN 225 with screw cap Outlet valves: - Integrated butterfly valve DN 50 - Screwable butterfly valve DN 50, DN 80, DN 150 - Screwable ball valve DN 50	
	Dimension:	Size:	1200 x 1000 x 1350 mm
	Volume :	1250000 mL	
	Weight:	66000 g steel, 68000 g plastic	

The bottles, canisters, drums and intermediate bulk containers meet the ADR requirements. They are labelled individually with all the use instructions.

IIIA 4.1.2 Suitability of the packaging and closures

The packaging material tested in an accelerated storage stability test showed no cracking, fogging discoloration or distortion or change in weight. There was no seepage through the screw cap.
A shelf life study with HAG 500 02 H is currently ongoing. The bottles will be examined for any detrimental effects at every sampling point.

IIIA 4.1.3 Resistance of the packaging material to its contents

A shelf life study with HAG 500 02 H is currently ongoing. The bottles will be examined for any detrimental effects at every sampling point.
The packaging tested in the accelerated storage stability test showed no signs of corrosion, distortion or deterioration after storage at 54 °C for 14 days. The container labels were made of paper and were legible after accelerated storage.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Application equipment:
After use, intensive cleaning of the sprayers used and tank rinsing with water (3 times 10 % of the tank volume) and suitable detergent (e.g. Agroclean) are appropriate to remove product residues quantitatively.

The equipment can afterwards be used in sensitive crops without damage. Daily cleaning of used equipment is recommended. Final cleaning using appropriate detergents is recommended.

Personnel protective equipment:
Personnel protective equipment which is worn during application of HAG 500 02 H (coverall and protective glasses) or gloves, being worn during mixing/loading can be washed with water.

IIIA 4.2.2 Effectiveness of the cleaning procedures

Report:	**KIIIA1 4.2.2/01, Norris, D., 2010**
Title:	Certificate of Analysis for Glyphosate Batch Number 37/163/09
Document No:	DNA1136
Guidelines:	Efficacy Guideline 302
GLP	No, not relevant

Tank washing procedure according efficacy guideline 302 (without tank cleaner, double rinse procedure) was conducted and the mean of 2 washing results was 0.012 % residue in tank.

It is concluded that the procedure as described under Point MIIIA1 4.2.1 is suitable and sufficient for cleaning application equipment after use of Glyphosate 450 SL AE.

Study Comments: MIIIA1 4.2.2	Acceptable

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated

products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

Report:	**KIIIA1 4.4.1/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE
Document No:	not indicated
Guidelines:	none
GLP	No

The safety data sheet complies with actual EEC regulations and is based on the present state of knowledge.

IIIA 4.4.1 Warehouse storage

Containers which are opened must be carefully resealed and kept upright to prevent leakage. Always keep in containers of same material as the original one.
Keep away from sources of heat and ignition.
Keep container tightly closed in a cool, well-ventilated place.
Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

IIIA 4.4.2 User level storage

Containers which are opened must be carefully resealed and kept upright to prevent leakage. Always keep in containers of same material as the original one.
Keep away from sources of heat and ignition.
Keep container tightly closed in a cool, well-ventilated place.
Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

The product should be stored under conditions which prevent it from entering any surface and ground water body and any misuse by non authorized persons. Minimum standards are for storage at the farm:

Compliance with recommendations for safe storage of crop protection products at the farm as given in GIFAP Guidelines for the avoidance, limitations and disposal of pesticide waste on the farm, chapter 2 4.

Requirements for storage rooms and vessels:

Containers which are opened must be carefully resealed and kept upright to prevent leakage. Always keep in the original container.

Do not store together with oxidizing agents.

The product must be stowed away from food, drink and animal feeding stuffs and without access for children.

Recommended storage temperature: 0 - 30°C. (Reference: Document C).

IIIA 4.4.3 Transport

The product is not defined under national/international road, rail, sea and air transport regulations as a hazardous material.

IIIA 4.4.4 Fire

Suitable extinguishing media:
Foam; extinguishing powder; Water spray jet; Carbon dioxide

Extinguishing media that must not be used for safety reasons:
Full water jet

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases
In the event of fire, the following can be released:
Carbon dioxide (CO2)
Carbon monoxide (CO)
Fire gas of organic material has to be classed invariably as respiratory poison.

Special protective equipment for fire-fighters
Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus. Wear protective clothing.

Other information
Cool endangered containers with water spray jet.

In addition to all the above points we refer to the DAR for Glyphosate, Vol 3, B 3.4.1. and 3.5.4.

IIIA 4.4.5 Nature of protective clothing proposed

Personal protective equipment
Special protective equipment for fire-fighters

Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus. Wear protective clothing.

Respiratory protection
If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Hand protection
In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective glove should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations to avoid permanent use of protective gloves.

Eye protection
Safety glasses (EN 166)

Skin protection
Clothing as usual in the chemical industry.

General protective and hygiene measures
Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Wash hands before breaks and after work. Have eye wash fountain available. Do not inhale vapours.

For this annex point we refer to the DAR for Glyphosate, Vol 3, B 3.5.5.

IIIA 4.4.6 Characteristics of protective clothing proposed

Please refer to chapter KIIIA1 4.4.5 above.

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Please refer to chapter KIIIA1 4.4.5 above.

IIIA 4.4.8 Procedures to minimise the generation of waste

To minimize waste of the product, users are required to rinse packages after emptying and to add the rinsate to the spraying liquid.

Product
Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging
Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

For this annex point we refer to the DAR for Glyphosate, Vol 3, B 3.

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

Please refer to chapter KIIIA1 4.4.4 above.

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Report:	**KIIIA1 4.5.1/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE
Document No:	not indicated
Guidelines:	none
GLP	No

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

Methods for cleaning up/taking up
Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When picked up, treat material as prescribed in chapter MIIIA1 4.5.3.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Report:	**KIIIA1 4.5.2/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE
Document No:	not indicated
Guidelines:	none
GLP	No

Immediately stop the source of the spill if safe to do so. Contain the spill to prevent any further contamination of surface, water or soil.
In addition please refer to protective measures listed below:

Personal precautions
Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

Environmental precautions
Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

Methods for cleaning up/taking up
Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When picked up, treat material as prescribed in chapter MIIIA1 4.5.3.

Handling
Advice on safe handling
Provide good ventilation of working area (local exhaust ventilation, if necessary). Avoid contact with skin and eyes.

Advice on protection against fire and explosion
Keep away from sources of heat and ignition.

Storage
Requirements for storage rooms and vessels
Containers which are opened must be carefully resealed and kept upright to prevent leakage. Always keep in containers of same material as the original one.

Advice on storage assembly
None known

Further information on storage conditions
Keep container tightly closed in a cool, well-ventilated place.

Exposure limit values
N O N E

Personal protective equipment
Respiratory protection
In case of aerosol and mist formation, take appropriate measures for breathing protection.

Hand protection
In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product . Before use, the protective glove should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer’s instructions and information relating to the use, storage, care and replacement of protective gloves.
Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Eye protection
Safety glasses (EN 166)

Skin protection

Clothing as usual in the chemical industry

General protective and hygiene measures
Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Wash hands before breaks and after work. Have eye wash fountain available. Do not inhale vapours.

Absorbed spillage or contaminated soil has to be collected, for small quantities best by an industrial vacuum cleaner, alternatively with broom and shovel. Solid surfaces may be further cleaned by washing with detergents. Pack absorbed material into tightly closable, disposable containers.

Water contaminated by a spillage and recovered by containment must be collected and burned in a commercial incinerator or treated in a waste water treatment plant.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Report:	**KIIIA1 4.5.4/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE
Document No:	not indicated
Guidelines:	none
GLP	No

Product
Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging
Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

IIIA 4.5.4 Protection of emergency workers and bystanders

Please refer to chapter KIIIA1 4.5.2 above.

IIIA 4.5.5 First aid measures

Report:	**KIIIA1 4.5.5/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE
Document No:	not indicated
Guidelines:	none
GLP	No

General information
In case of accident or if you feel unwell, seek medical advice immediately. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing. If the patient is likely to become unconscious, place and transport in stable sideways position.

After inhalation
Remove affected person from the immediate area. Ensure supply of fresh air. Take medical treatment.

After skin contact
Wash off immediately with soap and water. Consult a doctor if skin irritation persists.

After eye contact
Separate eyelids, wash the eyes thoroughly with water (15 min). In case of irritation consult an ophthalmologist.

After ingestion
Do not induce vomiting. Rinse out mouth and give plenty of water to drink. Summon a doctor immediately. Never give anything by mouth to an unconscious person.

For this annex point we refer to the DAR for Glyphosate, Vol 3, B 3.5.5.

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

Please refer to chapter MIIIA1 4.5.1 above.

IIIA 4.6.1 Details of proposed procedures for small quantities

Please refer to chapter MIIIA1 4.5.1 above.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Please refer to chapter MIIIA1 4.5.1 above.

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Please refer to chapter MIIIA1 4.5.1 above.

IIIA 4.6.4 Details of proposed procedures for large quantities

Please refer to chapter MIIIA1 4.5.1 above.

Large quantities of accidental spillage should be recovered as far as possible and worked up for re-use or disposed of in a commercial incinerator.

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Report:	**KIIIA1 4.6.5/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE

Document No:	not indicated
Guidelines:	none
GLP	No

Please refer to chapter MIIIA1 4.5.1 above.

A simple method for neutralisation/detoxification does not exist.

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Report:	**KIIIA1 4.6.6/01, Anonymous, 2010**
Title:	EC safety data sheet on Glyphosate 450 SL AE
Document No:	not indicated
Guidelines:	none
GLP	No

Please refer to chapter MIIIA1 4.5.1 above.

Since no simple method for neutralisation/detoxification is available, procedures for disposal of neutralized waste were not developed.

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

Not applicable because HAG 500 02 H contains no halogens.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging

Please refer to chapter MIIIA1 4.5.3 above.

IIIA 4.8.2 Methods other than controlled incineration for disposal

Please refer to chapter MIIIA1 4.5.3 above.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

See EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other

Countries

MRLs are set at European level, see Regulation (EC) No. 396/2005.

IIIA 11.3 Justified Proposals for Classification and Labelling

Proposals for classification and labelling of BAS 512 16 F in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Hazard symbols:	None
Indication of danger:	None
Risk phrases:	None
Safety phrases:	None

Toxicology

Please refer to Registration Report Part B Section 3.

Ecotoxicology/Environment

Please refer to Registration Report Part B Section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

In addition please refer to Part B Section 7: Efficacy Data and Information

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

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Appendix 1: List of data used in support of the evaluation

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Owner	How considered in dRR *
KIIIA1 2.1/01 2.3.1/01 2.4.2/01 2.5.2/01 2.5.3/01 2.6.1/01 2.7.1/01 2.8.2/01 2.8.4/01	Meinerling, M.; Herrmann, S.	2010a	Determination of the Accelerated Storage Stability of Glyphosate 450 SL AE Institut für Biologische Analytik und Consulting IBACON GmbH, Report No. 60732204 GLP, unpublished	Y	Helm AG	Y
KIIIA1 2.2.1/01	Kühne, M.	2010a	Glyphosate 450SL AE: Determination of the Explosive Properties Harlan Laboratories, Report No. D01467 Non-GLP, unpublished	Y	Helm AG	Y
KIIIA1 2.2.2/01	Kühne, M.	2010b	Glyphosate 450SL AE: Determination of the Oxidizing Properties Harlan Laboratories, Report No. D01478 Non-GLP, unpublished	Y	Helm AG	Y
KIIIA1 2.3.3/01	Nau, M.	2009	Auto-Flammability (Determination of the Temperature of Self-Ignition of volatile Liquids and of Gases) A.15 Siemens Prozess-Sicherheit Report No. 20090485.01 GLP, unpublished	Y	Helm AG	Y
KIIIA1 2.6.1/02	Meinerling, M.; Herrmann, S.	2009	Determination of the Relative Density of Glyphosate 450 SL AE Institut für Biologische Analytik und Consulting IBACON GmbH, Report No. 52527182 GLP, unpublished	Y	Helm AG	Y
KIIIA1 2.7.4/01	Meinerling, M.; Herrmann, S.	2010b	Determination of the Low Temperature Stability of Glyphosate 450 SL AE Institut für Biologische Analytik und Consulting IBACON GmbH, Report No. 52526204 GLP, unpublished	Y	Helm AG	Y
KIIIA1 4.2.2/01	Norris, D.,	2010	Certificate of Analysis for Glyphosate Batch Number 37/163/09 David Norris Analytical Laboratories Ltd, UK, Report No. DNA1l36 Non GLP, unpublished	Y	Helm AG	Y
KIIIA1 4.4 4.5 4.6	Anonymous	2010	EC safety data sheet on Glyphosate 450 SL AE Helm AG, Version 3.0.1 / GB Non-GLP, unpublished	Y	Helm AG	Y

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2: Critical Uses – justification and GAP tables

GAP rev. (No), date: 2012-09-17 (1)

PPP (product name/code) **HAG 500 02 H**
active substance 1 **glyphosate**

Formulation type: **SL**
Conc. of as 1: **450 g/L**

Applicant: **HELM AG**
Zone(s): Central Zone

professional use ☒
non professional use ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI**	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max	(days)	e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
1	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Field crops	F	TTTMM, TTTDD	spraying	stubble treatment; after harvest, up to 4 days before sowing	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
2	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Pome fruit	F	TTTMM, TTTDD	spraying	spring to summer	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
3	DE	Pome fruit	F	CONAR	spraying	spring to summer	a) 1 b) 1	a) 8.0 b) 8.0	a) 3.6 b) 3.6	100 - 400		Use not granted in DE
4	DE, HU, RO, AT, CZ, SK, SLO	Grape vine	F	TTTMM, TTTDD	spraying	utilisation as wine and table grape from 4th year after planting of the vine	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
						onwards; spring to summer						
5	DE	Grape vine	F	CONAR	spraying	utilisation as wine and table grape from 4th year after planting of the vine onwards; spring to summer	a) 1 b) 1	a) 8.0 b) 8.0	a) 3.6 b) 3.6	100 - 400		Use not granted in DE
6	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Cereals (barley, oats, rye, triticale, wheat)	F	TTTMM, TTTDD, YELSI*	spraying	except for seed production and brewing purposes; 89 - 89; up to 7 days before harvest, during late treatment	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		For DE additionally the note on crop: lodging cereals
7	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Grassland, pasture, meadow	F	TTTMM, TTTDD	spraying	5-7 days before sowing, during vegetative period	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
8	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Winter rape	F	TTTMM, TTTDD, YELSI*	spraying	except for seed production; 87 - 89; up to 14 days before harvest, during late treatment	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400		YELSI not requested in DE
9	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Winter rape	F	TTTMM, TTTDD	spraying	except for seed production; 00 - 08; Before emergence, after emergence of weeds	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400		The use will not be pursued in Germany.
	GB, BE,	Sugar beet BEAVA	F	TTTMM, TTTDD	spraying	Before emergence	a) 1	a) 1.6	a) 0.72	200 - 300		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI**	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max	(days)	e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
	NL, HU, RO, IRL, AT, CZ, SK, SLO					BBCH 00	b) 1	b) 1.6	b) 0.72			
	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Field pea PIBSA	F	TTTMM, TTTDD, YELSI	spraying	except for seed production; 87 - 89	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400		
	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Stone fruit NNNOS	F	TTTMM, TTTDD	spraying	spring to summer	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		

* no EPPO code

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:

Type: *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1).]

Conc. of as: g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) “EU” should be chosen.

Explanations to the particular columns:

No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.

Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).

If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a “joint list” of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning “crop destination or purpose of crop” and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).

Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) “Glasshouse” indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”. In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.

b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.
See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

Appendix 3: Experimental testing of the product's physico-chemical and technical characteristics:

The following physical, chemical and technical properties of the plant protection product were experimentally tested:

density, colour, pH, surface tension, storage stability at high temperatures (14 d at 54 °C), low temperature stability (7 d at 0 °C), persistent foaming and dilution stability.

No significant deviations from the data submitted by the applicant were detected.

The formulation complies with the chemical, physical and technical criteria which are stated in FAO specification 284/SL (2000).

REGISTRATION REPORT
Part B

Section 2 Analytical Methods
Detailed summary of the risk assessment

Product code: HAG 500 02 H

Active Substance: 450 g/L Glyphosate

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Helm AG

Date: 15/03/2013

Table of Contents

IIIA 5	METHODS OF ANALYSIS	3
IIIA 5.1	Analytical Standards and Samples	3
IIIA 5.1.1	Samples of the preparation	3
IIIA 5.1.2	Analytical standards for the pure active substance	3
IIIA 5.1.3	Samples of the active substance as manufactured	4
IIIA 5.1.4	Analytical standards for relevant metabolites and all other components included in the residue definition	4
IIIA 5.1.5	Samples of reference substances for relevant impurities	4
IIIA 5.2	Methods for the Analysis of the Plant Protection Product	4
IIIA 5.2.3	Applicability of existing CIPAC methods	5
IIIA 5.2.4	Description of analytical methods for the determination of relevant impurities	5
IIIA 5.2.5	Description of analytical methods for the determination of formulants	8
IIIA 5.3	Description of Analytical Methods for the Determination of Residues	8
IIIA 5.3.1	Evaluation of glyphosate	9
Appendix 1	List of data submitted in support of the evaluation	17
Appendix 2	Detailed evaluation of the additional studies relied upon	21
A 2.1	Analytical methods for glyphosate	21

IIIA 5 METHODS OF ANALYSIS

This document summarizes the information related to the analytical methods for the product HAG 500 02 H containing the active substance glyphosate which was approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

Where appropriate this document refers to the conclusions of the EU review of the active substance glyphosate. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; or when
- the EU review concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision.

The review report for glyphosate (6511/VI/99-final, 21 January 2002) is considered to provide the relevant information or a reference to where such information can be found.

The Annex I Inclusion Directive for glyphosate (2001/99/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the Review Report on glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29/06/2001 shall be taken into account. In this overall assessment no concerns were raised with regard to the data on analytical methods for the plant protection product HAG 500 02 H containing the active substance glyphosate.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of HAG 500 02 H can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was provided by the applicant but no analysis of the contents of the active substances or the relevant impurities was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of glyphosate were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

The following analytical method for the determination of the active substance in the plant protection product performed on HAG 500 02 H has not previously been reviewed.

Report:	KIIIA1 5.2.1/01, Henriet, J. et al., 1985
Title:	CIPAC Handbook Volume 1C - Analysis of Technical and Formulated Pesticides – Glyphosate 284, p. 2132 - 2134
Document No:	284
Guidelines:	CIPAC 284
GLP	No, study is a publication

Report:	KIIIA1 5.2.1/02 Meinerling, M, 2010
Title:	Determination of the accelerated storage stability of Glyphosate 450 SL AE
Document No:	60732204
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes.

Method description

In the CIPAC method (KIIIA1 5.2.1/01) the sample is dissolved in a phosphate buffered mobile phase. Glyphosate is determined by ion exchange chromatography using an ion exchange column which is packed with a strong anion exchange resin. Glyphosate is detected by UV at 195 nm. Quantisation is done by external standard method.

The validated method (KIIIA1 5.2.2/02) is based on the CIPAC method, but modified with respect to the following HPLC parameters:

Column: Perfectchrom 1000 SAX (250 x 4.6 mm),
mobile phase: 1.6848 g $KH_2(PO_4)$ are dissolved in 1920 mL pure water. 80 mL of methanol are added and the pH is adjusted to 1.9 using phosphoric acid.
flow: 1 mL/min
injection volume: 50 µL
detector: diode array detector at 200 to 400 nm
wavelength: 205 nm

Method validation

The validation data given below show that the method is suitable to analyse the active substance in a Glyphosate 450 SL AE formulation.

Table containing the methods and validation of the methods (formulation HAG 500 02 H)

Analyte	Linearity n = 5	Accuracy n = 5 mean [%]	Repeatability n = 5 [% RSD]	Specificity/Inteferences
glyphosate	0.3 – 1.3 times of expected conc.: r^2 = 1.0000	at 90 to 110 % of original concentration: 100 %	1.0 % (RSRr: 1.5 %)	The method is based on a CIPAC method which is inter-laboratory evaluated. Therefore, it could be expected that the specificity of this method is acceptable, but no chromatograms were submitted to prove this.

Summary

The active substance glyphosate in the formulation HAG 500 02 H can be quantified using the analytical HPLC method described above.

IIIA 5.2.3 Applicability of existing CIPAC methods

A CIPAC method for the analysis of SL formulations containing glyphosate is available and published in handbook 1C.

IIIA 5.2.4 Description of analytical methods for the determination of relevant impurities

Analytical methods for determination of formaldehyde and N-nitroso glyphosate in the formulated product HAG 500 02 H were provided. They are summarised as follows.

Formaldehyde

Report:	**IIIA1 5.2.4/01, Meinerling, M and Herrmann, S, 2012**	
Title:	Development and Validation of an Analytical Method for the Determination of Formaldehyde in Glyphosate 450 SL AE	
Document No:	72071101	
Guidelines:	SANCO/3030/99 rev 4	
GLP	Yes	
	Method:	The analysis of Formaldehyde was performed using HPLC-method with UV detection. Samples are injected after derivatisation with 2,4-dinitrophenylhydrazine. Quantification is performed using acetaldehyde as internal standard.
	Column:	US ES ALD (100 * 3mm)
	Mobile phase	50 % pure water / 50 % acetonitrile
	Detector:	UV at 240 nm
	Column flow:	0.8 mL/min
	Injection volume:	10 µL

	Specificity:	Specificity was established by comparing the retention time of the analyte peak obtained from the fortified samples with that obtained from the standard solutions. Specificity was also ensured by using the internal standard method and monitoring the relative retention time of analyte and internal standard signal.
	Interferences:	The mean measured peak area of blank samples (solvent blank as well as not fortified test item samples) did not contribute more than 4 % to the mean total peak area measured for the target analyte at LOQ level.
	Linearity:	Correlation of peak area of nine different standard solutions with their corresponding concentrations, using a linear regression. Regression coefficient (r): 0.9990 Calibration curve: y = 0.0044 · x – 0.1272
	Accuracy:	For method validation untreated test item samples as well as fortified samples were analysed. Typical chromatograms are to be found in the report. The recovery of Formaldehyde was 97 to 107 % at 0.04% w/w and 101 to 102 % at 0.2 % w/w.
	Precision:	The relative standard deviation was 3.8 % (at 0.04 % w/w) and 0.5 % (at 0.2 % w/w).

Study Comments: MIIIA1 5.2.4/01	Method is applicable for the determination of formaldehyde at a concentration of 0.04 % in glyphosate SL formulations.

N-nitroso glyphosate

Report:	**IIIA1 5.2.1/02, Norris, D, 2012**				
Title:	Analysis of Glyphosate 450 SL AE Formulation for N-Nitrosoglyphosate (NNG) content, with associated validation, in Compliance with Good Laboratory Practice.				
Document No:	DNA1666				
Guidelines:	SANCO/3030/99 rev 4				
GLP	Yes; laboratory certified by the Department of Health of the Government of the United Kingdom				
	Method:	The assay of N-Nitroso Glyphosate was performed using approximately 2.5g of formulation. The mass of the formulated material was accurately recorded, transferred to a 100mL volumetric flask in duplicate, sonicated to ensure thorough dilution and made up to volume with deionised water. These solutions were subsequently used for assay by injecting each duplicate solution once onto the HPLC-DAD.			
	Column:	Lichrospher 60-RP-Select B, 250mm x 4.0mm			
	Mobile phase	Acetonitrile : 2mmol Cetyl Trimethyl Ammonium Bromide (CTAB) in water adjusted to pH 2.0 with Phosphoric Acid			
	Gradient conditions	Analysis Time [minutes]	Acetonitrile [%]	CTAB Buffer [%]	Flow Rate [mL/min]
		0.0	40	60	1.0

		10.0	40	60	1.0
		11.0	90	10	1.0
		24.0	90	10	1.0
		25.0	40	60	1.0
		30.0	40	60	1.0
	Detector:	Diode array detector (240 nm)			
	Column flow:	1.0 mL/min			
	Injection volume:	100 µL			
	Specificity:	UV Specificity for N-nitroso glyphosate: A N-nitroso glyphosate standard and a sample (DNA1666/1) were prepared in deionised Water and analysed with the same analytical conditions on the HPLC-DAD. The specificity of the N-Nitroso G1yphosate reference standard gave a peak at 7.1 minutes with a spectral maxima at 215 nm, reducing to extinction by 250 nm. The sample DNA1666/1 gave a peak at 7.1 minutes with a spectral maxima at 215 nm, reducing to extinction by 250 nm in a similar manner to the standard. This shows that the method is specific to N-Nitroso Glyphosate and that the spectra produced by both the certified standard and the sample are the same. Examples of these chromatograms as well as additional 3D-spectra of the chromatograms can be found in the report.			
		MS and FTIR Specificity for N-nitroso g1yphosate Due to the nature of N-Nitroso Glyphosate and the trace level present within the sample material, it is not possible to generate representative MS or FTIR spectra.			
		Non-Analyte Interference for N-nitroso glyphosate Possible significant peaks interfering with N-nitroso glyphosate were accounted for by running a solvent blank, the formulation blank (DNA1666/2) and a glyphosate standard. There were no peaks present in these chromatograms at the same time as N-nitroso glyphosate. Examples of these chromatograms can be found in the report.			
	Linearity:	The linearity was determined from twenty injections often concentrations of standard ranging from a blank to 5 mg/L stabilized N-nitroso Glyphosate (4.50015 mg/L as N-nitroso glyphosate). The correlation coefficients meet the criterion of R^2 =1.0000 Equation: y = 0.0037x + 0.0014 Representative documentation e.g. chromatograms can be found in the report.			
	Accuracy:	Recovery precision was tested by analysing six spiked samples at a significant level. The formulation blank (DNA1666/2) was spiked with 0.05 mg/L of stabilized N-nitroso glyphosate, this equates to 0.0450015 mg/L as N-nitroso g1yphosate. This corresponds to 1.80006 mg/kg as the samples were made at 25 mg/mL concentration. To achieve this, 2.5g of formulation blank (DNA1666/2) was weighed into a 100 mL volumetric flask, spiked with 1 mL of 5 mg/L stabilized N-nitroso g1yphosate standard solution and then made to volume with deionised water. Each sample was injected once into the HPLC-DAD. The results indicate a percentage recovery range of 97.86 % to 101.3 %, with a mean of 99.82 %, a standard deviation of 1.176 and a percentage relative standard deviation of 1.178.			

	Precision:	To show the system precision a 0.05 mg/L stabilised N-nitroso g1yphosate (0.0450015 mg/L as N-nitroso glyphosate) standard was injected into the HPLC-DAD six times. The resulting values ranged from 0.0450 mg/L to 0.0457 mg/L with a mean of 0.0453 mg/L. A standard deviation of 0.000270 and a percentage relative standard deviation of 0.596 were calculated.
	Limit of Quantification	The LOQ is defined as the lowest point on the linearity range. For N-nitroso glyphosate the lowest point is 0.01 mg/L stabilized N-nitroso glyphosate. This equates to 0.0090003 mg/L as N-nitroso glyphosate. This corresponds to 0.360012 mg/kg as the samples were made at 25 mg/mL concentration. To achieve this, approximately 2.5 g of blank formulation (DNA1666/2) was weighed into a 100 mL volumetric flask, spiked with 1 mL of the 1 mg/L N-nitroso glyphosate working standard and then made to volume using deionised water. The results indicate a percentage recovery range of 99.04% to 104.0% with a mean of 102.2 % and a standard deviation of 1.984.

Study Comments: MIIIA1 5.2.4/02	Acceptable

IIIA 5.2.5 Description of analytical methods for the determination of formulants

No analytical methods for the determination of formulants or constituents of formulants were submitted, for the formulation does not contain toxicologically or ecotoxicologically relevant formulants or constituents of formulants.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

Conclusion

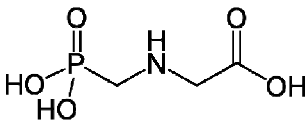
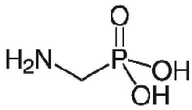
Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions provided that the applicant has full access to all studies cited and evaluated in this report.

Note

For the evaluation for Annex I inclusion several analytical methods were submitted to Germany as Rapporteur Member State. Many of those methods are no longer consistent with the current guidance document SANCO/825/00 rev. 8.1. New acceptable analytical methods for residues were not supplied with this application.

IIIA 5.3.1 Evaluation of glyphosate

Table IIIA 5.3-1: Information on the active substance glyphosate

Name of component of residue definiton substance code IUPAC name formula	Structural formula
glyphosate PMG N-(Phosphonomethyl)-glycin $C_3H_8NO_5P$	
AMPA (metabolite) Aminomethylphosphonic acid CH_6NO_3P	

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table IIIA 5.3-2: Relevant residue definitions

Matrix		Relevant residue	Reference Remarks
plant material		glyphosate	Regulation (EU) No 441/2012, annex II; annex III part B
foodstuff of animal origin		glyphosate	Regulation (EU) No 441/2012, annex II; annex III part B
soil	ecotoxicology	glyphosate and metabolite AMPA	DAR, vol. 1, section 2.6.2
water	ecotoxicology	glyphosate and metabolite AMPA	DAR, vol. 1, section 2.6.2
	human toxicology	glyphosate and metabolite AMPA	DAR, vol. 1, section 2.6.2
air		glyphosate	generally defined
body fluids/tissue		not residue relevant	not classified as T / T+

Table IIIA 5.3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.1 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
Plant, acidic commodities	0.1 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
Plant, dry commodities	0.1 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
Plant, high oil content	0.1 mg/kg	Regulation (EU) No 441/2012, annex

		II; annex III part B
Plant, difficult matrices (tea, herbal infusions)	2 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
meat	0.05 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
milk	0.05 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
eggs	0.05 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
fat	0.05 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
liver, kidney	0.05 mg/kg	Regulation (EU) No 441/2012, annex II; annex III part B
soil	0.05 mg/kg	common limit
drinking water	0.1 µg/L	general limit for drinking water
surface water	600 µg/L (glyphosate) 89800 µg/L (AMPA)	EC50 Algae, DAR, Vol. 1, List of end points, Chapter 2.6 EC50 Algae, DAR, Vol. 1, List of end points, Chapter 2.6
air	60 µg/m^3	AOEL sys.: 0.2 mg/kg bw/d
tissue (meat or liver)	not required	not classified as T / T+
body fluids	not required	not classified as T / T+

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of glyphosate in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of glyphosate in plant matrices is given in the following tables. For the detailed evaluation of additional studies refer to Appendix 2.

Table IIIA 5.3-4: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
high water content	Pentz, Bramble, 2007	Seal, Dillon, 2007	Schulz, Reichert, 1995 [1]
acidic	Pentz, Bramble, 2007	not necessary	Klimmek, Weber, 2008
fatty	Pentz, Bramble, 2007	not necessary	Schulz, Reichert, 1995 [1]
dry	Pentz, Bramble, 2007	Seal, Dillon, 2007	Schulz, Reichert, 1995 [1]
difficult	not required for the intended GAP	not required for the intended GAP	not required for the intended GAP

[1] EU agreed method, see DAR

Table IIIA 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	not necessary
Not required, because:	because of the ionic character an extractability in aqueous medium is plausible

Table IIIA 5.3-6: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in
Klimmek, Weber, 2008 ASB2008-5607	acidic, fatty	0.05 mg/kg	HPLC-FLD with post-column derivatization (using OPA)	no confirmation	additional study, see appendix 2
Pentz, Bramble, 2007 ASB2008-2635	high water content, acidic, dry, fatty	0.05 mg/kg	LC-MS/MS, phenyl-hexyl, ESI+, m/z 170→88 against internal standard 1,2-$^{13}C_2{}^{15}N$-glyphosate m/z 173→91	no confirmation	additional study, see appendix 2
Schulz, Reichert, 1995 MET9600118	high water content, dry; fatty	0.03 mg/kg 0.06 mg/kg	HPLC-FLD with post-column derivatization (using OPA)	no confirmation	section B.4.2.1 of the DAR
Seal, Dillon, 2007 ASB2008-2637	high water content, dry	0.05 mg/kg	LC-MS/MS, phenyl-hexyl, ESI+, m/z 170→88 against internal standard 1,2-$^{13}C_2{}^{15}N$-	no confirmation, ILV of Pentz, Bramble, 2007	additional study, see appendix 2

			glyphosate m/z 173→91		

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of glyphosate in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of glyphosate in animal matrices is given in the following tables. For the detailed evaluation of additional studies refer to Appendix 2.

Table IIIA 5.3-7: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
milk	Pentz, Bramble, 2007	Karnik, Dillon, 2007	Schneider, 1998 [2]
eggs	Pentz, Bramble, 2007	Karnik, Dillon, 2007	Schneider, 1998 [2]
meat	Pentz, Bramble, 2007	Karnik, Dillon, 2007	Schneider, 1998 [2]
fat	Pentz, Bramble, 2007	not necessary	not necessary [3]
kidney, liver	Pentz, Bramble, 2007	not necessary	Karnik, Dillon, 2007

[2] EU agreed method, see DAR
[3] Because of the low fat solubility of glyphosate relevant residues in fat are not expected.

Table IIIA 5.3-8: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	not necessary
Not required, because:	because of the ionic character an extractability in aqueous medium is plausible

Table IIIA 5.3-9: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
Karnik, Dillon, 2007 ASB2008-2634	milk, eggs, meat	0.025 mg/kg	LC-MS/MS, phenyl-hexyl, ESI+, m/z 170→88 against internal standard 1,2-$^{13}C^{15}N$-glyphosate m/z 173→91	confirmation for liver by ESI- (m/z 168→63), ILV of Pentz, Bramble, 2007	additional study, see appendix 2
Pentz, Bramble, 2007 ASB2008-2636	milk, eggs, meat; fat, liver, kidney	0.025 mg/kg 0.05 mg/kg	LC-MS/MS, phenyl-hexyl, ESI+, m/z 170→88 against internal standard 1,2-	no confirmation	additional study, see appendix 2

			$^{13}C^{15}N$-glyphosate m/z 173→91		
Schneider, 1998 MET9800122	milk, eggs, meat	0.02 mg/kg	GC-MS, m/z 411 for glyphosate derivative against derivative of internal standard ^{13}C-glyphosate (m/z 412)	no confirmation	section B.4.2.2 of the DAR

IIIA 5.3.1.4 Description of Methods for the Analysis of glyphosate in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and possible data gaps for analysis of glyphosate in soil is given in the following tables. For the detailed evaluation of additional studies refer to Appendix 2. The mentioned derivatives result from esterification with trifluorethanol and the reaction of the secondary amino group with trifluoracetic acid anhydride.

Table IIIA 5.3-10: : Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
glyphosate	Waggoner, 1995 [4]	Schneider, 2001
AMPA	Waggoner, 1995 [4]	Schneider, 2001

[4] EU agreed method, see DAR

Table IIIA 5.3-11: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Schneider, 2001 MET2005-371	0.05 mg/kg	GC-MS, m/z 411, 238, 384 for glyphosate derivative against derivative of internal standard ^{13}C-glyphosat (m/z 412, 239, 385) and, m/z 302, 126, 246 for AMPA derivative against derivative of internal standard ^{15}N-AMPA (m/z 303, 127)	no confirmation	additional study, see appendix 2
Waggoner, 1995 MET9600120	0.05 mg/kg	HPLC-FLD with OPA	no confirmation; glyphosate and AMPA	section B.4.3.1 of the DAR

IIIA 5.3.1.5 Description of Methods for the Analysis of glyphosate in Water (OECD KIII A 5.6)

An overview of the acceptable methods and possible data gaps for analysis of glyphosate in surface and drinking water is given in the following table. For the detailed evaluation of additional studies refer to

Appendix 2. The mentioned derivatives result from esterification with trifluorethanol and the reaction of the secondary amino group with trifluoracetic acid anhydride.

Table IIIA 5.3-12: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
glyphosate	drinking water	Roth, 1995 [5]	Schneider, 1995 [5]
AMPA	drinking water	Roth, 1995 [5]	Schneider, 1995 [5]
glyphosate	surface water	Schneider, 2002	Schneider, 2002
AMPA	surface water	Schneider, 2002	Schneider, 2002

[5] EU agreed method, see DAR

Table IIIA 5.3-13: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Roth, 1995 MET9600138	0.1 µg/L	HPLC-FLD with OPA	no confirmation; results of 5 labs	section B.4.3.2 of the DAR
Schneider, 1995 MET9600103	0.1 µg/L	GC-MS, m/z 113 for glyphosate derivative against derivative of internal standard ^{13}C-glyphosate (m/z 114) and, m/z 126 for AMPA-derivative against derivative of internal standard ^{15}N-AMPA (m/z 127)	no confirmation	section B.4.3.2 of the DAR
Schneider, 2002 MET2005-369	0.1 µg/L	GC-MS, m/z 411, 238, 384 for glyphosate derivative against derivative of internal standard ^{13}C-glyphosate (m/z 412, 239, 385) and, m/z 302, 126, 246 for AMPA-derivative against derivative of internal standard ^{15}N-AMPA (m/z 303, 127)	confirmation included	additional study, see appendix 2

IIIA 5.3.1.6 Description of Methods for the Analysis of glyphosate in Air (OECD KIII A 5.7)

An overview of the acceptable methods and possible data gaps for analysis of glyphosate in air is given in the following table.

Table IIIA 5.3-14: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
glyphosate	Roth, 1994 [6]	not required

[6] EU agreed method, see DAR

Table IIIA 5.3-15: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Roth, 1994 MET9600138	9 µg/m^3	HPLC-FLD	no confirmation	section B.4.3.3 of the DAR

IIIA 5.3.1.7 Description of Methods for the Analysis of glyphosate in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because glyphosate is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

IIIA 5.3.1.8 Other Studies/ Information

Further studies were provided by the applicant and were not considered for the following reasons:

- Anon., 1993 (ASB2010-14761): extent of validation data not sufficient
- Bushong, Eschbach, 1992 (MET9600122): extent of validation data not sufficient
- Bushong, Eschbach, 1992 (MET9600132): additional data for the considered method of Waggoner, 1995 (MET9600120)
- Egloff, 1995 (MET9600117): validation data are included in the considered method of Roth, 1995 (MET9600114)
- J.E.B., 1989 (MET9600137): extent of validation data not sufficient, method description not acceptable
- Jauhiainen et al., 1991 (MET9600092): matrices not relevant, extent of validation data not sufficient
- Klumpp, 1995 (MET9600079): validation data are included in the considered method of Roth, 1995 (MET9600114)
- Kunstmann, 1985 (MET9600133): LOQ does not meet the drinking water limit
- Oppenhuizen, Cowell, 1987 (MET9600134): LOQ does not meet the drinking water limit
- Oppenhuizen, 1993 (ASB2009-4452): extent of validation data not sufficient
- Oppenhuizen, Schuette, 1995 (MET9600119): document consists of chromatograms only, no complete study
- Pijanowski, 1988 (MET9600140): method uses chloroform for extraction
- Reding, 1999 (MET1999-959): method not state of the art, extent of validation data at LOQ not sufficient
- Robinson, 1998 (ASB2012-7836): method is very laborious, number of fortifications per level not

sufficient, calibration range not sufficient, LOQ for liver not sufficient, acceptable only as confirmatory method for eggs

- Roth, 1995 (ASB2010-14762): uncomplete version of the considered method of Roth, 1995 (MET9600114)
- Royer, 2000 (ASB2011-9180): method is too laborious for routine monitoring
- Schulz, 1995 (MET9600116): validation data are included in the considered method of Roth, 1995 (MET9600114)
- Schulz, 1995 (MET9600121): extent of validation data not sufficient
- Solé, 2007 (ASB2012-7837): method is very laborious, LOQ not sufficient for monitoring of the corresponding MRLs
- Todd, 1993 (MET9600139): extent of validation data not sufficient
- Weber, 1995 (MET9600115): validation data are included in the considered method of Roth, 1995 (MET9600114)

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIIA1 5.2.1/01	Henriet, J. *et al.*,	1985	CIPAC Handbook Volume 1C - Analysis of Technical and Formulated Pesticides – Glyphosate 284, p. 2132 - 2134 Non-GLP, published	N	-	Y
KIIIA1 5.2.1/02	Meinerling, M	2010	Determination of the accelerated storage stability of Glyphosate 450 SL AE, Institut für Biologische Analytik und Consulting IBACON GmbH, Report No.: 60732204 GLP, unpublished	Y	Helm AG	Y
IIIA1 5.2.4/01	Meinerling, M. and Herrmann, S.	2012	Development and Validation of an Analytical Method for the Determination of Formaldehyde in Glyphosate 450 SL AE Report No.: 72071101 GLP: Yes unpublished	Y	Helm AG	Y
IIIA1 5.2.4/02	Norris, D.	2012	Analysis of Glyphosate 450 SL AE Formulation for N-Nitrosoglyphosate (NNG) content, with associated validation, in Compliance with Good Laboratory Practice. Report No.: DNA1666 GLP: Yes unpublished	Y	Helm AG	Y
OECD: KIIA 4.7	Anon.	1993	Determination of Glyphosate (CAS No. 1071-83-6) in air AM 342 ASB2010-14761			N
OECD: KIIA 4.4	Bushong, J. M.; Eschbach, J. C.	1992	Analytical method for the determination of N-(phosphonomethyl) glycine (Glyphosate) and its metabolite (aminomethyl)phosphonic acid (AMPA) in soil BD-035-91 MET9600132			N
OECD: KIIA 4.3	Bushong, J. M.; Eschbach, J. C.	1992	Analytical method for the determination of N-(phosphonomethyl) glycine (glyphosate) and its metabolite (animomethyl) phosphonic acid (AMPA) in various matrices BD-045-91 MET9600122			N
OECD: KIIA 4.5	Egloff, K.	1995	Bestimmung der Konzentration an Glyphosat und AMPA in 6 Trinkwasserproben IF-94/15512-01 MET9600117			N
all	Germany	1998	Monograph Glyphosate (DAR) ASB2010-10302			Used
OECD: KIIA 4.7	J. E. B.	1989	Analytical method for determination of Glyphosate isopropylamine salt in air 42-EH-92-89 MET9600137			N
OECD: KIIA 4.3	Karnik, S.; Dillon, R.	2007	Independent laboratory validation of DuPont-20009, "Analytical method for the determination of N-Acetylglyphosate and other analytes in various animal matrices using			Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
			LC/MS/MS" DuPont-21372 ! 1806 ASB2008-2634			
OECD: KIIA 4.3	Klimmek, S.; Weber, H.	2008	First Amendment to final report - Validation of the analytical method DFG Method 405 for the determination of residues of Glyphosate and its metabolite AMPA in various plant materials FCS-0703V ASB2008-5607			Add
OECD: KIIA 4.5	Klumpp, M.	1995	Analyse von Glyphosat und AMPA in Wasser 94120/02-RW MET9600079			N
OECD: KIIA 4.5	Kunstman, J. L.	1985	Validation of residue method for determination of Glyphosate and Aminomethylphosphonic acid (AMPA) in water - A round-robin study MSL-4268 MET9600133			N
OECD: KIIA 4.4	Oppenhuizen, M. E.	1993	Analytical method for Glyphosate and AMPA in soil RES-014-91 ASB2009-4452			N
OECD: KIIA 4.5	Oppenhuizen, M. E.; Cowell, J. E.	1987	Interlaboratory validation of an analytical method for the determination of Glyphosate and its metabolite, Aminomethylphosphonic acid (AMPA) in environmental water MSL-7200 MET9600134			N
OECD: KIIA 4.3	Oppenhuizen, M.; Schuette, S.	1995	Supplement to validation of an analytical method for the determination of Glyphosate and AMPA in animal tissues MSL-7358 MET9600119			N
OECD: KIIA 4.3	Pentz, A. M.; Bramble, F. Q.	2007	Analytical method for the determination of Glyphosate and degradate residues in various crop matrices using LC/MS/MS (incl. Revision No. 1 dated 13.11.2007) DuPont-15444 ASB2008-2635			Add
OECD: KIIA 4.3	Pentz, A. M.; Bramble, F. Q.	2007	Analytical method for the determination of N-Acetylglyphosate and other analytes in various animal matrices using LC/MS/MS DuPont-20009 ASB2008-2636			Add
OECD: KIIA 4.3	Pijanowski, P.	1988	Validation of an analytical method for the determination of Glyphosate residues in animal tissues MSL-7358 MET9600140			N
OECD: KIIA 4.3	Reding, M.-A.	1999	Validation of the analytical method for the determination of Glyphosate and AMPA residues in cow tissues, raw cow milk and chicken eggs MLL 31027 ! ES-ME-0073-01 MET1999-959			N
OECD: KIIA 4.3	Robinson, N. J.	1998	Residue analytical method for the determination of [N-(Phosphonomethyl)glycine] (PMG) and Aminomethylphosphonic acid (AMPA) in animal products RAM 308/01 ASB2012-7836			N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD: KIIA 4.5	Roth, A.	1995	Analyse von dotierten Trinkwasserproben zur Demonstration der allgemeinen Anwendbarkeit der Methode DFG 405 in verschiedenen Laboratorien EF 94-26-01 MET9600114			Y
OECD: KIIA 4.7	Roth, A.	1994	Validation of an analytical method for the determination of glyphosate, the IPA salt of Glyphosate and AMPA in air EF-94-26-03 MET9600138			Y
OECD: KIIA 4.5	Roth, A.	1995	Analyse von dotierten Trinkwasserproben zur Demonstration der allgemeinen Anwendbarkeit der Methode DFG 405 in verschiedenen Laboratorien EF 94-26-01 ASB2010-14762			N
OECD: KIIA 4.3	Royer, A.	2000	Development and validation of an analytical method for the determination of Glyphosate and AMPA in plant (wheat, tomato, maize and lemon), animal (milk, egg and meat) products, soil and water (groundwater and surface water) - incl. amendment dated 02.05.2001 MON/GLYPH/2000.01 ! AA045979 ASB2011-9180			N
OECD: KIIA 4.5	Schneider, E.	1995	Glyphosate and AMPA: Validation of an analytical method for the determination in tap water with a determination limit of 100 ng/l PR94/036 MET9600103			Add
OECD: KIIA 4.3	Schneider, E.	1998	Validation of analytical method for determination in foodstuff of animal origin; DrK126 PR98/001 MET9800122			Add
OECD: KIIA 4.4	Schneider, E.	2001	Validation of an analytical method for the determination of Glyphosate in soil PR01/006 MET2005-371			Add
OECD: KIIA 4.5	Schneider, E.	2002	Validation of an analytical method for the determination of Glyphosate and AMPA residues in surface water and tap water - Monitoring method PR01/004 MET2005-369			Add
OECD: KIIA 4.4	Schulz, H.	1995	Schulz, H. Summary report: compilation of glyphosate and AMPA analytical methods used for analysis of soil samples from field soil dissipation experiments in Germany and Switzerland conducted in 1990 and 1991 IF -95/11387-00 MET9600121			N
OECD: KIIA 4.3	Schulz, H.; Reichert, H.	1995	Compilation of glyphosate analytical methods used for analysis of samples from residue trials conducted in the UK in 1992 and 1993 (wheat, barley, oats, grass, linseed, oilseed rape, peas and beans) and in Portugal in 1993 (apples) IF-94/21320-00 MET9600118			Y
OECD: KIIA 4.5	Schulz, M.	1995	Determination of the residues of			N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
			Glyphosate and its metabolite AMPA in drinking water RCC 379743 MET9600116			
OECD: KIIA 4.3	Seal, S.; Dillon, R.	2007	Independent laboratory validation of DuPont-15444, "Analytical method for the determination of Glyphosate and relevant metabolite residues in various crop matrices using LC/MS/MS" DuPont-21313 ! 1763 ASB2008-2637			Add
OECD: KIIA 4.3	Solé, C.	2007	Validation of residue method RAM 308.01 for the determination of PMG (ASF71) and AMPA in fat, liver and kidney T011644-06 ! SYN/GLY/07001 ASB2012-7837			N
OECD: KIIA 4.3	Todd, M.	1993	Glyphosate [N-(phosphonomethyl)glycine]: The development of an analytical method for the determination of residues in the edible tissues and milk of dairy cattle 676/10-1012 MET9600139			N
OECD: KIIA 4.4	Waggoner, T. B.	1995	Appendix 1 to Analytical method for the determination of N-(phosphonomethyl)glycine (Glyphosate) and its metabolite (aminomethyl)phosphonic acid (AMPA)in soil BD-035-91 MET9600120			Y
OECD: KIIA 4.5	Weber, H.	1995	Bestimmung der Rückstände von Glyphosat und AMPA in Trinkwasser ECO-9401 ! 23973/94 MET9600115			N

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Analytical methods for glyphosate

Methods for enforcement of residues in food and feed of plant origin

Analytical method 1

Reference: OECD KIIA 4.3

Report: Analytical method for the determination of glyphosate and degradate residues in various crop matrices using LC/MS/MS; Pentz, A.M., Bramble, F.Q.; 2007; DuPont-15444; ASB2008-2635

Guideline(s): Yes

SANCO/825/00 rev. 7

US EPA OPPTS 860.1340

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Samples are extracted three times with acidic water/methanol (96:4; v/v) solution. An aliquot of the extract is washed with methylene chloride and the aqueous fraction is filtered through a C18 SPE cartridge. After addition of internal standard, the filtrate is applied to a mixed mode SPE catridge (BondElute MAX). The analyte is eluted from the catridge with 1 % TFA in methanol/water (9:1; v/v). The eluate is evaporated to dryness and redissolved in aqueous 0.02 M phosphoric acid, filtered and analysed. Final determination is performed by LC-MS/MS (ESI+, m/z 170→88) on a phenyl hexyl column using external calibration and 1,2-$^{13}C_2{}^{15}N$-glyphosate as internal standard to compensate for matrix effects.

Results and discussions

Table A 2: Recovery results from method validation of different matrices using the analytical method. Standards were prepared in water

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
plums	0.05	5	95	4	

	0.5	5	91	4	
limes	0.05 0.5	5 5	100 99	8 6	
maize grain	0.05 0.5	12 12	77 79	7 10	
soybean seed	0.05 0.5	5 5	85 78	6 5	

Note: Only one representative matrix of each matrix group was reported here although various other matrices were investigated in the study.

Table A 3: Characteristics for the analytical method used for the quantitation of glyphosate residues in different matrices

	glyphosate	
Calibration function	$y = 0.003062x + 0.1214$ $R^2 = 0.9998$	
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 50 ng/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.025 – 2.5 mg/kg	
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	
Assessment of matrix effects is presented (yes/no)	no	
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	

Conclusion

The method has been sufficiently validated for the determination of residues of glyphosate in all four matrix groups with a LOQ of 0.05 mg/kg.

Comments of zRMS:	Acceptable for the determination of residues of glyphosate in all four matrix groups

Independent laboratory validation

Reference: OECD KIIA 4.3

Report: Independent laboratory validation of DuPont-15444, "Analytical method for the determination of Glyphosate and relevant metabolite residues in various crop matrices using LC/MS/MS"; Seal, S., Dillon, R.; 2007; DuPont-21313; ASB2008-2637

Guideline(s): Yes

SANCO/825/00 rev. 7

US EPA OPPTS 860.1340

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Samples are extracted three times with acidic water/methanol (96:4; v/v) solution. An aliquot of the extract is washed with methylene chloride and the aqueous fraction is filtered through a C18 SPE cartridge. After addition of internal standard, the filtrate is applied to a mixed mode SPE catridge (BondElute MAX). The analyte is eluted from the catridge with 1 % TFA in methanol/water (9:1; v/v). The eluate is evaporated to dryness and redissolved in aqueous 0.02 M phosphoric acid, filtered and analysed. Final determination is performed by LC-MS/MS (ESI+, m/z 170→88) on a phenyl hexyl column using external calibration and 1,2-$^{13}C_2{}^{15}N$-glyphosate as internal standard to compensate for matrix effects.

Results and discussions

Table A 4: Recovery results from the independent laboratory validation of grapes and soybean seed using the analytical method. Standards were prepared in water

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
grapes	0.05 0.2	5 5	81 80	8 7	
soybean seed	0.05 20	5 5	96 85	13 7	

Table A 5: Characteristics for the analytical method used for the independent laboratory validation of glyphosate residues in grapes and soybean seeds

	glyphosate	
Calibration function	not readable	
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 100 ng/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.025 – 5 mg/kg (high level soybean seed samples were diluted 100fold prior to determination)	
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	
Assessment of matrix effects is presented (yes/no)	no	

Interference >30% of LOQ in blank sample is absent (yes/no)	yes	

Conclusion

The method has sufficiently been validated for the determination of residues of glyphosate in commodities with high acid content and commodities with high fat content with a LOQ of 0.05 mg/kg. The results confirm the applicability of the primary method (Pentz, Bramble, 2007).

Comments of zRMS:	Acceptable for the determination of residues of glyphosate in commodities with high acid content and commodities with high fat content; ILV of Pentz, Bramble, 2007

Confirmatory method

Reference: OECD KIIA 4.3

Report: First Amendment to final report - Validation of the analytical method DFG Method 405 for the determination of residues of Glyphosate and its metabolite AMPA in various plant materials; Klimmek, S., Weber, H.; 2008; Specht Study No. FCS-0703V; ASB2008-5607

Guideline(s): Yes

SANCO/825/00 rev. 7

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Samples are extracted with diluted hydrochloric acid and the pH of the extrtact is adjusted to 2. The extract is passed through a Chelex 100 ligand exchange resin, which was loaded before with Fe(III) ions. Trapped glyphosate is eleuted with 6N HCl. The co-eluted ferric ions are removed by filtration through an anion exchange columns (AG 1-X8). Final determination is performed by HPLC-FLD (ion exclusion column, excitation 325 nm, emission 530 nm) including post-column derivatisation with o-phtaldialdehyde (OPA) using external calibration.

Results and discussions

Table A 6: Recovery results from the confirmatory method validation of different matrices using the confirmatory method. Standards were prepared in 0.02 M phosphate buffer

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments

oilseed rape	0.05 0.5	5 5	74 75	5 5	
citrus	0.05 0.5	5 5	73 77	4 10	

Table A 7: Characteristics for the confirmatory method used for the quantitation of glyphosate residues in different matrices

	glyphosate	
Calibration function	$y = 474154x + 2142$ $r = 0.9996$	
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.016 – 2.5 µg/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.004 – 0.7 mg/kg (citrus) 0.01 – 1.4 mg/kg (oilseed rape)	
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	
Assessment of matrix effects is presented (yes/no)	no	
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	

Conclusion

The method has sufficiently been validated for the determination of residues of glyphosate in commodities with high acid content and commodities with high oil content with a LOQ of 0.05 mg/kg.

Comments of zRMS:	Acceptable for the determination of residues of glyphosate in commodities with high acid content and commodities with high oil content

Methods for enforcement of residues in food and feed of animal origin

Analytical method 1

Reference: OECD KIIA 4.3

Report: Analytical method for the determination of N-acetylglyphosate and other analytes in various animal matrices using LC/MS/MS; Pentz, A. M., Bramble, F. Q.; 2007; DuPont-20009; ASB2008-2636

Guideline(s): Yes

SANCO/825/00 rev. 7

US EPA OPPTS 860.1340

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

For milk and egg matrices, samples are shaken with aqueous 0.1 % formic acid/methanol (96:4; v/v). The extracts are partitioned with hexane and the hexane layer discarded. The aqueous fraction is washed with methylene chloride and the aqueous layer is collected. The methylene chloride fraction is back extracted with additional 0.1 % formic acid/methanol (96:4; v/v) for quantitative recovery of the analyte. The aqueous fractions are combined and filtered through a C18 SPE cartridge. After addition of internal standard, the filtrate is applied to a mixed mode SPE catridge (BondElute MAX). The analyte is eluted from the catridge with 1 % TFA in methanol/water (9:1; v/v). The eluate is evaporated to dryness and redissolved in aqueous 0.02 M phosphoric acid.

For animal tissue matrices, samples are blended with C18 sorbent material prior to extraction with 0.1 N HCl solution (96 % water/4 % methanol). The extracts are diluted in acetonitrile and methanol to precipitate proteins. After centrifugation, extracts are further purified by SPE using the above mentioned mixed mode SPE cartridge. Final extracts are adjusted to 0.02 M phosphoric acid.

Final determination is performed by LC-MS/MS (ESI+, m/z 170→88) on a phenyl hexyl column using external calibration and 1,2-$^{13}C_2{}^{15}N$-glyphosate as internal standard to compensate for matrix effects.

Results and discussions

Table A 8: Recovery results from method validation of different matrices using the analytical method. Standards were prepared in 0.02 M phosphoric acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
whole milk	0.025 0.05 0.5	9 7 7	97 100 80	14 13 7	
skim milk	0.025 0.05 0.5	5 5 5	93 85 85	12 4 7	
cream	0.025 0.05 0.5	5 5 5	99 95 83	13 5 5	
whole egg	0.025 0.05 0.5	5 5 5	88 89 85	6 7 2	
egg yolks	0.025 0.05 0.5	5 5 5	98 90 89	10 8 7	
egg whites	0.025 0.05 0.5	5 5 5	83 88 89	7 3 6	

liver	0.05 0.5	11 9	90 82	10 5	
kidney	0.05 0.5	6 7	98 87	15 4	
fat	0.05 0.5	6 6	98 94	11 4	
meat	0.025 0.25	7 7	92 84	10 4	

Table A 9: Characteristics for the analytical method used for the quantitation of glyphosate residues in different matrices

	glyphosate	
Calibration function	$y = 66.25x + 3.927$ $R^2 = 0.9958$	
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 20 ng/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.00625 – 0.5 mg/kg (meat) 0.0125 – 1.0 mg/kg (others)	
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	
Assessment of matrix effects is presented (yes/no)	no	
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	

Conclusion

The method has sufficiently been validated for the determination of residues of glyphosate in milk, eggs and meat with a LOQ of 0.025 mg/kg and in fat, liver and kidney with a LOQ of 0.05 mg/kg.

Comments of zRMS:	Acceptable for the determination of residues of glyphosate in all representative animal matrices

Independent laboratory validation

Reference: OECD KIIA 4.3

Report: Independent laboratory validation of DuPont-20009, "Analytical method for the determination of N-acetalglyphosate and other analytes in various animal matrices using LC/MS/MS"; Karnik, S., Dillon, R.; 2007; DuPont-21372; ASB2008-2634

Guideline(s): Yes

SANCO/825/00 rev. 7

US EPA OPPTS 860.1340

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

For milk and egg matrices, samples are shaken with aqueous 0.1 % formic acid/methanol (96:4; v/v). The extracts are partitioned with hexane and the hexane layer discarded. The aqueous fraction is washed with methylene chloride and the aqueous layer is collected. The methylene chloride fraction is back extracted with additional 0.1 % formic acid/methanol (96:4; v/v) for quantitative recovery of the analyte. The aqueous fractions are combined and and filtered through a C18 SPE cartridge. After addition of internal standard, the filtrate is applied to a mixed mode SPE catridge (BondElute MAX). The analyte is eluted from the catridge with 1 % TFA in methanol/water (9:1; v/v). The eluate is evaporated to dryness and redissolved in aqueous 0.02 M phosphoric acid.
For animal tissue matrices, samples are blended with C18 sorbent material prior to extraction with 0.1 N HCl solution (96 % water/4 % methanol). The extracts are diluted in acetonitrile and methanol to precipitate proteins. After centrifugation, extracts are further purified by SPE using the above mentioned mixed mode SPE cartridge. Final extracts are adjusted to 0.02 M phosphoric acid.
Final determination is performed by LC-MS/MS (ESI+, m/z 170→88; liver: ESI-, m/z 168→63) on a phenyl hexyl column using external calibration and 1,2-$^{13}C^{15}N$-glyphosate as internal standard to compensate for matrix effects.

Results and discussions

Table A 10: Recovery results from method validation of different matrices using the analytical method. Standards were prepared in 0.02 M phosphoric acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
milk	0.025 0.05 0.25	10 10 10	100 102 99	8 9 6	
eggs	0.025 0.05 0.25	5 5 5	100 107 109	8 4 3	
meat	0.025 0.05 0.25	5 5 5	89 87 85	11 8 4	
liver	0.05 0.1 0.5	5 5 5	106 110 102	11 11 10	

Table A 11: Characteristics for the analytical method used for the quantitation of glyphosate residues in different matrices (example)

	glyphosate	
Calibration function	$y = 0.281x - 0.0052$ $r = 0.9994$	
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.25 – 20 ng/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.00625 – 0.5 mg/kg (meat) 0.0125 – 1 mg/kg (others)	
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	
Assessment of matrix effects is presented (yes/no)	no	
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	

Conclusion

The method has sufficiently been validated for the determination of residues of glyphosate in milk, eggs and meat with a LOQ of 0.025 mg/kg and in liver with a LOQ of 0.05 mg/kg. The results confirm the applicability of the primary method (Pentz, Bramble, 2007). As the method uses another mass transition for liver, it is not acceptable as ILV for liver, but only as confirmatory method.

Comments of zRMS:	Acceptable for the determination of residues of glyphosate in milk, eggs, meat and liver; ILV of Pentz, Bramble, 2007 (except for liver)

Description of Methods for the Analysis of Soil

Analytical method 1

Reference: OECD KIIA 4.4

Report: Validation of an analytical method for the determination of Glyphosate in soil; Schneider, E.; 2001; PR01/006; MET2005-371

Guideline(s): Not stated

Deviations: Not applicable

GLP: Yes

Acceptability: Yes

Materials and methods

The soil samples are fortified with internal standards and extracted with alkalized water and then centrifuged. The extracts are subjected to a cleanup by anion exchange resin and eluates are further treated with charcoal. The analytes are then derivatized with trifluoroacetic acid, trifluoroacetic anhydride and trifluoroethanol at 70 °C. The derivatives are soluted in dichloromethane and the solution is washed with aqueous ammonia solution. Final determination is performed by GC-MS (m/z 411 for glyphosate derivative and 302 for AMPA derivative) with a CP-Sil 19CB column using external calibration and ^{13}C-glyphosate as internal standard to compensate for matrix effects.

Results and discussions

Table A 12: Recovery results from method validation of soil using the analytical method. Standards were prepared in water

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
soil (glyphosate)	0.05 0.5	5 5	105 109	3 0.4	
soil (AMPA)	0.05 0.5	5 5	104 108	3 5	

Table A 13: Characteristics for the analytical method used for the quantitation of glyphosate and AMPA residues in soil

	glyphosate	AMPA
Calibration function	$y = -0.2192x^2 + 1.1581x + 0.0224$ $R^2 = 0.9999$	$y = -0.0201x^2 + 0.9546x + 0.0324$ $R^2 = 0.9999$
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2 – 30 µg/mL	2 – 30 µg/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.15 – 2.25 mg/kg	0.15 – 2.25 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method has sufficiently been validated for the determination of residues of glyphosate and AMPA in soil with a LOQ of 0.05 mg/kg per analyte. The calibration range does not meet the LOQ which can be accepted due to the use of an internal standard.

Comments of zRMS:	Acceptable for the determination of residues of glyphosate and AMPA in soil

Description of Methods for the Analysis of Water

Analytical method 1

Reference: OECD KIIA 4.5

Report: Validation of an analytical method for the determination of Glyphosate and AMPA residues in surface water and tap water - Monitoring method; Schneider, E.; 2002; PR01/004; MET2005-369

Guideline(s): Not stated

Deviations: Not applicable

GLP: Yes

Acceptability: Yes

Materials and methods

The samples are acidified to pH 2 with hydrochloric acid. After addition of internal standards, residues are extracted by passing through a Chelex 100 ligand exchange resin, which was loaded before with Fe(III) ions. Trapped glyphosate is eleuted with 6N HCl. The co-eluted ferric ions are removed by filtration through an anion exchange columns (AG 1-X8). Following evaporation to dryness, residues are derivatized with trifluoroacetic acid, trifluoroacetic anhydride and trifluoroethanol at 70 °C. The derivatives are soluted in dichloromethane and the solution is washed with aqueous ammonia solution. Final determination is performed by GC-MS (m/z 411 for glyphosate derivative and 302 for AMPA derivative) with a CP-Sil 19CB column using external calibration and ^{13}C-glyphosate as internal standard to compensate for matrix effects.

Results and discussions

Table A 14: Recovery results from method validation of drinking water and surface water using the analytical method. Standards were prepared in water

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery (%)	RSD (%)	Comments
surface water (glyphosate)	0.1 1	5 5	106 104	1 3	
surface water (AMPA)	0.1 1	5 5	101 105	3 3	
drinking water (glyphosate)	0.1	3	97	2	
drinking water (AMPA)	0.1	3	90	2	

Table A 15: Characteristics for the analytical method used for the quantitation of glyphosate and AMPA residues in drinking water and surface water

	glyphosate	**AMPA**
Calibration function	$y = 0.7376x + 0.0598$ $R^2 = 0.9958$	$y = 0.9104x + 0.0202$ $R^2 = 0.9992$
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.08 – 1.2 µg/mL	0.08 – 1.2 µg/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.2 – 3 µg/L	0.2 – 3 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method has sufficiently been validated for the determination of residues of glyphosate and AMPA in drinking water and surface water with a LOQ of 0.1 µg/L per analyte. The calibration range does not meet the LOQ which can be accepted due to the use of an internal standard. For drinking water a reduced data set was performed which is acceptable because the validation for surface water was successful.

Comments of zRMS:	Acceptable for the determination of residues of glyphosate and AMPA in drinking water and surface water

Description of Methods for the Analysis of Air

no additional methods

Description of Methods for the Analysis of Body Fluids and Tissues

no additional methods

Extraction efficiency of enforcement methods for foodstuff

no additional methods

Other Studies/ Information

no additional methods

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology

Detailed summary of the risk assessment

Product code: HAG 500 02 H

Active Substance: Glyphosate (450 g/L)

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Helm AG

Date: August 2012

Table of Contents

MIIIA 7 TOXICOLOGICAL STUDIES 4
MIIIA 7.1 Acute Toxicity 5
MIIIA 7.1.1 Acute oral toxicity 7
MIIIA 7.1.2 Acute percutaneous (dermal) toxicity 8
MIIIA 7.1.3 Acute inhalation toxicity of Glyphosate 450 SL AE in rats 10
MIIIA 7.1.4 Skin irritation 12
MIIIA 7.1.5 Eye irritation 13
MIIIA 7.1.6 Skin sensitisation 14
MIIIA 7.1.7 Supplementary studies for combinations of plant protection products 17
MIIIA 7.2 Short-Term Toxicity Studies 17
MIIIA 7.3 Safety Assessment of Pesticide Application 18
MIIIA 7.3.1 Selection of critical use(s) and justification 18
MIIIA 7.3.2 Evaluation of the Active Substance Glyphosate 20
MIIIA 7.3.2.1 Operator Exposure and Risk Assessment 20
MIIIA 7.3.2.1.1 Estimation of Operator Exposure and Risk Assessment 20
MIIIA 7.3.2.1.2 Measurement of Operator Exposure and Risk Assessment 21
MIIIA 7.3.2.2 Worker Exposure and Risk Assessment 21
MIIIA 7.3.2.2.1 Estimation of Worker Exposure and Risk Assessment 21
MIIIA 7.3.2.2.2 Measurement of Worker Exposure and Risk Assessment 22
MIIIA 7.3.2.3 Bystander and Resident Exposure and Risk Assessment 22
MIIIA 7.3.2.3.1 Estimation of Bystander and Resident Exposure and Risk Assessment 22
MIIIA 7.3.2.3.2 Measurement of Bystander and Resident Exposure and Risk Assessment 23
MIIIA 7.3.3 Conclusion of Exposure Estimation and Risk Assessment 23
MIIIA 7.4 Justified Proposals for Classification and Labelling and Safety Instructions 24
MIIIA 7.5 Dermal Absorption 24
MIIIA 7.5.1 Dermal absorption, in vivo in the rat 24
MIIIA 7.5.2 Comparative dermal absorption, in vitro using rat and human skin 25
MIIIA 7.6 Dislodgeable Residues 25
MIIIA 7.6.1 Dislodgeable Residues - foliar 25
MIIIA 7.6.2 Dislodgeable Residues - soil 25
MIIIA 7.6.3 Dislodgeable Residues - indoor surface re-volatilization 25
MIIIA 7.7 Epidemiology 25
MIIIA 7.8 Data on Formulants 25
MIIIA 7.8.1 Material safety data sheets for each formulant 25
MIIIA 7.8.2 Available toxicological data for each formulant 25

MIIIA 7.9 Domestic Animal/Livestock Safety....25
MIIIA 7.10 Other/Special Studies....25
Appendix 1: List of data submitted in support of the evaluation....26
Appendix 2: Exposure calculations....28
A 2.1 Operator Exposure Calculations....28
A 2.2 Worker exposure calculations....38
A 2.3 Bystander and resident exposure calculations....39
Appendix 3: Glossary....42

MIIIA 7 TOXICOLOGICAL STUDIES

This document reviews the toxicological studies for the formulation HAG 500 02 H (HEL-50002-H-0-SL) containing the 450 g/L glyphosate which was included into Annex I of Directive 91/414 (2001/99/EC).

The product is formulated as a soluble concentrate (SL), where the active substance is included in the form of glyphosate isopropylammonium salt. Within the GAP for HAG 500 02 H the application rate for the active substance refers to glyphosate as acid equivalent, since it is the herbicidally active form. If the data of this dossier does not relate to the free acid it will be specifically named.

A full risk assessment according to the German Model, the UK POEM and according to Uniform Principles is provided which demonstrates that the product is safe for operators, workers, bystanders and residents.

Where appropriate this document refers to the conclusions of the EU review of glyphosate. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; or when
- the EU review concluded that additional data/information should be considered at national re-registration.

<u>Note</u>: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered relevant for the evaluation and in this case a full study summary must be provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

HAG 500 02 H was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The EC Review Report for glyphosate (Glyphosate 6511/VI/99-final, 21.01.2002) is considered to provide the relevant review information or a reference to where such information can be found.

The following table provides the EU endpoints for glyphosate to be used in the evaluation here.

Agreed EU End-points of the active substance

End-Point	Glyphosate
Dermal penetration	Concentrate: < 3 % [1)] Spray dilutions: < 3 % [1)] EU (DG SANCO) Review Report 6511/VI/99-final
AOEL	0.2 mg/kg bw/d EU (DG SANCO) Review Report 6511/VI/99-final
Classification and proposed labelling with regard to toxicological data	Regulation (EC) No 1272/2008 (Table 3.2): Xi - Irritant R41 - Risk of serious damage to eyes
	Regulation (EC) No 1272/2008: Serious eye damage, cat. 1 H318 - Causes serious eye damage

[1)] In Germany a dermal absorption study is available which investigated a different plant protection product resulting in dermal absorption values of 1 % for the concentrate and the spray dilution. Although, from a scientific point of view these results could be applied for HAG 500 02 H as well, the figures employed by the applicant and mentioned above will be used for this product.

The Annex I Inclusion Directive for glyphosate (2001/99/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on glyphosate and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 21 January 2002 shall be taken into account. In this overall assessment no specific issues concerning operator, worker, or bystander exposure were mentioned for which Member States should pay particular attention to.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation. Appendix 2 of this document summarises the critical uses of HAG 500 02 H. Appendix 3 of this document contains details of the operator exposure calculations.

Information on the detailed composition of HAG 500 02 H can be found in the confidential dossier of this submission (Registration Report - Part C).

MIIIA 7.1 Acute Toxicity

Acute toxicity studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, all relevant data are provided.

Overall summary

The following tests were performed on Glyphosate 450 SL AE (identical to HAG 500 02 H): acute LD_{50} oral (rat), acute LD_{50} dermal (rat), acute LC_{50} inhalation (rat), skin irritation (rabbit), eye irritation (rabbit) and sensitisation of the skin (guinea pig). The results are summarised in Table 7.1-1 and individual study summaries are provided (MIIIA1 7.1.1 to 7.1.6).

Table 7.1-1: Acute toxicological data obtained with HAG 500 02 H

Parameter, incl. Test Guideline [Reference]	Species	Result [mg/kg or mg/m^3] or effect	Classification according to Directive 67/548/EEC or Reg. 1272/2008
Acute oral LD_{50} OECD 423 [[redacted] 2009/2010]	rat	LD_{50} > 2000 mg/kg bw	Not to be classified
Acute dermal LD_{50} OECD 402 [[redacted] 2009/2010]	rat	LD_{50} > 2000 mg/kg bw	Not to be classified
Acute inhalation LC_{50} OECD 403 [[redacted]. 2009/2010]	rat	LC_{50} > 4.4 mg/L air/4 hours	Not to be classified
Skin irritation OECD 404 [[redacted] 2009/2010]	rabbits	No skin irritation	Not to be classified
Eye irritation OECD 405 [[redacted] 2009/2010]	rabbits	No eye irritation	Not to be classified
Sensitisation, M&K OECD 406 [[redacted] 2009/2010]	guinea pigs	No skin sensitisation	Not to be classified

Table 7.1-2 Additional relevant toxicological information

Type of test, species (Guideline)	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)	Reference	Classification of HAG 500 02 H (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)
Short-term toxicity studies	No data – not required			
Toxicological data on active substance (not tested with the preparation)	None			
Toxicological data on non-active substances (not tested with the preparation)	None			
Further relevant toxicological information	No data – not required			

An overview on the classification and labelling of the preparation is given in paragraph 7.4.

HAG 500 02 H containing 450 g/L glyphosate has a very low toxicity by the oral, percutaneous and inhalation route. It is neither a skin nor an eye irritant nor possesses a sensitising potential according to the results of the Magnusson and Kligman test. According to Directive 67/548/EEC or Reg. 1272/2008, HAG 500 02 H needs not to be classified.

MIIIA 7.1.1 Acute oral toxicity

Acute oral toxicity studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, the relevant data are provided.

Report:	**KIIIA1 7.1.1, [redacted] (2009, including amendment 2010)**
Title:	Acute oral toxicity of Glyphosate 450 SL AE in rats
Document No:	24309, ASB2011-9343
Guidelines:	EC method B.1 tris (2004/73/EC); OECD No. 423; OPPTS 870.1100
Deviations	None
GLP	Yes; laboratory certified by 'Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz (Freie und Hansestadt Hamburg)'

Material and Methods:

The test item Glyphosate 450 SL AE (batch no. 3342/R, 475 g/L glyphosate acid technical (95 %), analysed 461 g glyphosate/L), a brownish liquid, was given to rats by oral administration to obtain information on the toxicity. Glyphosate 450 SL AE is identical to HAG 500 02 H.

The test procedure permits the identification of the 'acute-toxic-class' (ATC), a measurement of the acute toxicity by the oral route. The test item is administered orally by gavage at a single dose level to a group of experimental animals.

Following administration, observations were made and recorded systematically with individual records being maintained for each animal. Observations were performed before and immediately, 5, 15, 30 and 60 min, as well as 3, 6 and 24 hours after administration. All animals were observed for a period of 14 days. During the follow-up period, changes of skin and fur, eyes and mucous membranes, respiratory and the circulatory, autonomic and central nervous system and somatomotor activities as well as behaviour pattern were observed at least once per day until all symptoms had subsided. Thereafter the animals were observed each working day. Attention was also paid to possible tremor, convulsions, salivation, diarrhoea, lethargy, sleep and coma. Observations on mortality were made at least once daily to minimize loss of animals during the study. Individual body weights were recorded before administration of the test item and thereafter in weekly intervals up to the end of the study. Changes in weight were calculated and recorded. At the end of the experiments all animals were sacrificed, dissected and inspected macroscopically. All gross pathological changes were recorded. No microscopic examination was performed as no pathological findings were noted at necropsy.

According to the protocol, three female animals were treated with 2000 mg/kg bw (first step). If two to three animals die, testing with 300 mg/kg bw should be performed. If no to one animal dies, the test item should be retested (second step) with 2000 mg/kg bw, using three animals of the same sex. Since no mortality and clinical signs were noted, the study was terminated after the second step with 2000 mg/kg bw.

Findings:

Table 7.1.1-1: Acute oral toxicity of Glyphosate 450 SL AE in rats

Dose (mg/kg bw)	Toxicological results*	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Female rats				
2000 (1st step)	0/0/3	-	-	> 2000
Female rats				
2000 (2nd step)	0/0/3	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

- No clinical signs and no deaths were observed during the study.
- All animals gained expected weight throughout the whole test period.
- Macroscopic examination revealed no apparent abnormalities in all the animals.

Conclusion/endpoint:

Under the experimental conditions, the oral LD_{50} of Glyphosate 450 SL AE is higher than 2000 mg/kg in rats. Therefore, no classification is needed according to Dir. 67/548/EEC or Reg. 1272/2008.

Study Comments: MIIIA 7.1.1/01	Acceptable (no deviations from above mentioned test guideline), used for evaluation, applicant's description slightly modified by the zRMS
Agreed endpoint: MIIIA 7.1.1/01	Acute oral LD_{50} > 2000 mg/kg bw

MIIIA 7.1.2 Acute percutaneous (dermal) toxicity

Acute dermal toxicity studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, the relevant data are provided.

Report:	**KIIIA1 7.1.2, [redacted] (2009, including amendment 2010)**
Title:	Acute dermal toxicity study of Glyphosate 450 SL AE in CD rats
Document No:	24311, ASB2011-9344
Guidelines:	EC method B.3 (92/69/EEC), OECD No. 402, OPPTS 870.1200, Limit test
Deviations:	None
GLP	Yes; laboratory certified by 'Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz (Freie und Hansestadt Hamburg)'

Material and Methods:

The test item Glyphosate 450 SL AE (batch no. 3342/R, 475 g/L glyphosate acid technical (95 %), analysed 461 g glyphosate/L), a brownish liquid, was given to rats by dermal administration to obtain information on the toxicity. Glyphosate 450 SL AE is identical to HAG 500 02 H.

One dose group of 5 male and 5 female rats was examined (limit test). The dose used was 2000 mg/kg bw (1.67 mL/kg bw). The test item was applied once for 24 hours on the shaved intact dorsal skin of rats (5 cm x 6 cm, approx. 1/10 of body surface). The test item was applied to 8 layers of gauze. The gauze was covered with a plastic sheet and secured with adhesive plaster on the application site. At the end of the exposure period no residual test item had to be removed.

Following administration, observations were made and recorded systematically with individual records being maintained for each animal. Observations were performed before and immediately, 5, 15, 30 and 60 min, as well as 3, 6 and 24 hours after administration. All animals were observed for a period of 14 days. During the follow-up period (two weeks), changes of skin and fur, eyes and mucous membranes, respiratory and circulatory function, autonomic and central nervous system and somatomotor activity as well as behaviour pattern, were observed at least once a day until all symptoms subsided, thereafter each working day. Attention was also paid to possible tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. Observations on mortality were made at least once daily to minimize loss of animals during the study. Individual body weights were recorded before administration of the test item and thereafter in weekly intervals up to the end of the study. Changes in weight were calculated and recorded. The skin was observed for the development of erythema and oedema. At the end of the experiments, all animals were sacrificed, dissected and inspected macroscopically. All gross pathological changes were recorded. No histopathology was carried out as no macroscopical findings were noted at necropsy.

Findings:

Table 7.1.2-1: Acute dermal toxicity of Glyphosate 450 SL AE in rats

Dose (mg/kg bw)	Toxicological results*	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	> 2000
Female rats				
2000	0/0/5	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

- No clinical signs and no deaths were observed during the study.
- One animal appeared to reveal reduced body weight gain.
- Macroscopic examination revealed no apparent abnormalities in all the animals.

Conclusion/endpoint:

Under the experimental conditions, the dermal LD_{50} of Glyphosate 450 SL AE is higher than 2000 mg/kg in rats. Therefore, no classification is needed according to Dir. 67/548/EEC or Reg. 1272/2008.

Study Comments: MIIIA 7.1.2/01	Acceptable (no deviations from above mentioned test guideline), used for evaluation, applicant's description slightly modified by the zRMS
Agreed endpoint: MIIIA 7.1.2/01	Acute dermal LD_{50} > 2000 mg/kg bw

MIIIA 7.1.3 Acute inhalation toxicity of Glyphosate 450 SL AE in rats

Acute inhalation toxicity studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, the relevant data are provided.

Report:	**KIIIA1 7.1.3, [redacted] (2009, including amendment 2010)**
Title:	Acute inhalation toxicity study of Glyphosate 450 SL AE in CD rats
Document No:	24310, ASB2011-9345
Guidelines:	EC method B.2. (92/69/EEC), OECD No. 403, OPPTS 870.1300
Deviations:	None
GLP	Yes; laboratory certified by 'Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz (Freie und Hansestadt Hamburg)'

Material and Methods:

The test item Glyphosate 450 SL AE (batch no. 3342/R, 475 g/L glyphosate acid technical (95 %), analysed 461 g glyphosate/L), a brownish liquid, was given to rats to assess the acute inhalation toxicity of the test item when administered to rats for a single 4-hour period. Glyphosate 450 SL AE is identical to HAG 500 02 H.

A total of 10 animals (5/sex) were exposed for 4 hours to the test material at an actual liquid aerosol concentrations of 4.40 mg/L air (determined by HPLC) using a dynamic nose-only exposure chamber. The test item is a soluble concentrate with a high viscosity. Hence, a 50 % concentration of the test item in water (m/m) was the highest possible concentration to obtain an appropriate aerosol.

Clinical examination: During and following exposure (14 days observation period), observations were made and recorded systematically; individual records were maintained for each animal. A careful clinical examination was made at least once daily until all symptoms subsided, thereafter each working day. Observations on mortality were made at least once daily. Cageside observations changes in the skin and fur, eyes, mucous membranes, respiratory, circulatory, autonomic and central nervous system, as well as somatomotor activity and behaviour pattern. Particular attention was directed to observation of tremor, convulsions, salivation, diarrhoea, lethargy, sleep and coma. Individual weights of animals were determined before the exposure and weekly after exposure. Changes in weight were calculated and recorded when survival exceeds one day. At the end of the test, the animals were weighed and sacrificed. Pathology: Necropsy of all animals was carried out and all gross pathological changes were recorded. No microscopic examination was carried out as no pathological findings were noted at necropsy.

The particle size distribution during exposure determined by laser analysis is presented in Table 7.1.3-1. No finer aerosol could be generated due to the viscosity of the test item.

Findings:

The particle size data (measured in the breathing zone of the animals) are presented in Table 7.1.3-1.

Table 7.1.3-1 Particle size distribution in the exposure atmosphere (actual concentration: 4.4 mg/L air)

Cumulative proportion of particles (%)	Diameter (µm)
< 1	≤ 3.98
10	6.23
50	7.86
90	13.62
mean	7.86

The measured exposure concentration tested was 4.4 mg/L air. The achieved average of the mass median aerodynamic diameter (MMAD) of the particles was 7.86 µm.

Table 7.1.3-2: Acute inhalation toxicity of Glyphosate 450 SL AE in rats

Dose (mg/L air)	Toxicological results*	Duration of signs	Time of death	LC_{50} (mg/L air/ 4h)
Male rats				
4.4	0/5/5	30 min – 3 h	-	> 4.4
Female rats				
4.4	0/5/5	30 min – 3 h	-	> 4.4

* Number of animals which died/number of animals with clinical signs/number of animals used

- No deaths were observed during the study.
- Exposure revealed ataxia and slight dyspnoea in all male and female animals until 30 minutes or until 3 hours after end of exposure. Furthermore, slight tremor in all female animals was observed until 30 minutes after end of exposure.
- All animals gained the expected body weight.
- Macroscopic examination revealed no apparent abnormalities in all animals.

Conclusion/endpoint:

The LC_{50} of Glyphosate SL AE is > 4.40 mg/L air/4 hours. Due to the physical properties (viscosity) of the test item an aerodynamic diameter of 1-4 µm could not be achieved. The substance is not considered acutely toxic via inhalation. Therefore, no classification is needed according to Dir. 67/548/EEC or Reg. 1272/2008.

Study Comments: MIIIA 7.1.3/01	Acceptable (no relevant deviations from above mentioned test guideline), used for evaluation, applicant's description slightly modified by the zRMS
Agreed endpoint: MIIIA 7.1.3/01	Acute LC_{50} > 4.4 mg/L air/4 hours

MIIIA 7.1.4 Skin irritation

Skin irritation studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, the relevant data are provided.

Report:	**KIIIA1 7.1.4, [redacted] (2009, including amendment 2010)**
Title:	Acute dermal irritation/corrosion test (patch test) of Glyphosate 450 SL AE in rabbits
Document No:	24312, ASB2011-9348
Guidelines:	EC method B.4. (2004/73/EC), OECD No. 404, OPPTS 870.2500
Deviations	None
GLP	Yes; laboratory certified by 'Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz (Freie und Hansestadt Hamburg)'

Material and Methods:

The test item Glyphosate 450 SL AE (batch no. 3342/R, 475 g/L glyphosate acid technical (95 %), analysed 461 g glyphosate/L) was applied dermally to rabbits onto shaved intact dorsal skin in order to examine the acute dermal irritation/corrosion properties (patch test). Glyphosate 450 SL AE is identical to HAG 500 02 H.

Approximately 24 hours prior to the test, the fur was removed by closely clipping the hair of the dorsal area of the trunk of the animals. Abrading or lesions of the skin were carefully avoided. Animals with healthy intact skin were used only. 0.5 mL of neat Glyphosate 450 SL AE were applied to the test site (area: approx. 6 cm²), covered with a gauze patch and held in contact with the skin with non-irritating tape for 4 hours. No residual test item had to be removed afterwards.

<u>Initial test:</u>

A single patch was applied to one animal for 4 hours.

<u>Confirmatory test:</u>

As no corrosive or irritant effects were observed in the initial test, 2 further animals were treated 24 hours after the start of the initial test.

The skin sites were evaluated after exposure. Scores were reported 60 min, 24, 48, and 72 hours after patch removal.

Findings:

Under the present test conditions, three rabbits exposed for 4 hours towards 0.5 mL/patch (semi-occlusive) did not reveal any skin reactions at the examination time points 60 min, 24, 48 and 72 hours after patch removal. There were no systemic intolerance reactions.

Conclusion:

According to the results obtained under the present test conditions, Glyphosate 450 SL AE is non-irritating to the skin. Therefore, no classification is needed according to Dir. 67/548/EEC or Reg. 1272/2008.

Study Comments: MIIIA 7.1.4/01	Acceptable (no deviations from above mentioned test guideline), used for evaluation, applicant's description slightly modified by the zRMS
Agreed endpoint: MIIIA 7.1.4/01	Not irritating to the skin

MIIIA 7.1.5 Eye irritation

Eye irritation studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, the relevant data are provided.

Report:	**KIIIA1 7.1.5, [redacted] (2009, including amendment 2010)**
Title:	Acute eye irritation/corrosion test of Glyphosate 450 SL AE in rabbits
Document No:	24313, ASB2011-9346
Guidelines:	EC method B.5. (2004/73/EC), OECD No. 405, OPPTS 870.2400
Deviations:	None
GLP	Yes; laboratory certified by 'Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz (Freie und Hansestadt Hamburg)'

Material and Methods:

The test item Glyphosate 450 SL AE (batch no. 3342/R, 475 g/L glyphosate acid technical (95 %), analysed 461 g glyphosate/L) was placed into the conjunctival sac of the right eye of rabbits in order to examine for eye irritation/corrosion properties. Glyphosate 450 SL AE is identical to HAG 500 02 H.

A single dose of 0.1 mL of Glyphosate 450 SL AE was administered into the conjunctival sac of the right eye of each animal after gently pulling the lower lid away from the eyeball. The lids were then gently held together for about one second in order to prevent loss of the material. The left eye, which remained untreated, served as a control.

The test was performed initially using one animal. As no corrosive or severe irritant effects were observed in this animal, 2 further animals were employed 24 hours after start of the initial test. 24 hours after instillation the eyes were rinsed with 20 mL aqueous NaCl solution.

The eyes were examined ophthalmoscopically with a slit lamp prior to administration of the test substance and 1, 24, 48 and 72 hours after administration. The eye reactions were observed and recorded. 24 hours after administration the eyes were treated with fluorescein additionally and subsequently examined.

Findings:

Under the present test conditions, a single instillation of 0.1 mL Glyphosate 450 SL AE per animal into the conjunctival sac of the right eye of three rabbits caused the following effects:

Table 7.1.5-1: Acute eye irritation of Glyphosate 450 SL AE in rabbits

Time after administration (h)	Effects on the treated eye			
	Corneal Opacity	Iris	Redness of Conjunctivae	Chemosis
1	0/0/0*	0/0/0*	1/1/1*	0/0/0*
24	1/0/0	0/0/0	1/1/1	0/0/0
48	0/0/0	0/0/0	1/1/1	0/0/0
72	0/0/0	0/0/0	0/0/0	0/0/0

* Animal no. 1/2/3

Corneal opacity (grade 1) was observed in animal no. 1 24 hours after instillation. The fluorescein test performed 24 hours after instillation revealed corneal staining in animal no. 1 (up to 1/4 of the surface). Conjunctival redness (grade 1) was observed in all animals 60 minutes to 48 hours after instillation. The irises were not affected by instillation of the test item. There were no systemic intolerance reactions.

Conclusion:

According to the results obtained under the present test conditions, Glyphosate 450 SL AE was not irritating to the eyes. Therefore, no classification is needed according to Dir. 67/548/EEC or Reg. 1272/2008.

Study Comments: MIIIA 7.1.5/01	Acceptable (no deviations from above mentioned test guideline), used for evaluation, applicant's description slightly modified by the zRMS
Agreed endpoint: MIIIA 7.1.5/01	Not irritating to the eyes

MIIIA 7.1.6 Skin sensitisation

Skin sensitisation studies for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, the relevant data are provided.

Report:	**KIIIA1 7.1.6, [redacted] (2009, including amendment 2010)**
Title:	Examination of Glyphosate 450 SL AE in the skin sensitisation test in guinea pigs according to Magnusson and Kligman (Maximisation test)
Document No:	24314, ASB2011-9347

Guidelines:	EC method B.6. (96/54/EC), OECD No. 406, OPPTS 870.2600
Deviations	None
GLP	Yes; laboratory certified by 'Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz (Freie und Hansestadt Hamburg)'

Material and Methods:

The purpose of this study was to determine the potential of Glyphosate 450 SL AE (batch no. 3342/R, 475 g/L glyphosate acid technical (95 %), analysed 461 g glyphosate/L) to produce skin sensitisation reactions in guinea pigs in the Magnusson and Kligman test. Glyphosate 450 SL AE is identical to HAG 500 02 H.

Possible sensitising properties of the test item were evaluated by administration of the test item to the shoulder region, first by intracutaneous application (stage 1) and 7 days later by topical administration (stage 2, exposure time: 48 hours). In the challenge test (stage 3) the test item was again topically applied but to the flank region (exposure time: 24 hours). This area was then examined for reactions which might indicate sensitising properties of the test item.

In the preliminary test and in the main study a test concentration of 10 % in *aqua ad iniectabilia* was the highest concentration tested. Higher concentrations could not be administered intracutaneously with a 22G cannula commonly used for intacutaneous administration to guinea pigs due to the relatively high viscosity of the test item. The viscosity of Glyphosate 450 SL AE is max. 73.2 mPas.

<u>Preliminary study:</u>

The aim was to determine the appropriate dose level of the test item following intracutaneous and topical administration. Six animals were used for the topical administration and two animals for the intracutaneous administration. The shoulder and the flank region of the animals were shaved or shaved and depilated (approx. 5 x 5 cm). Only animals with healthy intact skin were used.

Intracutaneous: 0.1 mL of the prepared test item was administered intracutaneously (shoulder region). Three concentrations of the test item were injected intradermally into one, 3 further concentrations into a second animal.

Topical: 2 mL of the test preparation was applied to the shaven test area of three animals at two concentrations each and held in contact by an occlusive dressing (6 concentrations in sum, 0.01, 0.1, 0.5, 1, 5 or 10 %). Two concentrations of the test item were applied to the depilated flanks of each of three further animals (6 concentrations in sum).

The test item was removed after 24 (depilated) or 48 hours (shaven) and the application sites were assessed immediately for erythema and oedema up to 72 hours.

<u>Main study:</u>

In the test item group of 10 animals, solutions of Glyphosate 450 SL AE in *aqua ad iniectabilia* were applied for the intracutaneous induction (stage 1) at a concentration of 10 %, topical induction (stage 2) at 25 % and topical challenge (stage 3) at 10 %, respectively. Five animals served as a vehicle control group and were treated with *aqua ad iniectabilia*.

Stage 1 (induction):

Day 0: Three pairs of intradermal injections of 0.1 mL were given in the shoulder region which was cleared of hair so that one of each pair lay on each side of the midline.

Freund's complete adjuvant (diluted 1:1 with 0.9 % NaCI)
Glyphosate 450 SL AE
Glyphosate 450 SL AE 1:1 mixture (v/v) FCA/physiological saline

In the case of injection 3, the final concentration of the test item was equal to that in injection 2. Injections 1 and 2 were given close to each other and nearest to the head, while 3 was given towards the caudal part of the test area.

Stage 2 (induction):

Day 7: 7 days after the intracutaneous injection, the shoulder region of the same animals was shaved again and treated topically using the patch-test technique (exposure time: 48 hours). No cleaning of the skin was necessary afterwards.

Stage 3 (challenge):

Day 21: Two weeks after the topical application the flanks of the same animals were shaved and depilated for a further topical application using the patch-test technique. The test item was applied to the left flank, the vehicle to the right flank of the animal (exposure time: 24 hours). 21 hours after the filter paper had been removed, no cleaning of the treated skin was necessary.

Vehicle control group: *Aqua ad iniectabilia*

The vehicle control animals were treated in the same way as the animals of the test group, but received *aqua ad iniectabilia* instead of the test item. However, in stage 3 the left flank was treated with the test item, the right flank with the vehicle i.e. in the same way as in the test group.

Positive control group: Benzocaine solution

The animals of the positive control group were treated with a 2 % (w/v) benzocaine solution intracutaneously in stage 1, a 5 % (w/v) benzocaine solution topically in stage 2 and 3.

Skin observations and scoring:

Induction: The skin reaction results after the first induction exposure were evaluated at 24 and 48 hours, after the second induction at 48 and 72 hours after beginning of exposure.

Challenge: Days 23 and 24: 21 hours after removing the filter paper the challenge area was cleaned and cleared of hair if necessary. Three hours later (at 48 hours from the start of challenge application) the skin was investigated for reactions which were recorded. 24 hours later (72 hours after start of challenge) the skin was checked again.

Other observations: Mortality and clinical signs of the animals were examined daily. Animals were observed daily for mortality and clinical signs. Body weight was recorded at study start and termination.

Findings:

Preliminary study:

Six concentrations of Glyphosate 450 SL AE, i.e. 0.01, 0.1, 0.5, 1, 5 or 10 % solutions, were tested by intracutaneous injection. No skin reactions were observed up to the top concentration.
Six concentrations of Glyphosate 450 SL AE, i.e. 1, 5, 10, 25, 50 % solutions and the undiluted test item, were tested by topical application. No skin reactions were observed up to the concentration of 10 %. A concentration of 25 % revealed discrete or patchy erythema 24 to 72 hours after start of exposure. Administration of a concentration of 50 % and the undiluted test item caused mortality in the respective animal.

Main study:

A 10 % solution of Glyphosate 450 SL AE was chosen for the intracutaneous induction. This did not reveal any skin reactions. 2 mL of a 25 % solution which was chosen for the topical induction stage revealed discrete or patchy erythema (grade 1) 48 and 72 hours after start of exposure in all ten animals employed. Challenge with 2 mL of a 10 % solution revealed no skin irritation in any animal and, thus, the test item is considered non-sensitising.

The vehicle control caused no skin reactions. The positive control induced a sensitising reaction in all animals in the form of discrete or patchy erythema (grade 1). Body weight development and behaviour of the animals remained unchanged.

Conclusion:

Under the present test conditions Glyphosate 450 SL AE revealed no sensitising properties in guinea pigs using the Magnusson and Kligman test. Therefore, no classification is needed according to Dir. 67/548/EEC or Reg. 1272/2008.

Study Comments: MIIIA 7.1.6/01	Acceptable (no deviations from above mentioned test guideline), used for evaluation, applicant’s description slightly modified by the zRMS Since all scores of the 10 treated animals were 0 after challenge, no further animals have to be tested.
Agreed endpoint: MIIIA 7.1.6/01	Not sensitising to the skin

MIIIA 7.1.7 Supplementary studies for combinations of plant protection products

As the product is not recommended to be used together with other plant protection products or adjuvants in the tank mixture this point is not relevant.

MIIIA 7.2 Short-Term Toxicity Studies

No short-term studies using this formulation are available or necessary for EC registrations.

MIIIA 7.3 Safety Assessment of Pesticide Application

Table 7.3-1 Product information and toxicological reference values used for safety assessment of pesticide application

Product name and code	HAG 500 02 H
Formulation type	SL
Active substance(s) (incl. content)	Glyphosate, 450 g/L
Category	Herbicide
Container size(s), short description	1 L plastic bottle, 5 – 20 L can, 120 – 1250 L drum; Diameter of opening (up to 20 L cans): 40 – 56 mm
Statement as to whether the product was already evaluated as the 'representative formulation' during the Annex I inclusion	The safety of the application of HAG 500 02 H was not evaluated as part of the EU review of glyphosate.
AOEL systemic	0.2 mg/kg bw/d
Oral absorption	30 % (based on EU review report in the context of Annex I inclusion)
Inhalative absorption	100 %
Dermal absorption	Concentrate: 3 %, Dilution: 3 % (based on EU review report in the context of Annex I inclusion)

MIIIA 7.3.1 Selection of critical use(s) and justification

The critical GAPs used for the safety assessment of pesticide application are presented in Table 7.3.1-1.

Table 7.3.1-1 Critical uses (worst case) for safety assessment of pesticide application

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop) (a)**	**F G or I (b)**	**Pests or Group of pests controlled (c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (j)**
					Method / Kind (d-f)	**Timing / Growth stage of crop & season (g)**	**Max. number of applications (h)**	**L product / ha**	**kg as/ha**	**Water L/ha min / max**		
1 *	**Central Zone**	**Grape vine**	**F**	**Cornbine**	Spraying, Tractor mounted sprayer, broadcast, ground directed spraying as well as hand-held sprayer	**Spring to summer, from 4th year plant stand onwards**	**1**	**8**	**3.6**	**100 - 400**		
2 *	**Central Zone**	**Pome**	**F**	**Cornbine**	Spraying, Tractor mounted sprayer, broadcast, ground directed spraying as well as hand-held sprayer	**Spring to summer**	**1**	**8**	**3.6**	**100 - 400**		
3 **	**Central Zone**	**Pasture, meadows**	**F**	**Monocotyledonous weeds, Dicotyledonous weeds**	Spraying, Tractor mounted sprayer, broadcast, ground directed spraying	**5-7 days before sowing, during vegetative period**	**1**	**4**	**1.8**	**100 - 400**		

* Critical GAP for Operator Exposure (German Model as well as UK POEM), Worker Exposure and Bystander Exposure
** Critical GAP for Resident Exposure

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) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) 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
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

MIIIA 7.3.2 Evaluation of the Active Substance Glyphosate

MIIIA 7.3.2.1 Operator Exposure and Risk Assessment

MIIIA 7.3.2.1.1 Estimation of Operator Exposure and Risk Assessment

Table 7.3.2.1.1-1 Exposure models for intended uses

Critical use(s)	Grape vine, pome (max. 1 x 8 L HAG500 02 H/ha)
Model(s)	German model (available on http://www.bfr.bund.de/cm/343/anwendersicherheit_deutsches_modell_v1.xls) [Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992]
Critical use(s)	Grape vine, pome (max. 1 x 8 L HAG 500 02 H/ha)
Model(s)	Revised UK-POEM, (available on http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/UK_POEM1.xls) [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical Association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992]

Comments by the zRMS: MIIIA 7.3.2.1.1	The notifier provided additional exposure estimations considering special requirements of particular Member States of the Central Zone, e.g. The Netherlands, Hungary, Poland. These data were not included into this report, since overall the allocation of PPE is not more extensive according to the models of NL, Hungary and Poland as documented here for both prediction models, i.e. the German model and the UK POEM. Furthermore, no harmonised predictive operator exposure model has been available yet, so that calculations using the two models normally accepted for Annex I inclusion are provided.

Table 7.3.2.1.1-2 Estimated operator exposure towards glyphosate

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors under pome or grape vine (FCTM) Application rate: 3.6 kg a.s./ha 1)			
German Model • Body weight: 70 kg	no PPE	0.1386	69.3
	with PPE 3)	0.0653	32.7
UK POEM • 100 L water/ha • Body weight: 60 kg • 10 L can	no PPE 2)	1.6839	842
	with PPE 4)	0.1971	98.6

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand-held sprayer application outdoors under pome or grape vine (downwards, UK POEM); hand-held sprayer application outdoors in high crops (HCHH, German model, worst case) Application rate: 3.6 kg a.s./ha			
German Model • Body weight: 70 kg	no PPE	0.3966	198
	with PPE [3]	0.0085	41.8
UK POEM • 100 L water/ha • Body weight: 60 kg • 10 L can	no PPE [2]	2.0655	1033
	with PPE [4]	0.4174	209
Hand-held sprayer application outdoors under pome or grape vine Application rate: 1.8 kg a.s./ha			
UK POEM • 100 L water/ha • Body weight: 60 kg • 10 L can	no PPE [2]	1.1115	556
	with PPE [4]	0.2126	106

1) For the national authorisation procedure in Germany exposure would be estimated using generic data for high crops with tractor mounted spray equipment since no data are available for application of herbicides under these crops

2) no PPE: Operator wearing long sleeved shirt, long trousers (“permeable”) but no gloves

3) with PPE: gloves during mixing/loading (PPE acc. to the Federal Office of Consumer Protection and Food Safety (BVL); 2006; Personal protective equipment for handling plant protection products - Guidelines for requirements concerning personal protective equipment in plant protection

4) with PPE: gloves during mxing/loading and during application as well as impermeable coverall during application

For the detailed calculations it is referred to Appendix 2.

MIIIA 7.3.2.1.2 Measurement of Operator Exposure and Risk Assessment

Since safe use could be demonstrated under particular conditions, no operator exposure studies are necessary and were therefore not performed.

MIIIA 7.3.2.2 Worker Exposure and Risk Assessment

MIIIA 7.3.2.2.1 Estimation of Worker Exposure and Risk Assessment

Table 7.3.2.2.1-1 Exposure models for intended uses

Critical use(s)	Grape vine (max. 1 x 8 L HAG 500 02 H/ha)
Model	e.g. German re-entry model, Krebs et al. (2000) (available on http://www.bfr.bund.de/cm/343/schutz_von_personen_bei_nachfolgearbeiten_v1.xls) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienstes, 52(1), p. 5-9]

Comments by the zRMS: MIIIA 7.3.2.2.1	The notifier provided additional exposure estimations using EUROPOEM II as well as particular Dutch modifications thereof. These data were not included into this report, since under no conditions PPE had to be allocated for re-entry tasks, so that the outcome is the same as described for the German re-entry model: No undue health risk has to be anticipated for workers re-entering treated crops in the case of intended uses.

Table 7.3.2.2.1-2 Estimated worker exposure towards glyphosate

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Number of applications and application rate: 1 x 3.6 kg a.s./ha			
• 2 hours/day [1], • TC: 4500 cm^2/person/h [2] • Body weight: 60 kg	no PPE [3]	0.0162	8.1
	with PPE [4]	0.0008	0.4

1) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
2) TC for fruits from trees, worst case: EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture
3) no PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves
4) with PPE: PPE / see 'Instructions for use'

For the detailed calculations it is referred to Appendix 2.

MIIIA 7.3.2.2.2 Measurement of Worker Exposure and Risk Assessment

Since safe use could be demonstrated, no worker exposure studies are necessary and were therefore not performed.

MIIIA 7.3.2.3 Bystander and Resident Exposure and Risk Assessment

MIIIA 7.3.2.3.1 Estimation of Bystander and Resident Exposure and Risk Assessment

Table 7.3.2.3.1-1 Exposure models for intended uses

Critical use for bystander	Grape vine, pome (max. 1 x 8 L HAG500 02 H/ha)
Model	e.g. Martin S. et al. (2008) (available on http://www.bfr.bund.de/cm/343/schutz_von_nebenstehenden_und_anwohnern_v1.xls) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel]
Critical use for residents	Pasture and meadows (max. 1 x 4 L HAG 500 02 H/ha)
Model	e.g. Martin S. et al. (2008) (available on http://www.bfr.bund.de/cm/343/schutz_von_nebenstehenden_und_anwohnern_v1.xls) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel]

Comments by the zRMS: MIIIA 7.3.2.3.1	The notifier provided additional exposure estimations using different preditive models, e.g. UK Bystander Exposure Model or EUROPOEM II bystander exposure model. These data were not included into this report, since the outcome was the same in all cases: No undue health risk has to be anticipated for bystanders and residents for intended uses.

Table 7.3.2.3.1-2 Estimated bystander and resident exposure towards glyphosate

Model data	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors under pome or grape vine Application rate: 3.6 kg a.s./ha		
Bystanders (adult) • Drift rate: 8.02 % (3 m) [1)] • Body weight: 60 kg	0.0147	7.3
Bystanders (children) • Drift rate: 8.02 % (3 m) [1)] • Body weight: 16.15 kg	0.0118	5.9
Tractor mounted boom spray application outdoors on pasture and meadows (‘worst case’) Application rate: 1.8 kg a.s./ha		
Residents (adult) • Deposit: 100 % • Body weight: 60 kg	0.0068	3.4
Residents (children) • Deposit: 100 % • Body weight:16.15 kg	0.0176	8.8

[1)] drift corresponding to ornamentals > 50 cm at a distance of 3 m, used as a default value for applications of herbicides under high crops

For the detailed calculations it is referred to Appendix 2.

MIIIA 7.3.2.3.2 Measurement of Bystander and Resident Exposure and Risk Assessment

Since safe use could be demonstrated, no bystander or resident exposure studies are necessary and were therefore not performed.

MIIIA 7.3.3 Conclusion of Exposure Estimation and Risk Assessment

The risk assessment has shown that according to the German model the estimated exposure towards glyphosate in HAG 500 02 H will not exceed the systemic AOEL for operators, workers, bystanders and residents if prescribed PPE is worn by operators.
If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

However, according to the UK POEM estimated operator exposure will exceed the AOEL-S in the case hand-held equipment is assumed for application under grape vine or pome, even if gloves are used during mixing/loading and application. If HAG 500 02 H is applied by tractor mounted equipment under these plants safe use can be demonstrated in the case gloves are considered during mixing/loading and application.

MIIIA 7.4 Justified Proposals for Classification and Labelling and Safety Instructions

Justified Proposals for Classification and Labelling

In accordance with Directives 67/548/EEC and 1999/45/EC the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 7.4-1 Classification and labelling according to Directives 67/548/EEC and 1999/45/EC

Hazard symbol(s):	None
Indication(s) of danger:	None
Risk phrases:	None
Safety phrases:	None
Labelling texts and restrictions:	To avoid risks to man and the environment, comply with the instructions for use.

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification for toxicological hazards of the preparation according to GHS would be proposed:

Table 7.4-2 Classification and labelling according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	None
Signal word:	None
Hazard statement(s):	None
Labelling texts and restrictions:	To avoid risks to man and the environment, comply with the instructions for use.

Safety Instructions

Table 7.4-3 Safety phrases for use instructions

Safety instructions (codes according to BVL *))		Justification **)
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage	1
SB010	Keep out of the reach of children.	2
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be ob served.	1
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.	2
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.	3

*) http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/eAntrag-Codelisten-EN.pdf?__blob=publicationFile&v=6
**) Justification:
1 Mandatory for plant protection products
2 With regard to preventive health protection and good agricultural practice
3 Based on the exposure estimation according to the German model for the operator and the uniform principles for the protection of workers
With regard to the dangerous substance directive: None

MIIIA 7.5 Dermal Absorption

MIIIA 7.5.1 Dermal absorption, in vivo in the rat

The dermal absorption value of 3 % as contained in the list of end points of the Review Report on the active substance glyphosate (Review report for the active substance glyphosate, finalised on 29 June 2001 in view of the inclusion of glyphosate in Annex I of Directive 91/414/EEC) was used for estimation of operator, worker and bystander/resident exposure.

MIIIA 7.5.2 Comparative dermal absorption, in vitro using rat and human skin

The dermal absorption value of 3 % as contained in the list of end points of the Review Report on the active substance glyphosate (Review report for the active substance glyphosate, finalised on 29 June 2001 in view of the inclusion of glyphosate in Annex I of Directive 91/414/EEC) was used for estimation of operator, worker and bystander/resident exposure.

MIIIA 7.6 Dislodgeable Residues

MIIIA 7.6.1 Dislodgeable Residues - foliar

Assessment of worker exposure showed that potential worker exposure to glyphosate from the use of HAG 500 02 H is acceptable (see IIIA 7.5.1). Thus, there is no need to conduct any studies on dislodgeable foliar residues.

MIIIA 7.6.2 Dislodgeable Residues - soil

This is not an EC data requirement and is not required by Directive 91/414/EEC.

MIIIA 7.6.3 Dislodgeable Residues - indoor surface re-volatilization

This is not an EC data requirement and is not required by Directive 91/414/EEC.

MIIIA 7.7 Epidemiology

This is not an EC data requirement and is not required by Directive 91/414/EEC.

MIIIA 7.8 Data on Formulants

CONFIDENTIAL information - data provided separately (Part C).

MIIIA 7.8.1 Material safety data sheets for each formulant

CONFIDENTIAL information - data provided separately (Part C).

MIIIA 7.8.2 Available toxicological data for each formulant

CONFIDENTIAL information - data provided separately (Part C).

MIIIA 7.9 Domestic Animal/Livestock Safety

This is not an EC data requirement and is not required by Directive 91/414/EEC.

MIIIA 7.10 Other/Special Studies

There are no additional European requirements for formulated products.

Appendix 1: List of data submitted in support of the evaluation

References cited and not submitted

German BBA model (Lundehn J.R. et al.; Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products; Mitteilungen aus der Biologischen Bundesanstalt, Heft 277, Berlin 1992, Microsoft Excel workbook, 2003).

Revised UK-POEM (Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF 1986), and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF 1992)), available on http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/UK_POEM1.xls

Bystander Exposure Guidance, PSD 2008, available on:
http://www.pesticides.gov.uk/applicant_guide.asp?id=1246&link=%2Fuploadedfiles%2FWeb_Assets%2FPSD%2FBystander%2520exposure%2520guidance_final%2520version.pdf

Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992.

EUROPOEM II (Post-application exposure of workers to pesticides in agriculture, Report of the re-entry working group; EUROPOEM II Project FAIR3-CT96-1406, 2002).

Evaluation Manual for the Authorisation of Plant protection products and Biocides NL part Plant protection products, Chapter 4 Human toxicology; risk operator, worker and bystander version 1.0; January 2010

Martin S. et al. (2008), Guidance for Exposure and Risk evaluation for bystanders and residents exposed to plant protection products during and after application.

Lloyd G. A. and Bell G. J. (1983), Hydraulic Nozzles: comparative spray drift study.

Whitford, F., Kronenberg, J., Lunchick, C., Driver, J., Tomerlin, R., Wolt, J., Spencer, H., Winter, C., Whitmyre, G., 1999. Pesticides and human health risk assessment: policies, processes, and procedures. Purdue University West Lafayette, IN.

Table A 1: List of data submitted in support of the evaluation

Annex point	Author	Year	Title Report No. Authority registration No	Data protection claimed Y/N	Owner	How considered in dRR *
KIIIA1 7.1.1	[redacted]	2009/ 2010	Acute oral toxicity of Glyphosate 450 SL AE in rats [redacted] Report No: 24309 BfR Doc. No: ASB2011-9343			Y
KIIIA1 7.1.2	[redacted]	2009/ 2010	Acute dermal toxicity study of Glyphosate 450 SL AE in CD rats [redacted] Report No: 24311 BfR Doc. No: ASB2011-9344			Y
KIIIA1 7.1.3	[redacted]	2009/ 2010	Acute inhalation toxicity study of Glyphosate 450 SL AE in CD rats [redacted] Report No: 24310 BfR Doc. No: ASB2011-9345			Y
KIIIA1 7.1.4	[redacted]	2009/ 2010	Acute dermal irritation/corrosion test (patch test) of Glyphosate 450 SL AE in rabbits [redacted] Report No: 24312 BfR Doc. No: ASB2011-9348			Y
KIIIA1 7.1.5	[redacted]	2009/ 2010	Acute eye irritation/corrosion test of Glyphosate 450 SL AE in rabbits [redacted] Report No: 24313 BfR Doc. No: ASB2011-9346			Y
KIIIA1 7.1.6	[redacted]	2009/ 2010	Examination of Glyphosate 450 SL AE in the skin sensitisation test in guinea pigs according to Magnusson and Kligman (Maximisation test) [redacted] Report No: 24314 BfR Doc. No: ASB2011-9347			Y

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2: Exposure calculations

A 2.1 Operator Exposure Calculations

A 2.1.1 Operator Exposure German Model, Tractor-Mounted: Application rate 3.6 kg a.s./ha

Without and with PPE

Estimation of operator exposure towards Glyphosate: German model

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid		**Application technique:**	Field Crops, Tractor Mounted (FCTM)	
Application rate (AR):	3.6	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	3	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	3	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.2	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Operator exposure towards Glyphosate					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in grape vine, pome					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)}$ = ($D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)}$ = ($D_{M(H)}$ x AR x A x PPE [1)] x DA) / BW		
(2.4 x 3.6 x 20 x 3%) / 70			(2.4 x 3.6 x 20 x 0.01 x 3%) / 70		
External dermal exposure	172.8	mg/person	External dermal exposure	1.728	mg/person
External dermal exposure	2.469	mg/kg bw/d	External dermal exposure	0.025	mg/kg bw/d
Systemic dermal exposure	**0.074**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001**	**mg/kg bw/d**
Dermal exposure during application			-		
Hands			Hands		
$SDE_{OA(H)}$ = ($D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)}$ = ($D_{A(H)}$ x AR x A x PPE x DA) / BW		
(0.38 x 3.6 x 20 x 3%) / 70			(0.38 x 3.6 x 20 x 1 x 3%) / 70		
External dermal exposure	27.36	mg/person	External dermal exposure	27.36	mg/person
External dermal exposure	0.391	mg/kg bw/d	External dermal exposure	0.391	mg/kg bw/d
Systemic dermal exposure	**0.012**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.012**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)}$ = ($D_{A(B)}$ x AR x A x DA) / BW			SDEOA(B) = ($D_{A(B)}$ x AR x A x PPE x DA) / BW		
(1.6 x 3.6 x 20 x 3%) / 70			(1.6 x 3.6 x 20 x 1 x 3%) / 70		

External dermal exposure	115.2	mg/person	External dermal exposure	115.2	mg/person
External dermal exposure	1.646	mg/kg bw/d	External dermal exposure	1.646	mg/kg bw/d
Systemic dermal exposure	**0.049**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.049**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 3.6 x 20 x 3%) / 70			(0.06 x 3.6 x 20 x 1 x 3%) / 70		
External dermal exposure	4.32	mg/person	External dermal exposure	4.32	mg/person
External dermal exposure	0.062	mg/kg bw/d	External dermal exposure	0.062	mg/kg bw/d
Systemic dermal exposure	**0.002**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	319.68	mg/person	Total external dermal exposure	148.608	mg/person
Total external dermal exposure	4.567	mg/kg bw/d	Total external dermal exposure	2.123	mg/kg bw/d
Total systemic dermal exposure	**0.137**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.064**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in grape vine, pome					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 3.6 x 20 x 100%) / 70			(0.0006 x 3.6 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.043	mg/person	External inhalation exposure	0.043	mg/person
External inhalation exposure	0.001	mg/kg bw/d	External inhalation exposure	0.001	mg/kg bw/d
Systemic inhalation exposure	**0.001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.001**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 3.6 x 20 x 100%) / 70			(0.001 x 3.6 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.072	mg/person	External inhalation exposure	0.072	mg/person
External inhalation exposure	0.001	mg/kg bw/d	External inhalation exposure	0.001	mg/kg bw/d
Systemic inhalation exposure	**0.001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.001**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.115	mg/person	Total external inhalation exposure	0.115	mg/person
Total external inhalation exposure	0.002	mg/kg bw/d	Total external inhalation exposure	0.002	mg/kg bw/d
Total systemic inhalation exposure	**0.002**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.002**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	9.706	mg/person	Total systemic exposure	4.573	mg/person

Total systemic exposure	0.139	**mg/kg bw/d**	**Total systemic exposure**	0.065	**mg/kg bw/d**
% of AOEL	**69.3**	**%**	**% of AOEL**	**32.7**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

A 2.1.2 Operator Exposure German Model, High Crop Hand-Held: Application rate 3.6 kg a.s./ha

Without and with PPE

Estimation of operator exposure towards Glyphosate: German model

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid		**Application technique:**	High Crops, Hand Held (HCHH)	
Application rate (AR):	3.6	kg a.s./ha			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	3	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	10.6	mg/person/kg a.s.
	3	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	25	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	4.8	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	0.2	mg/kg bw/d	**Inhalation appl. (I_A):**	0.3	mg/person/kg a.s.

Operator exposure towards Glyphosate					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in grape vine, pome					
Dermal exposure during mixing/loading			-		
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x PPE [1)] x DA) / BW		
(205 x 3.6 x 1 x 3%) / 70			(205 x 3.6 x 1 x 0.01 x 3%) / 70		
External dermal exposure	738	mg/person	External dermal exposure	7.38	mg/person
External dermal exposure	10.543	mg/kg bw/d	External dermal exposure	0.105	mg/kg bw/d
Systemic dermal exposure	**0.316**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003**	**mg/kg bw/d**
Dermal exposure during application			-		
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE x DA) / BW		
(10.6 x 3.6 x 1 x 3%) / 70			(10.6 x 3.6 x 1 x 1 x 3%) / 70		
External dermal exposure	38.16	mg/person	External dermal exposure	38.16	mg/person
External dermal exposure	0.545	mg/kg bw/d	External dermal exposure	0.545	mg/kg bw/d
Systemic dermal exposure	**0.016**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.016**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE x DA) / BW		
(25 x 3.6 x 1 x 3%) / 70			(25 x 3.6 x 1 x 1 x 3%) / 70		

External dermal exposure	90	mg/person	External dermal exposure	90	mg/person
External dermal exposure	1.286	mg/kg bw/d	External dermal exposure	1.286	mg/kg bw/d
Systemic dermal exposure	**0.039**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.039**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \text{ x AR x A x DA}) / BW$			$SDE_{OA(C)} = (D_{A(C)} \text{ x AR x A x PPE x DA}) / BW$		
(4.8 x 3.6 x 1 x 3%) / 70			(4.8 x 3.6 x 1 x 1 x 3%) / 70		
External dermal exposure	17.28	mg/person	External dermal exposure	17.28	mg/person
External dermal exposure	0.247	mg/kg bw/d	External dermal exposure	0.247	mg/kg bw/d
Systemic dermal exposure	**0.007**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.007**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	883.44	mg/person	Total external dermal exposure	152.82	mg/person
Total external dermal exposure	12.621	mg/kg bw/d	Total external dermal exposure	2.183	mg/kg bw/d
Total systemic dermal exposure	**0.379**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.065**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in grape vine, pome					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \text{ x AR x A x IA}) / BW$			$SIE_{OM} = (I_M \text{ x AR x A x PPE x IA}) / BW$		
(0.05 x 3.6 x 1 x 100%) / 70			(0.05 x 3.6 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.18	mg/person	External inhalation exposure	0.18	mg/person
External inhalation exposure	0.003	mg/kg bw/d	External inhalation exposure	0.003	mg/kg bw/d
Systemic inhalation exposure	**0.003**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.003**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \text{ x AR x A x IA}) / BW$			$SIE_{OA} = (I_A \text{ x AR x A x PPE x IA}) / BW$		
(0.3 x 3.6 x 1 x 100%) / 70			(0.3 x 3.6 x 1 x 1 x 100%) / 70		
External inhalation exposure	1.08	mg/person	External inhalation exposure	1.08	mg/person
External inhalation exposure	0.015	mg/kg bw/d	External inhalation exposure	0.015	mg/kg bw/d
Systemic inhalation exposure	**0.015**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.015**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	1.26	mg/person	Total external inhalation exposure	1.26	mg/person
Total external inhalation exposure	0.018	mg/kg bw/d	Total external inhalation exposure	0.018	mg/kg bw/d
Total systemic inhalation exposure	**0.018**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.018**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	27.763	mg/person	Total systemic exposure	5.845	mg/person

Total systemic exposure	0.397	**mg/kg bw/d**	**Total systemic exposure**	0.083	**mg/kg bw/d**
% of AOEL	**198.3**	**%**	**% of AOEL**	**41.7**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

A 2.1.3 Operator Exposure UK POEM, Tractor-mounted: Application rate 3.6 kg a.s./ha

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)						
Active substance	**Glyphosat**					
Product	HAG 500 02 H					
Formulation type	water-based					
Concentration of a.s.	450	mg/mL				
Dose	8	L preparation/ha	(3.6 kg a.s./ha)			
Application volume	100	L/ha				
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Container	10 litres 45 mm closure					
Work rate/day	50	ha				
Duration of spraying	6	h				
PPE during mix./loading	None					
PPE during application	None					
Dermal absorption from product	3	%				
Dermal absorption from spray	3	%				
EXPOSURE DURING MIXING AND LOADING						
Container size	10	Litres				
Hand contamination/operation	0.1	mL				
Application dose	8	Litres product/ha				
Work rate	50	ha/day				
Number of operations	40	/day				
Hand contamination	4.00	mL/day				
Protective clothing	None					
Transmission to skin	100	%				
Dermal exposure to formulation	4.00	mL/day				
DERMAL EXPOSURE DURING SPRAY APPLICATION						
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Application volume	100	spray/ha				
Volume of surface contamination	10	mL/h				
Distribution	Hands		Trunk	Legs		
	65%		10%	25%		
Clothing	None		Permeable	Permeable		
Penetration	100%		5%	15%		
Dermal exposure	6.5		0.05	0.375	mL/h	
Duration of exposure	6	h				
Total dermal exposure to spray	41.55	mL/day				
ABSORBED DERMAL DOSE						
	Mix/load			Application		
Dermal exposure	4.00	mL/day		41.55	mL/day	
Concen. of a.s. product or spray	450.00	mg/mL		36.00	mg/mL	
Dermal exposure to a.s.	1800.00	mg/day		1495.80	mg/day	
Percent absorbed	3	%		3	%	
Absorbed dose	54.00	mg/day		44.8740	mg/day	
INHALATION EXPOSURE DURING SPRAYING						
Inhalation exposure	0.01	mL/h				
Duration of exposure	6	h				
Concentration of a.s. in spray	36.00	mg/mL				
Inhalation exposure to a.s.	2.16	mg/day				

Percent absorbed	100	%		
Absorbed dose	2.16	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	101.034	mg/day		
Operator body weight	60	kg		
Operator exposure	1.6839	mg/kg bw/day		
Amount of AOEL	842.0	%		

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)				
Active substance	**Glyphosat**			
Product	HAG 500 02 H			
Formulation type	water-based			
Concentration of a.s.	450	mg/mL		
Dose	8	L preparation/ha	(3.6 kg a.s./ha)	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 45 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	Gloves			
PPE during application	Gloves			
Dermal absorption from product	3	%		
Dermal absorption from spray	3	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0.1	mL		
Application dose	8	Litres product/ha		
Work rate	50	ha/day		
Number of operations	40	/day		
Hand contamination	4.00	mL/day		
Protective clothing	Gloves			
Transmission to skin	5	%		
Dermal exposure to formulation	0.20	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.20	mL/day	6.45	mL/day
Concen. of a.s. product or spray	450.00	mg/mL	36.00	mg/mL
Dermal exposure to a.s.	90.00	mg/day	232.20	mg/day
Percent absorbed	3	%	3	%
Absorbed dose	2.70	mg/day	6.966	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	36.00	mg/mL		

Inhalation exposure to a.s.	2.16	mg/day
Percent absorbed	100	%
Absorbed dose	2.16	mg/day
PREDICTED EXPOSURE		
Total absorbed dose	11.826	mg/day
Operator body weight	60	kg
Operator exposure	0.1971	mg/kg bw/day
Amount of AOEL	98.6	%

A 2.1.4 Operator Exposure UK POEM, Hand-Held Sprayer (15 L), Low Level Target: Application rate 3.6 kg a.s./ha

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)						
Active substance	**Glyphosat**					
Product	HAG 500 02 H					
Formulation type	water-based					
Concentration of a.s.	450	mg/mL				
Dose	8	L preparation/ha	(3.6 kg a.s./ha)			
Application volume	100	L/ha				
Application method	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target					
Container	10 litres 45 mm closure					
Work rate/day	1	ha				
Duration of spraying	6	h				
PPE during mix./loading	None					
PPE during application	None					
Dermal absorption from product	3	%				
Dermal absorption from spray	3	%				
EXPOSURE DURING MIXING AND LOADING						
Container size	10	Litres				
Hand contamination/operation	0.1	mL				
Application dose	8	Litres product/ha				
Work rate	1	ha/day				
Number of operations	7	/day				
Hand contamination	0.70	mL/day				
Protective clothing	None					
Transmission to skin	100	%				
Dermal exposure to formulation	0.70	mL/day				
DERMAL EXPOSURE DURING SPRAY APPLICATION						
Application technique	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target					
Application volume	100	spray/ha				
Volume of surface contamination	50	mL/h				
Distribution	Hands		Trunk		Legs	
	25%		25%		50%	
Clothing	None		Permeable		Permeable	
Penetration	100%		20%		18%	
Dermal exposure	10		2.5		4.5	mL/h
Duration of exposure	6	h				
Total dermal exposure to spray	102.00	mL/day				
ABSORBED DERMAL DOSE						
	Mix/load				Application	
Dermal exposure	0.70	mL/day			102.00	mL/day
Concen. of a.s. product or spray	450.00	mg/mL			36.00	mg/mL
Dermal exposure to a.s.	315.00	mg/day			3672.00	mg/day

Percent absorbed	3	%	3	%
Absorbed dose	9.45	mg/day	110.16	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.02	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	36.00	mg/mL		
Inhalation exposure to a.s.	4.32	mg/day		
Percent absorbed	100	%		
Absorbed dose	4.32	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	123.93	mg/day		
Operator body weight	60	kg		
Operator exposure	2.0655	mg/kg bw/day		
Amount of AOEL	1032.8	%		

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Glyphosat**				
Product	HAG 500 02 H				
Formulation type	water-based				
Concentration of a.s.	450	mg/mL			
Dose	8	L preparation/ha	(3.6 kg a.s./ha)		
Application volume	100	L/ha			
Application method	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target				
Container	10 litres 45 mm closure				
Work rate/day	1	ha			
Duration of spraying	6	h			
PPE during mix./loading	Gloves				
PPE during application	Gloves and impermeable coveralls				
Dermal absorption from product	3	%			
Dermal absorption from spray	3	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0.1	mL			
Application dose	8	Litres product/ha			
Work rate	1	ha/day			
Number of operations	7	/day			
Hand contamination	0.70	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.035	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target				
Application volume	100	spray/ha			
Volume of surface contamination	50	mL/h			
Distribution	Hands		Trunk	Legs	
	25%		25%	50%	
Clothing	Gloves		Impermeable	Impermeable	
Penetration	10%		5%	5%	
Dermal exposure	1.25		0.625	1.25	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	18.75	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	

Dermal exposure	0.0350	mL/day	18.75	mL/day
Concen. of a.s. product or spray	450.00	mg/mL	36.00	mg/mL
Dermal exposure to a.s.	15.75	mg/day	675.00	mg/day
Percent absorbed	3	%	3	%
Absorbed dose	0.4725	mg/day	20.25	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.02	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	36.00	mg/mL		
Inhalation exposure to a.s.	4.32	mg/day		
Percent absorbed	100	%		
Absorbed dose	4.32	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	25.0425	mg/day		
Operator body weight	60	kg		
Operator exposure	0.4174	mg/kg bw/day		
Amount of AOEL	208.7	%		

A 2.1.5 Operator Exposure UK POEM, Hand-Held Sprayer (15 L), Low Level Target: Application rate 1.8 kg a.s./ha

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)				
Active substance	**Glyphosat**			
Product	HAG 500 02 H			
Formulation type	water-based			
Concentration of a.s.	450	mg/mL		
Dose	4	L preparation/ha	(1.8 kg a.s./ha)	
Application volume	100	L/ha		
Application method	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target			
Container	10 litres 45 mm closure			
Work rate/day	1	ha		
Duration of spraying	6	h		
PPE during mix./loading	None			
PPE during application	None			
Dermal absorption from product	3	%		
Dermal absorption from spray	3	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0.1	mL		
Application dose	4	Litres product/ha		
Work rate	1	ha/day		
Number of operations	7	/day		
Hand contamination	0.70	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0.70	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target			
Application volume	100	spray/ha		
Volume of surface contamination	50	mL/h		
Distribution	Hands		Trunk	Legs
	25%		25%	50%
Clothing	None		Permeable	Permeable

Penetration	100%		20%	18%	
Dermal exposure	10		2.5	4.5	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	102.00	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.70	mL/day		102.00	mL/day
Concen. of a.s. product or spray	450.00	mg/mL		18.00	mg/mL
Dermal exposure to a.s.	315.00	mg/day		1836.00	mg/day
Percent absorbed	3	%		3	%
Absorbed dose	9.45	mg/day		55.08	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.02	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	18.00	mg/mL			
Inhalation exposure to a.s.	2.16	mg/day			
Percent absorbed	100	%			
Absorbed dose	2.16	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	66.69	mg/day			
Operator body weight	60	kg			
Operator exposure	1.1115	mg/kg bw/day			
Amount of AOEL	555.8	%			

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Glyphosat**		
Product	HAG 500 02 H		
Formulation type	water-based		
Concentration of a.s.	450	mg/mL	
Dose	4	L preparation/ha	(1.8 kg a.s./ha)
Application volume	100	L/ha	
Application method	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target		
Container	10 litres 45 mm closure		
Work rate/day	1	ha	
Duration of spraying	6	h	
PPE during mix./loading	Gloves		
PPE during application	Gloves and impermeable coveralls		
Dermal absorption from product	3	%	
Dermal absorption from spray	3	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	10	Litres	
Hand contamination/operation	0.1	mL	
Application dose	4	Litres product/ha	
Work rate	1	ha/day	
Number of operations	7	/day	
Hand contamination	0.70	mL/day	
Protective clothing	Gloves		
Transmission to skin	5	%	
Dermal exposure to formulation	0.035	mL/day	
DERMAL EXPOSURE DURING SPRAY APPLICATION			
Application technique	Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target		
Application volume	100	spray/ha	
Volume of surface contamination	50	mL/h	

Distribution	Hands 25%	Trunk 25%	Legs 50%	
Clothing	Gloves	Impermeable	Impermeable	
Penetration	10%	5%	5%	
Dermal exposure	1.25	0.625	1.25	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	18.75	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.035	mL/day	18.75	mL/day
Concen. of a.s. product or spray	450.00	mg/mL	18.00	mg/mL
Dermal exposure to a.s.	15.75	mg/day	337.50	mg/day
Percent absorbed	3	%	3	%
Absorbed dose	0.4725	mg/day	10.125	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.02	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	18.00	mg/mL		
Inhalation exposure to a.s.	2.16	mg/day		
Percent absorbed	100	%		
Absorbed dose	2.16	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	12.7575	mg/day		
Operator body weight	60	kg		
Operator exposure	0.2126	mg/kg bw/day		
Amount of AOEL	106.3	%		

A 2.2 Worker exposure calculations

A 2.2.1 Worker Exposure: Application rate 3.6 kg a.s./ha under grape vine

Without and with PPE

Estimation of worker (re-entry) exposure towards glyphosate

Input parameters considered for the estimation of worker exposure:

Intended use(s):	use as a herbicide under pome and grape vine		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	3.6	kg a.s./ha	**Transfer coefficient (TC):**	4500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	3	% ('worst case')			
AOEL	0.2	mg/kg bw/d			

Worker exposure towards glyphosate					
Without PPE			**With PPE**		
Worker (re-entry): Systemic dermal exposure after application in use as a herbicide under grapevine					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 4500 x 2 x 3.6 x 1 x 3%) / 60			(1 x 4500 x 2 x 3.6 x 1 x 5% x 3%) / 60		
External dermal exposure	32.4	mg/person	External dermal exposure	1.62	mg/person
External dermal exposure	0.54	mg/kg bw/d	External dermal exposure	0.027	mg/kg bw/d
Total systemic exposure	0.972	mg/person	Total systemic exposure	0.0486	mg/person

Total systemic exposure	**0.0162**	**mg/kg bw/d**	**Total systemic exposure**	**0.00081**	**mg/kg bw/d**
% of AOEL	**8.1**	**%**	**% of AOEL**	**0.4**	**%**

[1)] acceptable without PPE: allocation of BVL code SF245-01 for spray applications

A 2.3 Bystander and resident exposure calculations

A 2.3.1 Bystander Exposure: Application rate 3.6 kg a.s./ha under grape vine Resident Exposure: Application rate 1.8 kg/ha on meadows

Estimation of bystander exposure towards glyphosate during/after herbicide application under High Crops, Hand Held (HCHH)

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	use as a herbicide under grape vine and pome		**Drift (D):**	8.02	% (default: ornamentals > 50 cm, 3 m)
Application rate (AR):	3.6	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	360	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.3	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.172414	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	3	% ('worst case')	**Area Treated (A):**	1	ha/d (based on HCHH)
Inhalation absorption (IA):	100	%			
AOEL:	0.2	mg/kg bw/d	**Exposure duration (T):**	5	min

Bystander exposure towards glyphosate					
Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(360 x 8.02% x 1 x 3%) / 60			(360 x 8.02% x 0.21 x 3%) / 16.15		
External dermal exposure	28.872	mg/person	External dermal exposure	6.06312	mg/person
External dermal exposure	0.4812	mg/kg bw/d	External dermal exposure	0.375425	mg/kg bw/d
Systemic dermal exposure	**0.014436**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.011263**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in use as a herbicide under grape vine an on pasture and meadows (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.3 / 360 x 3.6 x 1 x 5 x 100%) / 60			(0.172414 / 360 x 3.6 x 1 x 5 x 100%) / 16.15		
External inhalation exposure	0.015	mg/person	External inhalation exposure	0.008621	mg/person
External inhalation exposure	0.00025	mg/kg bw/d	External inhalation exposure	0.000534	mg/kg bw/d
Systemic inhalation exposure	**0.00025**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000534**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.88116	mg/person	Total systemic exposure	0.190514	mg/person
Total systemic exposure	0.014686	**mg/kg bw/d**	**Total systemic exposure**	0.011797	**mg/kg bw/d**
% of AOEL	**7.3**	**%**	**% of AOEL**	**5.9**	**%**

Estimation of resident exposure towards glyphosate after application on pasture and meadows

Input parameters considered for the estimation of resident exposure:

Intended use(s):	use as a herbicide on pasture and meadows		**Deposit (D):**	100	%
Application rate (AR):	1.8	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.018	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m3
Dermal absorption (DA):	3	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	30	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.2	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards glyphosate					
Adults			**Children**		
Residents: Systemic dermal exposure after application in use as a herbicide under grape vine on pasture and meadows (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.018 x 1 x % x 5% x 7300 x 2 x 3%) / 60			(0.018 x 1 x % x 5% x 2600 x 2 x 3%) / 16.15		
External dermal exposure	13.14	mg/person	External dermal exposure	4.68	mg/person
External dermal exposure	0.219	mg/kg bw/d	External dermal exposure	0.289783	mg/kg bw/d
Systemic dermal exposure	**0.00657**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.008693**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in use as a herbicide under grape vine on pasture and meadows (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External inhalation exposure	0.01657	mg/person	External inhalation exposure	0.00831	mg/person
External inhalation exposure	0.000276	mg/kg bw/d	External inhalation exposure	0.000515	mg/kg bw/d
Systemic inhalation exposure	**0.000276**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000515**	**mg/kg bw/d**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.018 x 1 x % x 5% x 50% x 20 x 20 x 2 x 30%) / 16.15		

			External oral exposure	0.36	mg/person
			External oral exposure	0.022291	mg/kg bw/d
			Systemic oral exposure	**0.006687**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.018 x 1 x % x 20% x 25 x 30%) / 16.15		
			External oral exposure	0.09	mg/person
			External oral exposure	0.005573	mg/kg bw/d
			Systemic oral exposure	**0.001672**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.41077	mg/person	Total systemic exposure	0.28371	mg/person
Total systemic exposure	0.006846	**mg/kg bw/d**	**Total systemic exposure**	0.017567	**mg/kg bw/d**
% of AOEL	**3.4**	**%**	**% of AOEL**	**8.8**	**%**

Appendix 3: Glossary

There are no abbreviations in this chapter which are not listed in Appendix 1 "Standard terms and abbreviations" of "Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decision in OECD Countries", Revision 2, May 2005.

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: HAG 500 02 H

Active Substance: Glyphosate (450 g/L)

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Helm AG

Date: August 2011

Table of Contents

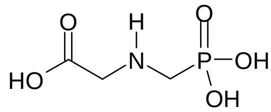
IIIA 8	METABOLISM AND RESIDUES DATA	3
IIIA 8.1	Evaluation of the active substance(s)	3
IIIA 8.1.1	Glyphosate	3
IIIA 8.1.1.1	Storage stability	3
IIIA 8.1.1.2	Metabolism in plants and plant residue definition(s)	3
IIIA 8.1.1.3	Metabolism in livestock and animal residue definition(s)	5
IIIA 8.1.1.4	Residues in rotational crops	5
IIIA 8.1.1.5	Residues in livestock	5
IIIA 8.2	Evaluation of the intended use(s)	7
IIIA 8.2.1	Selection of critical use and justification	7
IIIA 8.2.2	Various crops	10
IIIA 8.2.2.1	Residues in primary crops	10
IIIA 8.2.2.2	Distribution of the residue in peel/pulp	11
IIIA 8.2.2.3	Residues in processed commodities	11
IIIA 8.2.2.4	Proposed pre-harvest intervals, withholding periods	11
IIIA 8.3	Consumer intake and risk assessment	12
IIIA 8.4	Proposed maximum residue levels (MRLs)	12
IIIA 8.5	Conclusion	12
Appendix 1	List of data submitted in support of the evaluation	13
Appendix 2	Detailed evaluation of the additional studies relied upon	13
A 2.1	Storage stability	13
A 2.1.1	Residues in primary crops	13
A 2.2	Residues in processed commodities	13
A 2.3	Residues in rotational crops	13
A 2.4	Residues in livestock	13
A 2.5	Other studies/information	13
Appendix 3	Pesticide Residue Intake Modell (PRIMo)	14

IIIA 8 METABOLISM AND RESIDUES DATA

IIIA 8.1 Evaluation of the active substance(s)

IIIA 8.1.1 Glyphosate

Table IIIA 8.1-1: Information on the active substance glyphosate

Structural formula	
Common Name	Glyphosate

IIIA 8.1.1.1 Storage stability

A brief summary of the storage stability data on glyphosate is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR for glyphosate (RMS: Germany).

Table IIIA 8.1-2: Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stability of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA	Clover, maize grain, sorghum stover, soya bean forage, tomatoes stable for at least 24 months (glyphosate and AMPA) Maize (green plant, forage, grain) at least 9 months (N-acetyl-glyphosate, glyphosate, AMPA and N-acetyl-AMPA) Maize stover at least 1 month (N-acetyl-glyphosate, glyphosate, AMPA and N-acetyl-AMPA) Soya bean (forage, seeds, hay) at least 12 months (N-acetyl-glyphosate, glyphosate, AMPA and N-acetyl-AMPA)

IIIA 8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of glyphosate in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR for glyphosate (RMS: Germany) and in EFSA’s Reasoned Opinion on Modification of the residue definition of Glyphosate in genetically modified maize grain and soybeans, and in products of animal origin (EFSA Journal 2009; 7(9): 1310).

Table IIIA 8.1-3: Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.Nr and 8.6)

Plant groups covered	**Non-tolerant plants**: –Almond (foliar spray to soil) –Apples (foliar spray to soil and trunk) –Barley (roots, via soil, hydroponic solution) –Beans (roots, via soil), Beets (roots via soil) –Cabbage (roots via soil), Carrots (roots via soil) –Citrus (foliar spray to soil) –Coffee plants (roots via soil, foliar spray to trunks, hydroponic solution) –Cotton (roots via soil, hydroponic solution) –Grass/Pasture (foliar spray) –Grapes (foliar spray to soil and trunk, hydroponic solution) –Maize (roots via soil, hydroponic solution) –Oats (roots via soil, hydroponic solution) –Peas (roots, via soil) –Pecan (foliar spray to soil) –Potatoes (foliar spray to soil) –Rice (roots via soil, hydroponic solution) –Sorghum (roots via soil, hydroponic solution) –Soya beans (roots via soil, hydroponic solution) –Sugar beets (foliar spray to soil) –Sugar cane (foliar spray, hydroponic solution) –Walnut (foliar spray to soil) –Wheat (roots via soil, hydroponic solution) In all plants investigated a very slow metabolism of glyphosate to the metabolite AMPA was observed. Most of the residue consisted of unchanged parent substance. The uptake from soil via the roots was very limited. **Tolerant plants** (GOX-modified): –Cotton (foliar spray, roots via soil) –Maize (foliar spray, roots via soil) –Oilseed rape (foliar spray) –Soya beans (foliar spray, roots via soil) Genetically GOX-modified plants show an increased rate of biotransformation of glyphosate into AMPA. AMPA was the dominant residue in all plant species, Unchanged parent compound was still present, although at lower levels in comparison to unmodified plants. **Tolerant plants** (NAG-modified): –Maize (foliar spray) –Soya beans (foliar spray) In genetically NAG-modified plants most of the glyphosate is transformed into N-acetyl-glyphosate (NAG) instead of AMPA. N-acetyl-AMPA was also found, but at a very low level.
Rotational crops	Barley, carrots, lettuce (rotational crop studies) For further metabolism studies involving uptake via roots from soil see plant metabolism. No transfer of glyphosate into follow-up crops is expected.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes

Distribution of the residue in peel/ pulp	not applicable
Processed commodities (nature of residue)	Glyphosate: no study available. N-acetyl-glyphosate: stable (pH5 80°C 20min, pH6 100°C 60min and pH7 120°C 20min).
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Glyphosate
Plant residue definition for risk assessment	Sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl-AMPA, calculated as glyphosate
Conversion factor(s) (monitoring to risk assessment)	not specified

IIIA 8.1.1.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of glyphosate in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR for glyphosate (RMS: Germany).

Table IIIA 8.1-4: Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.Nr and 8.6)

Animals covered	Lactating goats, laying hens (glyphosate, N-acetyl-glyphosate and AMPA) Glyphosate, N-acetyl-glyphosate and AMPA are metabolised to a negligible amount. Most of the residue was excreted unchanged via urine or faeces.
Time needed to reach a plateau concentration in milk and eggs	2-3 days
Animal residue definition for monitoring	Glyphosate
Animal residue definition for risk assessment	Sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl-AMPA, calculated as glyphosate
Conversion factor(s) (monitoring to risk assessment)	not specified
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

IIIA 8.1.1.4 Residues in rotational crops

Not studies available and none required.

IIIA 8.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses within the zone) is provided in the following table.

Table IIIA 8.1-5: Calculation of the dietary burden (based on all relevant uses within the zone)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Grasses	20	–	–	–	–	142.8[a]	–	–	–	–
Kale/ Cabbage	14	–	–	–	–	0.05[b]	–	–	–	–
Grains, except maize	86	55	–	–	60	5.8[c]	3.709	–	–	4.047
Maize	86	–	–	–	–	0.25[d]	–	–	–	–
Bran (Wheat and Rye)	89	15	20	20	20	9.9[c]	1.669	2.225	2.225	2.225
Straw cereals	86	–	20	50	–	198[c]	–	46.05	115.1	–
Pulses	86	–	–	–	–	0.3[e]	–	–	–	–
Roots and Tubers (e.g. potatoes)	15	20	30	–	–	0.59[h]	0.787	1.18		
Swede/Turnip	10	–	–	–	–	0.08[g]	–	–	–	–
Sugar and fodder beet	20	–	–	–	–	0.35[f]	–	–	–	–
Oilseed (meal, cake)	86	10	30	30	20	6.65[i]	0.773	2.32	2.32	1.55
Intake (mg/kg dry weight feed)							**6.9**	**51.8**	**119.7**	**7.8**
Intake (mg/kg bw/d)							**0.44**	**1.88**	**5.13**	**0.31**
Intake (mg/animal/d)							**0.83**	**1035.4**	**1794.9**	**23.5**

[a] HR, based on the following cGAP: 1 x 1.4 kg as/ha, PHI: not specified (The application is on grassland intended for re-cultivation. Since glyphosate damages the pasture it is not expected to be fed to animals in significant amounts, although not explicitly prohibited by the label.)
[b] HR, based on the following cGAP: up to 4.3 kg as/ha and year, PHI: F, seed bed preparation (EU-use)
[c] STMR, based on the following cGAP: 1 x 1.8 kg as/ha, PHI: 7 d, PF: wheat -> bran = 9
[d] STMR, based on the following cGAP: 1 x 1.4 kg as/ha, PHI: 90 d
[e] STMR, based on the following cGAP: 1 x 2.16 kg as/ha, PHI: 7 d (EU-Use)
[f] HR, based on the following cGAP: 2 x 1.1 kg as/ha, PHI: F d
[g] HR, based on the following cGAP: 1 x 1.4 kg as/ha, PHI: F
[h] HR, based on the following cGAP: 1 x 2.2 kg as/ha, PHI: 7 d (EU-use)
[i] STMR, based on the following cGAP: 1 x 1.4 kg as/ha, PHI: 7 d, PF: rapeseed -> cake = 7

A brief summary of the available livestock feeding study/studies is given in the following table. Data, which has previously been evaluated at EU level is described in detail in the DAR for glyphosate (RMS: Germany).

Table IIIA 8.1-6: Conditions of requirement of livestock feeding studies on glyphosate

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	yes 119.7 mg/kg feed DM	yes 6.9 mg/kg feed DM	yes 7.8 mg/kg feed DM
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	yes	yes	yes

Table IIIA 8.1-7: Results of livestock feeding studies on glyphosate

	Ruminant:	Poultry:	Pig:
Feeding levels (mg/kg feed dry matter) in feeding studies	Lactating cows: 40, 120, 400	Laying hens: 40, 120, 400	Swine: 40, 120, 400
	Relevant dosing levels in feeding study: Ruminants: 120 mg/kg feed DM Poultry: 40 mg/kg feed DM Pig: 40 mg/kg feed DM Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.05 mg/kg	<0.05 mg/kg	<0.05 mg/kg
Liver	0.07 mg/kg	0.07 mg/kg	<0.05 mg/kg
Kidney	0.79 mg/kg	0.38 mg/kg	0.37 mg/kg
Fat	<0.05 mg/kg	<0.05 mg/kg	<0.05 mg/kg
Milk	<0.05 mg/kg		-
Eggs		<0.05 mg/kg	

IIIA 8.2 Evaluation of the intended use(s)

IIIA 8.2.1 Selection of critical use and justification

The critical GAP used for the consumer intake and risk assessment is selected from Table IIIA 8.2-1 which covers the intended individual GAPs in the central zone. All uses intended for authorization involve treatment at lower application rates and higher PHIs compared to the intended uses of the DAR. Therefore the evaluation within this document is solely based on the results of the assessment of the DAR.

Table IIIA 8.2-1: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(c)**	**Application**			**Application rate**			**PHI (days)** **(i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number** **a) per use** **b) per crop/ season** **(h)**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	Central Zone	NNNAC Field crops	F	TTTDD Weeds, dicotyledones TTTMM Weeds, monocotyledones	Tractor mounted sprayer, broadcast, ground directed spraying	Post harvest until sowing	a) 1 b) 1	4	1.8	100 - 200	F	Covered by conditions of use and / or growing period between application and harvest Wait 4 days until tillage
2	Central Zone	YACKR Stubble	F	TTTTT Weeds	Tractor mounted sprayer, broadcast, ground directed spraying	Stubble application after weed germination	a) 1 b) 1	4	1.8	200 - 300	F	Covered by the vegetation period
3	Central Zone	NNNOK Pome fruit	F	TTTDD Weeds, dicotyledones TTTMM Weeds, monocotyledones	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm weed height onwards	a) 1 b) 1	4	1.8	100 - 400	42	Band application. Best control of 1UMBF *(Umbelliferae*) at flowering.
4	Central Zone	NNNOS Stone fruit	F	TTTDD Weeds, dicotyledones TTTMM Weeds, monocotyledones	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm weed height onwards	a) 1 b) 1	4	1.8	100 - 400	42	Band application. Best control of 1UMBF *(Umbelliferae*) at flowering.
5	Central Zone	NNNOK Pome fruit	F	CONAR *Convolvulus arvensis*	Tractor mounted sprayer, broadcast, ground 1 directed spraying	From 15 – 20 cm height of CONAR onwards	a) 1 b) 1	8	3.6	100 - 400	42	Band application.
6	Central Zone	VITVI *Vitis vinifera*	F	TTTDD Weeds, dicotyledones TTTMM Weeds, monocotyledones	Tractor mounted sprayer, broadcast, ground directed spraying	From 10 – 20 cm weed height onwards	a) 1 b) 1	4	1.8	100 - 400	30	Band application from 4th year plant stand onwards. Best control of 1UMBF (Umbelliferae) at flowering.
7	Central Zone	VITVI *Vitis vinifera*	F	CONAR *Convolvulus arvensis*	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm height of CONAR onwards	a) 1 b) 1	8	3.6	100 - 400	30	Strip application from 4th year plant stand onwards.
8	Central Zone	YCERE Cereals	F	TTTDD Weeds, dicotyledones TTTMM Weeds, monocotyledones Including AGRRE *(Elytrigia repens*)	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 87-89	a) 1 b) 1	4	1.8	100 - 400	7	Including desiccation, lodged cereals and additional harvest facilitation, Ex brewing and seed production

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(c)**	**Application**			**Application rate**			**PHI (days)** **(i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number** **a) per use** **b) per crop/ season** **(h)**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
9	Central Zone	BRSNW Oilseed rape (winter) PIBSA Field pea	F	TTTTT Weeds	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 87 – 89	a) 1 b) 1	2.5	1.125	200 - 300	14	Additional harvest facilitation and crop desiccation Don’t apply on seed plantation
10	Central Zone	BRSNW Oilseed rape (winter)	F	TTTTT Weeds	Tractor mounted sprayer, broadcast, ground directed spraying	Before crop emergence BBCH 00	a) 1 b) 1	2.5	1.125	200 - 300	F	PHI covered by the vegetation period
11	Central Zone	BEAVA *Beta vulgaris*	F	TTTTT Weeds	Tractor mounted sprayer, broadcast, ground directed spraying	Before crop emergence BBCH 00	a) 1 b) 1	1.6	0.72	200 - 300	F	PHI covered by the vegetation period
12	Central Zone	NNNFW Grassland	F		Tractor mounted sprayer, broadcast, ground directed spraying	Plant height approx 15 cm, AGRRE 3 to 4 leaves per nod, 1UMBF in full florescence	a) 1 b) 1	4	1.8	100 - 400	F	Covered by conditions of use and / or growing period between application and harvest Re-sowing (renewal) of grassland

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) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) 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
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

IIIA 8.2.2 Various crops

IIIA 8.2.2.1 Residues in primary crops

The following table gives a brief overview of the supervised residue trials selected for the assessment of glyphosate. Data, which has been previously evaluated at EU level is described in detail in the DAR for glyphosate (RMS: Germany).
For the evaluation of residues for the dietary intake assessment N-acetyl-glyphosate, AMPA and N-acetyl-AMPA were not taken into account, since they do not occur in non-transgenic crops or their residue levels are at least 1-2 orders of magnitude below the expected level of parent glyphosate. An overview of AMPA residues in field crops is presented in the corresponding DAR, N-acetyl-glyphosate and N-acetyl-AMPA are discussed in a reasoned opinion by EFSA (EFSA Journal 2009; 7(9):1310).

Table IIIA 8.2-2: Overview of the selected supervised residue trials for glyphosate in various crops

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (glyphosate)	Risk assessment (glyphosate)			
Sugar beet	NEU	Outdoor	No studies required	No studies required	--	--	--
Winter rape (seed)	NEU	Outdoor	0.05 – 11.6 mg/kg (n=98)	0.05 – 11.6 mg/kg (n=98)	0.98	11.6	1
Barley grain	NEU	Outdoor	0.09 – 21.0 mg/kg (n=136)	0.09 – 21.0 mg/kg (n=136)	4.65	21.0	1
Barley straw	NEU	Outdoor	0.02 – 225.0 mg/kg (n=72)	0.02 – 225.0 mg/kg (n=72)	18.8	225.0	1
Oats grain	NEU	Outdoor	0.3 – 21.4 mg/kg (n=36)	0.3 – 21.4 mg/kg (n=36)	5.4	21.4	1
Oats straw	NEU	Outdoor	8.1 – 157.0 mg/kg (n=17)	8.1 – 157.0 mg/kg (n=17)	21.5	157.0	1
Rye grain	NEU	Outdoor	1.9 – 16.7 mg/kg (n=19)	1.9 – 16.7 mg/kg (n=19)	3.86	16.7	1
Rye straw	NEU	Outdoor	16.4 – 30.5 mg/kg (n=6)	16.4 – 30.5 mg/kg (n=6)	21.35	30.5	1
Wheat grain	NEU	Outdoor	0.02 – 16.9 mg/kg (n=100)	0.02 – 16.9 mg/kg (n=100)	0.85	16.9	1
Wheat straw	NEU	Outdoor	3.3 – 140.0 mg/kg (n=65)	3.3 – 140.0 mg/kg (n=65)	43.8	140.0	1
Pome fruit, stone fruit	NEU	Outdoor	No studies required	No studies required	--	--	--
Grapes	NEU SEU	Outdoor	0.01 – 0.7 mg/kg (n=17)	0.01 – 0.7 mg/kg (n=17)	0.05	0.7	1

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Further explanation is provided below.

Sugar beet
The intended use on sugar beets involved application before emergence of the crop (BBCH 00). Under consideration of the quick degradation in soil and a negligible uptake of glyphosate residues supervised field trials are not considered necessary.
However, supervised field trials data was presented in the DAR for glyphosate (RMS: Germany) for wiping application to mature sugar beets and spraying application to glyphosate tolerant varieties.

Winter rape
For available residue trials (cGAP NEU 1 x 1.5 kg as/ha, PHI: 10 d, spraying) see DAR for glyphosate (RMS: Germany).
In view of the point of application being shortly before harvest, the utilisation of rape forage as feed items is not considered relevant.

Cereals
For available residue trials (cGAP NEU 1 x 2.2 kg as/ha, PHI: 7 d, spraying) see DAR for glyphosate (RMS: Germany).
In view of the point of application being shortly before harvest, the utilisation of cereal forage as feed items is not considered relevant.

Pome fruit, stone fruit
The intended method of application involves band application with ground directed spraying. Commodities relevant for human consumption or animal feed are not affected by the treatment.
However in the DAR for glyphosate (RMS: Germany) supervised field trials are reported for Northern and Southern Europe (n=65), not resulting in residues above the LOQ of 0.05 mg/kg for glyphosate.

Grapes
The intended method of application involves band application with ground directed spraying. Commodities relevant for human consumption or animal feed are not affected by the treatment.
However in the DAR for glyphosate (RMS: Germany) supervised field trials (cGAP NEU 1 x 4.3 kg as/ha, PHI: 14 d, spraying) are reported for Northern and Southern Europe (n=17), not resulting in residues above the LOQ of 0.05 mg/kg for glyphosate in hanging fruits. Ground lying grapes showed residues of up to 0.7 mg/kg, on which the current MRL of 0.5 mg/kg is based.

Grassland
The intended use on grassland follows the purpose of re-cultivation instead of grazing. The utilisation of treated areas for feeding purposes is not considered as good agricultural practice.
However supervised field trials involving treatment of meadows are reported in the DAR for glyphosate (RMS: Germany), covering the intended application rates. For this annex point please refer to the DAR Vol. 3, B.6.6.14.

IIIA 8.2.2.2 Distribution of the residue in peel/pulp

Not applicable

IIIA 8.2.2.3 Residues in processed commodities

No data required.

IIIA 8.2.2.4 Proposed pre-harvest intervals, withholding periods

The pre-harvest intervals (PHI) according to table IIIA 8.2-3 are mostly less critical than those considered in EU assessment, see DAR for glyphosate (RMS: Germany).
Cereals may be treated for desiccation until 7 days before harvest. No additional withholding period is needed for animal feeding stuffs. This is confirmed in the EU review where no specific withholding period has been set.

IIIA 8.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table IIIA 8.3-1 and the toxicological reference values stated in Table IIIA 8.3-2. For the detailed calculation results it is referred to Appendix 1.

Table IIIA 8.3-1: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
All commodities	various	MRL	n.n.	not necessary, no ARfD allocated

Table IIIA 8.3-1: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.3 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	44 % (based on WHO cluster diet B)
NTMDI (% ADI) according to German VELS model	21 % (based on DE 2-4 years old child)
IEDI (EFSA PRIMo) (% ADI)	Not necessary
NEDI (German VELS model) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applicable
ARfD	Not allocated
IESTI (EFSA PRIMo) (% ARfD)	Not necessary
NESTI (German VELS model) (% ARfD)	Not necessary
Factors included in IESTI and NESTI	Not applicable

IIIA 8.4 Proposed maximum residue levels (MRLs)

Based on the residue data summarized in the DAR, MRLs were set for glyphosate and established in Regulation (EC) No 396/2005. No other proposal is made.

IIIA 8.5 Conclusion

No new data has been provided and full reference has been made to the DAR. Available data are sufficient for the evaluation of the uses applied for.
Existing MRLs as established in Regulation (EC) No 396/2005 are sufficient to cover residues arising from the intended uses.

The long-term and short-term intake of glyphosate residues is unlikely to present a public health concern.
As far as consumer health protection is concerned, the zRMS agrees with the authorization of the intended uses.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
all	Germany	1998	Monograph Glyphosate (DAR)			Used
all	EFSA	2009	Modification of the residue definition of glyphosate in genetically modified maize grain and soybeans, and in products of animal origin on request from the European Commission; EFSA Journal 2009; 7(9):1310			Used

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

None

A 2.1.1 Residues in primary crops

None

A 2.2 Residues in processed commodities

None

A 2.3 Residues in rotational crops

None

A 2.4 Residues in livestock

None

A 2.5 Other studies/information

None

Appendix 3 Pesticide Residue Intake Modell (PRIMo)

Glyphosate			
Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,3	ARfD (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2001	Year of evaluation:	2001

Prepare workbook for refined calculations

Undo refined calculations

lain choice of toxicological reference values.

risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum: 1 – 44

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
43,6	WHO Cluster diet B	28,5	Wheat	4,9	Sunflower seed	4,0	Soya bean	
36,7	DK child	18,3	Wheat	14,7	Rye	2,6	Oats	
32,6	WHO cluster diet D	21,7	Wheat	3,3	Sunflower seed	2,5	Soya bean	
30,9	WHO cluster diet E	13,1	Wheat	5,4	Barley	3,9	Soya bean	
27,1	WHO Cluster diet F	12,0	Wheat	4,3	Soya bean	4,0	Barley	
23,4	UK Toddler	13,1	Wheat	7,6	Sugar beet (root)	0,6	Potatoes	
23,2	IT kids/toddler	22,2	Wheat	0,1	Potatoes	0,1	Wild fungi	
22,9	IE adult	8,3	Barley	7,7	Wheat	1,3	Sunflower seed	
21,4	DE child	13,7	Wheat	2,6	Rye	1,4	Oats	
20,8	NL child	15,8	Wheat	1,0	Potatoes	0,7	Oats	
20,0	PT General population	13,1	Wheat	2,0	Soya bean	1,9	Sunflower seed	
17,7	ES child	14,8	Wheat	0,8	Sunflower seed	0,4	Peas	
16,2	UK Infant	8,7	Wheat	3,4	Sugar beet (root)	1,7	Oats	
15,9	WHO regional European diet	9,9	Wheat	2,2	Barley	0,9	Sunflower seed	
14,6	IT adult	13,8	Wheat	0,2	Wild fungi	0,1	Potatoes	
14,5	FR all population	11,0	Wheat	2,2	Sunflower seed	0,7	Table and wine grapes	
13,2	SE general population 90th percentile	10,7	Wheat	1,0	Rye	0,7	Potatoes	
13,0	ES adult	7,8	Wheat	3,3	Barley	0,7	Sunflower seed	
12,2	FR toddler	8,7	Wheat	1,1	Sunflower seed	0,8	Potatoes	
11,5	NL general	6,9	Wheat	2,5	Barley	0,5	Potatoes	
10,5	DK adult	6,7	Wheat	2,3	Rye	0,8	Oats	
9,7	UK vegetarian	6,8	Wheat	1,3	Sugar beet (root)	0,3	Oats	
9,2	LT adult	3,6	Rye	3,5	Wheat	0,6	Oats	
8,1	UK Adult	5,6	Wheat	1,3	Sugar beet (root)	0,2	Potatoes	
7,0	FI adult	3,3	Wheat	2,3	Rye	0,6	Oats	
4,7	FR infant	2,8	Wheat	0,7	Potatoes	0,4	Milk and cream,	
1,0	PL general population	0,6	Potatoes	0,1	Pome fruit	0,1	Peas	

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: HAG 500 02 H
Active Substance(s): Glyphosate 450 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Helm AG
Date: 20/07/2012

Table of Contents

SEC 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9) 3

5.1 GENERAL INFORMATION ON THE FORMULATION 3
5.2 PROPOSED USE PATTERN 3
5.3 INFORMATION ON THE ACTIVE SUBSTANCES 4
5.3.1 Glyphosate 4
5.4 SUMMARY ON INPUT PARAMETERS FOR ENVIRONMENTAL EXPOSURE ASSESSMENT 6
5.4.1 Rate of degradation in soil 6
5.4.2 Adsorption/desorption 10
5.4.3 Rate of degradation in water 12
5.5 ESTIMATION OF CONCENTRATIONS IN SOIL (PEC_{SOIL}) (KIIIA1 9.4) 13
5.6 ESTIMATION OF CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{SW}/PEC_{SED}) (KIIIA1 9.7) 14
5.7 RISK ASSESSMENT GROUND WATER (KIIIA1 9.6) 15
5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its metabolite (Tier 1 and 2) 15
5.7.2 Summary of risk assessment for ground water 18
5.8 POTENTIAL OF ACTIVE SUBSTANCE FOR AERIAL TRANSPORT 18

APPENDIX 1 LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION 19

APPENDIX 2 DETAILED EVALUATION OF STUDIES RELIED UPON 21

KIIA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT – ACTIVE SUBSTANCE 21
KIIIA1 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT – PLANT PROTECTION PRODUCT 21

APPENDIX 3 TABLE OF INTENDED USES JUSTIFICATION AND GAP TABLES 27

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product HAG 500 02 H containing the active substance Glyphosate in its intended uses in various according to Appendix 3.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation HAG 500 02 H

Code	HAG 500 02 H
plant protection product	HAG 500 02 H
applicant	Helm AG
date of application	21/04/2011
Formulation type (WP, EC, SC, …; density)	SL
active substance	Glyphosate
Concentration of as	450 g/L

5.2 Proposed use pattern

The critical GAPs used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs in the zone. A list of all intended uses within the zone is given in Appendix 3.

Table 5.2-1: Critical use pattern of HAG 500 02 H

Crop	Application timing	Application method Drift scenario	Interception	Max. Application rate, cumulative (g as/ha)	Soil effective application rate max. (g as/ha)
Cereals	BBCH 87-89	Tractor mounted sprayer, broadcast, ground directed spraying	90 %	1800	180
Field crops including Cereals	Post harvest until sowing	Tractor mounted sprayer, broadcast, ground directed spraying	0%	1800	1800
Field peas, Oilseed rape	BBCH 87-89	Tractor mounted sprayer, broadcast, ground directed spraying	80%	1125	225
Sugar beet	After sowing/before crop germination	Tractor mounted sprayer, broadcast, ground directed spraying	0%	720	720

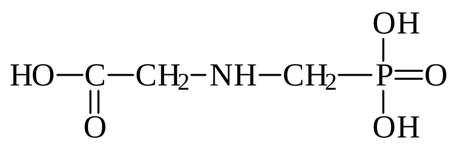
Oilseed rape	Post harvest until sowing / BBCH 00	Tractor mounted sprayer, broadcast, ground directed spraying	0%	1125	1125
Orchards	Sufficient leaves for uptake of a.s.	Tractor mounted sprayer, broadcast, ground directed spraying	0%	3600	3600
Vineyards	Sufficient leaves for uptake of a.s.	Tractor mounted sprayer, broadcast, ground directed spraying	0%	3600	3600
Grassland	Re-sowing of grassland	Tractor mounted sprayer, broadcast, ground directed spraying	0%	1800	1800

5.3 Information on the active substances

5.3.1 Glyphosate

5.3.1.1 Identity, further information on Glyphosate

Table 5.3-1: Identity, further information on Glyphosate

Active substance (ISO common name)	Glyphosate
IUPAC	*N*-(phosphonomethyl)-glycin
Function (e.g. fungicide)	Herbizide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	07/01/2002
Conditions of approval	Member States must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses.
Confirmatory data	None.
RMS	Germany
Minimum purity of the active substance as manufactured (g/kg)	950 g/kg
Molecular formula	$C_3H_8NO_5P$
Molecular mass	169.1 g/mol
Structural formula	

5.3.1.2 *Physical and chemical properties of Glyphosate*

Physical and chemical properties of Glyphosate as agreed at EU level (see LOEP 2001) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of Glyphosate relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	$1.31 \cdot 10^{-5}$ Pa (25 °C, acid)	LOEP (2001)
Henry's law constant (Pa × m³ × mol^{-1})	$2.1 \cdot 10^{-7}$ Pa · m³ ·mol^{-1}	LOEP (2001)
Solubility in water (at 25 °C in mg/L)	pH 2: 10.5 ± 0.2 g/L (20 °C, 995 g/kg) pH 7: 18.8 g/L	LOEP (2001) Russel, 1995
Partition co-efficient (at 25 °), log P_{OW}	pH 5 – 9: - 3.2 at 25 °C (999 g/kg)	LOEP (2001)
Dissociation constant, pKa	2.34 (20 °C), 5.73 (20 °C), 10.2 (25 °C)	LOEP (2001)
Hydrolytic degradation	pH 5,7 and 9: stable (25 °C)	LOEP (2001)
Photolytic degradation	33 d (pH 5), 69 d (pH 7), 77 d (pH 9) (Xenon lamp).	LOEP (2001)
Quantum yield of direct phototransformation in water > 290 nm	Not determined.	LOEP (2001)
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} = 1.6 d	LOEP (2001)

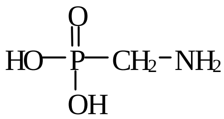
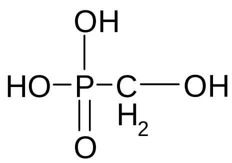
5.3.1.3 *Metabolites of Glyphosate*

Environmental occurring metabolites of glyphosate requiring further assessment according to the results of the assessment of glyphosate for EU approval are summarized in Table 5.3-3.

No new study on the fate and behaviour of glyphosate or HAG 500 02 H has been performed. Hence no potentially new metabolites need to be considered.

Table 5.3-3: Metabolites of glyphosate potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural**	**occurence in compartements**	**Satus of Relevance**

	formula/Molecular formula	(Max. at day)	(Glyphosate 6511/VI/99-final 21 January 2002)
Aminomethyl-phosphonic acid (AMPA) molar mass: 111.0 g/mol correction factor: 0.656		Soil: Max. 29,3 % at day 84 Water: Max. 16 % at day 14 Sediment: Max. 16 % at day 120	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: : not relevant Groundwater: not relevant (Step 2)[1)]
(Hydroxymethyl)-phosphonic acid molar mass: 112.0 g/mol correction factor: 0.662		Water: Max. 10.0% at day 61, 7.5% at day 100 / 2 x > 5 %	Aquatic organism: Water: not assessed

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Glyphosate

No new studies have been submitted regarding route and rate of degradation in soil of Glyphosate. However, DT_{50} values from the valid studies evaluated during EU assessment were recalculated by zRMS according to FOCUS Degradation Kinetics, 2006. The kinetic evaluation of the submitted studies is presented in Appendix 2. The recalculated values for Glyphosate are summarized in Table 5.4-1. This summary does include one study not submitted by the applicant but described in the DAR that was also reevaluated by the zRMS.

Table 5.4-1: Summary of aerobic degradation rates for Glyphosate - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10 kPa	Fit	Kinetic	Reference
Speyer 2.1/Sand	6.1	20	40 % MWHC	11.4	76.7		4.0	FOMC	Galicia and Flückiger (1993), DAR (1998)
				23.1		19.8*		SFO recalculated	
Speyer 2.2/Sand	6.0	20	40 % MWHC	7.5	156.8		8.7	DFOP [1)] k_{fast} 2.297 k_{slow} 0.011 g 0.458	Galicia and Flückiger (1993), DAR (1998)

				63.0		53.9*		SFO recalcu-lated from slow phase	
Speyer 2. /Loamy Sand	6.9	20	40 % MWHC	5.4	25.6		5.9	FOMC	Galicia and Flückiger (1993), DAR (1998)
				7.7		5.9*		SFO recalculated	
Les Evouettes /Silt loam	6.1	20	40 % MWHC	18.9	232.3		3.4	DFOP [1)] k_{fast} 0.109 k_{slow} 0.007 g 0.504	Galicia and Morgen-roth (1993), DAR (1998)
				99.0		60.3*		SFO recalcu-lated from slow phase	
Sandy loam	7.3	25	75 % FC	1.7	29.9		3.6	FOMC	Kesterson, A.L. and Atkins, R.H. (1991), DAR (1998)
				9.0		11.9*		SFO recalculated	
Silt loam	7.5	25	75 % FC	2.1	12.8		3.4	FOMC	Kesterson, A.L. and Atkins, R.H. (1991), DAR (1998)
				3.9		5.1*		SFO recalculated	
Humic sand/San d	5.2	20	1/3 bar	327	1086	327.0**	5.5[2)]	SFO	Matla and Vonk (1993), DAR (1998)
Sandy loam/ Sandy loam	7.5	20	1/3 bar	4.6	61,4		3.7	FOMC	Matla and Vonk (1993), DAR (1998)
				18.5		13.9**		SFO recalculated	
Low humic sand	7.2	20	1/3 bar	116	384	56.6**	5.4	SFO	Matla and Vonk (1993), DAR (1998)
Aggregated DT_{50} (n=9)			**Coefficient of variation (%)**			166			
			Geometric mean (d)			26.3			

1) 10% initially measured concentration not reached within experimental period

2) Outliner on day 14 excluded

* Normalisation with Input Decision 3.2 by using defaults for Soil moisture Grav.-% and Reference soil moisture Grav.-%

** Normalisation with Input Decision 3.2 by using user input for Soil moisture Grav.-% and default for Reference soil moisture Grav.-%

The DT_{50} values of Glyphosate do show a pH dependency that is summarized in Table 5.4-2.

Table 5.4-2: pH-dependency of laboratory DT_{50} values of Glyphosate

pH dependency (DT_{50})	Yes Statistical evaluation according to Kendall test: Kendall-τ: -0.572 p-value: 0.045 (< significance level of 0.05)
Geometric mean DT_{50} (d) for acidic soils	67.7 (n = 4)

AMPA

No new studies have been submitted regarding route and rate of degradation in soil of the metabolite AMPA. However, the DT_{50} value from the valid study evaluated during EU assessment was recalculated by zRMS according to FOCUS Degradation Kinetics, 2006. The kinetic evaluation of the submitted studies is presented in Appendix 2. The recalculated value for AMPA is given in Table 5.4-3.

Table 5.4-3: Summary of aerobic degradation rates for metabolite AMPA - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	Formation fraction	DT_{50} (d) 20 °C pF2/ 10 kPa	Fit	Kinetic	Reference
Les Evouettes /Silt loam1)	6.1	20	40 % MWHC	-	-	-	-	-	Galicia and Morgenroth (1993), DAR (1998)
Silt loam2)	7.5	25	75 % FC	39.7	0.56	52.2*	25.9	SFO	Kesterson, A.L. and Atkins, R.H. (1991), DAR (1998)
Aggregated DT_{50} (n=1)	**Coefficient of variation (%)**					-			
	Geomean (d)					-			
	90th perzentil					-			
	Maximum					52.2			
Formation Fraction from ai → AMPA (n=1)	**Arithmetic mean**				-				
	Maximum				0.56				

1) No degradation until day 112

2) Parent: FOMC

* Normalisation with Input Decision 3.2 by using defaults for Soil moisture Grav.-% and Reference soil moisture Grav.-%

5.4.1.2 Field studies

Glyphosate

No new studies have been submitted on the soil dissipation of Glyphosate under field conditions. However, DT_{50} values from these studies that were evaluated during EU assessment were recalculated by zRMS according to FOCUS Degradation Kinetics, 2006. Thereby, only valid studies conducted on arable land and agricultural soils in Europe, which are representative for the Central Zone with respect to soil type and climate, were considered. The kinetic evaluation of the submitted studies is described in Appendix 2. The recalculated and non-normalized DT_{50} values for Glyphosate are summarized in Table 5.4-4.

Table 5.4-4: Field degradation studies of Glyphosate

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Egerkingen /Switzerland, Clay loam, Application September	7.3	0-10	5.2	184.4	5.6		DFOP k_{fast} 1.423643 k_{slow} 0.008978 g 0.476	Schulz (1992a), DAR (1998)
			77.2				SFO recalculated from slow phase	
Bad Krotzingen/ Sandy loam/Germany Application September	6.0	0-10	2.9	74.8	8.3		DFOP k_{fast} 0.549248 k_{slow} 0.018553 g 0.60	Schulz (1992b), DAR (1998)
			37.4				SFO recalculated from slow phase	
Dietgen/Sandy clay loam/ Switzerland Application September	7.1	0-10	6.0	65.4	10.5		FOMC alpha = 0.864 beta = 4.890	Schulz (1992c), DAR (1998)
			19.7				SFO recalculated from DT_{90}	
Menslage/ Sand/Germany Application September	4.7	0-10	5.2	153.3	12.6		FOMC alpha = 0.521 beta = 1.871	Schulz (1992d), DAR (1998)
			42.2				SFO recalculated from DT_{90}	

5.4.2 Adsorption/desorption

Glyphosate

No new studies have been submitted regarding adsorption/desorption in soil of Glyphosate. The exposure modelling is based on the EU K_{foc}/K_{doc} values as summarized in Table 5.4-5.

Table 5.4-5: K_f, K_{foc} and 1/n (Freundlich exponent) values for Glyphosate

Soil Type	**OC (%)**	**pH (-)**	**K_d (mL g^{-1})**	**K_{doc} (mL g^{-1})**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Sand	0.8	5.7	263	32838	-	-	-	Waring (1992), DAR (1998)
Sand loam	1.6	7.1	811	50660	-	-	-	Waring (1992), DAR (1998)
Sandy clay loam	1.4	7.8	50	3598	-	-	-	Waring (1992), DAR (1998)
Loamy sand	0.6	8.3	5	884	-	-	-	Waring (1992), DAR (1998)
Silt loam	1.4	6.1	48	3404	-	-	-	Waring (1992), DAR (1998)
Loam (sediment)	3.0	7.1	510	17019	-	-	-	Waring (1992), DAR (1998)
Silty clay loam	1.45	6.5	-	-	324	22345*	0.92	Living-ston et al. (1986), DAR (1998)
Silt loam	0.87	7.4	-	-	33	3793*	0.80	Living-ston et al. (1986), DAR (1998)
Loamy sand	1.10	5.2	-	-	660	60000*	1.16	Living-ston et al. (1986), DAR

								(1998)
Arithmetic mean			-	-	-	21616**	0.96	-

* Calculation with Input Decision 3.2

** Arithmetic mean of K_{foc} and K_{doc} values combined

The K_{foc} and K_{doc} values of Glyphosate do show a pH dependency that is summarized in Table 5.4-6.

Table 5.4-6: pH-dependency of K_{foc} and K_{doc} values of Glyphosate

pH dependency (K_{foc} and K_{doc} combined)	Yes Statistical evaluation according to Kendall test: Kendall-τ: - 0.592 p-value: 0.036 (< significance level of 0.05)

AMPA

No new studies have been submitted regarding adsorption/desorption in soil of the metabolite AMPA. The exposure modelling is based on the EU K_{foc} values as summarized in Table 5.4-7.

Table 5.4-7: K_f, K_{foc} and 1/n (Freundlich exponent) values for AMPA

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Clay loam	2.1	7.7	77.1	3671*	0.786	Weeden (1993), DAR (1998)
Sand**	18.7	4.7	1570	8396*	0.904	Weeden (1993), DAR (1998)
Sand	1.3	7.4	15.7	1208*	0.752	Weeden (1993), DAR (1998)
Clay loam	0.9	7.6	53.9	5989*	0.791	Weeden (1993), DAR (1998)
Loamy sand	1.6	6.3	110	6875*	0.769	Weeden (1993), DAR (1998)
Sand	0.3	4.6	73.0	24333*	0.788	Weeden (1993), DAR (1998)
Arithmetic mean				8412	0.798	-

* Calculation with Input Decision 3.2

** According to OECD 106 the OC content (%) is too high. Since the corresponding K_{foc} (8396 mL g^{-1}) value is in the same order of magnitude as the other values, the K_{foc} value is used for further calculations.

The K_{foc}/K_f values of the metabolite AMPA do not show any pH dependency.

5.4.3 Rate of degradation in water

Glyphosate

No new water/sediment study has been submitted. However, DT_{50} values from the valid studies evaluated during EU assessment were recalculated by zRMS according to FOCUS Degradation Kinetics, 2006. The recalculation of the DT_{50} values is described in detail in Appendix 2.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-8.

Table 5.4-8: Degradation in water/sediment of glyphosate

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit (chi²)**	**$DissT_{50}$/ $DissT_{90}$ water**	**Kinetic, Fit**	**$DissT_{50}$/ $DegT_{50}$ sed.**	**Kinetic, Fit**	**Reference**
Bickenbach (DE)	18.7 (SFO 267.4*) / 533	DFOP, 3.3	2.3 (SFO 6.2**) / 20.6	FOMC, 3.0	-	-	Möllerfeld and Römbke, 1993
Unter Widdersheim (DE)	134.9 (SFO 513*) / >1000	DFOP, 5.0	1.4 (SFO 8.0**) / 26.6	FOMC, 6.9	-	-	Möllerfeld and Römbke, 1993
Zuidpolder (NL)	418 (SFO 5981*) / >1000	DFOP, 0.7	-	-	-	-	Muttzall, 1993
Kromme Rijn (NL)	28.8 (SFO 88.7*) / 233	DFOP, 1.3	-	-	-	-	Muttzall, 1993
I (Pond)	83.3 / 276.7	SFO, 8.3	1.5 (SFO 8.8**) / 29.2	DFOP, 5.5	-	-	Heintze, 1996
II (Creek)	16.8 / 55.7	SFO, 4.6	13.6 / 45.2	SFO, 5.3	-	-	Heintze, 1996
Geometric mean SFO	**216.1**		**8.8**				

* recalculated from k_{slow}

** recalculated by DT_{90} / 3.32

AMPA

No new water/sediment study has been submitted. However, DT_{50} values from the valid studies evaluated during EU assessment were recalculated by zRMS according to FOCUS Degradation Kinetics, 2006. The recalculation of the DT_{50} values is described in detail in Appendix 2.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-9.

Table 5.4-9: Degradation in water/sediment of glyphosate

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit (chi²)**	**$DissT_{50}$/ $DissT_{90}$ water**	**Kinetic, Fit**	**$DissT_{50}$/ $DegT_{50}$ sed.**	**Kinetic, Fit**	**Reference**
Bickenbach (DE)	47.8 / 158.7	SFO, 6.1	6.8 (SFO	DFOP, 3.9	-	-	Knoch and

			15.6**) / 51.9				Spirlet (1999)
Unter Widdersheim (DE)	-	-*	1.8 (SFO 10.7**) / 35.4	FOMC, 11.8	-	-	Knoch and Spirlet (1999)
Maximum SFO	**47.8**		**15.6**				

* no acceptable fit according to FOCUS Degradation Kinetics (2006)

** recalculated by DT_{90} / 3.32

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for glyphosate and AMPA as presented in Table 5.5-1.

Table 5.5-1: Input parameters for active substance ant its metabolite for PEC_{soil} calculation

Active substance	**DT_{50}**
glyphosate	6.9d (DFOP: k_{Fast} = 0.1266, k_{Slow} = 0.0038, g = 0.850, maximum, field studies, see 5.4.1.2)
AMPA	worst case parent kinetics for AMPA formation: 3.4 d (FOMC, alpha = 0.432, beta = 0.847, minimum, field studies, see 5.4.1.2) AMPA: 52.2 d (lab studies, see 5.4.1.1)

Due to the fast degradation of glyphosate and AMPA in soil (DT_{90} < 365 d) the accumulation potential does not need to be considered.

Beside PEC_{act} values also PEC_{twa}, 21 d values are required for risk assessment. PEC_{twa}, 21 d values are also presented in Table 5.5-2

Table 5.5-2: Results of PEC_{soil} calculation (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm)

plant protection product:		HAG 500 02 H				
use:		Qrchards and Vineyards (worst case covering all other uses)				
Number of applications/intervall		1				
application rate:		8 L/ha (3600 g glyphosate / ha) as worst case				
crop interception:		0 %				
active substance/preparation	**soil relevant application rate (g/ha)**	**PEC_{act} (mg/kg)**	**PEC_{twa} 21 d (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
glyphosate	3600	4.800	2.122	-	-	-
AMPA	100 % formation fraction from as	1.945 occurring on day 14	1.903	-	-	-
HAG 500 02 H	8000	10.677	-	-	-	-

5.6 Estimation of concentrations in surface water and sediment (PEC_{SW}/PEC_{sed}) (KIIIA1 9.7)

The calculation of the predicted environmental concentrations of glyphosate in surface water (PEC_{SW}) and sediment (PEC_{sed}) was based on the recommendations given in FOCUS (2011). Step 1 and Step 2 calculations were conducted by using the model Steps 1-2 in FOCUS – Surface water tool for exposure predictions, version 2.1.

The input parameters DT_{50} used for Step 1 and Step 2 assessments of glyphosate were derived from LOEP (2001). However, the underlying data were not evaluated according to FOCUS Degradation Kinetics (2006) as required for deriving PEC_{SW} values. Thus, the studies of the applicant (Anonymus, 2011r-w) are not discussed in detail. Instead new PEC_{SW} values are calculated by the zRMS by using DT_{50} input parameters derived from SFO-DT_{50} values calculated according to FOCUS Degradation Kinetics (2006). The relevant input parameters for the glyphosate used for PEC calculation are summarized in Table 5.6-1.

Table 5.6-1: Input parameters for active substance for $PEC_{SW/sed}$ calculations

Parameter	Endpoint used for $PEC_{SW/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	glyphosate		
Solubility in water (mg/L)	18800	no	LoEP provides only a value for glyphosate at pH2, therefore the data of Russel, 1995, was used
$DT_{50,soil}$ (d)	26.3	no	Geomean laboratory studies (see 5.4.1.1)
$DT_{50,wholesystem}$ (d)	216.1	no	Geomean water/sediment studies (see 5.4.3)
$DT_{50,water}$ (d)	8.8	no	Geomean water/sediment studies (see 5.4.3)
$DT_{50,sed}$ (d)	216.1	no	
$K_{f,oc}$ (mL g^{-1})	21 616	no	Arithmetic mean (see 5.4.2)

As a worst case assumption, no interception was assumed in all crops. HAG 500 02 H is used for ground directed spraying on weeds; therefore the crop scenario “cereals” was assumed to be representative for all use patterns including the uses in orchards and vine. These uses represent the worst case with an application rate of 3600 g/ha. Another scenario with 1800 g/ha and an application season from October to February was calculated. These two scenarios cover all indented uses.

Results of FOCUS SW step 2 calculations for the worst-case application scenarios of HAG 500 02 H are summarized in Table 5.6-2. Beside PEC_{act} value also PEC_{twa}, 21 d is given.

Table 5.6-2: Summary of highest global maximum FOCUS Step 2 PEC_{SW} and PEC_{sed} values for glyphosate

Application rate of ai (g/ha)	Crop type	Season of application	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Actual, 0 d	TWA, 21 d	Actual, 0 d

3600	cereals	Mar. – May	33.11	7.80	4140
1800	cereals	Oct.-Feb.	16.55	7.94	2070

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its metabolite (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

FOCUS calculations were performed by applicant with standard FOCUS scenarios to obtain outputs from FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 (Anonymus, 2011a-q, for details see Appendix 2 **Fehler! Verweisquelle konnte nicht gefunden werden.**). For glyphosate and its metabolite AMPA, the applicant used DT_{50} values as specified in LOEP (2001) as input parameters. However, the underlying data were not evaluated according to FOCUS Degradation Kinetics (2006) as required for deriving PEC_{GW} values. Thus, the studies of the applicant (Anonymus, 2011a-q) are not discussed in detail. Instead new PEC_{GW} values are calculated by the zRMS by using DT_{50} input parameters derived from SFO-DT_{50} values calculated according to FOCUS Degradation Kinetics (2006).

The PEC_{GW} calculations of glyphosate and its metabolite AMPA are performed for the worst case uses 00-006 and 00-007 by using the simulation model FOCUS PELMO 4.4.3. The input parameters related to application are summarized in Table 5.7-1.

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling

use evaluated	00-006 and 00-007
application rate (kg as/ha)	1 × 3600 g glyphosate/ha disregarding interception
crop (crop rotation)	Orchards (00-006) and vineyards (00-007), Sufficient leaves for uptake of a.s. in both uses
date of application	0 days after 1^{st} emergence in the year
interception (%)	0 %
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0 for glyphosate and AMPA*
simulation period (years)	26

* Default according to FOCUS (2000)

Glyphosate

Due to pH dependency of DT_{50} and K_{foc} of glyphosate two simulation runs with the relevant FOCUS scenarios are performed by zRMS.

For the first simulation runs the geometric mean DT_{50} and the arithmetic mean K_{foc} of all soils are used as input parameters.

For the second simulation runs the pH-tool in FOCUS PELMO 4.4.3 is used, thereby the worst case DT_{50} (acidic) is used as input parameters combined with the acidic FOCUS scenarios.

Table 5.7-2: Input parameters related to active substance for PEC_{GW} modelling

Parent	Glyphosate	Remarks/Reference
molecular mass	169.1	-
DT_{50} in soil (d)	26.3	SFO, geometric mean, normalised (20ºC, pF2), laboratory studies
DT_{50} in soil (d)	acidic soils: 67.7	SFO, geometric mean for acidic soils, normalised (20ºC, pF2), laboratory studies (n = 4)
K_{foc}	21616 (arithm mean) 60000 (pH 5.2) 884 (pH 8.3)	-
1/n	0.96	Arithmetic mean
pKs	5.73	-

Table 5.7-3: Input parameters related to metabolites of glyphosate for PEC_{GW} modelling

Metabolite 1	AMPA	Remarks/Reference
molecular mass	111.0	-
Formation fraction	0.56	Maximum (n = 1), laboratory studies
DT_{50} in soil (d)	52.2	SFO, maximum (n = 1), normalised (20ºC, pF2), laboratory studies
K_{foc}	8412	Arithmetic mean
1/n	0.798	Arithmetic mean

Table 5.7-4: PEC_{GW} at 1 m soil depth for glyphosate and its metabolite (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Use No/crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 4.4.3	
		Glyphosate	**AMPA**
00-006/orchards (apples selected as representative in FOCUS PELMO 4.4.3)	**Châteaudun**	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 5.7-5: PEC_{GW} at 1 m soil depth for glyphosate and its metabolite (second simulation run due to pH dependency)

Use No/crop 00-006/orchards (apples selected as representative in FOCUS PELMO 4.4.3)	Scenario		80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 4.4.3	
	Name	**pH-H_2O (1st horizon)**	**Glyphosate**	**AMPA**
	Hamburg	6.4	< 0.001	< 0.001
	Jokioinen	6.2	< 0.001	< 0.001
	Okehampton	5.8	< 0.001	< 0.001
	Porto	4.9	< 0.001	< 0.001

Table 5.7-6: PEC_{GW} at 1 m soil depth for glyphosate and its metabolite (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Use No/crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 4.4.3	
		Glyphosate	**AMPA**
00-007/vineyards	**Châteaudun**	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 5.7-7: PEC_{GW} at 1 m soil depth for glyphosate and its metabolite (second simulation run due to pH dependency)

Use No/crop 00-007/vineyards	Scenario		80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS PELMO 4.4.3	
	Name	**pH-H_2O (1st horizon)**	**Glyphosate**	**AMPA**
	Hamburg	6.4	< 0.001	< 0.001
	Porto	4.9	< 0.001	< 0.001

According to the PEC_{GW} modelling with FOCUS PELMO 4.4.3 a groundwater contamination of the active substance glyphosate at a concentration of ≥ 0.1 µg/L is not expected for the relevant FOCUS groundwater scenarios. For the metabolite AMPA a groundwater concentration of ≥ 0.1 µg/L can be excluded for the relevant FOCUS groundwater scenarios.

5.7.2 Summary of risk assessment for ground water

Results of modelling with FOCUS PELMO 4.4.3 show that the active substance glyphosate is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses. For the metabolite AMPA concentrations of ≥ 0.1 µg/L in groundwater can be excluded in the intended uses.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance glyphosate is between 10^{-5} und 10^{-4} Pa. Hence the active substance glyphosate is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of surface water by the active substance glyphosate due to deposition following volatilization should be considered.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
OECD: KIIA 7.8.3	Heintze, A.	1996	Degradation and metabolism of glyphosate in two water/sediment systems under aerobic conditions - Laboratory test, GLP	Yes	MOD	1)
OECD: KIIIA1 9.6	Anonymus	2011a	FOCUS PELMO Input parameters	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011b	Apple early	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011c	Apple late	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011d	Arable land early	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011e	Arable land late	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011f	Beans field	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011g	Beans vegetables	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011h	Beans vegetable - thiva 2nd	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011i	Oil seed rape early	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011j	Oil seed rape late	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011k	Pea animals	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011l	Spring cereals	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011m	Sugar beet	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011n	Winter cereals	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011o	Winter wheat high rate	Yes	HEL	2)

OECD: KIIIA1 9.6	Anonymus	2011p	FOCUS PEARL Input parameters	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011q	PEARL raw data	Yes	HEL	2)
OECD: KIIIA1 9.6	Anonymus	2011r	FOCUS PECsw Input parameters	Yes	HEL	2)
OECD: KIIIA1 9.7	Anonymus	2011s	Step 1	Yes	HEL	2)
OECD: KIIIA1 9.7	Anonymus	2011t	Step 2	Yes	HEL	2)
OECD: KIIIA1 9.7	Anonymus	2011u	FOCUS PECsw Input parameters	Yes	HEL	2)
OECD: KIIIA1 9.8	Anonymus	2011v	Step 1	Yes	HEL	2)
OECD: KIIIA1 9.8	Anonymus	2011w	Step 2	Yes	HEL	2)

*

1) accepted (study valid and considered for evaluation)

2) not accepted (study not valid and not considered for evaluation)

3) not considered (study not relevant for evaluation)

4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)

5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

KIIA 7 Fate and Behaviour in the Environment – Active Substance

The evaluation of the submitted studies concerning the OECD dossier No KIIA 7.2, KIIA 7.3.1 and KIIA 7.8.3 are presented in two separate documents (see PartB_Section5_CA_7385_Appendix 2.1 and PartB_Section5_CA_7385_Appendix 2.2).

KIIIA1 9 Fate and Behaviour in the Environment – Plant protection product

KIIIA1 9.1.6 Anonymus, 2011a

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	FOCUS PELMO Input parameters
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011b

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Apple early
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011c

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Apple late
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011d

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Arable land early
Date:	28th April 2011

Guideline(s): No (no guidelines available)
Deviations: -
GLP: -
Acceptability: No

KIIIA1 9.1.6 Anonymus, 2011e

Reference: KIIIA1 9.6
Author: Anonymus
Report: Arable land late
Date: 28th April 2011
Guideline(s): No (no guidelines available)
Deviations: -
GLP: -
Acceptability: No

KIIIA1 9.1.6 Anonymus, 2011f

Reference: KIIIA1 9.6
Author: Anonymus
Report: Beans field
Date: 28th April 2011
Guideline(s): No (no guidelines available)
Deviations: -
GLP: -
Acceptability: No

KIIIA1 9.1.6 Anonymus, 2011g

Reference: KIIIA1 9.6
Author: Anonymus
Report: Beans vegetables
Date: 28th April 2011
Guideline(s): No (no guidelines available)
Deviations: -
GLP: -
Acceptability: No

KIIIA1 9.1.6 Anonymus, 2011h

Reference: KIIIA1 9.6
Author: Anonymus
Report: Beans vegetable - thiva 2nd
Date: 28th April 2011
Guideline(s): No (no guidelines available)
Deviations: -
GLP: -
Acceptability: No

KIIIA1 9.1.6 Anonymus, 2011i

Reference: KIIIA1 9.6

Author:	Anonymus
Report:	Oil seed rape early
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011j

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Oil seed rape late
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011k

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Pea animals
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011l

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Spring cereals
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011m

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Sugar beet
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-

Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011n

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Winter cereals
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011o

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Winter wheat high rate
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011p

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	FOCUS PEARL Input parameters
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.6 Anonymus, 2011q

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	PEARL raw data
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

Comments of zRMS

For glyphosate and its metabolite AMPA, the applicant used DT_{50} values as specified in LOEP (2001) as input parameters. However, the underlying data were not evaluated according to FOCUS Degradation Kinetics (2006) as required for deriving PEC_{GW} values. Thus, the studies of the applicant (Anonymus, 2011a-q) are not discussed in detail. Instead new PEC_{GW} values are calculated by the ZRMS by using

DT_{50} input parameters derived from SFO-DT_{50} values calculated according to FOCUS Degradation Kinetics (2006) (see chapter 5.7).

KIIIA1 9.1.7 Anonymus, 2011r

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	FOCUS PECsw Input parameters
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.7 Anonymus, 2011s

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Step 1
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.7 Anonymus, 2011t

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Step 2
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.7 Anonymus, 2011u

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	FOCUS PECsw Input parameters
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.7 Anonymus, 2011v

Reference:	KIIIA1 9.6

Author:	Anonymus
Report:	Step 1
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

KIIIA1 9.1.7 Anonymus, 2011w

Reference:	KIIIA1 9.6
Author:	Anonymus
Report:	Step 2
Date:	28th April 2011
Guideline(s):	No (no guidelines available)
Deviations:	-
GLP:	-
Acceptability:	No

Comments of zRMS

The input parameters DT_{50} used for Step 1 and Step 2 assessments of glyphosate and AMPA were derived from LOEP (2001). However, the underlying data were not evaluated according to FOCUS Degradation Kinetics (2006) as required for deriving PEC_{SW} values. Thus, the studies of the applicant (Anonymus, 2011r-w) are not discussed in detail. Instead new PEC_{SW} values are calculated by the ZRMS by using DT_{50} input parameters derived from SFO-DT_{50} values calculated according to FOCUS Degradation Kinetics (2006) (see chapter 5.6).

Appendix 3 Table of Intended Uses justification and GAP tables

Crop and/ or situation (a)	Zone	Product code	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		
NNNAC Field crops	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Post harvest until sowing	1	--	0,504 – 1,8	100 – 200	1.080 - 1.800	Covered by conditions of use and / or growing period between application and harvest	Wait 4 days until tillage
YACKR Stubble	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Stubble application after weed germination	1	--	0,225 – 0,9	200 - 300	0.675 – 1.800	Covered by the vegetation period	
NNNOK Pome fruit	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm weed height onwards	1	--	0,45 – 1,8	100 – 400	1.800	42	Strip application. Best control of 1UMBF *(Umbelliferae)* at flowering.

Crop and/ or situation (a)	Zone	Product code	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		
NNNOS Stone fruit	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm weed height onwards	1	--	0,45 – 1,8	100 – 400	1.800	42	Strip application. Best control of 1UMBF *(Umbellifer ae*) at flowering.
NNNOK Pome fruit	Member States of Zone B	Glyphosate 450 SL	F	CONAR *Convolvulus arvensis*	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm height of CONAR onwards	1	--	0,9 – 3,6	100 – 400	3.600	42	Strip application.
VITVI *Vitis vinifera*	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 10 – 20 cm weed height onwards	1-2	90	0,45 – 1,8	100 – 400	1.800	30	Strip application from 4th year plant stand onwards. Best control of 1UMBF (Umbellifer ae) at flowering.

Crop and/ or situation (a)	Zone	Product code	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		
VITVI *Vitis vinifera*	Member States of Zone B	Glyphosate 450 SL	F	CONAR *Convolvulus arvensis*	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm height of CONAR onwards	1	--	0,9 – 3,6	100 – 400	3.600	30	Strip application from 4th year plant stand onwards.
YCERE Cereals	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones Including AGRRE *(Elytrigia repens*)	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 87-89	1	--	0,281 – 1,8	100 – 400	1.125 - 1.800	7	Including desiccation, lodged cereals and additional harvest facilitation, Ex brewing and seed production
BRSNW Oilseed rape (winter) PIBSA Field pea	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 87 – 89	1	--	0,375 - 0,5625	200 - 300	1.125	14	Additional harvest facilitation and crop desiccation Don’t apply on seed plantation

Crop and/ or situation (a)	Zone	Product code	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		
BRSNW Oilseed rape (winter)	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Before crop emergence BBCH 00	1	--	0,375 - 0,5625	200 - 300	1.125	Covered by the vegetation period	
BEAVA *Beta vulgaris*	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Before crop emergence BBCH 00	1	--	0,24 - 0,36	200 - 300	0.720	Covered by the vegetation period	
NNNFW Grassland	Member States of Zone B	Glyphosate 450 SL	F		SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Plant height approx 15 cm, AGRRE 3 to 4 leaves per nod, 1UMBF in full florescence	1	--	0,45 – 1,8	100 – 400	1.800	Covered by conditions of use and / or growing period between application and harvest	Re-sowing (renewal) of grassland

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

Appendix 2.1 Detailed evaluation of studies relied upon

KIIA 7 Fate and Behaviour in the Environment – Active Substance

KIIA 7.2 Galicia and Flückiger (1993)

Reference:	KIIA 7.2
Author(s):	Galicia and Flückiger
Report:	Degradation of 14C-Glyphosate in three soils incubated under aerobic conditions
Date:	07.04.1993
Guideline(s):	Richtlinie Teil IV, 4-1 Biologische Bundesanstalt für Land- und Forstwirtschaft der Bundesrepublik Deutschland, " Verbleib von Pflanzenschutzmitteln im Boden – Abbau, Umwandlung, Metabolismus", Dezember 1986
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was already evaluated in the DAR (1998). However, since the kinetic evaluation in the DAR is not according to FOCUS Degradation Kinetics (2006), the degradation rates were recalculated by the zRMS with FOCUS_DEGKIN v2 (SFO and FOMC) and KinGUI 2 (DFOP). The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 1: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Speyer 2.1 / Sand	83.4	0.049	14.1	46.8	12.3	-
Speyer 2.2 / Sand	70.2	0.019	35.8	118.8	24.2	-
Speyer 2.3 / Loamy Sand	90.4	0.113	6.2	20.4	8.0	-

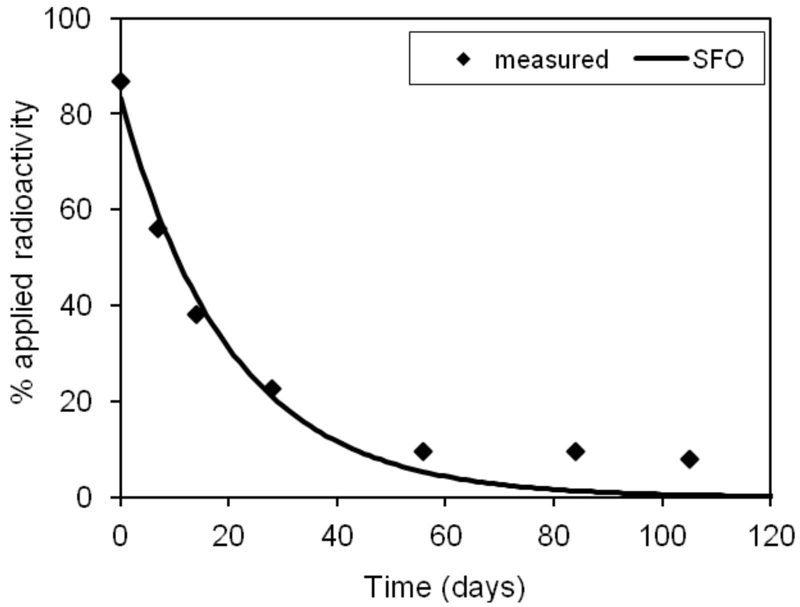


Figure A 1: **Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Speyer 2.1 / Sand**

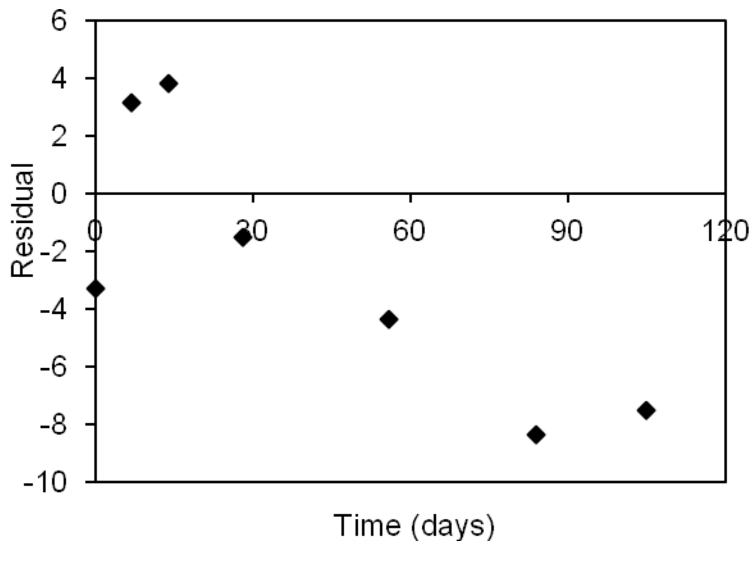


Figure A 2: **Residuals vs. time for Glyphosate using SFO kinetics, Speyer 2.1 / Sand**

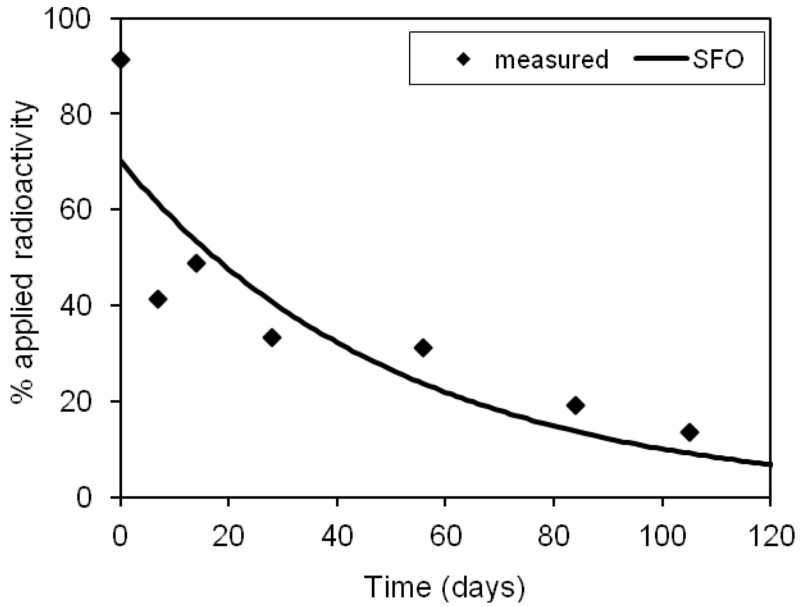


Figure A 3: **Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Speyer 2.2 / Sand**

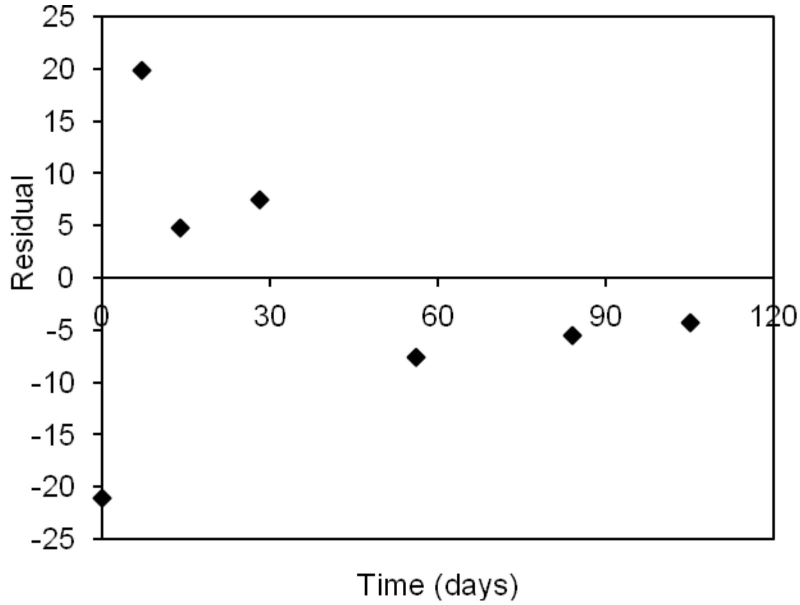


Figure A 4: **Residuals vs. time for Glyphosate using SFO kinetics, Speyer 2.2 / Sand**

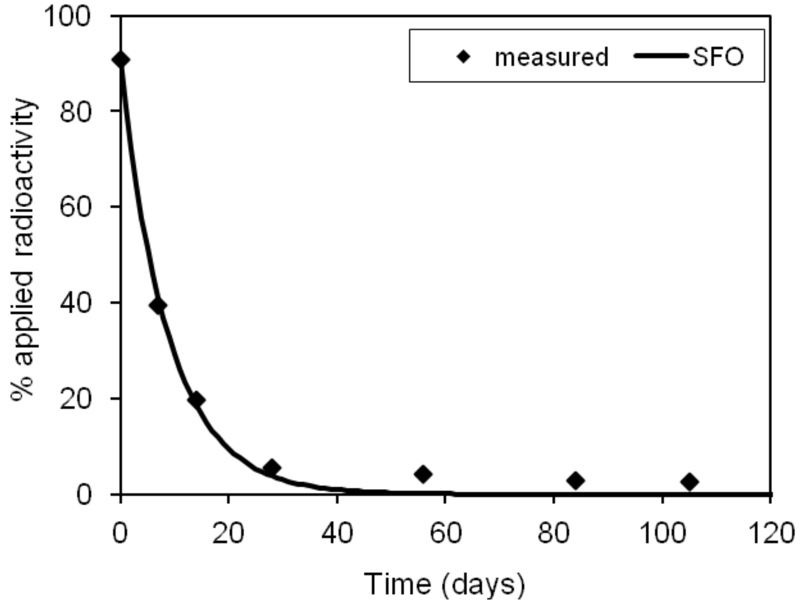


Figure A 5: **Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Speyer 2.3 / Loamy Sand**

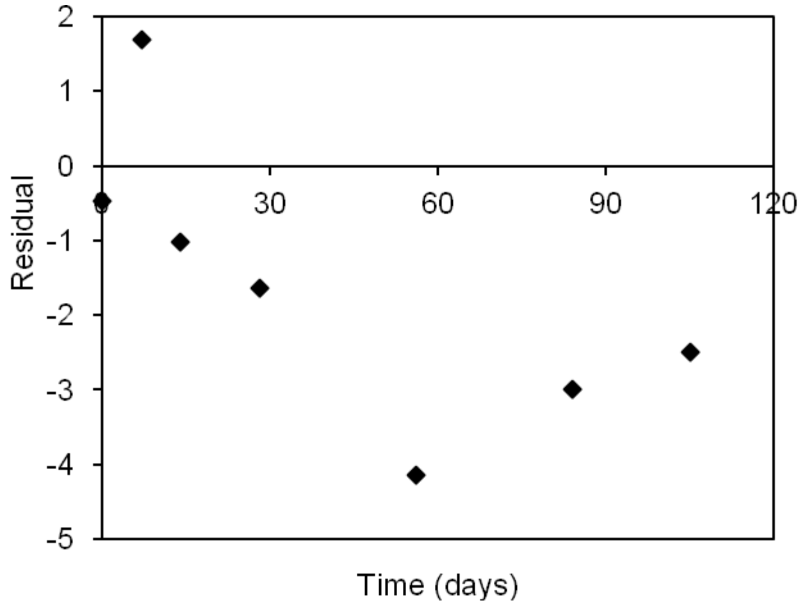


Figure A 6: **Residuals vs. time for Glyphosate using SFO kinetics, Speyer 2.3 / Loamy Sand**

The degradation of Glyphosate in the three soils is not well described by SFO kinetics, as the residues at the late sampling dates are underestimated by the model.

The degradation was therefore calculated with FOMC kinetics (Speyer 2.1 and Speyer 2.3) or, in case Glyphosate does not degrade to 10 % of the initial amount within the study period, with DFOP kinetics (Speyer 2.2). The results are shown below.

Table A 2: **Kinetic evaluation for Glyphosate using FOMC / DFOP kinetics**

Speyer 2.1 / Sand (FOMC)

M_0	alpha	beta	DT_{50}	DT_{90}	χ^2 error	DT_{50} SFO 1)	Visual Assessment.	
87.0	**1.343**	**16.846**	**11.4**	**76.7**	**4.0**	**23.1**	+	
Speyer 2.2 / Sand (DFOP)								
M_0	**k_{fast}**	**k_{slow}**	**g**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO 2)**	**Visual Assessm ent.**
91.3	**2.297**	**0.011**	**0.458**	**7.5**	**156.8**	**8.7**	**63.0**	+
Speyer 2.3 / Loamy Sand (FOMC)								
M_0	**alpha**	**beta**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO 1)**	**Visual Assessment.**	
91.1	**2.529**	**17.234**	**5.4**	**25.6**	**5.9**	**7.7**	+	

1) Recalculated (DT_{90} / 3.32)

2) Recalculated (from k_{slow})

HS kinetics were also calculated for Speyer 2.2, resulting in the same endpoints as the DFOP kinetics (DT_{50} = 7.5 d, DT_{90} = 156.9 d, χ^2 error = 8.7). The results are not further presented here.

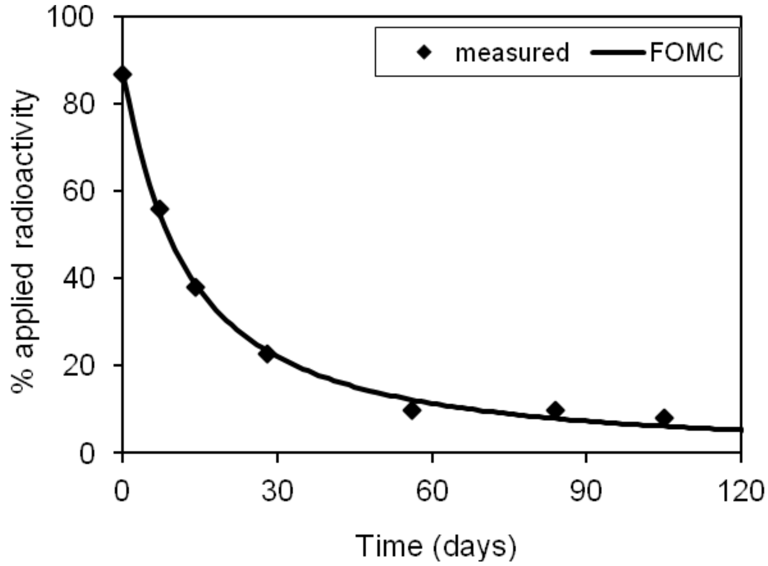


Figure A 7: Measured & predicted residues vs. time for Speyer 2.1 / Sand (FOMC)

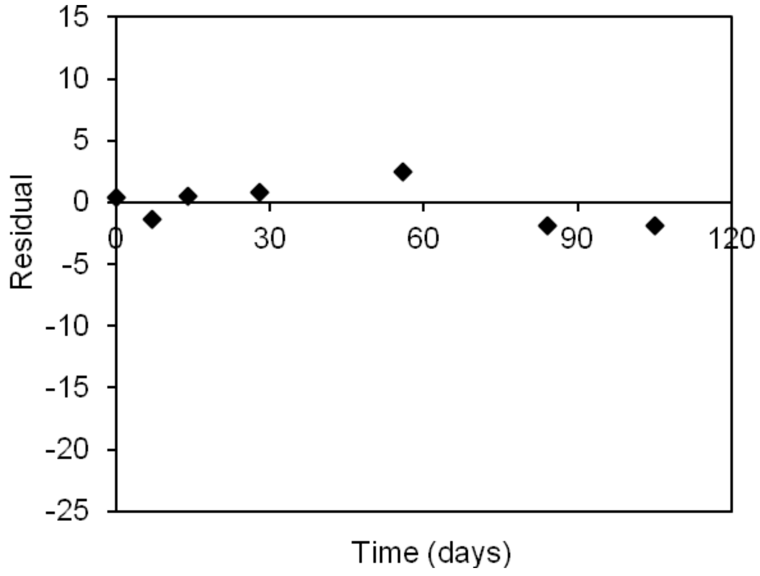


Figure A 8: **Residuals vs. time for Speyer 2.1 / Sand (FOMC)**

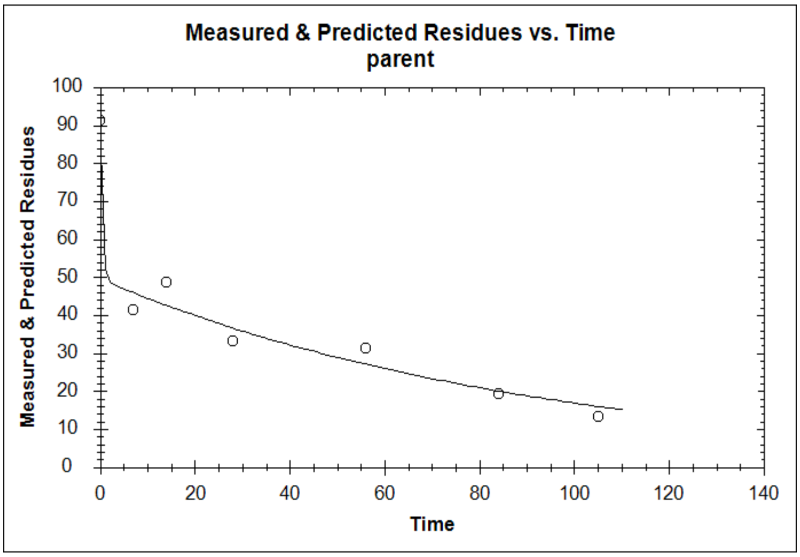


Figure A 9: **Measured & predicted residues vs. time for Speyer 2.2 / Sand (DFOP)**

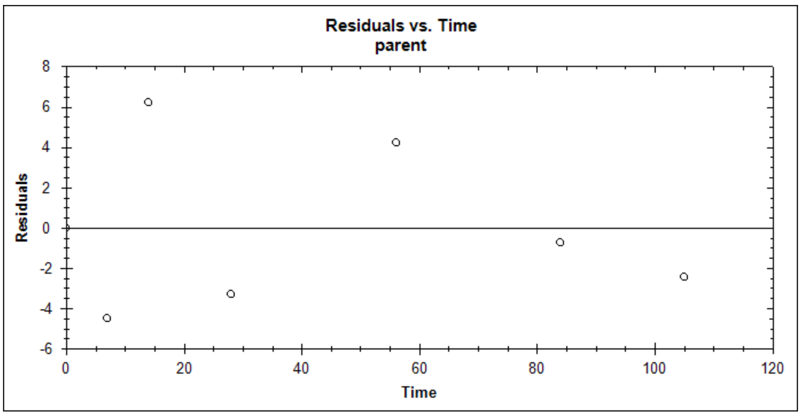


Figure A 10: **Residuals vs. time for Speyer 2.2 / Sand (DFOP)**

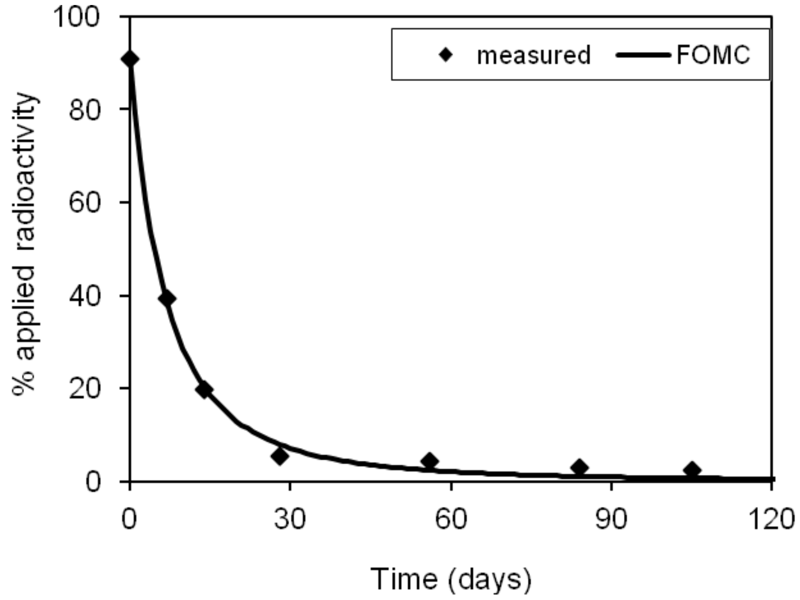


Figure A 11: Measured & predicted residues vs. time for Speyer 2.3 / Loamy Sand (FOMC)

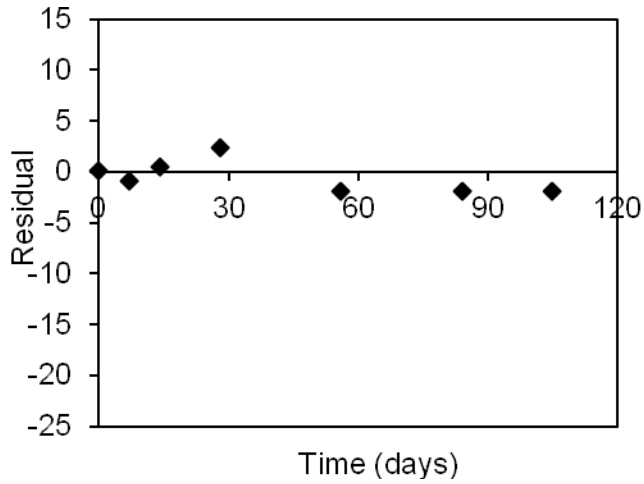


Figure A 12: Residuals vs. time for Speyer 2.3 / Loamy Sand (FOMC)

<u>*Conclusion*</u>

DFOP and FOMC kinetics show the best fit for the degradation of glyphosate in the three tested soils.

<u>*Comments of zRMS*</u>

Not applicable (evaluation performed by the zRMS).

KIIA 7.2 Galicia and Morgenroth (1993)

Reference:	KIIA 7.2
Author:	Galicia, H. and Morgenroth, U.
Report:	Degradation and metabolism of 14C-Glyphosate in soil incubated under aerobic conditions
Date:	06.04.1993

Guideline(s):	US EPA 540/90-82-021 Subdivision N, Section 162-01; BBA Richtlinie Teil IV, 4-1
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was already evaluated in the DAR (1998). However, since the kinetic evaluation in the DAR is not according to FOCUS Degradation Kinetics (2006), the degradation rates were recalculated by the zRMS with KinGUI 2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 3: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Les Evouettes / silt loam	13.6	0.0173	40.0	132.8	13.6	-

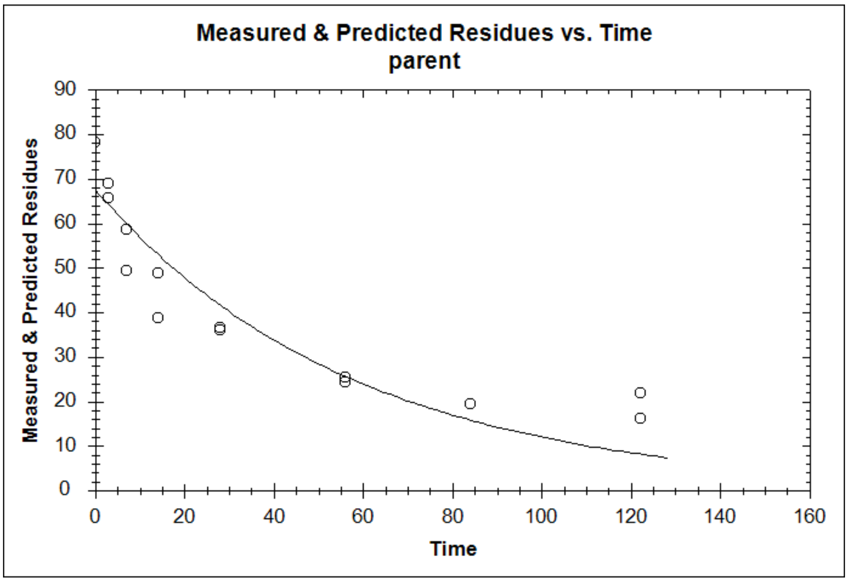


Figure A 13: Measured & predicted residues vs. time Les Evouettes / silt loam (SFO)

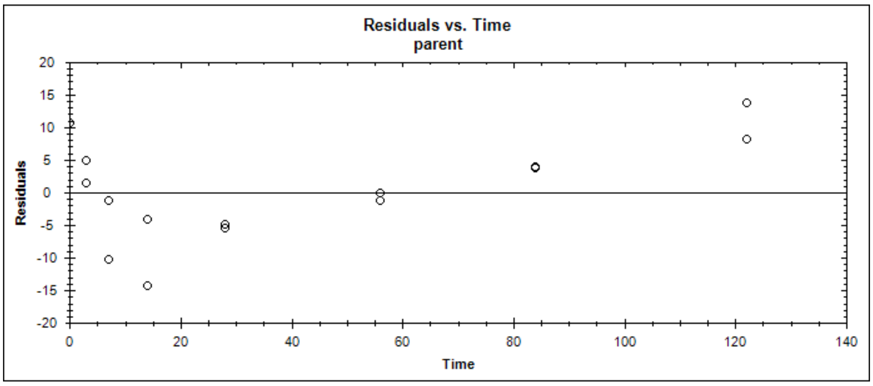


Figure A 14: Residuals vs. time, Les Evouettes / silt loam (SFO)

The degradation of Glyphosate in the silt loam is not well described by SFO kinetics, as the residues at the late sampling dates are underestimated by the model. As Glyphosate did not degrade to 10 % of the initial amount within the study period, the degradation was therefore modeled calculated with with DFOP kinetics.

Table A 4: Kinetic evaluation for Glyphosate using DFOP kinetics

Les Evouettes / silt loam (DFOP)								
M_0	**k_{fast}**	**k_{slow}**	**g**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment.**
78.3	0.109	0.007	0.504	18.9	232.3	3.4	99.0	+

1) Recalculated (from k_{slow})

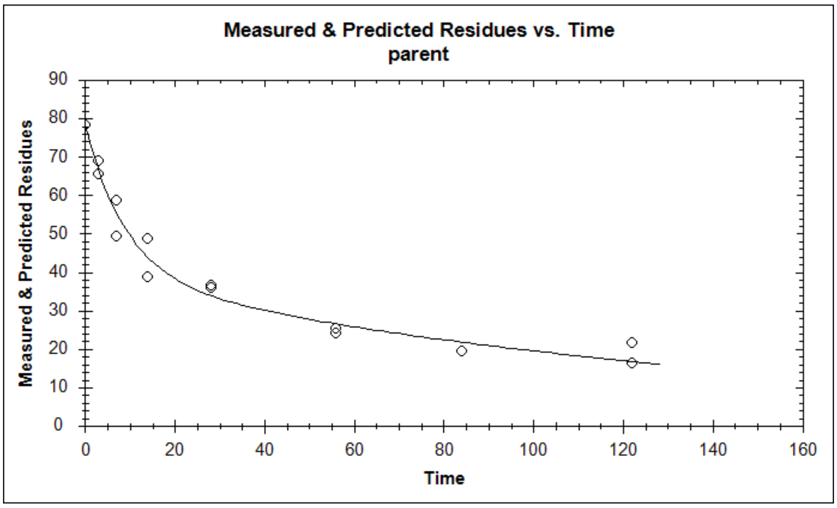


Figure A 15: Measured & predicted residues vs. time for Les Evouettes / silt loam (DFOP)

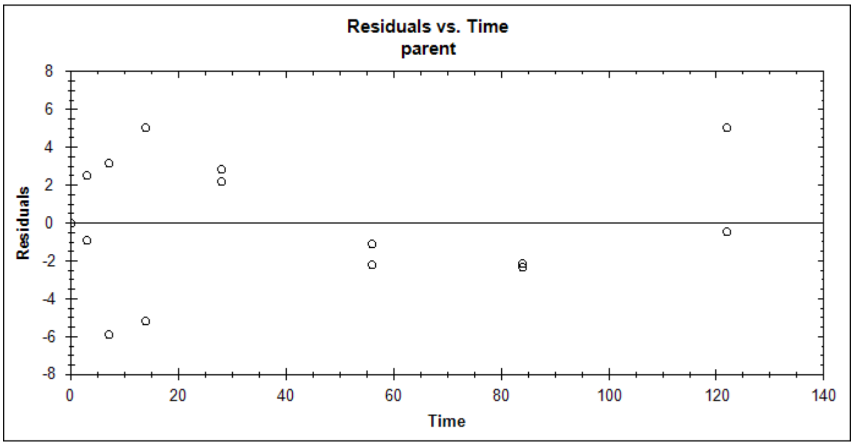


Figure A 16: Residuals vs. time for Les Evouettes / silt loam (DFOP)

Conclusion

DFOP kinetics show the best fit for the degradation of glyphosate in the tested soil.

Comments of zRMS

Not applicable (evaluation performed by the zRMS).

KIIA 7.2 Kesterson and Atkins (1991)

Reference:	KIIA 7.2
Author:	Kesterson, A.L. and Atkins, R.H.
Report:	Aerobic Metabolism of [14C] Glyphosate in Sandy Loam and Silt Loam Soils with Biometer Flask
Date:	02.01.1991
Guideline(s):	US EPA 540/90-82-021 Subdivision N, Section 162-01
GLP:	No
Acceptability:	Yes (see comments below)

Materials and methods

The study was already evaluated in the DAR (1998) and considered as not valid. The main concerns were the study temperature of 25°C instead of 20°C and that the microbiological activity was not tested. The first point can be overcome by temperature normalization. The second is considered as not leading to insufficient conservative endpoints, as a low activity would lead to slower degradation. Therefore, the study was included in the assessment and degradation rates were calculated according to FOCUS Degradation Kinetics (2006) by the zRMS with FOCUS_DEGKIN v2 (SFO parent) and KinGUI 2 (FOMC parent combined with SFO metabolilte). The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 5: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Sandy Loam	45.2	0.289	2.4	8.0	16.9	-
Silt Loam	67.4	0.272	2.5	8.5	10.3	-

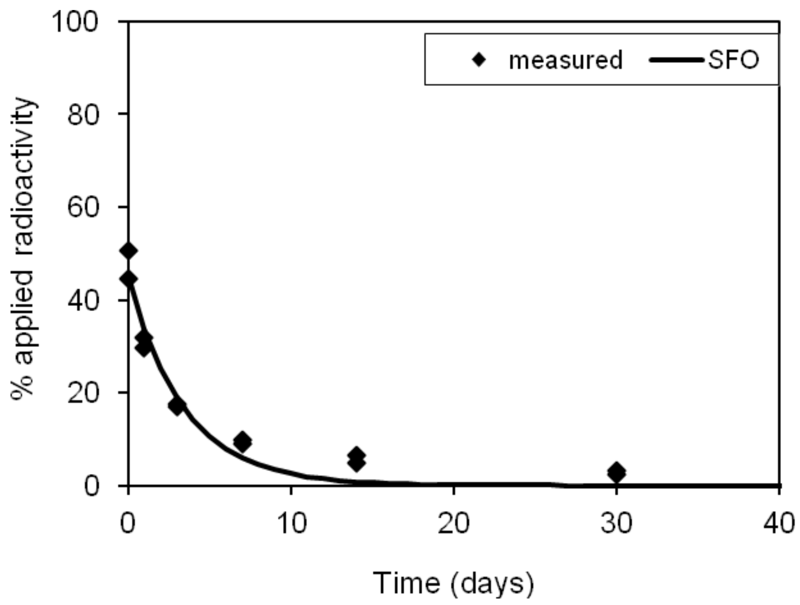


Figure A 17: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Sandy Loam

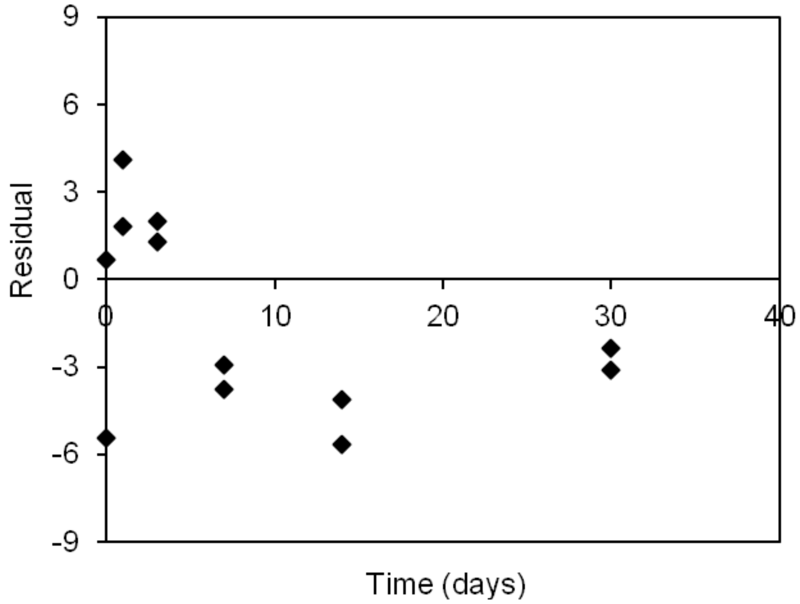


Figure A 18: Residuals vs. time for Glyphosate using SFO kinetics, Sandy Loam

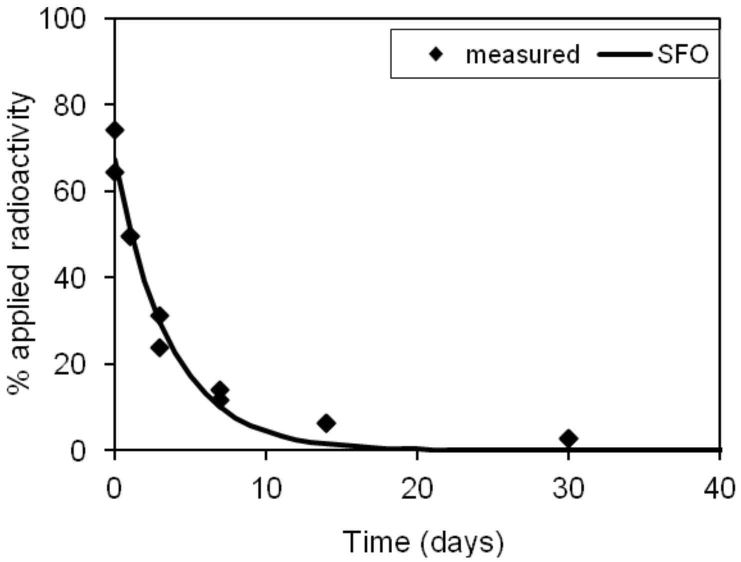


Figure A 19: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Silt Loam

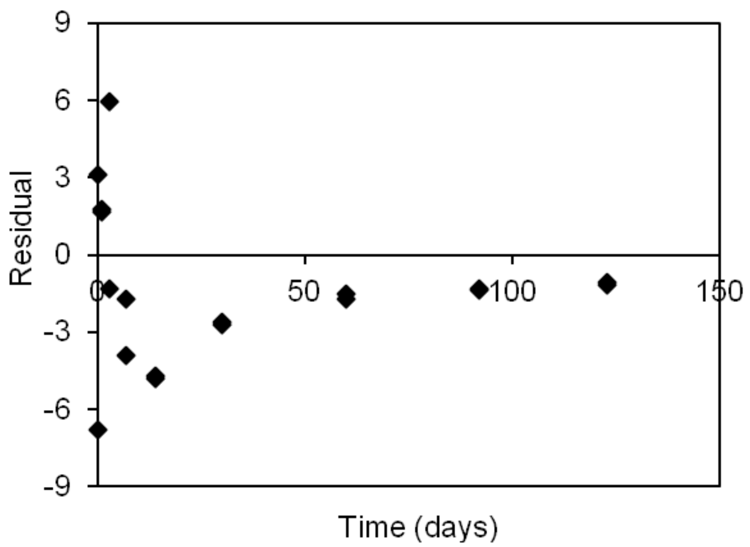


Figure A 20: Residuals vs. time for Glyphosate using SFO kinetics, Silt Loam

The degradation of Glyphosate in the two soils is not well described by SFO kinetics, as the residues at the late sampling dates are underestimated by the model.

The degradation rates were calculated with FOMC kinetics as residues below 10 % of the initial amount were reached within the study period.

Table A 6: Kinetic evaluation for Glyphosate using FOMC kinetics

Sandy Loam							
M_0	**alpha**	**beta**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment.**
47.8	0.913	1.512	1.7	29.9	3.6	9.0	+
Silt Loam							
M_0	**alpha**	**beta**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment.**
70.0	1.518	3.593	2.1	12.8	3.4	3.9	+

1) Recalculated (DT_{90} / 3.32)

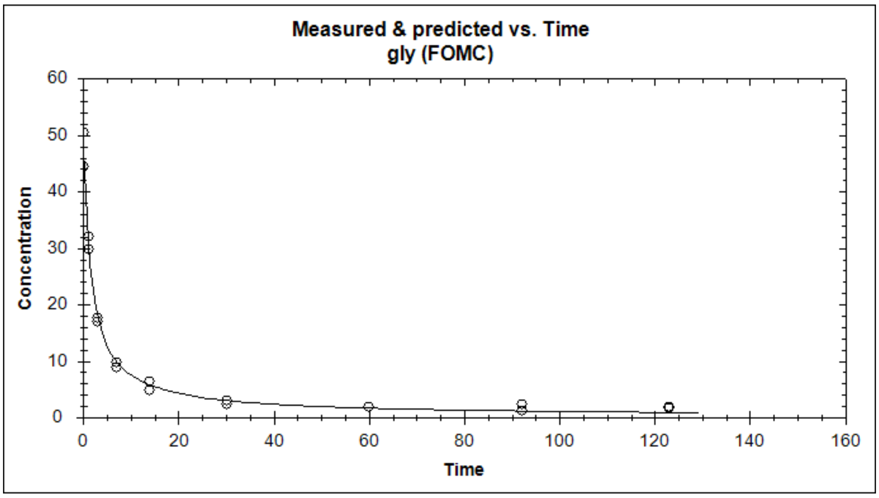


Figure A 21: Measured & predicted residues vs. time for Sandy Loam (FOMC)

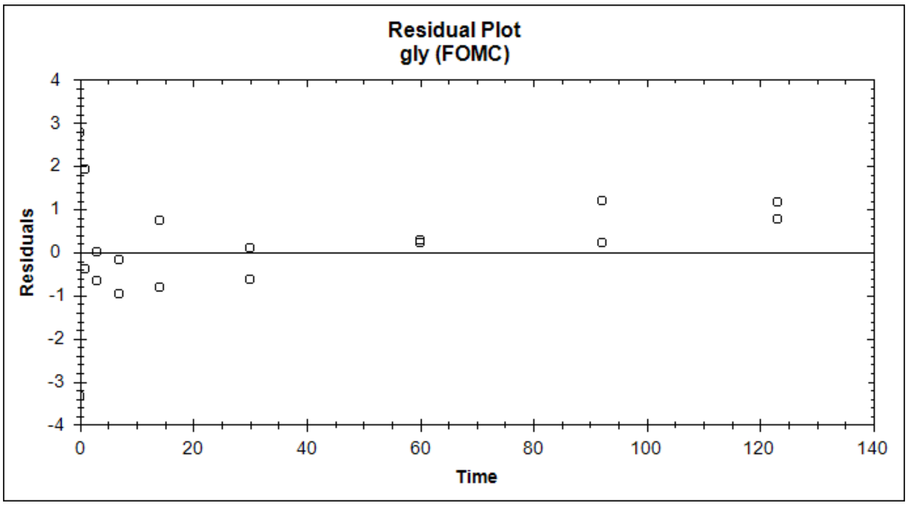


Figure A 22: Residuals vs. time for Sandy Loam (FOMC)

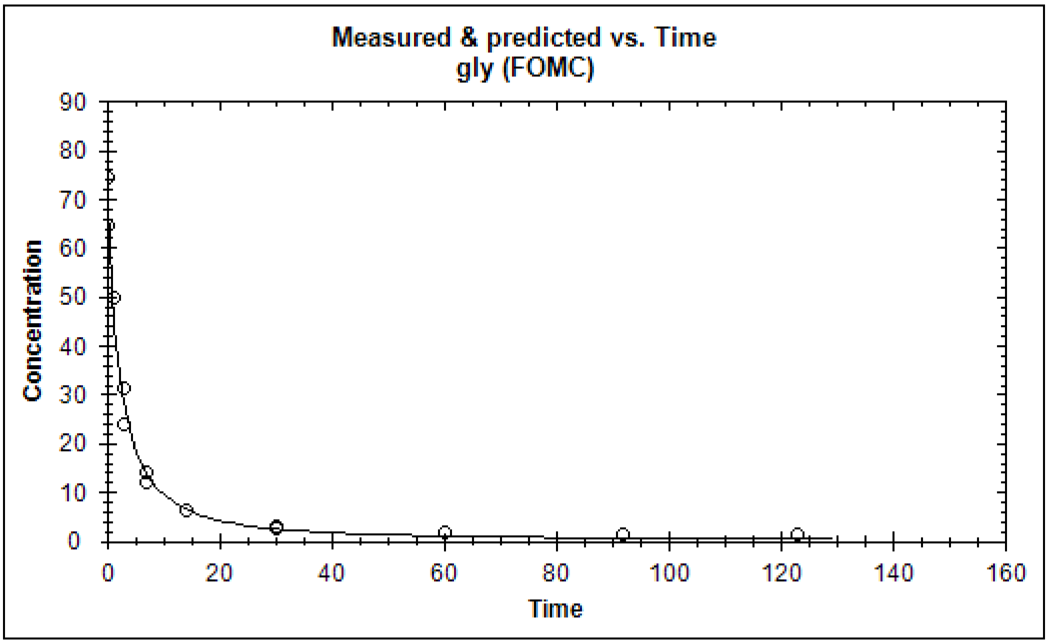


Figure A 23: Measured & predicted residues vs. time for Silt Loam (FOMC)

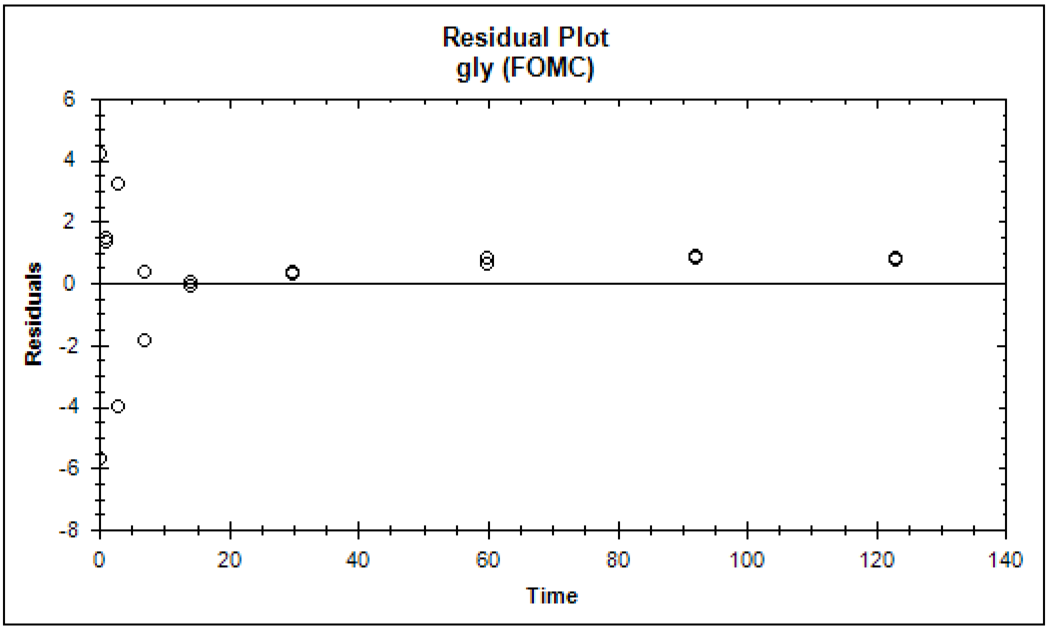


Figure A 24: Residuals vs. time for Silt Loam (FOMC)

The degradation of the metabolite AMPA was included by using the SFO model with the parent degrading according to FOMC. Results of the kinetic evaluation of AMPA are summarized in Table A 1. The graphics are shown further down.

Table A 7: Kinetic evaluation forAMPA using SFO kinetics

Soil	FF	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Sandy Loam	0.81	0.023	29.9	99.5	30.1	-
Silt Loam	0.56	0.017	39.7	131.8	25.9	+

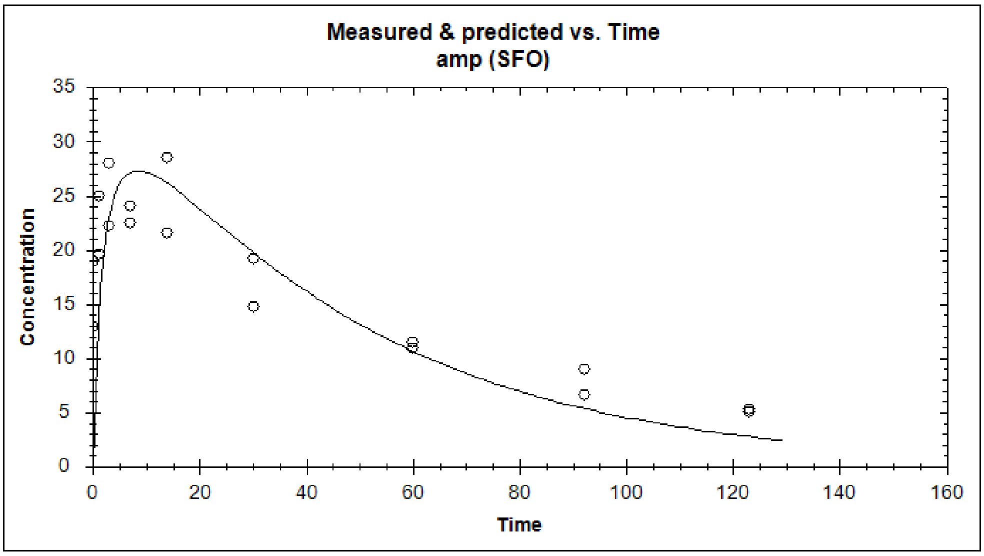


Figure A 25: Measured & predicted residues vs. time for AMPA using SFO kinetics (parent FOMC), Sandy Loam

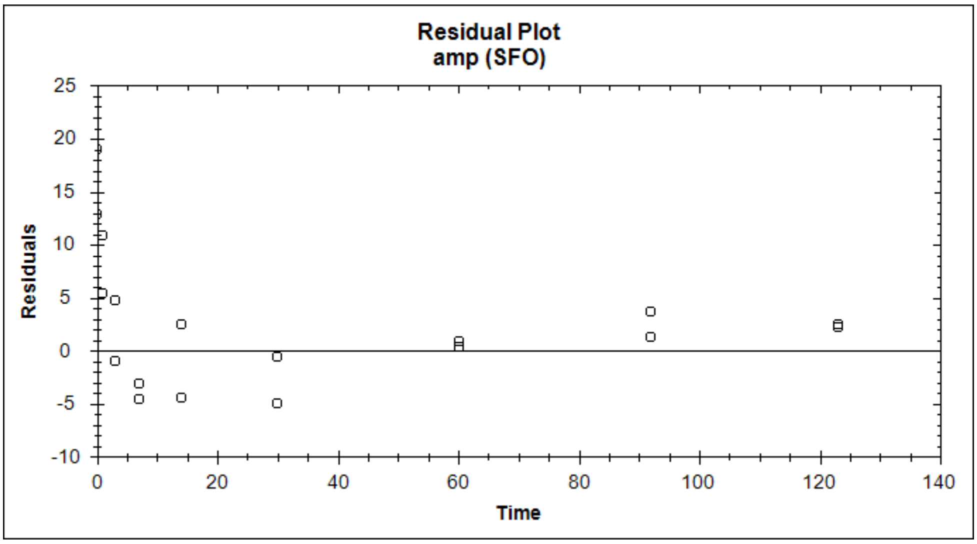


Figure A 26: **Residuals vs. time for AMPA using SFO kinetics (parent FOMC), Sandy Loam**

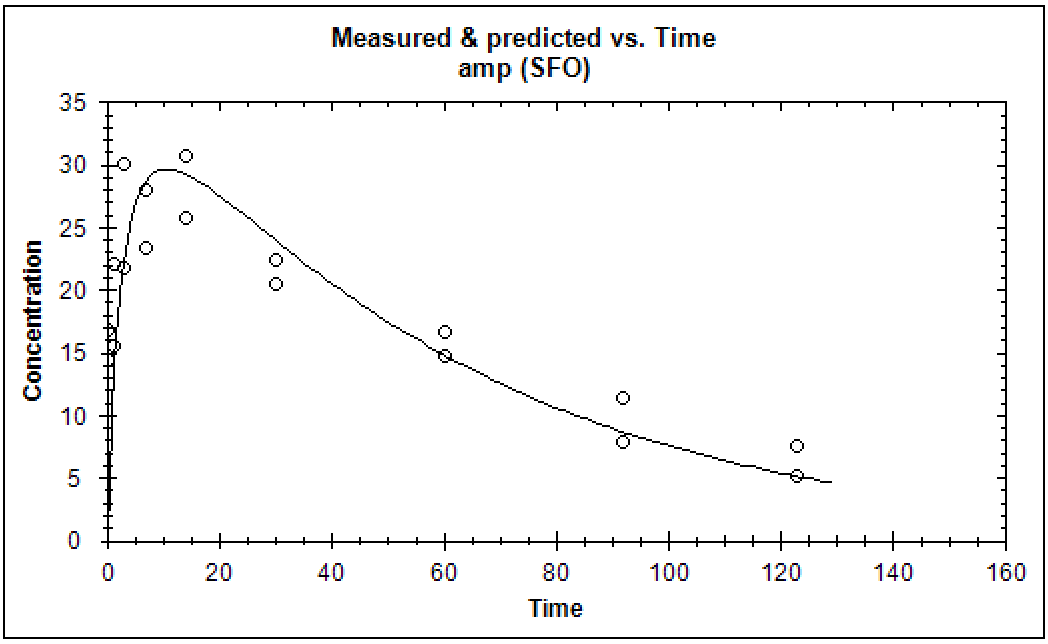


Figure A 27: **Measured & predicted residues vs. time for AMPA using SFO kinetics (parent FOMC), Silt Loam**

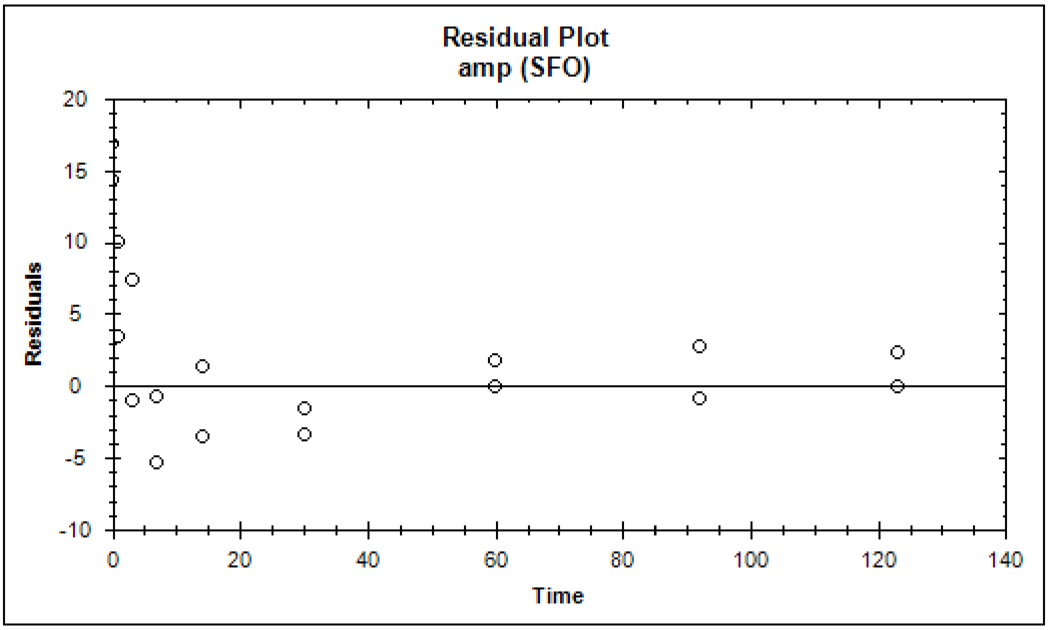


Figure A 28: Residuals vs. time for AMPA using SFO kinetics (parent FOMC), Silt Loam

Conclusion

FOMC kinetics show the best fit for the degradation of glyphosate in the two tested soils, the degradation of ampa can be well described by SFO kinetics in case of the silt loam, whereas the result for the sandy loam is not satisfactory due to the poor fit (visual assessment and calculated error).

Comments of zRMS

Not applicable (evaluation performed by the zRMS).

KIIA 7.3.1 Schulz (1992a)

Reference:	KIIA 7.3.1
Author:	Schulz, H.
Report:	Field Soil Dissipation Rate Determination of Glyphosate 360, (Egerkingen, Switzerland)
Date:	14.09.1992
Guideline(s):	BBA Richtlinie Teil IV, 4-1
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was already evaluated in the DAR (1998). However, since the kinetic evaluation in the DAR is not according to FOCUS Degradation Kinetics (2006), the degradation rates were recalculated by the zRMS with FOCUS_DEGKIN v2 (SFO and FOMC) and KinGUI 2 (DFOP). The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 8: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0 (% 0d)	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment

Egerkingen (CH), Clay Loam,	81.0	0.025	27.6	91.6	23.8	-

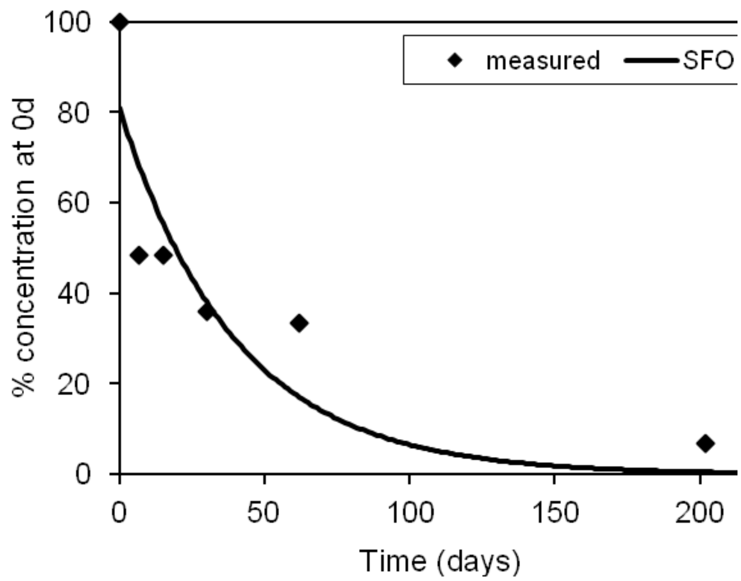


Figure A 29: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Egerkingen (CH), Clay Loam

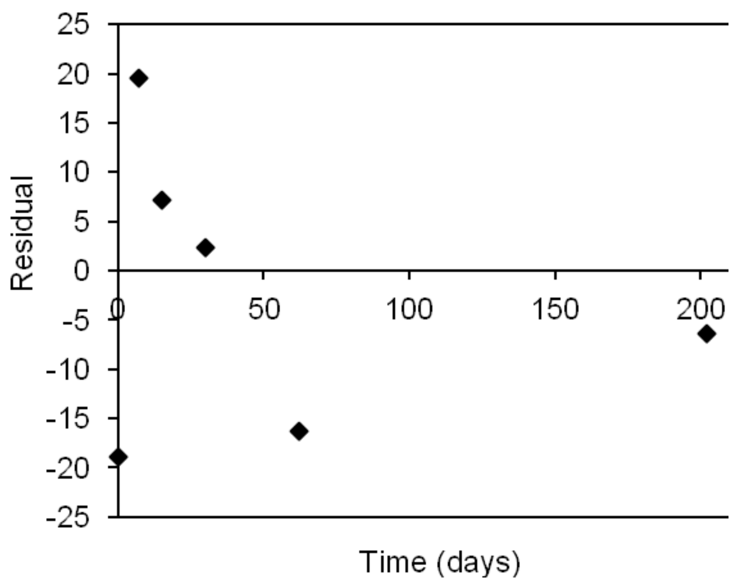


Figure A 30: Residuals vs. time for Glyphosate using SFO kinetics, Egerkingen (CH), Clay Loam

The degradation of Glyphosate in the clay loam soil is not well described by SFO kinetics. As Glyphosate did degrade to below 10 % of the initial amount within the study period, the degradation was simulated using FOMC kinetics.

Table A 9: Kinetic evaluation for Glyphosate using FOMC kinetics

Egerkingen (CH), Clay Loam

M_0 (% 0d)	alpha	beta	DT_{50}	DT_{90}	χ^2 error	DT_{50} SFO[1)]	Visual Assessment.
99.6	0.370	1.727	9.5	871.3	11.9	363.4	-

1) Recalculated (DT_{90} / 3.32)

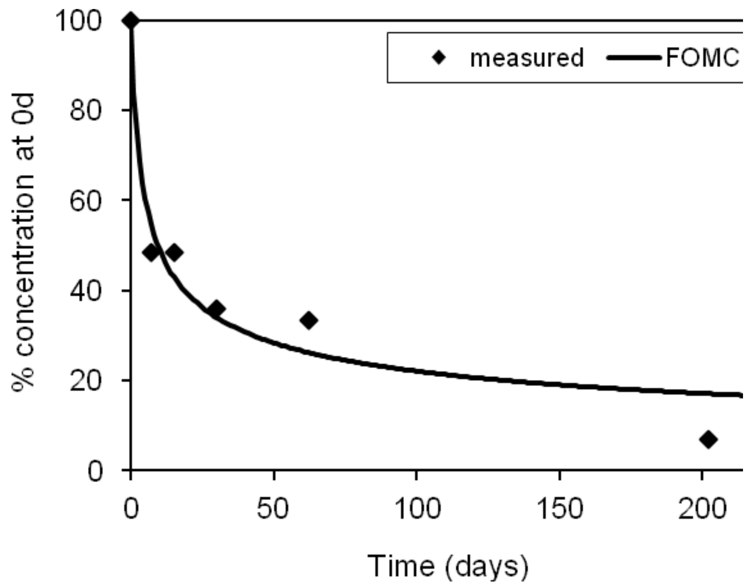


Figure A 31: Measured & predicted residues vs. time for Egerkingen (CH), Clay Loam (FOMC)

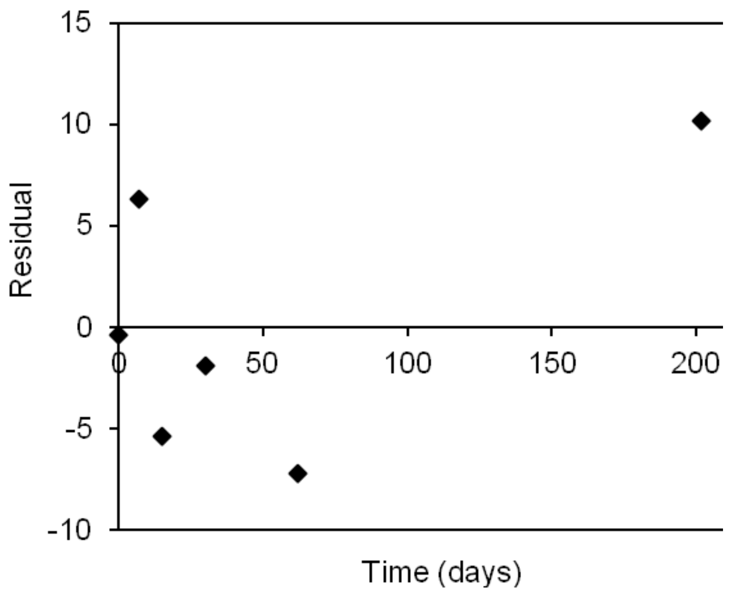


Figure A 32: Residuals vs. time for Egerkingen (CH), Clay Loam (FOMC)

Due to the poor fit of the FOMC model, the DFOP model was additionally tested.

Table A 10: Kinetic evaluation for Glyphosate using DFOP kinetics

Egerkingen (CH), Clay Loam								
M_0 (mg/kg)	k_{fast}	k_{slow}	g	DT_{50}	DT_{90}	χ^2 error	DT_{50} SFO[1)]	Visual Assessment.
1.32	1.424	0.009	0.47	5.2	184.4	5.6	77.2	+

1) Recalculated (from k_{slow})

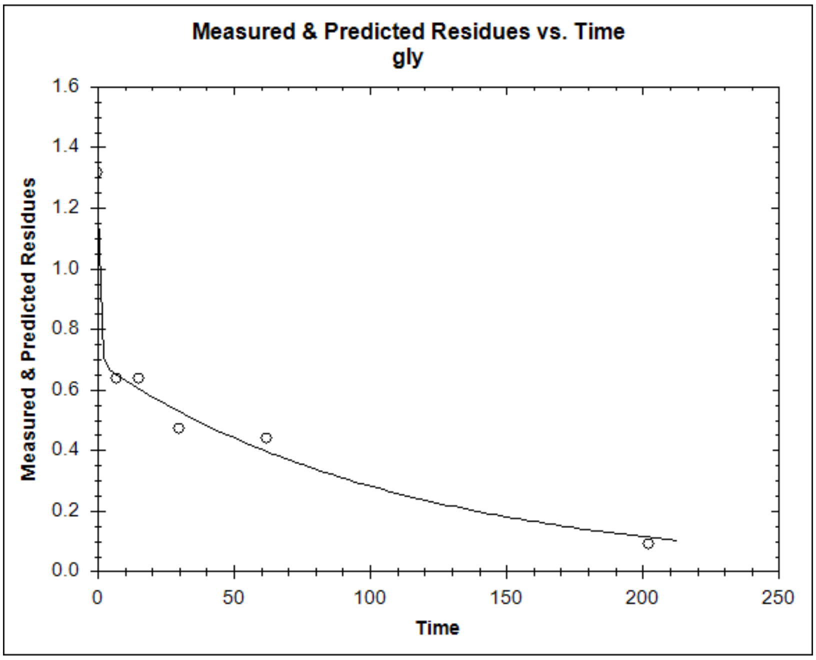


Figure A 33: Measured & predicted residues vs. time for Egerkingen (CH), Clay Loam (DFOP)

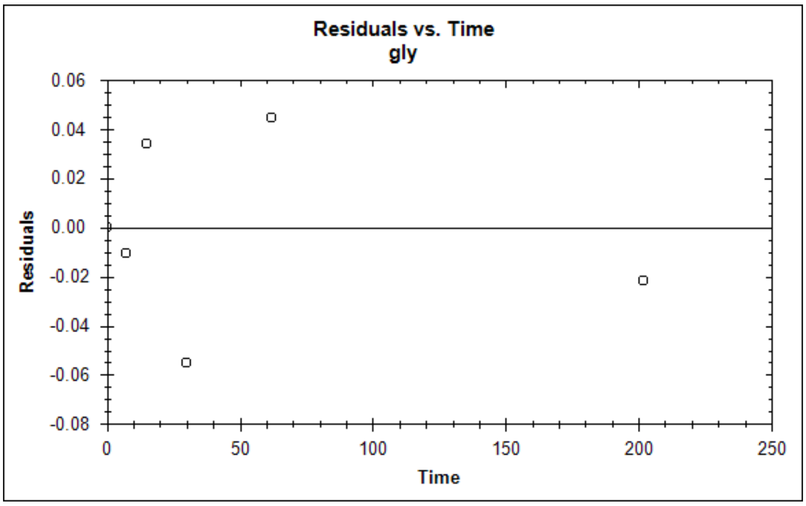


Figure A 34: Residuals vs. time for Egerkingen (CH), Clay Loam (DFOP)

Conclusion

DFOP kinetics show the best fit for the degradation of glyphosate in the tested soil.

Comments of zRMS

Not applicable (evaluation performed by the zRMS).

KIIA 7.3.1 Schulz (1992b)

Reference:	KIIA 7.3.1
Author:	Schulz, H.
Report:	Field Soil Dissipation Rate Determination of Glyphosate 360 (Bad Krozingen, Germany)
Date:	19.03.1992
Guideline(s):	BBA Richtlinie Teil IV, 4-1
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was already evaluated in the DAR (1998). However, since the kinetic evaluation in the DAR is not according to FOCUS Degradation Kinetics (2006), the degradation rates were recalculated by the zRMS with KinGUI 2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 11: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0 (mg/kg)	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Bad Krotzingen (DE), Sandy Loam	2.32	0.086	8.0	26.7	22.7	-

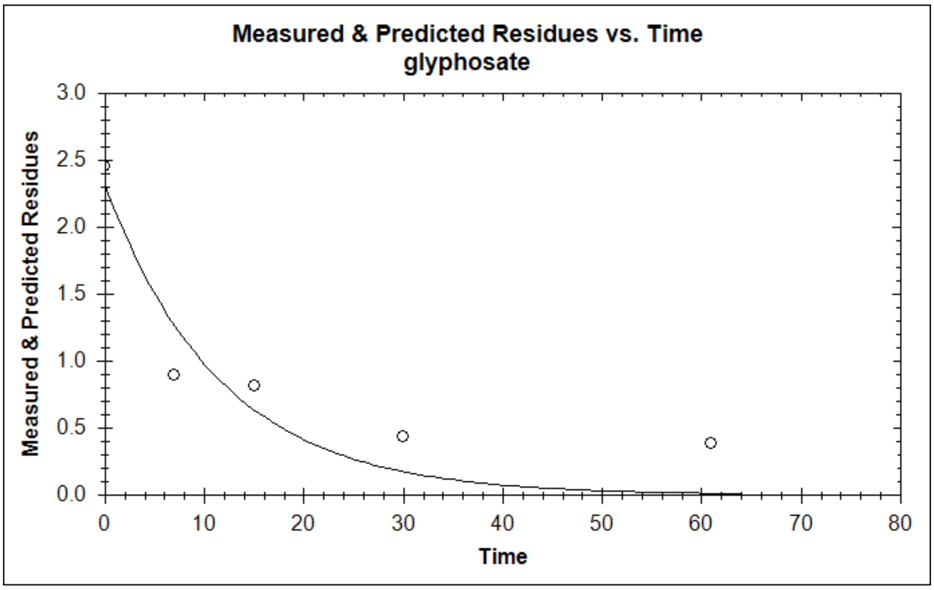


Figure A 35: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Bad Krotzingen (DE), Sandy Loam

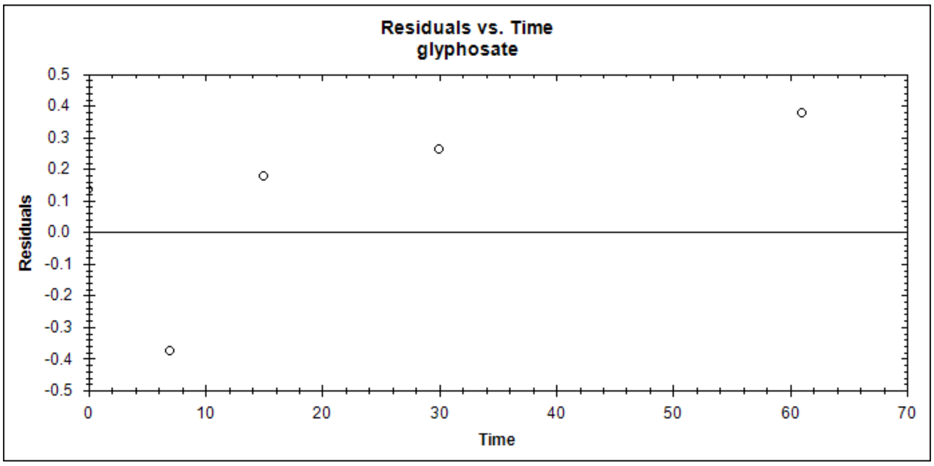


Figure A 36: Residuals vs. time for Glyphosate using SFO kinetics, Bad Krotzingen (DE), Sandy Loam

The degradation of Glyphosate in the clay loam soil is not well described by SFO kinetics. As Glyphosate did not degrade to below 10 % of the initial amount within the study period, the degradation was simulated using DFOP kinetics.

Table A 12: Kinetic evaluation for Glyphosate using DFOP kinetics

Bad Krotzingen (DE), Sandy Loam								
M_0	**k_{fast}**	**k_{slow}**	**g**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessm ent.**
2.46	0.549	0.019	0.60	2.9	74.8	8.3	37.4	+

1) Recalculated (from k_{slow})

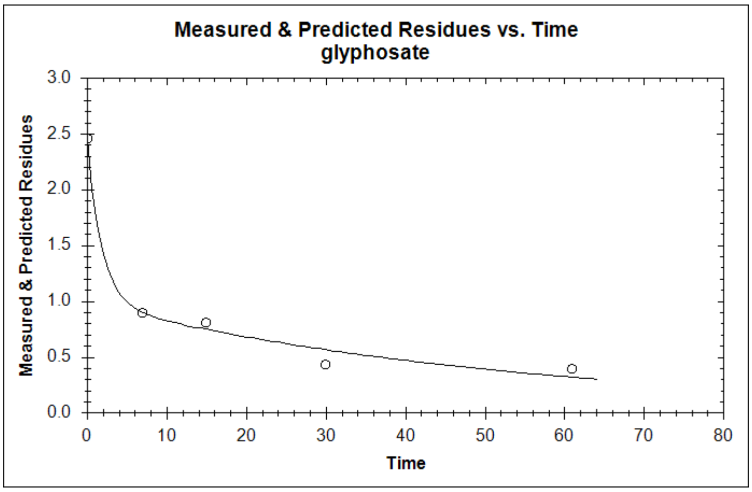


Figure A 37: Measured & predicted residues vs. time for Bad Krotzingen (DE), Sandy Loam (DFOP)

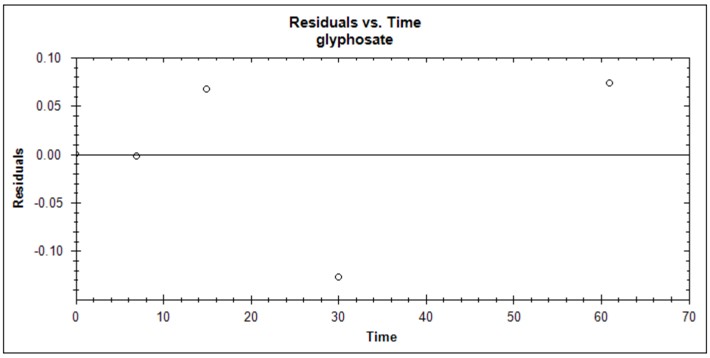


Figure A 38: Residuals vs. time for Bad Krotzingen (DE), Sandy Loam (DFOP)

Conclusion

DFOP kinetics show an acceptable fit for the degradation of glyphosate in the tested soil.

Comments of zRMS

Not applicable (evaluation performed by the zRMS).

KIIA 7.3.1 Schulz (1992c)

Reference:	KIIA 7.3.1
Author:	Schulz, H.
Report:	Field Soil Dissipation Rate Determination of Glyphosate 360, (Diegten, Switzerland)
Date:	19.03.1992
Guideline(s):	BBA Richtlinie Teil IV, 4-1
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was already evaluated in the DAR (1998). However, since the kinetic evaluation in the DAR is not according to FOCUS Degradation Kinetics (2006), the degradation rates were recalculated by the zRMS with FOCUS_DEGKIN v2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 13: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0 (mg/kg)	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Dietgen (CH), Sandy Clay Loam	1.71	0.086	8.1	26.9	24.9	-

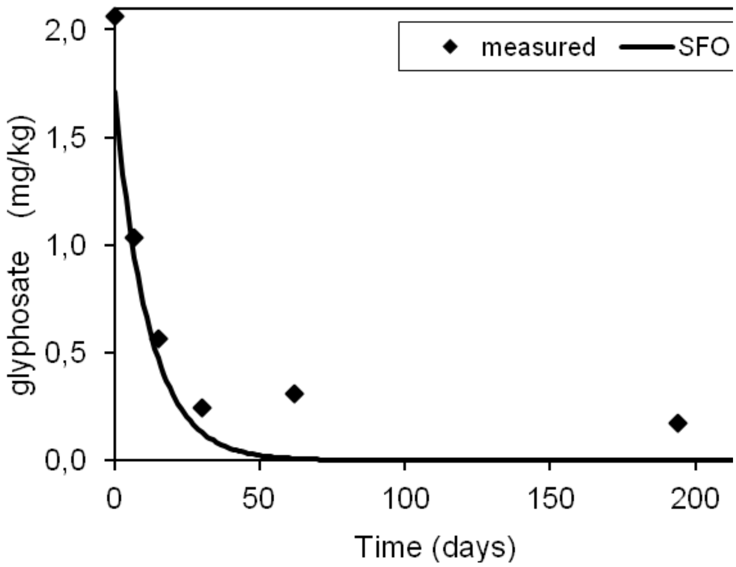


Figure A 39: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Dietgen (CH), Sandy Clay Loam

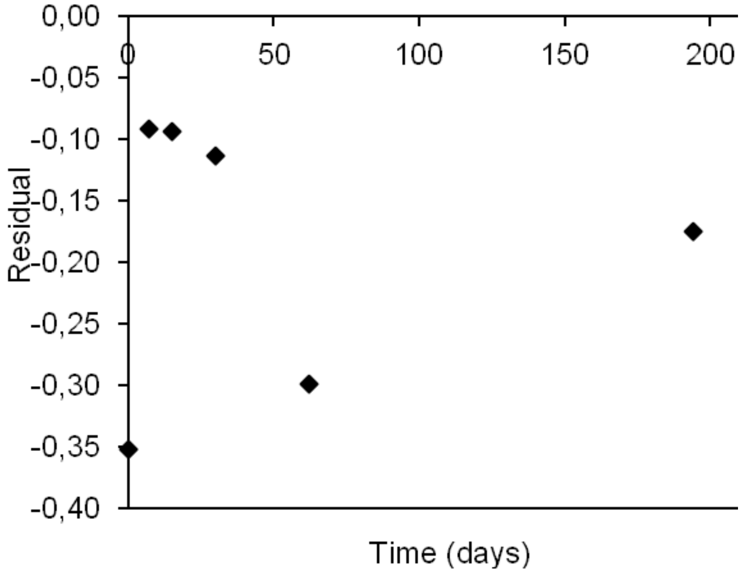


Figure A 40: Residuals vs. time for Glyphosate using SFO kinetics, Dietgen (CH), Sandy Clay Loam

The degradation of Glyphosate is not well described by SFO kinetics. As Glyphosate did degrade to below 10 % of the initial amount within the study period, the degradation was simulated using FOMC kinetics.

Table A 14: Kinetic evaluation for Glyphosate using FOMC kinetics

Dietgen (CH), Sandy Clay Loam							
M_0 [%]	**alpha**	**beta**	**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment.**
100.36	0.864	4.890	6.0	65.4	10.5	19.7	+

1) Recalculated (DT_{90} / 3.32)

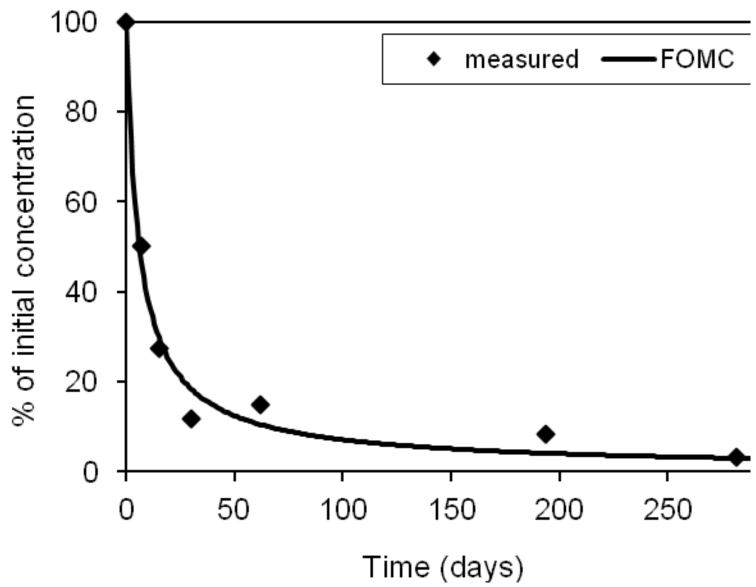


Figure A 41: Measured & predicted residues vs. time for Dietgen (CH), Sandy Clay Loam (FOMC)

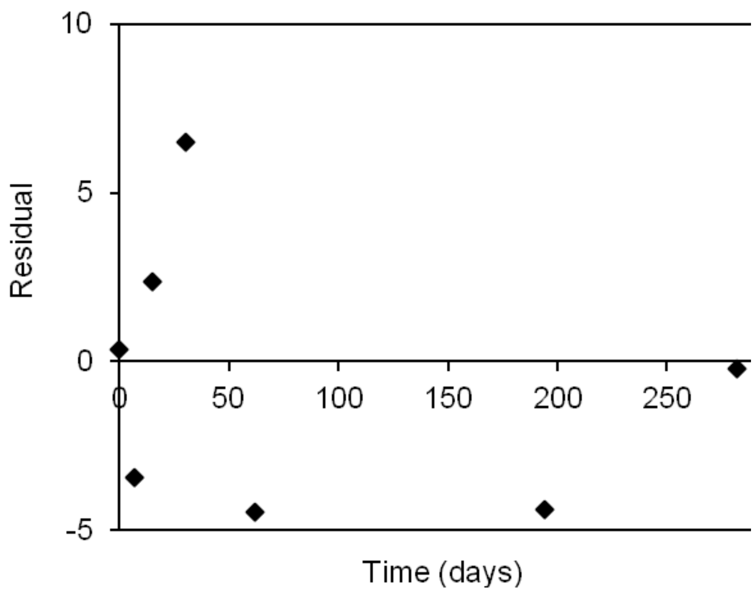


Figure A 42: Residuals vs. time for Dietgen (CH), Sandy Clay Loam (FOMC)

<u>*Conclusion*</u>

FOMC kinetics show a reasonable fit for the degradation of glyphosate in the tested soil.

<u>*Comments of zRMS*</u>

Not applicable (evaluation performed by the zRMS).

KIIA 7.3.1 Schulz (1992d)

Reference:	KIIA 7.3.1
Author:	Schulz, H.
Report:	Field Soil Dissipation Rate Determination of Glyphosate 360, (Menslage, Germany)
Date:	30.11.1992
Guideline(s):	BBA Richtlinie Teil IV, 4-1
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was already evaluated in the DAR (1998). However, since the kinetic evaluation in the DAR is not according to FOCUS Degradation Kinetics (2006), the degradation rates were recalculated by the zRMS with KinGUI 2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 1. The graphics are shown further down.

Table A 15: Kinetic evaluation for Glyphosate using SFO kinetics

Soil	M_0 (mg/kg)	k	DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Menslage (DE), Sand	2.56	0.07989	8.7	28.8	28.4	-

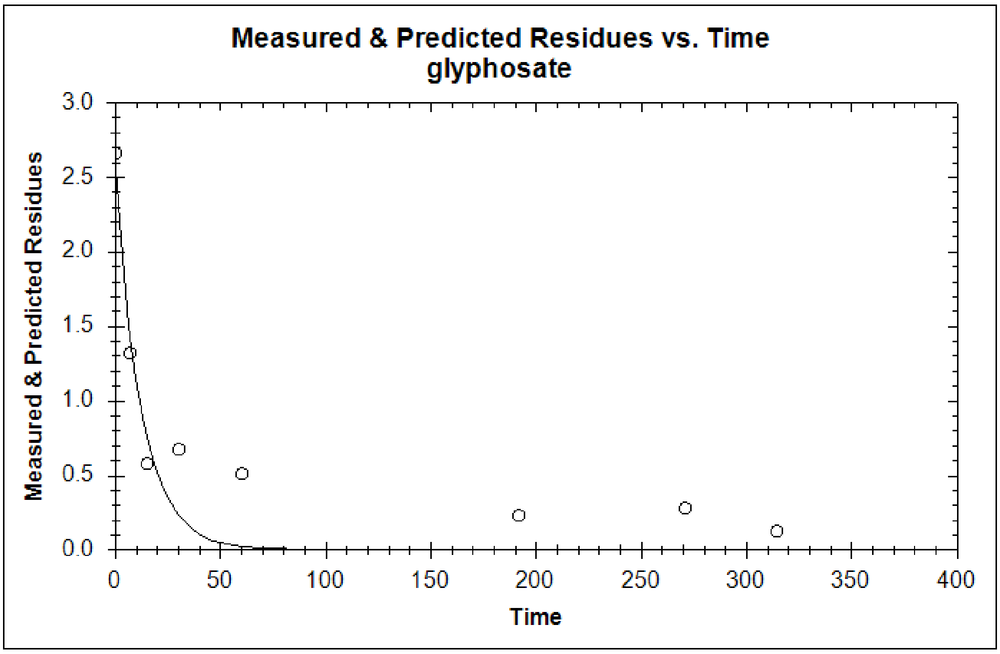


Figure A 43: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Menslage (DE), Sand

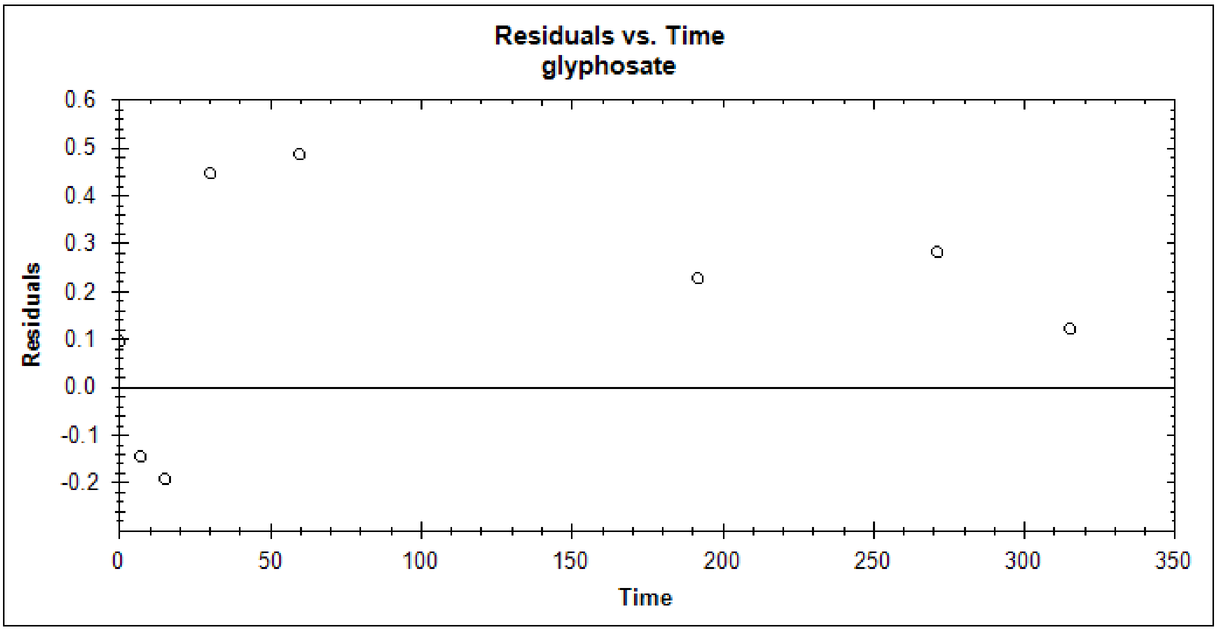


Figure A 44: Residuals vs. time for Glyphosate using SFO kinetics, Menslage (DE), Sand

The degradation of Glyphosate in the clay loam soil is not well described by SFO kinetics. As Glyphosate did degrade to below 10 % of the initial amount within the study period, the degradation was simulated using FOMC kinetics.

Table A 16: Kinetic evaluation for Glyphosate using FOMC kinetics

Menslage (DE), Clay Loam							
M_0 (mg/kg)	alpha	beta	DT_{50}	DT_{90}	χ^2 error	DT_{50} SFO[1)]	Visual Assessment.
2.66	0.521	1.871	5.2	153.3	12.6	46.2	+

1) Recalculated (DT_{90} / 3.32)

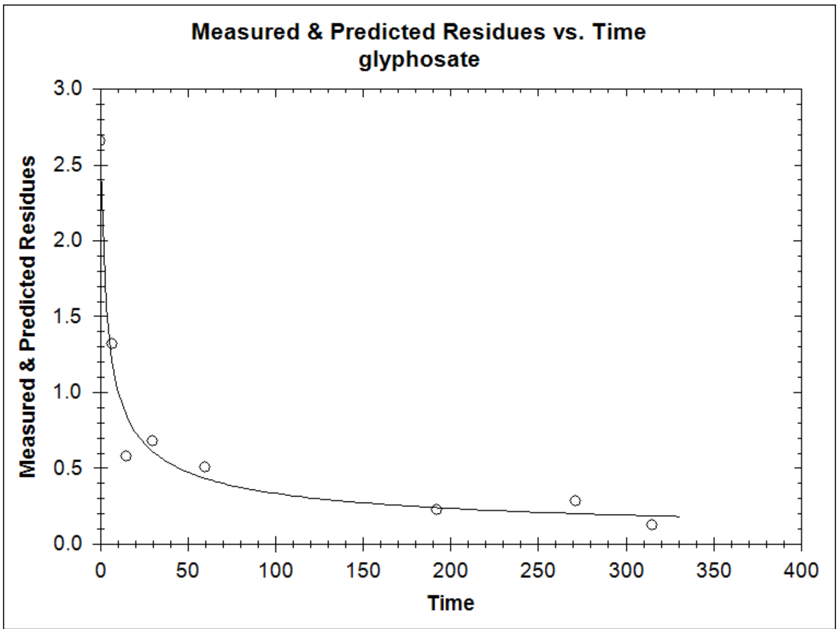


Figure A 45: Measured & predicted residues vs. time for Menslage (DE), Sand (FOMC)

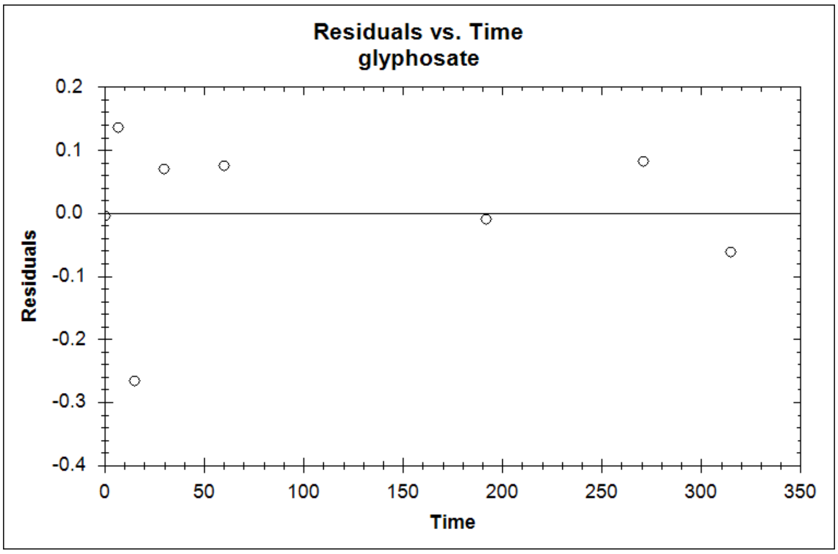


Figure A 46: Residuals vs. time for Menslage (DE), Sand (FOMC)

Conclusion

FOMC kinetics show an acceptable fit for the degradation of glyphosate in the tested soil.

Comments of zRMS

Not applicable (evaluation performed by the zRMS).

Appendix 2.2 Detailed evaluation of studies relied upon

KIIA 7 Fate and Behaviour in the Environment – Active Substance

KIIA 7.8.3 Möllerfeld and Römbke (1993)

Reference:	KIIA 7.8.3
Author:	Möllerfeld, J., Römbke, J.
Report:	Determination of the degradability and persistence of 14C-Glyphosate in the water/sediment-system
Date:	17.05.1993
Guideline(s):	Richtlinie Teil IV, 5-1 Biologische Bundesanstalt für Land- und Forstwirtschaft der Bundesrepublik Deutschland, "Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment-System", Dezember 1990
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study (Möllerfeld and Römbke, 1993) was already evaluated in the DAR (1998). However, since no SFO-DT_{50} values for the whole system and the water phase were available as required for deriving PEC_{SW} values with FOCUS Surface Water and EVA 2.1 (only relevant for German risk assessment), they were calculated by the zRMS according to FOCUS Degradation Kinetics (2006) , Level P-I. All kinetic evaluations and statistical calculations for the quality checks were conducted with KinGUI 2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate and AMPA are summarized in Table A 1 and Table A 2. The graphics are shown further down.

It has to be stated that the study was performed with glyphosate and therefore, for the metabolite AMPA the residues were used from the day on which the maximum occurred (day 14 in the water phases of both systems). Thus, only four paired values in each case were available for the kinetic evaluation.

Table A 1: Kinetic evaluation for Glyphosate using SFO kinetics

M_0			k			DT_{50}	DT_{90}	χ^2 error	Visual Assess ment
Esti-mate	St. Dev.	Prob > t	Esti-mate	St. Dev.	Prob > t				
Water/sediment system I (Bickenbach)									
91.4	3.73447	2.09E-14	0.01937	0.0036	3.05E-05	35.8	118.9	12.13	-
Water/sediment system II (Unter Widdersheim)									
85.7	3.211726	5.36E-15	0.00797	0.001591	6.41E-05	87.0	288.9	10.65	-
Water phase I (Bickenbach)									
85.2	3.03467	2.44E-15	0.21045	0.03065	1.89E-06	3.3	10.9	12.3	-
Water phase II (Unter Widdersheim)									
80.2	6.0578	2.43E-10	0.3706	0.1204	0.0036	1.9	6.2	21.55	-

Table A 2: Kinetic evaluation for AMPA using SFO kinetics

M_0	k	DT_{50}	DT_{90}	χ^2	Visual

Esti-mate	St. Dev.	Prob > t	Esti-mate	St. Dev.	Prob > t			error	Assess ment
Water phase I (Bickenbach)									
16.2	0.61379	9.73E-08	0.025916	0.002249	1.28E-05	26.7	88.9	7.738	+
Water phase II (Unter Widdersheim)									
5.8	0.252105	2.23E-07	0.04605	0.005117	5.26E-05	15.1	50.0	5.648	+

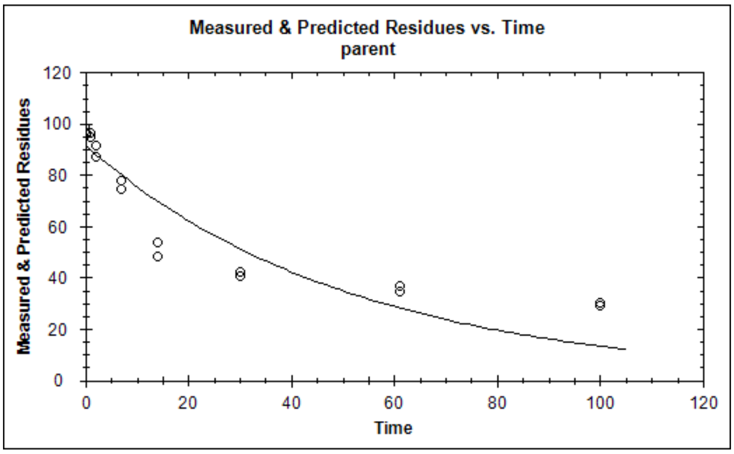


Figure A 1: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water/sediment system I (Bickenbach)

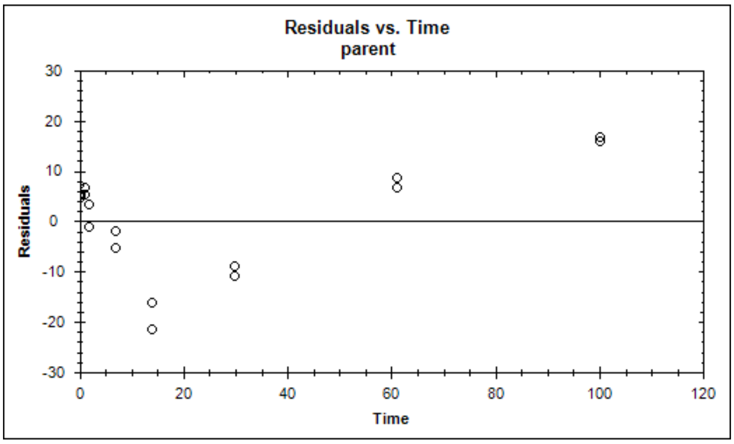


Figure A 2: Residuals vs. time for Glyphosate using SFO kinetics, Water/sediment system I (Bickenbach)

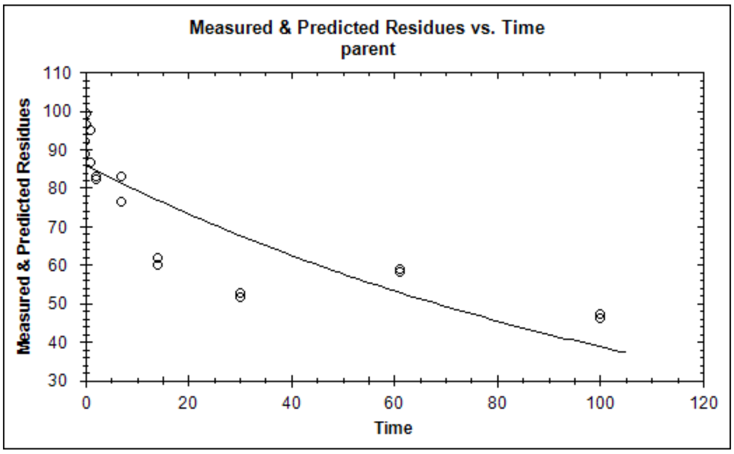


Figure A 3: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water/sediment system II (Unter Widdersheim)

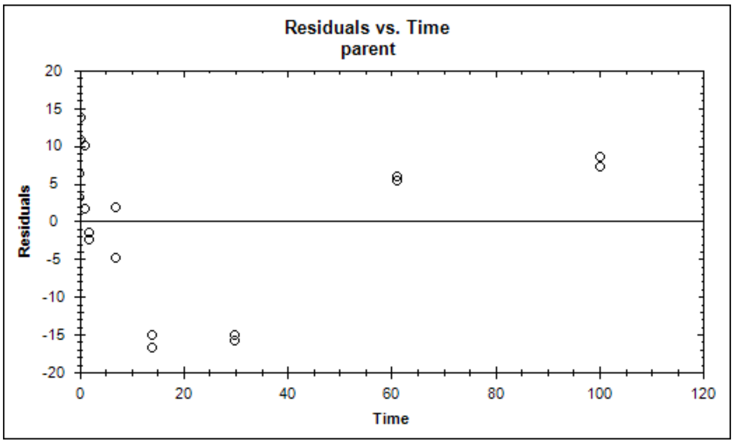


Figure A 4: Residuals vs. time for Glyphosate using SFO kinetics, Water/sediment system II (Unter Widdersheim)

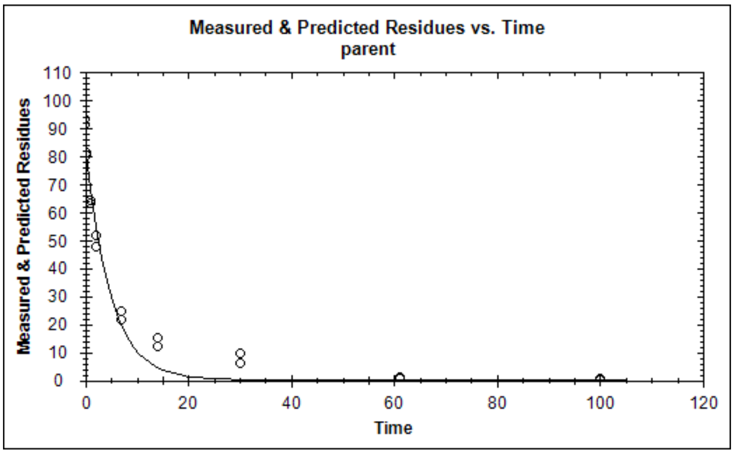


Figure A 5: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water phase I (Bickenbach)

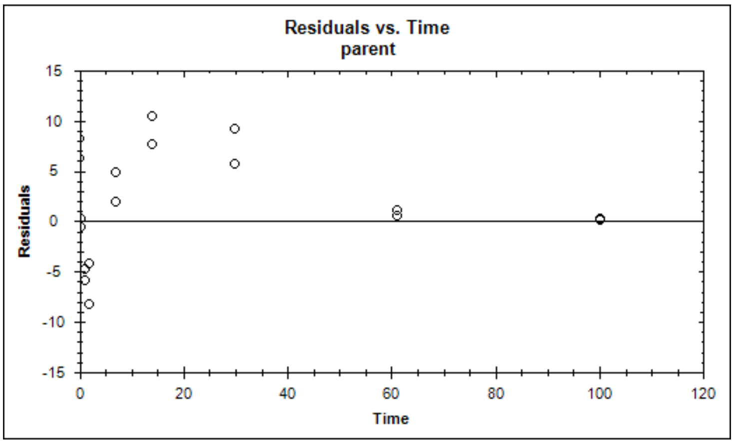


Figure A 6: **Residuals vs. time for Glyphosate using SFO kinetics, Water phase I (Bickenbach)**

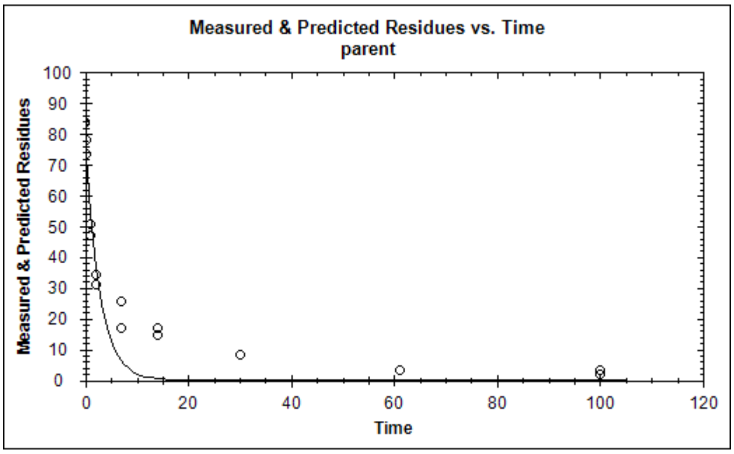


Figure A 7: **Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water phase II (Unter Widdersheim)**

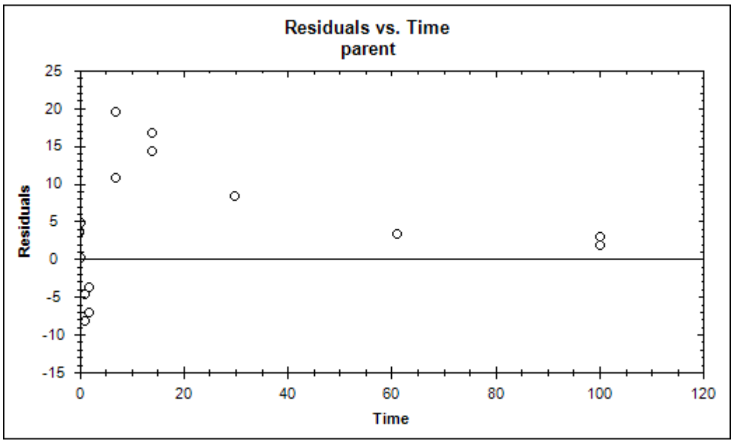


Figure A 8: **Residuals vs. time for Glyphosate using SFO kinetics, Water phase II (Unter Widdersheim)**

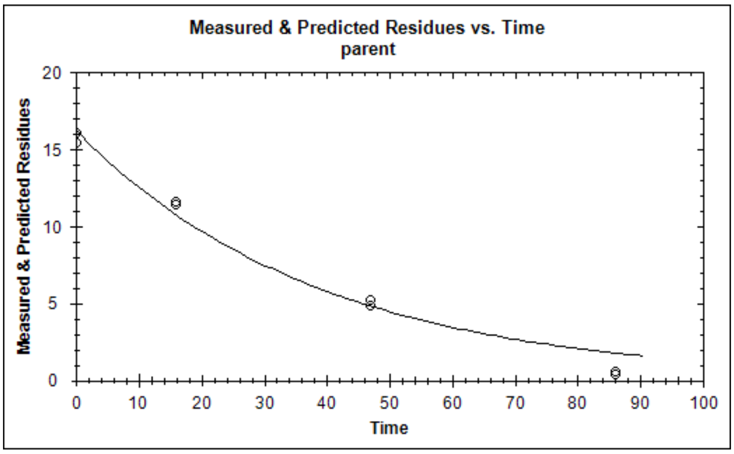


Figure A 9: **Measured & predicted residues vs. time for AMPA using SFO kinetics, Water phase I (Bickenbach)**

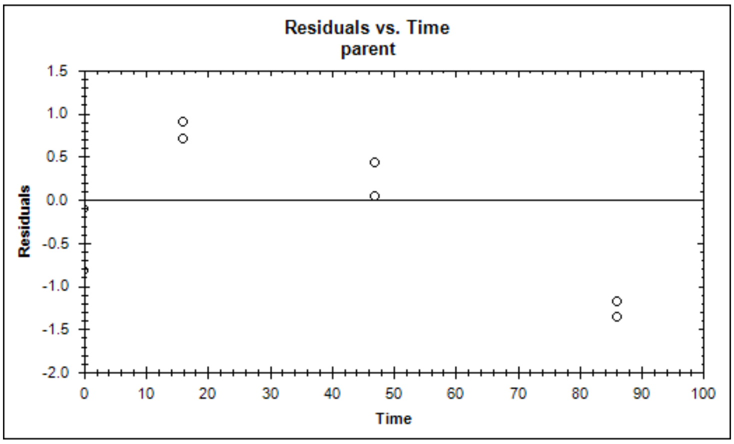


Figure A 10: **Residuals vs. time for AMPA using SFO kinetics, Water phase I (Bickenbach)**

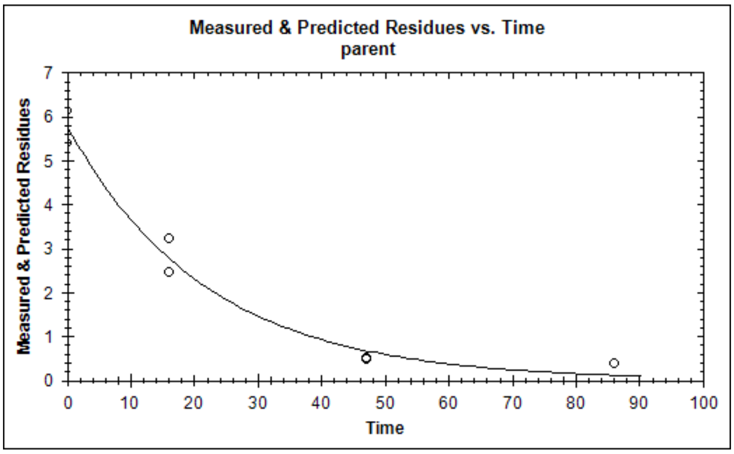


Figure A 11: **Measured & predicted residues vs. time for AMPA using SFO kinetics, Water phase II (Unter Widdersheim)**

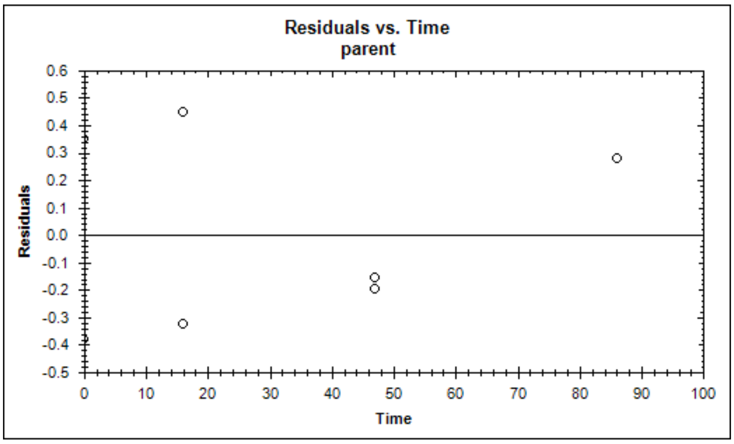


Figure A 12: Residuals vs. time for AMPA using SFO kinetics, Water phase II (Unter Widdersheim)

Visual assessments, the calculated χ^2 errors and the calculated t-test probabilities (Prob > t) indicate that the dissipation of AMPA in the water phases could be well described by SFO kinetics.

The degradation of Glyphosate in the water/sediment systems and for the water phase is not well described by SFO kinetics.

In the water/sediment, the degradation of the parent substance does not reach 10 % of the initial amount within the study period, thus DFOP and HS kinetics were calculated. The results of the kinetic evaluation using DFOP kinetics are shown below.

Table A 3: Kinetic evaluation for Glyphosate using DFOP kinetics

Water/sediment system I (Bickenbach)								
M_0			**k_{fast}**			**k_{slow}**		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
98.9	1.36	<2.0E-16	0.086132	0.013682	9.85E-06	0.002592	0.001925	0.0998
g			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO1)**	**Visual Assessment**	
Estimate	**St. Dev.**	**Prob > t**						
0.602	0.058067	3.00E-08	18.7	533.3	3.3	267.4	+	
Water/sediment system II (Unter Widdersheim)								
M_0			**k_{fast}**			**k_{slow}**		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
94.1	2.179633	<2.0E-16	0.10609	0.033189	0.00323	0.001351	0.001566	0.20145
g			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO1)**	**Visual Assessment**	
Estimate	**St. Dev.**	**Prob > t**						
0.400	0.068015	2.00E-05	134.9	nc	5.0	513	+	

1) Recalculated (from **k_{slow}**)

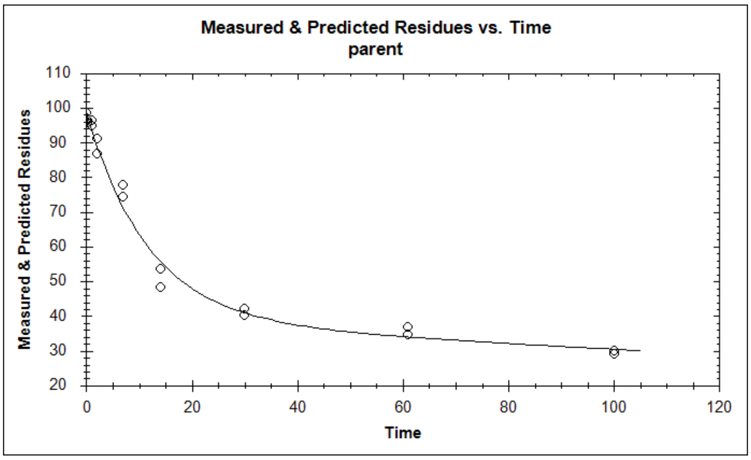


Figure A 13: Measured & predicted residues vs. time for Glyphosate using DFOP kinetics, Water/sediment system I (Bickenbach)

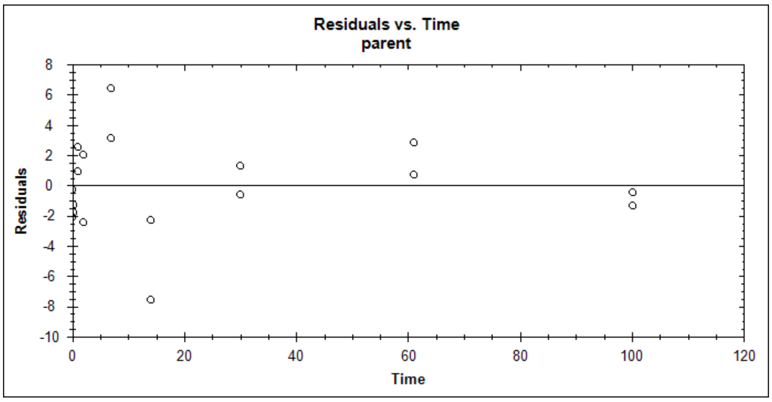


Figure A 14: Residuals vs. time for Glyphosate using DFOP kinetics, Water/sediment system I (Bickenbach)

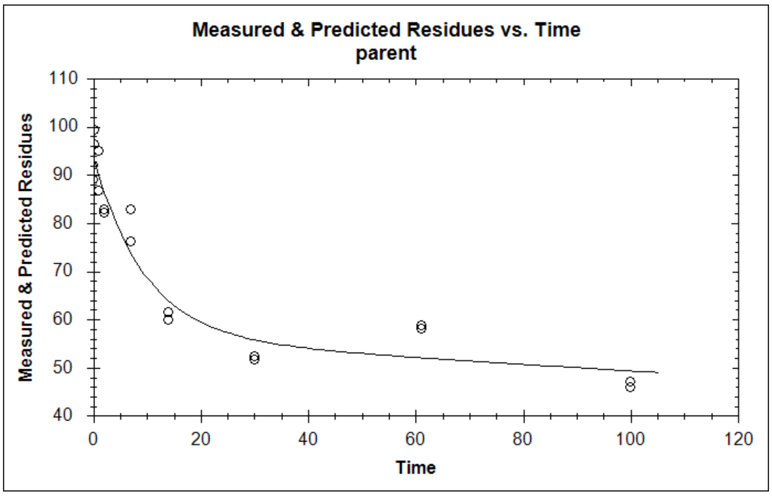


Figure A 15: Measured & predicted residues vs. time for Glyphosate using DFOP kinetics, Water/sediment system II (Unter Widdersheim)

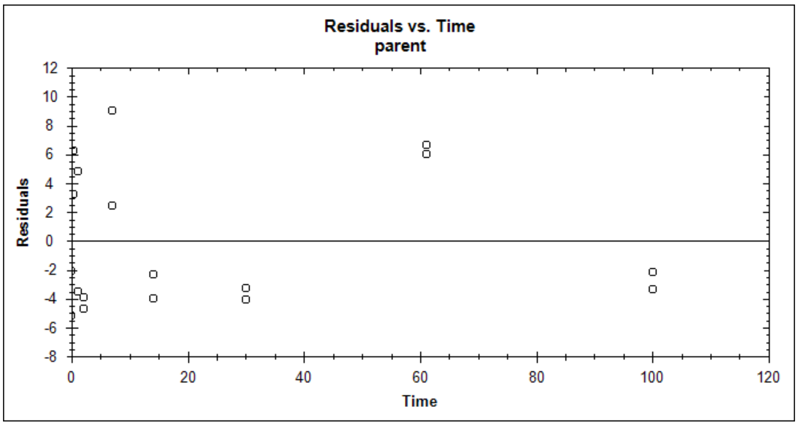


Figure A 16: Residuals vs. time for Glyphosate using DFOP kinetics, Water/sediment system II (Unter Widdersheim)

HS kinetics were also calculated but the fit was not as good as for the DFOP kinetics (χ^2 errors of 12.8 % and 7.0 % for System I and II). The results are not further presented here.

In the water phase, the dissipation of the parent substance does reach 10 % of the initial amount within the study period. Therefore, the data were first evaluated using the Gustafson and Holden model (FOMC). As the model fits are reasonably well, further kinetics were not tested.

The results of the kinetic evaluation using FOMC kinetics including visual assessment for Glyphosate in the water phase of both systems are summarized in Table A 4. The graphics are shown below.

Table A 4: Kinetic evaluation for Glyphosate using FOMC kinetics

Water phase I (Bickenbach)						
M_0			**α**			**Visual Assessment**
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	
91.1	1.15953	< 2e-16	1.02217	0.08674	2.77E-09	+
β			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**
Estimate	**St. Dev.**	**Prob > t**				
2.41927	0.36225	3.69E-06	2.3	20.6	3.0	6.2
Water phase II (Unter Widdersheim)						
M_0			**α**			**Visual Assessment**
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	
85.9	2.26758	< 2e-16	0.6364	0.06939	7.70E-08	+
β			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**
Estimate	**St. Dev.**	**Prob > t**				
0.73235	0.17612	0.00042	1.4	26.6	6.9	8.0

1) Recalculated (DT_{50} SFO = DT_{90} FOMC / 3.32)

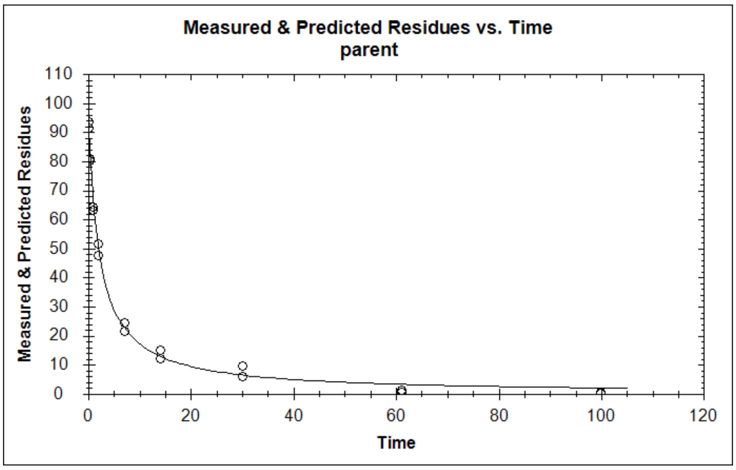


Figure A 17: **Measured & predicted residues vs. time for Glyphosate using FOMC kinetics, Water phase I (Bickenbach)**

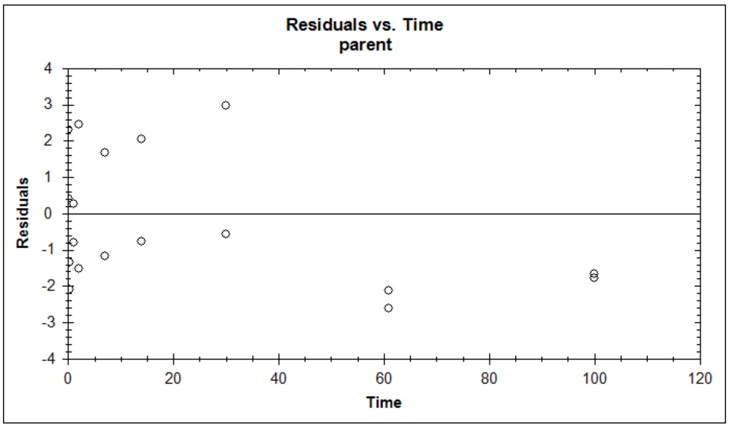


Figure A 18: **Residuals vs. time for Glyphosate using FOMC kinetics, Water phase I (Bickenbach)**

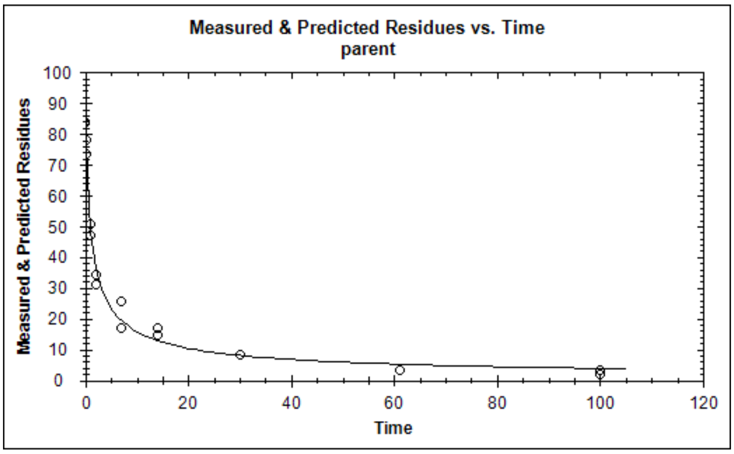


Figure A 19: **Measured & predicted residues vs. time for Glyphosate using FOMC kinetics, Water phase II (Unter Widdersheim)**

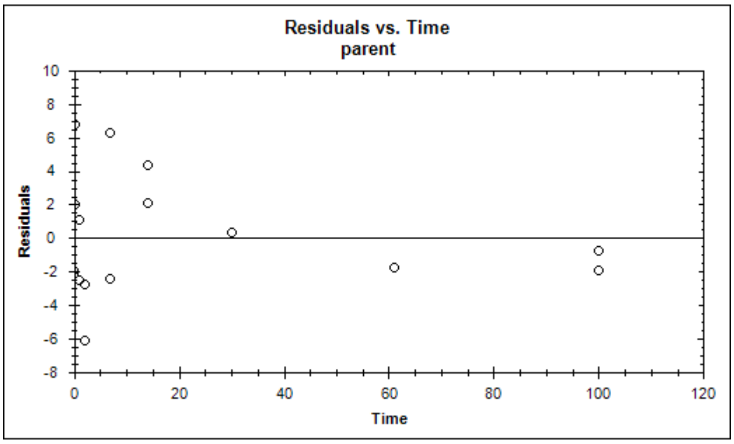


Figure A 20: Residuals vs. time for Glyphosate using FOMC kinetics, Water phase II (Unter Widdersheim)

Conclusion

DFOP kinetics show the best fit for the degradation of glyphosate in both water/sediment systems, whereas the dissipation from the water phase is well described with FOMC kinetics. The degradation of AMPA in both water/sediment systems is well described by SFO kinetics.

Comments of zRMS

The study was performed with glyphosate and therefore, for the metabolite AMPA the residues were used from the day on which the maximum occurred (day 14 in the water phases of both systems). Thus, only four paired values in each case were available for the kinetic evaluation. Since an additional study (Knoch and Spirlet, 1999) was performed with AMPA using the same water sediment systems, the results of the kinetic evaluation for AMPA from the study Möllerfeld and Römbke (1993) were not considered during further assessment.

KIIA 7.8.3 Knoch and Spirlet (1999)

Reference:	KIIA 7.8.3
Author:	Knoch, E., Spirlet, M.
Report:	Aminomethylphosphonic acid: Water/sediment metabolism
Date:	20.09.1999
Guideline(s):	SETAC Procedures for assessing the environmental fate and ecotoxicity of pesticides
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study (Knoch and Spirlet, 1999) was already evaluated in the Addendum (2000). However, since no SFO-DT_{50} values for the whole system and the water phase were available as required for deriving PEC_{SW} values with FOCUS Surface Water and EVA 2.1 (only relevant for German risk assessment), they were calculated by the zRMS according to FOCUS Degradation Kinetics (2006) , Level P-I. All kinetic evaluations and statistical calculations for the quality checks were conducted with KinGUI 2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics including visual assessment for AMPA are summarized in Table A 5. The graphics are shown further down.

Table A 5: Kinetic evaluation for AMPA using SFO kinetics

M_0	k	DT_{50}	DT_{90}	χ^2	Visual

Esti-mate	St. Dev.	Prob > t	Esti-mate	St. Dev.	Prob > t			error	Assess ment
Water/sediment system I (Bickenbach)									
96.7	2.009208	< 2e-16	0.014511	0.001271	2.10E-09	47.8	158.7	6.084	+
Water/sediment system II (Unter Widdersheim)									
92.5	3.769297	1.98E-14	0.021169	0.003941	3.12E-05	32.7	108.8	12.05	+
Water phase I (Bickenbach)									
90.8	2.862945	3.60E-16	0.067292	0.008661	4.05E-07	10.3	34.2	10.28	+
Water phase II (Unter Widdersheim)									
85.5	5.36651	9.72E-10	0.18073	0.04581	0.000972	3.8	12.7	17.2	+

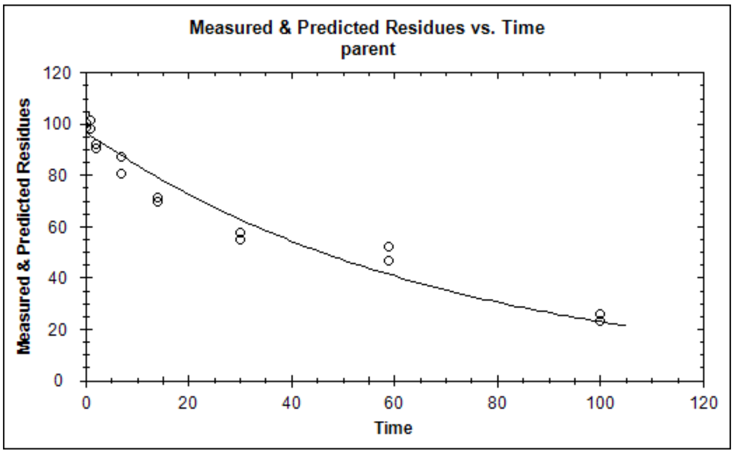


Figure A 21: Measured & predicted residues vs. time for AMPA using SFO kinetics, Water/sediment system I (Bickenbach)

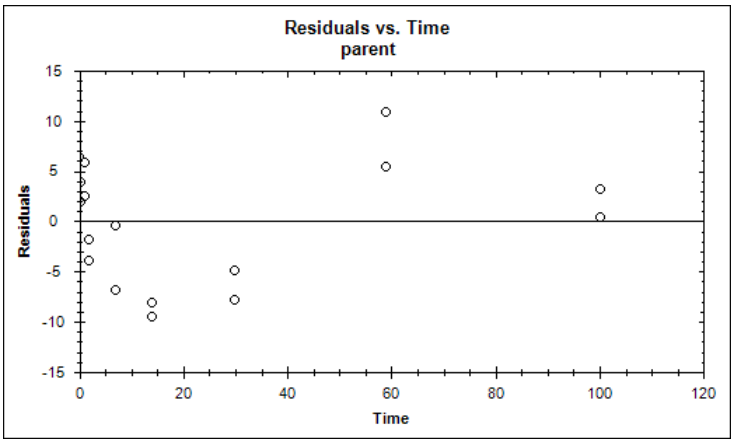


Figure A 22: Residuals vs. time for AMPA using SFO kinetics, Water/sediment system I (Bickenbach)

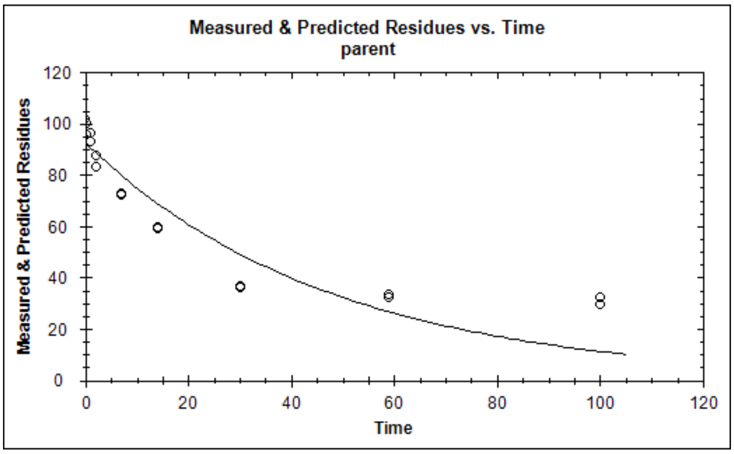


Figure A 23: Measured & predicted residues vs. time for AMPA using SFO kinetics, Water/sediment system II (Unter Widdersheim)

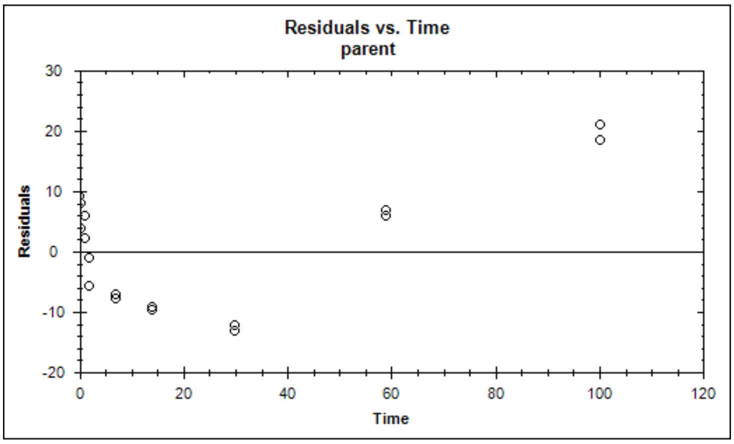


Figure A 24: Residuals vs. time for AMPA using SFO kinetics, Water/sediment system II (Unter Widdersheim)

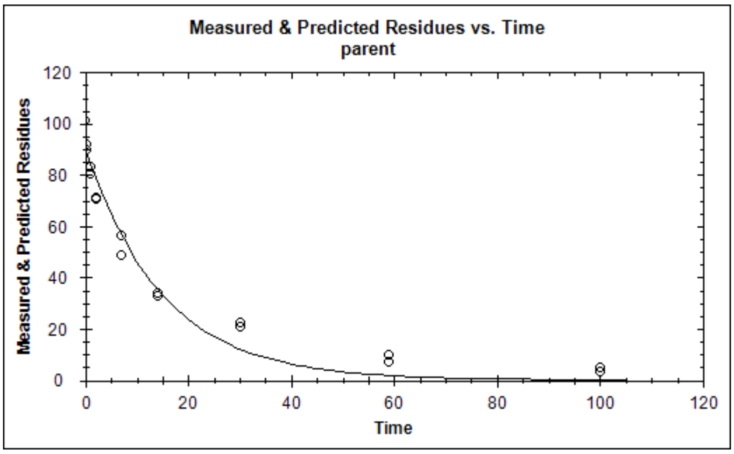


Figure A 25: Measured & predicted residues vs. time for AMPA using SFO kinetics, Water phase I (Bickenbach)

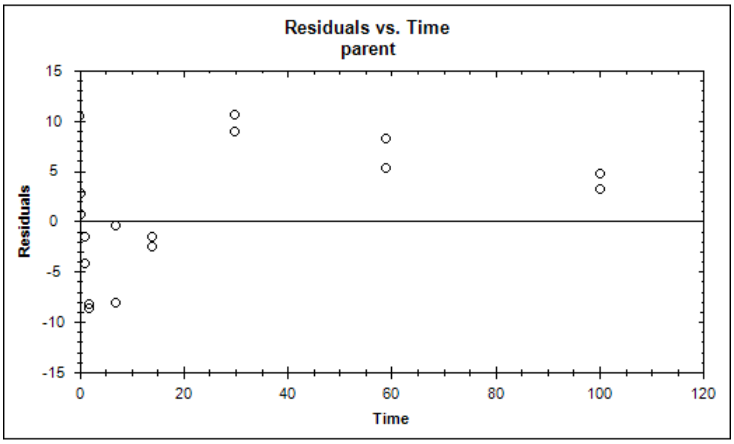


Figure A 26: Residuals vs. time for AMPA using SFO kinetics, Water phase I (Bickenbach)

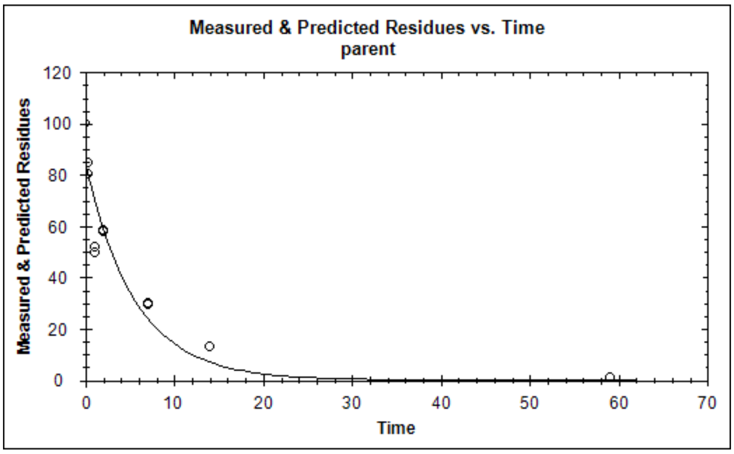


Figure A 27: Measured & predicted residues vs. time for AMPA using SFO kinetics, Water phase II (Unter Widdersheim)

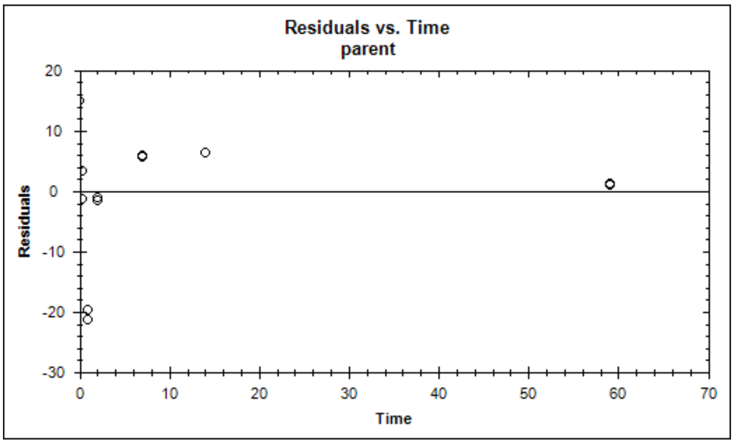


Figure A 28: Residuals vs. time for AMPA using SFO kinetics, Water phase II (Unter Widdersheim)

Visual assessment, the calculated χ^2 error and the calculated t-test probabilities (Prob > t) indicate that the degradation of AMPA in the water/sediment system I (Bickenbach) could be well described by SFO kinetics.

According to visual assessment, the fit to the measured data is not acceptable for the degradation of AMPA in the water/sediment system II (Unter Widdersheim). Since 10 % of the initially measured concentration was not reached within the experimental period, the data were evaluated using the hockey-stick model (HS) and the bi-exponential model (DFOP) (see p. 198 in Focus Degradation Kinetics (2006)).

The visual fit to the measured data is also not acceptable for the dissipation of AMPA in the water phase of system I (Bickenbach). Since 10 % of the initially measured concentration was reached within the experimental period, the data were evaluated using the Gustafson and Holden model (FOMC), the hockey-stick model (HS) and the bi-exponential model (DFOP) (see p. 198 in Focus Degradation Kinetics (2006)).

For the dissipation of AMPA in the water phase of system II (Unter Widdersheim) the calculated χ^2 error (17.2 %) does not indicate a good fit. Since 10 % of the initially measured concentration was reached within the experimental period, the data were evaluated using the Gustafson and Holden model (FOMC), the hockey-stick model (HS) and the bi-exponential model (DFOP) (see p. 198 in Focus Degradation Kinetics (2006)).

The model fits HS and DFOP were clearly insufficient to describe the degradation of AMPA in the water/sediment system II (Unter Widdersheim) as outlined in Focus Degradation Kinetics (2006). Therefore, these data could not be used to derive an endpoint for PEC_{SW} values with FOCUS Surface Water.

Regarding visual fits and statistical calculations the DFOP kinetic evaluation gave the best and fully reliable results for the dissipation of AMPA in the water phase of system I (Bickenbach). Therefore, DT_{90} DFOP can be used to recalculate DT_{50} SFO as required for deriving PEC_{SW} values with EVA 2.1. The results of the kinetic evaluation using DFOP kinetics including visual assessment for AMPA in the water phase of system I (Bickenbach) are summarized in Table A 6. The graphics are shown below.

Table A 6: Kinetic evaluation for AMPA using DFOP kinetics

Water phase I (Bickenbach)					
M_0			**k_{fast}**		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
98.7	1.93265	< 2e-16	0.49694	0.14976	0.00254
k_{slow}			**g**		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
0.03517	0.005	2.96E-06	0.37986	0.0549	3.55E-06
DT_{50}	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment**	
6.8	51.9	3.938	15.6	+	

1) Recalculated (DT_{50} SFO = DT_{90} DFOP / 3.32) according to Focus Degradation Kinetics (2006), Level P-I (p. 198)

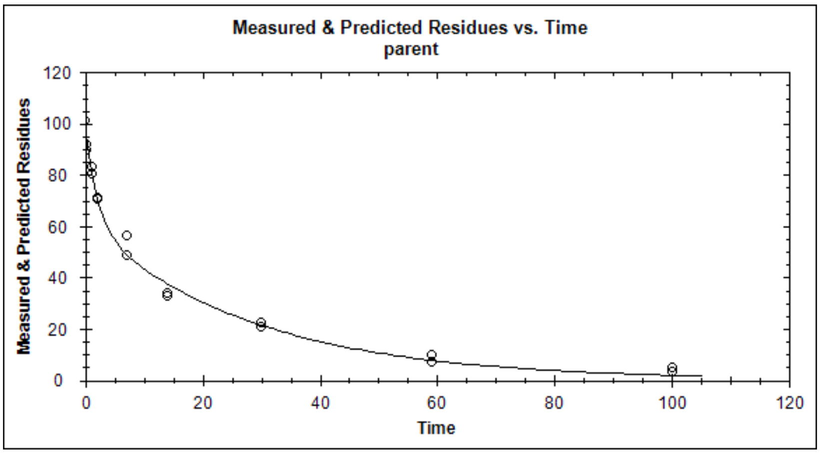


Figure A 29: Measured & predicted residues vs. time for AMPA using DFOP kinetics, Water phase I (Bickenbach)

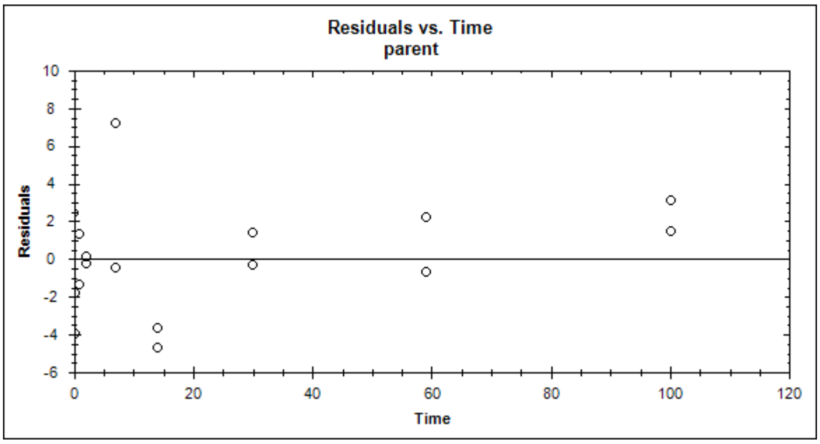


Figure A 30: Residuals vs. time for AMPA using DFOP kinetics, Water phase I (Bickenbach)

Regarding visual fits and statistical calculations the FOMC kinetic evaluation gave acceptable results for the dissipation of AMPA in the water phase of system II (Unter Widdersheim). Therefore, DT_{90} FOMC can be used to recalculate DT_{50} SFO as required for deriving PEC_{SW} values with EVA 2.1. The results of the kinetic evaluation using FOMC kinetics including visual assessment for AMPA in the water phase of system II (Unter Widdersheim) are summarized in Table A 7. The graphics are shown below.

Table A 7: Kinetic evaluation for AMPA using FOMC kinetics

Water phase II (Unter Widdersheim)						
M_0			**α**			**Visual Assessment**
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	
98.2	5.3138	6.26E-10	0.6194	0.1721	0.00209	+
β			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**
Estimate	**St. Dev.**	**Prob > t**				
0.8809	0.5594	0.07182	1.8	35.4	11.76	10.7

1) Recalculated (DT_{50} SFO = DT_{90} FOMC / 3.32)

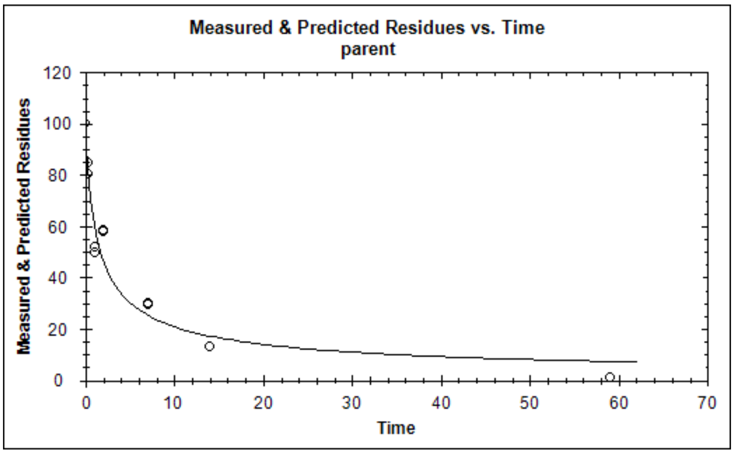


Figure A 31: Measured & predicted residues vs. time for AMPA using FOMC kinetics, Water phase II (Unter Widdersheim)

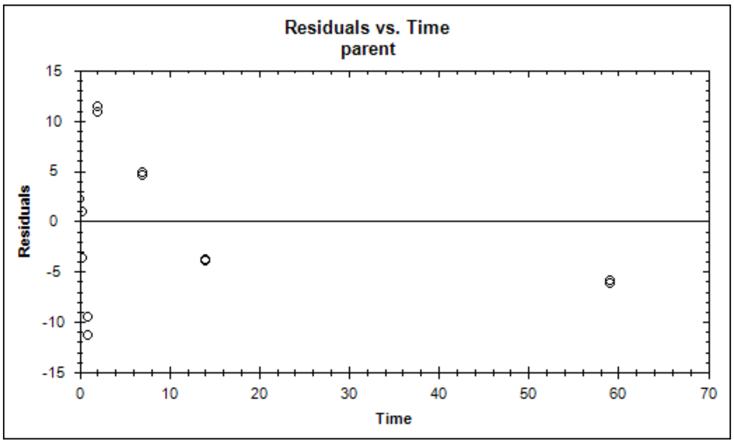


Figure A 32: Residuals vs. time for AMPA using FOMC kinetics, Water phase II (Unter Widdersheim)

<u>*Conclusion*</u>

The degradation of AMPA in the water/sediment system I (Bickenbach) is well described by SFO kinetics. The proposed model fits SFO, HS and DFOP according to Focus Degradation Kinetics (2006) were clearly insufficient to describe the degradation of AMPA in the water/sediment system II (Unter Widdersheim). Therefore, these data could not be used to derive an endpoint for PEC_{SW} values with FOCUS Surface Water.

DFOP kinetics show the best fit for the dissipation of AMPA in the water phase of system I (Bickenbach), whereas the dissipation of AMPA in the water phase of system II (Unter Widdersheim) can be described by FOMC kinetics.

<u>*Comments of zRMS*</u>

Not applicable (evaluation performed by the zRMS).

KIIA 7.8.3 Heintze (1996)

Reference:	KIIA 7.8.3
Author:	Heintze, A.
Report:	Degradation and metabolism of glyphosate in two water/sediment systems under aerobic conditions - Laboratory test
Date:	16.12.1996
Guideline(s):	BBA IV 5-1 (1990) “Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment-System”

Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The rate of degradation and the metabolic pathway of Glyphosate in two water/sediment systems under aerobic conditions were determined according to BBA IV 5-1 (1990) "Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment-System".

Water/Sediment system

The water-sediment systems tested were Pond and Creek, which preliminary differ in their organic carbon content and therefore in their microbial activity. The water-sediment systems are further characterized in Table A8.

Table A 8: Characterization of the test systems

	Pond	**Creek**
Origin	Bauschlott	Ottenhofen
Water		
pH	8.26	7.85
Oxygen concentration (mg/L)	15.6	11.3
Redox potential (mV)	88	90
Sediment		
pH	6.64	7.85
Organic carbon (%)	3.31	0.11
Particle size distribution (Clay/silt/sand) (%)	11/79.1/9.8	1.1/1.7/97.2
Sediment classification	Loamy silt	Sand
Cation exchange capacity (mval/100 g)	22.1	4.3
Redox potential (mV)	- 192	208
Microbial biomass (µg C/g dry matter) Beginning of the study/ End of the study	1017 ± 25/ 1024 ± 24	121 ± 3/ 214 ± 5

Water was sampled down to a depth of 10 to 30 cm and the sediment was sampled from the top 20 cm of each system. The water sediment systems were stored in the laboratory for 14 d at approximately 4 ºC and afterwards prepared for acclimatization. Prior to use the sediment was sieved through a 2 mm sieve and the water through a 0.2 mm sieve. Approx. 360 g Creek sediment and 230 g wet Pond sediment were transferred into flasks. The water/ sediment system was incubated at 20 ± 2 ºC until an equilibrium based on measured variables was reached. The oxygen concentration, pH and redox potential were measured regularly. A visual settling of colloid particles took place. Bach system was aerated four times for one hour each day.

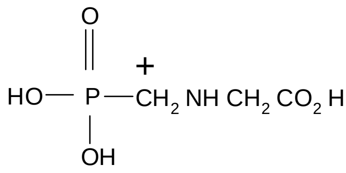
Experimental Design

The study was performed with a closed gas flow system using 1000 mL all-glass metabolism flasks (inner diameter: ≈ *10.1* cm surface: ≈ 80 cm²) containing about 500 mL ± 40 ml water and 300 g ± 100 g sediment. These amounts were obtained by assuming a height of the water column of about 6 cm and an approx. 2.5 cm thick sediment layer with a bulk density of approx. 1.5 cm³. The system was ventilated discontinuously (at least 60 min each day) with CO_2-free (liquid carbon dioxide trap) moistened air (bubbled through water). The out-coming air was passed through a trapping system for organic volatiles (ethylene glycol) and two solid phase carbon dioxide traps and one liquid carbon dioxide trap (NaOH). Aeration took place at least until the air has been exchanged for a minimum of 5 times. Each test system 24 flasks, each sampling interval in duplicate, was set up comprising 20 treated flasks and four non treated controls, which were used to determine biomass at 0 d and at the end of the study. The samples were incubated at 20 ± 2 ºC protected from light. Redox potential, pH and oxygen concentration were determined one day prior to the treatment in all flasks in the water.

Test Substance

Each test system (flask) was treated on surface with 691.2 µg Glyphosate / 80 cm², equivalent to 4.32 kg/ha. Further information about the test substance is presented in Table A9.

Table A 9: Test substance

	Non-radiolabelled test substance	**Radiolabelled test substance**
Name	Glyphosate technical	Glyphosate-14C, free acid
CAS number	1071-83-6	1071-83-6
Chemical name	N-(phospbonomethyl) glycine	N-(phospbonomethyl) glycine
Molecular weight	169.1 g/mol	171 g/mol at this specific radioactivity
Position of the radiolabel	-	 + Labelled position
Specific radioactivity	-	54 mCi/mmol (2 GBq/mmol)
Radiochemical purity	-	98.3%
Storage conditions	dark and dry, > 4 °C and < 30 °C	Dry and dark, below 4 °C
Dosage of labelled and non-labelled test amount per flask	675.6 µg	15.6 µg
Expiry date	04/1998	Not available, a standard was prepared in the beginning and after finishing the study to determine stability

Sampling and analysis

The radiochemical purity of 14C-Glyphosate was supplied by Amersham and confirmed by thin-layer chromatography (TLC). The specific activity of the 14C-Glyphosate was determined and quantified by liquid scintillation counting (LSC) and the results proved by high-performance liquid chromatography (HPLC). The mass of Glyphosate was determined by the area of the peak and a relative calculation compared to the mass applied.

Organic Volatiles

The radioactivity evolved from the water/sediment system was adsorbed in ethylene glycol traps. These traps were removed and replaced by fresh traps at sampling date or at least after 28 ± 2 days, whichever was shorter, until the end of the incubation period. Usually an aliquot of 1 mL ethylene glycol was taken from the trap, mixed with liquid scintillation cocktail and the rate as well as the degree of 14C-Glyphosate degradation was determined by liquid scintillation counting.

Carbon dioxide

Evolved radioactive carbon dioxide was trapped into gas traps filled with 50 mL of 2 M sodium hydroxide solution at the beginning of the study and then with a solid phase system. These traps were removed and replaced by fresh traps at sampling date or at least after 28 ± 2 days. The solid phase system was constructed as follows: A dehumidifying chamber filled with 2 to 3 g of a desiccating agent based on silica gel was followed by 2 chambers of carbon dioxide adsorber filled with sodium hydroxide on support or soda lime pellets. 6 g were used in the first chamber and 2 g were used in the second chamber. Glass wool was used as a separator between the adsorbing agents. The absorbed carbon dioxide was completely transferred to the liquid scintillation cocktail by acidifying the adsorber in a gas generating apparatus followed by a carbon dioxide trap filled with liquid scintillation cocktail used for total carbon combustors. The radioactivity was determined by liquid scintillation counting.

Redox Potential, pH and Oxygen Concentration

Redox potential (water and sediment), pH (water) and oxygen concentration (water) were determined in all flasks at the sampling date of the corresponding flask or at least after approx. four weeks.

Sediment and Water

At the following times, two flasks of each system were taken for analysis: 0 h, 6 h, 24 h, 48 h and 7 d, 14 d, 29 d, 58 d, 98 d and 120 d after treatment. The samples were analyzed to determine the rate, type and degree of metabolism of 14C-Glyphosate. After the determination of the height of the sediment and water layer, redox potential, pH and oxygen concentration were determined in the water and in the sediment. Afterwards the water was separated from the sediment by pour-out and the water phase was filtrated. Water and sediment were analyzed within 24 h from the samples which were stored in the refrigerator until analysis (≤ 8 ºC). Otherwise the samples were stored in a freezer (< - 18 ºC over almost the whole period) up to analysis. At the end of the study, sediments of the remaining control vessels were analyses for microbial activity, pH and redox potential. Water phases were analyzed for pH, redox potential, total N and p. concentration of oxygen, TOC or DOC.

Sediment (about 30 g d.w.) was extracted by 3 times shaking for 1 h with 50 ml 1 mol/L ammonium solution at room temperature on a flatbed shaker and finally extracted with 50 m1 acetone/water for 1 h. The glyphosate and the AMPA content in the ammonium extract were determined following the method described in “Rückstandsanalytik von Pflanzenschutzmitteln” (GAB SOP 12.3.2-1) excluding the analytical chromatography for the determination of AMPA and Glyphosate content which was performed as described in this report. The radioactivity in the sample that did not remain on the columns or precipitate during sample preparation was determined by LSC. The solution was concentrated by evaporation under vacuum and otherwise prepared for an analytical determination of the radioactivity. The radioactivity of acetone/water extract was determined by LSC. Because the activity was less than 5 % at each sampling date, the extract was discarded each time. Partitioning of extractables was performed by HPLC and TLC. Extracts were measured by LSC. Extracts containing more than 5 % of the radioactivity applied were characterized by HPLC or and TLC and co-chromatography of available reference compounds in each of the two systems. The resolution of TLC was not good enough for determination of the partitioning between glyphosate and AMP A. Therefore, only HPLC results were taken for the calculations of degree of metabolisation. Remaining non-extractables (3 x 1 g) and filters were determined by combustion and the radioactivity determined by LSC. Precipitates during sample preparation were dissolved in water, an aliquot mixed with LSC-cocktail and radioactivity determined by LSC.

The radioactivity in the water was determined by LSC. The glyphosate and the AMPA content in the water phase were determined following the method described in “Rückstandsanalytik von Pflanzenschutzmitteln” (GAB SOP 12.3.2-1) excluding the analytical chromatography for the determination of AMPA and Glyphosate content which was performed as described in this report. The radioactivity in the sample that did not remain on the columns or precipitate during sample preparation was determined by LSC. The solution was concentrated by evaporation under vacuum and otherwise prepared for an analytical determination of the radioactivity. Remaining non-extractables on filters were determined by combustion and the radioactivity determined by LSC. Precipitates during sample preparation were dissolved in water, an aliquot mixed with LSC-cocktail and radioactivity determined by LSC.

Results and discussions

Distribution of radioactivity

The distribution of radioactivity between water, sediment, volatiles and carbon dioxide in the water/ sediment systems Pond is shown in Table A 10.

Table A 10: Distribution of radioactivity between water, sediment, volatiles and carbon dioxide in the Pond water/sediment system in % of the applied radioactivity

Time (d)	Water	Sediment	Volatiles	Carbon dioxide	Total
0	84	14.16	0	0	98.16
0.25	73.01	26.77	0.01	0.04	99.83
1	52.78	52.89	0.01	0.04	105.72
2	41.55	62.32	0.01	0.06	103.94
7	37.23	71.87	0.01	0.19	109.3
14	19.27	86.35	0.01	0.55	106.18
29	12.43	91.67	0.01	0.7	104.81
58	1.55	93.13	0.01	6.7	101.4
97	3.08	77.95	0.02	9.63	90.69
120	3.79	17.9	0.03	14.77	96.5

In the water/sediment system Pond radioactivity turned over to the sediment almost completely (from 15 % immediately after the treatment to 92 % after 29 d). The increase in the sediment corresponded to a decrease of radioactivity in the water phase from 84 % to 4 % after 120 d. Negligible amounts of volatiles < 0.1 %) were evolved throughout the incubation period. Significant mineralization to carbon dioxide was observed after 29 d (15 % after 120 d).

The distribution of radioactivity between water, sediment, volatiles and carbon dioxide in the water/ sediment systems Creek is shown in Table A 11.

Table A 11: Distribution of radioactivity between water, sediment, volatiles and carbon dioxide in the Creek water/sediment system in % of the applied radioactivity

Time (d)	Water	Sediment	Volatiles	Carbon dioxide	Total
0	92.31	8.74	0	0	101.05
0.25	91.71	9.33	0.01	0.03	101.08
1	86.09	12.99	0.01	0.08	99.17
2	81.42	19.88	0.01	0.26	101.57
7	72.11	25.55	0.01	1.26	98.93
14	66.19	26.36	0.01	2.57	95.13
29	49.91	36.2	0.01	7.99	94.11
58	38.75	35.78	0.02	12.33	86.88
97	22.99	30.54	0.04	26.32	79.89
120	20.57	31.76	0.04	30.08	82.45

In the water/sediment system Creek radioactivity increased in the sediment continuously from 9 % immediately after the treatment and reached its maximum at 29 d (36 %). The radioactivity increase in the sediment corresponded to a decrease of radioactivity in the water phase in the first 14 d (from 92 % to 66 %). After this time, the further decrease of activity in the water phase corresponds to the mineralization to carbon dioxide. Negligible amounts of volatiles (< 0.1 %) were evolved throughout the incubation period. The total carbon dioxide mineralization was 30 % of the applied radioactivity after 120 d incubation period.

Degradation of Glyphosate and its metabolites in the water and sediment phase

The content of Glyphosate and its metabolites in the water phases and sediments of the tested systems Pond and Creek are shown in Table A 12, Table A 13, Table A 14 and Table A 15.

Table A 12: Content of Glyphosate and its metabolite AMPA in the water phase in % of the applied radioactivity in the Pond water/sediment system

Time (d)	NCR	Glyphosate	AMPA
0	11.84	70.57	1.59
0.25	16.91	55.18	0.93
1	11.72	39.57	1.49
2	8.82	31.36	1.38
7	7.85	27.42	1.97
14	3.29	14.32	1.67
29	2.44	8.2	1.79
58	1.13	0.24	0.12
97	1.55	1.04	0.49
120	1.32	1.83	0.64

Table A 13: Content of Glyphosate and its metabolite AMPA in the water phase in % of the applied radioactivity in the Creek water/sediment system

Time (d)	NCR	Glyphosate	AMPA
0	6.42	85.9	0
0.25	14.2	77.51	0
1	10.68	72.78	2.63
2	7.82	69.89	3.71
7	12.99	52.97	6.16
14	16.2	42.54	7.45
29	24.83	16.69	8.39
58	22.39	6.03	10.34
97	16.62	1.43	4.95
120	12.47	0	8.1

Table A 14: Content of Glyphosate and its metabolite AMPA in the sediment in % of the applied radioactivity in the Pond water/sediment system

Time (d)	Bound Residues	NCR	Glyphosate	AMPA
0	2.6	6.8	3.6	1.2
0.25	2.84	12.3	8.8	2.9
1	10.06	18.1	19.9	4.9
2	11.62	11.4	33.4	5.9
7	19.85	14.9	31.6	5.5
14	25.12	19.4	35.5	6.3
29	24.46	16.6	40	10.5
58	29.46	20	33	10.7
97	16.13	20.8	27.1	13.9
120	17.15	15.2	29.8	15.7

Table A 15: Content of Glyphosate and its metabolite AMPA in the sediment in % of the applied radioactivity in the Creek water/sediment system

Time (d)	Bound Residues	NCR	Glyphosate	AMPA
0	1.1	1.4	5.6	0.6
0.25	1.3	1.5	5.1	1.4
1	2.05	2.1	6.9	2
2	2.65	4.2	9.4	3.7
7	4.83	4.9	8.9	7
14	4.12	6.9	6.6	8.7
29	9.81	7.1	7.2	12.2
58	10.43	6.3	6.3	12.8
97	8.02	7.4	0	15.1
120	9.49	6.4	0	15.9

Disappearance in the water phase of the water/sediment system Pond was primarily caused by a continuous transfer from the water phase to the sediment phase, probably caused by sorption processes. In the sediment, rising amounts of degradation products indicated that the degradation process was still in progress after 120 d in both systems. The main fractions were the uncharacterized group of bound residues (Pond), the soluble or extractable group of non-chromatographable residues and the metabolite AMPA. Another metabolite was detected in the water phase but not identified as it only appeared in samples taken from the water/sediment system Pond (58 d) with an amount of less than 0.1 % of the applied activity.

Kinetic evaluation by the zRMS

In the study (Heintze, 1996), no SFO-DT_{50} values for Glyphosate concerning the whole system and the water phase are reported as required for deriving PEC_{SW} values with FOCUS Surface Water and EVA 2.1 (only relevant for German risk assessment). Therefore, they were calculated by the zRMS according to FOCUS Degradation Kinetics (2006), Level P-I. All kinetic evaluations and statistical calculations for the quality checks were conducted with KinGUI 2.

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are presented in Table A 16. In this table the visual fits are assessed as well. The graphics are shown further down.

Table A 16: Kinetic evaluation for Glyphosate using SFO kinetics

M_0			k			DT_{50}	DT_{90}	χ^2 error	Visual Assessment
Estimate	St. Dev.	Prob > t	Estimate	St. Dev.	Prob > t				
Water/sediment system I (Pond)									
63.7	2.596535	4.08E-09	0.008323	0.001464	0.000231	83.3	276.7	8.342	+
Water/sediment system II (Creek)									
85.8	1.617875	8.90E-12	0.041363	0.002963	3.36E-07	16.8	55.7	4.608	+
Water phase I (Pond)									
55.9	5.42947	3.43E-06	0.1232	0.05118	0.0213	5.6	18.7	23.79	-
Water phase II (Creek)									
79.7	1.694835	2.32E-11	0.050956	0.004033	7.23E-07	13.6	45.2	5.322	+

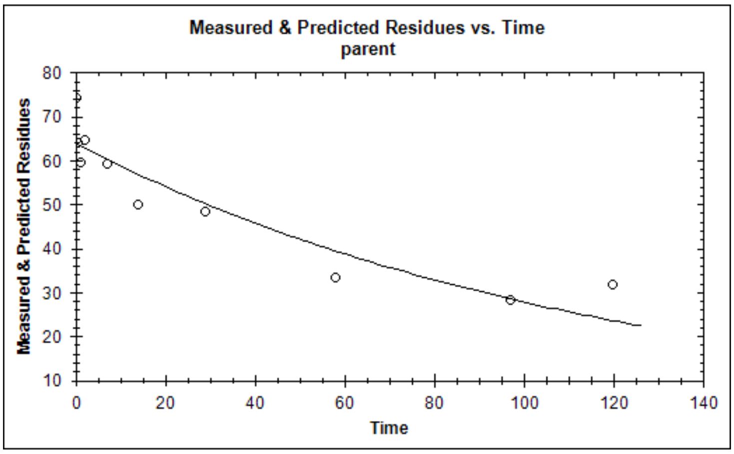


Figure A 33: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water/sediment system I (Pond)

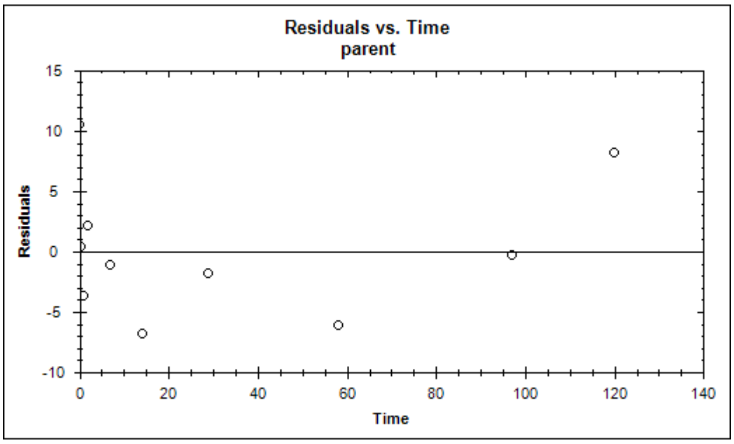


Figure A 34: Residuals vs. time for Glyphosate using SFO kinetics, Water/sediment system I (Pond)

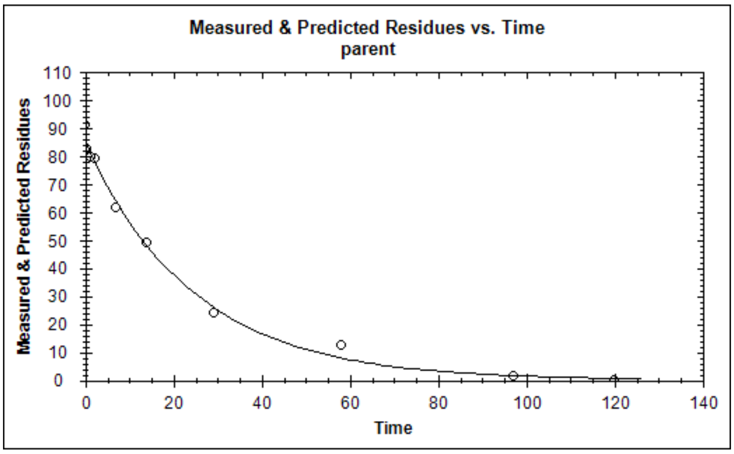


Figure A 35: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water/sediment system II (Creek)

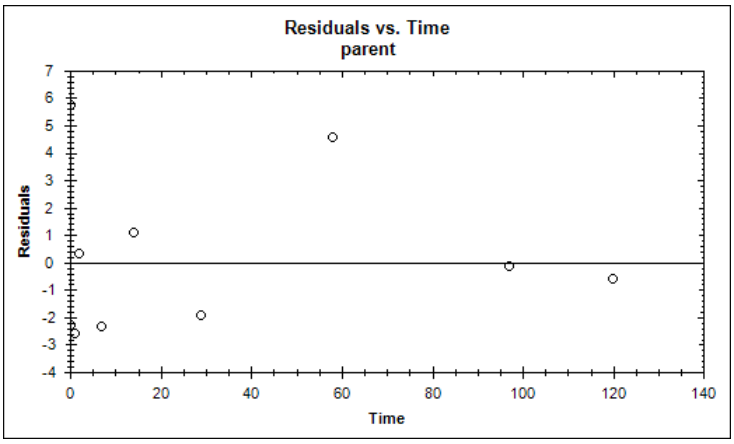


Figure A 36: Residuals vs. time for Glyphosate using SFO kinetics, Water/sediment system II (Creek)

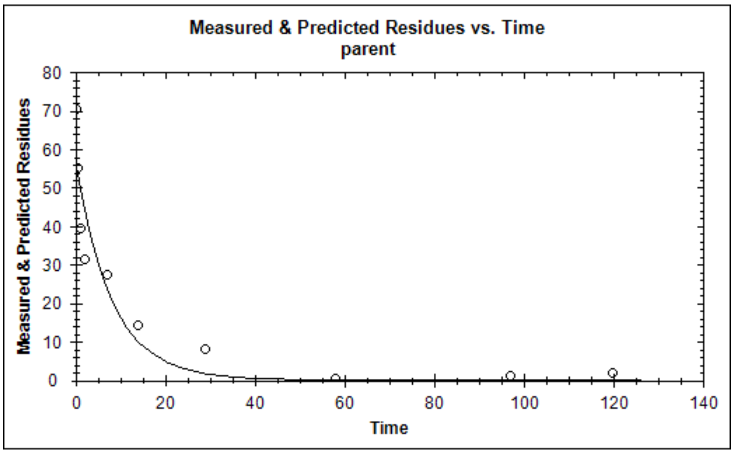


Figure A 37: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water phase I (Pond)

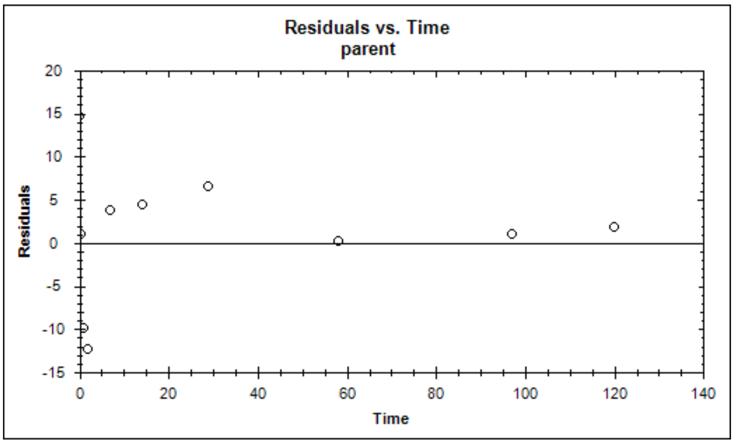


Figure A 38: Residuals vs. time for Glyphosate using SFO kinetics, Water phase I (Pond)

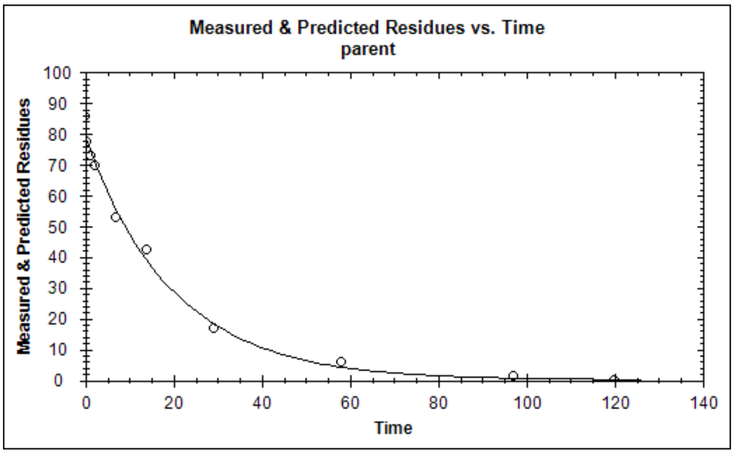


Figure A 39: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water phase II (Creek)

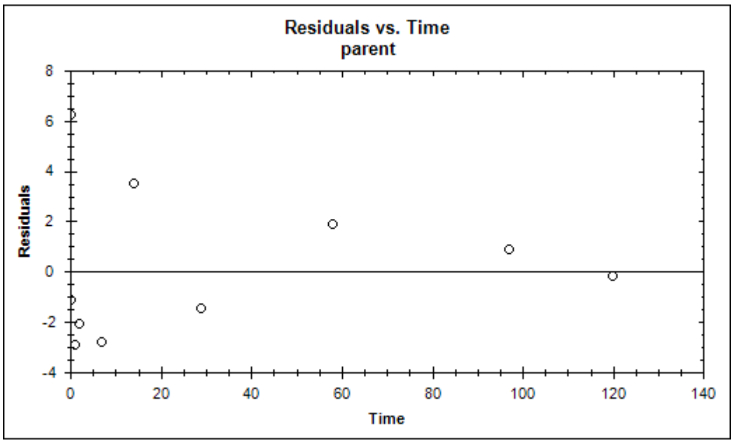


Figure A 40: Residuals vs. time for Glyphosate using SFO kinetics, Water phase II (Creek)

Visual assessments, the calculated χ^2 errors and the calculated t-test probabilities (Prob > t) indicate that the degradation of Glyphosate in the water/sediment systems and the dissipation of Glyphosate in the water phases could be well described by SFO kinetics except for the dissipation of Glyphosate in the water phase of system I (Pond). Here, the dissipation of Glyphosate was overestimated (see Figure A 37 and Figure A 38) and the calculated χ^2 error (23.8 %) does not indicate a good fit. Since 10 % of the initial measured concentration was reached within the experimental period, the data were re-evaluated using the Gustafson and Holden model (FOMC), the hockey-stick model (HS) and the bi-exponential model (DFOP) (see p. 198 in Focus Degradation Kinetics (2006)).

Regarding visual fits and statistical calculations the DFOP kinetic evaluation gave the best and fully reliable results for Glyphosate in the water phase of system I (Pond). Therefore, DT_{90} DFOP can be used to recalculate DT_{50} SFO as required for deriving PEC_{SW} values with EVA 2.1. The results of the kinetic evaluation using DFOP kinetics including visual assessment for Glyphosate in the water phase of system I (Pond) are summarized in Table A 17. The graphics are shown below.

Table A 17: Kinetic evaluation for Glyphosate using DFOP kinetics

Water phase I (Pond)					
M_0			k_{fast}		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
70.4	1.958568	1.55E-08	2.186883	0.515657	0.002717
k_{slow}			g		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
0.056654	0.007783	0.000171	0.522084	0.035388	3.05E-06

DT_{50}	DT_{90}	χ^2 error	DT_{50} SFO[1)]	Visual Assessment
1.5	29.2	5.535	8.8	+

1) Recalculated (DT_{50} SFO = DT_{90} DFOP / 3.32) according to Focus Degradation Kinetics (2006), Level P-I (p. 198)

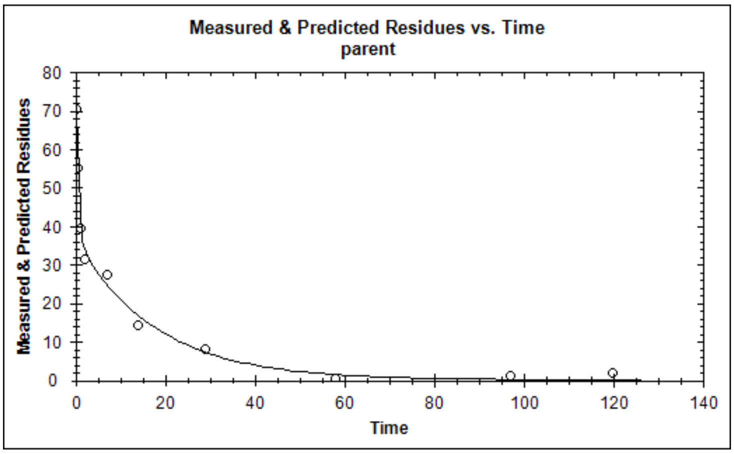


Figure A 41: Measured & predicted residues vs. time for Glyphosate using DFOP kinetics, Water phase I (Pond)

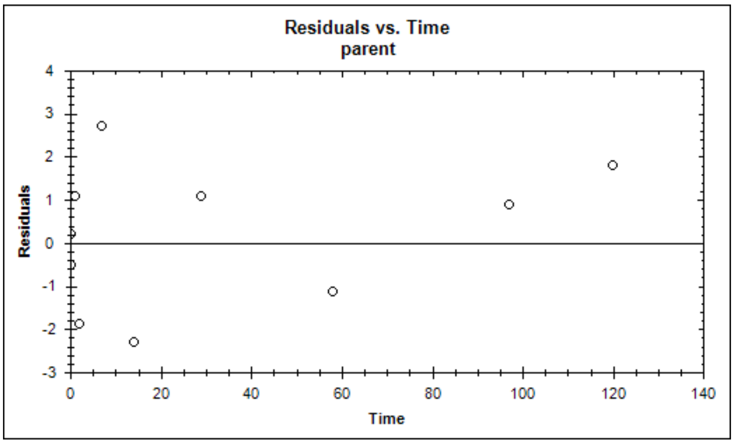


Figure A 42: Residuals vs. time for Glyphosate using DFOP kinetics, Water phase I (Pond)

Conclusion

In the study (Heintze, 1996) the decrease the Glyphosate concentration is caused by metabolism and degradation of the compound as well as by transfer process from the water to the sediment, probably caused by sorption processes.

The degradation of Glyphosate in both water/sediment systems and the dissipation of Glyphosate in the water phase of system II (Creek) are well described by SFO kinetics. DFOP kinetics show the best fit for the dissipation of Glyphosate in the water phase of system I (Pond)

Comments of zRMS

The study is acceptable.

KIIA 7.8.3 Muttzall (1993)

Reference:	KIIA 7.8.3
Author:	Muttzall, P.I.
Report:	Water/sediment biodegradation of [^{14}C]glyphosate

Date:	18.03.1993
Guideline(s):	Yes (Dutch Guideline „Aanvraag tot toelating van een betrijdingsmiddel“ ,1991)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study (Muttzall, 1993) was already evaluated in the DAR (1998). However, since no SFO-DT_{50} values for the whole system and the water phase were available as required for deriving PEC_{SW} values with FOCUS Surface Water and EVA 2.1 (only relevant for German risk assessment), they were calculated by the zRMS according to FOCUS Degradation Kinetics (2006). All kinetic evaluations and statistical calculations for the quality checks were conducted with KinGUI 2. The results are presented in the following.

Results and discussions

The results of the kinetic evaluation using single first-order (SFO) kinetics for Glyphosate are summarized in Table A 18. The graphics are shown further down.

A DT_{50} for the dissipation from the water phase could not be determined because there were not sufficient data points.

Table A 18: Kinetic evaluation for Glyphosate using SFO kinetics

M_0			k			DT_{50}	DT_{90}	χ^2 error	Visual Assess ment
Esti-mate	St. Dev.	Prob > t	Esti-mate	St. Dev.	Prob > t				
Water/sediment system I (Zuidpolder)									
87.0	7.209	1.03E-6	0.007925	0.002441	0.00588	87.5	290.5	13.58	-
Water/sediment system II (Kromme Rijn)									
92.3	6.160	1.94e-07	0.015681	0.002803	0.000257	44.2	146.8	12.34	-

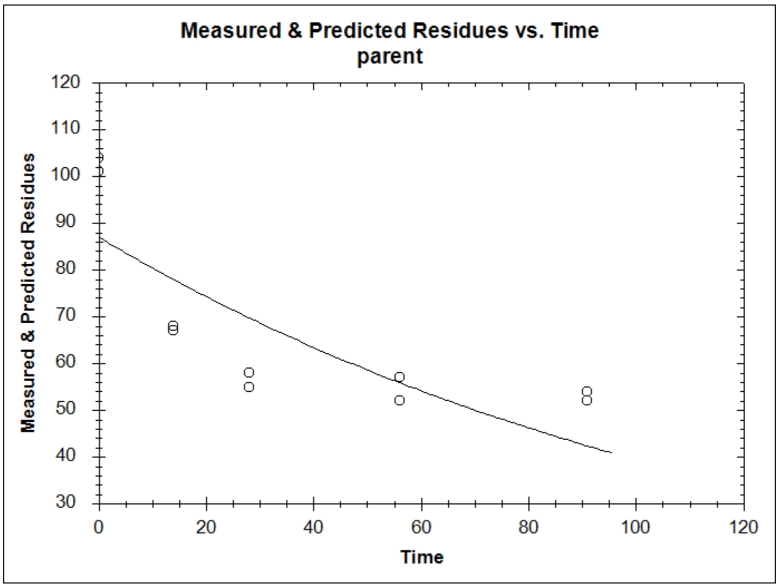


Figure A 43: Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water/sediment system I (Zuidpolder)

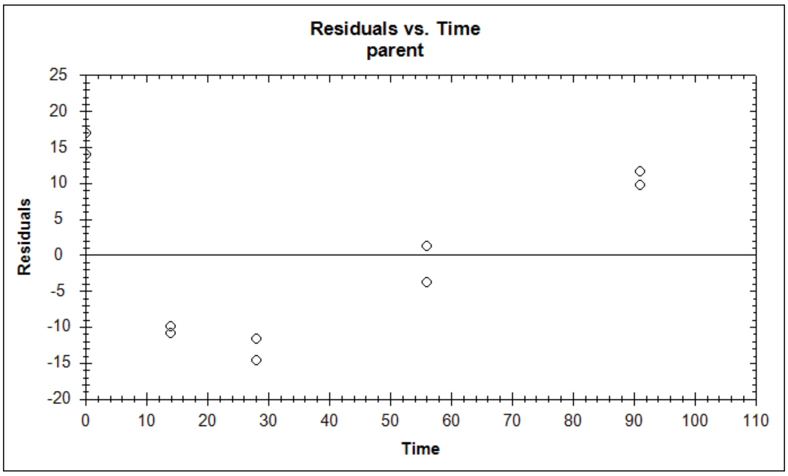


Figure A 44: **Residuals vs. time for Glyphosate using SFO kinetics, Water/sediment system I (Zuidpolder)**

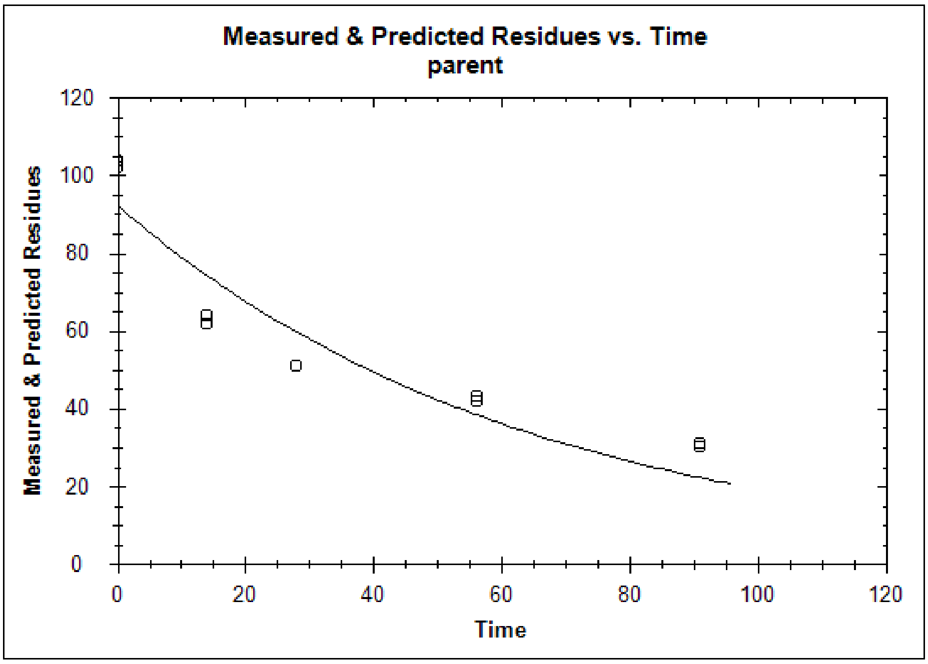


Figure A 45: **Measured & predicted residues vs. time for Glyphosate using SFO kinetics, Water/sediment system II (Kromme Rijn)**

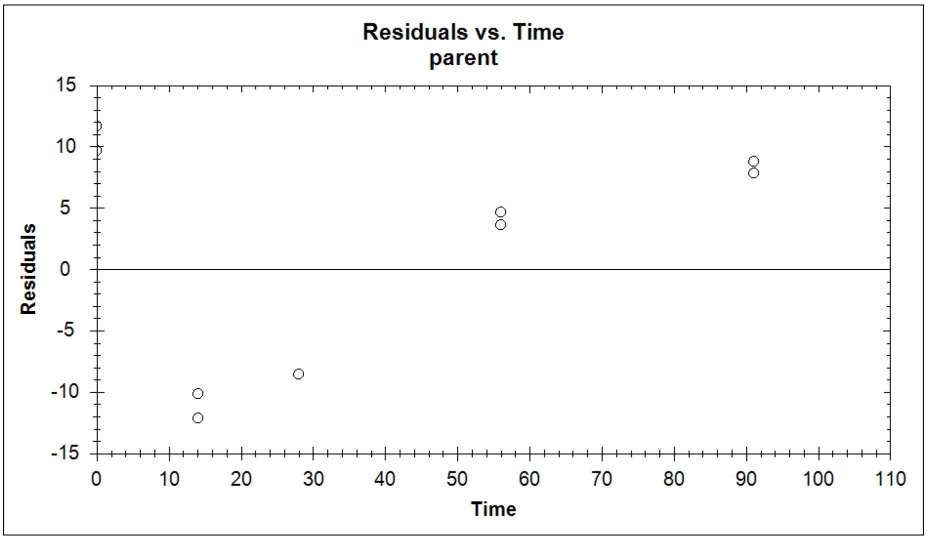


Figure A 46: Residuals vs. time for Glyphosate using SFO kinetics, Water/sediment system II (Kromme Rijn)

Visual assessments indicate that the degradation of Glyphosate in the water/sediment systems is not well described by SFO kinetics.

As the degradation of the parent substance does not reach 10 % of the initial amount within the study period, DFOP and HS kinetics were calculated. The results of the kinetic evaluation using DFOP kinetics are shown below.

Table A 19: Kinetic evaluation for Glyphosate using DFOP kinetics

Water/sediment system I (Zuidpolder)								
M_0			**k_{fast}**			**k_{slow}**		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
102.5	9.235e-02	3.23e-10	9.235e-02	1.59e-02	0.000582	1.159e-04	9.93e-04	0.455453
g			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment**	
Estimate	**St. Dev.**	**Prob > t**						
0.475	3.941e-02	9.88e-06	418.4	-	0.72	5981	+	
Water/sediment system II (Kromme Rijn)								
M_0			**k_{fast}**			**k_{slow}**		
Estimate	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**	**Estimate**	**St. Dev.**	**Prob > t**
103.0	9.999e-01	2.82e-11	1.379e-01	2.46e-02	6.80e-04	7.817e-03	7.06e-04	1.61e-05
g			**DT_{50}**	**DT_{90}**	**χ^2 error**	**DT_{50} SFO[1)]**	**Visual Assessment**	
Estimate	**St. Dev.**	**Prob > t**						
0.38	2.735e-02	4.170e-06	28.9	232.9	1.29	88.7	+	

1) Recalculated (from $\mathbf{k_{slow}}$)

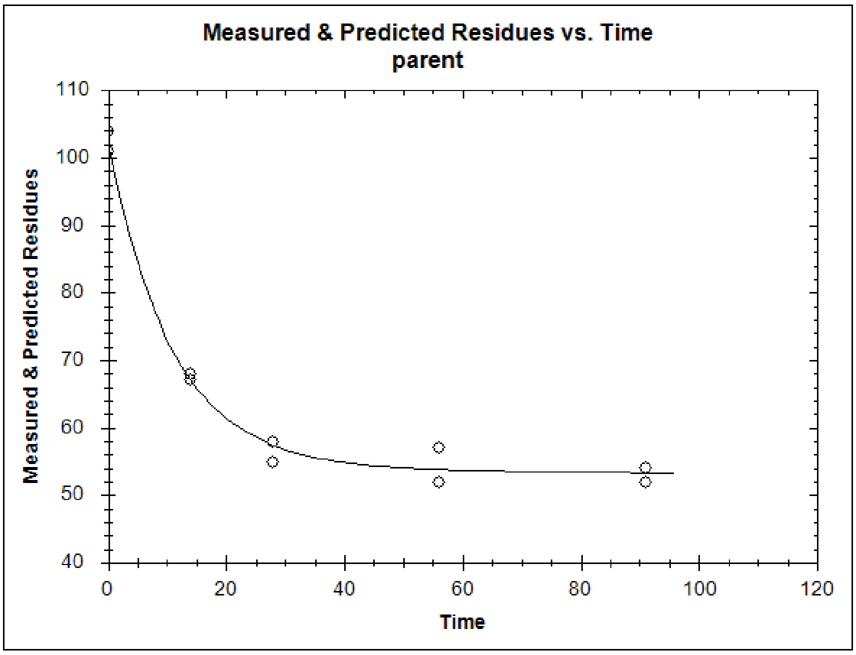


Figure A 47: **Measured & predicted residues vs. time for Glyphosate using DFOP kinetics, Water/sediment system I (Zuidpolder)**

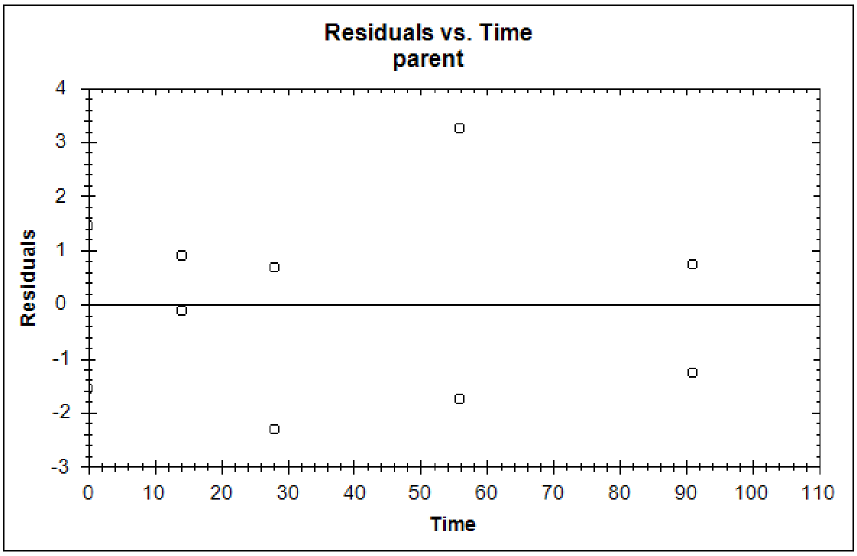


Figure A 48: **Residuals vs. time for Glyphosate using DFOP kinetics, Water/sediment system I (Zuidpolder)**

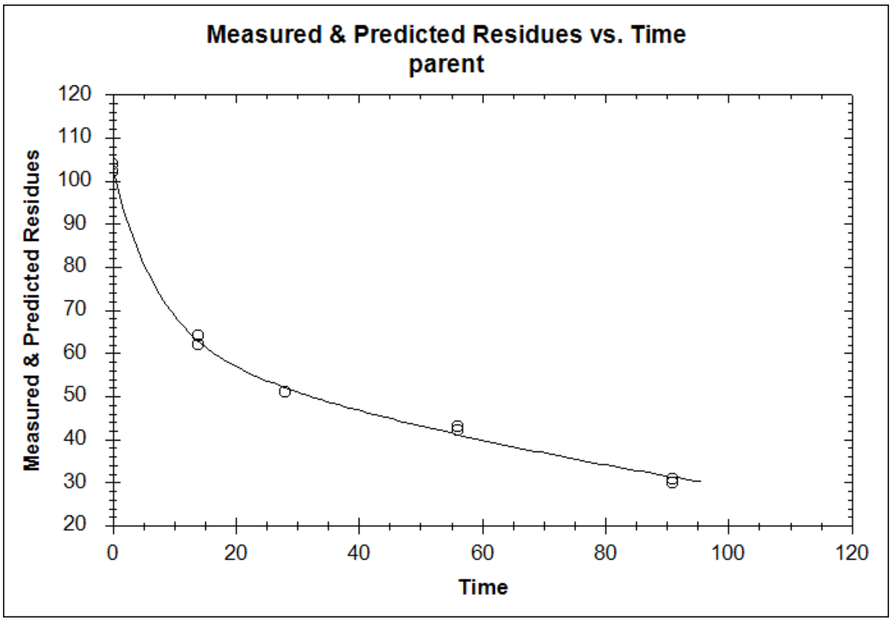


Figure A 49: Measured & predicted residues vs. time for Glyphosate using DFOP kinetics, Water/sediment system II (Kromme Rijn)

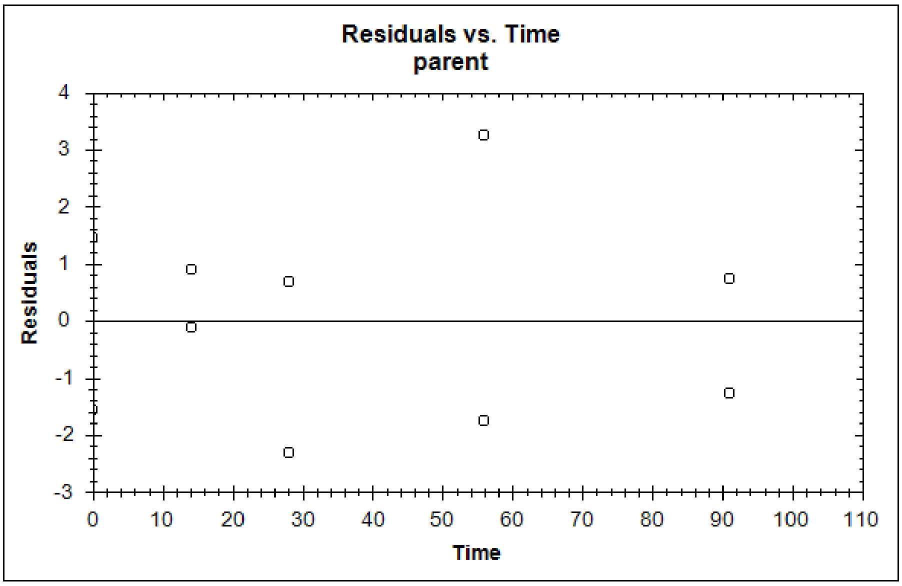


Figure A 50: Residuals vs. time for Glyphosate using DFOP kinetics, Water/sediment system II (Kromme Rijn)

HS kinetics were also calculated but the fit was not as good as for the DFOP kinetics (χ^2 errors of 3.9 % and 2.4 % for System I and II). The results are not further presented here.

Conclusion

DFOP kinetics show the best fit for the degradation for both of the water/sediment systems. Endpoints for modeling are DT50 values of 5981 d and 88.7 d, respectively.

Comments of zRMS

Not applicable (evaluation performed by the zRMS).

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: HAG 500 02 H

Active Substance(s): Glyphosate 450 g/L

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: Helm AG

Date: 20/07/2012

Table of Contents

SEC 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9) ... 3

5.1 General Information on the formulation ... 3
5.2 Proposed use pattern ... 3
5.3 Information on the active substances ... 4
5.3.1 Glyphosate ... 4
5.4 Summary on Inputparameter for environmental exposure assessment ... 4
5.4.1 Rate of degradation in soil ... 4
5.4.2 Adsorption/desorption ... 5
5.4.3 Rate of degradation in water ... 8
5.5 Estimation of concentrations in soil (KIIIA1 9.4) ... 9
5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7) ... 10
5.6.1 PEC_{SW} after exposure by spraydrift and deposition following volatilisation ... 10
5.6.2 PEC_{SW} after exposure by surface run-off and drainage ... 11
5.7 Risk assessment for groundwater (KIIIA1 9.6) ... 12
5.7.1 Direct leaching into groundwater ... 13
5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage ... 14

APPENDIX 1 TABLE OF INTENDED USES IN GERMANY (ACCORDING TO BVL 10.08.2011) ... 17

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product HAG 500 02 H in its intended uses in various crops is documented in detail in the core assessment of the plant protection product HAG 500 02 H dated from 20.07.2012 performed by Germany.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product HAG 500 02 H in Germany according to uses listed in Appendix 1.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see Part B Section 6 National addendum and Part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation HAG 500 02 H

Code	HAG 500 02 H
plant protection product	HAG 500 02 H
applicant	Helm AG
date of application	21/04/2011
Formulation type (WP, EC, SC, …; density)	SL
active substance	Glyphosate
Concentration of as	450 g/L

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 1.

The intended uses in Germany are covered by the core assessment.

Table 5.2-1: Classification of intended uses in Germany for HAG 500 02 H

Group/ use No	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001, 00-007	Field crops, Grassland / -	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0 %	1800	1800

B/ 00-002, 00-004	Pome fruit, Vineyards/ -	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0 %	1800	1800
C/ 00-003, 00-005	Pome fruit, Vineyards/ -	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0 %	3600	3600
D/ 00-006	Cereals/ BBCH 89	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,90%	1800	180
E/ 00-008	Oilseed rape (winter)/ BBCH 87-89	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,80 %	1125	225
F/ 00-009	Oilseed rape (winter)/ BBCH 00-08	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0%	1125	1125

5.3 Information on the active substances

5.3.1 Glyphosate

See core assessment.

5.4 Summary on Inputparameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

Glyphosate

See core assessment

AMPA

See core assessment

5.4.2 Adsorption/desorption

Glyphosate

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). The results are summarized in Table 5.4-1 and Table 5.4-2.glyphosate

Soil Type	**OC (%)**	**pH (-)**	**Kd (mL g-1)**	**Kdoc (mL g-1)**	**Kf (mL g-1)**	**Kfoc (mL g-1)**	**1/n (-)**	**Reference**
Sand	0.8	5.7	263	32838	-	-	-	Waring (1992), DAR (1998)
Sand loam	1.6	7.1	811	50660	-	-	-	Waring (1992), DAR (1998)
Sandy clay loam	1.4	7.8	50	3598	-	-	-	Waring (1992), DAR (1998)
Loamy sand	0.6	8.3	5	884	-	-	-	Waring (1992), DAR (1998)
Silt loam	1.4	6.1	48	3404	-	-	-	Waring (1992), DAR (1998)
Loam (sediment)	3.0	7.1	510	17019	-	-	-	Waring (1992), DAR (1998)
Silty clay loam	1.45	6.5	-	-	324	22345*	0.92	Living-ston et al. (1986), DAR (1998)
Silt loam	0.87	7.4	-	-	33	3793*	0.80	Living-ston et al. (1986), DAR

								(1998)
Loamy sand	1.10	5.2	-	-	660	60000*	1.16	Living-ston et al. (1986), DAR (1998)
Arithmetic mean			-	-	-	21616**	0.96	-

* Calculation with Input Decision 3.2

** Arithmetic mean of Kfoc and Kdoc values combined

Table 5.4-2Table 5.4-1: K_f, K_{foc} and 1/n (Freundlich exponent) values for glyphosate

Soil Type	**OC (%)**	**pH (-)**	**K_d (mL g^{-1})**	**K_{doc} (mL g^{-1})**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Sand	0.8	5.7	263	32838	-	-	-	Waring (1992), DAR (1998)
Sand loam	1.6	7.1	811	50660	-	-	-	Waring (1992), DAR (1998)
Sandy clay loam	1.4	7.8	50	3598	-	-	-	Waring (1992), DAR (1998)
Loamy sand	0.6	8.3	5	884	-	-	-	Waring (1992), DAR (1998)
Silt loam	1.4	6.1	48	3404	-	-	-	Waring (1992), DAR (1998)
Loam (sediment)	3.0	7.1	510	17019	-	-	-	Waring (1992), DAR (1998)
Silty clay loam	1.45	6.5	-	-	324	22345*	0.92	Living-ston et al. (1986), DAR (1998)
Silt loam	0.87	7.4	-	-	33	3793*	0.80	Living-ston et al.

								(1986), DAR (1998)
Loamy sand	1.10	5.2	-	-	660	60000*	1.16	Living-ston et al. (1986), DAR (1998)
Arithmetic mean			-	-	-	21616**	0.96	-

* Calculation with Input Decision 3.2

** Arithmetic mean of K_{foc} and K_{doc} values combined

Table 5.4-2: Statistic values according to INPUT DECISION 3.2 for glyphosate for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 5.73	
correlation K_{foc} and pH	Kendall-τ: -0.592 p-value: 0.036	significant → use pH tool
correlation K_f and pH	Kendall-τ: - 0.366 p-value: 0.208	not relevant
correlation K_f and oc	Kendall-τ: 0.535 p-value: 0.030	not relevant
coefficient of variation K_{foc}	-	not relevant
coefficient of variation Kf	-	not relevant
Correlation K_f and other soil parameter (clay, CEC)	-	not significant
K_{foc} for PEC_{GW}	60000 (pH 5.2) 884 (pH 8.3)	pH-Tool, Hamburg scenario and Kremsmünster scenario
1/n PECgw	0.96	arithmetic mean all soils n= 3

AMPA

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). The results are summarized in Table 5.4-3 and Table 5.4-4.

Table 5.4-3: K_f, K_{foc} and 1/n (Freundlich exponent) values for AMPA

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Clay loam	2.1	7.7	77.1	3671*	0.786	Weeden (1993), DAR (1998)

Sand**	18.7	4.7	1570	8396*	0.904	Weeden (1993), DAR (1998)
Sand	1.3	7.4	15.7	1208*	0.752	Weeden (1993), DAR (1998)
Clay loam	0.9	7.6	53.9	5989*	0.791	Weeden (1993), DAR (1998)
Loamy sand	1.6	6.3	110	6875*	0.769	Weeden (1993), DAR (1998)
Sand	0.3	4.6	73.0	24333*	0.788	Weeden (1993), DAR (1998)
Arithmetic mean				8412	0.798	-

* Calculation with Input Decision 3.2

** According to OECD 106 the OC content (%) is too high. Since the corresponding K_{foc} (8396 mL g^{-1}) value is in the same order of magnitude as the other values, the K_{foc} value is used for further calculations.

Table 5.4-4: Statistic values according to INPUT DECISION 3.2 forAMPA for PEC_{GW} modelling

correlation K_{foc} and pH	Kendall-τ: -0.733 p-value: 0.060	not significant
correlation K_f and pH	Kendall-τ: -0.200 p-value: 0.707	not significant
correlation K_f and oc	Kendall-τ: 0.467 p-value: 0.130	not significant
coefficient of variation K_{foc}	-	too high (> 60%)
coefficient of variation Kf	-	too high (> 100%)
Correlation K_f and other soil parameter (clay, CEC)	-	not significant
K_f for PEC_{GW}	1.-3. Horizon: 34.8 4.-6. Horizon: 0	k_f-values specific for soil horizons
1/n PECgw	0.798	arithmetic mean of all soils n= 6

5.4.3 Rate of degradation in water

Glyphosate

See core assessment.

AMPA

See core assessment.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for HAG 500 02 H according to EU assessment considering 5 cm soil depth are given in Table 5.5-2 of Part B, Section 5.5 of the core assessment.

For German exposure assessment the applied soil depth in case of glyphosate is 2.5 cm.

Due to the fast degradation of the active substance glyphosate (DT_{90} < 365 d, Kinetic DFOP, field data) and the metabolite AMPA (DT_{90} < 365 d, Kinetic SFO, lab data) in soil the accumulation potential of does not need to be considered.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for glyphosate as presented in Table 5.5-1.

Table 5.5-1: Input parameter for HAG 500 02 H for PEC_{soil} calculation

Active substance/metabolite	**DT_{50}**
glyphosate	6.9d (DFOP: k_{Fast} = 0.1266, k_{Slow} = 0.0038, g = 0.850, maximum, field studies, see core assessment chapter 5.4.1.2)
AMPA	worst case parent kintics for AMPA formation: 3.4 d (FOMC, alpha = 0.432, beta = 0.847, minimum, field studies, see core assessment chapter 5.4.1.2) AMPA: 52.2 d (lab studies, see core assessment chapter 5.4.1.1)

For the metabolite formation of AMPA, 100 % formation fraction were considered.

Additional $PEC_{soil,act}$ was calculated for the formulation HAG 500 02 H for a soil depth of 2.5 cm.

No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for glyphosate, AMPA and for the formulation HAG 500 02 H are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended uses in orchards and vineyards used for German risk assessment

plant protection product:		HAG 500 02 H				
use:		Group C (worst case covering all other uses)				
Number of applications/intervall		1				
application rate:		8 L/ha (3600 g glyphosate / ha) as worst case				
crop interception:		0 %				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
glyphosate	3600	2.5	9.600	-	-	-
AMPA	100 % formation fraction from as	2.5	3.890 on day 14	-	-	-

HAG 500 02 H	8000	2.5	21.333	-	-	-
use:		Group B (covering all other uses except Group C)				
Number of applications/intervall		1				
application rate:		4 L/ha (1800 g glyphosate / ha) as worst case				
crop interception:		0 %				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC$_{act}$ (mg/kg)**	**tillage depth (cm)**	**PEC$_{bkgd}$ (mg/kg)**	**PEC$_{accu}$ = PEC$_{act}$ + PEC$_{bkgd}$ (mg/kg)**
glyphosate	1800	2.5	4.800	-	-	-
AMPA	100 % formation fraction from as	2.5	1.945occu rring on day 14	-	-	-
HAG 500 02 H	4000	2.5	10.677	-	-	-

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of glyphosate for the intended for uses of HAG 500 02 H using FOCUS Surface Water are given in Table 5.6-2 of Part B, Section 5.6 of the core assessment.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC$_{SW}$ after exposure by spraydrift and deposition following volatilisation

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance glyphosate is between 10^{-5} and 10^{-4} Pa. Hence the active substance glyphosate is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of surface water by the active substance glyphosate due to deposition following volatilization needs to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. Even though glyphosate is considered as semivolatile with a vapour pressure of 1.31 x10^{-5} Pa (25 °C, acid), the contribution of volatilasation is negligible. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. .

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-1.

Table 5.6-1: Endpoints of glyphosate used for the PEC$_{SW}$ calculations with EVA 2.1

Parameter	Active substance glyphosate	Reference
vapour pressure at 20 °C (Pa)	1.31 x10-5 Pa (25 °C, acid)	LoEP

Solubility in water (mg/L)	18800	see core assessment chapter 5.3.1.2
hydrolysis/photolysis	1000 (default)	

The calculated PECsw values after exposure via spray drift and volatilization with subsequent deposition for the active substance glyphosatefor the intended for use in vineyard (worst case application rate) are summarized in Table 5.6-2. Regarding the PECsw values of the active substance glyphosate of the other intended uses of the plant protection product HAG 500 02 H see National addendum Part B section 6, chapter 6.2.2.

Table 5.6-2: PEC_{SW} for the active substance glyphosate after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance		glyphosate						
use pattern/gap:		Group C , covering all intented uses						
application rate/number of applications / interval		1 x 3600 g a.i./ha (worst case)						
relevant PEC if applicable twa-interval		PEC_{ini}						
scenario/percentile:		Agriculture/ 90th percentile of drift probabilities						
distance (m)		PEC_{sw} via drift						
			PEC_{sw} via volatilisation		PEC_{sw} (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50%red.
1	2.77	33.24			33.240	3.32	8.31	16.62
5	0.57	6.84			6.8	0.7	1.7	3.4
10	0.29	3.48			3.5	0.3	0.9	1.7
15	0.20	2.40			2.4	0.2	0.6	1.2
20	0.15	1.80			1.8	0.2	0.5	0.9

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

The concentration of the active substance glyphosate in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0. The applicant submitted the dossier before the 31. November 2011. Therefore, also EXPOSIT 2.02_kd could be used for risk assessment of HAG 500 02 H. The results were compared, and as EXPOSIT 3.0 led to lower PECs, this model was used for risk assessment.

The endpoints for glyphosate used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-3.

Table 5.6-3 Input parameters for glyphosate used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	**Glyphosate**	**Reference to Part B, Section 5, Core assessment**
$K_{foc,\ Runoff}$	21616	arithmetic mean, Table 5.6-4 of core assessment

$K_{foc, mobility class}$	21616	arithmetic mean, Table 5.65.6-5 of core assessment
DT_{50} soil (d)	113.6	90th percentile lab studies, see Table 5.65.6-1 of core assessment
Solubility in water (mg/L)	18800	see core assessment chapter 5.3.1.2
Mobility class	1	-

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance glyphosate for the intended for use in orchards and vineyards (worst case application rate) are summarized in Table 5.6-5.

Table 5.6-5 PEC_{SW} of glyphosate in an adjacent ditch due to surface run-off and drainage

Active substance: glyphosate **Use pattern/GAP:** Group C/uses 00-003, 00-005 **Application rate:** 3600 g/ha (worst case)	
Exposure by surface runoff	
vegetated buffer strip (m)	**PECsw in adjacent ditch (µg/L)**
0	1.90
5	1.65
10	1.41
20	0.99
Exposure by drainage	
time of application	**PECsw in adjacent ditch (µg/L)**
autuum/winter/early spring	0.55
Spring/summer	1.70

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of glyphosate and its metabolite AMPA for the intended uses of HAG 500 02 H in orchards and vineyards according to EU assessment using FOCUS PELMO 4.4.3 are given in Table 5.7-4, Table 5.7-5, Table 5.7-6 and Table 5.7-7 of Part B, Section 5 of the core assessment.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.2 and subsequent simulations are performed for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster” of FOCUS PELMO 4.4.3.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

The worst case scenarios used for PECgw modelling are summarized in Table 5.7-1. It covers the intended uses of HAG 500 02 H in orchards and vineyards according to Table 5.2-1 (see also Appendix 1).

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 4.4.3

use evaluated	group C: uses 00-003 and 00-005
application rate (kg as/ha)	1 × 3600 g glyphosate/ha disregarding interception
crop (crop rotation)	Orchards (00-003) and vineyards (00-005), Sufficient leaves for uptake of a.s. in both uses
date of application	0 days after 1st emergence in the year
interception (%)	0 %
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0 for glyphosate and AMPA*
simulation period (years)	26

* Default according to FOCUS (2000) and Holdt et al. (2011)

Glyphosate

The endpoints used for groundwater modelling for glyphosate and its metabolite AMPA according to INPUT DECISION 3.2 are summarized in Table 5.7-2.

Table 5.7-2: Input parameters related to glyphosate for PEC_{GW} modelling

Parent	**Glyphosate**	**Remarks/Reference to Part B, Section 5, Core assessment**
molecular mass	169.1	-
DT_{50} in soil (d)	67.7 (acidic soils)	SFO, geometric mean for acidic soils, normalised (20ºC, pF2), laboratory studies (n = 4), Hamburg Scenario
K_{foc}	60000 (pH 5.2) 884 (pH 8.3)	pH-Tool, Hamburg scenario and Kremsmünster scenario
1/n	0.96	Arithmetic mean
pK_s	5.73	-
Metabolite	**AMPA**	**Remarks/Reference to Part B, Section 5, Core assessment**
molecular mass	111.0	-

Formation fraction	0.56	Maximum (n = 1), laboratory studies
DT_{50} in soil (d)	52.2	SFO, maximum (n = 1), normalised (20ºC, pF2), laboratory studies
K_f	1.-3. horizon: 34.8 4.-6. horizon: 0	k_f-values specific for soil horizons (1.-3. horizon: 10. percentile (CV > 100 %)), Hamburg scenario
1/n	0.798	Arithmetic mean

According to INPUT DECISION 3.2, more precisely the evaluation of K_{foc} for glyphosate, the pH-tool should be used combined with the FOCUS scenarios Hamburg and Kremsmünster. Due to the evaluation of DT_{50} for glyphosate only the FOCUS Hamburg scenario should be considered in the groundwater simulation, besides horizon specific K_f values for AMPA were only calculated for the FOUCUS Hamburg scenario. For these reasons, the groundwater simulation was not performed by using the FOCUS Kremsmünster scenario. The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3: PEC_{GW} at 1 m soil depth of glyphosate and its metabolite AMPA considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3	
		Glyphosate	**AMPA**
00-003/orchards (apples selected as representative in FOCUS PELMO 4.4.3)	Hamburg	< 0.001	< 0.001
00-005/vineyards	Hamburg	< 0.001	< 0.001

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance glyphosate in concentrations of ≥ 0.1 µg/L is not expected.

For the metabolite AMPA a groundwater concentration of ≥ 0.1 µg/L can be excluded according to the results of the groundwater simulation with FOCUS-PELMO 4.4.3.

5.7.1.2 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS PELMO 4.4.3 show that the active substance glyphosate is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L. For the metabolite AMPA concentrations of ≥ 0.1 µg/L in groundwater can be excluded.

Consequences for authorization:

None.

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

The concentration of the active substance glyphosate in bank filtrate due to surface runoff and drainage is calculated using the model EXPOSIT 3.0. The applicant submitted the dossier before the 31. November 2011. Therefore, also EXPOSIT 2.02_kd could be used for risk assessment of HAG 500 02 H. The results were compared, and as EXPOSIT 3.0 led to lower PECs, this model was used for risk assessment.

The input parameters for glyphosate used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-4.

Table 5.7-4 Input parameters for glyphosate used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	**Glyphosate**	**Reference to Part B, Section 5, Core assessment**
$K_{foc,\ Runoff}$	21616	arithmetic mean, Table 5.4-5 of core assessment
$K_{foc,\ mobility\ class}$	21616	arithmetic mean, Table 5.4-5 of core assessment
DT_{50} soil (d)	113.6	90^{th} percentile lab studies, see Table 5.4-1 of core assessment, field studies not considered due to application timing
Solubility in water (mg/L)	18800	see core assessment chapter 5.3.1.2
Mobility class	1	-
Reduction by bank filtration	23.5 %	measured values, see Schmidt, 2005 (TZW Karlsruhe)

The calculated PECgw for glyphosate after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-5.

Table 5.7-5 PEC_{gw} for glyphosate after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.0)

Active substance		**glyphosate**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
A,B/ 00-001, 00-002, 00-004, 00-007*	1800 g/ha 0 %	0	0.058	autumn/winter/ early spring	0.052
		5	0.050		
		10	0.043	spring/summer	0.017
		20	0.030		
required labelling		none			
C/ 00-003, 00-005	3600 g/ha 0 %	0	**0.116**	autumn/winter/ early spring	not relevant for use
		5	**0.101**		
		10	0.087	spring/summer	0.034
		20	0.061		
required labelling		NG 402			

* also covering the remaining uses (E/00-008, D/00-006, F/00-009)

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance glyphosate due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can only be excluded in case risk mitigation measures depending on the use are applied.

Metabolites

The soil metabolites of glyphosate (see Part B core assessment, Section 5, Table 5.3-3) are formed > 10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.0. However, due to the long DT50 of 113.6 d used in the assessment of glyphosate, PECs of glyphosate will always be higher than the PECs of AMPA.

Accordingly, an assessment of groundwater contamination by the soil metabolites of glyphosate due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration is not necessary.

Consequences for authorization:

The authorization of the plant protection product HAG 500 02 H is linked with following labeling:

Use No. 00-003, 00-005 NG 402

Appendix 1 Table of Intended Uses in Germany (according to BVL 10.08.2011)

PPP (product name/code) **HAG 500 02 H** **Formulation type:** **SL**
active substance 1 **glyphosate** **Conc. of as 1:** **450 g/L**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
00-001	DE	Field crops	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	Stubble application, until 4 days before sowing	a) 1 b) 1	a) 4 L/ha	a) as1.8 kg/ha	100/200	-	
00-002	DE	Pome Fruit	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	Spring to summer, 15 – 20 cm weed height	a) 1 b) 1	a) 4 L/ha	a) as1.8 kg/ha	100/400	-	Strip application
00-003	DE	Pome Fruit	F	*Convolvulus arvensis*	Broadcast, Tractor mounted sprayer	Spring to summer	a) 1 b) 1	a) 8 L/ha	a) as3.6 kg/ha	100/400	-	Strip application
00-004	DE	Vineyards	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	Spring to summer, 10 – 20 cm weed height	a) 1 b) 1	a) 4 L/ha	a) as1.8 kg/ha	100/400	-	Strip application
00-005	DE	Vineyards	F	*Convolvulus arvensis*	Broadcast, Tractor mounted		a) 1 b) 1	a) 8 L/ha	a) as3.6 kg/ha	100/400	-	Strip application

					sprayer							
00-006	DE	Cereals	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	BBCH 89	a) 1 b) 1	a) 4 L/ha	a) as1.8 kg/ha	100/400	7	Additional harvest facilitation and crop desiccation
00-007	DE	Grassland	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	5-7 days before sowing, during vegetation period	a) 1 b) 1	a) 4 L/ha	a) as1.8 kg/ha	100/400	-	-
00-008	DE	Oilseed rape (winter)	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	BBCH 87 - 89	a) 1 b) 1	a) 2.5 L/ha	a) as1.125 kg/ha	200/300	14	Additional harvest facilitation and crop desiccation
00-009	DE	Oilseed rape (winter)	F	Weeds Dicotyledones, Weeds Monocotyledones	Broadcast, Tractor mounted sprayer	BBCH 00 - 08	a) 1 b) 1	a) 2.5 L/ha	a) as1.125 kg/ha	200/300	-	-

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **HAG 500 02 H**
Active Substance: **450 g/L Glyphosate**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: **Helm AG**
Date: **July 2012**

Table of content

ECOTOXICOLOGICAL STUDIES 4
6.1 PROPOSED USE PATTERN AND CONSIDERED METABOLITES 5
6.1.1 Proposed use pattern 5
6.1.2 Consideration of metabolites 5
6.2 EFFECTS ON BIRDS 6
6.2.1 Overview and summary 6
6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1) 9
6.2.3 Drinking water exposure 13
6.2.4 Details on formulation type in proportion per item 14
6.2.5 Acute toxicity of the formulation 14
6.2.6 Metabolites 14
6.2.7 Supervised cage or field trials 14
6.2.8 Acceptance of bait, granules or treated seeds (palatability testing) 14
6.2.9 Effects of secondary poisoning 14
6.3 EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS 16
6.3.1 Overview and summary 16
6.3.2 Toxicity exposure ratio 17
6.3.3 Drinking water exposure 26
6.3.4 Details on formulation type in proportion per item 26
6.3.5 Acute toxicity of the formulation 26
6.3.6 Metabolites 26
6.3.7 Supervised cage or field trials 27
6.3.8 Acceptance of bait, granules or treated seeds (palatability testing) 27
6.3.9 Effects of secondary poisoning 27
6.4 EFFECTS ON AQUATIC ORGANISMS 28
6.4.1 Overview and summary 28
6.4.2 Toxicity to Exposure ratio 31
6.4.3 Acute toxicity and chronic toxicity of the formulation 32
6.4.4 Metabolites of glyphosate 32
6.4.5 Accumulation in aquatic non-target organisms 32
6.5 EFFECTS ON BEES 33
6.6 EFFECTS ON ARTHROPODS OTHER THAN BEES 33
6.6.1 Overview and summary 36
6.6.2 Risk assessment for Arthropods other than Bees 41
6.7 EFFECTS ON EARTHWORMS, OTHER NON-TARGET SOIL ORGANISMS AND ORGANIC MATTER BREAKDOWN 43
6.7.1 Overview and summary 43
6.7.2 Toxicity to Exposure Ratio 46
6.7.3 Residue content of earthworms 46
6.8 EFFECTS ON SOIL MICROBIAL ACTIVITY 47
6.8.1 Overview and summary 47
6.9 EFFECTS ON NON-TARGET PLANTS 48
6.9.1 Overview and summary 48
6.10 OTHER NON-TARGET SPECIES (FLORA AND FAUNA) 51
6.11 OTHER/SPECIAL STUDIES 51
6.12 SUMMARY AND EVALUATION 52
6.12.1 Predicted distribution and fate in the environment and time courses involved 52
6.12.2 Short and long term risks for non-target species, populations, communities and processes 52

APPENDIX 1 LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION 56

APPENDIX 2 DETAILED EVALUATION OF STUDIES RELIED UPON 60

A2-1 ACTIVE SUBSTANCE (GENERALLY ONLY RELEVANT IN THE CASE THAT NEW ANNEX II DATA IS PROVIDED AFTER GLYPHOSATE APPROVAL) 61

A2-2 FORMULATION...61

APPENDIX 3 TABLE OF INTENDED USES JUSTIFICATION AND GAP TABLES 87

ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product HAG 500 02 H containing the active substance glyphosate, which is currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fullfills the criteria under Annex VI Reg. 2229/2004.

The DAR of the active substance glyphosate dates 11 December 2008 (RMS DE). Several addenda to the monograph have been compiled, the most recent from January 2000. The review report for glyphosate dates 2002 (6511/IV/99-final, 21 January 2002).

HAG 500 02 H was not the representative formulation considered in the EU review process as part of the approval of the active substance glyphosate.

A full risk assessment according Commission Regulation (EU) No 546/2011 is provided.

Addenda are included containing country specific assessments for some annex points. In those cases this document should be read in conjunction with the relevant addenda.

Where appropriate, this document refers to the conclusions of the EFSA, especially when data on the active substance is relied upon in the risk assessment of the formulation. Each section will begin with a table providing the EU endpoints used in this evaluation.

Appendix 1 of this document contains the list of references included in this document in support of the evaluation.

Appendix 2 of this document reports the detailed evaluation of studies relied upon.

Appendix 3 of this document is the table of intended uses for HAG 500 02 H.

Information on the detailed composition of HAG 500 02 H can be found in the confidential dossier of this submission (Registration Report - Part C).

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation HAG 500 02 H containing the active substance glyphosate and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarized below. Moreover, an overview of the metabolites of glyphosate that will be addressed in the risk assessment is given below.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment are presented in Table 6.1-1 that reports also a classification of intended uses for HAG 500 02 H (see also Section 5). A list of all intended uses within the central zone/EU is given in Appendix 3.

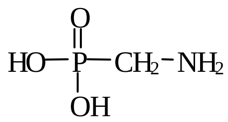
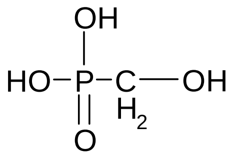
Table 6.1-1: Critical use pattern of HAG 500 02 H

Group/ use No	Crop/growth stage	Application method Drift scenario	No. of applications, Minimum appl. interval, appl. time, interception	Application rate, cumulative (g a.s./ha)	Soil effective application rate (g a.s./ha)
A/ 00-001, 00-007	Field crops, Grassland / -	Tractor mounted sprayer, broadcast, ground directed spraying	1 x - 0 %	1800	1800
B/ 00-002, 00-004	Pome fruit, Vineyards/-	Tractor mounted sprayer, broadcast, ground directed spraying	1 x - 0 %	1800	1800
C/ 00-003, 00-005	Pome fruit, Vineyards/ -	Tractor mounted sprayer, broadcast, ground directed spraying	1 x - 0 %	3600	3600
D/ 00-006	Cereals/ BBCH 89	Tractor mounted sprayer, broadcast, ground directed spraying	1 x - 90%	1800	180
E/ 00-008	Oilseed rape (winter)/ BBCH 87-89	Tractor mounted sprayer, broadcast, ground directed spraying	1 x - 80 %	1125	225
F/ 00-009	Oilseed rape (winter)/ BBCH 00-08	Tractor mounted sprayer, broadcast, ground directed spraying	1 x - 0%	1125	1125

6.1.2 Consideration of metabolites

The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU review of glyphosate. Further information is provided and in Part B, Section 5. Environmental occurring metabolites of glyphosate requiring further assessment according to the results of the assessment of glyphosate for EU approval are summarized in Table 6.1-2.

Table 6.1-2: Metabolites of glyphosate potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of active substance and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurence in compartements (Max. at day/	Satus of Relevance (Review report 6511/IV/99-final, 21 January 2002)
Aminomethyl-phosphonacid (AMPA)		Soil: Max. 29.3 % at day 84 Water: Max. 16 % at day 14 Sediment: Max. 16 % at day 120	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: : not relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]
(Hydroxymethyl)-phosphonic acid		Water: Max. 10.0% at day 61, 7.5% at day 100 / 2 x > 5 %	Aquatic organism: Water: not assessed

6.2 Effects on Birds

6.2.1 Overview and summary

Avian acute oral and long-term reproduction studies have been carried out with glyphosate. Full details of avian toxicity studies are provided in the respective EU DAR. The studies were evaluated and the relevant acute endpoint agreed during EU review process is used for the risk assessment. Regarding the endpoint used to assess the long-term risk to birds, please refer to the next chapter for detailed discussion.

Effects on birds of HAG 500 02 H were not evaluated as part of the EU review of glyphosate. However, the provision of further data on the formulation HAG 500 02 H is not considered essential as the available data on glyphosate are deemed to be sufficient to assess the risk of birds exposed to HAG 500 02 H.

The risk assessment for effects on birds and other terrestrial vertebrates is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.2.1.1 Toxicity

The studies with the relevant acute and long-term endpoints which are used in the risk assessment procedure are listed in the following table.

Table 6.2-1: Toxicity of glyphosate to birds with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Colinus virginianus	glyphosate	1 d	LD_{50} > 2000 mg/kg bw	Hakin et al. 1991, Rep. No. CHV 48/91266	26907
Colinus virginianus	glyphosate	5d	LC_{50} > 4640 ppm	Fink R., 1973, Report No.: HL-73-76	35153
Colinus virginianus	glyphosate	119d	NOEC = 200 mg/kg food or NOEL = 18.1 mg/kg bw/d NOAEL = 102.23 mg/kg bw/d	Beavers and Fink, 1978, Report No.: WI-78-52	35159/ 37256

As indicated above, an acute oral study with the formulated product has not been conducted. Consequently, the toxicity of HAG 500 02 H has been assessed considering data generated on the individual active substance. The endpoint used to evaluate the acute risk to birds was the LD_{50} > 2000 mg/kg bw as agreed during the EU review of the active substance glyphosate.

Concerning the effects of glyphosate on bird reproduction, studies have been conducted with bobwhite quail (Beavers and Fink 1978/ WI 78-52) and mallard duck (Beavers and Fink 1978/ WI 78-53) for the active substance glyphosate. For mallard duck, no effect were observed up to the highest concentration tested (NOEC = 1000 ppm).

In the study with bobwhite quail, a reduction in eggshell thickness was detected at 50 ppm. Even though this effects was significant, no linear dose response could be determined since no further effect on eggshell thickness were observed at the tested higher doses (200 and 1000 ppm).

A significant reduction in egg weight was observed at the highest concentration tested (1000 ppm). Therefore, a NOEC of 18.1 mg a.s./kg b.w./d. was determined and agreed during the EU review process. However, changes in egg weight are not considered a standard endpoint in avian reproduction studies according to guideline OECD 206 and all other relevant endpoints determined did not show any unacceptable differences compared to the control treatment –including No. of eggs, No. 14 d old survivals and hatchlings weight. The differences in egg weight between control and the treatment with 1000 ppm amounted to a decrease of approx. 7.5 % (10.26 g ± 0.38 g vs. 9.48 g ± 0.47 g in control and 1000 ppm treatment, respectively). Since especially all parameters concerning hatchling weight and survival were not affected at any concentration, it can be assumed that the observed changes in egg weight do not represent a population relevant adverse effect. Therefore, this endpoint will be considered as a NOAEL of 1000 ppm, corresponding to 102.23 mg/kg/bw/d and will be used for the assessment of the chronic risk for birds exposed to glyphosate according to the GAP of HAG 500 02 H.

6.2.1.2 Exposure

HAG 500 02 H is an herbicide formulation containing glyphosate as active substances. The product is formulated as a suspension concentrate. It will be used against weeds in field crops including cereals, peas, sugar beet, oilseed rape, orchards, vineyard and grassland. Furthermore it will be used in cereals at BBCH 87-89.

Exposure to glyphosate of standard generic focal species via contaminated food was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

$$\mathrm{DDD} = \sum_i \frac{\mathrm{PD}_i \times \mathrm{FIR}_{total}}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}$$
$$= \sum_i \frac{\mathrm{FIR}_i}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}$$

where:

DDD = Daily dietary dose (mg/kg bw/day)

PDi = composition of diet obtained from the treated area

FIRi = Food intake rate of indicator species i (g fresh weight/d)

bw = Body weight (g)

RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling

AR = Application rate (kg/ha)

PT = Proportion of diet obtained in the treated area (0…1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a “reasonable worst case”. If a potential risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier 2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

6.2.1.3 Risk Assessment –overall conclusions

For risk assessment purposes, the intended uses of HAG 500 02 H were grouped according to the amount of glyphosate to be applied and details of the application (see also Table 6.1-1, page 5).

The results of the acute and reproductive risk assessments are summarized in the following table.

Table 6.2-2: Summary of the calculated Toxicity to Exposure Ratio (TER) for birds

Compound	Risk assessment level	generic focal species	Time scale	TER	TER trigger
glyphosate	Tier 1	Small insectivorous species "redstart"	Acute	22.3	10
	Tier 1	Small granivorous bird "finch"	Long-term	8.8	5

TER shown in bold are below the relevant trigger

Based on the presumptions of the Tier 1 assessment, the calculated TER values addressing the risk for birds exposed to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required due to log P_{OW} values of glyphosate being below the trigger. Please refer to chapter 6.2.9.

6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.2.2.1 Acute toxicity to exposure ratio (TERA)

Tier 1

In the Tier 1 risk assessment step, the defined daily dietary doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). As for the indicator species in the screening step (not presented here), the generic focal species are considered to be representative for all species potentially at risk. In the Tier 1 assessment, a mixed diet approach is followed when appropriate and interception of the spray by the crop is taken into account for the calculation of residue levels for different food types.

If more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. If more than one generic focal species is relevant in terms of application time and growth stage, then the potential risk should be assessed for all relevant generic focal species. If the same generic focal species is relevant for several application times according to the BBCH growth stages, the risk assessment for this generic focal species is conducted once using the highest mean short-cut value, since this mirrors a realistic worst case scenario.

The relevant short-cut values for these scenarios are summarized in the following table.

Table 6.2-3: Avian generic focal species for the use of HAG 500 02 H and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438. Generic focal species are chosen with regards to the ground directed application of HAG 500 02 H

Crop	generic focal species	Shortcut value (90th percentile RUD
vineyard	Small insectivorous species "redstart"	27.4
	Small granivorous bird "finch"	14.8

	Small omnivorous bird "lark"	14.4
orchard	Small insectivorous/worm feeding species "thrush"	7.4
	Small granivorous bird "finch"	27.4
grassland	Large herbivorous bird "goose"	30.5
	Small insectivorous bird "wagtail"	26.8
bare soil	Small granivorous bird "finch"	24.7
	Small omnivorous bird "lark"	24.7
	Small insectivorous bird "wagtail"	24.7

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$$DDD_{\text{single application}} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^{1}$$

[1] see section 4.1 of EFSA/2009/1438

$$DDD_{\text{multiple application}} = DDD_{\text{single application}} \times MAF_{90}{}^{1}$$

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ \text{(mg/kg bw/day)}}{\text{Acute DDD (mg/kg bw/day)}}$$

The resulting TER_A values are summarised in the following table.

Table 6.2-4: Acute risk assessment (TER_A) for birds. See text for details

Crop	generic focal species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
vineyard	Small insectivorous species "redstart"	3.6	27.4	1	98.64	> 2000	22.3
	Small granivorous bird "finch"	3.6	14.8	1	53.28		37.5
	Small omnivorous bird "lark"	3.6	14.4	1	51.84		38.6
orchard	Small insectivorous/ worm feeding species "thrush"	3.6	7.4	1	26.64		75.1
	Small granivorous bird "finch"	3.6	27.4	1	98.64		22.3
grassland	Large herbivorous bird "goose"	1.8	30.5	1	54.9		36.4
	Small insectivorous bird "wagtail"	1.8	26.8	1	48.24		41.5
bare soil	Small granivorous bird "finch"	1.8	24.7	1	44.46		45.0
	Small omnivorous bird "lark"	1.8	17.4	1	31.32		63.9
	Small insectivorous bird "wagtail"	1.8	10.9	1	19.62		102.0
TERs shown in bold fall below the relevant trigger.							

Based on refined Tier 1 assessment step, the calculated TER values for the acute risk resulting from an exposure of birds to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for birds due to the intended use of HAG 500 02 H in all indication groups according to the label.

6.2.2.2 Short -term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.2.3 Long-term toxicity exposure ratio (TER_{LT})

Tier 1

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.2-5: Avian generic focal species for the intended uses of HAG 500 02 H and relevant shortcut values for long-term exposure

Crop	generic focal species	Shortcut value (mean RUD)
vineyard	Small insectivorous species "redstart"	11.5
	Small granivorous bird "finch"	6.9
	Small omnivorous bird "lark"	6.5
orchard	Small insectivorous/worm feeding species "thrush"	2.7
	Small granivorous bird "finch"	12.6
grassland	Large herbivorous bird "goose"	16.2
	Small insectivorous bird "wagtail"	11.3
bare soil	Small granivorous bird "finch"	11.4
	Small omnivorous bird "lark"	8.2
	Small insectivorous bird "wagtail"	5.9

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT_{50} of 10 days for the calculation of the DDD (daily dietary dose):

$$DDD_{\text{single application}} = \text{application rate [kg/ha]} \times \text{shortcut value} \times \text{TWA*}$$

* see section 4.3 of EFSA/2009/1438

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{\text{NOEL (mg/kg bw/day)}}{\text{Long - term DDD (mg/kg bw/day)}}$$

As described in the previous chapter, the relevant lowest NOAEL for the assessment of the chronic, reproductive risk for bird exposed to glyphosate is 102.23 mg a.s./kg bw/d. from the study with bobwhite quail of Beavers and Fink (1978/ WI 78-52).

The relevant long-term endpoints is provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for birds exposed to glyphosate following applications of HAG 500 02 H.

Table 6.2-6: Long-term risk assessment (TER_{LT}) for birds exposed to HAG 500 02 H according to the intended uses

Substance	generic focal species	Application rate (kg a.s./ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
vineyard	Small insectivorous species "redstart"	3.6	11.5	0.53	1	10.971	102.23	9.3
	Small granivorous bird "finch"		6.9			6.583		15.5
	Small omnivorous bird "lark"		6.5			6.201		16.5
orchard	Small insectivorous/ worm feeding species "thrush"	3.6	2.7	0.53	1	2.576		39.7
	Small granivorous bird "finch"		12.6			12.020		8.5
grassland	Large herbivorous bird "goose"	1.8	16.2	0.53	1	7.727		13.2
	Small insectivorous bird "wagtail"		11.3			5.390		19.0
bare soil	Small granivorous bird "finch"	1.8	11.4	0.53	1	5.438		18.8
	Small omnivorous bird "lark"		8.2			3.911		26.1
	Small insectivorous bird "wagtail"		5.9			2.814		36.3
TERs shown in bold fall below the relevant trigger.								

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for birds.

6.2.3 Drinking water exposure

In case of early post-emergence uses as intend for HAG 500 02 H birds might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of glyphosate formed on a field after rainfall. The ratios do not exceed the value of 3000 for glyphosate (Koc = 21616 L/kg) thus it is not necessary to conduct a drinking water risk assessment for birds.

6.2.4 Details on formulation type in proportion per item

6.2.4.1 Baits: Concentration of active substance in bait in mg/kg

HAG 500 02 H is not formulated as bait. The formulation is intended for use as a foliar spray, and therefore this information is not required.

6.2.4.2 Pellets, granules, prills or treated seed

HAG 500 02 H is not formulated as pellets, granules, prills or treated seeds. HAG 500 02 H is intended for use as a foliar spray, and therefore this information is not required.

Amount of active substance in or on each item

Not applicable.

Proportion of active substance LD_{50} per 100 items and per gram of items

Not applicable.

Size and shape of pellet, granule or prill

Not applicable.

6.2.5 Acute toxicity of the formulation

Avian toxicity tests with the formulation were not performed and are not considered necessary.

6.2.6 Metabolites

Avian toxicity tests with metabolites of glyphosate were not performed and are not considered necessary.

6.2.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of HAG 500 02 H pose no unacceptable acute or long-term risks to birds, and therefore further studies are not considered necessary.

6.2.8 Acceptance of bait, granules or treated seeds (palatability testing)

HAG 500 02 H is intended for use as a foliar spray, and therefore this information is not required.

6.2.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} values of glyphosate is logP <–3.2 (pH

2–5, 20°C), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). According to Sanco 6511/VI/99-final, 21 January 2002 the toxicologically significant compound is the parent glyphosate. Glyphosate is nearly completely excreted (approx. 30% via urine) and glyphosate is poorly metabolized to AMPA (< 0.5 %). Furthermore log K_{ow} was estimated via EpisuiteProgramm and SMILES code (C(N)P(=O)(O)O) to be -2.47 for AMPA and therefore indicates not the potential for bioaccumulation.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

The assessment of the risk from an exposure to glyphosate for mammals is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Toxicity

Table 6.3-1: Toxicity of glyphosate to mammals with reference to agreed endpoints

Species	Substance	System	Toxicity	Reference
Rat	glyphosate	Acute oral toxicity	LD_{50} > 2000 mg/kg bw	Review report 6511/IV/99-final, 21 January 2002
Mouse	Glyphosate (IPA-salt)	Acute oral toxicity	LD_{50} = 3669 mg/kg bw	Wang, S.C. (1987), Rep. No. TX58AO1 Glyphosate Monograph , chapter B.8.1.5
Rat	glyphosate	Prenatal developmental toxicity to mammals	NOAEL / NOEL= 300 mg/kg bw/d	Atkins C. et al (1993), Glyphosate Monograph , chapter B.5.5. 1 Review report 6511/IV/99-final, 21 January 2002

6.3.1.2 Exposure

Exposure to standard generic indicator species was estimated according to the ‘EC Guidance Document on Risk Assessment for Birds and Mammals Council (EFSA/2009/1438). Please see chapter 6.2.1.2, page 7 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

6.3.1.3 Risk assessment –overall conclusions

The overall conclusion on the risk assessment for mammals and the calculated TER-values are shown in the following table.

Table 6.3-2: Minimum TER values for mammals after uses of HAG 500 02 H in the intended uses in Group A (covers B, D, E, F) and C

Intended use	Risk assessment level	Indicator mammal	Time scale	TER	TER trigger
use in all Groups A-F	Screening	small herbivorous mammal	Acute	**4**	10
		small herbivorous mammal	Long-term	**1**	5
	Tier 1	small herbivorous mammal	Acute	**4**	5
		small herbivorous mammal	Long-term	2.2	2
		Large herbivorous mammal	Acute	20	10
		Large herbivorous mammal	Long-term	14	5
	Tier 1, refinement	small herbivorous mammal	Acute	8	5
		Large herbivorous mammal	Acute	37	10
TERs shown in bold fall below the relevant trigger.					

Based on the presumptions of Tier 1, the calculated TER values for acute and long-term risk resulting from an exposure of mammals to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H up to 3600 g glyphosate/ha achieve the acceptability criteria TER ≥ 10 (for Wood mouse (*Apodemus sylvaticus L.)* or a Common vole (*Microtus arvalis*), ≥ 5) and TER ≥ 5 (for Wood mouse or a Common vole ≥ 2), respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals from the intended uses. Please refer to the text for details of the risk description parameters

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Screening step

In the screening step, indicator species are used. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

The indicator mammal species for the intended uses are listed in the following table.

Table 6.3-3: Indicator species for mammals according to intended use of HAG 500 02 H and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438

Crop	Indicator species	Shortcut value (90th percentile RUD)
vineyard, orchard, grassland	small herbivorous mammal	136.4

bare soil	small granivorous mammal	14.4

For the estimation of Daily dietary doses (DDD) and the calculation of TER-values please refer to 6.2.2.1

Table 6.3-4: Acute screening risk assessment (TERA) for mammals. See text for details

Crop	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD50 (mg/kg bw)	TERA
vineyard, orchard, grassland	small herbivorous mammals	3.6	136.4	1	491	> 2000	**4**
vineyard, orchard, grassland	small herbivorous mammals	1.8	136.4	1	246		**8**
bare soil	small granivorous mammal	1.8	14.4	1	26		77
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of mammals to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H do not achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of HAG 500 02 H in vineyard and orchards according to the label with maximum application, further refinement is necessary.

Tier 1

In the Tier 1 risk assessment step, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). Please refer to chapter 6.2.2.1 for general considerations when choosing generic focal species.

The relevant short-cut values for assessed scenarios are summarized in the following table.

Table 6.3-5: Mammal generic focal species for of HAG 500 02 H and relevant shortcut values

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (90th percentile RUD)
vineyards	Application ground directed	Large herbivorous mammal "lagomorph"	27.2
		Small herbivorous mammal "vole"	136.4
		Small omnivorous mammal "mouse"	17.2
orchard	Application not crop directed	Small herbivorous mammal "vole"	109.2
		Large herbivorous mammal "lagomorph"	28.1

		Small omnivorous mammal "mouse"	17.2
grassland	All season	Large herbivorous mammal "lagomorph"	32.6
		Small herbivorous mammal "vole"	136.4
bare soil	BBCH < 10	Small omnivorous mammal "mouse"	14.3

The outcome of the Tier 1 risk assessment step is presented in the following table.

Table 6.3-6: Assessment of the acute risk to mammals from HAG 500 02 H in the intended uses

Crop	Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (90th percentile)	DDD (mg a.s./kg bw/d)	LD50 (mg a.s./kg bw/d)	TER
vineyard	Application ground directed	Large herbivorous mammal "lagomorph"	3.6	1	27.2	98	> 2000	20
		Small herbivorous mammal "vole"		1	136.4	491		**4**
		Small omnivorous mammal "mouse"		1	17.2	62		116
orchard	Application not crop directed	Small herbivorous mammal "vole"	3.6	1	109.2	393		5
		Large herbivorous mammal "lagomorph"		1	28.1	101		20
		Small omnivorous mammal "mouse"		1	17.2	62		32
grass-land	All season	Large herbivorous mammal "lagomorph"	1.8	1	32.6	59		34
		Small herbivorous mammal "vole"		1	136.4	246		8
bare soil	BBCH < 10	Small omnivorous mammal "mouse"	1.8	1	14.3	26		78
TERs shown in bold fall below the relevant trigger.								

Since for the generic focal species unacceptable risk is still indicated, for the glyphosate intended use in vineyard further refinement is necessary.

In the Review Report for the active substance glyphosate (SANCO/6511/VI/99-final, 21 January 2002, p. 1-56), a LD_{50} of > 2000 mg/kg bw is determined and derives from acute toxicity studies in rat with the active substance. All acute endpoints in studies with rats are above the highest investigated doses, the maximum up to 8000 mg/kg bw.

In further acute oral toxicity studies reporting glyphosate (and IPA salt) toxicity to mouse, however, lethal doses were determined (please refer to glyphosate monograph, chapter B.5.2.1.1). In an acute oral toxicity study with glyphosate IPA-salt in mouse (Wang et al., 1987), the LD_{50} amounted to 3669 mg/kg bw and is the lowest reported in the monograph. Since the study was considered to be acceptable and this value is the lowest LD_{50} determined, it will be used for a refined risk assessment.

The outcome of the Tier 1 risk assessment in the scenario vineyard and grassland with the determined LD_{50} as endpoint is presented in the following table.

Table 6.3-7: Assessment of the acute risk to mammals from HAG 500 02 H in the intended uses vineyard and grassland (Tier 1) considering the LD50 of 3669 mg a.s./kg bw/d.

Crop	Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (90th percentile)	DDD (mg a.s./kg bw/d)	LD50 (mg a.s./kg bw/d)	TER
vineyard/ orchard	Application ground directed	Large herbivorous mammal "lagomorph"	3.6	1	27.2	98	3669	37
		Small herbivorous mammal "vole"		1	136.4	491		8
		Small omnivorous mammal "mouse"		1	17.2	62		59
grass-land	Application not crop directed	Large herbivorous mammal "lagomorph"	1.8	1	32.6	59		63
		Small herbivorous mammal "vole"		1	136.4	246		15
TERs shown in bold fall below the relevant trigger.								

Based on a specification of the ecotoxicological endpoint (LD50 = 3669 instead of > 2000 mg a.s./kg bw/d), the calculated TER values for the acute risk resulting from an exposure of mammals to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H with 3600 g a.s./ha do not achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects.

Higher tier risk refinement of PD: Fraction of food type in diet

It is possible to refine the diet using published data. In common voles inhabiting a meadow in central EU, dicotyledonous species predominate in the diet during spring and summer, while in autumn the proportion of monocotyledons increases. The average number of plant species was 4.3 per stomach (range: 1-9). When comparing the available biomass it was conclusive that a supply of about 70% monocotyledon and 30% dicotyledon biomass meets a food intake of roughly 33% monocotyledon and 67% dicotyledons (Rinke, T. 1991. Percentage of volume versus number of species: availability and intake of grasses and forbs in Microtus arvalis. Folia Zoologica 40(2): 143-151).

Crop	Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (90th percentile)	DDD (mg a.s./kg bw/d)	LD50 (mg a.s./kg bw/d)	TER
vineyard/	Application	Small herbivorous	3.6	1	136.4	Monocotyled	3669	9

orchard	ground directed	mammal "vole"				on: 114 Dicotyledon: 315		

In cases where the relevant model species for assessment of the risk from the intended uses of the active substance is a Wood mouse (*Apodemus sylvaticus L.)* or a Common vole (*Microtus arvalis*), the TER acceptability criterion according to commission implementing regulation (EU) No 546/2011, Annex, Part I C,2. Specific principles, point 2.5.2. Specific principles may be modified in the higher tier assessment.

In terms of size and potential exposure, Wood mice and Common voles already represent the 'worst case' for agricultural areas in Europes' central zone. Due to high reproduction rate (R-strategists) and short generation time, local common vole populations are supposed to compensate effects on individuals as long as a base level of unaffected animals will remain in the population to facilitate recovery via reproduction.

In general, information on population trends is missing for many small mammal species that are not huntable or classified as pest species (Meinig, H., P. Boye & R. Hutterer (2009) Rote Liste und Gesamtartenliste der Saugetiere (Mammalia) Deutschlands, Stand Oktober 2008. Band 1: Wirbeltiere. In: Rote Liste gefahrdeter Tiere, Pflanzen und Pilze Deutschlands. Bundesamt fur Naturschutz (Hrsg.) *Naturschutz und Biologische Vielfalt* 70(1): 115-153). Even for pest species, like the Common Vole, data availability on current population densities is poor since the development of high densities as become rare due to modern agricultural management techniques and intensive monitoring of these events therefore decreased (Meinig *et al.*, 2009). It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of Wood mice or Common voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures).

Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient. The results of the assessment indicate an acceptable risk for mammals due to the intended use of HAG 500 02 H according to the label up to maximum application of 3600 g a.i/ha.

Member States should pay particular attention when the active substance is applied in regions with vulnerable agricultural landscape. Higher margins of safety might be required in special agricultural areas and risk mitigation measures should be applied where appropriate.

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been performed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-8: Mammal generic focal species for the intended uses of HAG 500 02 H and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
vineyard, orchard, grassland	small herbivorous mammal	72.3
bare soil	small granivorous mammal	6.6

Please refer to section 6.2.2.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

The relevant lowest NOEL for the reproduction exposure scenario for glyphosate is NOEL= 300 mg/kg bw/d (rat). Full details of the toxicity studies are provided in the respective EU DAR. The following table reports the calculated long-term toxicity exposure ratios (TER_{LT}) for mammals exposed to glyphosate following applications of HAG 500 02 H.

Table 6.3-9: Long-term screening risk assessment (TER_{LT}) for mammals exposed to HAG 500 02 H according to the intended uses

Crop	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
vineyard, orchard, grassland	small herbivorous mammal	3.6	72.3		1	260	300	**1**
bare soil	small granivorous mammal	1.8	6.6		1	12		25
TERs shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of mammals to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H does not achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point

2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of HAG 500 02 H in vineyard, orchard and grassland according to the label, further refinement is necessary.

Tier 1 risk assessment

For the Tier 1 risk assessment, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009. Annex I). Please refer to section 6.2.2 for general consideration in the choice of generic focal species in risk assessment procedures.

The relevant short-cut values for scenarios evaluated are summarized in the following table.

Table 6.3-10: Mammal generic focal species for the intended uses of HAG 500 02 H and relevant shortcut values for long-term risk assessment

Intended use	Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
vineyard	Application on ground directed	Large herbivorous mammal "lagomorph"	11.1
		Small herbivorous mammal "vole"	72.3
		Small omnivorous mammal "mouse"	7.8
orchard	not crop directed	Large herbivorous mammal "lagomorph"	14.3
		Small herbivorous mammal "vole"	72.3
		Small omnivorous mammal "mouse"	7.8
grassland	All season	Large herbivorous mammal "lagomorph"	17.3
		Small herbivorous mammal "vole"	72.3
bare soil	BBCH < 10	Small omnivorous mammal "mouse"	5.7

The outcome of the Tier 1 risk assessment step is presented in the following table.

Table 6.3-11: Reproductive mammal risk assessment of HAG 500 02 H (Tier 1)

crop	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg a.s./kg bw/d)	NOEL (mg a.s./ kg bw/d)	TER
vineyard	Large herbivorous mammal "lagomorph"	3.6	0.53	11.1	1	21.049	300	14.3
	Small herbivorous mammal "vole"			72.3		137.102		2.2
	Small omnivorous mammal "mouse"			7.8		14.791		20.3
orchard	Large herbivorous mammal "lagomorph"	3.6		14.3		27.117		11.1
	Small herbivorous mammal "vole"			72.3		137.102		2.2
	Small omnivorous mammal "mouse"			7.8		14,791		20.3
grassland	Large herbivorous mammal "lagomorph"	1.8		17.3		16.403		18.3
	Small herbivorous mammal "vole"			72.3		68.551		4.4
bare soil	Small omnivorous mammal "mouse"	1.8		5.7		5.404		55.5
TERs shown in bold fall below the relevant trigger.								

Based on the tier 1 long-term risk assessment acceptable risk is indicated for applications of HAG 500 02 H in grassland and bare soil with an application rat of 1800 g/ha. Applications in orchards and vineyard with an application rate of 3600 g a.s./ha fall below the proposed trigger of TER ≥ 5.

Higher tier risk assessment concerning residue decline

Default assumptions are based on a DT_{50} of 10 days on plants and a time window of 21 days, which leads to a default TWA factor of 0.53. Dissipation and degradation of residues from plant material, may be more rapid in the environment. Glyphosate is known to rapidly decline in plant material with a DT50 of about 2.8 days (please refer to chapter B.8.1.5 of the glyphosate Monograph). Therefore, for the food type ‘plant material’ the default ftwa has been recalculated resulting in ftwa = 0.18 (based on a DT50 of 2.8 days and averaging time of 21 days).

Table 6.3-12: Reproductive mammal risk assessment of HAG 500 02 H (Higher tier)

crop	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg a.s./kg bw/d)	NOEL (mg a.s./ kg bw/d)	TER
vineyard	Large herbivorous mammal "lagomorph"	3.6	0.19	11.1	1	7.644	300	39.2
	Small herbivorous mammal "vole"			72.3		49.791		6.0
	Small omnivorous mammal "mouse"			7.8		5.372		55.8
orchard	Large herbivorous mammal "lagomorph"	3.6		14.3		9,848		30.5
	Small herbivorous mammal "vole"			72.3		49,791		6.0
	Small omnivorous mammal "mouse"			7.8		5,372		55.8
grassland	Large herbivorous mammal "lagomorph"	1.8		17.3		5.957		50.4
	Small herbivorous mammal "vole"			72.3		24.895		12.1
bare soil	Small omnivorous mammal "mouse"	1.8		5.7		1.963		152.9
TERs shown in bold fall below the relevant trigger.								

As described in the chapter addressing the acute risk for mammals, in cases where the relevant model species for assessment of the risk from the intended uses is a mouse or a vole, the TER acceptability criterion may be modified (TER ≥ 2 in the long-term exposure scenario). Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of small herbivorous mammal "vole" to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the modified acceptability criteria TER ≥ 5 resp. ≥ 2 for long-term effects. Moreover based on higher tier risk assessment also the TER acceptability criterion TER ≥ 5 in the long-term exposure scenario were met. The results of the assessment indicate an acceptable risk for mammals due to the intended use of HAG 500 02 H in vineyard and orchard with an application rate of 3600 g a.i /ha according to the label and all other intended uses. It should be notetd that the application of a modified TER-criterion concerning the small herbivorous mammal " common vole" *(Microtus arvalis)* is not a uniform principle, but a german approach for the identification of focal species in higher tier risk assessment. Member States should pay particular attention when the active substance is applied in regions with vulnerable agricultural landscape. Higher margins of safety are required in special agricultural areas and risk mitigation measures should be applied where appropriate.

6.3.3 Drinking water exposure

In case of early post-emergence uses as intend for HAG 500 02 H mammals might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by mammals (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of glyphosate formed on a field after rainfall. The ratios do not exceed the value of 3000 for glyphosate (Koc = 21616 L/kg), thus it is not necessary to conduct a drinking water risk assessment for birds

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4 for details on the formulation type of HAG 500 02 H.

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.4.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.

Amount of active substance in or on each item

Please refer to section 6.2.4.

Proportion of active substance LD_{50} per 100 items and per gram of items

Please refer to section 6.2.4.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.

6.3.5 Acute toxicity of the formulation

Mammal toxicity tests with the formulation were not performed and are not considered necessary.

6.3.6 Metabolites

Mammal toxicity tests with metabolites of glyphosate were not performed, since it is possible to extrapolate from data obtained with the active substances.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of HAG 500 02 H pose no unacceptable acute or long-term risks to mammals, and therefore further studies are not considered necessary.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

HAG 500 02 H is intended for use as a foliar spray, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} values of glyphosate is logP < –3.2 (pH 2–5, 20°C) the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). According to Sanco 6511/VI/99-final, 21 January 2002 the toxicologically significant compound is the parent glyphosate. Glyphosate is nearly completely excreted (approx. 30% via urine) and glyphosate is poorly metabolized to AMPA (<0.5%). Furthermore log K_{ow} was estimated via EpisuiteProgramm and SMILES code (C(N)P(=O)(O)O) to be -2.47 for AMPA and therefore indicates not the potential for bioaccumulation.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

The following EU agreed endpoints for aquatic organisms exposed to the active substance glyphosate are reported in the list of endpoints of glyphosate Monograph (Volume 3, Annex B-8: Ecotoxicology, 11 December 1998).

The applicant provides further studies on the effect of the formulation HAG 500 02 H on aquatic organisms. Detailed study summaries for the studies performed with the formulated product HAG 500 02 H are presented in Appendix 2.

6.4.1.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to glyphosate and HAG 500 02 H with indication to agreed endpoints

Species	Substance	System	Toxicity (mg a.s./L)		Reference
Fish, acute toxicity					
O.mykiss	HAG 500 02H	96 h	LC_{50}	> 38.4	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.2.2.1/01
O.mykiss	glyphosate		LC_{50}	38	Review Report (SANCO/6511/VI/99-final)
O.mykiss	AMPA		LC_{50}	> 180	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998
Fish, long-term toxicity					
P. promelas	glyphosate	254 days	NOEC	25.7	Review Report (SANCO/6511/VI/99-final)
Invertebrates, acute toxicity					
D.magna	HAG 500 02H	48 h	EC_{50}	> 38.4	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.2.2.2/01
	glyphosate			40	Review Report (SANCO/6511/VI/99-final)
	AMPA			> 180	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998
Invertebrates, long-term toxicity					
Daphnia magna	glyphosate	21 days	NOEC	30	Review Report (SANCO/6511/VI/99-final)
Algae					
P. subcapitata	HAG 500 02H	72 h	E_yC_{50}	1.6	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.2.2.3/01

N. pelliculosa			E_yC_{50}	4.04	Hoffmann, K. & Deierling, T. (2009) Ref. IIIA 10.2.2.3/02
S.costatum	**glyphosate**	**7 days**	$\mathbf{E_bC_{50}}$	**0.64**	**Review Report (SANCO/6511/VI/99-final)**
N. palea		96 h	E_rC_{50}	4.5	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998
P. subcapitata	AMPA	72 h	E_yC_{50}	89.8	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998
Aquatic higher plants					
L.gibba	HAG 500 02H	7 days	E_yC_{50}	24.3 (dry weight) 16.4 (frond number)	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.8.2.1/01
L. gibba	glyphosate	14 days	EC_{50}	12	Review (SANCO/6511/VI/99-final)
Mesocosm study	-	-	-	-	-

For the active ingredient glyphosate the most sensitive endpoint divided by the safety factor of 10 is [E_bC_{50}] = 0.064 mg a.s./L (*Skeletonema costatum*). As the assessment performed for the algae endpoint is supposed to cover the risk for other aquatic organisms, the risk assessment is done only for this endpoint.

Glyphosate forms two major metabolites; Aminomethyl-phosphonic acid (AMPA), max. 16 % at day 14 and (Hydroxymethyl)-phosphonic acid (max. 10.0% at day 61, 7.5% at day 100).

As the metabolite AMPA shows a clearly lower toxicity for fish, daphnids and algae than the active substance, no quantitative risk assessment was performed. The risk assessment for the active substance is supposed to address the risk resulting from metabolite as well.

Since no data are available for the metabolite (Hydroxymethyl)-phosphonic acid, a ten-fold higher toxicity for aquatic organisms can be assumed for risk assessment purposes. As degradation of glyphosate results in equal or less than 10 % of this metabolite and the Mol correction factor is 0.6, the risk assessment for the metabolite (Hydroxymethyl)-phosphonic acid is covered by that of glyphosate.

It is predicted that the risk for aquatic organisms exposed to glyphosate metabolites according to the intended use of HAG 500 02 H will be low.

6.4.1.2 Exposure

HAG 500 02 H is an herbicidal formulation containing glyphosate as active substances. The product is a SL formulated containing 450 g/L glyphosate.

The applications are considered to take place as single application. It will be used against weeds in field crops including cereals, peas, sugar beet, oilseed rape, orchards, vineyard and grassland. Furthermore it will be used in cereals during BBCH 87-89.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. The studies and data provided permit to perform a risk assessment relevant to the exposure of aquatic organisms to HAG 500 02 H under practical conditions of use. When HAG 500 02 H is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift during application, by run-off and drainage.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated based on the application rates of 3600 g glyphosate/ha and 1800 g glyphosate /ha. For details on the FOCUS modeling, see CA Part B, Section 5.7.

The relevant global maximum FOCUS Step 2 PEC_{SW} for risk assessments covering all proposed use patterns are summarized in the following table.

Table 6.4-2: Summary of highest global maximum FOCUS surface water PECsw and PECsed values for glyphosate and their metabolites - Step 2

Plant protection product:	HAG 500 02 H		
Crop	crop scenario “cereals” was assumed to be representative for all use patterns including the uses in orchards and vine		
Application method (-)	ground directed spraying on weeds		
Crop interception:	no		
Number of applications/interval	1		
Application rate:	These uses represent the worst case with an application rate of 3600 g a.s./ha. Another scenario with 1800 g a.s./ha and an application season from October to February was calculated. These two scenarios cover all indented uses.		
glyphosate			
FOCUS STEP Scenario	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
	Actual, 0 h	TWA, 21 d	Actual, 0 h
STEP 1	-	-	-
STEP 2, Northern Europe, Mar. – May (Application rate of 3600 as g/ha)	33.11	7.80	4140
STEP 2, Oct.-Feb. (Application rate of 1800 as g/ha)	16.55	7.94	2070

6.4.1.3 Risk assessment –overall conclusions

Based on the FOCUS Step 2 PECs, the aquatic TER values for glyphosate are above the trigger of 10, indicating a low and acceptable acute risk for aquatic organisms from glyphosate and its water metabolites following application of HAG 500 02 H at the proposed application rates.

TER values for the most sensitive aquatic organisms based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.4-3: Aquatic TER values for glyphosate after applications of HAG 500 02 H

Test organism	EC_{50} NOE(AE)C (µg/L)	FOCUS Step	Scenario	Max. PEC_{SW} worst case (µg/L)	TER_{LT}	Trigger value
Skeletonema costatum	640 (E_bC_{50})	2	N-EU, Mar.-May	33.11	19	10
		2	N-EU, , Oct.-Feb	16.55	39	
TER-values in bold are below the relevant trigger						

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to glyphosate was assessed according to the intended uses.

As first step, the initial maximum PEC_{SW} values (Step 2) were compared to the relevant acute and long-term toxicity endpoints available for glyphosate. Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for glyphosate is E_bC_{50} : 0.64 mg glyphosate/L (*Skeletonema costatum).* Risk assessment is driven by this endpoint; the ratio endpoint/corresponding safety factor is higher for all other organisms.

In the table below, the TER values relative to the most sensitive endpoint of each organisms' group are given.

Table 6.4-4: Aquatic organisms: PECsw for glyphosate and relevant ecotoxicological endpoints for each organism' group.

FOCUS Scenario	PEC global max (µg/L)	Fish acute *O. mykiss* LC_{50} (µg/L)	Fish prolonged *O. mykiss* NOEC (µg/L)	Invertebrates acute *D. magna* EC_{50} (µg/L)	Invertebrates prolonged *D. magna* NOEC (µg/L)	Algae *P. subcapitata* E_bC_{50} (µg/L)
		38000	25700	>38400	30000	640
Step 2						
N-EU Mar.-May	33.11	1148	776	1160	906	19
N-EU Oct.-Feb	16.55	2296	1553	2320	1813	39
TER criterion		100	10	100	10	10

Based on the calculated concentrations of glyphosate in surface water (PEC_{SW} FOCUS Step 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to glyphosate according to the GAP of the formulation HAG 500 02 H the acceptability criteria TER ≥ 100 resp. ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of HAG 500 02 H according to the label.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of HAG 500 02 H on aquatic organisms. Section 6.4.2 gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of glyphosate

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of glyphosate metabolites on aquatic organisms. Section 6.4.1.1 gives the details of the risk assessment for aquatic organisms on the basis of all available data.

Glyphosate forms two major metabolites in surface water: glyphosate metabolite Aminomethyl-phosphonsäure (AMPA) (max. 16 % at day 14) and (Hydroxymethyl)-phosphonic acid (max. 10.0% at day 61, 7.5% at day 100). The glyphosate metabolite AMPA is also formed in sediment (max. 16 % at day 120). Moreover, the glyphosate metabolite AMPA is formed in soil with max. 29.3 % at day 84.

Contamination via run-off and drainage cannot be excluded. Ecotoxicological studies are available for the metabolite AMPA for fish, daphnia and algae. For (Hydroxymethyl)-phosphonic acid no ecotoxicological studies are available.

Since no data are available for the metabolite (Hydroxymethyl)-phosphonic acid, a ten-fold higher toxicity for aquatic organisms can be assumed for risk assessment purposes. As degradation of glyphosate results in equal or less than 10 % of this metabolite and the Mol correction factor is 0.6, the risk assessment for the metabolite (Hydroxymethyl)-phosphonic acid is covered by that of glyphosate.

The comparison of the study results for the metabolite AMPA with the results of studies performed with glyphosate shows that glyphosate is more toxic for aquatic organisms than the metabolite. It is predicted that the risk for aquatic organisms exposed to glyphosate metabolites according to the intended use of HAG 500 02 H will be low.

6.4.5 Accumulation in aquatic non-target organisms

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

6.5 Effects on Bees

Exposure

The recommended use pattern for HAG 500 02 H includes application in cereals,
field pea, oilseed rape, grassland and sugar beet at a maximum application rate of up to 4 L/ha and at up to 8 L/ha in orchard and vine. The maximum single application rate of 8 L/ha is equivalent to 9568 g product/ha.

Bees may be exposed to formulated HAG 500 02 H by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew. Exposure of honey bees was considered based on the maximum recommended rates for HAG 500 02 H in order to consider an extreme worst-case scenario.

Toxicity

Acute toxicity of the formulation to bees

Report:	KIIIA1 10.4.2.1/01: Sekine, T. , 2010
Title:	Effects of Glyphosate 450 SL AE (acute contact and oral) on Honey bees (*Apis mellifera* L.) in the Laboratory. Project 50354035. IBACON GmbH, Rossdorf, Germany.
Guidelines:	OECD 213/214
GLP	Yes

Material and Methods:

The acute oral and contact toxicity of HAG 500 02 H was determined with young adult worker honey bees of the species *Apis mellifera* in a limit test. Each treatment consisted of 5 replicates with 10 bees per each. Therefore a total of 50 bees each were set up for the test item group, the reference item group and the control group.

In the oral test the test substance was administered after suspension in 50% sugar solution with a single intended dose of 200 µg product/bee resulting in actual intake of 217.2 µg product/bee. In the contact test the test substance was applied after suspension in tap water (with 0.5 % Adhäsit®) at a single dose of 200 µg product/bee. The test suspension was applied to the dorsal side of the bee thorax using a calibrated micro-pipette.

Parallel to the test item treatment, 4 reference treatments with 5 replicates each with 10 bees per replicate were run. The reference item was a dimethoate formulation which was applied to the bees at intended dose levels of 0.05, 0.08, 0.15 and 0.30 µg/bee. An additional control group was administered 50% sucrose solution. In the contact test with the reference item dose levels were 0.10, 0.15, 0.20 and 0.30 µg/bee. An additional control group was dosed with the vehicle only.

Bee mortality was assessed 4, 24 and 48 hours after removing the test item. The bees were characterised as healthy, affected, moribund or dead.

Findings:

No test item induced mortality occurred during 48 hours of oral and contact exposure nor in the test item treatment nor in the control. No behavioural abnormalities attributed to exposure of the test item to the bees occurred. Therefore the oral 48-hour LD_{50} is higher than 217.2 µg product/bee and the contact 48-hour LD_{50} is higher than 200 µg product/bee.

Treatment with the reference substance resulted in dose related mortality after 48 hours. The oral LD_{50} was determined to be of 0.15 µg dimethoate/bee and the contact LD_{50} was determined to be 0.16 µg dimethoate/bee. Therefore, the validity criteria were met.

Study comment: The study is acceptable since all validity criteria were fulfilled.

The results of laboratory bee toxicity studies with the active substance glyphosate and the formulation HAG 500 02 H are presented in table 6.5-1.

Table 6.5-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	GLP	Guideline	Reference
Glyphosate 450 SL AE (= HAG 500 02 H)	oral 48 h	>> 217.2 µg product/bee	yes	OECD 213/214	Sekine, T., 2010; project 50354035
	contact 48 h	>> 200 µg product/bee			
Glyphosate tech.	oral 48 h	= 100 µg /bee	*	*	*
	contact 48 h	> 100 µg /bee			

* EU agreed endpoints for bees (SANCO/6511/VI/99-final, 2002)

Hazard quotients for bees

Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

Hazard Quotient = max. application rate [g test substance/ha] / LD_{50} [µg test substance/bee]

Table 6.5-2: Hazard quotients for honeybees

Test substance	Exposure route	LD_{50}	Max. single application	Hazard quotient	HQ assessment trigger

			rate	(HQ)	
HAG 500 02 H	oral	>> 217.2 µg product/bee	9568 g product/ha	< 45	50
	contact	>> 200 µg product/bee		< 48	50

Oral toxicity

Results are presented in Table 6.5-1.

Contact toxicity

Results are presented in Table 6.5-1

Effects on bees of residues on crops

Not required.

Cage tests

Not required.

Field tests

Not required.

Investigation into special effects

Not required.

Larval toxicity

Not required since HAG 500 02 H is not an IGR.

Long residual effects

Not required.

Disorienting effects on bees

Not required.

Tunnel tests

Not required.

Risk assessment

HAG 500 02 H is a SL formulation containing the active substance glyphosate which was included into Annex I of Directive 91/414 (Commission Directive 2001/99/EC, 20 November 2001). Effects of HAG 500 02 H on bees were not evaluated as part of the EU review of glyphosate.

Due to the results of laboratory tests both technical glyphosate and the formulation HAG 500 02 H containing 450 g/L glyphosate are considered practically non toxic to bees. All hazard quotients are well below the trigger of 50, indicating a low risk to bees in the field. Bee brood testing is not required since HAG 500 02 H is not an IGR.

Overall conclusion:
It is concluded that HAG 500 02 H will not adversely affect bees or bee colonies when used as recommended. No special labelling is necessary.

List of data submitted in support of the evaluation

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.4.2.1	Sekine, T., Schmitzer, S.	Effects of Glyphosate 450 SL AE (acute contact and oral) on Honey bees (Apis mellifera L.) in the Laboratory	2010	Doc. No. 50354035 220602
KIIA 8.7	Fraser, W.D., Jenkins, G.	The acute contact and oral toxicities of CP67573 and MON2139 to worker honey bees.	1972	HU85X09 4 220648

6.6 Effects on Arthropods Other Than Bees

6.6.1 Overview and summary

Effects on arthropods other than bees for HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Data on HAG 500 02 H have been submitted by the applicant and are evaluated here. They are considered adequate to assess the risk for non-target arthropods following the use of HAG 500 02 H according to the intended uses.

6.6.1.1 Toxicity

The toxicity of HAG 500 02 H to non-target arthropods has been investigated for the indicator species *Aphidius rhopalosiphi*, *Typhlodromus pyri* and *Poecilius cupreus*.

The study with *Typhlodromus pyri* did not show a linear dose-response in the parameter mortality and reproduction. Statistic standard models (Probit, Weibull, Logit 4 parameter) could not sufficiently describe the results (pChi2 < 0.001). Hence, a reliable LR50 could not be calculated statistically. Therefore, the LR_{50} was set to > 320 g a.s. /ha. Since sublethal endpoints are considered to be relevant for a Tier 2 risk assessment step, the lowest dose tested (35.6 g a.s./ha) with effects on reproduction was employed in the risk assessment (surrogate endpoint reproduction = 35.6 g a.s./ha). Please refer to Appendix 2 for further details.

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the table below.

Table 6.6-1: Toxicity of HAG 500 02 H to non-target arthropods with reference to agreed endpoints

Species	Substance	System	Toxicity	Reference	ICS-No.

P. cupreus	glyphosate 450 SL AE (450g/L)	Extended lab testing	LR_{50} > 3.6 kg a.s./ha (mortality)	Schmitzer, S. 2010 Doc. No. 50357007	78779
T. pyri	glyphosate 450 SL AE (450g a.i. /L)	Extended lab testing	Statictically not evaluable, $pChi_2$ < 0,001 320 < LR_{50}<< 960 g a.s./ ha (mortality) Estimated ER_{50} <35.6 g a.s./ ha (reproduction); surrogate endpoint reproduction = 35.6 g a.s./ha	Schwarz, A. 2010 Doc. No. 50356062	78778
A.rhopalosiphi	glyphosate 450 SL AE (450g a.i. /L)	Extended lab testing	LR_{50} > 5.76 kg a.s./ha (mortality)	Moll, M. 2010 Doc. No. 50355002	78777

6.6.1.2 Exposure

In field

Non-target arthropods living in the crop can be exposed to residues from HAG 500 02 H by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items.

HAG 500 02 H will be used against weeds, in cereals (BBCH 89) and oil seed rape (BBCH 87-89).

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of HAG 500 02 H is calculated according to published agreement after ESCORT 2 workshop (Candolfi et al. 2001[1] -hereafter referred to as ‘Guidance Document’) using the following equation:

$$PER_{in-field} = \text{Application rate (g a.s./ha)} \times \text{MAF}$$

where:

MAF = generic multiple application factor used to take into account the potential build-up of applied substances between applications. This factor integrates number of applications, application interval and degradation kinetics of the active substance

Default MAF values for given numbers of applications are listed in the Guidance Document. Since HAG 500 02 H will be applied once a season at a maximum application rate of 8 L/ha (3600 g glyphosate / ha), as a worst-case assumption the maximum in-field exposure (Predicted Environmental Rate, PER) to arthropods is therefore 8 L formulation/ha, assuming 0% crop interception for the calculation of the rates reaching the soil. The maximum predicted environmental rate (PER) occurring in the field after application of HAG 500 02 H at the maximum application rate is presented in the following table.

[1] Candolfi, M.P.; Barrett, K.L.; Campbell, P.; Forster, R.; Grandy, N.; Huet, M.C.; Lewis. G.; Oomen, P.A.; Schmuck, R.; Vogt, H. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT2 Workshop European Standard Characteristics of Non-Target Arthropod Regulatory Testing. Wageningen, The Netherlands, 46 pp.

Table 6.6-2: In-field foliar predicted environmental rates (PER) for HAG 500 02 H

Substance	Application rate (L Product/ha)	PER (foliar) (L Product/ha)	PER (soil) (L Product/ha)
HAG 500 02 H	8 (3600 g a.s./ ha)	8 (3600 g a.s./ ha)	8 (3600 g a.s./ ha)

Off-field

Exposure of non-target arthropods living in non-target off-field areas to HAG 500 02 H will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000[2]) as shown in the following equation:

$$\text{Off- field PER} = \frac{\text{Maximum in-field PER x \% drift}}{\text{vegetation distribution factor (vdf)}}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups, accounting for a dilution in 3-dimensional vegetation structures in the field

The model used to estimate spray drift exposure in off-crop habitats was developed for drift onto a two-dimensional water surface and, as such, does not account for interception and dilution by three-dimensional vegetation in off-crop areas. Therefore, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure, to be used in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a dilution factor of 5 more appropriated.

“The vdf of 10 proposed in SETAC (2001) and used in the EU concept was derived by considering ‘Leaf Area Indices’ and plant interception, see Gonzalez-Valero et al. (2000); Koch and Weisser (2001); Weisser et al. (2001). ESCORT II SETAC (2001) and the Guidance Document on Terrestrial Ecotoxicology (EC, 2002) state that the current basis from which the vdf values are derived is not sufficient and further research needs to be done to calculate a more reliable value (e.g. validation of the vdf using field data).

The German Federal Environmental Agency proposed a value of 5 instead of 10 for the vdf at the PRAPeR Expert Meeting 03 on Ecotoxicology (Round 01), held 2006 in Porto, see UBA (2006). This exposure estimation was based mainly on the ‘Retention Area Index’ (RAI) characterizing the total retention area of sprayed plant protection products in a canopy per base area. As a ‘realistic worst case

[2] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

scenario, meadow canopies < 20 cm height was chosen (Koch and Weisser, 2004; German Federal Environment Agency UBA, 2006).
The derived vdf of 5 agreed well with field data by Koch et al. (2003), who compared measured residues of plant protection products on two dimensional surfaces with the measured residues on meadows next to a treated area (factor of 4.4 to 6.5 between median spray residues on leaves when a standard nozzle was used for spray application). Hence UBA proposed a vdf of five as a more reliable value to extrapolate from a two dimensional exposure situation to the exposure situation in the field.

German Federal Environment Agency (UBA), 2006. Exposure calculation for arthropods in field border structures - selection of an appropriate 'vegetation distribution factor'. Parma.
Koch H and Weisser P, 2004. Die Gesamtoberflaeche in Saumstrukturen als potentielle Retentionsflaeche fuer Driftpartikel, Retention Area Index (RAI). Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 56, 65-69.
Koch H, Weisser P and Landfried M, 2003. Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 55, 181-188.
EC (European Commission), 2002. Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002) rev.2 final, 17.10.2002. 1 - 39.
Gonzalez-Valero J, Campbell P, Fritsch H, Grau R and Romijn K, 2000. Exposure assessment for terrestrial non-target arthropods. Anzeiger fuer Schaedlingskunde, 73, 163-168.
Koch H and Weisser P, 2001. Spray deposits of crop protection products on plants â€" the potential exposure of non-target arthropods. Chemosphere, 44, 307-312.
SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2."

The drift value at 1 m distance is 2.77% of the application rate (90th percentile drift). The drift factor (% drift/100) is therefore 2.77/100 = 0.0277. As for this herbicide a ground-directed application is given, the field crop drift values are used for all crops.

For the results of the study with *T. pyri* exposed to HAG 500 02 H (see toxicity values), a vegetation distribution factor has to be considered (study conducted in 2D environment).

The resulting PER off-field values are shown in the following table.

Table 6.6-3: Off-field foliar Predicted environmental rates (PER) resulting from the intended uses of HAG 500 02 H

Study type	Max. rate (ml Prod./ha)	MAF	Maximum in-field PER (ml Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (g a.s./ha)
2-dimensional	4000	1	4000 (1800 g a.s./ha)	2.77%	5	9.972
2-dimensional	8000	1	8000 (3600 g a.s./ha)	2.77%	5	19.944

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing an in-field buffer strip of a given width. The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[3]) are given in the table below.

Table 6.6-4: Maximum off-field predicted environmental rates of HAG 500 02 H following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1/3m (2.77% drift)	Maximum PERoff-field at 5m (0.57% drift)	Maximum PERoff-field at 10m (0.29% drift)
(g a.s./ha)			
8 L/ha (3600 g a.s./ha) worst case Group C	19.94	4.10	2.1
4 L/ha (1800 g a.s./ha) All other uses	9.97	2.05	1.0

6.6.1.3 Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to HAG 500 02 H is given in the table below.

Table 6.6-5: Acceptability criteria for higher tier data and minimal TER values for arthropod species other than bees after use of HAG 500 02 H

Test substance	Species	Test type	Endpoint ER50 (g a.s./ ha)	Worst-case PER in-field (ml Prod./ha)	effects < 50 % ?	PER off-field (5 m) (g a.s./ ha)	PER off-field x correction factor (5) (5 m)	effects < 50 % ? (5 m)	TER Off-field (5 m)
HAG 500 02 H	*T.pyri*	Lab. 2D	35.6 (surrogate reproduction endpoint)	8000 (3.6 kg a.s./ha)	**no**	4.10	20.50	yes	8.7
				4000 (1.8 kg a.s./ha)	**no**	2.05	10.25	yes	17.4
values in bold are below the acceptability criteria									

Based on the calculated rates of HAG 500 02 H in in-field and off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria of less than 50% effects at calculated drift rates resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment

[3] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

indicate an acceptable risk for non-target arthropods due to the intended use of HAG 500 02 H in all indication groups according to the label with risk mitigation measures. Risk mitigation measures will have to be implemented to reduce the exposure of non-target arthropods to HAG 500 02 H in off-field areas comparable to 5 m in-field buffer strip. Management practices relevant for Germany are given in the respective Addendum.

6.6.2 Risk assessment for Arthropods other than Bees

6.6.2.1 In-field

The potential risk for non-target arthropods exposed in-field to HAG 500 02 H was assessed by calculating the hazard quotient (HQ = exposure/toxicity) as the ratio of the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) estimated in standard toxicity tests with non-target arthropods according to the formula:

$$\text{In field HQ} = \frac{\text{In - field PER}}{LR_{50}}$$

The resulting HQ in-field values for the standard species are presented in the following table. With regard to extended laboratory tests and semi-field tests lethal, and sublethal effects of less than 50 % are considered acceptable provided that the tests covered the appropriate field rate.

Table 6.6-6: In-field HQ values for non-target arthropods other than bees and acceptability criteria for higher tier data

Species	L/ER50 (g a.s./ha)	PER (g a.s./ha)	In-field HQ	effects < 50 % at PER?
Typhlodromus pyri	320 < LR_{50}<< 960 35.6 (ER_{50} surrogate endpoint)	3600	**3.8** << HQ <**11.3** 101	no
		1800	**1.9** << HQ <**5.6** 51	no

In-field, the acceptability criteria are not met for *Typhlodromus pyri*, since they indicate that effects greater than 50 % are to be expected at application rates (Candolfi et al., 2001). The results indicate that HAG 500 02 H poses high risk to non-target arthropods in-field following application according to the intended uses. It should be considered that the use in vineyard and orchard is considered not to be crop directed and only the vegetation under the crop is treated (strip application). For options implementing risk mitigation at national level please refer to chapter 6 of ESCORT 2 guidance document. Generally, it has to be demonstrated that there is a potential for recolonisation /recovery at least within one year but preferably in a shorter period depending on the biology (seasonal pattern) of the species.

6.6.2.2 *Off-field*

HQ approach

In order to assess the potential risk of HAG 500 02 H to non-target arthropods in off-field areas, the predicted environmental rate in the off-field (see chapter 6.6.1.2) is compared to the toxicity endpoints according to the following formula:

$$Off - field\ \ HQ = \frac{Off - field\ PER}{LR_{50}} \times correction\ \ factor$$

where:

Correction factor (also ‘safety factor’) = amounts to 10 in conjunction with Tier I data from tests on glass plates; amounts to 5 for Tier II data (2 species additionally to the sensitive ones) from extended laboratory tests/field tests. The factor accounts for extrapolation from testing few representative species to the species diversity expected in off-crop areas.

With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % are considered acceptable provided that the tests covered the appropriate field rate.

Table 6.6-7: Acceptability criteria for higher tier non-target arthropods data

Species	Test type	L/ER_{50} (g a.s./ha)	PER in-field (g a.s/ha)	Distance (m)	PERoff-field (g a.s./ha)	PER off-field x correction factor (5) (g a.s./ha)	are effects < 50% at PER x correction factor?
T. pyri	7 d Extended lab testing	35.6 (ER_{50} surrogate endpoint)	3600	1	19.94	99.7	**no**
				5	4.1	20.5	yes
				10	2.1	10.5	yes
			1800	1	9.97	49.9	yes
				5	2.05	10.3	yes
				10	1.0	5	yes

The comparison of the effects of glyphosate on *Typhlodromus pyri* at the calculated drift rates indicate that HAG 500 02 H does not pose an unacceptable risk to non-target arthropods in off-field areas with an application rate of 1800 g a.s./ha.

With an application rate of 3600 g a.s./ha, risk mitigation measures have to be implemented, comparable to 5 m in-field buffer strip.

TER approach

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to HAG 500 02 H was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50\ \left(\frac{L\ Product}{ha}\right)}{Off-field\ PER\ \left(\frac{L\ Product}{ha}\right)}$$

The risk is considered acceptable if the off-field TER values obtained are > 10 when the ecotoxicological data resulted from Tier 1 tests on glass plates or > 5 when the data were obtained in higher tier test (extended lab or field tests).

The resulting $TER_{off\text{-}field}$ values are given in the following table. Since the calculated TER values for *T. pyri* were below the trigger of 5, risk mitigation measures have to be implemented. They correspond to 5 meter buffer strip in-field.

Table 6.6-8: Calculated TER values for non-target arthropods exposed to HAG 500 02 H in off-field areas according to intended uses.

Species	Test type	L/ER_{50} (g a.s./ha)	PER off-field (g a.s./ha)	Distance (m)	PER off-field (g a.s./ha)	TER
T. pyri	2D	35.6 (ER_{50} surrogate endpoint)	3600	1	19.9	**1.8**
				5	4.1	8.7
				10	2.0	17.8
			1800	1	9.97	**3.6**
				5	2.0	17.4
				10	1.0	35.6

Based on the calculated rates of glyphosate in off-field areas, the TER values for the risk resulting from an exposure of non-target arthropods to HAG 500 02 H according to the GAP of the formulation HAG 500 02 H the acceptability criteria of TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of HAG 500 02 H according to the label. Risk mitigation measures have to be implemented, corresponding to 5 m vegetated buffer strip. Management practices relevant for Germany are given in the respective Addendum.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Overview and summary

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing glyphosate whenever contamination of soil may occur as a result of the intended uses of HAG 500 02 H.

Effects on earthworms and other soil non-target organisms resulting from an exposure to HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, all relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the intended uses of HAG 500 02 H are provided here, listed in Appendix 1 and summarized Appendix 2 (new studies).

6.7.1.1 Toxicity

Table 6.7-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to HAG 500 02 H with indication to agreed endpoints

Species	Substance	System	Toxicity (mg a.s./kg)	Reference	ICS-No.
Eisenia fetida	HAG 500 02 H	Acute 14d	LC_{50} : > 450 (Mortality)	Witte, B. (2009), MIIIA1, 10.6.2/01	78780
Eisenia fetida	glyphosate (IPA-salt)	chronic 56 d	NOEC ≥28.79 Reproduction	Hayward, J.C. and Mallet, M. Report no: CEMR - 1173	41621
	glyphosate (glyphosate acid)		NOEC ≥ 21.31		
	AMPA		NOEC ≥ 28.12		

The log K_{OW} value for glyphosate is below the agreed trigger value of 2. Therefore, no correction of the endpoints is required in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils and a resulting lower bioavailability of the active substance to soil organisms.

6.7.1.2 Exposure

According to the GAP, HAG 500 02 H is intended to be applied once a season with a maximum application rate of 8 L formulation/ha (i.e. 3600 g a.s./ha) for the indication group C and with a maximum application rate of 4 L formulation/ha (i.e. 1800 g a.s./ha) for all other uses. It will be used against weeds, in cereals (BBCH 89) and oil seed rape (BBCH 87-89).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances glyphosate and the major soil degradation products are presented in the table below. Calculations considered the maximum application rate with 0 % foliar interception for applications to orchards and vineyards. PEC values for the soil metabolites were calculated considering the maximum percentage of their formation observed in either the aerobic or anaerobic soil degradation studies and correcting for molecular weight.

All calculations assumed an even distribution of the substances in the top 5 cm horizon with a soil bulk density of 1.5 g/mL. Accumulation in the soil profile due to the persistence of glyphosate was considered when necessary.

Table 6.7-2: Maximum PEC_S for glyphosate and major soil degradation product AMPA following application in the intended use vineyard and orchard.

Intended use	Orchards and Vineyards (worst case covering all other uses)
Number of applications/interval	1
application rates	8 L/ha (3600 g a.s./ha) as worst case
crop interception	0%
Substance	Maximum PEC_{Soil} (mg/kg soil dw)
glyphosate	4.800
AMPA	1.945 occurring on day 14
HAG 500 02 H	10.677

6.7.1.3 Risk assessment –TER vaulues and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.7-3: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of HAG 500 02 H according to the intended uses.

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
glyphosate	8 L/ha (3600 g a.s./ha) as worst case	Acute	LC_{50} > 450	4.800	94	10
		Long-term	NOEC ≥ 28.79 (IPA-salt)		6	5
		Long-term	NOEC ≥ 21.31 (glyphosate acid)		**4.4**	5
AMPA		Acute	-		-	10
		Long-term	NOEC ≥ 28.12		6	5

Based on the predicted concentrations of glyphosate in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to HAG 500 02 H according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10. Regarding long term risk, it should be considered that results obtained in the reproduction study could not show significant differences on growth or reproduction of *Eisenia fetida* at the highest concentration tested. Both endpoints (28.79 mg/kg for the IPA salt and 21.31 mg/kg for glyphosate acid) originate from studies with no effects in the highest dose group. These concentrations stand for a 5 times higher concentration expected from the use of the maximum recommended application rate of 3600 g glyphosate/ha. Furthermore the IPA salt is contained in the formulated product HAG 500 02H. Using the NOEC for the isopropylamine salt of glyphosate, which is 28.79 mg/kg, a TER of 6.0 is estimated. Therefore, the results of the assessment indicate an acceptable long-term risk for soil organisms due to the intended use of HAG 500 02 H in vineyard and orchard according to the label.

As AMPA is considered to be of no greater toxicological concern than its parent compound in general and has a lower NOEC (≥ 28.12 mg /kg). The TER value describing the long term risk for earthworms exposed to the glyphosate metabolite AMPA meets the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

6.7.2 Toxicity to Exposure Ratio

6.7.2.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to HAG 500 02 H was assessed by comparing the maximum PEC_{soil} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_A values are shown in Table 6.7-3 above.

6.7.2.2 Chronic risk

The potential chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to glyphosate as well as the major soil degradation products of glyphosate was assessed by comparing the maximum PEC_{soil} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_{LT} values are shown in Table 6.7-3 above.

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on organic matter breakdown (litterbag) is required where:

- DT_{90fiel}d of the active substance is > 365 days or
- $DT_{90field}$ of of the active substance is between 100 and 365 days and
- Effects on soil microflora > 25 % or TER_{LT} earthworm < 5

None of these criteria is met for Glyphosate, since $DT_{90field}$ value is less than 365 days and no risk was identified for soil fauna and soil micro-organisms (see next chapter).

6.7.3 Residue content of earthworms

The log K_{ow} values of glyphosate < 3. Thus, glyphosate is not deemed to bioaccumulate in earthworms. Therefore, studies determining residue content of glyphosate in earthworms are not necessary.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing glyphosate whenever contamination of soil may occur as a result of the intended uses of HAG 500 02 H.

Effects on soil microorganisms resulting from an exposure to HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, all relevant study data for the assessment of the risk to soil microorganisms from the intended uses of HAG 500 02 H are provided here, listed in Appendix 1 and summarized Appendix 2 (new studies).

6.8.1.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for soil microbial activity following exposure to HAG 500 02 H

Process	Substance	Exposure	Effect	Reference	ICS-No.
N-tranformation	Glyphosate 450 SL AE	28d	< 25 % deviation from control 12.8 mg/kg soil dw	Feil et al. 2010	78781
			< 25 % deviation from control 64 mg/kg soil dw		
C-transformation		28d	< 25 % deviation from control 12.8 mg/kg soil dw		
			< 25 % deviation from control 64 mg/kg soil dw		

For the active ingredient in HAG 500 02 H, the soil concentrations which caused no deviations greater than ±25 % in the activity of the soil microorganisms are 6-times higher than the corresponding maximum PEC_{soil}, when applied up to 64 mg/kg soil dry weight.

Exposure

Please refer to section 6.7.1.2 above for the predicted environmental concentrations in soil (PEC_{soil}) of glyphosate.

6.8.1.2 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the active substance glyphosate when HAG 500 02 H is applied according to GAP are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure.

The results of the comparison expressed as Margin of Safety (MoS) are presented in the following table.

Table 6.8-2: Summary of risk assessment for soil micro-organisms exposed to HAG 500 02 H

Substance	Endpoint	Effect (NOEC) / dose (mg/kg soil dw)	PECS (mg/kg)	MoS
Glyphosate 450 SL AE (provisional designation corresponding to the company code of HAG 500 02 H)	Carbon respiration	< 25 % deviation from control/ 12.8 mg/kg soil dw	4.800	>2.6
		< 25 % deviation from control/ 64 mg/kg soil dw		>13.3
	Nitrogen transforamation	< 25 % deviation from control/ 12.8 mg/kg soil dw		>2.6
		< 25 % deviation from control/ 64 mg/kg soil dw		>13.3

Based on the predicted concentrations of glyphosate in soils, the risk to soil microbial processes following exposure to glyphosate according to the GAP of the formulation HAG 500 02 H is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, when applied up to 64 mg/kg soil dry weight.

6.9 Effects on Non-Target Plants

6.9.1 Overview and summary

Effects on non-target plants resulting from an exposure to HAG 500 02 H were not evaluated as part of the EU review of glyphosate. Therefore, all relevant study data for the assessment of the risk to non-target plants from the intended uses of HAG 500 02 H are provided here, listed in Appendix 1 and summarized Appendix 2 (new studies).

6.9.1.1 Toxicity

The potential effects of HAG 500 02 H on seedling emergence and vegetative vigour in non-target terrestrial plants has been tested (10 non-target terrestrial plants were tested in the vegetative vigour test and 6 non-target terrestrial plants in the seedling emergence test).

The risk to non-target plants following exposure to HAG 500 02 H is calculated using the most sensitive endpoint ER_{50} = 125 ml product /ha (fresh weight, representing 56.3 g a.s. /ha in *Brassica oleracea*) and worst-case PECs for the indication groups: 1 x 3600 g a.s./ha and 1x 1800 g a.i /ha.

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure HAG 500 02 H

Species	Substance	Exposition	Results Toxicity	Reference	ICS-No.
Seedling emergence					
Brassica oleracea *Vicia faba* ***Helianthus annus*** *Lolium perenne*	glyphosate 450 SL AE (450 g a.s./L) (provisional designation	Seedling emergence	ER_{50} = 7858 ml glyphosate 450 SL AE/ ha; (fresh weight)	Bützler, R., Meinerling, M. 2010	78783

Cucumis sativus *Allium cepa*	corresponding to the company code of HAG 500 02 H)		3536 g a.s./ha		
Vegetative vigour					
Allium cepa *Lolium perenne* *Daucus carota* *Beta vulgaris* *Lolium perenne* *Lycopersicon esc.* *Cucumis sativus* *Helianthus annuus* *Vicia faba* ***Brassica oleracea***	glyphosate 450 SL AE (450 g a.s./L) (provisional designation corresponding to the company code of HAG 500 02 H)	Vegetative vigour	ER_{50} = 125 ml product /ha (fresh weight) 56.3 g a.s. /ha	Bützler, R., Mollandin, G. 2010	78782

6.9.1.2 Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

PERoff-field= Maximum in-field PER (including MAF) x %drift

For calculation of PER in-field, please refer to section 6.6.1.2, page 37.

The resulting maximum off-field predicted environmental rates (PER off-field without vegetation distribution factor) are summarized in the following table.

Table 6.9-2: Maximum off-field predicted environmental rates of HAG 500 02 H following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m/ 3m (2.77 % drift)	Maximum PERoff-field at 5 m (0.57 % drift)	Maximum PERoff-field at 10m (0.27% drift)
	(g a.s./ha)		
8 L/ha (3600 g a.s./ha) as worst case Group C	99.72	20.52	9.97
8 L/ha (3600 g a.s./ha) Group C 90 % drift reduction	9.972	2.052	0.99
4 L/ha (1800 g a.s./ha) All other intended uses	49.86	10.26	4.9

6.9.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.9-3: Summary of risk assessment for non-target terrestrial plants exposed to HAG 500 02 H

Intended in-field rate	Endpoint	ER_{50} (mL product/ha)	PERin-field (mL product/ha)	Distance (m)	Exposure PERoff-field (g a.i/ ha)	TER
8 L/ha (3600 g a.s./ ha) as worst case Group C	Vegetative vigour	ER_{50} : 125 ml product /ha (fresh weight) 56.3 g a.s. /L	8 L/ha (3600 g a.s./ ha) as worst case Group C	3	99.72	**1**
				5	20.52	**3**
				10	9.97	6
			8 L/ha (3600 g a.s./ha) as worst case Group C 90% drift reduction	3	9.97	6
				5	2.052	27
4 L/ha (1800 g a.s./ ha)	Vegetative vigour	ER_{50} : 125 ml product /ha (fresh weight) 56.3 g a.s. /L	4 L/ha (1800 g a.s./ ha)	1	49.86	**1**
				5	10.26	6
			4 L/ha (1800 g a.s /ha) 90% drift reduction	1	4.986	11
				5	1.026	55

Based on the predicted rates of HAG 500 02 H in off-field areas, the TER values describing the risk for non-target plants following exposure to glyphosate according to the GAP of the formulation HAG 500 02 H does achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of HAG 500 02 H in all indication groups according to the label in case risk mitigation is considered.

Risk mitigation measures will have to be implemented to reduce the exposure of non-target terrestrial plants to HAG 500 02 H comparable to drift reduction technique or 5 m in-field buffer strip for the indication groups A, B, D, E, and F. For use in orchards and vineyards risk mitigation measure via buffer zone indicate a safe use with 10 m buffer zone.

Management practices relevant for Germany in vineyard and orchard considering drift reduction technique are given in the respective Addendum.

6.10 Other Non-Target Species (Flora and Fauna)

-/-

6.11 Other/Special Studies

-/-

6.12 Summary and Evaluation

6.12.1 Predicted distribution and fate in the environment and time courses involved

Please refer to Section 5 of this submission.

6.12.2 Short and long term risks for non-target species, populations, communities and processes

6.12.2.1 Birds

Based on refined Tier 1 assessment step, the calculated TER values for the acute risk resulting from an exposure of birds to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for birds due to the intended use of HAG 500 02 H in all indication groups according to the label.

Concerning the effects of glyphosate on bird reproduction, studies have been conducted with bobwhite quail (Beavers and Fink 1978/ WI 78-52) and mallard duck (Beavers and Fink 1978/ WI 78-53) for the active substance glyphosate. For mallard duck, no effect were observed up to the highest concentration tested (NOEC = 1000 ppm).

In the study with bobwhite quails, a reduction in eggshell thickness was detected at 50 ppm. Even though this effects was significant, no linear dose response could be determined since no further effect on eggshell thickness were observed at the tested higher doses (200 and 1000 ppm).

A significant effect reduction in egg weight was observed at the highest concentration tested (1000 ppm). Therefore, a NOEC of 18.1 mg a.s./kg b.w./d. was determined and agreed during the EU review process. Changes in egg weight are not considered a standard endpoint in avian reproduction studies according to guideline OECD 206 and all other relevant endpoints determined did not show any unacceptable differences compared to the control treatment –including No. of eggs, No. 14 d old survivals and hatchlings weight. The differences in egg weight between control and the treatment with 1000 ppm amounted to a decrease of approx. 7.5 % (10.26 g ± 0.38 g vs. 9.48 g ± 0.47 g in control and 1000 ppm treatment, respectively). Since especially all parameters concerning hatchling weight and survival were not affected at any concentration, it can be assumed that the observed changes in egg weight do not represent a population relevant adverse effect. Therefore, this endpoint will be considered as a NOAEL of 1000 ppm, corresponding to 102.23 mg/kg/bw/d and will be used for the assessment of the chronic risk for bird exposed to glyhosate according to the GAP of HAG 500 02 H.

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation

(EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for birds.

Consequences: No

6.12.2.2 Terrestrial Vertebrates other than Birds

In the Review Report for the active substance glyphosate (SANCO/6511/VI/99-final, 21 January 2002, p. 1-56), a LD_{50} of > 2000 mg/kg bw is determined and derives from acute toxicity studies in rat with the active substance. All acute endpoints in studies with rats are above the highest investigated dosis, the maximum up to 8000 mg/kg bw. Since for the generic focal species unacceptable risk was indicated, further refinement is necessary.

In further acute oral toxicity studies reporting glyphosate (and IPA salt) toxicity to mouse, however, lethal doses could be determined (please refer to glyphosate monograph, chapter B.5.2.1.1). In an acute oral toxicity study with glyphosate IPA-salt in mouse (Wang et al., 1987) a LD50 of 3669 mg/kg bw was determined and is the lowest reported. The study was considered to be acceptable. Since it is the lowest LD50 determined, this value was used for a refined risk assessment.

Based on the presumptions of Tier 1, the calculated TER values for acute and long-term risk resulting from an exposure of mammals to the active substance glyphosate according to the GAP of the formulation HAG 500 02 H up to 3600 g glyphosate/ha achieve the acceptability criteria TER ≥ 10 (for mouse and vole ≥ 5) and TER ≥ 5 (for mouse and vole ≥ 2), respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals from the intended uses.

Consequences: No

6.12.2.3 Aquatic organisms

Based on the calculated concentrations of glyphosate in surface water (PEC_{SW} FOCUS Step 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to glyphosate according to the GAP of the formulation HAG 500 02 H the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of HAG 500 02 H according to the label.

Consequences: No

6.12.2.4 Bees

Please refer to the risk assessment procedure as provided by JKI.

6.12.2.5 Non-target Arthropods other than Bees

In-field, the acceptability criteria are not met for *Typhlodromus pyri*, since they indicate that effects greater than 50 % are to be expected at application rates (Candolfi et al., 2001). The results indicate that HAG 500 02 H poses high risk to non-target arthropods in-field following application according to the intended uses. Risk mitigation measures have to be implemented. Generally, it has to be demonstrated that there is a potential for recolonisation /recovery at least within one year but preferably in a shorter period depending on the biology (seasonal pattern) of the species.

The comparison of the effects of glyphosate on *Typhlodromus pyri* at the calculated drift rates indicate that HAG 500 02 H does not pose an unacceptable risk to non-target arthropods in off-field areas with an application rate of 1800 g a.s./ha.

With an application rate of 3600 g a.s./ha, risk mitigation measures have to be implemented, comparable to 5 m in-field buffer strip.

Based on the calculated rates of glyphosate in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to HAG 500 02 H according to the GAP of the formulation HAG 500 02 H the acceptability criteria of TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of HAG 500 02 H according to the label.

Risk mitigation measures have to be implemented, corresponding to 5 m buffer strip. Management practices relevant for Germany are given in the respective Addendum.

Consequences:

In-field HQ: Risk mitigation measures have to be implemented.

Off-field HQ:

Indication group A, B, D, E and F (except C): No

Indication group C: Risk mitigation measure (5 m buffer strip)

6.12.2.6 Earthworms and other non-target Meso- and Macrofauna

Based on the predicted concentrations of glyphosate in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to HAG 500 02 H according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10. However, the TER value describing the long term risk for earthworms fails the the acceptability criteria TER ≥ 5 slightly according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Nevertheless it should be considered that results obtained by the reproduction study could not show significant differences on growth or reproduction of *Eisenia fetida* at the highest concentration tested. Therefore the stated endpoint represents a NOEC ≥ 21.31 mg glyphosate/kg. These concentration stands for a 5 times higher concentration expected from the use of the maximum recommended application rate of 3600 g glyphosate /ha. Therefore the results of the assessment indicate a low long-term risk for soil organisms due to the intended use of HAG 500 02 H in vineyard and orchard according to the label.

AS AMPA is considered to be of no greater toxicological concern than its parent compound in general and has a lower NOEC (≥ 28.12 mg /kg). The TER value describing the long term risk for earthworms meets the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences: No

6.12.2.7 Soil Microbial Activity

Based on the predicted concentrations of glyphosate in soils, the risk to soil microbial processes following exposure to HAG 500 02 H according to the GAP of the formulation HAG 500 02 H is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, when applied up to 64 mg/kg soil dry weight.

Consequences: No

6.12.2.8 Non-target Plants

Based on the predicted rates of HAG 500 02 H in off-field areas, the TER values describing the risk for non-target plants following exposure to glyphosate according to the GAP of the formulation HAG 500 02 H does achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of HAG 500 02 H in all indication groups according to the label in case risk mitigation is considered.

Risk mitigation measures will have to be implemented to reduce the exposure of non-target terrestrial plants to HAG 500 02 H comparable to drift reduction technique or 5 m in-field buffer strip for the indication groups A, B, D, E, and F. For use in orchards and vineyards risk mitigation measure via buffer zone indicate a safe use with 10 m buffer zone.

Management practices relevant for Germany in vineyard and orchard considering drift reduction technique are given in the respective Addendum.

Consequences:

In-field HQ: Risk mitigation measures have to be implemented.

Off-field HQ:

Indication group A, B, D, E and F (except C): Risk mitigation measure (5 m buffer strip)

Indication group C: Risk mitigation measure (10 m buffer strip)

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA1 10.2.2.1/01	Hoffmann, K. & Wydra, V.	2009	Acute toxicity of Glyphosate 450 SL AE to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static limit test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50353230 GLP, unpublished	Y	Helm AG
KIIIA1 10.2.2.2/01	Hoffmann, K. & Wydra, V.	2009	Acute Toxicity of Glyphosate 450 SL AE to Daphnia magna in a Static 48-hour Immobilization Limit-Test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50352220 GLP, unpublished	Y	Helm AG
KIIIA1 10.2.2.3/01	Hoffmann, K. & Wydra, V.	2009	Toxicity of Glyphosate 450 SL AE to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50351210 GLP, unpublished	Y	Helm AG
KIIIA1 10.2.2.3/01	Hoffmann, K. & Deierling, T.	2011	Toxicity of Glyphosate 450 SL AE to Navicula pelliculosa in an Algal Growth Inhibition Test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 52529210 GLP, unpublished	Y	Helm AG
KIIIA1 10.4.2.1/01	Sekine, T. & Schmitzer, S.	2009	Effects of Glyphosate 450 SL AE (acute contact and oral) on Honey bees (*Apis mellifera L.*) in the Laboratory Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50354035 GLP, unpublished	Y	Helm AG

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA1 10.4.2.2/01	Sekine, T. & Schmitzer, S.	2009	Effects of Glyphosate 450 SL AE (acute contact and oral) on Honey bees (*Apis mellifera L.*) in the Laboratory Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50354035 GLP, unpublished	Y	Helm AG
KIIIA1 10.5.2/01	Moll, M.	2009	Effects of Glyphosate 450 SL AE on the Parasitoid *Aphidius rhopalosiphi*, Extended Laboratory in the Laboratory – Dose Response Test - Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50355002 GLP, unpublished	Y	Helm AG
KIIIA1 10.5.2/02	Schwarz, A.	2009	Effects of Glyphosate 450 SL AE on the Predatory Mite *Typhlodromus pyri*, Extended Laboratory Study - Dose Response Test - Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50356062 GLP, unpublished	Y	Helm AG
KIIIA1 10.5.2/03	Schmitzer, S.	2009	Effects of Glyphosate 450 SL AE on the Carabid Beetle *Poecilus cupreus*, Extended Laboratory Study Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50357007 GLP, unpublished	Y	Helm AG
KIIIA1 10.6.2/01	Witte, B.	2010	Acute toxicity (14 days) of Glyphosate 450 SL AE to the earthworm *Eisenia fetida* in artificial soil Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 52522021 GLP, unpublished	Y	Helm AG

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA1 10.7.1.1/01	Feil, N.	2009	Effects of Glyphosate 450 SL AE on the Activity of the Soil Microflora in the Laboratory Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50359080 GLP, unpublished	Y	Helm AG
KIIIA1 10.7.1.2/01	Feil, N.	2009	Effects of Glyphosate 450 SL AE on the Activity of the Soil Microflora in the Laboratory Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50359080 GLP, unpublished	Y	Helm AG
KIIIA1 10.8.1.2/01	Bützler, R., Mollandin, G.	2009	Effects of Glyphosate 450 SL AE on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50362087 GLP, unpublished	Y	Helm AG
KIIIA1 10.8.1.3/01	Bützler, R., Meinerling, M.	2009	Effects of Glyphosate 450 SL AE on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50361086 GLP, unpublished	Y	Helm AG
KIIIA1 10.8.2.1/01	Hoffmann, K., Wydra, V.	2009	Toxicity of Glyphosate 450 SL AE to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test Institut für Biologische Analytik und Consulting IBACON GmbH Report No.: 50350240 GLP, unpublished	Y	Helm AG

Additional information provided by the applicant

Evaluation of uncertainties of the refined avian reproductive deterministic risk assessment

Parameter, assumption or omission	Potential to lower 'true worst-case' risk	Explanation	Potential to heighten 'true worst-case' risk	Explanation
Toxicity data	- / --	The NOED from the avian reproductive toxicity study with bobwhite quail was based on a 17 weeks treatment period. Exposure in a field situation will not occur over a prolonged time period due to rapid degradation of Glyphosate in plant material (DT_{50} = 3 d). Therefore, reproductive toxicity is clearly overestimated due to the unrealistic repeated dose scenario.		Exposure in a field situation will not occur over a prolonged time period due to rapid degradation of Glyphosate in plant material (DT_{50} = 3 d) and an application interval of 90 days. Therefore, there is no potential to heighten true worst case risk.
Residue decline		Using the accepted DT_{50} of 3 days for Glyphosate in plant material reported in the DAR based on measured initial residues on grass instead of the default value of 10 days is not expected to lower the true worst-case risk.		Using the accepted DT_{50} of 3 days for Glyphosate in plant material reported in the DAR based on measured initial residues on grass instead of the default value of 10 days is not expected to heighten the true worst-case risk.

Additional information provided by the RMS

Parameter, assumption or omission	Explanation
Toxicity data, acute oral toxicity in mammals	In the Review Report for the active substance glyphosate (SANCO/6511/VI/99-final, 21 January 2002, p. 1-56), a LD50 of > 2000 mg/kg bw is determined and derives from acute toxicity studies in rat with the active substance. All acute endpoints in studies with rats are above the highest investigated dosis, the maximum up to 8000 mg/kg bw. Since for the generic focal species unacceptable risk was indicated, further refinement is necessary. In further acute oral toxicity studies reporting glyphosate (and IPA salt) toxicity to mouse, however, lethal doses could be determined (please refer to glyphosate monograph, chapter B.5.2.1.1). In an acute oral toxicity study with glyphosate IPA-salt in mouse (Wang et al., 1987) a LD50 of 3669 mg/kg bw was determined and is the lowest reported. The study was considered to be acceptable. Since it is the lowest LD50 determined, this value was used for a refined risk assessment.

Appendix 2 Detailed evaluation of studies relied upon

Reports only studies, which

(a) have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance) or

(b) have been evaluated in a peer reviewed process at EU level but where in exceptional cases derived endpoints have to be revised in the light of current scientific and technical knowledge.

A2-1 Active substance (generally only relevant in the case that new annex II data is provided after glyphosate approval)

A2-2 Formulation

MIII A1 10.2 Effects on Aquatic Organisms

MIIIA1 10.2.2 Acute toxicity of the formulation

MIIIA1 10.2.2.1/01 Fish

The following acute toxicity to fish study performed on HAG 500 02 H is provided in support of the assessment.

Report:	**KIIIA1 10.2.2.1/01, Hoffmann, K. and Wydra, V. (2009)**
Title:	Acute toxicity of Glyphosate 450 SL AE to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static limit test
Document No:	50353230
Guidelines:	OECD Guideline for Testing of Chemicals, Section 2, No. 203, Fish, Acute Toxicity Test, July 17, 1992 EU Commission Directive 92/69/EEC, Annex Part C, C.1: Acute Toxicity for Fish, Official Journal of the European Communities No. L 383 A, December 29, 1992
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The acute toxicity of the test item HAG 500 02 H (synonym: Glyphosate 450 SL AE) to rainbow trout (*Oncorhynchus mykiss*) was determined in a 96-hour static limit test. 7 rainbow trout were exposed to a nominal concentration of 100 mg test item/L (corresponding to: 38.4 mg a.s./L). An additional control group of the same number of fish was exposed to untreated test medium. The loading rate was less than 1 g fish wet weight per liter test medium. The total hardness of the test medium was 250 mg/L as $CaCO_3$. The test media were slightly aerated during the test.

HAG 500 02 H (Helm Sample no. 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The actual concentration was determined by analysis of the active substance glyphosate using a validated liquid chromatography method with UV-detection (HPLC-UV). The Limit of Detection was 0.067 mg reference item/L (glyphosate, purity 98.0%), the Limit of Quantification was 10 mg test item/L (corresponding to 3.84 mg a.s./L). Determinations were performed from duplicate samples of the test medium of the only test concentration and the control at the start and at the end of the test.

Findings:

At the start of the test just before introduction of the fish 110% of the nominal test concentration were found. After 96 hours test duration 111% of the nominal values were determined. During the test period of 96 hours the fish were exposed to a mean of 110% of nominal test concentration. Therefore, all reported results are related to nominal concentrations of the test item.

In the control and at the only test concentration of 100 mg/L (38.4 mg a.s./L), all fish survived until the end of the experiment and no sublethal effects occurred. All biological results (observed sublethal effects, mortalities and the LC_{50}-values) are listed in Table 10.2.2.1-1.

Table 10.2.2.1-1: Results of acute toxicity testing of HAG 500 02 H in rainbow trout

Endpoint	Concentration [mg test item/L] 1)	Concentration [mg a.s./L] 1)
96-hour LC_{50}	> 100	> 38.4
96-hour NOEC	100	38.4
96-hour LOEC	> 100	> 38.4

1) All values refer to mean measured test concentrations

Conclusion:

HAG 500 02 H showed no acute toxicity to rainbow trout. The LC_{50} after 96 hours was determined to be > 100 mg nominal test item/L equivalent to 38.4 mg a.s./L.

Study Comments: MIIIA1 10.2.2.1/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.2.2.1	The 96-hour LC_{50} is > 38.4mg a.s./L.

MIIIA1 10.2.2.2/01 Aquatic invertebrates (daphnia)

The following aquatic invertebrate (daphnia) study performed on HAG 500 02 H is provided in support of the assessment.

Report:	**KIIIA1 10.2.2.2/01, Hoffmann, K. and Wydra, V. (2009)**
Title:	Acute Toxicity of Glyphosate 450 SL AE to *Daphnia magna* in a Static 48-hour Immobilization Limit-Test
Document No:	50352220
Guidelines:	OECD Guideline for Testing of Chemicals, No. 202, *Daphnia sp.*, Acute Immobilisation Test, 2004 EU Commission Directive 92/69/EEC, C.2, Acute Toxicity for Daphnia, 1992
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The acute toxicity of the test item HAG 500 02 H (synonym: glyphosate 450 SL AE) to *Daphnia magna* was determined in a 48-hour static limit-test. In this test, 20 daphnia (aged less than 24 h) per control and the only test concentration (divided into four replicates of five animals) were introduced in test medium.

HAG 500 02 H (Helm Sample no. 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The actual concentrations were determined by analysis of the active substance glyphosate at the nominal concentration of 100 mg test item/L (equivalent to 38.4 mg a.s./L) using a validated liquid chromatography method with UV-detection (HPLC-UV). The Limit of Detection was 0.03 mg reference item/L (glyphosate, purity 99.7 %), the Limit of Quantification was 10 mg test item/L. Determinations were performed at the start and the end of the test.

Findings:

The analytically determined concentration at the start of the test corresponded to 106% of the nominal test concentration. After 48 hours test duration, 104% of the nominal value was determined. During the test the daphnia were exposed to a mean of 105% of nominal. Therefore, all reported results refer to nominal concentration.

After 48 hours of exposure no immobilisation of the test animals was observed in the control and in the only test concentration of 100 mg/L. The biological results are presented in Table 10.2.2.2-1.

Table 10.2.2.2-1: Results of acute toxicity testing of HAG 500 02 H in Daphnia magna

Endpoint	Concentration [mg test item/L] [1)]	Concentration [mg a.s./L] [1)]
48-hour EC_{50}	>100	> 38.4
48-hour NOEC	100	38.4
48-hour LOEC	> 100	> 38.4

[1)] All values refer to nominal test concentration

Conclusion:

The toxic effect of the test item Glyphosate 450 SL AE to *Daphnia magna* was assessed in a static limit-test. The 48-hour NOEC was determined to be 100 mg test item/L (corresponding to be 38.4 mg a.s./L). The 48-hour EC_{50} value was determined to be > 100 mg test item/L (> 38.4 mg a.s./L).

Study Comments: MIIIA1 10.2.2.2/02	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.2.2.2	The 48-hour $EC_{50}$is > 38.4mg a.s./L.

MIIIA1 10.2.2.3/01 Algae

The following algae toxicty studies performed on HAG 500 02 H are provided in support of the assessment.

Report:	**KIIIA1 10.2.2.3/01, Hoffmann, K. and Wydra, V., 2009**
Title:	Toxicity of Glyphosate 450 SL AE to *Pseudokirchneriella subcapitata* in an Algal Growth Inhibition Test
Document No:	50351210
Guidelines:	OECD Guideline for Testing of Chemicals, Section 2, No. 201: Freshwater Alga and Cyanobacteria Growth Inhibition Test, March 2006 EU Commission Directive 92/69/EEC, Annex Part C, C.3: Algal Inhibition Test, 1992
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The influence of HAG 500 02 H (synonym: Glyphosate 450 SL AE) on the growth and the biomass of the freshwater green algal species *Pseudokirchneriella subcapitata* was investigated in a 72-hour static test. Five test concentrations of 50, 16, 5.0, 1.6 and 0.50 mg test item/L (corresponding to 19.2, 6.1, 1.9, 0.6 and 0.2 mg a.s./L), and an untreated control were used. The test was started (0 hours) by inoculation of 5,000 algal cells per mL of test medium. These cells were taken from an exponentially growing pre-culture that was set up 4 days prior to the test under the same conditions as in the test.

HAG 500 02 H (Helm Sample no. 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The actual concentrations were determined by analysis of the active substance glyphosate using a validated liquid chromatography method with UV-detection (HPLC-UV). The Limit of Detection was 0.008 mg reference item/L (glyphosate, purity 99.7 %), the Limit of Quantification was 0.25 mg test item/L. Determinations were performed at the start and the end of the test.

Findings:

All validity criteria according to OECD 201 were met. At the start of the test 91% of the nominal test concentrations were found (average of all test concentrations). After 72 hours, 91% of the nominal value was determined (average of all test concentrations). During the test the algae were exposed to a mean of 91% of nominal. Therefore, all reported results refer to nominal concentrations. The lowest concentration was <LOD (Limit of detection).

The appearance of the test item in test water did not result in remarkable observations.

In the control a 158-fold increase of cell densities was observed within 72 hours. HAG 500 02 H had a statistically significant inhibitory effect on the growth of *Pseudokirchneriella subcapitata* after the test period of 72 hours at concentrations of 1.6 mg test item/L (= 72-hour LOEC based on growth and yield) and above. The endpoint yield was the most sensitive parameter tested. The 72-hour E_yC_{50} was determined to be 4.1 mg test item/L.

The biological results are presented in Table 10.2.2.3-1.

Table 10.2.2.3-1: Results of acute toxicity testing of HAG 500 02 H on *Pseudokirchneriella subcapitata*

Endpoint	Growth rate	Yield
72-hour EC_{50} [mg formulation/L]	38.2	4.1
72-hour EC_{50} [mg a.s./L]	14.7	1.6
72-hour NOEC [mg formulation/L]	0.5	0.5
72-hour NOEC [mg a.s./L]	0.2	0.2

Conclusion

The influence of Glyphosate 450 SL AE on the growth and biomass of the freshwater green algae *Pseudokirchneriella subcapitata* was assessed in a static dose-response test. The 72-hour E_rC50 value was calculated to be 38.2 mg test item (14.7 mg a.s./L) and the 72-hour E_yC50 was calculated to be 4.1 mg test item (1.6 mg a.s./L). The 72-hour NOE_rC and NOE_yC were determined to be 0.5 mg/L (0.2 mg a.s./L) and the associated 72-hour LOE_rC and LOE_yC is 1.6 mg/L (0.6 mg a.s./L).

The results correspond to an E_yC_{50} of 4.1 mg/L for the most sensitive endpoint and a NOE_yC of 0.5 mg/L for HAG 500 02 H.

MIIIA1 10.2.2.3/02 Algae

Report:	**KIIIA1 10.2.2.3/02, Hoffmann, K. and Deierling, T., 2011**
Title:	Toxicity of Glyphosate 450 SL AE to *Navicula pelliculosa* in an Algal Growth Inhibition Test
Document No:	52529210
Guidelines:	OECD Guideline for Testing of Chemicals, Section 2, No. 201: Freshwater Alga and Cyanobacteria Growth Inhibition Test, March 2006 EU Commission Regulation No. 761/2009, Annex Part C, C.3: Algal Inhibition Test, August 2009
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, Energie, Landwirtschaft und Verbraucherschutz, Germany)

Material and Methods:
The influence of HAG 500 02 H (synonym: Glyphosate 450 SL AE) on the growth of the diatom algal species *Navicula pelliculosa* was investigated in a 72-hour static dose-response test. Five test concentrations of 100, 32, 10, 3.2 and 1.0 mg test item/L (corresponding to 45, 14.4, 4.5, 1.44 and 0.45 mg a.s./L), and an untreated control were used. The test was started (0 hours) by inoculation of

10,000 algal cells per mL of test medium. These cells were taken from an exponentially growing pre-culture that was set up 4 days prior to the test under the same conditions as in the test.

HAG 500 02 H (Helm Sample no. 37/219/09) was used with a nominal content of glyphosate of 450 g/L.

The quantification of the test item was performed using HPLC-method with fluorescence detection for glyphosate after post column derivatisation to a highly fluorescent compound. The Limit of Detection was 0.05 mg reference item/L (glyphosate, purity 99.2 %), the Limit of Quantification was 0.75 mg test item/L. Determinations were performed at the start and the end of the test.

Findings:

All validity criteria according to OECD 201 were met. At the start of the test 106 % of the nominal test concentrations were found (average of all test concentrations). After 72 hours test duration, 108 % of the nominal value was determined (average of all test concentrations). Only the average of the test concentrations of 3.2 to 100 mg test item/L was used since the samples of the control and the first concentration of nominal 1.0 mg test item/L was mixed up during the sampling. It is proved that the contamination of the control happened at the end of the test because the samples of the test start showed an correct dosing. During the test the algae were exposed to a mean of 107 % of nominal. Therefore, all reported results refer to nominal concentrations.

The appearance of the test item in test water did not result in remarkable observations.

In the control a 68.7-fold increase of cell densities was observed within 72 hours. HAG 500 02 H had a statistically significant inhibitory effect on the yield of *Navicula pelliculosa* after the test period of 72 hours at concentrations of 3.2 mg test item/L (= 72-hour LOEC based yield) and above. The endpoint yield was the most sensitive parameter tested. The 72-hour E_yC_{50} was determined to be 8.97 mg test item/L.

The biological results are presented in Table 10.2.2.3-1.

Table 10.2.2.3-1: Results of acute toxicity testing of HAG 500 02 H on *Navicula pelliculosa*

Endpoint	Growth rate	Yield
72-hour EC_{50} [mg formulation/L]	40.4	8.97
72-hour EC_{50} [mg a.s./L]	18.2	4.04
72 hour NOEC [mg formulation/L]	3.2	1.0
72 hour NOEC [mg a.s./L]	1.4	0.45

Conclusion

The influence of Glyphosate 450 SL AE on the growth and biomass of the freshwater green algae *Navicula pelliculosa* was assessed in a static dose-response test. The 72-hour E_rC50 value was calculated to be 40.4 mg test item (18.2 mg a.s./L) and the 72-hour E_yC50 was calculated to 8.97 mg test item (4.04 mg a.s./L). The 72-hour NOE_rC and NOE_yC were determined to be 3.2 and 1.0 mg/L (corresponding to 1.44 and 0.45 mg a.s./L) and the associated 72-hour LOE_rC and LOE_yC is 10 mg/L and 3.2 mg/L (corresponding to 4.5 and 1.44 mg a.s./L).

The results correspond to an E_yC_{50} of 8.97 mg/L for the most sensitive endpoint and a NOE_yC of 1.0 mg/L for HAG 500 02 H.

Study Comments: MIIIA1 10.2.2.3/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.2.2.3	The 72-hour E_yC_{50} is 8.97 mg a.s./L.

MIIIA1 10.4.2 Acute toxicity of the formulation to bees

MIIIA1 10.4.2.1/01 Oral

The following bee acute oral study performed on HAG 500 02 H is provided in support of the assessment.

Report:	**KIIIA1 10.4.2.1/01, Sekine, T. and Schmitzer, S., 2009a**
Title:	Effects of Glyphosate 450 SL AE (acute contact and oral) on Honey bees (*Apis mellifera* L.) in the Laboratory
Document No:	50354035
Guidelines:	OECD Guideline for Testing of Chemicals, Section 2, No. 213: Honeybees, acute oral toxicity test, September 1998
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The acute oral toxicity of HAG 500 02 H was determined with young adult worker honey bees of the species *Apis mellifera* in a limit test. Each treatment consisted of 5 replicates with 10 bees per replicate. Therefore, a total of 50 bees each were set up for the test item group, the reference item group and the control group.

The test substance was administered to the bees after suspension in 50% sugar solution. The study was performed as limit test with a single intended test dose of 217.2 µg formulation/bee corresponding to 97.7 µg a.s./bee. The test suspension was offered to the bees for a period of maximum one hour, afterwards the amount of sugar solution, ingested by the test organisms, was measured

Parallel to the test item treatment, reference item treatments were run with bees from the same colonies (i.e. 4 reference treatments with 5 replicates each with 10 bees per replicate). The reference item was a dimethoate formulation which was applied to the bees at intended dose levels of 0.05, 0.08, 0.15 and 0.30 µg/bee. An additional control group was administered 50% sucrose solution.

Bee mortality was assessed 4, 24 and 48 hours after removing the test item. The bees were characterised as healthy (alive and unaffected), affected (still upright and attempting to walk, but showing signs of reduced co-ordination; or generally inactive with respect to the bees in the control), moribund (lying on their back or side, still twitching, but generally unable to right themselves) or dead (no longer moving).

Findings:

No test item induced mortality occurred during the experiment. No behavioural abnormalities attributed to exposure of the test item to the bees occurred during the experimental time of 48 hours. Since no mortality occurred in the 217.2 µg product/bee group, the contact LD_{50} value can be considered as > 217.2 µg product/bee.

Treatment with the reference substance resulted in dose related mortality after 48 hours. An oral LD_{50} of 0.15 µg dimethoate/bee was determined. Therefore, the validity criteria were met, as the oral LD_{50} at the 48-hour assessment was in the range of 0.10 - 0.35 µg dimethoate/bee.

Conclusion:

HAG 500 02 H when tested for acute oral toxicity in worker honey bees did not cause mortality at the limit dose of 217.2 µg formulation/bee. The LD_{50} was found to be > 217.2 µg formulation/bee equivalent to 97.7 µg a.s./bee.

Study Comments: MIIIA1 10.4.2.1/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.4.2.1	See JKI

MIIIA1 10.4.2.2/01 Contact

The following bee acute contact study performed on HAG 500 02 H was provided in support of the assessment.

Report:	**KIIIA1 10.4.2.2/01, Sekine, T. and Schmitzer, S., 2009b**
Title:	Effects of Glyphosate 450 SL AE (acute contact and oral) on Honey bees (*Apis mellifera* L.) in the Laboratory
Document No:	50354035
Guidelines:	OECD Guideline for Testing of Chemicals, Section 2, No. 214: Honeybees, acute contact toxicity test, September 1998
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The acute contact toxicity of HAG 500 02 H was determined with young adult worker honey bees of the species *Apis mellifera* in a limit test. Each treatment consisted of 5 replicates with 10 bees per replicate.

Therefore, a total of 50 bees each for the test item group, the reference item group and the control group were set up.

The test substance was applied to the bees after suspension in tap water (with 0.5 % Adhäsit®). The study was performed as limit test with a single intended test dose of 200 µg formulation/bee. The test suspension was applied to the dorsal side of the bee thorax using a calibrated micro-pipette.

Parallel to the test substance treatment, reference substance treatments were run with bees from the same colonies (4 reference item treatments with 5 replicates each with 10 bees each). The reference substance was a dimethoate formulation which was applied to the bees at intended dose levels of 0.10, 0.15, 0.20 and 0.30 µg/bee. An additional control group was dosed with the vehicle only.

Bee mortality was assessed 4, 24 and 48 hours after treatment application. The bees were characterised as healthy (alive and unaffected), affected (still upright and attempting to walk, but showing signs of reduced co-ordination; or generally inactive with respect to the bees in the control), moribund (lying on their back or side, still twitching, but generally unable to right themselves) or dead (no longer moving).

Findings:

At the end of the contact toxicity test (48 hours after application), there was no mortality at 200.0 µg product/bee. No mortality occurred in the control (water + 0.5% Adhäsit®). No behavioural abnormalities attributed to exposure of the test item to the bees occurred during the experimental time of 48 hours.

In the treatments with the reference item, dose related mortality was seen at the 48-hour assessment. The contact 48-hour LD_{50} of the reference item was calculated to be 0.16 µg dimethoate/bee. Therefore, the validity criteria were met, as the contact LD_{50} at the 24-hour assessment was in the range of 0.10 - 0.30 µg dimethoate/bee.

Conclusion:

HAG 500 02 H when tested for acute contact toxicity in worker honey bees did not cause mortality at the limit dose of nominal 200 µg formulation/bee. The LD_{50} was found to be > 200 µg formulation/bee equivalent to 90.0 µg a.s./bee.

Study Comments: MIIIA1 10.4.2.2/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.4.2.2	Please refer to the risk assessment procedure as provided by JKI.

MIIIA1 10.5 Acute toxicity of the formulation to non-target arthropods other than bees

MIIIA1 10.5.2/01 Extended laboratory studies

Report:	**KIIIA1 10.5.2/01, Moll, M. (2009)**
Title:	Effects of Glyphosate 450 SL AE on the Parasitoid *Aphidius rhopalosiphi*, Extended Laboratory Study – Dose Response Test -
Document No:	50355002
Guidelines:	MEAD-BRIGGS, M. A. *et al.* (2000): A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stephani-Perez) (Hymenoptera: Braconidae) and current improvements by the ring-test group (Mead Briggs *et al.* 2006).
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The influence of HAG 500 02 H (synonym: Glyphosate 450 SL AE) on parasitoid wasps was investigated in an extended laboratory study with *Aphidius rhopalosiphi* over 48 hour for mortality on treated leaf surfaces. Additionally, an assessment for sublethal effects on parasitisation activity of the females survivors was done.

HAG 500 02 H (Sponsor's sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

This study encompassed 7 treatment groups (Control, 0.360, 0.720, 1.44, 2.88 and 5.76 kg a.s./ha and reference item). Perfekthion was used as reference item and was applied at an application rate of 10.0 mL/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto leaves (vine leaves) via laboratory spraying equipment, which were then air dried. Each treatment group consisted of 4 replicates each containing 10 parasitoids (7 females and 3 males). Survival of the parasitoids was assessed after 2, 24 and 48 hours. At 48 hours, for treatment groups with < 50% corrected mortality survived females were removed and their reproductive capacity was assessed by confining them individually over untreated barley plants infested with the host cereal aphids, *Rhopalosiphum padi*. The adult parasitoids were removed after 24 hours and the aphid-infested plants left for further 11 - 12 days before the numbers of aphid mummies that had developed were assessed.

Findings:

The mortality values of the control as well as the mortality values of the reference item treatment fulfilled the study validity criteria.

In the replicates of the control no mortality occurred and the mean mortality in the test concentrations up to 1440 g a.s./ha did not significantly differ from the control. At the rate of 2.88 kg a.s./ha (corresponding to 6.06 L product/ha) and above the mean mortality was significantly different from the control.

A repellent effect of the test item was observed at all dose rates during the initial 3 hours of the study. The settling rate of the parasitoids on the treated leaves was 0.0 - 3.0% in the different dose rates. The reduction was statistically significant up to and including 5.76 kg a.s./ha where 10.5% of the wasps settled on the plants. Due to the increasing mortality at the higher dose rates it is assumed that the parasitoids were exposed to the test item in spite of the repellent effect.

The reproductive capacity of *A. rhopalosiphi* was tested at all dose rates and was not affected at any dose rate tested. The results are shown in Table 10.5.2-1.

Table MIIIA1 10.5.2-1Results from testing of the influence of HAG 500 02 H on *Aphidius rhopalosiphi*

Concentration		**Mortality after 48 hours of exposure**		**Reproductive assessment**	
HAG 500 02 H [mL product/ha]	**Glyphosate [g a.s./ha]**	**mean [%]**	**corrected mean [%]1)**	**Mummies/female**	**Effect on reproduction [%]**
control		0.0	-	56.0	
758	360	0.0	2.5	51.7	7.6
1520	720	7.5	15	46.2	17.4
3030	1440	7.5	15	47.0	16.0
6060	2880	12.5 *	37.5	47.8	14.5
12100	5760	32.5 *	22.5	40.8	27.2
reference item		100	100		

* significantly higher mortality than control (Fisher exact test, $\alpha = 0.05$)
1) Corrected mortality according to Abbot and improvements by Schneider-Orelli

The endpoints derived from this study are shown in Table 10.5.2-2.

Table MIIIA1 10.5.2-2Endpoints from testing of HAG 500 02 H on *Aphidius rhopalosiphi*

Endpoint	**Rate**	
	HAG 500 02 H [mL product/ha]	Glyphosate [g a.s./ha]
LR_{50} after 48 hours of exposure	> 12100	> 5760

Conclusion:

Under extended laboratory conditions the LR_{50} of HAG 500 02 H is estimated to be greater than 5.76 kg a.s./ha. The reproductive capacity of *A. rhopalosiphi* was tested at all dose rates. There was no effect on reproduction up to and including 5.76 kg a.s./ha compared to the control.

MIIIA1 10.5.2/02 Extended laboratory studies

Report:	**KIIIA1 10.5.2/02, Schwarz, A. (2009)**
Title:	Effects of Glyphosate 450 SL AE on the Predatory Mite *Typhlodromus pyri*, Extended Laboratory Study – Dose Response Test -
Document No:	50356062
Guidelines:	BLÜMEL, S. et al. (2000): Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products OOMEN 1988: Guideline for the evaluation of side-effects of pesticides on *Phytoseiulus persimilis* A.-H.
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The influence of HAG 500 02 H (synonym: Glyphosate 450 SL AE) on predatory mites was investigated in an extended laboratory study with *Typhlodromus pyri* in a 14-day test via contact on treated leaf surfaces. In this period mortality and reproduction was investigated.

HAG 500 02 H (Sponsor’s sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

This study encompassed 7 treatment groups (Control, 35.6, 107, 320, 960 and 2880 g a.s./ha and reference item). The reference item was applied at an application rate of 40 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto vine leaves via laboratory spraying equipment, which were then air dried. Each treatment group consisted of 6 replicates each containing 10 mites. Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment, surviving mites from the control group and from all test item groups where the corrected mortality was 50% were sexed and the number of eggs per females was recorded on 3 assessment days within one week.

Findings:

All validity criteria were met. Mortality was significantly different in all test item treatment groups up to the highest tested rate of 2880 g a.s./ha. Less than 50 % mortality was found at rates of up to 320 g a.s./ha.

The effect on reproduction was statistically significant at 35.6 g a.s./ha. Reproduction was reduced by 90.9% compared to the control. At 107 g a.s./ha the effect on reproduction was not statistically significant and below 50% compared to the control. At 320 g a.s./ha the effect on reproduction was not statistically significant but slightly above 50%. The statistically significant difference in the lowest dose rate is not considered as a test item treatment effect and could be explained with biological variances. The biological test results are shown in Table MIIIA1 10.5.3-3 and Table MIIIA1 10.5.3-4.

Table MIIIA1 10.5.3-3Results from testing of the influence of HAG 500 02 H on *Typhlodromus pyri*

Concentration		Mortality after 7 days of exposure		Reproductive assessment	
HAG 500 02 H [mL product/ha]	Glyphosate [g a.s./ha]	mean [%]	corrected mean [%]1)	Eggs/female	Effect on reproduction [%]
control		15.0	--	4.2	--
74.9	35.6	31.7*	19.6	0.4**	90.9
225	107	40.0*	29.4	2.2	47.4
674	320	30.0*	17.6	2.0	51.4
2020	960	98.3*	98.0	--	--
6060	2880	100*	100	--	--
reference item		100	100	--	--

* Significantly higher mortality than control (Fisher exact test, α = 0.05)
** Significantly decreased number of eggs per female (Dunnett-test, α = 0.05)
1) Corrected mortality according to Abbot and improvements by Schneider-Orelli

Table MIIIA1 10.5.2-4Endpoints from testing of HAG 500 02 H on *Typhlodromus pyri*

Endpoint	Glyphosate [g a.s./ha]	
	Calculation Applicant	Calculation zRMS DE
LR_{50} after 7 days of exposure	352	>320
ER_{50} after 7 days of exposure	-/-	<35.6

Conclusion:
Under extended laboratory conditions the LR_{50} as calculated by the applicant for HAG 500 02 H is 0.352 kg a.s./ha (95% confidence limits could not be determined). zRMS evaluated the study (see table above and box below).
The reproductive capacity of *T. pyri* was tested at 35.6, 107 and 320 g a.s./ha. The effect on reproduction was statistically significant at 35.6 g a.s./ha. Reproduction was reduced by 90.9%. At 107 g a.s./ha, the effect on reproduction was not statistically significant and below 50% compared to the control. At 320 g a.s./ha, the effect on reproduction was not statistically significant but slightly above 50%.

Study Comments: MIIIA1 10.5.2/01	The study is valid but not plausible. The study with *Typhlodromus pyri* did not show a linear dose-response in the parameter mortality and reproduction. Statistic standard models (Probit, Weibull, Logit 4 parameter) could not sufficiently describe the results (pChi2 < 0.001). Hence, a reliable ER50 could not be calculated. Generally, sublethal endpoints are considered as relevant for risk assessment. At the lowest tested rate 35.6 g a.s./ha, effects on reproduction > 90 % have been observed. Since at higher rates (107 and 320 g a.s./ha) the effects on

	reproduction were approx. 50 %, the lowest rate tested with effects on reproduction is set as endpoint for the assessment of the chronic risk to *T. pyri*.
Agreed endpoint/s: MIIIA1 10.5.2	ER_{50} value was estimated to be < 0.0356 kg a.s./ha. Surrogate endpoint reproduction 0.0356 kg a.s./ha

MIIIA1 10.5.2/03 Extended laboratory studies

Report:	**KIIIA1 10.5.2/03, Schmitzer, S. (2009)**
Title:	Effects of Glyphosate 450 SL AE on the Carabid Beetle *Poecilus cupreus*, Extended Laboratory Study
Document No:	50357007
Guidelines:	HEIMBACH, U. et al. (2000): A method for testing effects of plant protection products on the carabid beetle Poecilus cupreus (Coleoptera, Carabidae) under laboratory and semi-field conditions.
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The influence of HAG 500 02 H (synonym: Glyphosate 450 SL AE) on the carabid beetle *P. cupreus* was investigated under extended laboratory conditions to assess sub-lethal effects as behaviour and food consumption of the survivors.

HAG 500 02 H (Sponsor's sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The beetles were exposed to direct application on natural soil LUFA 2.1. The study encompassed three treatments (3600 g a.s./ha, water treated control, reference item), each treatment consisted of 5 test units each containing 6 individuals (3 males and 3 females)/test unit. Assessment of mortality and behaviour were performed 2 hours, 1, 2, 4, 7, 10 and 14 days after application. Food consumption was assessed on day 2, 4, 7, 10 and 14 after application.

Findings:

After 14 days no mortality was observed in the HAG 500 02 H treatment group. In the water treated control one of the 30 beetles had died (3.3%) during the entire trial. The mean food consumption (mean number of eaten pupae per beetle over the entire observation period) was 2.4 in the test item group and 2.2 in the control, respectively. This results in 109% food consumption in the test item variant relative to the control. No test item related behavioral abnormalities were observed during the entire time of the experiment. The biological test results are shown in Table MIIIA1 10.5.2-5.

Table MIIIA1 10.5.2-5Results from testing of the influence of HAG 500 02 H on *Poecilus cupreus*

Concentration		**Mortality after 14 days of exposure**		**Food Consumption**	
HAG 500 02 H [mL product/ha]	**Glyphosate [g a.s./ha]**	**mean [%]**	**corrected mean [%]1)**	**Pupae consumed per beetle 2)**	**Effect on Food consumption [%] 2)**
control		3.3	--	2.2	--
9600	3600	0.0	-3.4	2.4	+9
reference item		100	100	--	--

1) Corrected mortality according to Abbot and improvements by Schneider-Orelli
2) the tabulated results represent rounded values calculated on the exact raw data

Conclusion:

No effects on either mortality, feeding activity or behaviour of the ground dwelling predator *Poecilus cupreus* were observed after exposure to an application rate of 3.6 kg a.s./ha (corresponding to 9.60 L HAG 500 02 H/ha) in 400 L water/ha on natural soil.

Study Comments: MIIIA1 10.5.2/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.5.2	The LR50 is > 3.6 kg a.i./ha.

MIIIA1 10.6.2/01 Acute toxicity

The following acute earthworm study performed on HAG 500 02 H was provided in support of the assessment.

Report:	**KIIIA1 10.6.2/01, Witte, B., 2009**
Title:	Acute toxicity (14 days) of Glyphosate 450 SL AE to the earthworm *Eisenia fetida* in artificial soil
Document No:	52522021
Guidelines:	OECD Guidelines for Testing of Chemicals, No. 207, "Earthworm, Acute Toxicity Tests", adopted April 4, 1984 ISO-Guideline 11268-1 (1993): “Soil Quality - Effects of pollutants on earthworms (*Eisenia fetida*) - Part 1: Determination of acute toxicity using artificial soil substrate”
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

Exposure of the earthworms took place for 14 days in treated artificial soil. The study encompassed two treatment groups (1000 mg test item/ kg soil dry weight and water treated control). The single concentration of the test item was mixed homogeneously into the soil which was filled in glass vessels before the earthworms were introduced on top of the soil. One test item concentration and control was tested, each treatment group contained 4 replicates with 10 earthworms each. An assessment of worm mortality and behavioural effects was performed after 7 and 14 days, measurement of weight change as sub-lethal parameter was done after 14 days.

HAG 500 02 H (Sponsor's sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

At the start of the test, the mean body wet weight of the worms in the test item treatment group and control replicates ranged from 357 to 419 mg. The worms used were adults with a clitellum and were approximately twelve months old. Four replicates of ten earthworms each were prepared for each test concentration and the control.

Findings:

After 14 days of exposure, no mortality and no statistically significant difference in biomass development were observed at the single (dose limit) test item concentration of 1000 mg/kg soil dry weight compared to the control. The 14-day LC_{50} was estimated to be greater than 1000 mg test item/kg soil dry weight. No behavioural effects were observed in any treatment group. The biological test results after 14 days of exposure are presented in Table 10.6.2-1.

Table 10.6.2-1: Results of acute toxicity testing of HAG 500 02 H in earthworms (*Eisenia fetida*)

Endpoint	**Soil concentration [mg test item/kg]**	**Soil concentration [mg a.s./kg]**
14-day LC_{50}	> 1000	> 450
14-day NOEC	1000	450
14-day LOEC	> 1000	> 450

Conclusion:

In a 14 day acute toxicity study with HAG 500 02 H to earthworms (*Eisenia fetida*) the 14-day LC_{50} was estimated to be greater than 1000 mg test item/kg soil. The No Observed Effect Concentration (NOEC) related to mortality and biomass was determined to be 1000 mg test item/kg soil (450 mg a.s./kg), i.e. the highest tested concentration. The study is considered to represent worst case laboratory conditions.

Study Comments: MIIIA1 10.6.2/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.6.2	The LR_{50} is > 450 mg a.s./kg.

MIIIA1 10.7 Effects on Soil Microbial Activity

KIIIA1 10.7.1.1/01 Soil nitrogen transformation

Report:	**KIIIA1 10.7.1.1/01, Feil, N., 2009a**
Title:	Effects of Glyphosate 450 SL AE on the Activity of the Soil Microflora in the Laboratory
Document No:	50359080
Guidelines:	OECD-Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation Test, Guideline 216, January 2 1,2000
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The purpose of this study was to assess the effects of HAG 500 02 H on the activity (soil nitrogen transformation) of the soil micro-organisms in the laboratory.

HAG 500 02 H (Sponsor's sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

Determination of nitrogen-transformation (ammonium-, nitrite- and nitrate-nitrogen levels) was performed in soil enriched with lucerne meal (concentration in soil 0.5%). This study encompassed 3 treatment groups (Control, 12.8 and 64 mg test item/kg soil dry weight). NH_4-, NO_2- and NO_3-nitrogen formed from the nitrification process were determined by means of a Dionex ion chromatography system (DX-120 IC, AS 50 autosampler, ECD and UVD 340S UV photometer). Subsamples were withdrawn from the soil bulk batches at 0, 7, 14 and 28 days after treatment and subjected to the analysis.

In this study, one fresh agricultural soil, mid loamy sand, was moistened to 44.4 – 47.1 % of its maximum water-holding capacity and incubated in the dark at 20 ± 2 °C following treatment with the test substance. Control soil was not treated with the test substance but was incubated under identical conditions as the treated soil. The pH-value was in the range of 7.0 - 7.2.

Furthermore, additional samples were treated with a reference substance, sodium chloride at a rate of 16 g/kg dry soil in a separate study within one year of the start of the experimental phase of this study, to show the validity of the test system and method used.

Findings:

The soil nitrate formation rates were calculated on an incremental basis (i.e. between successive sampling dates). The difference in the soil nitrate formation rate between the control and both test concentrations was below the OECD guideline 216 trigger value of 25% throughout the experiment. In the last interval between days 14 and 28, the deviations from control were -7.36% and -5.52% for the lower and higher test concentration of HAG 500 02 H, respectively. These deviations were statistically significantly different (Student-t-test, $\alpha = 0.05$) for both dose rates.

The soil nitrate content deviated less than 25% from the control within the experiment. On day 28 after application the deviations were -2.05% and 1.15% at the dose rates of 12.8 and 64 mg test item/kg soil dry weight, respectively. The differences from control were not statistically significant (Student-t-test/ Welch-t-test, α = 0.05).

The mineral nitrogen content (as required by the EPPO and SETAC guidelines) reflected the soil nitrate content since nitrite and ammonium were found only at relatively low concentrations throughout the study. On day 28, the deviation from the control was -1.60% and 2.95% at the lower and higher test concentrations, respectively. In both cases the difference from the control was below 25%, the deviations were not statistically significant (Student-t-test/ welch-t-test, α = 0.05) on day 28. The results on soil microbial nitrogen turnover are shown in Table IIIA 10.7.1.1-1.

Table 10.7.1.1-1: Results from testing of the influence of HAG 500 02 H on microbial nitrogen turnover in soil

Treatment	NO_3 - Nitrogen (mg / kg soil dry weight) Mean Values							
	Day 0		Day 7		Day 14		Day 28	
	Nitrate-N content	Deviation to control	Nitrate-N content	Deviation to control	Nitrate-N content	Deviation to control	Nitrate-N content	Deviation to control
Negative control	9.605	--	1.911	--	8.754	--	31.570	--
Low dose 12.8 mg/kg soil dw	9.802	2.05	1.628	-14.81	9.756 *	11.45	30.924	-2.05
High dose 64 mg/kg soil dw	9.844	2.49	2.197	14.97	10.416 *	18.99	31.933	1.15

Treatment	NO_3 - Nitrogen Formation Rate (mg / kg soil dry weight per day) [1]							
	Interval Day 0 - 7		Interval Day 7 - 14		Interval Day 14 - 28			
	Nitrate-N formation	Deviation to control	Nitrate-N formation	Deviation to control	Nitrate-N formation	Deviation to control		
Negative control	-1.10	--	0.98	--	1.63	--		
Low dose 12.8 mg/kg soil dw	-1.17	6.36	1.16 *	18.37	1.51 *	-7.36		
High dose 64 mg/kg soil dw	-1.09	-0.91	1.18 *	20.41	1.54 *	-5.52		

Treatment	Mineral Nitrogen [2] (mg / kg soil dry weight) Mean Values							
	Day 0		Day 7		Day 14		Day 28	
	N-content	Deviation to control	N-content	Deviation to control	N-content	Deviation to control	N-content	Deviation to control
Negative control	16.071	--	4.052	--	10.842	3.17	33.118	1.99

Low dose 12.8 mg/kg soil dw	15.986	-0.53	3.901	-3.73	11.426	5.39	35.587	-1.60
High dose 64 mg/kg soil dw	15.245	-5.14	4.596 *	13.43	12.114 *	11.73	34.094	2.95

1 = related to successive intervals between samplings
2 = mineral nitrogen = sum of nitrite, nitrate and ammonium-nitrogen
positive values = stimulatory effect
negative values = inhibitory effect
dw = dry weight
* = Value is significantly different from the control (Student t-test / in case of inhomogeneity Welch-t-test; α = 0.05)

Conclusion:

Based on the results of this study, it is concluded that HAG 500 02 H had no impact on soil nitrate content and soil nitrate formation rate of soil microflora when applied up to 64 mg/kg soil dry weight.

It is concluded that HAG 500 02 H will not have any long term influence on soil micro-organisms.

KIIIA1 10.7.1.1/02 Soil carbon transformation

Report:	**KIIIA1 10.7.1.1/01, Feil, N., 2009b**
Title:	Effects of Glyphosate 450 SL AE on the Activity of the Soil Microflora in the Laboratory
Document No:	50359080
Guidelines:	OECD-Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation Test, Guideline 216, January 2 1,2000
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The purpose of this study was to assess the effects of HAG 500 02 H on the activity (carbon mineralisation) of the soil micro-organisms in the laboratory.

HAG 500 02 H (Sponsor’s sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The Determination of carbon transformation in soil was done after addition of glucose. The study encompassed 3 treatment groups (Control, 12.8 and 64 mg test item/kg soil dry weight). A BSB-Sensomat System® was used to determine the CO_2-production over a period of up to 24 hours at different sampling intervals. Subsamples were withdrawn from the soil bulk batches at 0, 7, 14 and 28 days after treatment and subjected to the analysis.

In this study, one fresh agricultural soil, mid loamy sand, was moistened to 44.4 – 47.1 % of its maximum water-holding capacity and incubated in the dark at 20 ± 2 °C following treatment with the test substance.

Control soil was not treated with the test substance but was incubated under identical conditions as the treated soil. The pH-value was in the range of 7.0 - 7.2.

Furthermore, additional samples were treated with a reference substance, sodium chloride at a rate of 16 g/kg dry soil in a separate study within one year of the start of the experimental phase of this study, to show the validity of the test system and method used.

Findings:
The observed differences in carbon transformation between the different treatments were clearly below the trigger value of +25% as set in OECD guideline 217.

At day 28 after application, the differences between the respiration rates of HAG 500 02 H treated soils and the control soil were -1.60% and 2.74% at 12.8 and 64 mg test item/kg soil dry weight, respectively. The differences from control were not statistically significant ($p>0.05$).

The variation between the replicate control samples was clearly below the validity criterion of 15% (OECD test guideline 217) throughout the test. The effects of HAG 500 02 H on soil microbial short-term respiration are shown in Table IIIA 10.7.1.2-1.

Table 10.7.1.2-1: Results from testing of the influence of HAG 500 02 H on microbial short-term respiration in soil

Treatment	Soil Respiration (mg CO_2 / kg soil dry weight 1 h) Mean Values							
	Day 0		Day 7		Day 14		Day 28	
	Respira-tion Rate	Deviation to control [%]	Respira-tion Rate	Deviation to control [%]	Respira-tion Rate	Deviation to control [%]	Respira-tion Rate	Deviation to control [%]
Negative control	10.028	-	9.443	-	10.559	-	9.533	-
Low dose 12.8 mg/kg soil dw	10.675	6.45	9.736	3.10	10.866	2.91	9.380	-1.60
High dose 64 mg/kg soil dw	11.439 *	14.07	10.089	6.84	11.443 *	8.37	9.794	2.74

positive values = stimulatory effect
negative values = inhibitory effect
dw = dry weight
* = Value is significantly different from the control (Student t-test / in case of inhomogeneity Welch-t-test; $\alpha = 0.05$)

Conclusion:

Based on the results of this study, it is concluded that HAG 500 02 H had no impact on soil respiration of soil microflora when applied up to 64 mg/kg soil dry weight.

It is concluded that HAG 500 02 H will not have any long term influence on soil micro-organisms.

Study Comments: MIIIA1 10.7.1/01	The study is acceptable.

Agreed endpoint/s: MIIIA1 10.7.1	Effects on the Activity of soil respiration, soil nitrate content and soil nitrate formation are < 25%.

MIIIA1 10.8.1.2 Vegetative vigour

Report:	**KIIIA1 10.8.1.2/01, Bützler, R. and Molandin, G. 2009a**
Title:	Effects of Glyphosate 450 SL AE on Terrestrial (Non-Target) Plants: Vegetative Vigour Test
Document No:	50362087
Guidelines:	OECD Guideline for Testing of Chemicals No. 227 "Terrestrial Plant Test: Vegetative Vigour Test" (adopted July 19, 2006)
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:
HAG 500 02 H (synonym: Glyphosate 450 SL AE) was applied on 10 plant species from nine different plant families at the following rates: *Brassica oleracea* (wild cabbage, 1580 to 8000 mL/ha), *Vicia faba* (Field bean, 1580 to 8000 mL/ha), *Helianthus annuus* (Sunflower, 27.4 to 702 mL/ha), *Cucumis sativus* (Cucumber, 1580 to 8000 mL/ha), *Lycopersicon esculentum* (Tomato, 312 to 1580 mL/ha), *Beta vulgaris* (Beet, 468 to 2370 mL/ha), *Daucus carota* (Carrot, 312 to 8000 mL/ha), *Avena sativa* (Oat, 702 to 3556 mL/ha) *Lolium perenne* (Ryegrass, 702 to 3556 mL/ha) and *Allium cepa* (Onion, 312 to 8000 mL/ha). All rates refer to the formulated product and were based on a non GLP preliminary test.

The plants were sown at different times and than grown until they had reached the second to fourth true leaf stage, before application of the test item in 200 L/ha of tap water. A minimum of 20 plants was treated per rate and species and observed thereafter over a period of 21 days. The endpoints were mortality, visual phytotoxicity symptoms and fresh weight (above ground parts). The growth stages according to BBCH-Monograph were recorded at the start and at the end of the test.

The study was performed in a growth chamber. Exposure conditions were as follows: The day temperature was 22 °C to 26 °C, the night temperature was 18 °C to 22 °C. The humidity was 51 to 95 %. Photoperiod: 16 hours light : 8 hours dark. Mean light intensity during the day was 8685 lux (5120 to 16560 lux).

HAG 500 02 H (Sponsor’s sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The concentration of the active substance was analytically determined by HPLC-UV-method in the stock solution.

Findings:

Phytotoxic effects observed were chlorosis, necrosis and growth reduction (all species). Additionally *Lycopersicon esculentum* and *Allium cepa* showed abnormal growth of leaves and *Avena sativa* and *Lolium perenne* showed abnormal growth of leaves and stems.

The analytical recovery of the active ingredient glyphosate in the stock solution was 98% of the nominal value. Consequently, the reported biological results are based on the nominal concentrations.

The most sensitive species in terms of fresh weight was *Helianthus annuus* with an ER_{50} value of 125 mL product/ha (NOER of 27.4 mL/ha), followed by *Lycopersicon esculentum* with an ER_{50} of 718 mL product/ha. It was followed by *Lolium perenne*, *Brassica oleracea*, *Avena sativa* and *Beta vulgaris* with ER_{50} values of 1119, 1189, 1269 and 1529 mL product/ha, respectively. They were followed by *Daucus carota* with an ER_{50} value of 2457 mL product/ha, which was followed by *Cucumis sativus* and *Vicia faba* with ER_{50} values of 3445 and 3886 mL product/ha, respectively. The least sensitive species was *Allium cepa* with an ER_{50} value of 4357 mL product/ha.

Statistically significant mortality was observed for *Helianthus annuus* at 312 and 702 mL HAG 500 02 H/ha (40 and 75 %, respectively), for *Beta vulgaris* at 2370 mL HAG 500 02 H/ha (92 %), for *Avena sativa* at 2370 and 3556 mL HAG 500 02 H ha (93 and 100 %, respectively) and for *Lolium perenne* at 1580, 2370 and 3556 mL HAG 500 02 H/ha (33, 83 and 100 %, respectively). The ER_{50} values as well as the respective NOER- and LOER-values for influence on fresh weight are shown in Table 10.8.1.2-1.

Table 10.8.1.2-1: Results of testing of HAG 500 02 H in non-target plants

End point	*Brassica oleracea*	*Vicia fbia*	*Helianthus annuus*	*Cucumis sativus*	*Lycopersicon esculentum*
Fresh weight					
ER_{50} [mL test item/ha]	1189	3886	125	3445	718
NOER [mL test item/ha]	< 1580	< 1580	27.4	< 1580	468
LOER [mL test item/ha]	1580	1580	61.7	1580	702

Table 10.8.1.2-2 (continued): Results of testing of HAG 500 02 H in non-target plants

End point	*Beta vulgaris*	*Daucus carota*	*Avena sativa*	*Lolium perenne*	*Allium cepa*
Fresh weight					
ER_{50} [mL test item/ha]	1529	2457	1269	1119	4357
NOER [mL test item/ha]	468	702	< 702	702	702
LOER [mL test item/ha]	702	1580	702	1580	1580

Conclusion:

HAG 500 02 H showed effects on the fresh weight and at high doses on growth stages of non-target plants. In addition various phytotoxicity symptoms were observed. The most sensitive species was *Helianthus annuus* with an ER_{50} value of 125 mL product/ha in relation to fresh weight, whereas *Allium cepa* proved least sensitive with an ER_{50} of 4357 mL product/ha.

Study Comments: MIIIA1 10.8.1.2/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.8.1.2	The ER_{50} (*Helianthus annuus*) is 125 mL product/ha in relation to fresh weight (56.3 g a.i. /L).

MIIIA1 10.8.1.3 Seedling emergence

Report:	**KIIIA1 10.8.1.2/01, Bützler, R. and Molandin, G. 2009b**
Title:	Effects of Glyphosate 450 SL AE on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test
50361086	50361086
Guidelines:	OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test" (adopted July 19,2006)
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

HAG 500 02 H (synonym: Glyphosate 450 SL AE) was applied on seeds of six plant species from six different plant families at the following rates: *Brassica oleracea* (wild cabbage, 1221 to 8000 mL/ha), *Vicia faba* (Field bean, 8000 mL/ha), *Helianthus annuus* (Sunflower, 8000 mL test item/ha), *Cucumis sativus* (Cucumber, 1221 to 8000 mL/ha), *Lolium perenne* (Ryegrass, 8000 mL/ha) and *Allium cepa* (Onion, 1221 to 8000 mL/ha), whereas the first four species are dicotyledon and the latter two are monocotyledon. The tested rates were based upon a non GLP preliminary test.

The test item was applied the day after sowing in 400 L/ha of tap water onto the soil. 30 seeds were tested per rate and species and exposed over a period of 14 to 21 days after 50% germination in the control, depending on the growth of the seedlings. The observed endpoints were germination, mortality, visual phytotoxicity symptoms and ECx values based on fresh weight (above ground parts). Furthermore the growth stages according to BBCH-Monograph were recorded at the end of the test. The study was performed in a growth chamber. Exposure conditions were as follows: The day temperature was 21 °C to 26 °C, the night temperature was 18 °C to 23 °C. The humidity was 45 to 92 %. Photoperiod: 16 hours light / 8 hours dark. Mean light intensity during the day was 8990 lux (6010 to 13740 lux).

HAG 500 02 H (Sponsor’s sample no.: 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The concentration of the active substance was analytically determined by HPLC-UV-method in the stock solution.

Findings:
All validity criteria were met. Seed germination was not significantly reduced in comparison to the control for any of the tested species at any dose level. Mortality was observed for *Cucumis sativus* at 5000 mL/ha (3 %), *Lolium perenne* at 8000 mL/ha (3 %) and for *Allium cepa* at 1953 and 5000 mL product/ha (4 % each). None of the mortality counts turned out to be statistically significant.

The most sensitive species in terms of fresh weight was *Brassica oleracea* with an ER_{50} value of 7858 mL product/ha. The only other significant effect in terms of fresh weight was observed for *Vicia faba* at 8000 mL product/ ha (16.2 % reduction). All other species (*Helianthus annuus*, *Cucumis sativus*, *Lolium perenne* and *Allium cepa*) showed a NOER of 8000 mL product/ha.

The analytical recovery rate of the active ingredient glyphosate in the stock solution was 94% of the nominal value. Consequently, the reported biological results are based on the nominal concentrations.

The ER_{50}, NOER and LOER values for influence on fresh weight are listed in Table 10.8.1.3-1.

Table 10.8.1.3-1: Results of testing of HAG 500 02 H on fresh weight of non-target plants

End point	Wild cabbage *B. oleracea*	Field bean *V. faba*	Sunflower *H. annuus*	Cucumber *C. sativus*	Ryegrass *L. perenne*	Onion *A. cepa*
Fresh weight						
ER_{50} [mL test item/ha]	7858	> 8000	> 8000	> 8000	> 8000	> 8000
NOER [mL test item/ha]	5000	< 8000	8000	8000	8000	8000
LOER [mL test item/ha]	8000	8000	> 8000	> 8000	> 8000	> 8000

Conclusion:

HAG 500 02 H was tested for effects on seedling emergence and seedling growth of 6 species out of 6 different plant families. The most sensitive species was *Brassica oleracea* with an ER_{50} of 7858 mL product/ha in relation to fresh weight, whereas all other plant species were less sensitive with ER_{50} values of > 8000 mL test item/ha.

Study Comments: MIIIA1 10.8.1.3/01	The study is acceptable.
Agreed endpoint/s: MIIIA1 10.8.1.3	The ER_{50} (*Brassica oleracea*) is 7858 mL product/ha in relation to fresh weight (3536.3 g a.i. /L).

MIIIA1 10.8.2.1 Lemna growth test

Report:	**KIIIA1 10.8.2.1/01, Hoffmann, K. and Wydra, V., 2009**
Title:	Toxicity of Glyphosate 450 SL AE to the Aquatic Plant *Lemna gibba* in a Static Growth Inhibition Test
50361086	50350240
Guidelines:	OECD Guideline 221: "*Lemna* sp. Growth Inhibition Test", adopted March 23, 2006.
GLP	Yes (laboratory certified by the German GLP Monitoring Authority: Hess. Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz, Germany)

Material and Methods:

The influence of the formulated product HAG 500 02 H (synonym: Glyphosate 450 SL AE) on the growth of the freshwater aquatic plant *Lemna gibba* was investigated in a 7-day static test. Nominal test concentrations of 100, 32, 10, 3.2, 1.0 mg test item/L and a control were tested. These concentrations correspond to 38.4, 12.3, 3.8, 1.2 and 0.38 mg a.s./L.

HAG 500 02 H (Helm Sample no. 37/163/09) was used with a nominal content of glyphosate of 450 g/L.

The test design included three replicates per test concentration and control. Each replicate consisted of a 250-mL glass flask filled with 100 mL test medium and covered with glass dishes. Three colonies consisting of four fronds were introduced into the test vessels resulting in twelve fronds per vessel. Frond and colony numbers were recorded at the start of the test and at days 3, 5 and 7, where also additionally the appearance of the colonies was observed.

The actual concentrations of the test item in the test media were analytically determined using a validated liquid chromatography method with UV-detection (HPLC-UV). The Limit of Detection was 0.01 mg reference item/L (glyphosate, purity 99.7 %), the Limit of Quantification was 0.5 mg test item/L. Duplicate samples were taken from the test media of all test concentrations and the control at the start and at the end of the test.

Findings:

At the start of the test 112 % of the nominal test item concentration was found (average of all test concentrations). After 7 days 96 % of the nominal value was determined (average of all test concentrations). In the test media the test item was sufficiently stable during the test period of 7 days. Therefore, all reported biological results are related to the nominal concentrations of the test item.

The doubling time of the frond number in the control was 1.5 days. The shape of fronds and colonies after the test period of 7 days was not different to those in the control up to and including the nominal test concentration of 10 mg/L. At the higher test item concentrations the fronds showed deviations from the control replicates after three to seven days; i.e. smaller fronds, gibbous growth and chlorosis.

Effects were determined for the growth rate and yield, each based on both the frond number and the dry weight. The test item had a concentration dependent inhibitory effect on the growth of *Lemna gibba.* Statistically significant inhibition occurred at 32 mg test item/L (LOEC) and above after 7 days of exposure for yield (frond number and dry weight) and growth rate (frond number and dry weight). The biological results are presented in Table 10.8.2.1-1.

Table 10.8.2.1-1: Results of toxicity testing of HAG 500 02 H in higher aquatic plants (*Lemna gibba*)

Endpoint	**Growth rate [mg/L]**		**Yield [mg/L]**	
	Frond number	**Dry weight**	**Frond number**	**Dry weight**
7-day EC_{50} [mg test item/L]	93.4	> 100	42.6	63.3
7-day EC_{50} [mg a.s./L]	35.9	> 38.4	16.4	24.3

Conclusion:

The influence of HAG 500 02 H on the growth of the freshwater plant *Lemna gibba* was assessed in a static test. The 7-day E_RC_{50} as calculated to be 93.4 and > 100 mg test item/L for frond number and dry weight, respectively. The 7-day EyC_{50} was calculated to be 42.6 and 63.3 mg test item/L for frond number and dry weight, respectively. The 7-day NOE_RC and the LOE_RC were determined to be 10 and 32 mg test item/L, respectively. The 7-day NOE_yC and the LOE_yC were determined to be 10 and 32 mg test item/L, respectively.

Study Comments: KIIIA1 10.8.2.1/01	The study is acceptable.
Agreed endpoint/s: KIIIA1 10.8.2.1/01	The 7-day EyC_{50} are 16.4 mg/L (frond number) and 24.3 mg/L (dry weight).

Appendix 3 Table of Intended Uses justification and GAP tables

Crop and/ or situation (a)	Zone	Product code	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		
NNNAC Field crops	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Post harvest until sowing	1	--	0,504 – 1,8	100 – 200	1.080 - 1.800	Covered by conditions of use and / or growing period between application and harvest	Wait 4 days until tillage
YACKR Stubble	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Stubble application after weed germination	1	--	0,225 – 0,9	200 - 300	0.675 – 1.800	Covered by the vegetation period	
NNNOK Pome fruit	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm weed height onwards	1	--	0,45 – 1,8	100 – 400	1.800	42	Strip application. Best control of 1UMBF *(Umbelliferae)* at flowering.
NNNOS Stone fruit	Member States of	Glyphosate 450 SL	F	TTTDD Weeds	SL	450	Tractor mounted	From 15 – 20 cm weed	1	--	0,45 – 1,8	100 – 400	1.800	42	Strip application.

Crop and/ or situation (a)	Zone	Product code	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		
	Zone B			Dicotyledones TTTMM Weeds Monocotyledones			sprayer, broadcast, ground directed spraying	height onwards							Best control of 1UMBF (Umbelliferae) at flowering.
NNNOK Pome fruit	Member States of Zone B	Glyphosate 450 SL	F	CONAR Convolvulus arvensis	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm height of CONAR onwards	1	--	0,9 – 3,6	100 – 400	3.600	42	Strip application.
VITVI Vitis vinifera	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones TTTMM Weeds Monocotyledones	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 10 – 20 cm weed height onwards	1-2	90	0,45 – 1,8	100 – 400	1.800	30	Strip application from 4th year plant stand onwards. Best control of 1UMBF (Umbelliferae) at flowering.
VITVI Vitis vinifera	Member States of Zone B	Glyphosate 450 SL	F	CONAR Convolvulus arvensis	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	From 15 – 20 cm height of CONAR onwards	1	--	0,9 – 3,6	100 – 400	3.600	30	Strip application from 4th year plant stand onwards.
YCERE Cereals	Member States of Zone B	Glyphosate 450 SL	F	TTTDD Weeds Dicotyledones	SL	450	Tractor mounted sprayer,	BBCH 87-89	1	--	0,281 – 1,8	100 – 400	1.125 - 1.800	7	Including desiccation, lodged cereals

Crop and/ or situation (a)	Zone	Product code	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		
				TTTMM Weeds Monocotyledones Including AGRRE (Elytrigia repens)			broadcast, ground directed spraying								and additional harvest facilitation, Ex brewing and seed production
BRSNW Oilseed rape (winter) PIBSA Field pea	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 87 – 89	1	--	0,375 - 0,5625	200 - 300	1.125	14	Additional harvest facilitation and crop desiccation Don't apply on seed plantation
BRSNW Oilseed rape (winter)	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Before crop emergence BBCH 00	1	--	0,375 - 0,5625	200 - 300	1.125	Covered by the vegetati on period	
BEAVA Beta vulgaris	Member States of Zone B	Glyphosate 450 SL	F	TTTTT Weeds	SL	450	Tractor mounted sprayer, broadcast, ground directed spraying	Before crop emergence BBCH 00	1	--	0,24 - 0,36	200 - 300	0.720	Covered by the vegetati on period	
NNNFW Grassland	Member States of Zone B	Glyphosate 450 SL	F		SL	450	Tractor mounted sprayer,	Plant height approx 15 cm, AGRRE 3 to 4	1	--	0,45 – 1,8	100 – 400	1.800	Covered by conditio	Re-sowing (renewal) of grassland

Crop and/ or situation (a)	Zone	Product code	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		
							broadcast, ground directed spraying	leaves per nod, 1UMBF in full florescence						ns of use and / or growing period between application and harvest	

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

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: HAG 500 02 H

Active Substances: Glyphosate 450 g/L

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: Helm AG

Submission Date: July 2012

TABLE OF CONTENT

SEC 6 ECOTOXICOLOGICAL STUDIES ... 3

6.1 EFFECTS ON BIRDS ... 3
6.2 EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS ... 3
6.3 EFFECTS ON AQUATIC ORGANISMS ... 3
6.3.1 Overview and summary ... 3
6.3.2 Toxicity exposure ratios ... 7
6.4 EFFECTS ON BEES ... 10
6.5 EFFECTS ON ARTHROPODS OTHER THAN BEES (IIIA1 10.5) ... 10
6.6 EFFECTS ON EARTHWORMS AND OTHER SOIL NON-TARGET MACRO-ORGANISMS (IIIA1 10.6) ... 12
6.6.1 Overview and summary ... 12
6.6.2 Overall conclusion ... 14
6.6.3 Effects on organic matter breakdown (IIIA1 10.7) ... 16
6.7 EFFECTS ON SOIL MICROBIAL ACTIVITY (IIIA1 10.7) ... 16
6.7.1 Overview and summary ... 16
6.7.2 Toxicity exposure ratios ... 17
6.8 EFFECTS ON NON-TARGET PLANTS (IIIA1 10.8) ... 17
6.8.1 Overview and summary ... 17
6.8.2 Toxicity exposure ratios ... 18
6.9 EFFECTS ON NON-TARGET AQUATIC PLANTS (IIIA 10.8.2) ... 20
6.10 SUMMARY AND EVALUATION OF POINTS 5 AND 6 (IIA1 10.11) ... 21
6.10.1 Predicted distribution and fate in the environment and time courses involved (IIIA1 10.11.1) 21
6.10.2 Non-target species at risk and extent of potential exposure (IIIA1 10.11.2) ... 21
6.10.3 Short- and long-term risks for non-target species, populations, communities and processes (IIIA1 10.11.3) ... 21
6.10.4 Risk of fish kills and fatalities in large vertebrates or terrestrial predators (IIIA1 10.11.4) ... 22
6.10.5 Precautions necessary to avoid/minimise environmental contamination and to protect non-target species (IIIA1 10.11.5) ... 22

APPENDIX 1 LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION ... 24

APPENDIX 2 TABLE OF INTENDED USES ... 25

APPENDIX 3 ADDITIONAL INFORMATION PROVIDED BY THE APPLICANT ... 26

Sec 6 ECOTOXICOLOGICAL STUDIES

Please refer to the core dossier for the central zone.

This document presents the national addendum for Germany and should be read in conjunction with the core assessment for section 6. The national addendum addresses national requirements differing from the standard EU modelling and risk assessment procedures. It refers moreover to specific management and risk mitigation practices that can be implemented in Germany.

6.1 Effects on Birds

Please refer to the core dossier for the central zone.

6.2 Effects on Terrestrial Vertebrates Other Than Birds

Please refer to the core dossier for the central zone.

6.3 Effects on Aquatic Organisms

6.3.1 Overview and summary

Please refer to the core assessment.

6.3.1.1 Toxicity

The endpoints considered for the risk assessment for aquatic organisms are indicated in the following tables. Only the most sensitive endpoints of valid studies are presented here.

Table 6.3-1: Toxicity endpoints for aquatic organisms

Species	Substance	System	Toxicity (mg a.s./L)		Reference/ ICS-Nr.	
Fish, acute toxicity						
O.s mykiss	HAG 500 02 H	96 h	LC_{50}	> 38.4	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.2.2.1/01	78772
O. mykiss	glyphosate		LC_{50}	38	Review Report for the active substance glyphosate (SANCO/6511/VI/99-final)	39353
O.mykiss	AMPA		LC_{50}	> 180	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998	30906
Fish, long-term toxicity						
P. promelas	glyphosate	254 days	NOEC	25.7	Review Report for the active substance glyphosate (SANCO/6511/VI/99-final)	26902
Invertebrates, acute toxicity						
Daphnia magna	HAG 500 02 H	48 h	EC_{50}	> 38.4	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.2.2.2/01	78773
	glyphosate			40	Review Report for the active substance glyphosate (SANCO/6511/VI/99-final)	46773
	AMPA			> 180	Monograph glyphosate, Volume 3,	31698

Species	Substance	System	Toxicity (mg a.s./L)		Reference/ ICS-Nr.	
					Annex B-8, 11 December 1998	
Invertebrates, long-term toxicity						
Daphnia magna	glyphosate	21 d	NOEC	30	Review Report for the active substance glyphosate (SANCO/6511/VI/99-final)	37260
Sediment dwelling organisms						
-	-	-	-	-	-	-
Algae						
Pseudokirchne-riella subcapitata	HAG 500 02 H	72 h	E_yC_{50}	1.6	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.2.2.3/01	78774
Navicula pelliculosa			E_yC_{50}	4.04	Hoffmann, K. & Deierling, T. (2009) Ref. IIIA 10.2.2.3/02	78775
Skeletonema costatum	**glyphosate**	**7 days**	$\mathbf{E_bC_{50}}$	**0.64**	**Review Report for the active substance glyphosate (SANCO/6511/VI/99-final)**	**35179**
Nitzschia palea		96 h	E_rC_{50}	4.5	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998	
Pseudokirchne-riella subcapitata	AMPA	72 h	E_yC_{50}	89.8	Monograph glyphosate, Volume 3, Annex B-8: Ecotoxicology 11 December 1998	30903
Aquatic higher plants						
Lemna gibba	HAG 500 02 H	7 days	E_yC_{50}	24.3 (dw) 16.4 (fronds)	Hoffmann, K. & Wydra, V. (2009) Ref. IIIA 10.8.2.1/01	78784
Lemna gibba	glyphosate	14 days	EC_{50}	12	Review Report for the active substance glyphosate (SANCO/6511/VI/99-final)	44184
Mesocosm	-	-	-	-	-	

For the active ingredient glyphosate, the most sensitive endpoint divided by the respective safety factor of 10 is the E_bC_{50} = 0.064 mg/L (*Skeletonema costatum*). As the assessment performed for the algae endpoint covers the risk for other aquatic organisms, the risk assessment is performed only for this endpoint.

Glyphosate forms two major metabolites; Aminomethyl-phosphonic acid (AMPA), max. 16 % at day 14 and (Hydroxymethyl)-phosphonic acid (max. 10.0% at day 61, 7.5% at day 100).

As the metabolite AMPA shows a clearly lower toxicity for fish, daphnids and algae compared to the active substance, no quantitative risk assessment was performed. The risk assessment for the active substance is supposed to address the risk resulting from metabolite as well.

Since no data are available for the metabolite (Hydroxymethyl)-phosphonic acid, a ten-fold higher toxicity for aquatic organisms can be assumed for risk assessment purposes. As degradation of glyphosate results in equal or less than 10 % of this metabolite and the Mol correction factor is 0.6, the risk assessment for the metabolite (Hydroxymethyl)-phosphonic acid is covered by that of glyphosate.

It is predicted that the risk for aquatic organisms exposed to glyphosate metabolites according to the intended use of HAG 500 02 H will be low.

6.3.1.2 Exposure

In agreement with the German modelling scheme, TERs are calculated for all relevant exposure routes; i.e. spraydrift, run-off and drainage entry. The Predicted Environmental Concentrations in surface water (PEC_{SW}) have been calculated based on the maximum application rates of 3600 g glyphosate/ha.

In addition to the FOCUS based evaluation presented in the core dossier, an aquatic risk assessment is presented based on the two German evalution models: EXPOSIT 3.0 and EVA 2.1. The risk evaluations are based on the most sensitive aquatic endpoint EC_{50} = 0.64 mg/L (*Skeletonema costatum*) according to the Review report glyphosate 6511/IV/99-final, 21 January 2002.

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance glyphosate is between 10^{-5} and 10^{-4} Pa. Hence the active substance glyphosate is regarded as semivolatile (volatilisation only from plant surfaces).

For details on the EXPOSIT modelling in accordance with German national requirements, reference is made to the dRR document Part B, Section 5, Point 6 (national addendum Germany). The input parameters for glyphosate used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in the following table.

Table 6.3-2: Input parameters for glyphosate used for modelling surface water exposure via run-off and drainage with EXPOSIT 3.01

Parameter	active substance glyphosate	Reference
K foc. Runoff*	21616	arithmetic mean, Table 6.3-3 of core assessment
Kfoc. mobility class**		
DT50 soil (d)***	113.6	90th percentile lab studies, see Table 6.3-4 of core assessment
Solubility in water (mg/L)	18800	see core assessment chapter 5.3.1.2

*median (see DRR Part B Section5 CA. Table 9.3.1-1)

**arithmetic mean. according to Input Decision 3.1 (used for calculation)

***geometric mean. according to Input Decision 3.1

6.3.1.3 Overall conclusion

The risk for the entry routes run-off and drainage is acceptable without drift buffer zones or drift reduction technique for all indication groups. The risk to aquatic organisms following exposure to HAG 500 02 H via spraydrift is acceptable without drift buffer zones or drift reduction technique.

Table 6.3-5: Risk mitigation measures for intended uses in Germany for HAG 500 02 H

Group/ use No	Crop/growth stage	Application method Drift scenario	No. of applications, Min. application interval, application time, interception	Application rate, cumulative (g a.s/ha)	Risk mitigation measures
A/ 00-001, 00-007	Field crops, Grassland / -	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0 %	1800	no
B/ 00-002, 00-004	Pome fruit, Vineyards/-	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0 %	1800	no
C/ 00-003,	Pome fruit, Vineyards/-	Tractor mounted sprayer, broadcast, ground directed	1 x,-,0 %	3600	no

00-005		spraying			
D/ 00-006	Cereals/ BBCH 89	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,90%	1800	no
E/ 00-008	Oilseed rape (winter)/ BBCH 87-89	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,80 %	1125	no
F/ 00-009	Oilseed rape (winter)/ BBCH 00-08	Tractor mounted sprayer, broadcast, ground directed spraying	1 x,-,0%	1125	no

The risk to aquatic organisms following exposure to HAG 500 02 H is calculated using the the most sensitive aquatic endpoint EC_{50} = 0.64 mg a.s./L (*Skeletonema costatum*) and worst-case PECs (all indication groups: 1 x 3600 g a.s./ha, see table below).

Table 6.3-6: Predicted environmental concentrations in surface water – spraydrift. run-off and drainage entry

Test organism	Test substance	EC_{50}[µg/L]	Buffer distance [m]	PEC_{SW} [µg/L]	TER_{LT}	Trigger value
Drift entry (agriculture; 1 x 3600 g a.s./ha)						
Aquatic invertebrates. algae. macrophytes	glyphosate	640	0	1200	0.5	10
			1	33.24	19	
			5	6.84	94	
			10	3.48	184	
			15	2.40	267	

Table 6.3-6: cont.

Test organism	Test substance	EC_{50}[µg/L]	Buffer distance [m]	PEC_{SW} [µg/L]	TER_{LT}	Trigger value
Run-off entry						
Aquatic invertebrates. algae. macrophytes	glyphosate	640	0	1.90	336	10
			5	1.65	388	
			10	1.41	453	
			20	0.99	645	
Drainage entry						
Aquatic invertebrates. algae. macrophytes	glyphosate	640	Autumn/winter/ early spring [not required]	0.55	1159	10
			Spring/summer	1.70	377	
TER in bold fall below the relevant trigger						

6.3.2 Toxicity exposure ratios

6.3.2.1 Toxicity Exposure Ratios (TER) for the entry into surface waters via spraydrift

The toxicity of the formulated product HAG 500 02 H is mainly driven by the active substance glyphosate. The calculation of PECsw after exposure via spray drift is performed using the model EVA 2.1. Eventhough glyphosate is considered as semivolatile with a vapour pressure of 1.31 $x10^{-5}$ Pa (25 °C, acid) , the contribution of volatilasation is negligible.

Classification for the intended uses in Germany for HAG 500 0 2H are presented in document Part B, Section 5, Point 6 (national addendum Germany). For all indication groups, the scenario "agriculture with 0 % interception" has been used as a worst case assumption. For the indication group C, the scenario "agriculture with 0 % interception" has also been applied as application of HAG 500 02 H is ground directed. Both calculations are based on the EC_{50} = 0.64 mg a.s./L (*Skeletonema costatum*) and the respective PEC values leading to following TERs.

Based on the calculated concentrations of glyphosate in surface waters, the calculated TER-values for the acute and long-term risk resulting from an exposure of aquatic organisms to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER ≥ 10. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of HAG 500 02 H in all the indications applying an application rate of 3600 g a.s./ha without risk mitigation measures.

Table 6.3-7: TER-values regarding the exposure via spraydrift scenario "agriculture" (Model: EVA 2.1.)

Compound:		glyphosate						
Crop / Application rate:		agriculture; 1 x 3600 g a.s./ha						
Growth stage and season		0 % interception						
DT50 water (SFO):		-						
PEC-selection:		actual						
Drift-Percentile:		90_{th} percentile of drift probabilities						
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PECsw [µg as/L]; conventional and drift reducing technique			
[m]	[%]	[µg/L]	[%]	[µg/L]	0% conv.	90% red.	75% red.	50% red.
0	100.00	1200			1200	120	300	600
1	2.77	33.24			33.2	3.3	8.3	16.6
5	0.57	6.84			6.8	0.7	1.7	3.4
10	0.29	3.48			3.5	0.3	0.9	1.7
15	0.20	2.40			2.4	0.2	0.6	1.2
20	0.15	1.80			1.8	0.2	0.5	0.9
Relevant toxicity endpoint: EC_{50} = 0.64 mg a.s./L (*Skeletonema costatum*) Relevant TER: 10								
Buffer zone [m]					**TER**			
0					0.5	--	--	--
1					19	193	77	39
5					94	936	374	187
10					184	1839	736	368
15					267	2667	1067	533
20					356	3556	1422	711
Risk mitigation measures			none					

6.3.2.2 *Toxicity Exposure Ratios (TER) for the entry into surface waters via run-off and drainage*

For details on the EXPOSIT modelling in accordance with German national requirements, reference is made to the dRR document Part B, Section 5, Point 6 (national addendum Germany). The input parameters for glyphosate used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in the following table.

Table 6.3-8: Inputparameters for Exposit 3.0

Parameter	active substance glyphosate	Reference
K foc. Runoff*	21616	arithmetic mean, Table 6.3-9 of core assessment
Kfoc. mobility class**		
DT50 soil (d)***	113.6	90th percentile lab studies, see Table 6.3-10 of core assessment
Solubility in water (mg/L)	18800	see core assessment chapter 5.3.1.2

*median (see DRR Part B Section5 CA. Table 9.3.1-1)

**arithmetic mean. according to Input Decision 3.1 (used for calculation)

***geometric mean. according to Input Decision 3.1

The following table shows the calculated TER-values regarding the exposure via run-off and drainage. Calculation is based on the model Exposit 3.01. Analogous to the exposure via spraydrift, the risk assessment for the exposure via run-off and drainage is based on the EC50 = 0.64 mg/L (*Skeletonema costatum).*

Table 6.3-11: Exposit 3.01 calculations for glyphosate

Compound:	glyphosate	
Application rate:	1 x 3600 g a.s./ha; as worst case	
Relevant toxicity endpoint:	EC_{50} = 0.64 mg a.s./L (*Skeletonema costatum*)	
Relevant TER:	10	
Run-off		
Buffer zone [m]	PEC [µg/L]	TER
0	1.90	336
5	1.65	388
10	1.41	453
20	0.99	645
Drainage		
Time of application	PEC [µg/L]	TER
Autumn/winter/early spring [not required]	0.55	1159
Spring/summer	1.70	377
Risk mitigation measures	none	

The EC_{50} = 0.64 mg/L (*Skeletonema costatum*) and the calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance glyphosate (worst case application rate considering an application rate of 1 x 3600 g a.s./ha) result in an acceptable risk for the entry routes run-off and drainage for all indication groups.

6.4 Effects on Bees

Please refer to Part B Sec 6 of the core dossier.

6.5 Effects on Arthropods Other Than Bees (IIIA1 10.5)

Please refer to the core dossier for the central zone.

The endpoints considered for the risk assessment for arthropods are indicated in the following tables. Only the most sensitive endpoints of valid studies are presented here.

6.5.1.1 Toxicity

Information about ecotoxicological endpoints for non target arthropods is considered to be relevant for all countries. Therefore please refer to the core assessment Part B, section 6, chapter 6.

Table 6.5-1: Toxicity endpoint for arthropods

Species	Substance	Exposure	Toxicity	Reference	ICS-Nr.
Poecilus cupreus	glyphosate 450 SL AE (450g a.s./L)	14 d Extended lab testing	LR_{50} > 3.6 kg a.s./ha Mortality	Schmitzer, S. 2010 Doc. No. 50357007	78779
Typhlodromus pyri	glyphosate 450 SL AE (450g a.s. /L)	7 d Extended lab testing	Statictically not evaluable, $pChi_2$ < 0,001 320 < LR_{50}<< 960 g a.s./ ha (mortality) Estimated ER_{50} <35.6 g a.s./ ha (reproduction); surrogate endpoint reproduction = 35.6 g a.s./ha	Schwarz, A. 2010 Doc. No. 50356062	78778
Aphidius rhopalosiphi	glyphosate 450 SL AE (450 g a.s. /L)	2 d Extended lab testing	LR_{50} > 5.76 kg a.s./ha Mortality	Moll, M. 2010 Doc. No. 50355002	78777

The toxicity of HAG 500 02 H to non-target arthropods has been investigated for the indicator species *Aphidius rhopalosiphi*, *Typhlodromus pyri* and *Poecilius cupreus*.

The study with *Typhlodromus pyri* did not show a linear dose-response in the parameter mortality and reproduction. Statistic standard models (Probit, Weibull, Logit 4 parameter) could not sufficiently describe the results (pChi2 < 0.001). Hence, a reliable LR_{50} could not be calculated statistically. Therefore, the LR_{50} was set to > 320 g a.s. /ha. Since sublethal endpoints are considered to be relevant for a Tier 2 risk assessment step, the lowest dose tested (35.6 g a.s./ha) with effects on reproduction was employed in the risk assessment (surrogate endpoint reproduction = 35.6 g a.s./ha). Please refer to Appendix 2 of the core assessment for further details.

6.5.1.2 Exposure

The calculation of PECsw after exposure via spray-drift is performed using the model EVA 2.1. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000).

6.5.1.3 Overall Conclusion

Table 6.5-2: Risk assessment for terrestrial non-target arthropods exposed to of HAG 500 02 H in the indication group C

Substance:	HAG 500 02 H							
Indication:	Worst-case application							
Application rate	1 x 3600 g a.s./ha							
MAF:	1							
Scenario/Percentile:	Agriculture / 90_{th}							
Interception:	None							
Distance	Drift		Volatilisation/ Deposition		PECact (g/ha) (incl. Volatilisation, Interception)			
(m)	(%)	(g/ha)	(%)	(g/ha)	konv. T.	90% Red.	75% Red.	50% Red.
1	2.77	99.72	-	-	19.94	1.99	4.99	9.97
5	0.57	20.52	-	-	4.10	0.41	1.03	2.05
relevant toxiciy:	surrogate endpoint reproduction ER_{50} : 35.6 g a.s./ha (*Typhlodromus pyri)*							
relevant TER:	5							
Distance (m)					**TER**			
1					2	18	**7**	4
5					**9**	87	35	17
Risk mitigation:	NT 102							

The off-field TER values for non-target arthropods (here calculated with the EC50 for *T. pyri*) without risk mitigation measures are below the trigger value, indicating that HAG 500 02 H does pose an unacceptable risk to non-target arthropods in off-field areas. Risk mitigation via 75 % drift reduction (NT102) or 5 m buffer zone for an application rate of 1x 3600 g a.s /ha is needed (intended use group C).

Table 6.5-3: Risk assessment for non target arthropods exposed to of HAG 500 02 H in Group A, B, D, E and F

Substance:		HAG 500 02 H						
Indication:		Group A, B, D, E and F (except Group C)						
Application rate		1 x 1800 g a.s./ha						
MAF:		1						
Scenario/Percentile:		Agriculture / 90th						
Interception:		None						
Distance	Drift		Volatilisation/ Deposition		PECact (g/ha) (incl. Volatilisation, Interception)			
(m)	(%)	(g/ha)	(%)	(g/ha)	konv. T.	90% Red.	75% Red.	50% Red.
1	2.77	49.86	-	-	9.97	1.00	2.49	4.99
5	0.57	10.26	-	-	2.05	0.21	0.51	1.03
relevant toxiciy:	surrogate endpoint reproduction ER_{50} : 35.6 g a.s./ha (*Typhlodromus pyri*)							
relevant TER:	5							
Distance (m)					**TER**			
1					4	38	14	**7**
5					**17**	173	69	35
Risk mitigation:	NT 101t							

The off-field TER values *T. pyri* are below the trigger value, indicating that HAG 500 02H does pose an unacceptable risk to non-target arthropods in off-field areas. Risk mitigation via 50 % drift reduction (NT101t) or 5m buffer zone for an application rate of 1x 1800 g a.s. /ha is needed.

6.6 Effects on Earthworms and Other Soil Non-target Macro-organisms (IIIA1 10.6)

6.6.1 Overview and summary

Please refer to the core dossier for the central zone.

6.6.1.1 Toxicity

Information about ecotoxicological endpoints for earthworms and other soil non-target macro-organisms is considered to be relevant for all countries. Therefore please refer to the core assessment Part B, section 6, chapter 6.

Table 6.6-1: Toxicity endpoint for earthworms

Spezies	Substance	Exposure	Toxicity (mg a.s./kg soil dw)	Reference	ICS-Nr.
Eisenia fetida	glyphosate 450 SL AE (446 g/a.s./L)	14 d akut	LC_{50} > 450	Witte, B.,2010 Doc. No. 52522021	78780
Eisenia fetida	glyphosate	56 d	NOEC ≥ 21.31	Hayward, J.C. and Mallet, M.; CEMR - 1173 Review report 6511/IV/99-final, 21 January 2002	41621
Eisenia fetida	AMPA	56 d	NOEC ≥ 28.12		
Eisenia fetida	glyphosate (IPA-salt)	56 d	NOEC ≥ 28.79		

Exposure

Results of PECsoil calculation for HAG 500 02 H according to EU assessment considering 5 cm soil depth are given in Part B, Section 5 of the core assessment.

Table 6.6-2: Results of PECsoil calculation for the intended use in orchards and vineyards used for German risk assessment

plant protection product:		HAG 500 02 H				
use:		Group C (worst case covering all other uses)				
Number of applications/intervall		1				
application rate:		8 L/ha (3600 g glyphosate / ha) as worst case				
crop interception:		0 %				
active substance/ formulation	soil relevant application rate (g/ha)	soil $depth_{act}$ (cm)	PEC_{act} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
glyphosate	3600	2.5	9.600	-	-	-
AMPA	100 % formation fraction from as	2.5	3.890 on day 14	-	-	-
HAG 500 02	8000	2.5	21.333	-	-	-
use:		Group B (covering all other uses except Group C)				
Number of applications/intervall		1				
application rate:		4 L/ha (1800 g glyphosate / ha) as worst case				
crop interception:		0 %				
active substance/ formulation	soil relevant application rate (g/ha)	soil $depth_{act}$ (cm)	PEC_{act} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
glyphosate	1800	2.5	4.800	-	-	-
AMPA	100 % formation fraction from as	2.5	1.945 on day 14	-	-	-
HAG 500 02	4000	2.5	10.677	-	-	-

For German exposure assessment, the calculated predicted environmental concentration soil (PEC soil) is based on experimental data (Fent et al., 1999[1]). Generally, for active substances with a Kf,oc < 500, a soil depth of 2.5 cm is taken into account whereas for active substances with a Kf,oc > 500 a soil depth of 1 cm is taken into account. As soil bulk density 1.5 g cm-3 is assumed. In case of glyphosate, additional data do not support the assumption of a very low mobility (Schmidt, 2005; see also chapter 5.7.2). Therefore, a soil depth of 2.5 cm is considered for the predicted distribution of glyphosate in the soil profile after application.

A risk assessment with an application rate of 8 L/ha (3600 g a.s./ha) and 4 L /ha (1800 g a.s./ha) including the calculated PEC_{soil} values for the active substance glyphosate and the major soil degradation product AMPA, which is formed in amounts of >10 %, is presented. For details please refer to Part B-Section 5.

6.6.2 Overall conclusion

Earthworms may be directly exposed to HAG 500 02 H residues deposited onto the soil surface after spray application. The TER-values were derived using the toxicity data for the active substance glyphosate as well as for the metabolite AMPA. The results of the risk assessment are summarized in the following table.

Table 6.6-3: Risk assessment for earthworms.

Test substance	Worst-case use pattern	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg dw soil	TER	TER trigger
glyphosate	8 L/ha (3600 g a.s./ha) as worst case	Acute	LC_{50} > 450	9.60	>47	10
		Long-term	NOEC ≥ 28.79 (IPA-salt)		**>3**	5
		Long-term	NOEC ≥ 21.31 (glyphosate acid)		**>2**	5
glyphosate	4 L/ha (1800 g a.s./ha) as worst case	Acute	LC_{50} > 450	4.80	>94	10
		Long-term	NOEC ≥ 28.79 (IPA-salt)		6	5
		Long-term	NOEC ≥ 21.31 (glyphosate acid)		**>4**	5
AMPA	8 L/ha (3600 g a.s./ha) as worst case	Long-term	NOEC ≥ 28.12	3.89 on day 14	7	5
TER values in bold are below the trigger						

Based on the worst case scenario considering an application rate of 8 L/ha (3600 g glyphosate / ha), the acceptability criteria TER ≥ 10 for acute effects, according to Annex VI to directive 1107/2009 (EG), uniform principles, point 2.5.2.5 is reached, indicating that HAG 500 02 H poses low acute risk to earthworms when applied at the maximum application rate.

The risk assessment for HAG 500 02 H concerning chronic effects results in chronic TER values below the acceptability criteria TER ≥ 5 for use in indication Group C (3600 g glyphosate / ha). The results of

[1] Fent, Löffler, Kubiak (1999): Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999).

the assessment indicate an unacceptable risk for earthworms due to the intended use of HAG 500 02 H in orchard and vineyard with an application rate 3600 g a.s./ha. The reduced application rate of 4 L/ha (1800 g glyphosate / ha) covering all other uses except Group C pose low chronic risk to earthworms.

As the metabolite AMPA is considered to be of no greater toxicological concern than its parent compound in general and has a lower NOEC (≥ 28.12 mg/kg), it can be assumed that the toxicity of AMPA is addressed via the longterm study. The risk for earthworms is considered to be acceptable.

6.6.2.1 Toxicity exposure ratios. TERA and TERLT (IIIA1 10.6.1)

Acute risk

The potential acute risk for earthworms exposed to HAG 500 02 H , the active substance glyphosate as well as the major soil degradation product AMPA was assessed by comparing the maximum PEC_{soil} with the 14-day LC_{50} value to generate acute TER values.

The log Kow value for glyphosate is below 2. Therefore, no correction of the endpoints is required in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils. An acute earthworm toxicity study was carried out with glyphosate 450 SL AE (450 g a.s./L). The 14-day LC_{50} of glyphosate 450 SL AE for earthworms is considered to be > 1000 mg/kg soil (equivalent to >450 mg a.s./kg soil).

The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TERA values are shown in the following table, considering the highest initial PEC in soil (i.e. 0% interception during applications):

Table 6.6-4: Acute TER values for earthworms following applications of HAG 500 02 H with maximum application rate 8 L/ha (3600 g glyphosate / ha).

Test substance	Maximum initial PEC (mg/kg)	Timescale	LC_{50} (mg/kg)	TER
glyphosate	9.6	acute	> 450	> 47

Based on the worst case scenarios vineyard and orchard, the acceptability criteria TER ≥ 10 for acute effects, according to Annex VI to directive 1107/2009 (EG), uniform principles, point 2.5.2.5 is reached, indicating that HAG 500 02 H poses low acute risk to earthworms when applied at the maximum application rate of 8 L/ha (3600 g a.s./ha).

Long-term risk

A study on the reproduction of earthworms was submitted concerning the active substance glyphosate and the major soil degradation product AMPA (Review report 6511/IV/99-final, 21 January 2002). The log Kow value for glyphosate is below 2. Therefore, no correction of the endpoints is required in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils.

$$TER_{LT} = \frac{NOEC\,(mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_{LT} values are presented below in the following table, considering the highest initial PEC in soil (i.e. 0 % interception during applications).

Table 6.6-5: Long-term TER values for earthworms following applications of HAG 500 02 H with maximum application rate 8 L/ha (3600 g glyphosate / ha).

Test substance	Maximum initial PEC (mg/kg)	Timescale	NOEC (mg/kg)	TER
glyphosate	9.6	Long-term	21.31	**2**
AMPA	3.97	Long-term	28.12	7

Based on the worst case scenario, the acceptability criteria TER ≥ 5 for long-term effects, according to directive 1107/2009 (EG), Annex VI. uniform principles, point 2.5.2.5 is not reached for the formulation HAG 500 02 H with maximum application rate 8 L/ha (3600 g a.s./ha) representing the scenario in vineyard and orchards.

The chronic risk to earthworms is inacceptable at the intended worst-case application rate of 8 L/ha (3600 g a.s./ha) in group C, indications 00-003 and 00-005.

Table 6.6-6: Long-term TER values for earthworms following applications of HAG 500 02 H with an application rate 4 L/ha (1800 g glyphosate / ha).

Test substance	Maximum initial PEC (mg/kg)	Timescale	LC_{50} (mg/kg)	TER
glyphosate	4.8	Long-term	28.79	6
AMPA	1.987	Long-term	28.12	14

Based on an application rate of 4 L/ha (1800 g a.s./ha), the acceptability criteria TER ≥ 5 for long-term effects, according to directive 1107/2009 (EG), Annex VI. uniform principles, point 2.5.2.5 are reached for the formulation HAG 500 02 H. Therefore, HAG 500 02 H poses low risk to earthworms when applied once up to 4 L/ha (1800 g a.s./ha) in the indication groups A, B, D, E and F.

6.6.3 Effects on organic matter breakdown (IIIA1 10.7)

Please refer to the core dossier for the central zone.

6.7 Effects on Soil Microbial Activity (IIIA1 10.7)

6.7.1 Overview and summary

Please refer to the core dossier for the central zone.

6.7.1.1 Toxicity

Please refer to the core dossier for the central zone. All effects were below the trigger value < 25% after 28d exposure, indicating that the proposed use of HAG 500 02H poses acceptable risk.

6.7.1.2 Exposure

Please see registration Report national addendum Part B , Section 5.

6.7.1.3 *Overall conclusion*

SANCO/10329/2002 rev 2-final states that testing soil micro-organisms is always required when contamination of the soil is possible. The Predicted Environmental Concentrations of the formulation, the the active substances and the major soil degradation product AMPA are below the concentrations at which no unacceptable effects (< 25 %) were observed after 28 days of exposure.

Studies have been conducted with glyphosate 450 SL AE to determine the effects on soil micro-organisms (Feil et al. 2010). Effects of glyphosate 450 SL AE showed effects < 25 % on respiration, soil nitrate formation, when applied up to 64 mg/kg dry weight (equivalent to 24 kg a.s /ha, in 2.5 cm soil depth / >6 PEC) after 28 d of exposure. The risk assessment results are summarized in the following table.

Table 6.7-1: Risk assessment for soil microbial activity functions

Substance	Endpoint	Effect (NOEC) / dose (mg/kg soil dw)	PEC_S (mg/kg)	MoS
glyphosate 450 SL AE	Carbon respiration	< 25 % derivation from control/ 12.8 mg/kg soil dw	9.600	>1.3
		< 25 % derivation from control/ 64 mg/kg soil dw		>6.6
glyphosate 450 SL AE	Nitrogen transforamation	< 25 % derivation from control/ 12.8 mg/kg soil dw	9.600	>1.3
		< 25 % derivation from control/ 64 mg/kg soil dw		>6.6

For the active ingredient glyphosate, the tested application rates of HAG 500 02 H caused no deviations > 25% in the soil microbial acivity studies. Moreover, the tested appliacation rates are > 6 x the estimated PEC according to the worst case intended use in vineyard, Group C. Consequently it can be concluded that HAG 500 02 H applied at the proposed worst-case use patterns does not pose an unacceptable risk to soil microorganisms.

6.7.2 Toxicity exposure ratios

Please refer to the previous chapter

6.8 Effects on Non-Target Plants (IIIA1 10.8)

6.8.1 Overview and summary

Based on the most sensitive endpoints for vegetative vigour, treatment of HAG 500 02 H according to the proposed uses with an application rate of 1x1800 g a.i/ ha , poses low and acceptable risk to terrestrial non-target plants under consideration of risk mitigation measures in form of NT 102 (drift reduction of 75 % -1 m or 0 % - 5 m).

An acceptable risk to terrestrial non-target plants due to treatment with HAG 500 02 H with the proposed worst-case application rate of 3600 g a.i./ha is indicated by TER-values above the trigger of 5, if drift reduction technique of 90 % is applied or 5m buffer zone with 50 % drift reduction technique.

6.8.1.1 *Toxicity*

Please refer to the core dossier for the central zone.

The potential effects of HAG 500 02 H on seedling emergence and vegetative vigour non-target terrestrial plants have been tested with 6 and 10 non-target terrestrial plant species, respectively.

Table 6.8-1: Ecotoxicological endpoints for non-target plants following exposure to HAG 500 02 H

Species	Substance	Exposition	Results Toxicity	Reference	ICS-No.
Seedling emergence					
Brassica oleracea *Vicia faba* ***Helianthus annus*** *Lolium perenne* *Cucumis sativus* *Allium cepa*	glyphosate 450 SL AE (450 g a.s./L)	Seedling emergence	ER_{50} : 7858 ml glyphosate 450 SL AE/ ha; (fresh weight) 3536 g a.s./ha	Bützler, R., Meinerling, M. 2010	78783
Vegetative vigour					
Allium cepa *Lolium perenne* *Daucus carota* *Beta vulgaris* *Lolium perenne* *Lycopersicon esc.* *Cucumis sativus* *Helianthus annuus* *Vicia faba* ***Brassica oleracea***	glyphosate 450 SL AE (450 g a.s./L)	Vegetative vigour	ER50 : 125 ml product /ha (fresh weight) **56.3 g a.s./ha**	Bützler, R., Mollandin, G. 2010	78782

The risk to non-target plants following exposure to HAG 500 02 H is calculated by using the most sensitive endpoint ER_{50} : 125 ml product /ha (fresh weight, representing 56.3 g a.i. /ha in *Brassica oleracea*) and worst-case PECs for the indication groups: 1 x 3600 g a.i./ha and 1x 1800 g/ha.

6.8.1.2 Exposure

The calculation of PECsw after exposure via spray-drift is performed using the model EVA 2.1. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000).

6.8.2 Toxicity exposure ratios

The risk assessment based on the lowest effect endpoint for vegetative vigour and the relevant predicted environmental rates in the off-field area after treatment with HAG 500 02 H in accordance to the proposed use rate is presented in the tables:

Table 6.8-2: Risk assessment for terrestrial non-target plants exposed to of HAG 500 02 H, intendes uses A, B, D, E, F

Substance:	HAG 500 02 H							
Indication:	Group A, B, D, E and F							
Application rate	1 x 1800 g a.s./ha							
MAF:	1							
Scenario/Percentile:	Agriculture / 90th							
Interception:	None							
Distance (m)	Drift		Volatilisation/ Deposition		PECact (g/ha) (incl. Volatilisation, Interception)			
	(%)	(g/ha)	(%)	(g/ha)	konv. T.	90% Red.	75% Red.	50% Red.
1	2.77	49.86	-	-	49.86	4.99	12.47	24.93
5	0.57	10.26	-	-	10.26	1.03	2.57	5.13
relevant toxiciy:	ER_{50} : 125 ml product /ha (fresh weight, representing 56.3 g a.s./ha in *Brassica oleracea*)							
relevant TER:	5							
Distance (m)					**TER**			
1					1	11	**5**	2
5					**5**	55	22	11
Risk mitigation:	NT 102							

Based on the most sensitive endpoints for vegetative vigour, exposure to HAG 500 02 H according to the proposed uses with an application rate of 1x1800 g a.i/ ha poses an acceptable risk to terrestrial non-target plants under consideration of risk mitigation measures in form of NT 102 (drift reduction of 75 % -1 m or 0 % - 5 m).

Table 6.8-3: Risk assessment for terrestrial non-target plants exposed to of HAG 500 02 H, indended use C

Substance:	HAG 500 02 H							
Indication:	Group C							
Application rate	1 x 3600 g a.s./ha							
MAF:	1							
Scenario/Percentile:	Agriculture/90th							
Interception:	None							
Distance (m)	Drift		Volatilisation/ Deposition		PECact (g/ha) (incl. Volatilisation, Interception)			
	(%)	(g/ha)	(%)	(g/ha)	konv. T.	90% Red.	75% Red.	50% Red.
1/3	2.77	99.72	-	-	99.72	9.97	24.93	49.86
5	0.57	20.52	-	-	20.52	2.05	5.13	10.26
relevant toxiciy:	ER_{50} : 125 ml product /ha (fresh weight, representing 56.3 g a.s./ha in *Brassica oleracea*)							
relevant TER:	5							
Distance (m)					TER-values (calculated)			
1/3					1	**6**	2	1
5					3	27	11	**6**
Risk mitigation:	NT 103							

An acceptable risk to terrestrial non-target plants due to treatment with HAG 500 02 H with the proposed worst-case application rate of 3600 g a.s./ha is indicated by TER-values above the trigger of 5, if drift reduction technique of 90 % is applied or 5m buffer zone with 50 % drift reduction technique.

6.9 Effects on non-target aquatic plants (IIIA 10.8.2)

Please refer to assessment made under chapter 6.4.

6.10 Summary and Evaluation of Points 5 and 6 (IIA1 10.11)

6.10.1 Predicted distribution and fate in the environment and time courses involved (IIIA1 10.11.1)

Please refer to the core dossier for the central zone.

6.10.2 Non-target species at risk and extent of potential exposure (IIIA1 10.11.2)

Please refer to the core dossier for the central zone.

6.10.3 Short- and long-term risks for non-target species, populations, communities and processes (IIIA1 10.11.3)

Birds

Please refer to the core dossier for the central zone.

Terrestrial vertebrates other than birds

Please refer to the core dossier for the central zone.

Aquatic organisms

Risk assessments for aquatic organisms were conducted based on the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 final).

Predicted environmemtal concentrations in surface water have been calculated in accordance with German national requirements for drift, run-off and drainage entry into surface water.

Based on the calculated concentrations of glyphosate the calculated TER-values for the acute and long-term risk resulting from an exposure of aquatic organisms to glyphosate according to the GAP of the formulation HAG 500 02 H achieve the acceptability criteria TER $\geq$ 10. The results of the assessment indicate an acceptable risk for aquatic organisms for to the intended use of HAG 500 02 H in all indications applying up to 3600 g a.s./ha without risk mitigation measures.

Honeybees

Please refer to the core dossier for the central zone.

Arthropods other than bees

The study with *Typhlodromus pyri* did not show a linear dose-response in the parameter mortality and reproduction. Statistic standard models (Probit, Weibull, Logit 4 parameter) could not sufficiently describe the results (pChi2 < 0.001). Hence, a reliable LR50 could not be calculated statistically. Therefore, the LR_{50} was set to > 320 g a.s. /ha. Since sublethal endpoints are considered to be relevant for a Tier 2 risk assessment step, the lowest dose tested (35.6 g a.s./ha) with effects on reproduction was employed in the risk assessment (surrogate endpoint reproduction = 35.6 g a.s./ha). Please refer to Appendix 2 for further details.

The off-field TER values *T. pyri* are below the trigger value, indicating that HAG 500 02H does pose an unacceptable risk to non-target arthropods in off-field areas.

For an application rate of 1x 3600 g a.s /ha risk mitigation via 75 % drift reduction (NT102) or 5m buffer zone is needed.

For an application rate of 1x 1800 g a.s/ha Risk mitigation via 50 % drift reduction (NT101t) or 5m buffer zone is needed.

Earthworms and other soil macro-organisms

Risk assessments for earthworms and other soil non-target macro-organisms were conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final). The assessments for acute and chronic exposure have been conducted based on the formulated product HAG 500 02 H.

Predicted environmental concentrations in soil were calculated based on German national requirements; i.e. for a soil penetration depth of 2.5 cm for substances with KOC < 500 L/kg.

Based on the worst-case scenarios vineyard and orchard the acceptability criteria TER ≥ 10 for acute effects, according to Annex VI to directive 1107/2009 (EG), uniform principles, point 2.5.2.5 is reached, indicating that HAG 500 02 H poses low acute risk to earthworms when applied at the maximum application rate of 8 L/ha (3600 g a.s./ha).

The reduced application rate of 4 L/ha (1800 g a.s./ ha) covering all other uses except Group C pose, according to the TER values, low chronic risk to earthworms.

Based on the worst-case scenario, the acceptability criteria TER ≥ 5 for long-term effects, according to directive 1107/2009 (EG), Annex VI. uniform principles, point 2.5.2.5 is not reached for the formulation HAG 500 02 H with maximum application rate 8 L product/ha (3600 g a.s./ ha) in the risk assessment for earthworms. The TER values below the the acceptability criteria for use in indication Group C/ 00-003 and 00-005 (3600 g a.s./ha), indicate an unacceptable long term risk for earthworms.

Soil Microbial Activity

The risk assessment for soil microflora functions was conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final) based on data for the formulated product HAG 500 02 H.

All effects on soil microflora carbon respiration and nitrogen transformation) caused by HAG 500 02 H were below the trigger value < 25% after 28d exposure, indicating that the proposed uses pose acceptable risk.

Non-target organisms (flora and fauna)

Based on the most sensitive endpoints for vegetative vigour, treatment of HAG 500 02 H according to the proposed uses with an application rate of 1x1800 g a.s/ ha , poses low and acceptable risk to terrestrial non-target plants under consideration of risk mitigation measures in form of NT 102 (drift reduction of 75 % -1 m or 0 % - 5 m).

An acceptable risk to terrestrial non-target plants due to treatment with HAG 500 02 H with the proposed worst-case application rate of 3600 g a.s./ha is indicated by TER-values above the trigger of 5, if drift reduction technique of 90 % is applied or 5m buffer zone with 50 % drift reduction technique (NT 103).

6.10.4 Risk of fish kills and fatalities in large vertebrates or terrestrial predators (IIIA1 10.11.4)

Please refer to the core dossier for the central zone.

6.10.5 Precautions necessary to avoid/minimise environmental contamination and to protect non-target species (IIIA1 10.11.5)

Because of the toxicity of the active ingredient as well as the formulation following labels have to be signed out in Germany:

NW 262	The product is toxic for algae (EC_{50}: 0,64 mg glyphosate/L (*Skeletonema costatum))*
NW 468:	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NT 102:	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures. In order to protect terrestrial non-target plant species in off-field areas a risk mitigation measure is required in form of 75 % drift reduction in indication group with an application rate of 1x 1800g a.s./ha in group A, B, D, E and F.
NT 103:	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures. In order to protect terrestrial non-target plant species in off-field areas a risk mitigation measure is required in form of 90 % drift reduction in indication group C with an application rate of 1x 3600g a.s./ha.

Appendix 1 List of data submitted in support of the evaluation

Please refer to the core dossier for the central zone.

Appendix 2 Table of Intended Uses

Please refer to the core dossier for the central zone.

Appendix 3 Additional information provided by the applicant

Please refer to the core dossier for the central zone.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed summary

Product code: HAG 500 02 H

Reg. No.: 007385-00/00

Active Substance: 450 g/L glyphosate

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Helm AG

Date: 2011-04-28

Evaluator: Julius Kühn-Institut

Date: 2013-02-12

Table of Contents

IIIA1 6	Efficacy Data and Information (including Value Data) on the Plant Protection Product	3
IIIA1 6.1.1	Preliminary range-finding tests	9
IIIA1 6.1.2	Minimum effective dose tests	9
IIIA1 6.1.3	Efficacy tests	26
IIIA1 6.1.4	Effects on yield and quality	41
IIIA1 6.1.4.1	Impact on the quality of plants and plant products	41
IIIA1 6.1.4.2	Effects on the processing procedure	43
IIIA1 6.1.4.3	Effects on the yield of treated plants and plant products	43
IIIA1 6.2	Adverse effects	45
IIIA1 6.2.1	Phytotoxicity to host crop	45
IIIA1 6.2.2	Adverse effects on health of host animals	47
IIIA1 6.2.3	Adverse effects on site of application	47
IIIA1 6.2.4	Adverse effects on beneficial organisms (other than bees)	47
IIIA1 6.2.5	Adverse effects on parts of plant used for propagating purposes	54
IIIA1 6.2.6	Impact on succeeding crops	54
IIIA1 6.2.7	Impact on other plants including adjacent crops	54
IIIA1 6.2.8	Possible development of resistance or cross-resistance	54
IIIA1 6.3	Economics	59
IIIA1 6.4	Benefits	59
IIIA1 6.4.1	Survey of alternative pest control measures	59
IIIA1 6.4.2	Compatibility with current management practices including IPM	59
IIIA1 6.4.3	Contribution to risk reduction	59
IIIA1 6.5	Other/special studies	59
IIIA1 6.6	Summary and assessment of data according to points 6.1 to 6.5	59
IIIA1 6.7	List of test facilities including the corresponding certificates	61
Appendix 1:	List of data submitted in support of the evaluation	63
Appendix 2:	GAP tables	75
Appendix 3:	Additional information provided by the applicant (e.g. detailed modelling data)	78

IIIA1 6 Efficacy Data and Information (including Value Data) on the Plant Protection Product

General information

Germany is zRMS and belongs according to Regulation EC No 1107/2009 to the central registration zone (zone B). According to EPPO PP1/241 (zones of comparable climate in the EPPO region) Germany is part of the maritime EPPO zone.

Concerned member states (cMS) are United Kingdom, Belgium, the Netherlands, Hungary, Romania, Ireland, Austria, Czech Republic, Slovakia, and Slovenia. In these countries the applicant requests a registration. United Kingdom, Belgium, the Netherlands, Ireland, Austria, Czech Republic and Germany as zRMS belong to the maritime EPPO zone. Meanwhile Hungary, Romania, Slovakia and Slovenia are part of the south-east EPPO zone.

This document summarises the information related to the efficacy of the plant protection product HAG 500 02 H containing 450 g/L glyphosate which was included into Annex I of Directive 91/414 EEC by 1 July 2002 (Commission Directive 2001/99/EC).

Recent registration situation/history of the PPP

Glyphosate was first registered in Germany in the mid -1970’s. It is extensively registered throughout the world for a wide range of uses at a range of dose rates.
Detailed information was not given by the applicant.

Information on the active ingredients (Uptake and mode of action)

Glyphosate is an organic phosphorus compound, belonging to the chemical class of glycines, with no or low soil residual activity. Herbicides containing glyphosate differ in the salt formulation. Glyphosate may present as glyphosate-ammonium-salt, as glyphosate-isopropylammonium-salt or as glyphosate-potassium-salt. Glyphosate is a non-selective herbicidal active substance. Glyphosate is taken up by the leaves and other green parts of the plant and is translocated systemically (apoplastic and symplastic) in the whole plant, also in underground parts like roots, rhizomes or stolons. Glyphosate uptake through the roots is negligible because the active substance is strongly adsorbed in the soil. The extensive adsorption of glyphosate together with a ready degradation in soil, are the principal deactivation and dissipation mechanisms in the soil environment.
In plants, glyphosate inhibits the shikimic acid pathway. Glyphosate binds to and blocks the activity of its target enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), an enzyme of the aromatic amino acid biosynthetic pathway. The inhibition of the enzyme prevents the plant from synthesizing the essential aromatic amino acids (e.g. phenylalanine, tyrosine, and tryptophane) needed for protein biosynthesis. This reduces the production of protein in the plant, and inhibits plant growth. EPSPS is present in all plants. It leads to an accumulation of the amino acids glutamine, glutamic acid, shikimic acid and ammonia. As a consequence of missing aromatic amino acids the formation of phenolic compounds is inhibited (e.g. lignin, flavanoids).

First signs of wilting occur in annual weeds 4 days and in perennial weeds 7 to 10 days after herbicide application. Leaf symptoms are usually detected 7 to 14 days after application, while a complete death of the plant takes up to 30 days. As light affects the metabolism via photosynthesis, a higher activity in plants means a better distribution of glyphosate and thus greater herbicidal effect. Increasing temperatures result in increased biochemical activity, and thus in an increased rate of efficacy. Optimum temperatures are 10 to 20 °C. High humidity affects the quality of the leaf surface and thus promotes the uptake of the herbicide.
Plant metabolism studies have been conducted on numerous crops. The only significant metabolite in plants was aminomethylphosphonic acid (AMPA).

Information on crops and pests

According to the importance (occurrence, cultivation) in the member states (MS) the intended pest/crop can be classified in Germany as follows:

Table 6-1: Importance of intended pest/crop in Germany

Pest/Crop	EPPO	Country	Classification	
Pest/target				
Grass weeds	TTTMM	Germany		major
Broad-leaved weeds	TTTDD	Germany		major
Desiccation	YELSI*	Germany		major
Crop				
Field crops	NNNAC	Germany		major
Orchards pome fruit	NNNOK	Germany		major
Grape	VITVI	Germany		major
Cereal	NNNGG	Germany		major
Grassland	NNNFW	Germany		major
Winter rape	BRSNW	Germany		major

* no EPPO code

HAG 500 02 H is intended for use in Member States of EU-zone B. Uses on agricultural land (stubble), cereals, oilseed rape, sugar beet, peas, pome fruit, vineyards and grass land were applied for. According to the master label not all uses are intended for all Member States.

Most of the intended crops are grown in all Member States of the EU-zone B. The importance in the individual Member States is shown in Table 6-2.

Table 6-2: Total acreage of crops in EU Member States of zone B given in 1000 ha (Source Eurostat, 04.05.2012)

MS	Crop (year)						
	Cereals (2011)	**Oilseed rape (2009)**	**Sugar beet (2011)**	**Peas (2009)**	**Pome fruit (2010)**	**Grapes (2011)**	**Grass land (2009)**
BE	345 (2009)	9.7	62.3	1.0	15.94	0 (2009)	496.3
CZ	1479.5	354.8	58.3	21.1	9.7	16.0	907.9
DE	6500.6	1471.2	398.1	48.3	33.9	102 (2008)*	4741.4
IR	295.5	6.5	0	0 (2011)	0 (2002)	n.d.a.	3097.7
LUX	28.8	4.6	0	0.2	0.26	1.221	67.4
HU	2675.7	258.5	14.4	19.1	45.1	73.9	1004.2
NL	212	2.6	73.3	1.2	16.7	0	827.2
AT	807.3	56.9	46.6	15.2	6.4	43.8	1731.3
PL	7803	810	203.3	14.5	201.4	0.5	3179.7

RO	5274.6	419.9	18.9	22.7	61.5	173.5	4371.7
SI	95.0	2.7 (2003)	5.4 (2003)	0.4 (2004)	3.0	15.8	308.3 (2003)
SK	740.8	167.6	18.1	7.5	2.8	9.9	523.6
UK	3.1	570	113	42.0	17.2	1.3 (2010)	11259

The applicant stated that all crops can be considered as major crops in Member States of EU-zone B.
A broad spectrum of weeds can be successfully controlled with HAG 500 02 H. Important weeds occur in all Member States independent from their localisation in EPPO climatic zones “maritime”, “north-east” or “south-east”. A tabular presentation of susceptibility of weeds is contained in the label.

Information on the intended uses (2013-02-08)

Uses for Germany

Use No.	**007385-00/00-001**
Area of application	agriculture (field crops)
Crop(s)/object(s)	field crops
Notes on crop	stubble treatment
Pest(s)/target(s)/aim(s)	dicotyledonous weeds, monocotyledonous weeds
Area of use	outdoors
Time of treatment	after harvest, up to 4 days before sowing
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	4 L/ha in 100 to 400 L water/ha
----------------------------	----------------------------
Use No.	**007385-00/00-002**
Area of application	fruit growing
Crop(s)/object(s)	pome fruit
Pest(s)/target(s)/aim(s)	dicotyledonous weeds, monocotyledonous weeds
Notes on pest stage(s) (BBCH)	treatment at 15-20 cm weed height
Area of use	outdoors
Time of treatment	spring to summer
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Notes on application technique	row treatment
Dose rate(s) in amount of water to be used	4 L/ha in 100 to 400 L water/ha
----------------------------	----------------------------

According to the master label, this use is intended only for Germany

Use No.	**007385-00/00-003**
Area of application	fruit growing
Crop(s)/object(s)	pome fruit
Pest(s)/target(s)/aim(s)	field bindweed
Area of use	outdoors
Time of treatment	spring to summer
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Notes on application technique	row treatment
Dose rate(s) in amount of water to be used	8 L/ha in 100 to 400 L water/ha
----------------------------	----------------------------
Use No.	**007385-00/00-004**
Area of application	viticulture
Crop(s)/object(s)	grape vine
Notes on crop	utilisation as wine and table grape from 4th year after planting of the vine onwards
Pest(s)/target(s)/aim(s)	dicotyledonous weeds, monocotyledonous weeds
Notes on pest stage(s) (BBCH)	treatment at 10-20 cm weed height
Area of use	outdoors
Time of treatment	spring to summer
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Notes on application technique	row treatment
Dose rate(s) in amount of water to be used	4 L/ha in 100 to 400 L water/ha
----------------------------	----------------------------

According to the master label, this use is intended only for Germany

Use No.	**007385-00/00-005**
Area of application	viticulture
Crop(s)/object(s)	grape vine
Notes on crop	utilisation as wine and table grape from 4th year after planting of the vine onwards
Pest(s)/target(s)/aim(s)	field bindweed
Area of use	outdoors
Time of treatment	spring to summer
Max. number of treatments for the use	1
Max. number of treat-	1

ments per crop or season	
Application technique/type of treatment	spraying
Notes on application technique	row treatment
Dose rate(s) in amount of water to be used	8 L/ha in 100 to 400 L water/ha

In use no. 006 desiccation is restricted to lodging cereals only for Germany.

Use No.	**007385-00/00-006**
Area of application	agriculture (field crops)
Crop(s)/object(s)	cereals (barley, oats, rye, triticale, wheat)
Crop stage(s) (BBCH)	89
Notes on crop	except for seed production and brewing purposes
Notes on crop	lodging cereals except seed and brewer's corn
Pest(s)/target(s)/aim(s)	dicotyledonous weeds, monocotyledonous weeds, desiccation
Area of use	outdoors
Time of treatment	up to 7 days before harvest, during late treatment
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	4 L/ha in 100 to 400 L water/ha
----------------------------	----------------------------
Use No.	**007385-00/00-007**
Area of application	grassland
Crop(s)/object(s)	grassland, pasture, meadow
Notes on crop	grassland renewal
Pest(s)/target(s)/aim(s)	monocotyledonous weeds, dicotyledonous weeds
Area of use	outdoors
Time of treatment	5-7 days before sowing, during growing season
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	4 L/ha in 100 to 400 L water/ha

According to the letter from the applicant dated on 2012-05-09, in use no. 008 desiccation is not requested for Germany

Use No.	**007385-00/00-008**
Area of application	agriculture (field crops)
Crop(s)/object(s)	winter rape
Crop stage(s) (BBCH)	87 to 89
Notes on crop	except for seed production
Pest(s)/target(s)/aim(s)	monocotyledonous weeds, dicotyledonous weeds, ~~desiccation~~
Area of use	outdoors
Time of treatment	up to 14 days before harvest, during late treatment
Max. number of treat-	1

ments for the use	
Max. number of treat-ments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	2,5 L/ha in 100 to 400 L water/ha

According to the letter from the applicant dated on 2012-05-09, use no. 009 is no longer pursued for Germany.

Oilseed rape – pre-emergence

Use No.	**007385-00/00-009**
Area of application	agriculture (field crops)
Crop(s)/object(s)	winter rape
Crop stage(s) (BBCH)	00 to 08
Notes on crop	except for seed production
Pest(s)/target(s)/aim(s)	monocotyledonous weeds, dicotyledonous weeds
Area of use	outdoors
Time of treatment	before emergence, after emergence of weeds
Max. number of treat-ments for the use	1
Max. number of treat-ments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	2,5 L/ha in 100 to 400 L water/ha

According to the GAP-table from the applicant dated on 2011-04-28, the following uses are additionally intended only for cMS (AT, BE, CZ, HU, IE, PL, SK, SI, NL, UK):

Sugar beet – pre-emergence

Area of application	agriculture (field crops)
Crop(s)/object(s)	Sugar beet
Crop stage(s) (BBCH)	00
Pest(s)/target(s)/aim(s)	monocotyledonous weeds, dicotyledonous weeds
Area of use	outdoors
Time of treatment	before emergence
Max. number of treat-ments for the use	1
Max. number of treat-ments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1,6 L/ha in 200 to 300 L water/ha

Field pea – pre-harvest

Area of application	agriculture (field crops)
Crop(s)/object(s)	Field pea
Notes on crop	except for seed production
Crop stage(s) (BBCH)	87 to 89
Pest(s)/target(s)/aim(s)	monocotyledonous weeds, dicotyledonous weeds, desiccation
Area of use	outdoors

Time of treatment	up to 7 days before harvest
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	2,5 L/ha in 200 to 300 L water/ha

The following application is part of the GAP-table and is discussed in the dRR of the applicant, but is not described in the master label:

Stone fruit

Area of application	fruit growing
Crop(s)/object(s)	stone fruit
Pest(s)/target(s)/aim(s)	dicotyledonous weeds, monocotyledonous weeds
Notes on pest stage(s) (BBCH)	treatment at 15-20 cm weed height
Area of use	outdoors
Time of treatment	spring to summer
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Notes on application technique	row treatment
Dose rate(s) in amount of water to be used	4 L/ha in 100 to 400 L water/ha

IIIA1 6.1.1 Preliminary range-finding tests

The applicant indicates that glyphosate is a well-known herbicide active substance and range finding tests (conducted in the laboratory, in the glasshouse or as small scale field trials) are not required. According to the applicant, preliminary range finding tests were not necessary.

IIIA1 6.1.2 Minimum effective dose tests

A large number of trials was conducted with HAG 500 02 H as a glyphosate containing soluble concentrate formulation in several crops in European countries of the maritime EPPO zone and the north-east EPPO zone (Poland) in 2009 and 2010 to evaluate the minimum effective dose. Weed occurrence and cropping systems are comparable between Germany and Poland. Therefore the results of minimum effective dose tests from Poland can be considered for the assessment. No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Intended use: 007385-00/00-001

In total 26 trials were conducted in stubbles in UK (8), Germany (7), France (9) and Poland (2) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/98(2), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone (EPPO PP1/241).

The intended target dose rate of HAG 500 02 H of 1800 g a.s./ha, equivalent to 4.0 L product/ha was tested in all of the 26 trials. In the five UK trials, the four German trials and the five French trials a 20% lower dose of the intended target dose of 1800 g a.s./ha HAG 500 02 H was tested (HAG 500 02 H applied at 1440 g a.s./ha equivalent to 3.2 L product/ha). For the UK trials the standard reference products were Roundup Energy (450 g as/L glyphosate) applied at the following dosages: 1440 g a.s./ha equivalent to 3.2 L product/ha and Roundup Ultra Max (450 g as/L glyphosate) applied at 1800 g a.s./ha, equivalent to 4.0 L product/ha and Roundup Energy (450 g as/L glyphosate) applied at 2520 g a.s./ha, equivalent to 5.6 L product/ha.
For the German and the French trials Roundup Ultra Max (450 g as/L glyphosate) was applied at the following doses: 1440 g a.s./ha equivalent to 3.2 L product/ha, 1800 g a.s./ha, equivalent to 4.0L product/ha. In a French trial the standard reference products were Roundup Flash (450 g as/L glyphosate) applied at 1440 g a.s./ha equivalent to 3.2 L product/ha and Roundup Ultra Max (450 g as/L glyphosate) applied 1800 g a.s./ha, equivalent to 4.0 L product/ha.
In the three UK trials, the three German trials and the four French trials two approximately 40% and 60% lower dose rates than the intended target dose rate of 1800 g a.s./ha were tested. In these trials the dose rate was 720 g a.s./ha HAG 500 02 H, equivalent to 1.6 L product/ha and 1080 g a.s./ha HAG 500 02 H, equivalent to 2.4 L product/ha. For the UK trials the standard reference products were Roundup Energy (450 g as/L glyphosate) applied at the following doses: 1080 g a.s./ha equivalent to 2.4 L product/ha and Roundup Ultra Max (450 g as/L glyphosate) applied at 1800 g a.s./ha, equivalent to 4.0 L product/ha. For the German trials and three French trials Roundup Ultra Max (450 g as/L glyphosate) was applied at the following doses: 1080 g a.s./ha, equivalent to 2.4 L product/ha and 1800 g a.s./ha, equivalent to 4.0 L product/ha. In a French trial the standard reference products were Roundup Flash (450 g as/L glyphosate) applied at the dose of 1080 g a.s./ha, equivalent to 2.4 L product/ha and Roundup Ultra Max (450 g as/L glyphosate) applied at 1800 g a.s./ha, equivalent to 4.0 L product/ha.

In the two Polish trials two approximately 50% and 60% lower dose rates than the intended target dose rate of 1800 g a.s./ha were tested. In these trials the dose rates were 900 g a.s./ha HAG 500 02 H, equivalent to 2.0 L product/ha and 1125 g a.s./ha HAG 500 02 H, equivalent to 2.5 L product/ha. The standard reference product Roundup Energy (450 g as/L glyphosate) was applied at the following doses: 900 g a.s./ha equivalent to 2.0 L product/ha, 1125 g a.s./ha equivalent to 2.5 L product/ha and 1800 g a.s./ha, equivalent to 4.0 L product/ha.

The reported trials have been conducted in 2009 and 2010. HAG 500 02 H was applied once on green, intensively growing weeds (>10 cm) before sowing. 35 different weed species were monitored and assessed during 22 to 44 days after application (DAA). Weed species occurring within the studies are given in Table 6.1.2-1.

Table 6.1.2-1: Effectiveness (%) of decreasing application rates of HAG 500 02 H in stubble (assessment 22-44 DAA). Trials from 2009-2010

Weed species	**n**	**HAG 500 02 H (L/ha)**	**mean**	**min**	**max**	**Reference product mean**
Agrostis stolonifera (AGSST)	1	2.4	-	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Elytrigia repens (AGRRE)	3 3	1.6 – 2.0	76	70	84	78
		2.5	89	81	95	91
		4.0	92	84	98	92
Alopecurus myosuroides	1	2.4	100	-	-	100

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
(ALOMY)	2	3.2	100	100	100	100
	3	4.0	100	100	100	100
Amaranthus retroflexus (AMARE)	1	2.5	100	-	-	100
		3.2	-	-	-	-
		4.0	100	-	-	100
Avena ludoviciana (AVELU)	1	2.4	89	-	-	89
		3.2	-	-	-	-
		4.0	88	-	-	90
Brassica napus (BRSNW)	1	2.0	83	-	-	85
	1	2.5	99	-	-	99
	3	3.2	94	89	100	90
	4	4.0	97	91	100	97
Chenopodium album (CHEAL)	1	2.0	68	-	-	70
	1	2.5	75	-	-	83
	1	3.2	99	-	-	100
	2	4.0	95	91	99	98
Cirsium arvense (CIRAR)	3	2.4	-	-	-	-
		3.2	100	100	100	100
		4.0	100	100	100	100
Cirsium vulgare (CIRVU)	1	2.4	-	-	-	-
		3.2	98	-	-	96
		4.0	100	-	-	100
Convolvulus arvensis (CONAR)	2	2.4	-	-	-	-
		3.2	41	8	75	48
		4.0	47	13	81	61
Echinochloa crus-galli (ECHCG)	2	2.0	83	82	82	85
	2	2.5	91	91	91	94
	1	3.2	70	-	-	-
	3	4.0	91	72	100	92
Geranium molle (GERMO)	1	1.6	85	-	-	-
		2.4	89	-	-	91
		4.0	92	-	-	91
Hordeum vulgare (HORVW)	1	1.6	100	-	-	-
		2.4	99	-	-	99
		4.0	100	-	-	100
Lamium purpureum (LAMPU)	2	1.6	97	97	97	-
		2.4	100	100	100	100
		4.0	100	100	100	100
Matricaria recutita (MATCH)	1	2.4	-	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Mercurialis annua (MERAN)	2	1.6	62	46	79	-
		2.4	67	56	77	67
		4.0	74	67	80	78
Poa annua (POAAN)	1	1.6	97	-	-	-
	1	2.4	98	-	-	98
	1	3.2	99	-	-	99
	2	4.0	99	98	100	100

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Polygonum aviculare (POLAV)	1	2.4	-	-	-	-
		3.2	99	-	-	100
		4.0	99	-	-	100
Fallopia convolvulus (POLCO)	1	2.4	-	-	-	-
		3.2	85	-	-	87
		4.0	91	-	-	96
Polygonum persicaria (POLPE)	1	2.4	-	-	-	-
		3.2	96	-	-	100
		4.0	98	-	-	99
Rumex obtusifolius (RUMOB)	1	2.4	-	-	-	-
		3.2	7	-	-	9
		4.0	11	-	-	14
Senecio vulgaris (SENVU)	1	2.4	-	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Setaria verticillata (SETVE)	1	2.4	-	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Sonchus asper (SONAS)	1	2.4	-	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Stellaria media (STEME)	3	1.6 - 2.0	97	94	100	89
		2.5	98	96	100	99
		4.0	99	98	100	100
Taraxacum officinale (TAROF)	1	1.6	97	-	-	-
		2.4	100	-	-	99
		4.0	100	-	-	100
Triticum aestivum (TRZAW)	2	1.6	96	96	96	-
		2.4	97	97	97	98
		4.0	98	98	98	99
Veronica persica (VERPE)	2	1.6 - 2.0	91	84	97	86
	1	2.4	-	-	-	-
	2	2.5	98	97	98	99
	1	3.2	100	-	-	100
	3	4.0	100	100	100	100
Veronica arvensis (VERAR)	2	1.6 - 2.0	95	93	97	100
		2.5	97	93	100	99
		4.0	99	97	100	99
Vicia faba subsp. *minor* (VICFM)	1	2.4	-	-	-	-
		3.2	80	-	-	89
		4.0	82	-	-	89
Viola arvensis (VIOAR)	5	1.6 – 2.0	78	66	93	79
	5	2.5	86	72	96	87
	2	3.2	81	66	96	79
	7	4.0	88	75	100	90

Generally the results from the trials demonstrate, that a reduction of the dose rate below 1800 g a.s./ha, equivalent to 4.0 L product/ha will cause a high variability of the weed control achieved. Therefore, 4.0 L /ha HAG 500 02 H is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

Conclusions

A sufficient number of trials were submitted for the maritime EPPO zone and Poland. 4.0 L /ha is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

No trials were carried out in the south-east EPPO zone and no data extrapolation was made. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-002

In total seven trials were conducted in pome fruits (6 trials in apple, one trial in pear) in France (3), Germany (2) and Poland (2) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/90(2), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO Zone and no data extrapolation was made. Climate conditions are not comparable with the maritime EPPO zone. Therefore the results of the maritime EPPO zone cannot be transferred to the south-east EPPO Zone (cMS Hungary, Romania, Slovakia and Slovenia).

Three apple (MABSD) trials were performed in France. Two trials were performed in 2009 and one trial was conducted in 2010. One apple (MABSD) trial and one pear (PYUCO) trial was conducted 2009 in Germany. Two apple (MABSD) trials were carried out in Poland in 2009.

In all trials HAG 500 02 H was tested at the following doses: 1080 g a.s./ha, equivalent to 2.4 L product/ha, 1440 g a.s./ha, equivalent to 3.2 L product/ha and 1800 g a.s./ha, equivalent to 4.0 L product/ha. In the French and German trials performed in 2009 the standard reference product was Roundup Ultra Max (450 g as/L glyphosate) applied at the following doses: 1440 g a.s./ha, equivalent to 3.2 L product/ha, 1800 g a.s./ha, equivalent to 4.0 L product/ha. In the French trials conducted in 2010 the standard reference products were Roundup Flash (450 g as /L glyphosate) applied at the following doses: 1440 g a.s./ha, equivalent to 3.2 L product/ha, Roundup Ultra Max (450 g as /L glyphosate) applied at 1800 g a.s./ha, equivalent to 4.0 L product/ha. In the Polish trials the standard reference product was Roundup 360 SL (360 g as/L glyphosate) applied at the following doses: 1080 g a.s./ha, equivalent to 3.0 L product/ha and 1800 g a.s./ha, equivalent to 5.0 L product/ha.

The reported trials have been conducted in 2009 and 2010. The product HAG 500 02 H was applied on green, intensively growing weeds (10 to 25 cm). In the seven orchard trials 27 weed species were monitored and assessed during 7 to 61 days after application.

Table 6.1.2-2: Effectiveness (%) of decreasing application rate of HAG 500 02 H in pome fruits (Assessment 7-61 DAA). Trials from 2009-2010

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Trifolium arvense (TRFAR)	2	2.4	97	95	98	-
		3.2	94	91	98	97
		4.0	97	96	98	97
Taraxacum officinale (TAROF)	3	2.4	95	90	100	-
		3.2	96	93	99	94
		4.0	96	93	98	98
Gnaphalium uliginosum (GNAUL)	1	2.4	100	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Stellaria media (STEME)	5	2.4	95	90	100	-
		3.2	96	93	100	100
		4.0	98	94	100	97
Elytrigia repens (AGRRE)	1	2.4	97	-	-	-
		3.2	97	-	-	99
		4.0	98	-	-	99
Poa annua (POAAN)	3	2.4	100	100	100	-
		3.2	100	100	100	100
		4.0	100	100	100	100
Poa trivialis (POATR)	2	2.4	100	100	100	-
		3.2	100	100	100	100
		4.0	100	100	100	100
Bellis perennis (BELPE)	1	2.4	93	-	-	-
		3.2	95	-	-	95
		4.0	95	-	-	95
Urtica dioica (URTDI)	1	2.4	62	-	-	-
		3.2	59	-	-	64
		4.0	64	-	-	78
Epilobium adnatum (EPIAD)	2	2.4	35	15	54	-
		3.2	41	20	62	32
		4.0	55	30	80	68
Ranunculus repens (RANRE)	1	2.4	100	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Lamium amplexicaule (LAMAM)	2	2.4	91	91	91	92
		3.2	92	92	92	100
		4.0	98	98	98	100
Galinsoga parviflora (GASPA)	1	2.4	47	-	-	-
		3.2	50	-	-	37
		4.0	52	-	-	47
Cardamine hirsuta (CARHI)	2	2.4	100	100	100	-
		3.2	100	100	100	100
		4.0	100	100	100	100
Senecio vulgaris (SENVU)	3	2.4	95	90	100	-
		3.2	97	94	100	100
		4.0	96	91	100	97
Veronica persica (VERPE)	1	2.4	100	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Geranium dissectum (GERDI)	1	2.4	13	-	-	-
		3.2	16	-	-	15
		4.0	32	-	-	27
Lolium perenne (LOLPE)	1	2.4	51	-	-	-
		3.2	55	-	-	80
		4.0	81	-	-	85
Chenopodium album (CHEAL)	2	2.4	94	91	97	94
		3.2	96	93	99	-
		4.0	98	96	100	97
Polygonum aviculare (POLAV)	1	2.4	93	-	-	95
		3.2	95	-	-	-
		4.0	96	-	-	96
Capsella bursa-pastoris (CAPBP)	2	2.4	99	98	100	98
		3.2	100	99	100	-
		4.0	99	99	100	97
Polygonum convolvulus (POLCO)	1	2.4	91	-	-	94
		3.2	93	-	-	-
		4.0	97	-	-	96
Lamium purpureum (LAMPU)	1	2.4	91	-	-	92
		3.2	92	-	-	-
		4.0	98	-	-	96
Chenopodium poly-spermum (CHEPO)	1	2.4	86	-	-	-
		3.2	96	-	-	88
		4.0	93	-	-	92
Veronica hederifolia (VERHE)	1	2.4	100	-	-	-
		3.2	100	-	-	98
		4.0	100	-	-	100
Mercurialis annua (MERAN)	1	2.4	88	-	-	-
		3.2	90	-	-	91
		4.0	92	-	-	96
Avena sterilis (AVEST)	1	2.4	95	-	-	-
		3.2	100	-	-	95
		4.0	96	-	-	98

Generally the results from these trials demonstrate, that a reduction of the dose rate of HAG 500 02 H below 1800 g a.s./ha, equivalent to 4.0 L product/ha will cause a higher variability of the weed control achieved. The trial results demonstrate that in some trials weed control is clearly inferior at 2.4 L/ha and 3.2 L/ha compared to the target dose rate of 4.0 L HAG 500 02 H/ha. Therefore, 4.0 L/ha HAG 500 02 H is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species. This is confirmed by the long-lasting experience with products containing glyphosate as active substance.

Conclusions

A sufficient number of trials were submitted for the maritime EPPO zone. 4.0 L/ha is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-003
Two trials were conducted in apple in the Germany in 2009 and 2010. All trials were carried out according to EPPO-standard (PP 1/90(2), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone and no data extrapolation was made. Climate conditions are not comparable with the maritime EPPO zone. Therefore the results of the maritime EPPO zone cannot be transferred to the south-east EPPO Zone (cMS Hungary, Romania, Slovakia and Slovenia).

The intended target dose rate of 3600 g a.s./ha HAG 500 02 H, equivalent to 8 L product/ha was the highest dose rate tested. Additionally two lower dose rates of HAG 500 02 H like 3600 g a.s./ha were tested in the trial. The lowest dose rate of HAG 500 02 H was 2160 g a.s./ha, equivalent to 4.8 L product/ha. The second lowest dose rate was 2880 g a.s./ha, equivalent to 6.4 L product/ha of HAG 500 02 H. The standard reference product was Roundup Ultra Max (450 g as/L glyphosate) applied at a dose rate of 2880 g a.s./ha, equivalent to 6.4 L product/ha. The product HAG 500 02 H was applied once when CONAR had developed sufficient leaves for uptake of glyphosate, at 10 – 25 cm weed height.

Data related to the minimum effective dose tests is given in Table 6.1.2-3.

Table 6.1.2-3: Effectiveness (%) of decreasing application rate of HAG 500 02 H in orchards-pome fruits (assessment 28-31 DAA). Trials from 2009-2010

Weed species	**n**	**HAG 500 02 H (L/ha)**	**mean**	**min**	**max**	**Reference product mean**
Convolvulus arvensis (CONAR)	2	4.8	80	68	93	-
		6.4	87	80	94	91
		8.0	93	93	94	-

The trials showed the best control against *Convolvulus arvensis* (CONAR) when HAG 500 02 H was applied at 3600 g a.s./ha, equivalent to 8.0 L/ha in comparison to the two lower doses 2880 g a.s./ha, equivalent to 4.8 L/ha and 2160 g a.s./ha, equivalent to 6.4 L/ha. See also results from intended use 005.

Conclusions

A sufficient number of trials were submitted for the maritime EPPO zone. 4.0 L /ha is considered to be the lowest dose rate providing reliable control of CONAR.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-004

A total of four trials were conducted in grapes in France (3) and Germany (1) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/64(3), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone and no data extrapolation was made. Climate conditions are not comparable with the maritime EPPO zone. Therefore the results of the maritime EPPO zone cannot be transferred to the south-east EPPO zone (cMS Hungary, Romania, Slovakia and Slovenia).

The intended target dose rate of HAG 500 02 H was 1800 g a.s./ha, equivalent to 4.0 L product/ha. Two lower dose rates of HAG 500 02 H than 1800 g a.s./ha were tested in all conducted efficacy trials. The lowest dose rate of HAG 500 02 H was 1080 g a.s./ha, equivalent to 2.4 L product/ha. The second lowest dose rate was 1440 g a.s./ha HAG 500 02 H, equivalent to 3.2 L product/ha.
In all trials conducted in 2009 the standard reference product was Roundup Ultra Max (450 g as/L glyphosate) applied at the following doses: 1440 g a.s./ha equivalent to 3.2 L product/ha, 1800 g a.s./ha, equivalent to 4.0 L product/ha. In the French trial conducted in 2010 the commercial standard reference products were Roundup Flash (450 g as/L glyphosate) applied at the following doses: 1440 g a.s./ha equivalent to 3.2 L product/ha, Roundup Ultra Max (450 g as/L glyphosate) applied at 1800 g a.s./ha, equivalent to 4.0 L product/ha. The product HAG 500 02 H was applied once from 10 – 20 cm weed height onwards by spraying.

In the four grape trials 16 different weed species were monitored and assessed during 7 to 61 days after application. Data related to the minimum effective dose tests is given in Table 6.1.2-4.

Table 6.1.2-4: Effectiveness (%) of decreasing application rate of HAG 500 02 H in grape (assessment 7-61 DAA). Trials from 2009-2010

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Capsella bursa-pastoris (CAPBP)	2	2.4	92	89	95	-
		3.2	93	92	94	97
		4.0	98	97	99	98
Stellaria media (STEME)	2	2.4	99	98	100	-
		3.2	98	96	100	99
		4.0	99	99	100	99
Cirsium arvense (CIRAR)	1	2.4	59	-	-	-
		3.2	72	-	-	84
		4.0	71	-	-	85
Taraxacum officinale (TAROF)	3	2.4	61	49	72	-
		3.2	66	59	72	66
		4.0	73	64	82	67
Lamium purpureum (LAMPU)	3	2.4	99	98	100	-
		3.2	98	97	100	99
		4.0	99	99	100	99

Weed species	**n**	**HAG 500 02 H (L/ha)**	**mean**	**min**	**max**	**Reference product mean**
Fumaria officinalis (FUMOF)	1	2.4	100	-	-	-
		3.2	98,0	-	-	99
		4.0	100	-	-	100
Geranium molle (GERMO)	1	2.4	100	-	-	-
		3.2	98,0	-	-	100
		4.0	100	-	-	100
Hordeum murinum (HORMU)	1	2.4	97,0	-	-	-
		3.2	98	-	-	98
		4.0	98	-	-	97
Geranium dissectum (GERDI)	2	2.4	14	0	27	-
		3.2	16	0	32	16
		4.0	40	0	80	32
Veronica persica (VERPE)	2	2.4	100	100	100	-
		3.2	93	87	100	100
		4.0	99	97	100	100
Festuca sp. (FESSS)	1	2.4	0	-	-	-
		3.2	0	-	-	0
		4.0	0	-	-	0
Picris hieracioides (PICHI)	1	2.4	100	-	-	-
		3.2	100	-	-	100
		4.0	100	-	-	100
Erodium cicutarium (EROCI)	1	2.4	70	-	-	-
		3.2	80	-	-	82
		4.0	90	-	-	97
Lolium multiflorum (LOLMU)	1	2.4	45	-	-	-
		3.2	50	-	-	57
		4.0	61	-	-	62
Erigeron annuus (ERIAN)	1	2.4	76	-	-	-
		3.2	65	-	-	77
		4.0	65	-	-	82
Caucalis lappula (CUCLA)	1	2.4	26	-	-	-
		3.2	30	-	-	36
		4.0	29	-	-	35

Generally the results from these trials demonstrate that reducing the dose rate of HAG 500 02 H below 1800 g a.s./ha will cause a higher variability of the weed control achieved. Therefore, 4.0 L/ha HAG 500 02 H is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

Conclusions

A sufficient number of trials were submitted for the maritime EPPO zone. 4.0 L /ha is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-005

Two trials were conducted in grape in the Germany in 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/64(3), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone.

The intended target dose rate of 3600 g a.s./ha HAG 500 02 H, equivalent to 8 L product/ha was the highest tested dose rate. Additionally two lower dose rates of HAG 500 02 H like3600 g a.s./ha were tested in the trials. The lowest dose rate of HAG 500 02 H was 2160 g a.s./ha, equivalent to 4.8 L product/ha. The second lowest dose rate was 2880 g a.s./ha equivalent to 6.4 L product/ha of HAG 500 02 H. The standard reference product was Roundup Ultra Max (450 g as/L glyphosate) applied at a dose rate of 2880 g a.s./ha equivalent to 6.4 L product/ha. The product HAG 500 02 H was applied once when CONAR had developed sufficient leaves for uptake of glyphosate, at 10-25 cm weed height.

Data related to the minimum effective dose tests is given in Table 6.1.2-5.

Table 6.1.2-5: Effectiveness (%) of decreasing application rate of HAG 500 02 H in grape (assessment 29-33 DAA). Trials from 2009-2010

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Convolvulus arvensis (CONAR)	2	4.8	86	83	90	-
		6.4	81	74	87	93
		8.0	91	90	92	-

Both trials showed the best control against *Convolvulus arvensis* (CONAR) if HAG 500 02 H was applied at 3600 g a.s./ha, equivalent to 8.0 L/ha compared to the two lower dosages of 2880 g a.s./ha, equivalent to 4.8 L/ha and 2160 g a.s./ha, equivalent to 6.4 L/ha. See also results from intended use 003.

<u>Conclusions</u>

A sufficient number of trials were submitted for the maritime EPPO zone. 4.0 L /ha is considered to be the lowest dose rate providing reliable control of a CONAR.
No trials were carried out in the south-east zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-006

Desiccation

There were no trials conducted regarding the minimum effective dose test desiccation in TRZAW, TRZAS, HORVS, TTLSO, HORVW and TTLWI. The applicant state that trials are not required due to the long-lasting experience with the active substance glyphosate. It is pointed out that from earlier experience it is known, that 1125 g a.s./ha, equivalent to 2.5 L product/ha is the minimum effective dose desiccation. Experimental results are required for the maritime and south-east EPPO zone.

Weed control

For weed control in total 16 trials were conducted in winter cereals in Poland (6), Germany (6), France (3) and UK (1) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/93(2), PP 1/152(3), PP 1/181(3)) and GEP.
Four trials were performed in winter wheat (TRZAW), one trial in winter barley (HORVW) and one trial in winter triticale (TTLWI) in Poland in 2009. Two trials were conducted in winter wheat (TRZAW) in Germany in 2009. Two trials were performed in winter wheat (TRZAW) in Germany in 2010. One trial was performed in winter barley (HORVW) in Germany in 2009 and one trial was conducted in winter barley (HORVW) in 2010. One trial was performed in winter wheat (TRZAW) in France in 2009 and one trial was conducted in winter wheat (TRZAW) in France in 2010. One trial was performed in winter barley (HORVW) in France in 2010. One trial was performed in winter wheat (TRZAW) in UK in 2009.

The intended target dose rate of HAG 500 02 H of 1800 g a.s./ha, equivalent to 4.0 L product/ha was tested in all of the 16 trials. Rating was done 14 – 34 days after application.

Table 6.1.2-6: Effectiveness (%) of decreasing application rate of HAG 500 02 H before crop harvest (assessment 14-34 DAA). Trials from 2009-2010

Weed species	n	DAA	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Elytrigia repens (AGRRE)	10	20-34	1.5 – 2.0	72	12	99	-
			2.5 – 3.2	76	21	100	75 - 81
			4.0	83	37	100	79
Apera spica-venti (APESV)	4	14	1.5	69	60	80	72
			2.5 – 3.2	89	84	97	90- 93
			4.0	96	91	100	98
Capsella bursa-pastoris (CAPBP)	2	14	1.5	78	57	98	81
			3.2	95	90	100	95
			4.0	100	100	100	100
Chenopodium album (CHEAL)	2	14	1.5	82	65	98	81
			3.2	96	91	100	96
			4.0	97	95	100	98
Cirsium arvense (CIRAR)	2	20	2.0	22	12	32	31
			3.2	34	21	46	56
			4.0	44	34	54	42
Cynodon dactylon (CYNDA)	1	14	2.0	22	-	-	56
			3.2	54	-	-	79
			4.0	54	-	-	77
Echinochloa crus-	1		1.5	80	-	-	81

Weed species	n	DAA	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
galli (ECHCG)		14	3.2	100	-	-	100
			4.0	100	-	-	100
Galium aparine (GALAP)	2	14	1.5	75	51	99	75
			3.2	92	85	100	93
			4.0	99	97	100	99
Galinsoga parviflora (GASPA)	1	14	1.5	82	-	-	82
			3.2	100	-	-	100
			4.0	100	-	-	100
Geranium pusillum (GERPU)	1	14	1.5	81	-	-	77
			3.2	100	-	-	99
			4.0	100	-	-	100
Lamium purpureum (LAMPU)	1	14	1.5	60	-	-	62
			3.2	89	-	-	92
			4.0	100	-	-	100
Matricaria inodora (MATIN)	2	14	1.5	82	65	100	84
			3.2	92	84	100	87
			4.0	98	96	100	100
Papaver rhoeas (PAPRH)	3	14	1.5	71	60	77	75
			3.2	88	86	90	90
			4.0	99	99	100	98
Fallopia convolvulus (POLCO)	2	14	1.5	74	63	84	87
			3.2	89	82	95	93
			4.0	98	97	99	99
Stellaria media (STEME)	2	14	1.5	83	60	100	87
			3.2	92	80	100	92
			4.0	95	90	100	97
Veronica arvensis (VERAR)	1	24	1.5	85	-	-	84
			3.2	100	-	-	100
			4.0	100	-	-	100
Veronica persica (VERPE)	1	14	1.5	61	-	-	62
			2.5	77	-	-	82
			4.0	95	-	-	97
Veronica triphyllos (VERTR)	1	14	1.5	80	-	-	82
			2.5	87	-	-	90
			4.0	94	-	-	94
Viola arvensis (VIOAR)	5	14	1.5	75	62	89	75
			3.2	90	82	99	93
			4.0	97	94	100	98

Generally the results from the trials demonstrate, that a reduction of the dose rate below 1800 g a.s./ha, equivalent to 4.0 L product/ha will cause a high variability of the weed control achieved. The trial results demonstrate that for different weed species the control is clearly inferior at 1.5 L/ha, 2.0 L/ha as well as 2.5 L/ha compared to the control at the target dose rate of 4.0 L HAG 500 02 H/ha. In some trials HAG500 02 H applied at 3.2 L/ha reached a comparable weed control than the target dose of 4.0 L/ha HAG 500 02 H. In these cases HAG 500 02 H applied at the target dose of 4.0 L reached at the first assessment dates in the first crop mostly higher results than HAG 500 02 H applied at 3.2 L.

For the weed species *Elytrigia repens* (AGRRE), *Stellaria media* (STEME) and *Cirsium arvense* (CIRAR) the target dose of 4.0 L HAG 500 02 H/ha reached the highest weed control.
Therefore, 4.0 L/ha HAG 500 02 H is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species. This is confirmed by the long-lasting experience with products containing glyphosate as active substance.

<u>Conclusions</u>
Desiccation
No trials were submitted for desiccation. The applicant is asked to submit a sufficient number of trials according to EPPO standard PP 1/226 (1).

The applicant suggests that the efficiency of desiccation is independent of climate differences which exist between EPPO climate zones. Furthermore the applicant claims that the results from Poland can be transferred to the other climate zones without limitation. Further trials will not be carried out.

Weed control
For weed control a sufficient number of trials were submitted for the maritime EPPO zone. 4.0 L /ha is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-007
In total six trials were conducted in grass land renewal UK (4) and Germany (2) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/94(3), PP 1/152(3)) and GEP. No trials were carried out in the south-east EPPO zone and no data extrapolation was made. Climate conditions are not comparable with the maritime EPPO zone. Therefore the results of the maritime EPPO zone cannot be transferred to the south-east EPPO zone (cMS Hungary, Romania, Slovakia and Slovenia).

In all trials HAG 500 02 H was tested at the following doses 900 g a.s./ha, equivalent to 2.0 L product/ha, 1440 g a.s./ha, equivalent to 3.2 L product/ha and 1800 g a.s./ha, equivalent to 4.0 L product/ha.
In the UK trials the standard reference products were Roundup Energy (450 g as/L glyphosate) applied at the dose rates of 1080 g a.s./ha, equivalent to 2.4 L product/ha, 1440 g a.s./ha, equivalent to 3.2 L product/ha and Roundup Ultra Max (450 g as/L glyphosate) applied at 1800 g a.s./ha, equivalent to 4.0 L product/ha. In the German trials the standard reference product was Roundup Ultra Max (450 g as/L glyphosate) applied at the following doses: 1080 g a.s./ha, equivalent to 2.4 L product/ha, 1440 g a.s./ha, equivalent to 3.2 L product/ha and 1800 g a.s./ha, equivalent to 4.0 L product/ha.

The reported trials have been conducted in 2009 and 2010. The product HAG 500 02 H was applied once on green, intensively growing weeds and grass plants (>10 cm) before sowing.

17 different weed species were monitored and assessed during 7 to 253 days after application. Data relating to the minimum effective dose tests for each trial are given in table 6.1.2-7.

Table 6.1.2-7: Effectiveness (%) of decreasing application rate of HAG 500 02 H in grassland (assessment 21-84 DAA). Trials from 2009-2010

Weed species	n	DAA	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Trifolium arvense (TRFAR)	2	24	2.0	39	16	61	42
			3.2	46	14	78	51
			4.0	55	24	78	54
Taraxacum officinale (TAROF)	2	24	2.0	39	12	65	40
			3.2	45	15	75	50
			4.0	51	19	82	55
Ranunculus repens (RANRE)	2	52	2.0	27	19	34	45
			3.2	37	22	52	53
			4.0	49	25	72	55
Cerastium fontanum (CERFO)	1	84	2.0	80	-	-	93
			3.2	95	-	-	96
			4.0	22	-	-	98
Stellaria media (STEME)	1	84	2.0	80	-	-	94
			3.2	95	-	-	97
			4.0	96	-	-	98
Plantago lanceolata (PLALA)	1	24	2.0	64	-	-	66
			3.2	80	-	-	87
			4.0	92	-	-	96
Rumex acetosa (RUMAC)	2	24	2.0	47	42	52	50
			3.2	60	49	71	65
			4.0	66	55	78	69
Poa annua (POAAN)	1	24	2.0	99	-	-	99
			3.2	99	-	-	99
			4.0	99	-	-	99
Plantago mayor (PLAMA)	1	24	2.0	51	-	-	55
			3.2	52	-	-	60
			4.0	57	-	-	72
Sisymbrium officinale (SSYOF)	1	24	2.0	45	-	-	60
			3.2	45	-	-	60
			4.0	60	-	-	62
Cerastium arvense (CERAR)	1	24	2.0	82	-	-	87
			3.2	85	-	-	90
			4.0	80	-	-	87
Grassland (NNNFW)	2	24	2.0	39	7	70	42
			3.2	41	9	72	46
			4.0	42	9	75	41
Urtica urens (URTUR)	1	24	2.0	22	-	-	50
			3.2	35	-	-	50
			4.0	42	-	-	47
Lolium perenne	2		2.0	89	80	99	91

Weed species	n	DAA	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
(LOLPE)		24	3.2	92	85	99	94
			4.0	96	92	99	95

The trial results demonstrate that in some trials weed control is clearly inferior at 2.4 L/ha and 3.2 L/ha compared to the target dose rate of 4.0 L HAG 500 02 H/ha. Therefore, 4.0 L/ha HAG 500 02 H is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species. This is confirmed by the long-lasting experience with products containing glyphosate as active substance.

Generally the results from the trials demonstrate, that a reduction of the dose rate of HAG 500 02 H below 1800 g a.s./ha, equivalent to 4.0 L product/ha will cause a higher variability of the weed control achieved. Therefore, 4.0 L /ha HAG 500 02 H is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

Conclusions
A sufficient number of trials were submitted for the maritime EPPO zone. 4.0 L /ha is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-008
No results were submitted. Experimental results are required for the maritime and south-east EPPO zone.
There were no trials conducted regarding the minimum effective dose test desiccation in BSRNW. The applicant stated this is due to the long-lasting experience with the active substance glyphosate. From this experience it is known, that 1125 g a.s./ha, equivalent to 2.5 L product/ha is the minimum effective dose desiccation. These statements are generally not sufficient for evaluation.

Conclusions
No data were submitted.

The applicant claims: The registration for desiccation of winter oil seed rape will not be pursued in Germany, but in the other MS.

Intended use: 007385-00/00-009
No results were submitted.
The applicant explain that the use ‘pre-emergence oilseed rape’ is dealing with similar cultivation conditions e.g. regarding row spacing as the use ‘pre-emergence sugar beet’ and

thus with comparable species of mono- and dicotyledonous weeds. Therefore, the applicant argued that all data reported and all information given under efficacy test ‘pre-emergence sugar beet - mono- and dicotyledonous weeds’ also applies for the use ‘pre-emergence oilseed rape’. The higher dosage (1125 g/ha as, equivalent to 2.5 L/ha product) applied for in the use ‘pre-emergence oilseed rape’ is based on the assumption of higher infestation intensities of weeds in winter oilseed rape. The date of application and the weed flora in sugar beet and oilseed rape is not comparable. Therefore additional experimental results are required.

For sugar beet the applicant explain: There were no trials conducted regarding the minimum effective dose test for pre-emergence in sugar beet. These are not required due to the long-lasting experience as well as published literature for the active substance glyphosate. From earlier experience it is known, that 720 g a.s./ha, equivalent to 1.6 L product/ha is the minimum effective dose for a reliable control of many weed species in pre-emergence of sugar beet.

Conclusions
No data were submitted.

The applicant has requested a limitation for the intended use. After that an application should not be made in winter rape for seed production. From the zRMS`s point of view this limitation is not necessarily needed, because the herbicide will not have any contact with seeds or rape plants after application.

The applicant claims: The registration for pre-emergent weed control in oilseed rape will not be pursued in Germany but in the other MS.

Intended use: Sugar beet
For sugar beet the applicant explains: There were no trials conducted regarding the minimum effective dose test for pre-emergence in sugar beet. These are not required due to the long-lasting experience as well as published literature for the active substance glyphosate. From earlier experience it is known, that 720 g a.s./ha, equivalent to 1.6 L product/ha is the minimum effective dose for a reliable control of many weed species in pre-emergence of sugar beet.

Conclusions
No data were submitted. Studies according to EPPO standard PP 1/225 are required.

Intended use: Stone fruit
There were no trials conducted regarding the minimum effective dose in stone fruits. The use ‘orchards stone fruit’ is dealing with the similar weed species and cultivation conditions as the use ‘orchards pome fruit’ - mono- and dicotyledonous weeds. Therefore, all data reported and all information given under minimum effective dose tests – ‘orchards pome fruit - mono- and dicotyledonous weeds’ also applies for the use ‘orchards stone fruit’.

Conclusions
A sufficient number of trials were submitted for the maritime EPPO zone for pome fruits. 4.0 L/ha is considered to be the lowest dose rate providing reliable control of a broad spectrum of weed species. The results can be transferred to stone fruits.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Intended use: Peas (pre-harvest for weed control and desiccation) and winter rape (pre-harvest for desiccation)

Desiccation
There were no trials conducted regarding the minimum effective dose test desiccation in peas and winter rape. Experimental results are required for the maritime and south-east EPPO zone according EPPO standard.

Weed control
Results were submitted with a dose rate of 2.5 and 4.0 L/ha. Experiments with dose rates below the requested dose rate were not carried out. Experimental results according EPPO standard PP 1/225 are required for the maritime and south-east EPPO zone.

Conclusions

Desiccation
No data were submitted. Studies according to EPPO standard PP 1/225 are required.

Weed control
No data were submitted with dose rates below the requested dose rate. Experimental results according EPPO standard PP 1/225 are required for the maritime and south-east EPPO zone.

IIIA1 6.1.3 Efficacy tests

Intended use: 007385-00/00-001

In total 26 trials were conducted in stubbles in UK (8), Germany (7), France (9) and Poland (2) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/98(2), PP 1/152(3), PP 1/181(3)) and GEP. Weed occurrence and cropping systems are comparable between Germany and Poland. Therefore the results of efficacy tests can be considered for the assessment. No trials were carried out in the south-east EPPO zone and no data extrapolation was made. Climate conditions are not comparable with the maritime EPPO zone. Therefore the results of the maritime EPPO zone cannot be transferred to the south-east EPPO zone (cMS Hungary, Romania, Slovakia and Slovenia).

Table 6.1.3-1: Effectiveness (%) of 4.0 L/ha (HAG 500 02 H) in stubble (assessment 22-44 DAA). Trials from 2009-2010

Weed species	n	mean	min	max	Reference product mean
Agrostis stolonifera (AGSST)	1	100	-	-	100
Elytrigia repens (AGRRE)	3	92	84	98	92
Alopecurus myosuroides (ALOMY)	3	100	100	100	100
Amaranthus retroflexus (AMARE)	1	100	-	-	100
Avena ludoviciana (AVELU)	1	88	-	-	89
Brassica napus (BRSNN)	2	96	-	-	96
Brassica napus (BRSNW)	3	97	91	100	96
Chenopodium album (CHEAL)	2	95	91	99	97
Cirsium arvense (CIRAR)	3	100	100	100	100

Weed species	n	mean	min	max	Reference product mean
Cirsium vulgare (CIRVU)	1	100	-	-	100
Convolvulus arvensis (CONAR)	2	47	13	81	61
Echinochloa crus-galli (ECHCG)	3	91	72	100	92
Geranium molle (GERMO)	1	92	-	-	91
Hordeum vulgare (HORVW)	1	100	-	-	100
Lamium purpureum (LAMPU)	2	100	100	100	100
Matricaria recutita (MATCH)	1	100	-	-	100
Mercurialis annua (MERAN)	2	74	67	80	78
Poa annua (POAAN)	2	99	98	100	100
Polygonum aviculare (POLAV)	1	99	-	-	100
Fallopia convolvulus (POLCO)	1	91	-	-	96
Polygonum persicaria (POLPE)	1	98	-	-	99
Rumex obtusifolius (RUMOB)	1	11	-	-	14
Senecio vulgaris (SENVU)	1	100	-	-	100
Setaria verticillata (SETVE)	1	100	-	-	100
Sonchus asper (SONAS)	1	100	-	-	100
Stellaria media (STEME)	3	99	98	100	100
Taraxacum officinale (TAROF)	1	100	-	-	100
Triticum aestivum (TRZAW)	2	98	98	98	99
Veronica persica (VERPE)	3	100	100	100	100
Veronica arvensis (VERAR)	2	99	97	100	99
Vicia faba subsp. *minor* (VICFM)	1	82	-	-	89
Viola arvensis (VIOAR)	7	88	75	100	90

In general HAG 500 02 H demonstrated a good level of effectiveness against different weed species present in the trials similar to that of the country specific standard reference products.

Conclusions

A sufficient number of trials were submitted for the maritime EPPO zone. The effectiveness is demonstrated with an application rate of 4.0 L /ha.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.
The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-002

In total seven trials were conducted in pome fruits (six trials in apple and one trial in pear) in France (3), Germany (2) and Poland (2) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/90(2), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone.
The intended target dose rate of 1800 g a.s./ha HAG 500 02 H was tested in all trials in comparison to a standard reference products relevant in the different countries.

Table 6.1.3-2: Effectiveness (%) of 4.0 L/ha (HAG 500 02 H) in pome fruits (assessment 28-60 DAA). Trials from 2009-2010

Weed species	**n**	**HAG 500 02 H**			**Reference product**		
		mean	**min**	**max**	**mean**	**min**	**max**
Trifolium arvense (TRFAR)	2	97	96	98	97	94	99
Taraxacum officinale (TAROF)	3	96	93	98	98	97	99
Gnaphalium uliginosum (GNAUL)	1	100	-	-	100	-	-
Stellaria media (STEME)	5	98	94	100	97	91	100
Elytrigia repens (AGRRE)	1	98	-	-	99	-	-
Poa annua (POAAN)	3	100	100	100	100	100	100
Poa trivialis (POATR)	2	100	100	100	100	100	100
Bellis perennis (BELPE)	1	95	-	-	95	-	-
Urtica dioica (URTDI)	1	64	-	-	78	-	-
Epilobium adnatum (EPIAD)	2	55	30	80	68	45	92
Ranunculus repens (RANRE)	1	100	-	-	100	-	-
Lamium amplexicaule (LAMAM)	2	98	98	98	100	99	100

Galinsoga parviflora (GASPA)	1	53	-	-	47	-	-
Cardamine hirsuta (CARHI)	2	100	100	100	100	100	100
Senecio vulgaris (SENVU)	3	96	91	100	97	95	100
Veronica persica (VERPE)	1	100	-	-	100	-	-
Geranium dissectum (GERDI)	1	32	-	-	27	-	-
Lolium perenne (LOLPE)	1	81	-	-	85	-	-
Chenopodium album (CHEAL)	2	98	96	100	97	96	99
Polygonum aviculare (POLAV)	1	96	-	-	96	-	-
Capsella bursa-pastoris (CAPBP)	2	99	99	100	97	96	98
Polygonum convolvulus (POLCO)	1	97	-	-	96	-	-
Lamium purpureum (LAMPU)	1	98	-	-	96	-	-
Chenopodium poly-spermum (CHEPO)	1	93	-	-	92	-	-
Veronica hederifolia (VERHE)	1	100	-	-	100	-	-
Mercurialis annua (MERAN)	1	92	-	-	96	-	-
Avena sterilis (AVEST)	1	96	-	-	98	-	-

In summary HAG 500 02 H demonstrated a good level of efficacy against different weed species present in the trials similar to that of the country specific standard reference products.

Conclusions

A sufficient number of trials were submitted for the countries of the maritime EPPO zone. The effectiveness is demonstrated with an application rate of 4.0 L /ha.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-003

Two trials were conducted in apple in the Germany 2009 and 2010. No trials were carried out in the south-east EPPO zone.

The intended target dose rate of 3600 g a.s./ha HAG 500 02 H, equivalent to 8.0 L product/ha was tested in the trial in comparison to the standard product Roundup Ultra Max applied at 2880 g a.s./ha, equivalent to 6.4 L product/ha.

Table 6.1.3-3: Effectiveness (%) of HAG 500 02 H (8.0 L/ha) in orchards – pome fruits (assessment 28-31 DAA). Trials from 2009-2010

Weed species	n	HAG 500 02 H (L/ha)	mean	min	max	Reference product mean
Convolvulus arvensis (CONAR)	2	8.0	93	92	94	91

Overall, HAG 500 02 H demonstrated a good level of efficacy against CONAR in the trials similar to that of the country specific standard reference products.
See also results from intended use 005.

<u>Conclusions</u>
A sufficient number of trials were submitted for the countries of the maritime zone. The effectiveness is demonstrated with an application rate of 8 L /ha. According to general experiences, efficacy against CONAR is well known for the maritime EPPO climate zone.

No trials were carried out in the south-east EPPO zone.

The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-004
In total four trials in grape were conducted in 2009 to 2010 in France (3) and Germany (1). All trials were carried out according to EPPO-standards (PP 1/64(3), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone and no data extrapolation was made. Climate conditions are not comparable with the maritime EPPO zone. Therefore the results of the maritime zone cannot be transferred to the south-east EPPO zone (cMS Hungary, Romania, Slovakia and Slovenia).

The intended target dose rate of 1800 g a.s./ha HAG 500 02 H was tested in all trials in comparison to a standard reference products relevant in the different countries.

Table 6.1.3-4: Effectiveness (%) of 4.0 L/ha (HAG 500 02 H) in grape (assessment 7-61 DAA). Trials from 2009-2010

Weed species	n	HAG 500 02 H			Reference product		
		mean	min	max	mean	min	max
Capsella bursa-pastoris (CAPBP)	2	98	97	99	98	98	99
Stellaria media (STEME)	2	99	99	100	99	99	100
Cirsium arvense (CIRAR)	1	71	-	-	85	-	-
Taraxacum officinale (TAROF)	3	73	64	82	67	55	80

Lamium purpureum (LAMPU)	3	99	99	100	99	98	100
Fumaria officinalis (FUMOF)	1	100	-	-	100	-	-
Geranium molle (GERMO)	1	100	-	-	100	-	-
Hordeum murinum (HORMU)	1	98	-	-	97	-	-
Geranium dissectum (GERDI)	2	40	0	80	32	4	60
Veronica persica (VERPE)	2	99	97	100	100	100	100
Festuca sp. (FESSS)	1	0	-	-	0	-	-
Picris hieracioides (PICHI)	1	100	-	-	100	-	-
Erodium cicutarium (EROCI)	1	90	-	-	97	-	-
Lolium multiflorum (LOLMU)	1	61	-	-	62	-	-
Erigeron annuus (ERIAN)	1	65	-	-	82	-	-
Caucalis lappula (CUCLA)	1	29	-	-	35	-	-

Overall, HAG 500 02 H demonstrated a level of efficacy against different weed species present in the trials similar to that of the country specific standard reference products.

Conclusions

A sufficient number of trials were submitted for the countries of the maritime EPPO zone. The effectiveness is demonstrated with an application rate of 4.0 L /ha.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-005

Two trials were conducted in grape in Germany and France 2009. All trials were carried out according to EPPO-standards (PP 1/64(3), PP 1/152(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone.

The intended target dose rate of 3600 g a.s./ha HAG 500 02 H, equivalent to 8.0 L product/ was tested in the trial in comparison to the commercial standard product Roundup Ultra Max applied at 2880 g a.s./ha, equivalent to 6.4 L product/ha.

In the German trial HAG 500 02 H applied at 3600 g a.s./ha has shown sufficient control (92 to 93%) against CONAR, 14 to 56 days after application, slightly lower than Roundup Ultra Max applied at 2880 g a.s./ha but with no statistically significant differences. In the French trial HAG 500 02 H applied at 3600 g a.s./ha has shown sufficient control (90%) against CONAR, 33 days after application comparable to Roundup Ultra Max applied at 2880 g a.s./ha.

Table 6.1.3-5: Effectiveness (%) of HAG 500 02 H (8.0 L/ha) in grape (assessment 28-31 DAA). Trials from 2009

Weed species	**n**	**HAG 500 02 H**			**Reference product**		
		mean	**min**	**max**	**mean**	**min**	**max**
Convolvulus arvensis (CONAR)	2	91	90	92	93	91	94

See also results from intended use 003.

<u>Conclusions</u>
A sufficient number of trials were submitted for the countries of the maritime EPPO zone. The effectiveness is demonstrated with an application rate of 8.0 L /ha.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-006
<u>Desiccation in absence of weeds:</u>
In total 21 trials were conducted in cereals in Poland in 2009. Three trials were performed in winter barley, four trials in spring barley, four trials in winter triticale, three trials in spring wheat, four trials in winter wheat and three trials in spring triticale. All trials were carried out according to EPPO-standards (PP 1/93(2), PP 1/152(3), PP 1/181(3)) and GEP. Weed occurrence and cropping systems are comparable between Germany and Poland. Therefore the results of efficacy tests can be considered for the assessment. No trials were carried out in the maritime and south-east EPPO zone.

The trials in cereals (TRZAS, HORVS, TTLSO, HORVW, TTLWI) were carried out with a dose rate of 2.5 L/ha and 5.0 L/ha, but not with the intended dose rate of 4.0 L/ha. The trials in winter wheat (TRZAW) were carried out with a dose rate of 3.2 L/ha and 6.4 L/ha.

In all trials HAG 500 02 H was applied once at BBCH 89 (fully ripe and hard grain, difficult to divide with thumbnail), 14 days before harvest in absence of weeds.
The trial results demonstrate that HAG 500 02 H is for the use dessiccation in TRZAW, TRZAS, HORVS, TTLSO, HORVW and TTLWI as a pre-harvest treatment can be considered as a harvesting aid.

Generally HAG 500 02 H applied at 1125 g a.s./ha in TRZAS, HORVS, TTLSO, HORVW, TTLWI, equivalent to 2.5 L product/ha showed the same accelerated crop ripening process than the double dose of HAG 500 02 H applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha.

HAG 500 02 H applied at 1440 g a.s./ha in TRZAW, equivalent to 3.2 L product/ha showed the same accelerated crop ripening process than the double dose of HAG 500 02 H applied at 2880 g a.s./ha, equivalent to 6.4 L product/ha.

For desiccation in absence of weeds a dose rate of 1125 g a.s./ha in TRZAS, HORVS, TTLSO, HORVW, TTLWI, equivalent to 2.5 L product/ha and of 1440 g a.s./ha in TRZAW, equivalent to 3.2 L product/ha is sufficient for efficacy.

Conclusions

Trials were carried out for one year in Poland. The efficacy is demonstrated with an application rate of 4.0 L /ha. Poland does not belong to the maritime or south east EPPO zone. The results from Poland can be used as supporting data for the countries of the maritime EPPO zone. But it is essential to have results from the requested zone, but according to general experiences, efficacy is well known for the maritime EPPO climate zone.

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To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO guideline PP 1/226(1)). No trials were carried out in the maritime EPPO zone and in the south-east EPPO zone.

Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant suggests that the efficiency of desiccation is independent of climate differences which exist between EPPO climate zones. Furthermore the applicant claims that the results from Poland can be transferred to the other climate zones without limitation. Further trials will not be carried out.

Weed control:

In total 16 trials were conducted in winter cereals in Poland (6), Germany (6), France (3) and UK (1) in the years 2009 and 2010. All trials were carried out according to EPPO-standards (PP 1/93(2), PP 1/152(3), PP 1/181(3)) and GEP.

Table 6.1.3-6: Effectiveness (%) of 4.0 L/ha (HAG 500 02 H) before crop harvest (assessment 14-34 DAA). Trials from 2009-2010

Weed species	**n**	**DAA**	**mean**	**min**	**max**	**Reference product mean**
Elytrigia repens (AGRRE)	10	20-34	83	37	100	79
Apera spica-venti (APESV)	4	14	96	91	100	98
Capsella bursa-pastoris (CAPBP)	2	14	100	100	100	100
Chenopodium album (CHEAL)	2	14	97	95	100	98
Cirsium arvense (CIRAR)	2	20	44	34	54	42
Cynodon dactylon (CYNDA)	1	14	54	-	-	77

Weed species	n	DAA	mean	min	max	Reference product mean
Echinochloa crus-galli, (ECHCG)	1	14	100	-	-	100
Galium aparine (GA-LAP)	2	14	99	97	100	99
Galinsoga parviflora (GASPA)	1	14	100	-	-	100
Geranium pusillum (GERPU)	1	14	100	-	-	100
Lamium purpureum (LAMPU)	1	14	100	-	-	100
Matricaria inodora (MATIN)	2	14	98	96	100	100
Papaver rhoeas (PAPRH)	3	14	99	99	100	98
Fallopia convolvulus (POLCO)	2	14	98	97	99	99
Stellaria media (STEME)	2	14	95	90	100	97
Veronica arvensis (VERAR)	1	24	100	-	-	100
Veronica persica (VERPE)	1	14	95	-	-	97
Veronica triphyllos (VERTR)	1	14	94	-	-	94
Viola arvensis (VIOAR)	5	14	97	94	100	98

In general HAG 500 02 H demonstrated a level of efficacy against different weed species present in the trials similar to that of the commercial country-specific standard reference products in the first crop, the following agricultural land till and the following crop.

Conclusions

A sufficient number of trials were submitted for the maritime EPPO zone and Poland. The effectiveness is demonstrated with an application rate of 4.0 L /ha.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.
The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-007

In total six trials were conducted in grass land renewal in UK (4) and Germany (2) in the years 2009 to 2010. All trials were carried out according to EPPO-standards (PP 1/94(3), PP 1/152(3), PP 1/118 (3)) and GEP. No trials were carried out in the south-east EPPO zone.
The intended target dose rate of 1800 g a.s./ha HAG 500 02 H was tested in all trials in comparison to the standard reference products relevant in the different countries. Data are given in Table 6.1.3-7.

Table 6.1.3-7: Effectiveness (%) of 4.0 L/ha (HAG 500 02 H) in grassland (assessment 21-52 DAA). Trials from 2009-2010

Weed species	**n**	**DAA**	**mean**	**min**	**max**	**Reference product mean**
Trifolium arvense (TRFAR)	2	24	55	24	78	54
Taraxacum officinale (TAROF)	2	24	51	19	82	55
Ranunculus repens (RANRE)	2	52	49	25	72	55
Cerastium fontanum (CERFO)	1	84	22	-	-	98
Stellaria media (STEME)	1	84	96	-	-	98
Plantago lanceolata (PLALA)	1	24	92	-	-	96
Rumex acetosa (RUMAC	2	24	66	55	78	69
Poa annua (POAAN)	1	24	99	-	-	99
Plantago mayor (PLAMA)	1	24	57	-	-	72
Sisymbrium officinale (SSYOF)	1	24	60	-	-	62
Cerastium arvense (CERAR)	1	24	80	-	-	87
Grassland (NNNFW)	2	24	42	9	75	41
Urtica urens (URTUR)	1	24	42	-	-	47
Lolium perenne (LOLPE)	2	24	96	92	99	95

In summary, HAG 500 02 H showed a level of efficacy against different weed species present in the trials similar to that of the standard reference product Roundup Ultra Max.

Conclusions

A sufficient number of trials were submitted for the countries of the maritime EPPO zone. The effectiveness is demonstrated with an application rate of 4.0 L /ha.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant claims that data from the maritime and the north-east (Poland) EPPO climate zone can be transferred to the south-east zone. Furthermore the applicant claims that the climate conditions are similar for same crops in the whole central European Zone and that the efficacy of glyphosate has been known for a long time. Results from experiments with HAG 500 02 H and reference herbicides have proven comparable efficiency within two EPPO climate zones. The applicant suggests that therefore the results can be transferred to the south-east zone.

Intended use: 007385-00/00-008

Desiccation in absence of weeds:

In total four trials were conducted in oilseed rape in Poland in 2009. All trials were carried out according to EPPO-standards (PP 1/152(3), PP 1/181(3), PP 1/49(3)) and GEP. No trials were carried out in the maritime and the south-east EPPO zone and no data extrapolation was made. Climate conditions of the south-east are not comparable with the maritime EPPO zone. Therefore the results of the maritime EPPO zone cannot be transferred to the south-east EPPO zone (cMS Hungary, Romania, Slovakia and Slovenia).

The intended target dose rate of HAG 500 02 H was 1125 g a.s./ha, equivalent to 2.5 L product/ha. In all trials the dose rate was covered by the intended GAP under consideration of a deviation < 0.5% of the target dose rate as the target dose amounted to 1130 g a.s./ha. Additionally a double dose of the target dose of HAG 500 02 H 2250 g a.s./ha, equivalent to 5.0 L product/ha was tested in all conducted trials. The product HAG 500 02 H was applied once at BBCH 89 (fully ripe and hard grain, difficult to divide with thumbnail), 14 days before harvest in absence of weeds.

The trial results demonstrate that for the use dessiccation in oilseed rape (BSRNW) as a pre-harvest treatment HAG 500 02 H can be considered as a harvesting aid.

Generally HAG 500 02 H applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha showed the same accelerated crop desiccation and ripening process (96,25%) than the double dose of HAG 500 02 H applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha (100%).

Conclusions

Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east EPPO zone. The efficacy is demonstrated with an application rate of 2.5 L /ha.

To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO standard PP 1/226(1)). No trials were carried out in the maritime EPPO zone and in the south-east EPPO zone. For registration additional trials from a second year of experiments are necessary. The trials should be carried out in the maritime and the south east EPPO climate zone.

The applicant suggests that the efficiency of desiccation is independent of climate differences which exist between EPPO climate zones. Furthermore the applicant claims that the results from Poland can be transferred to the other climate zones without limitation. Further trials will not be carried out.

Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

The applicant claims: The registration for desiccation of winter oil seed rape will not be pursued in Germany, but in the other MS.

Weed control:

In total four oilseed rape (BRSNW) trials were conducted in Poland in 2009.

Table 6.1.3-8: Effectiveness (%) of 2.5 L/ha in oilseed rape (assessment 14 DAA).

Weed species	**n**	**mean**	**min**	**max**	**Reference product mean**
Elytrigia repens (AGRRE)	4	78	75	82	78
Centaurea cyanus (CENCY)	2	84	81	87	84
Chenopodium album (CHEAL)	2	84	75	93	84
Echinochloa crus-galli (ECHCG)	2	93	87	99	94
Galium aparine (GALAP)	1	82	-	-	84
Galinsoga parviflora (GASPA)	1	94	-	-	94
Geranium pusillum (GERPU)	1	97	-	-	92
Matricaria recutita (MATCH)	1	85	-	-	90
Papaver rhoeas (PAPRH)	1	74	-	-	76
Stellaria media (STEME)	3	91	82	96	91
Viola arvensis (VIOAR)	5	79	72	84	80

Conclusions

The efficacy is demonstrated with an application rate of 2.5 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east EPPO zone.

To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO guideline PP 1/226(1)). No trials were carried out in the maritime and in the south-east EPPO zone. For registration additional trials from a second year of experiments are necessary. The trials should be carried out in the maritime and the south east EPPO climate zone.

The applicant claims that the results from Poland can be transferred to the other climate zones without limitation. Further trials will not be carried out.

Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Intended use: 007385-00/00-009

No results were submitted.

The applicant pointed out, that the use ‘pre-emergence oilseed rape’ is dealing with similar cultivation conditions e.g. regarding row spacing as the use ‘pre-emergence sugar beet’ and thus with comparable species of mono- and dicotyledonous weeds. Therefore, all data reported and all information given under efficacy test ‘pre-emergence sugar beet’ - mono- and dicotyledonous weeds also applies for the use ‘pre-emergence oilseed rape’. The higher dosage (1125 g/ha as, equivalent to 2.5 L/ha product) applied for in the use ‘pre-emergence oilseed rape' is based on the assumption of higher infestation intensities of weeds in winter oilseed rape.

Conclusions
The date of application and the weed flora in sugar beet and oilseed rape is not comparable. Therefore experimental results from the use 'pre-emergence oilseed rape' are required. The applicant pointed out that the intended dose rate based on an assumption. This is not acceptable. For the assessment trials over two years are necessary. The trials should be carried out in the maritime and the south east EPPO climate zone.
The applicant has requested a limitation for the intended use. After that an application should not be made in winter rape for seed production. From the zRMS`s point of view this limitation is not necessarily needed, because the herbicide will not have any contact with seeds or rape plants after application.

The applicant claims: The registration for pre-emergent weed control in oilseed rape will not be pursued in Germany but in the other MS.

Intended use: Sugar beet
In total four trials were conducted in sugar beet in Poland in the year 2009. All trials were carried out according to EPPO-standards (PP 1/52(3), PP 1/152(3), PP 1/135(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone.
The intended target dose rate of 720 g a.s./ha HAG 500 02 H was tested in all trials in comparison to the standard reference products relevant in the different countries. Data are given in table 6.1.3-9.

Table 6.1.3-9: Effectiveness (%) of 1.6 L/ha (HAG 500 02 H) in sugar beet (assessment 28 DAA). Trials from 2009

Weed species	n	HAG 500 02 H			Reference product		
		mean	min	max	mean	min	max
VIOAR (*Viola arvensis*)	3	83	70	90	86	75	94
APESV (*Apera spica-venti*)	1	84	-	-	97	-	-
VERTR (*Veronica triphyllos*)	1	99	-	-	100	-	-
STEME (*Stellaria media*)	1	92	84	100	93	86	100
AGRRE (*Elytrigia repens*)	1	91	-	-	98	-	-
MATCH (*Matricaria chamomilla*)	1	86	-	-	92	-	-
CENCY (*Centaurea cyanus*)	1	93	-	-	100	-	-
CHEAL (*Chenopodium album*)	2	93	90	95	94	90	97
ANTAR (*Anthemis arvensis*)	1	94	-	-	94	-	-
CAPBP (*Capsella bursa-pastoris*)	1	93	-	-	94	-	-
POLPE (*Polygonum persicaria*)	2	93	91	94	95	94	96
HORVS (*Hordeum vulgare)*	1	88	-	-	94	-	-
SINAR (*Sinapis arvensis*)	1	98	-	-	99	-	-
POLCO (*Polygonum convolvulus*)	1	90	-	-	93	-	-
GALAP (*Galium aparine*)	1	90	-	-	92	-	-
THLAR (*Thlaspi arvense*)	1	100	-	-	99	-	-

Conclusions

The efficacy is demonstrated with an application rate of 1.6 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south-east EPPO zone.

To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO standard PP 1/226). No trials were carried out in the maritime and in the south-east EPPO zone. For registration additional trials from a second year of experiments are necessary. The trials should be carried out in the maritime and the south-east EPPO climate zone.
The applicant claims that the results from Poland can be transferred to the other climate zones without limitation. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Intended use: Stone fruit
There were no trials conducted regarding the efficacy in stone fruits. The use 'orchards stone fruit' is dealing with the similar weed species and cultivation conditions as the use 'orchards pome fruit' - mono- and dicotyledonous weeds. Therefore, all data reported and all information given under efficacy – 'orchards pome fruit - mono- and dicotyledonous weeds' also apply for the use 'orchards stone fruit'.

<u>Conclusions</u>
A sufficient number of trials were submitted for the maritime EPPO zone for pome fruits. The effectiveness is demonstrated with an application rate of 4.0 L /ha. The results can be transferred to stone fruits.

No trials were carried out in the south-east EPPO zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Intended use: Peas (pre-harvest for weed control and desiccation) and winter rape (pre-harvest for desiccation)

<u>Desiccation</u>
In total seven trials were conducted in peas (3) and winter rape (4) in Poland in the year 2009. All trials were carried out according to EPPO-standards (PP 1/49(3), PP 1/91(2), PP 1/152(3), PP 1/135(3), PP 1/181(3)) and GEP. No trials were carried out in the south-east EPPO zone. Data are given in table 6.1.3-10.

Table 6.1.3-10: Desiccation (%) (rate 2.5 L/ha) in absence of weeds – oilseed rape and field peas – 14 DAA

Crop	Number of trials (n)	mean	min	max
peas	3	94.6	92.5	98.8
Oilseed rape	4	97.5	90.0	100.0

The efficacy is demonstrated with an application rate of 2.5 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east EPPO zone.

<u>Conclusions</u>

Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east EPPO zone.
To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO standard PP 1/226). No trials were carried out in the maritime and in the south-east EPPO zone. For registration additional trials from a second year of experiments are necessary. The trials should be carried out in the maritime and the south-east EPPO climate zone.

Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Weed control
In total four trials in oilseed rape (BRSNW) were conducted in Poland in 2009.The results can be transferred to field pea.

Table 6.1.3-11: Effectiveness (%) of 2.5 L/ha in oilseed rape (assessment 14 DAA).

Weed species	**n**	**mean**	**min**	**max**	**Reference product mean**
Elytrigia repens (AGRRE)	4	78	75	82	78
Centaurea cyanus (CENCY)	2	84	81	87	84
Chenopodium album (CHEAL)	2	84	75	93	84
Echinochloa crus-galli (ECHCG)	2	93	87	99	94
Galium aparine (GALAP)	1	82	-	-	84
Galinsoga parviflora (GASPA)	1	94	-	-	94
Geranium pusillum (GERPU)	1	97	-	-	92
Matricaria recutita (MATCH)	1	85	-	-	90
Papaver rhoeas (PAPRH)	1	74	-	-	76
Stellaria media (STEME)	3	91	82	96	91
Viola arvensis (VIOAR)	5	79	72	84	80

Conclusions
The efficacy is demonstrated with an application rate of 2.5 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south-east EPPO zone. The results from Poland can be transferred to the maritime climate zones without limitation.

To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO standard PP 1/226). No trials were carried out in the maritime and in the south-east EPPO zone. For registration additional trials from a second year of experiments are necessary. The trials should be carried out in the maritime and the south-east EPPO climate zone.

Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Intended use: 007385-00/00-001
Not relevant, because the herbicide is not sprayed on crops.

Intended use: 007385-00/00-002
No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: 007385-00/00-003
No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: 007385-00/00-004
No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: 007385-00/00-005
No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: 007385-00/00-006
In total 17 trials were conducted in cereals in Poland in 2009. Three trials were performed in winter barley, four trials in spring barley, four trials in winter triticale, three trials in spring wheat and three trials in spring triticale. HAG 500 02 H was applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha and at 2250 g a.s./ha, equivalent to 5.0 L product/ha. The requested dose rate (4.0 L/ha) was not tested.
Additionally 4 trials were conducted in winter wheat in Poland in 2009 with an application rate of 1440 g a.s./ha, equivalent to 3.2 L product/ha and 2880 g a.s./ha, equivalent to 6.4 L product/ha. For winter wheat the requested dose rate (4.0 L/ha) was not tested.

The following assessments were included in the studies: Desiccation (drying) and plant ripening (maturity), grain moisture in percent, TWG (Thousand grain weight) in g, density in kg/100L and the yield in ton/ha. Maturity was assessed during 7 to 21 days after application.

<u>Cereals</u>
The treatments with HAG 500 02 H applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha and HAG 500 02 H 2250 g a.s./ha, equivalent to 5.0 L product/ha showed a statistically significant faster crop ripening process (maturity). In all trials and at both dose rates of HAG 500 02 H the proportion of ripe crop plants, assessed 7-21 DAA, was statistically significantly higher compared to the untreated plots. In 10 out of 17 trials there were no statistically significant differences in maturity between the two doses of HAG 500 02 H 14 days after application. 21 days after application no statistically significant differences were observed between the two doses in any of the trials.

<u>Winter wheat</u>
HAG 500 02 H applied at 1440 g a.s./ha, equivalent to 3.2 L product/ha and 2880 g a.s./ha, equivalent to 6.4 L product/ha showed a statistically significant accelerated crop ripening process (maturity). In all trials at both dose rates of HAG 500 02 H the portion of ripe crops assessed 7-21 DAA was statistically significant higher compared to the untreated plot.

In two of four trials there were no statistically significant differences in the maturity between the two doses of HAG 500 02 H 14 days after application. 21 days after application no statistically significant differences were observed between the two doses in any of the trials.

Conclusion
<u>Cereals</u>

The requested dose rate (4.0 L/ha) was not tested. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east EPPO zone. Generally HAG 500 02 H applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha showed the same ripening process than the double dose of HAG 500 02 H applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha.
For the assessment trials with the requested dose rate over two years are necessary. The trials should be carried out in the maritime and the south east EPPO climate zone.

Winter wheat
The requested dose rate (4.0 L/ha) was not tested. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east climate zone. Generally, HAG 500 02 H applied at 1440 g a.s./ha, equivalent to 3.2 L product/ha showed the same ripening process than the double dose of HAG 500 02 H applied at 2880 g a.s./ha, equivalent to 6.4 L product/ha. For the assessment trials with the requested dose rate over two years are necessary. The trials should be carried out in the maritime and the south east EPPO climate zone.
The applicant claims that the results from Poland can be transferred to the other climate zones without limitation.
Separate results of trials of desiccation are not available for different EPPO climate zones. The applicant suggests that the date of application (BBCH 89) is similar to weed control before harvest. The applicant claims that the results from the maritime EPPO zone should be taken into consideration.

Intended use: 007385-00/00-007
Not relevant, reseeding of grassland.

Intended use: 007385-00/00-008
In total four trials were conducted in oilseed rape in Poland in 2009. The following assessments were included in the studies: Desiccation (drying) and plant ripening (maturity), grain moisture in per cent, TWG (Thousand grain weights) in g.

HAG 500 02 H applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha and HAG 500 02 H 2250 g a.s./ha, equivalent to 5.0 L product/ha showed a statistically significant accelerated crop ripening process (maturity). In all trials the portion of ripe crops assessed 7-21 DAA was statistically significant higher in both dose rates of HAG 500 02 H compared to the untreated plots.

Conclusions
The efficacy is demonstrated with an application rate of 2.5 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south east EPPO climate zone.
To demonstrate the performance of a herbicide, it is necessary to conduct a number of trials in different regions and years (EPPO standard PP 1/226(1)). No trials were carried out in the maritime zone and in the south-east EPPO zone.

The applicant claims that the results from Poland can be transferred to the other climate zones without limitation.

Intended use: 007385-00/00-009
No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: Sugar beet
No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: Stone fruit

No results were submitted. Further data are not required because glyphosate is inactive in soils.

Intended use: Peas (pre-harvest for weed control and desiccation) and winter rape (pre-harvest for desiccation)

No results were submitted. Further data are not required because the crop is the target plant.

IIIA1 6.1.4.2 Effects on the processing procedure

No results were submitted. Based on several decades of practical use it can be assumed that glyphosate is not expected to have any impact on the processing procedure of plants and plant products.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Intended use: 007385-00/00-001
Not relevant, because the herbicide is not sprayed on crops.

Intended use: 007385-00/00-002
Three trials in apple were performed in Poland in 2009. One trial was conducted in 2009 and one trial was conducted in 2010 in Germany. All trials were carried out according to EPPO-standard PP 1/90(2), PP 1/152(3), PP 1/181(3) and GEP. Additionally five trials were conducted in pears in Poland (3) and Germany (2).

In all trials HAG 500 02 H was tested at the following doses: 1800 g a.s./ha, equivalent to 4.0 L product/ha and 3600 g a.s./ha, equivalent to 8.0 L product/ha. Additionally in the three polish trials HAG 500 02 H was applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha and 4500 g a.s./ha, equivalent to 10.0 L product/ha. HAG 500 02 H was applied on bare soil in spring under weed-free conditions.

<u>Apples</u>
In all trials the maturity of the crop in percent has been assessed. In the Polish trials and one German trial the yield was assessed in tons (metric ton; 1000 kg). In another German trial the relative yield (percent of untreated /plot) was calculated. Yield quality – evaluation of the fruits size during harvest was assessed according to the scale:

< 65 mm; 65-85 mm; > 85 mm in all Polish trials,
< 65 mm; 65-70 mm; 70-80 mm and 80 - 90 mm in the German trial
< 55 mm; 55-65 mm; > 65 mm in another the German trial

Fruit size scales dependent for example on the crop variety or local cultivation conditions.

Generally, all conducted trials showed that HAG 500 02 H used in apple orchards at the crop stages BBCH 67-74, and applied at dose rates of 1800 g a.s./ha, equivalent to 4.0 L product/ha, 2250 g a.s./ha, equivalent to 5.0 L product/ha, 3600 g a.s./ha, equivalent to 8.0 L product/ha and 4500 g a.s./ha, equivalent to 10.0 L product/ha didn’t have any significant influence on fruit ripening (maturity) and yield as well as on the occurrence of different fruit size classes. HAG 500 02 H applied at the recommended dose rate of 1800 g a.s./ha, equivalent to 4.0 L product/ha in apples didn’t have any significant influence on the quantity or quality of yield.

<u>Pears</u>
Yield quality of the fruits size during harvest was assessed according to the scale:

< 65 mm; 65-85 mm; > 85 mm in all Polish trials,
< 65 mm; 65-85 mm in the German trial 122H_GE01,

<60 mm; 60-70 mm; >70 mm in the German trial: 122H_GE04

Fruit size scales dependent for example on the crop variety or local cultivation conditions.

Generally, all conducted trials showed that the product HAG 500 02 H used in pear orchards at crop stages BBCH 67-74 and applied at dose rates of 1800 g a.s./ha, equivalent to 4.0 L product/ha, 2250 g a.s./ha, equivalent to 5.0 L product/ha, 3600 g a.s./ha, equivalent to 8.0 L product/ha and 4500 g a.s./ha, equivalent to 10.0 L product/ha didn't have any significant influence on fruit ripening (maturity) and yield as well as on the occurrence of different fruit size classes.

<u>Conclusions</u>
A sufficient number of trials were submitted for the maritime EPPO climate zone and Poland. HAG 500 02 H didn't have any influence on fruit ripening (maturity) and yield as well as on the occurrence of different fruit size classes.

No trials were carried out in the south-east EPPO climate zone.
The applicant claims that the results from the maritime EPPO zone and Poland should be taken into consideration. Furthermore the applicant claims the efficacy of glyphosate has been known for a long time.

Intended use: 007385-00/00-003
See intended use 002.

Intended use: 007385-00/00-004
No results were submitted. Negative impacts are not expected.
The applicant claims that the results from intended use 002 and 003 are transferable.

Intended use: 007385-00/00-005
No results were submitted. Negative impacts are not expected.
The applicant claims that the results from intended use 002 and 003 are transferable.

Intended use: 007385-00/00-006
No statistically significant differences in the density of grain (kg/100L) or yield (t/ha) between the treated plots and the untreated control were observed in any of the trials.

<u>Conclusions</u>
HAG 500 02 H applied at 1440 g a.s./ha and 2880 g a.s./ha in TRZAW had no influence on yield.

No trials were carried out in the south-east EPPO climate zone.
The applicant claims that the results from the maritime EPPO zone and Poland should be taken into consideration. Furthermore the applicant claims the efficacy of glyphosate has been known for a long time.

Intended use: 007385-00/00-007
Not relevant, reseeding of grassland

Intended use: 007385-00/00-008
Four trials were performed in oilseed rape in Poland in 2009. All trials are described in detail in the section efficacy tests. Poland does not belong to the maritime or south east EPPO climate zone.

In none of the trials a statistically significant difference in yield (t/ha) between the treated plots and the untreated control were observed.

Conclusions
HAG 500 02 H applied at 1440 g a.s./ha and 2880 g a.s./ha had no influence on yield.
The applicant claims that the results from Poland can be transferred to the other climate zones without limitation.

Intended use: 007385-00/00-009
No results were submitted. With the requested efficacy trials, yield data must also submitted for the maritime and south east EPPO climate zone.

Intended use: Sugar beet
No results were submitted.

Intended use: Stone fruit
No results were submitted. The results from intended use 002 are transferable.

Intended use: Peas (pre-harvest for weed control and desiccation) and winter rape (pre-harvest for desiccation)
No results were submitted. Further data are not required because the crop is the target plant.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

Intended use: 007385-00/00-001
Not relevant, because the herbicide is not sprayed on crops.

Intended use: 007385-00/00-002
Phytotoxicity assessments were carried out according to EPPO standard PP1/135(3) in all trials. Three trials in apple were performed in Poland in 2009. One trial was conducted in 2009 and one trial was conducted in 2010 in Germany. Specific crop selectivity trials in pears were conducted in Poland (3) and Germany (2) in the years 2009 and 2010 in absence of weeds.
In all trials HAG 500 02 H was tested at the following doses: 1800 g a.s./ha, equivalent to 4.0 L product/ha and 3600 g a.s./ha, equivalent to 8.0 L product/ha. Additionally in the three Polish trials HAG 500 02 H was applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha and 4500 g a.s./ha, equivalent to 10.0 L product/ha.
Additionally the crop selectivity of HAG 500 02 H was determined in all six trials on apple and one pear trial which have been conducted at the target dose rate of 1800 g a.s./ha equivalent to 4.0 L product/ha and the following doses1080 g a.s./ha equivalent to 2.4 L product/ha, 1440 g a.s./ha equivalent to 3.2 L product/ha and 2160 g a.s./ha equivalent to 4.8 L product/ha in the minimum effective dose tests.

Any possible phytotoxic effects were recorded. Any visible symptoms were quantified and accurately described i.e. phytotoxicity as % of total leaf areas affected by chlorosis and necrosis, any other symptom of plot differences observed was assessed by a scale appropriate to symptom.

Conclusions
All different apple and pear varieties showed a good tolerance and no phytotoxicity was observed after the application of HAG 500 02 H which was applied with different doses.

No results were submitted for the south east EPPO zone.
The applicant claims that the results from the maritime EPPO zone and Poland should be taken into consideration.

Intended use: 007385-00/00-003
See intended use 002.

Intended use: 007385-00/00-004
Phytotoxicity assessments were carried out according to EPPO standard PP1/135(3) in all trials. All trials are described in detail in the section minimum effective dose tests.
No specific crop selectivity trials in grape are available for HAG 500 02 H. The crop selectivity of HAG 500 02 H was determined in all 4 trials on grape which have been conducted at the target dose rate of 1800 g a.s./ha equivalent to 4.0 L product/ha and the following doses 1080 g a.s./ha equivalent to 2.4 L product/ha, 1440 g a.s./ha equivalent to 3.2 L product/ha and 2160 g a.s./ha equivalent to 4.8 L product/ha.
Any possible phytotoxic effects were recorded. Any visible symptoms were quantified and accurately described i.e. phytotoxicity as % of total leaf area affected by chlorosis and necrosis, any other symptom of plot differences observed was assessed by a scale appropriate to symptom.

<u>Conclusions</u>
All different grape varieties showed a good tolerance and no phytotoxicity was observed after the application of HAG 500 02 H which was applied with different doses.

No results were submitted for the south east EPPO climate zone.
The applicant claims that the results from the maritime EPPO zone and Poland should be taken into consideration.

Intended use: 007385-00/00-005
No results were submitted. No phytotoxicity is expected for the maritime EPPO climate zone. See also intended use 002.
No results were submitted for the south east EPPO climate zone.
The applicant claims that the results from the maritime EPPO zone and Poland should be taken into consideration.

Intended use: 007385-00/00-006
<u>Desiccation</u>
Not relevant**.** The crop is the target of herbicide application.
The applicant stated:
In total 21 trials were conducted in cereals in Poland in 2009. Three trials were performed in winter barley, four trials in spring barley, four trials in winter triticale, three trials in spring wheat, three trials in spring triticale and four trials in winter wheat. All trials are described in detail in the section efficacy tests.

In all trials a slight reduction in crop vigour was observed in the treated plots compared to the untreated plots 7 days after application as well as 14 days after application except in two trials. HAG 500 02 H applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha showed a higher vigour in 12 of 17 trials compared to HAG 500 02 H applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha, 7 days after application. 14 days after application in 9 of 17 trials HAG 500 02 H applied at 1125 g a.s./ha showed a statistically significant higher vigour than HAG 500 02 H applied at 2250 g a.s./ha.

Intended use: 007385-00/00-007
No specific crop selectivity trials in grassland are available for HAG 500 02 H.
Not relevant**.** Weeds and grassland is the target of the herbicide application.

Intended use: 007385-00/00-008

Desiccation

Not relevant**.** The crop is the target of herbicide application.

The applicant stated:

Four trials were performed in oilseed rape in Poland in 2009. All trials are described in detail in the section efficacy tests.

In all trials a slight reduction in crop vigour was observed in the treated plots compared to the untreated plots 7 days after application and 14 days after application except for two trials.

Intended use: 007385-00/00-009

No results were submitted. With the requested efficacy trials, phytotoxicity data must also submitted for the maritime and south east EPPO climate zone.

Intended use: Sugar beet

No results were submitted.

Intended use: Stone fruit

No results were submitted. The results from intended use 002 are transferable.

Intended use: Peas (pre-harvest for weed control and desiccation) and winter rape (pre-harvest for desiccation)

No results were submitted. Further data are not required because the crop is the target plant.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial arthropods

The herbicide HAG 500 02 H (450 g/L glyphosate, SL) is proposed for a single treatment per year in field crops including cereals and oilseed rape, pome fruits, vine and grassland. The proposed application method in orchards and vineyards is strip application. The intended uses range from 4 to 8 L product/ha, corresponding to a maximum rate of 3600 g a.s./ha.

The applicant stated that in all 122 trials [efficacy studies, Section 7] no negative effects on beneficial or non-target organisms were reported, without referring to the fact whether or not such side effects were actually investigated in these studies.

Appropriate ecotoxicological studies on beneficial arthropods (see Section 6, MIIIA1 10.5) were conducted with the formulation Glyphosate 450 SL AE (461 g/L glyphosate).

The applicant decided not to perform studies on artificial substrate as the toxicity of glyphosate to the predatory mite *Typhlodromus pyri* is well known. Therefore three extended laboratory studies with the two indicator species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) and one additional species (*Poecilus cupreus*) were submitted (see Table 6.2.4-1).

Aphidius rhopalosiphi:

The LR_{50} was > 5760 g a.s./ha. The test item is not expected to cause mortality > 25% when applied at the highest proposed rate. (The corrected mortality, reported by the applicant in Table MIIIA1 10.5.2-1, was incorrectly calculated.)
The reproductive capacity was barely affected up to 5760 g a.s./ha.
A statistically significant repellent effect of the test item was observed at all dose rates during the initial 3 hours of the study. The average settling rate of the parasitoids on the treated leaves was 0.0 - 3.0% at the different dose rates, whereas it was 10.5% in the control treatment.

Typhlodromus pyri:
Mortality was 98% at 1/4 of the highest proposed rate, the LR_{50} amounts to 352 g a.s./ha. Reproduction was reduced by 90% at a rate of 36 g a.s./ha.

Poecilus cupreus:
In the extended laboratory limit test, no effects on either mortality, feeding rate or behaviour were observed at the highest proposed rate of 3600 g a.s./ha.

Table 6.2.4-1: Effects of Glyphosate 450 SL AE (461 g/L glyphosate) on beneficial arthropods in extended laboratory studies

Species (Exposed Stage)	Substrate	Appl. Rate Glyphosate [g a.s./ha]	Corrected Mortality [%]	Sublethal Effect [%]	Reference
A. rhopalosiphi (A)	Barley	360	0	8 (Re)	IBACON 50355002 Moll (2010)
		720	7.5	18 (Re)	
		1440	7.5	16 (Re)	
		2880	12	15 (Re)	
		5760	32	27 (Re)	
T. pyri (PN)	Vine leaves	36	20	90 (Re)	IBACON 50356062 Schwarz (2010)
		107	29	48 (Re)	
		320	18	52 (Re)	
		960	98		
		2880	100		
P. cupreus (A)	LUFA 2.1	3600	-3	-9 (F)	IBACON 50357007 Schmitzer (2009)

PN = protonymphs, A = adults, Re = reproduction, F = food consumption
The validity criteria were met in all studies.

Five other laboratory and semi-field studies on the effects of the SL-formulations Roundup and Glyfos (360 g/L glyphosate) on relevant leaf and soil dwelling antagonists were available (see Table 6.2.4-2).

Chrysoperla carnea:
In a laboratory test using glass plates, already 0.2-fold the highest proposed rate caused 52% mortality.

Carabidae:
In a laboratory test with Trechus *quadristriatus* using quartz sand and in a semi-field study with *Bembidion lampros* on a fallow, only marginal or no mortality occurred at the highest proposed rate of 3600 g a.s./ha.

Linyphiid spiders:

In a laboratory test with *Meioneta rurestris* using glass plates, the highest proposed rate caused 86% mortality already within 2 days.
In a semi-field study with various linyphiid species no effect on the activity density (D-Vac-samples) occurred, but the trial lasted only 3 days and was disturbed by heavy rain.

The studies with soil dwelling antagonists lasted generally only 2 – 5 days and not 14 days as currently recommended. No reference item was tested in these trials, thus the susceptibility of the test animals and hence the validity of the studies could not be checked. No sublethal effects were recorded.
Therefore the results of the studies CHEM-90-1, XX-90-603 and CHEM-91-1 cannot be used for a classification.

Table 6.2.4-2: Effects of Roundup *) and Glyfos **) (360 g/L glyphosate) on beneficial arthropods

Species (Exposed Stage)	Substrate	Appl. Rate Glyphosate [g a.s./ha]	Corrected Mortality [%]	Sublethal Effect [%]	Reference
C. carnea (La)	Glass	720 *)	52	-25 (Re)	XX-90-601 Bigler & Wald-burger (1985) 1)
T. quadristriatus (A), (Carabidae)	Quartz sand	3600 **)	14		CHEM-90-1 Halsall (1990) 2)
B. lampros (A), (Carabidae)	Semi-field, fallow	3600 *)	-14		XX-90-603 Mead-Briggs & Halsall (1990) 3)
M. rurestris (Liny-phiidae)	Glass	3600 **)	86		CHEM-90-2 Halsall (1990) 4)
Linyphiidae (mainly *Erigone atra*, but also *Leptyphantes tenuis*, *Milleriana inerrans*, *Meioneta rurestris, Oedothorax* spp.)	Semi-field, winter wheat 12 x 12 m²	3600 **)	0		CHEM-91-1 Halsall (1991) 5)

La = larvae, A = adults, Re = reproduction
1 - 5): No reference item was used.
2 - 5): Only 2 to 5-day long exposure

The presented results of Hassan et al. (1988) with Roundup (360 g a.s./L) show that in laboratory tests rates of only 360 - 720 g a.s./ha on glass plates or leaves (without definite attribution of tested substrate and rate) causes effects of 50 – 79 % with *Trichogramma cacoeciae*, *Typhlodromus pyri, Chrysoperla carnea* and *Semiadalia 11-notata*. Several other species were not affected > 50 %, but due to the low doses this result is not relevant for evaluation. In a laboratory test with *Bembidion lampros* on sand 2160 g a.s./ha caused an effect between 80 – 99%.

Conclusion

At the highest proposed application rate of 3600 g a.s./ha, the product HAG 500 02 H is harmless for the parasitoid *Aphidius rhopalosiphi* and the ground beetle *Poecilus cupreus* with both lethal and sublethal effects < 25% under extended laboratory conditions.
The product was harmful for the predatory mite *Typhlodromus pyri* at the highest proposed rate which caused 100% mortality under extended laboratory conditions. Although the exposure of predatory mites in orchards and vineyards is diminished by the proposed ground directed strip

application, the product is still considered harmful, since already 1% of the highest proposed rate caused a sublethal effect of 90%.
A formulation of glyphosate similar to HAG 500 02 H was harmful for the linyphiid *Meioneta rurestris* with effects > 80% at the highest proposed rate under laboratory conditions. The test conditions of the semi-field test were not acceptable to prove the harmlessness under more natural conditions.
Therefore the product should be classified as harmful for populations of relevant spiders.
HAG 500 02 H is to consider harmful for the lacewing species *Chrysoperla carnea*, *Trichogramma cacoeciae* and *Semiadalia 11-notata*, since already 0.2-fold the highest proposed rate of a similar formulation of glyphosate caused 50 - 79% mortality under laboratory conditions (substrates unknown).
The product is harmful for the ground beetle *Bembidion lampros.*
No appropriate results could disprove that the proposed rate will cause effects > 75%.

Effects on soil quality

Effects on soil macro-organisms being used as indicators of soil quality

Effects on earthworms

Ecotoxicological endpoints for earthworms exposed to
HAG 500 02 H and glyphosate

Acute earthworm toxicity studies have been carried out with HAG 500 02 H and glyphosate. Chronic earthworm toxicity studies have been carried out with glyphosate (IPA salt).

Further details of the acute study with the formulation are given in Point 6.2.4-3 below.

— Acute tests

Table 6.2.4-3: Results of acute toxicity testing of HAG 500 02 H in earthworms (*Eisenia fetida*)

Endpoint	Soil concentration [mg test item/kg]	Soil concentration [mg a.s./kg]
14-day LC_{50}	> 1000	> 450
14-day NOEC	1000	450
14-day LOEC	> 1000	> 450

— Sublethal tests

According to SANCO/10329/2002 studies on sublethal effects are required, where:

- $DT_{90field}$ is not less than 100 days **and** the number of applications is less than 3
- $DT_{90field}$ is above 365 days
- Number of applications is greater than 6
- The acute risk gives a TER of less than 10.

Due to the fact that none on the assumptions above are fulfilled a sub-lethal earthworm study is not required. However, as the soil metabolite AMPA is reaching maximum levels of 26 – 29% of applied parent after 14 days the risk to earthworms of can`t be excluded. A sub-lethal toxicity test on earthworms with the IPA-salt was performed.

— Field tests

According to SANCO/10329/2002 earthworm field studies are not required if the TER_{lt} is > 5. As no long-term study is required a field test is also not necessary.

Further details of the acute and chronic studies with glyphosate are given in the Glyphosate Monograph (Volume 3, Annex B-8: Ecotoxicology, 11 December 1998). The acute and chronic earthworm toxicity endpoints are summarised in Table 6.2.4-4.

Table 6.2.4-4: Summary of earthworm toxicity endpoints for HAG 500 02 H and glyphosate

Test Substance	Exposure	Toxicity Parameter	Results [mg a.s./kg soil]	Reference
Acute toxicity				
HAG 500 02 H	14 days	LC_{50}	> 450	Witte, B. (2009), MIIIA1, 10.6.2/01
glyphosate	14 days	LC_{50}	> 480	Review Report for the active substance Glyphosate (SANCO/6511/VI/99-final)
Chronic toxicity				
glyphosate	8 weeks	NOEC	28.79 (IPA-salt)	Review Report for the active substance Glyphosate (SANCO/6511/VI/99-final)

Exposure

Risk to earthworms from the use of glyphosate was assessed according to the “Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC” (SANCO/10329/2002, issued 17th October 2002)” and was based on an acute study with the formulation and a long-term study with the active ingredient. Additionally, one major degradation product of the applied parent occurred and was identified as aminomethylphosphonic acid (AMPA). As this metabolite is formed in amounts of > 10% the risk to earthworms of this soil metabolite was also assessed according to current guidance document. The initial predicted environmental concentration (PEC) and the plateau concentration of glyphosate and its soil metabolite was calculated for soil as described in chapter MIIIA1 9.4.1 and MIIIA1 9.5.1. The resulting maximum plateau PEC_S values are used in the risk assessment and presented in Table 6.2.4-5.

Table 6.2.4-5: Maximum peak soil PEC values for glyphosate and its major metabolite AMPA – Central zone – critical GAP

Crop	Application Rate	Plateau concentration glyphosate	Plateau concentration AMPA
	[g a.s./ha]	[mg a.s./kg soil]	[mg a.s./kg soil]
Cereals Field crops	1800	2.489	0.556
Oilseed rape (covering sugar beet)	1125	1.556	0.347
Vine Orchard	3600	4.200	2.263
Grassland (covering stubble)	1800	1.680	0.907

The TER values are calculated based on the calculated plateau concentration and the lowest acute toxicity endpoint (LC_{50} of > 450 mg a.s./kg soil). The respective TER values are presented in Table 6.2.4-6.

Table 6.2.4-6: Acute toxicity exposure ratios (TERA) for earthworms exposed to glyphosate – Central zone – critical GAP

Crop	LC_{50}	Plateau concentration glyphosate	TER_A
	[mg a.s./ha]	[mg a.s./kg soil]	
Cereals Field crops	> 450	2.489	> 181
Oilseed rape (covering sugar beet)		1.556	> 289
Vine Orchard		4.200	> 107
Grassland (covering stubble)		1.680	> 268

The TER values resulting from the endpoints are well above the respective Annex VI trigger value for earthworms of 10 indicating acceptable acute risk to earthworms from the application of HAG 500 02 H according to GAP. However, as the $DT_{90field}$ is calculated to be 432 d ($DT_{50field}$ = 130 d * 3.32 (factor for kinetic first order)) and a continued or repeated exposure cannot be excluded a long-term risk assessment for earthworm is triggered.

The soil metabolite AMPA reached maximum levels of 26 – 29% of applied parent in soil metabolism studies. As the maximum level of AMPA is reached after 14 days it can be considered that the toxicity of AMPA to earthworms can be assessed within a chronic earthworm study with the parent.

The long-term effect on earthworms and other soil micro-organism was calculated based on the initial PEC_{soil} and the lowest long-term toxicity endpoint (NOEC of 28.79 mg a.s./kg soil) from a reproduction study. The resulting TER_{LT} are presented in Table 6.2.4-6.

Table 6.2.4-6: Long term toxicity exposure ratios (TERLT) for earthworms exposed to glyphosate – Central zone – critical GAP

Crop	NOEC	Plateau concentration glyphosate	TER_{LT}
	[mg a.s./ha]	[mg a.s./kg soil]	
Cereals Field crops	28.79	2.489	11.6
Oilseed rape (covering sugar beet)		1.556	18.5
Vine Orchard		4.200	6.85
Grassland (covering stubble)		1.680	17.1

The TER_{LT}-values based on a long-term endpoint are well above the respective Annex VI trigger value for earthworms of 5 indicating acceptable long-term risk to earthworms for the application of glyphosate according to GAP. As the soil metabolite AMPA is reaching maximum levels after 14 days of 26 – 29% of applied parent the risk to earthworms of AMPA is considered to be covered by the study on sub-lethal effects with glyphosate.

Conclusion
It is concluded that risk to earthworms from the use of glyphosate at the recommended application rates is acceptable.

Effects on other non-target macro-organisms

A test for assessing the effects on Collembola reproduction is required where

- The DT_{90f} lies between 100 and 365 days **and**
- Standard HQ for (*Typhlodromus* and *Aphidius*) > 2

For glyphosate only data of the DT_{90lab} are available. The DT_{90lab} for glyphosate is about 159 days. It can be expected that the $DT_{90field}$ is greater than 100 d. However, the calculated hazard quotients based on extended laboratory studies are above the respective trigger. Therefore a study on effects on other soil non-target macro-organisms is not required.

Effects on organic matter breakdown

A test for assessing the effects on organic matter breakdown (litterbag) is required where

- DT_{90f} > 365 days

or

- DT_{90f} is between 100 and 365 days and
- Effects on soil microflora > 25% or TER_{LT} earthworm < 5
- or Collembola TERLT < 5

An organic matter breakdown study for glyphosate is not required because it can be expected that the $DT_{90field}$ is < 365 days (DT_{90lab} for glyphosate is about 159 days). Further on, calculated TER_{LT} earthworm are > 5 and effects on soil microflora is < 25%.

Evaluation
It is concluded that the proposed use of HAG 500 02 H will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Instructions and information: None

Effects on soil micro-organisms

Effects on soil non-target micro-organisms exposed to HAG 500 02 H

Ecotoxicological endpoints for soil micro-organisms

Test item	Test design[1]	EU agreed endpoints	Reference
Glyphosate 450 SL AE	C	No significant effect > 25% at day 28 at 12.8 mg and 64.0 mg product/kg soil dw.	Feil, N. (2009) Final report IBACON Project 50359080
	N		
Roundup®	dehydrogenase activity	No significant effect > 25% at day 28 at 15.6 mg and 78.0 mg product/kg soil dw.	Todt, K. (1990) Final report of NA 90 9151/Part 1
	N		

[1] C = Carbon Mineralization, N = Nitrogen transformation.

Risk assessment for soil microflora functions

HAG 500 02 H tested as Glyphosate 450 SL AE formulation had no significant effect of ≥ ± 25% compared to the control on soil microbial activity up to 64.0 mg product/kg soil dw. As the proposed use of HAG 500 02 H an acceptable risk to soil microbial activity can be concluded.

Overall conclusion with respect to effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

There were no additional studies conducted concerning the influence of the herbicide HAG 500 02 H on plants used for propagating purposes. In literature information on inhibition of seed germination in crops treated with glyphosate is given. Because of this, the treatment of cereals to desiccate for example is excluded according to the GAP.

IIIA1 6.2.6 Impact on succeeding crops

There were no additional studies conducted concerning the impact of HAG 500 02 H on succeeding crops. Since glyphosate has no potential for a build-up or an accumulation in soil under field conditions and glyphosate has no soil activity it can be assumed that there is no negative impact on succeeding crops.

IIIA1 6.2.7 Impact on other plants including adjacent crops

HAG 500 02 H is a non selective herbicide. Therefore, HAG 500 02 H should be used with care and in line with good plant protection practice. Directions for use for example in regard to uncontrolled spay drift to neighbouring fields, weather conditions or water volumes have to be observed. If requirements of good plant protection practice are observed it can be assumed that there are no negative impacts on other plants, including adjacent crops.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Mechanism of resistance

The herbicide HAG 500 02 H contains the active substance glyphosate. The mode of action of this active substance is to inhibit an enzyme involved in the synthesis of basic aromatic amino acids. Glyphosate has been classified by the Herbicide Resistance Action Committee (HRAC) as a herbicide inhibiting the enzyme EPSP synthase (HRAC group G).

Since most mutations of the EPSPS enzyme prevent its proper function and result in the death of the plant, mutations were regarded as unlikely to give rise to glyphosate-resistant weed populations. A number of experiments with different active ingredients had shown a low frequency of glyphosate resistance compared to resistance to imidazoline and a sulfonlyurea. This difference in frequency seems to be related to the number and frequency of potential changes in the target enzyme, which affect the binding potential of the herbicide. Accordingly many changes are possible in the ALS enzyme; meanwhile only two specific changes in glyphosate binding to plant EPSPS are known to confer resistance. Target-site mutations generally result in 'high levels' of resistance (i.e. 1000X) and is the common resistance mechanism for the ALS inhibitor and ACCase inhibitor groups. In contrast, glyphosate resistant weed species with target-site mutations demonstrate relatively 'weak' resistance (i.e. 2-3X). A rare second target-site mechanism is over expression of EPSPS that has been identified as the primary resistance mechanism in an *Ama-*

ranthus species (Table 6.2.8-1). This is the first instance of this type of target-site resistance found for a herbicide.
Several types of non-target site mechanisms have been defined for glyphosate (Table 6.2.8-1).These include; (1) reduced movement of glyphosate as a result of a hypersensitive effect (rapid tissue necrosis) of leaf tissue treated with glyphosate (*Ambrosia* sp.), (2) reduced translocation to rhizome/root tissue (*Sorghum* sp.), and (3) accumulation/sequestration of glyphosate in the vacuole preventing lethal concentrations getting into plastids, the site of the shikimic acid pathway (*Lolium* sp).

Table 6.2.8-1: Glyphosate-resistant weeds species and the identified mechanisms of resistance

Species	Country	Situation	Mechanism of resistance
Amaranthus palmeri	United States	Glyphosate resistant cotton	Amplification of EPSP synthase
Conyza bonariensis	Spain	Olive orchard	Impaired glyphosate translocation; vascular sequestration
Conyza canadensis	United States	Glyphosate resistant soybean and cotton	Impaired glyphosate translocation
Eleusine indica	Malaysia	Fruit orchard	Decreased EPSP synthase sensitivity (Pro_{106} to Ser, Pro_{106} to Thr)
Eleusine indica	Philippines	Noncropped area	Decreased EPSP synthase sensitivity (Pro_{106} to Ser, Pro_{106} to Thr)
Lolium multiflorum	Chile	Almond orchard	Decreased EPSP synthase sensitivity (Pro_{106} to Ser, Pro_{106} to ALA)
Lolium multiflorum	United States	Orchards and vineyards	Decreased EPSP synthase sensitivity (Pro_{106} to Ser, Pro_{106} to Ala)
Lolium multiflorum	United States	Filbert orchard	Impaired glyphosate translocation
Lolium multiflorum	United States	Glyphosate resistant soybean and cotton	Impaired glyphosate translocation
Lolium rigidum	Australia	Fruit orchard Chemical fallow	Impaired glyphosate translocation
Lolium rigidum	Australia	Vineyard	Decreased EPSP synthase sensitivity (Pro_{106} to Thr)
Lolium rigidum	South Africa	Vineyard	Decreased EPSP synthase sensitivity (Pro_{106} to Ala)
Lolium rigidum	United States	Almond orchard	Decreased EPSP synthase sensitivity (Pro_{106} to Ser)

Evidence of resistance and cross resistance
Whereas glyphosate was first introduced as a commercial herbicide in 1974 under the trade name of Roundup, the first documented case of glyphosate resistance was reported 22 years later in the case of a *Lolium* species from an Australian orchard in 1996, based on an intensive selection pressure over 15 years with two or three applications per year. Since 1996 several additional resistant weed populations have been identified, encompassing cased from all over the world, including Europe. Most cases of glyphosate resistance have been recorded from the USA with considerable numbers also for South America and Australia. In the USA the most af-

fected crop is cotton since many farmers are heavily dependent on glyphosate to control weeds. This high use frequency is not common in central Europe. However, certainly care has to be taken in order to avoid the development of the glyphosate resistance problems as they are developing elsewhere.

Several weed species belonging to different botanical families, have become resistant to glyphosate in the last 15 years. Currently (May 2012) the online database of Ian Heap (www.weedscience.org) lists 23 plant species for which resistance has been documented, including 10 monocotyledonous and 11 dicotyledonous.

Looking more in detail on the situation in Europe, currently 10 cases of resistance are known, encompassing five different weed species, the dicotyledonous *Conyza bonariensis, C. canadensis* and *C. sumatrensis*, as well as the monocotyledonous *Lolium multiflorum* and *L. rigidum*. Spain is currently the most affected European country with five known glyphosate resistant weed species. The other countries are Portugal, France, Italy and the Czech Republic. Besides one case (*C. canadensis)* in the Czech Republic, Northern and Central Europe are not affected up to now. In the following Table the cases of weed resistance against glyphosate reported from Europe are summarized (Table 6.2.8-2).

Table 6.2.8-2: Spread of Glycines (G/9) resistant weeds in Europe

Weed species	**Country**	**Year**	**Use**	**Affected sites**	**Infested area (acres)**
Dicotyledonous					
Conyza bonariensis	Spain	2004	olive	6-10	1001-10000
	Portugal	2010	orchards	1	101-500
Conyza canadensis	Spain	2006	orchards	2-5	101-500
	Czech Republic	2007	railways	2-5	unknown
Conyza sumatrensis	Spain	2009	orchards	1	11-50
Monocotyledonous					
Lolium multiflorum	Spain	2006	orchards	2-5	101-500
Lolium rigidum	France	2005	orchards, vineyards, asparagus	6-10	501-1000
	France	2005	orchards, vineyards, asparagus	6-10	501-1000
	Spain	2006	orchards	2-5	101-500
	Italy	2007	orchards, vineyards	2-5	501-1000

Nearly all European cases of glyphosate-resistant weeds are reported for orchards and other perennial crops from Southern Europe. All cases have been reported from the last seven years, maybe indicating a growing impact of glyphosate resistance. The most serious problem seems to be *L. rigidum* with reported cases from four different countries including a higher number of affected sites. The economic impact of glyphosate resistance in *L. rigidum* and the other resistant species has so far been very small in Europe because there are easy and effective options available to farmers to manage the resistant plants by use of other herbicides or also through cultural practice.

For all glyphosate-resistant weeds species from Europe, research has shown that these particular species, respective biotypes, may also be cross-resistant to other HRAC Group G herbicides. Multiple resistances seems to be a serious issue in the case of some glyphosate-resistant weeds outside Europe where resistance against up to four different herbicide groups (different modes of action) has been detected.

Analysis of the inherent risk
Pesticide risk
Also the above listed resistance enhancing factors show clearly that a special resistance risk for glyphosate has to be considered, the impact in Central Europe is still comparatively low. According to the general observations based on the extensive use on a worldwide scale for more than 30 years the applicant claims that this active ingredient can so far be regarded as a low risk herbicide in the Central Zone in Europe. However, the increasing numbers of resistant populations worldwide including populations with multiple resistances to other MoA indicate a considerable and increasing resistance risk of glyphosate.

Weed risk
According to the applicant most target species of glyphosate represent only a minimal risk or impose “some risk”. Nevertheless it has to be considered that some weed species, especially grasses represent a serious target-associated risk. A high risk situation is evident for some of the weed species controlled by HAG 500 02 H like *Lolium* spp. and *Conyza* spp. which have already evolved resistance in Europe. These species are also most prone to be resistant to other herbicides. While it is difficult to estimate the number of hectares resistant to any herbicide, an online survey of glyphosate resistant weeds (Heap 2012) indicates that *Conyza* and *Lolium* are most widespread. Other target species can also be considered as being high risk species as they have evolved resistance to many different MoA. *Lolium rigidum* has developed resistance to the following MoA: ACCase-Inhibitors (Fops and Dims), ALS- Inhibitors (Sulfonylureas), Photosystem-II- Inhibitors (Triazine and Ureas), „bleachers“ (Triazoles) and Mitoses-Inhibitors (Carbamates). In Central Europe, resistance is so far only evident in *Conyza canadensis* in the Czech Republic. As the herbicide is also intended to be registered in the Czech Republic, the resistance risk may be enhanced in this member state. According to the applicant, the inherent resistance risk of glyphosate can be considered as low to moderate depending on the respective weed species.

No sensitivity data are provided. The applicant claims that glyphosate has been used commercially for almost 40 years. Therefore it may be difficult to find a still unexposed weed population. EPPO (2001) recommends the establishment of sensitivity data by comparing the sensitivity of resistant biotypes with that of populations showing no resistance and by undertaking greenhouse screening of many species over many years. This reference setting would also be possible for the new herbicide HAG 500 02 H. The available data from field trials with HAG 500 02 H in Europe show no evidence of a change in weed susceptibility. It is known that natural plant populations can vary in their susceptibility to glyphosate containing herbicides. There is great variability with growth stage, particularly for perennial weeds, which are reflected in label recommendations for optimal application timing.

Analysis of the agronomic risk
Glyphosate formulated as 450 g/L Soluble Concentrate (SL) formulation (product name HAG 500 02 H) and is intended for control of monocotyledonous and dicotyledonous weeds pre-emergence, pre-harvest and post-harvest on stubbles in field crops. It is further intended for control of monocotyledonous and dicotyledonous weeds in vineyards and pome fruit orchards. Uses on agricultural land (stubble), cereals, oilseed rape, sugar beet, peas, pome fruit, vineyards and grass land were applied for. Not all uses are intended for all Member States.

As HAG 500 02 H is a broad spectrum herbicide, an unrestricted use pattern would mean use against all weed species and frequent applications throughout the growing period/season. The specific recommendations for the applied dose rates and the timing of application have been successfully used commercially for nearly 30 years without significant resistance development under European conditions. Annual weeds are mostly susceptible throughout their life cycle. However, for perennial weeds the timing of application during their growth cycle can be critical to obtain good control. In annual cropping systems, the use of glyphosate may be combined with other, non-chemical, weed management techniques. For example, pre-harvest or post-harvest uses are sometimes followed by ploughing or minimum cultivation. Such agricultural cultivation measurements can be considered to reduce selection pressure by destroying annual weeds and suppressing perennial weeds. In arable crops the product may be used once to twice per season (pre-planting and pre-harvest/desiccation). Usually further herbicides are normally used within the crop to control dicotyledonous or grass weeds. As the cultivation of genetically-modified crops with resistance to glyphosate in Europe is currently not permitted, the application of glyphosate is limited to pre-planting and pre-harvest/desiccation.
Furthermore in perennial crops glyphosate is not usually the sole herbicide used, since it is only active on growing, emerged weeds. This restricts both the season and exact timing of use. During the year herbicides with other modes of action are usually applied, often in conjunction with cultivation or mowing, as part of the standard weed control programme. The use of complementary methods of weed control will reduce the risk of development of resistant weeds. Similarly, application of glyphosate in alternation with other herbicides can be considered to reduce the selection pressure for resistance. Even though risk development is rather unlikely in the agricultural practice of the Central European Zone, in permanent cultures (grapes and orchards) there seems to be a higher risk for resistance development as glyphosate may be used as the only herbicide. The applicant claims that the resistance risk can be regarded as low to moderate in permanent cultures.
However, the design of the respective crop rotations and the associated frequency of application of HAG 500 02 H may differ in the various Member States in the Central Zone and a national-specific assessment of the agronomic risk is therefore recommended. The applicant has provided information on importance of the main crop species in the individual Member States (Table 6-2).

It is concluded by the applicant that the overall agronomic resistance risk implemented by glyphosate can still be regarded as “low to moderate” under current normal European agricultural practice although the resistance risk of some of the parameters might be considerable.

Summary and conclusion
According to the applicant, the risk of glyphosate resistance development in Europe appears to be still comparatively low and should be manageable if appropriate procedures and methods are considered, including non-chemical control measures, e.g. cultivation, mechanical weed control, a modified use of glyphosate, e.g. frequency, timing, dose rate, tank mixtures, the application of herbicides from different mode of action classes or adaptations in agricultural practices, e.g. crop rotation, use of cover crops, ploughing or conservation tillage. This conclusion can be generally followed. However, the increasing use of glyphosate in many cropping systems in the central registration zone of Europe constitutes an increasing risk of resistance evolution in a number of weed species. The general resistance risk of HAG 500 02 H is therefore assessed as being low to medium.

Management strategy
Considering the already detected cases of glyphosate resistance in Europe and in order to keep different weed populations susceptible for a longer period of time, the applicant claims that general recommendations should be followed regarding the application of herbicides, e.g. IPM systems should be taken into account combined with good agricultural practices, and the applier should not only rely on herbicides. No particular resistance management strategies are recom-

mended for the use of glyphosate containing products at the moment as the risk is only low to medium. However, the general recommendations of HRAC and further institutions for the prevention and delimitation of herbicide resistance should always be taken into account by the users of HAG 500 02 H.

IIIA1 6.3 Economics

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4 Benefits

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.5 Other/special studies

There were no other or special studies conducted with HAG 500 02 H.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

The submission of the present draft Registration Report (dRR) serves the core registration of HAG 500 02 H (glyphosate) in the central registration zone (B) of the European Union. A national addendum for Germany was not submitted. The national label for Germany is available. A master label for the central zone (B) is also available. In the master label some uses are named which are not requested by the applicant in Germany: Sugar beet and field peas.

The applicant applies for a herbicide containing the active ingredient glyphosate. The evaluation of the test compound is based on results of field trials conducted in Germany, the United Kingdom, France and Poland (north east zone) during the years 2009 to 2010. Weed occurrence and cropping systems are comparable between Germany and Poland. Therefore the results from Poland can be considered for the assessment. No trials were carried out in the EPPO south-east climate zone. Due to the different climatic conditions an extrapolation of the data to the countries of the south-east EPPO zone is not possible. The trials satisfy the requirements for registration with regard to comprehension and quality of the studies. The GEP-requirement is taken care of.

Minimum effective dose tests were conducted in a variety of crops in the maritime EPPO climate zone and in Poland regarding the control of mono- and dicotyledonous weeds. The trials demonstrate that for all intended uses the requested dose rate is needed. No usable data were submitted for the intended use 009 and the intended use in sugar beet. No minimum effective dose trials were submitted for the south-east climate zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Efficacy tests were conducted in a variety of crops in the maritime EPPO climate zone and in Poland regarding the control of mono- and dicotyledonous weeds. HAG 500 02 H was tested in all trials in comparison to the commercial standard reference products relevant in the different countries. In the trials HAG 500 02 H demonstrated a level of efficacy against the different weed species present in the trials similar to that of the commercial country specific standard reference products. No usable data were submitted for the intended use 009 and for some intended uses only one-year result were submitted. No efficacy tests were submitted for the south-east climate zone. Due to the different climatic conditions an extrapolation of the data on the countries of the south-east is not possible.

Efficacy tests in woody plants for the control of *Convolvulus arvensis* (CONAR) as well as other mono- and dicotyledonous weeds were conducted in grape and pome fruits. For the control of mono- and dicotyledonous weeds in grape a total of four trials was conducted in 2009 and 2010. For example for 7 weed species (CAPBP, CIRAR, LAMPU, FUMOF, GERMO, VERPE and PICHI) a control level of 98-100% was achieved using a dosage of 1800 g a.s./ha HAG 500 02 H. Furthermore, the effectiveness of HAG 500 02 H for the control of mono- and dicotyledonous weeds using a target dose of 1800 g a.s./ha was tested in 7 trials in pome fruit orchards. In these trials HAG 500 02 H showed a good control effect on 27 weed species. A partial, moderate or useful level of control (60-80%) or a reduction (40-60%) of weed species respectively was observed for some weed species like LOLMU, ERIAN, URTDI, EPIAD, GERDI and CUCLA. In the case of *Convolvulus arvensis* (CONAR) two trials were conducted in grape and two trials in pome fruit orchards in 2009. The results have shown that the overall control effect in woody plants regarding the control of *Convolvulus arvensis* (CONAR) was sufficiently. The results can be transferred to stone fruits.

Regarding efficacy of weed control in grassland re-sowing and grassland renewal six trials were conducted in the years 2009 and 2010. In these 4 trials HAG 500 02 H showed a level of efficacy against the different weed species present in the trials similar to that of the standard reference product Roundup Ultra Max.

For the efficacy of HAG 500 02 H for desiccation in the absence of weeds in TRZAS, HORVS, TTLSO, HORVW and TTLWI 17 trials were conducted considering the requested dose rate.

To test the efficacy of HAG 500 02 H for desiccation in winter oilseed rape four trials were conducted in 2009. HAG 500 02 H applied at 1125 g a.s./ha, equivalent to 2.5 L product/ha showed the same accelerated crop desiccation and ripening process than the double dose of HAG 500 02 H applied at 2250 g a.s./ha, equivalent to 5.0 L product/ha.

In stubbles the efficacy of HAG 500 02 H against various weed species was tested in 26 trials in 2009 and 2010. In these trials HAG 500 02 H demonstrated a level of efficacy against the different weed species present in the trials similar to that of the commercial country specific standard reference products.

The efficacy of HAG 500 02 H against *Elytrigia repens* (AGRRE) in winter cereals (TRZAW, HORVW, TTLWI) regarding desiccation and harvest facilitation was tested in 16 trials in 2009 and 2010. HAG 500 02 H demonstrated a level of efficacy against the different weed species present in the trials similar to that of the commercial country-specific standard reference products in the first crop and the following crop.

In 2009 four trials were conducted to test the efficacy of HAG 500 02 H for the control of *Elytrigia repens* (AGRRE) and other weeds in oilseed rape (BRSNW). The trials have shown, that in general HAG 500 02 H had a level of efficacy against the different weed species present in the trials similar to that of the commercial country specific standard reference products in the first crop and the following crop.

In sugar beet the efficacy is demonstrated with an application rate of 1.6 L /ha. Trials were carried out only for one year in Poland. Poland does not belong to the maritime or south-east EPPO zone.

HAG 500 02 H was tested in various field trials for its effects on yield and quality of plants and plant products. The test product HAG 500 02 H applied at the requested dose rate showed comparable results than the commercial standard reference product.

Adverse effects such as phytotoxicity to host crop were tested for example in grape. For this crop no specific crop selectivity trials are available for HAG 500 02 H. The crop selectivity of HAG 500 02 H was determined in all 4 trials in grape which have been conducted at the target dose rate of 1800 g a.s./ha, equivalent to 4.0 L product/ha and the following doses 1080 g a.s./ha, equivalent to 2.4 L product/ha, 1440 g a.s./ha, equivalent to 3.2 L product/ha and 2160 g a.s./ha, equivalent to 4.8 L product/ha. All different grape varieties showed a good product tolerance and no phytotoxicity were observed.

In none of the trials negative effects on beneficial or non-target organisms were observed.

There were no special studies conducted concerning the influence of the product HAG 500 02 H on plants used for propagating purposes. In literature information on inhibition of seed germination in crops treated with glyphosate is given. Because of this, the treatment of cereals to desiccate is excluded according to the GAP for example.

Also no additional studies were conducted on the impact of the product HAG 500 02 H on succeeding crops. Because glyphosate has no potential for a build-up or an accumulation in soil under field conditions it can be assumed that there is no negative impact on succeeding crops.

As HAG 500 02 H is non selective herbicide the product should be used with care and in line with good plant protection practice. Directions for use for example in regard to uncontrolled spay drift to neighbouring fields, weather conditions or water volumes have to be observed. If requirements of good plant protection practice are observed it can be assumed that there are no negative impacts on other plants, including adjacent crops.

The product HAG 500 02 H formulated as 450 g/L glyphosate containing SL formulation is intended to be used as non-selective herbicide against monocotyledonous and dicotyledonous weeds in on a number of field crops as well as in vineyards and orchards (pome fruit) and for desiccation. The active substance glyphosate is a commonly used herbicide in agriculture worldwide. Despite the intensive use of glyphosate in many important crops on a worldwide scale, the number of documented cases of resistance is still comparatively low. However, the increasing use of glyphosate in many cropping systems in the Central Zone of Europe constitutes an increasing risk of resistance. The general resistance risk of HAG 500 02 H is therefore assessed as being low to medium. The applicant has not provided any information on the individual resistance risk within the different member states in the Central zone.

IIIA1 6.7 List of test facilities including the corresponding certificates

No.	Trial organisation	Address	GEP yes/no
1	Agrostat Sp. Z o.o.	Experimental department : Zalesie 12, 63-233 Jaraczewo, Poland IIIA 7.1.1 Test facility : Ul. Ziebicka 2, 60-164 Poznan, Poland	yes
2	Agrostat Gesellschaft für landwirtschafliches Versuchswesen m.b.H	In den Gruben 6 74572 Herrentierbach Germany	yes

Trials were also carried out in France and UK. Trial organisations of these countries are not included in the List of test facilities.

Appendix 1: List of data submitted in support of the evaluation

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 3.9	Anonymous	Entwurf Gebrauchsanleitung Glyphosate 450 SL	2011	220464
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on VITVI (Vitis vinifera / European grape). Registration purpose. France 2009	2010	115H_FR01 220475
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on VITVI (Vitis vinifera / European grape). Registration purpose. France 2009	2010	115H_FR02 220476
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on VITVI (Vitis vinifera / European grape). France 2010	2010	115H_FR07 220477
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on VITVI (Vitis vinifera / European grape). Registration purpose. Germany 2009	2009	115H_GE01 220478
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. France 2009	2010	115H_FR03 220479
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. France 2009	2010	115H_FR06 220480
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on MABSD (Malus domestica / Apple). France 2010	2010	115H_FR08 220481
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono- and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. Germany 2009	2009	115H_GE02 220482
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on PYUCO (Pyrus communis / Common pear). Registration purpose. Germany 2009	2009	115H_GE03 220483
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. Poland 2009	2009	115H_PL01 220484
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. Poland 2009	2009	115H_PL02 220485
KIIIA1 6.1.2	Schmidt, I.	Determination of efficacy and selectivity of HAG 500 02 H against perennial and annual mono- and dicotyledonous weeds on VITVI (Vitis vinifera / European grape). Registration purpose. Germany 2009/2010	2010	116H_GE03 220486

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Schmidt, I.	Determination of efficacy and selectivity of HAG 500 02 H against perennial and annual mono- and dicotyledonous weeds on VITVI (Vitis vinifera / European grape). Registration purpose. France 2009	2010	116H_FR01 220487
KIIIA1 6.1.2	Schmidt, I.	Determination of efficacy and selectivity of HAG 500 02 H against perennial and annual mono- and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. Germany 2009/2010	2010	116H_GE01 220488
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial and annual mono- and dicotyledonous weeds on MABSD (Malus domestica / Apple). Registration purpose. Germany 2010	2010	116H_GE04 220489
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on NNNFW (plants in grassland). Registration purpose. UK 2009	2010	120H_UK01 220490
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on NNNFW (plants in grassland). Registration purpose. UK 2009	2010	120H_UK02 220491
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual and perennial weeds on NNNFW (plants in grassland) for grassland renewal. Registration purpose. UK 2010	2010	120H_UK03 220492
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual and perennial weeds on NNNFW (plants in grassland) for grassland renewal. Registration purpose. UK 2010	2010	120H_UK04 220493
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on NNNFW (plants in grassland) for grassland renewal. Registration purpose. Germany 2010	2010	120H_DE03 220495
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual and perennial weeds on NNNFW (plants in grassland). Registration purpose. Germany 2010	2010	120H_DE04 220496
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on stubble before planting of arable crops. Registration purpose. UK 2009	2010	114H_UK04 220497
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on stubble before planting of arable crops. Registration purpose. UK 2009	2010	114H_UK05 220498
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on stubble sprayed after harvest before sowing of arable crops in the fall. Registration purpose. UK 2009	2010	119H_UK01 220499
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on stubble sprayed after harvest before sowing of arable crops in the fall. Registration purpose. United Kingdom 2009	2010	119H_UK02 220500
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on stubble sprayed after harvest before sowing of arable crops in the fall. Registration purpose. United Kingdom 2009	2010	119H_UK03 220501

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on stubble after harvest. United Kingdom 2010	2010	114H_UK06 220502
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting. Registration purpose. UK 2010	2010	119H_UK04 220503
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting of winter wheat. Registration purpose. UK 2010	2010	119H_UK05 220504
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on stubble sprayed 1 - 3 days after harvest before sowing of winter oil seed rape in fall. Registration purpose. Germany 2009	2009	119H_DE01 220505
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on stubble sprayed 30 - 45 days after harvest before sowing of winter wheat in the fall. Registration purpose. Germany 2009	2009	119H_DE02 220506
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting. Registration purpose. Germany 2010	2010	119H_DE03 220507
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting. Registration purpose. Germany 2010	2010	119H_DE04 220508
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H applied in field crops against annual mono- and dicotyledonous weeds on stubble before planting. Germany 2010	2010	114H_GE10 220509
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H applied in field crops against annual mono- and dicotyledonous weeds on stubble before planting. Germany 2010	2010	114H_GE11 220510
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H applied in field crops against annual mono- and dicotyledonous weeds on stubble before planting. Germany 2010	2010	114H_GE12 220511
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on stubble before planting of arable crops. Registration purpose. France 2009	2010	114H_FR01 220512
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on stubble before planting of arable crops. Registration purpose. France 2009	2010	114H_FR02 220513
KIIIA1 6.1.2	Schmdit, I.	Efficacy and selectivity of HAG 500 02 H against annual mono- and dicotyledonous weeds on stubble before planting of arable crops. Registration purpose. France 2009	2010	114H_FR05 220514
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial and annual weeds on stubble sprayed after harvest before sowing of arable crops in the fall. Registration purpose. France 2009	2010	119H_FR01 220515

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H applied in field crops against annual mono- and dicotyledonous weeds on stubble before planting. France 2010	2010	114H_FR11 220516
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial weeds on stubble sprayed after harvest before sowing of arable crops in the fall. Registration purpose. France 2009	2010	119H_FR02 220517
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting. Registration purpose. France 2010	2010	119H_FR03 220518
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting. Registration purpose. France 2010	2010	119H_FR05 220519
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against perennial mono- and dicotyledonous weeds on stubble before planting. Registration purpose. France 2010	2010	119H_FR06 220520
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on YACKR (Arable land, stubble). Registration purpose. Poland 2009	2009	125H_PL01 220521
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on YACKR (Arable land, stubble). Registration purpose. Poland 2009	2009	125H_PL02 220522
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	134H_PL01 220523
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	134H_PL02 220524
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	134H_PL03 220525
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	134H_PL04 220526
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on HORVW (Hordeum vulgare -winter / Winter barley). Registration purpose. Poland 2009	2009	135H_PL01 220527
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TTLWI (Triticale / Winter triticale). Registration purpose. Poland 2009	2009	138H_PL01 220528

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) on TRZAW (Triticum aestivum (winter) / Winter wheat) sprayed before harvest. Registration purpose. Germany 2009	2009	118H_GE02 220529
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against CIRAR (Cirsium arvense / Canada thistle) and AGRRE (Elytrigia repens / Quackgrass) on TRZAW (Triticum aestivum (winter) / Winter wheat) sprayed before harvest. Registration purpose. Germany 2	2009	118H_GE03 220531
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) on TRZAW (Triticum aestivum (winter) / Winter wheat) sprayed before harvest. Registration purpose. Germany 2010	2010	118H_GE05 220532
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) and CIRAR (Cirsium arvense / Canada thistle) on TRZAW (Triticum aestivum (winter) / Winter wheat) applied before harvest. Registration purpose. Germany 2	2010	118H_GE06 220533
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) on HORVW (Hordeum vulgare-winter / Winter barley) sprayed before harvest. Registration purpose. Germany 2009	2009	118H_GE01 220534
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) on HORVW (Hordeum vulgare -winter / Winter barley) applied before harvest. Registration purpose. Germany 2010	2010	118H_GE04 220535
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Couchgrass) on TRZAW (Triticum aestivum (winter) / Winter wheat) sprayed before harvest. Registration purpose. France 2009	2010	118H_FR01 220536
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against CYNDA (Cynodon dactylon / Bermuda grass) on TRZAW (Triticum aestivum (winter) / Winter wheat) applied before harvest. Registration purpose. France 2010	2010	118H_FR04 220537
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) on HORVW (Hordeum vulgare -winter / Winter barley) applied before harvest. Registration purpose. France 2010	2010	118H_FR03 220539
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) on TRZAW (Triticum aestivum (winter) / Winter wheat) sprayed before harvest. Registration purpose. UK 2009	2010	118H_UK01 220540
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	139H_PL01 220542
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against monocotyledonous and dicotyledonous weeds on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	139H_PL02 220543

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	139H_PL03 220544
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	139H_PL04 220545
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on HORVS (Hordeum vulgare (spring) / Spring barley). Registration purpose. Poland 2009	2009	136H_PL01 220546
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on TTLSO (Triticale / Spring triticale). Registration purpose. Poland 2009	2009	140H_PL01 220547
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against AGRRE (Elytrigia repens / Quackgrass) and CONAR (Convolvu-lus arvensis / Small bindweed) on HORVS (Hordeum vulgare (spring) / Spring barley) sprayed before harvest. Registration purpose. UK 20	2010	118H_UK03 220548
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	137H_PL01 220549
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	137H_PL02 220550
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	137H_PL03 220551
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	137H_PL04 220552
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on PIBSA (Pisum sativum var. arvense / Field pea). Registration purpose. Poland 2009	2009	141H_PL01 220553
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on PIBSA (Pisum sativum var. arvense / Field pea). Registration purpose. Poland 2009	2009	141H_PL02 220554
KIIIA1 6.1.2	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against CIRAR (Cirsium arvense / Creeping thistle) on VICFM (Vicia faba subsp. minor / Field bean) sprayed before harvest. Registration purpose. UK 2009	2010	118H_UK02 220555

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	123H_PL01 220556
KIIIA1 6.1.3	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	123H_PL02 220557
KIIIA1 6.1.3	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	123H_PL03 220558
KIIIA1 6.1.3	Schmidt, I.	Efficacy and selectivity of HAG 500 02 H against mono-cotyledonous and dicotyledonous weeds on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	123H_PL04 220559
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVW (Hordeum vulgare (winter) / Winter barley). Registration purpose. Poland 2009	2009	127H_PL01 220560
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVW (Hordeum vulgare (winter) / Winter barley). Registration purpose. Poland 2009	2009	127H_PL02 220561
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVW (Hordeum vulgare (winter) / Winter barley). Registration purpose. Poland 2009	2009	127H_PL03 220562
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVS (Hordeum vulgare (spring) / Jeczmien jary). Registration purpose. Poland 2009	2009	128H_PL01 220563
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVS (Hordeum vulgare (spring) / Jeczmien jary). Registration purpose. Poland 2009	2009	128H_PL02 220564
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVS (Hordeum vulgare (spring) / Jeczmien jary). Registration purpose. Poland 2009	2009	128H_PL03 220565
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on HORVS (Hordeum vulgare (spring) / Jeczmien jary). Registration purpose. Poland 2009	2009	128H_PL04 220566
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLWI (Triticale / Winter triticale). Registration purpose. Poland 2009	2009	130H_PL01 220567
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLWI (Triticale / Winter triticale). Registration purpose. Poland 2009	2009	130H_PL02 220568
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLWI (Triticale / Winter triticale). Registration purpose. Poland 2009	2009	130H_PL03 220569

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLWI (Triticale / Winter triticale). Registration purpose. Poland 2009	2009	130H_PL04 220570
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	131H_PL01 220571
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	131H_PL02 220572
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAS (Triticum aestivum (spring) / Spring wheat). Registration purpose. Poland 2009	2009	131H_PL03 220573
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLSO (Triticale / Spring triticale). Registration purpose. Poland 2009	2009	132H_PL01 220574
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLSO (Triticale / Spring triticale). Registration purpose. Poland 2009	2009	132H_PL02 220575
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TTLSO (Triticale / Spring triticale). Registration purpose. Poland 2009	2009	132H_PL03 220576
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	126H_PL01 220577
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	126H_PL02 220578
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	126H_PL03 220579
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on TRZAW (Triticum aestivum (winter) / Winter wheat). Registration purpose. Poland 2009	2009	126H_PL04 220580
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	129H_PL01 220581
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	129H_PL02 220582
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	129H_PL03 220583
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2009	2009	129H_PL04 220584

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on PIBSA (Pisum sativum var. arvense / Field pea). Registration purpose. Poland 2009	2009	133H_PL01 220585
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on PIBSA (Pisum sativum var. arvense / Field pea). Registration purpose. Poland 2009	2009	133H_PL02 220586
KIIIA1 6.1.3	Schmidt, I.	Crop desiccation and selectivity of HAG 500 02 H on PIBSA (Pisum sativum var. arvense / Field pea). Registration purpose. Poland 2009	2009	133H_PL03 220587
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on MABSD (Malus domestica /Apple). Registration purpose. Poland 2009	2009	121H_PL01 220588
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on MABSD (Malus domestica /Apple). Registration purpose. Poland 2009	2009	121H_PL02 220589
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on MABSD (Malus domestica /Apple). Registration purpose. Poland 2009	2009	121H_PL03 220590
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on MABSD (Malus domestica /Apple). Registration purpose. Germany 2009	2009	122H_GE02 220591
KIIIA1 6.1.4.3	Schmidt, I.	Field study to evaluate the selectivity of HAG 500 02 H in woody plants. Registration purpose. Germany 2010	2010	122H_GE03 220592
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on PYUCO (Pyrus communis / Common pear). Registration purpose. Poland 2009	2009	121H_PL04 220594
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on PYUCO (Pyrus communis / Common pear). Registration purpose. Poland 2009	2009	121H_PL05 220595
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on PYUCO (Pyrus communis / Common pear). Registration purpose. Poland 2009	2009	121H_PL06 220596
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on PYUCO (Pyrus communis / Common pear). Registration purpose. Germany 2009	2009	122H_GE01 220597
KIIIA1 6.1.4.3	Schmidt, I.	Field study to evaluate the selectivity of HAG 500 02 H in woody plants. Registration purpose. Germany 2010	2010	122H_GE04 220598
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	124H_PL01 220599
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	124H_PL02 220600
KIIIA1 6.1.4.3	Schmidt, I.	Selectivity of HAG 500 02 H on BEAVA (Beta vulgaris vulg. altissima / Sugarbeet). Registration purpose. Poland 2009	2009	124H_PL03 220601
KIIIA1 10.5.2	Moll, M.	Effects of Glyphosate 450 SL AE on the Parasitoid Aphidius rhopalosiphi, Extended Laboratory Study - Dose Response Test -	2010	Doc. No. 50355002 220604

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.5.2	Schwarz, A.	Effects of Glyphosate 450 SL AE on the Predatory Mite Typhlodromus pyri, Extended Laboratory Study - Dose Response Test -	2010	Doc. No. 50356062 220605
KIIIA1 10.5.2	Schmitzer, S.	Effects of Glyphosate 450 SL AE on the Carabid Beetle Poecilus cupreus, Extended Laboratory Study	2010	Doc. No. 50357007 220606
KIIIA1 10.6.2	Witte, B.	Acute toxicity (14 days) of Glyphosate 450 SL AE to the earthworm Eisenia fetida in artificial soil	2010	Doc. No. 52522021 220607
KIIIA1 10.7.1	Feil, N.	Effects of Glyphosate 450 SL AE on the Activity of the Soil Microflora in the Laboratory	2010	Doc. No. 50359080 220608
MIIIA1 Sec 6	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 6 Ecotoxicology - Core assessment	2011	220618
MIIIA1 Sec 6	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 6 Ecotoxicology - Core assessment (word)	2011	220619
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment	2011	220620
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment (word)	2011	220621
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 4 - Summary of data on trails site and application details per use (EPPO code)	2011	220622
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 4 - Summary of data on trails site and application details per use (EPPO code) (word)	2011	220623
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 5 - Summary of data on minimum effective dose tests - effectiveness trials per use (crop/harmful organism); (EPPO code)	2011	220624
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 5 - Summary of data on minimum effective dose tests - effectiveness trials per use (crop/harmful organism); (EPPO code) (word)	2011	220625
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 6 - Central summary per weed species	2011	220626
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 6 - Central summary per weed species (word)	2011	220627

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 7 - Effects on yield and quality	2011	220628
MIIIA1 Sec 7	Anonymous	Draft Registration Report - Part B - HAG 500 02 H - DE - Section 7: Efficacy Data and Information - Core assessment - Appendix 7 - Effects on yield and quality (word)	2011	220629
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KIIA 8.8	Halsall, N.	A semi-field evaluation of the toxicity of the herbicide Glyphosate 360 to the linyphiid spider	1991	CHEM-91-1 220635
KIIA 8.8	Halsall, N.	An evaluation of the toxicitity (PMG 360) glyphosate to the linyphiid spider Meioneta rurestris	1990	CHEM-90-2 220636
KIIA 8.8	Halsall, N.	An evaluation of the toxicity (PMG 360) glyphosate to the carabid beetle Trechus quadristriatus	1990	CHEM-90-1 220637
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KIIA 8.8	Mead-Briggs, M. and Halsall, N.	An evaluation of the toxicity of Roundup to the carabid beetle, Bembidion lampros under semi-field conditions.	1990	MON-90-1 ! XX-90-603 220639
KIIA 8.8	Hassan, et al.	Results of the fourth joint pesticide testing programme carried out by the IOBC/WPRS Working Group "Pesticides and Beneficial Organisms".	1988	220641
KIIA 8.9.2	Hayward, J. C. and Mallett, M. J.	A laboratory investigation of the effects of glyphosate and its breakdown product AMPA on reproduction in the earthworm Eisenia fetida	2000	Rep.-No.: CEMR-1173 220644
KIIA 8.9.1	Thun, S.	Acute toxicity in earthworms according to OECD 207, test article: "Technical isopropylamin salt of glyphosate = Mon 0319"	1991	80-91-2078-00-90 220645
KIIA 8.9.1	Wüthrich, V.	Acute toxicity (LC50) of glyphosate to earthworms	1990	250784 220646
KIIA 8.9.1	Thun, S.	First amendment final report acute toxicity in earthworms according to OECD 207, test article: "Mon 0319"	1995	80-91-2078-06-91 220647
KIIA 8.10	Trevors, J.T.	Bacterial biodiversity in soil with an emphasis on chemically-contaminated soils	1900	k.A. 220649
MIIA Sec 6	Anonymous	MIIA Section 6	1995	220759
KIIIA1 3.9	Anonymous	Anhang 5_Gebrauchsanleitung_DE.	2012	261544
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Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 6	Anonymous	Amendment to Draft Registration Report - Part B - HAG 500 02 H - DE - Section 6 Ecotoxicology - Core assessment (word)	2012	261552
MIIIA1 Sec 7	Helm AG	Amendment to Registration Report - Part B - Section 7_HAG 500 02.doc	2012	261554
MIIIA1 Sec 6	Anonymous	Amendment to Draft Registration Report - Part B - HAG 500 02 H - DE - Section 6 Ecotoxicology - Core assessment (word)	2012	261556

Appendix 2: GAP tables

glyphosate (0405)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
1	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Field crops	F	TTTMM, TTTDD	spraying	stubble treatment; after harvest, up to 4 days before sowing	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
2	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Pome fruit	F	TTTMM, TTTDD	spraying	spring to summer	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
3	DE	Pome fruit	F	CONAR	spraying	spring to summer	a) 1 b) 1	a) 8.0 b) 8.0	a) 3.6 b) 3.6	100 - 400		
4	DE, HU, RO, AT, CZ, SK, SLO	Grape vine	F	TTTMM, TTTDD	spraying	utilisation as wine and table grape from 4th year after planting of the vine onwards; spring to summer	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
5	DE	Grape vine	F	CONAR	spraying	utilisation as wine and table grape from 4th year after planting of the vine onwards; spring to summer	a) 1 b) 1	a) 8.0 b) 8.0	a) 3.6 b) 3.6	100 - 400		
6	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK,	Cereals (barley, oats, rye, triticale, wheat)	F	TTTMM, TTTDD, YELSI*	spraying	except for seed production and brewing purposes; 89 - 89;	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		For DE additionally the note on crop: lodging cereals

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
	SLO					up to 7 days before harvest, during late treatment						
7	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Grassland, pasture, meadow	F	TTTMM, TTTDD	spraying	5-7 days before sowing, during vegetative period	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		
8	DE, GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Winter rape	F	TTTMM, TTTDD, YELSI*	spraying	except for seed production; 87 - 89; up to 14 days before harvest, during late treatment	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400		YELSI not requested in DE
9	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Winter rape	F	TTTMM, TTTDD	spraying	except for seed production; 00 - 08; Before emergence, after emergence of weeds	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400		The use will not be pursued in Germany.
	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Sugar beet BEAVA	F	TTTMM, TTTDD	spraying	Before emergence BBCH 00	a) 1 b) 1	a) 1.6 b) 1.6	a) 0.72 b) 0.72	200 - 300		

	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Field pea PIBSA	F	TTTMM, TTTDD, YELSI	spraying	except for seed production; 87 - 89	a) 1 b) 1	a) 2.5 b) 2.5	a) 1.125 b) 1.125	100 - 400		
	GB, BE, NL, HU, RO, IRL, AT, CZ, SK, SLO	Stone fruit NNNOS	F	TTTMM, TTTDD	spraying	spring to summer	a) 1 b) 1	a) 4.0 b) 4.0	a) 1.8 b) 1.8	100 - 400		

* no EPPO code

Appendix 3: Additional information provided by the applicant (e.g. detailed modelling data)

Master label

Glyphosate 450 SL

Contains 450 g/L glyphosate acid equivalent in a soluble liquid and 8 g/L of Natriumchlorid as part of a co-formulant

A non-selective herbicide for post harvest (stubble) control of broadleaved weeds and grasses in field crops, for pre-harvest control of broadleaved weeds and grasses in spring and winter cereals and for desiccation of cereals

The Control of Substances Hazardous to Health (COSHH) Regulations may apply to the use of this product at work.

For use only as an agricultural herbicide

Weed	Crop	Country
Mono-/ Dicotyledonous weeds	Field crops	AT, BE, CZ, DE, HU, IRE, PL, RO, SK, SLO, NL, UK
Mono-/ Dicotyledonous weeds	Cereals	AT, BE, CZ, DE, HU, IRE, PL, RO, SK, SLO, NL, UK
Desiccation	Cereals	AT, BE, CZ, DE, HU, IRE, PL, RO, SK, SLO, NL, UK
Mono-/ Dicotyledonous weeds	Oilseed rape	AT, BE, CZ, DE, HU, IRE, PL, RO, SK, SLO, NL, UK
Desiccation	Oilseed rape	AT, BE, CZ, HU, IRE, PL, RO, SK, SLO, NL, UK
Mono-/ Dicotyledonous weeds	Sugar Beet	AT, BE, CZ, HU, IRE, PL, RO, SK, SLO, NL, UK
Mono-/ Dicotyledonous weeds	Field pea	AT, BE, CZ, HU, IRE, PL, RO, SK, SLO, NL, UK
Desiccation	Field pea	AT, BE, CZ, HU, IRE, PL, RO, SK, SLO, NL, UK
Mono-/ Dicotyledonous weeds	Pome fruit	AT, BE, CZ, DE, HU, IRE, PL, RO, SK, SLO, NL, UK
Mono-/ Dicotyledonous weeds	Grapes	DE, SLO, HU, CZ, SK, AT, RO
Grassland renewal	Grassland	AT, BE, CZ, DE, HU, IRE, PL, RO, SK, SLO, NL, UK

Weed control

Glyphosate 450 SL is a systemic herbicide applied on leaves. It is taken up by green parts of the plant (leaves, green shoots and not ligneous bark) and translocated to the underground parts (roots, runners etc.) inhibiting the growth and development within 24 hours followed by plant death. First symptoms of the product reaction (jaundice and wilting) are visible 7 to 10 days after product application. Complete plant death takes place after approximately 3 weeks. High temperature and air humidity as well as strong insolation fasten activity of Glyphosate 450 SL.

Susceptible Weeds: The susceptibility ratings of weeds in the following table refer to good spray cover and good growing conditions.

Susceptible:		
Avena sterilis	*Erodium cicutarium*	*Polygonum aviculare*
Agrostis stolonifera	*Fallopia convolvulus*	*Polygonum persicaria*
Alopecurus myosuroides	*Fumaria officinalis*	*Persicaria lapathifolia*
Amaranthus retroflexus	*Galium aparine*	*Ranunculus repens*
Apera spica-venti	*Galinsoga parviflora*	*Rumex obtusifolius*
Avena ludoviciana	*Geranium molle*	*Senecio vulgaris*
Bellis perennis	*Geranium pusillum*	*Setaria verticillata*
Brassica napus	*Gramineae*	*Sinapis arvensis*
Capsella bursa-pastoris	*Gnaphalium uliginosum*	*Sonchus asper*
Cardamine hirsuta	*Lamium amplexicaule*	*Stellaria media*
Centaurea cyanus	*Lamium purpureum*	*Taraxacum officinale*
Cerastium fontanum	*Lolium perenne*	*Thlaspi arvense*
Chenopodium album	*Matricaria recutita*	*Trifolium repens*
Chenopodium polyspermum	*Matricaria inodora*	*Trifolium arvense*
Cirsium arvense	*Mercurialis annua*	*Veronica arvensis*
Cirsium vulgare	*Papaver rhoeas*	*Veronica triphyllos*
Convolvulus arvensis	*Picris hieracioides*	*Veronica persica*
Cynodon dactylus	*Plantago lanceolata*	*Veronica hederifolia*
Echinochloa crus-galli	*Poa annua*	*Viola arvensis*
Elytrigia repens	*Poa trivialis*	*Volunteer cereals*

Moderately susceptible:		
Anthemis arvensis	Epilobium adnatum	Hordeum murinum
Cerastium arvense	Erigeron annuus	Lolium multiflorum
	Rumex acetosa	Vicia faba

Moderately resistant:		
Cerastium fontanum	Geranium dissectum	Sisymbrium officinale
Caucalis lappula	Plantago major	Urtica dioica
		Urtica urens

Crop specific information

Field crops

Maximum individual dose of product: 4L/ha

Use: The maximum dose rate depends on weed infestation.
Max. 1 application per crop.
Water volume: 100 – 200 L/ha (DE: 100 – 400 L/ha)
After crop harvest on stubbles, until 5 days before sowing

Harvest intervals	days before harvest covered by conditions of use and/or growing period between application and harvest

All crops can be cultivated on fields where Glyphosate 450 SL was applied

Cereals:

Maximum individual dose of product:	2.5 - 4L/ha
Use:	At BBCH 89 for desiccation and weed control. Except for seed production and brewage The maximum dose rate depends on weed infestation Max. 1 application per crop and year Water volume: 100 – 400 L/ha
Harvest intervals	7 days

All crops can be cultivated on fields where Glyphosate 450 SL was applied

Oilseed rape – pre-emergence:

Maximum individual dose of product:	2,5 L/ha
Use:	Pre-emergence (BBCH 00-08) for weed control. The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha (DE: 100 – 400 L/ha)
Harvest intervals	days before harvest covered by conditions of use and/or growing period between application and harvest

All crops can be cultivated on fields where Glyphosate 450 SL was applied

Oilseed rape – pre-harvest:

Maximum individual dose of product:	2,5 L/ha
Use:	At BBCH 87 - 89 for desiccation and weed control. The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha (DE: 100 – 400 L/ha)
Harvest intervals	14 days

All crops can be cultivated on fields where Glyphosate 450 SL was applied

Sugar beet – pre-emergence:

Maximum individual dose of product:	1,6 L/ha
Use:	Pre-emergence (BBCH 00) for weed control. The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha

Harvest intervals	days before harvest covered by conditions of use and/or growing period between application and harvest

All crops can be cultivated on fields where Glyphosate 450 SL was applied

Field pea – pre-harvest:

Maximum individual dose of product:	2,5 L/ha
Use:	For desiccation in absence of weeds before crop harvest when moisture of seeds is below 30% at BBCH 87 – 89.. The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha
Harvest intervals	7 days

All crops can be cultivated on fields where Glyphosate 450 SL was applied. Do not apply on seed plantation.

Pome fruit:

Maximum individual dose of product:	4 L/ha and for field bindweed 8L/ha (bindweed inDE only)
Use:	Apply once by ground directed strip application from 15 – 20 cm weed height onwards. The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha
Harvest intervals	42 days

Grapevine:

Maximum individual dose of product:	4 L/ha and for field bindweed 8L/ha (bindweed inDE only)
Use:	Apply once by ground directed strip application in grapes from 4th year of plant stand against weeds from 10 – 20 cm weed height onwards. The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha
Harvest intervals	30 days

Grassland - renewal:

Maximum individual dose of product:	4 L/ha
Use:	For control of weeds in grassland renewal apply 5 -7 days before sowing. Apply once at ground directed

	application at approximately 15 cm plant height. Best control of couchgrass at 3 to 4 leaves per not. Best control of plants of parsley family in full florescence The maximum dose rate depends on weed infestation Max. 1 application per crop and year. Water volume: 200 – 300 L/ha
Harvest intervals	days before harvest covered by conditions of use and/or growing period between application and harvest

SAFETY PRECAUTIONS
Operator protection
WASH CONCENTRATE from skin or eyes immediately
WHEN USING DO NOT EAT, DRINK OR SMOKE
WASH HANDS AND EXPOSED SKIN before eating and drinking and after work

Environmental protection
Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.

Storage and disposal
KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS
KEEP OUT OF REACH OF CHILDREN
KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place.
This material and its container must be disposed of in a safe way.
WASH OUT CONTAINER THOROUGHLY, empty washings into spray tank, and dispose of safely.

To avoid risks to man and the environment, comply with the instructions for use.
Safety data sheet available for professional user on request.

HELM AG

Contents: **xxxx**

Nordkanalstrasse 28
D-20097 Hamburg
Germany
Approval Holder: Helm AG

Batch No.

Tel: +49 / 40 / 2375 0
Fax: +49 / 40 / 2375 1845

This product is approved under the Plant Protection Products Regulations (as amended).

DIRECTIONS FOR USE

IMPORTANT: This information is approved as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product.

Restrictions

Due to high level of activity of the herbicide, take extreme care to avoid damage by drift onto plants outside the target area, or onto ponds, waterways or ditches. A protection zone of 5 m from non-target areas has to be set. Thorough cleansing of equipment is also very important.
Effects on brewing and baking have not been established. Consult grain merchant or processor before use.

Application of the product in the zone of the protected water intake is prohibited.
Do not contaminate water with the product or its package.
In order to protect crops not aimed to be sprayed
Do not apply, before weed emergence, onto wet plants or before expected rainfall (rainfall within one hour after spraying can decrease the efficacy).

Weed resistance

This product contains glyphosate which is an 'EPSP synthase', also classified by the Herbicide Resistance Action Committee as 'Group G' (glycines).
When herbicides with the same mode of action are used repeatedly over several years in the same field, selection of resistant biotypes can take place. These can propagate and may become dominating. A weed species is considered resistant to a herbicide if it survives a correctly-applied treatment at the recommended dose.
Development of resistance within a weed species can be avoided or delayed by sequencing or tank-mixing with suitable products having a different mode of action.
A strategy for preventing resistance should be adopted. The Weed Resistance Action Group has produced guidelines and copies are available from the HGCA, CPA, your distributor, crop advisor and product manufacturer.

Soil and weather

GLYPHOSATE 450 SL can be used on all soil types. Weed control may be reduced when leaves of weeds ar wet from previous rain.

Volume and application

Apply the recommended rate of GLYPHOSATE 450 SL in 200 to 300 L/ha water except for field crops use 100 to 200 L/ha water and for cereals 100 to 400 L/ha water. In Germany use 100 -400 L/ha water for all crops. Use suitable ground equipment to give good spray cover of the weeds. Use a conventional field crop sprayer at a pressure of 2-3 bars and apply as a MEDIUM spray (as defined by BCPC).

Mixing

Half fill the spray tank with clean water and start the re-circulation system. Pour the required quantity of product into the spray tank. Top up the spray tank with water to the required level. Continue agitation until the tank is sprayed out. Spray immediately after mixing.

Compatibility

HAG 500 02 H is not intended for use in tank-mixture.

Crops

HAG 500 02 H can be used on field crops post-harvest, in cereals at crop stage BBCH 89, in pome fruit, in oilseed rape at crop stage 87-89 and in grassland before sowing for removal of weeds.

Timing

GLYPHOSATE 450 SL should be applied pre-harvest at BBCH 89 in cereals and at BBCH 87-89 or BBCH 00-08 in oilseed rape. Use GLYPHOSATE 450 SL post-harvest in field crops on stubbles until 5 days before sowing and 5 to 7 days before grassland renewal, for pre-emergence application in sugar beets at BBCH 00 and for desiccation in field peas at BBCH 87 – 89. In pome fruit and grapevine use

GLYPHOSATE 450 SL from 15-20 cm and 10-20 cm weed height onwards, respectively. Weeds should be green and in the intense growing phase.
GLYPHOSATE 450 SL should be used in pome fruit in strip application when weeds are 15 – 20 cm high.
GLYPHOSATE 450 SL should be used for grassland renewal before sowing.

Dose

Apply GLYPHOSATE 450 SL at 4 litres/hectare in field crops post-harvest, at 2,5 to 4 litres/ha in cereals pre-harvest, at 2.5 L/ha in oilseed rape pre-harvest or pre-emergence and at 4 L/ha for grassland renewal, 1,6 L/ha in sugar beet pre-emergence, 2,5 L/ha in field pea pre-harvest and at 4 L/ha grapevine and pome fruit and 8 L/ha against field bindweed, respectively (only in Germany).

Subsequent cropping

All crops can be cultivated on fields where HAG 500 02 H was applied. Seeding or planting can be started 5 days after application.

Spray tank clean-out

It is important that the spray tank, boom, hoses filters and nozzles are thoroughly washed out to remove all traces of HAG 500 02 H immediately after spraying and before the sprayer is used again;

1. Drain sprayer completely, then wash out tank boom and hoses with clean water. Drain again.
2. Fill the tank with clean water. Flush through boom and hoses then leave sprayer for 10 minutes with agitation on. Then drain completely.
3. Flush the tank, boom and hoses with clean water twice.

Ensure any spray contamination on the outside of the sprayer is removed by washing in clean water.