

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 1100 D

Product name(s): CANDELA

Chemical active substance:

Glyphosate, 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: February 2018

Update date: October 2022

MS Finalisation date: 18/10/2022

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Sharda Poland Sp. z o.o./ CEU version

Version history

When	What
10/2018	Dossier sent for evaluation to Merit Mark (PL)
02/2019	Applicant update
03/2021	zRMS finalised evaluation
10/2022	Applicant update
10/2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Glyphosate 54% SL Candela are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for winter cereals (wheat, barley, rye, oat, triticale), spring barley, oilseed rape, maize, sunflower, pome fruits (apple, pear), grapevine, stone fruits (peach, apricot, cherry, plum). A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

Within the presented dRR no new data were submitted. The presented data were taken by the applicant from EFSA opinions on glyphosate (2013, 2015) and glyphosate Renewal Assessment Report (2013, 2015) to support the intended uses. In addition within this report the applicant encloses the list of already evaluated studies (understood by the zRMS as being the source of the presented data) and by e-mail provides an information that the necessary LoA is in possession of the relevant PL authority (MRiRW).

All the data presented were evaluated during glyphosate renewal. On this basis the intended GAP can be accepted. Moreover the proposed lowered GAP (twice less rate than EU rate) for desiccation use does not pose the probability of the adopted MRL exceedance.

The approval for the requested uses can be granted.

February 2021: Dessication use in wheat removal according to the current authority arrangements in the residues area. All decisions regarding the restoration of desiccation will be taken by MRiRW (PL). The data provided by the applicant are the generally known data in EU and currently not considered a good basis for the approval of desiccation.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 20 mg/kg (barley, oat and sunflower), 10 mg/kg (wheat, oilseed rape and rye), 1 mg/kg (maize), 0,5 mg/kg (grapevine), 0,1* mg/kg (pome fruits and stone fruits) for Glyphosate as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of Glyphosate residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

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Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Winter cereals (wheat, barley, rye, oats, triticale)	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Application before seedling	a) 1 b) 1	-	-	200-400	a) 1.89 b) 1.89	-	
2	Winter wheat	CEU	-	F	Dessication before harvest	SL	54 %	Foliar spray	BBCH 89	a) 1 b) 1	-	-	200-400	a) 1.08 b) 1.08	7	
3	Oilseed rape	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Application before seedling	a) 1 b) 1	-	-	200-400	a) 1.89 b) 1.89	-	
4	Spring barley	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Application before seedling	a) 1 b) 1	-	-	200-400	a) 1.89 b) 1.89	-	
5	Sunflower	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Application before seedling	a) 1 b) 1	-	-	200-400	a) 1.89 b) 1.89	-	
6	Maize	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Application before seedling	a) 1 b) 1	-	-	200-400	a) 1.89 b) 1.89	-	
7	Pome fruit (Apple, pear)	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Spring application BBCH 31-69	a) 1 b) 1	-	-	800-1000	a) 1.89 b) 1.89	-	

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8	Grapevine	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Spring application BBCH 13-69	a) 1 b) 1	-	-	600-1000	a) 1.89 b) 1.89	-	
9	Stone fruit (Peach, apricot, plum, cherry)	CEU	-	F	Annual and perennial grass and broadleaved weeds	SL	54 %	Foliar spray	Spring application BBCH 31-59	a) 1 b) 1	-	-	800-1000	a) 1.89 b) 1.89	-	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

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7.1.2 Summary of the evaluation

The preparation Glyphosate 54% SL is composed of Glyphosate.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Glyphosate

Reference value	Source	Year	Value	Study relied upon	Safety factor
Glyphosate					
ADI	Note taking of new reference values Standing Committee on	2015	0.5 mg/kg bw per day	Developmental toxicity, rabbit	100
ARfD	Plants, Animals, Food and Feed of 10/11 December	2015	0.5 mg/kg bw	Developmental toxicity, rabbit	100

7.1.2.1 Summary for Glyphosate

Table 7.1-3: Summary for Glyphosate

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter cereals (wheat, barley, rye, oats, triticale)	Yes	Yes	N/A	Yes	Yes	No	No
2	Winter wheat (desiccation use)	Yes	Yes	N/A	Yes	Yes (dose 2 times lower than critical GAP)		No
3	Oilseed rape	Yes	Yes	N/A	Yes	Yes		No
4	Spring barley	Yes	Yes	N/A	Yes	Yes		No
5	Sunflower	Yes	Yes	N/A	Yes	Yes		No
6	Maize	Yes	Yes	N/A	Yes	Yes		No
7	Pome fruit (Apple, pear)	Yes	Yes	N/A	Yes	Yes		No
8	Grapevine	Yes	Yes	N/A	Yes	Yes		No
9	Stone fruit (Peach, apricot, plum, cherry)	Yes	Yes	N/A	Yes	Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

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To cover the uses of maize, sunflower, Winter cereals and Spring barley in applications before seeding, based on the EU guidance “SANCO 7525/VI/95 - rev.10.3, where it is stated that 2 trials are sufficient in case of a nil-residue situation, and considering that residues were all <LOQ in a wide range of crops, extrapolations to all other crops, as proposed by the RMS, are agreed.

To cover the use of Winter wheat as desiccation use, based on information of Conclusion of Peer Review EFSA Journal 2015;13(11):4302; Pre-harvest uses in all crops include uses for weed control (higher doses) and harvest aid, sometimes referred to as desiccation (lower doses). The critical GAP is the high dose recommended used for weed control, and in residue trials of RAR, appear trials carried out with a GAP near of proposed by Sharda Cropchem for the use of Winter wheat as desiccation use

The effects of processing on the nature of Glyphosate residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
 These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops. Summary for Glyphosate 54% SL

Table 7.1-4: Information on Glyphosate 54% SL (KCA 6.8)

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Winter cereals (wheat, barley, rye, oats, triticale)	NR	NR	NR	
Winter wheat	7	NR	NR	
Oilseed rape	NR	NR	NR	
Spring barley	NR	NR	NR	
Sunflower	NR	NR	NR	
Maize	NR	NR	NR	
Pome fruit (Apple, pear)	NR	NR	NR	
Grapevine	NR	NR	NR	
Stone fruit (Peach, apricot, plum, cherry)	NR	NR	NR	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for Glyphosate 54% SL
Crop group	Led by Glyphosate	-	-	
Leafy vegetables	NR	-	-	NR
Root and tuber vegetables	NR	-	-	NR
Fruits and fruiting vegetable	NR	-	-	NR
Pulses and oilseeds	NR	-	-	NR
Cereals	NR			NR

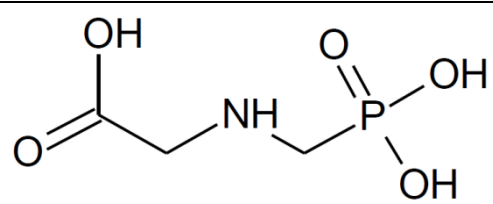
NR: not relevant

Assessment

7.2 Glyphosate

General data on Glyphosate are summarized in the table below (last updated 2017/11/28)

Table 7.2-1: General information on Glyphosate

Active substance (ISO Common Name)	Glyphosate
IUPAC	N-(phosphonomethyl)glycine
Chemical structure	
Molecular formula	C ₃ H ₈ NO ₅ P
Molar mass	169.1 g/mol
Chemical group	-
Mode of action (if available)	Inhibitors of EPSP synthesis. These chemicals inhibit the amino-acid synthesis.
Systemic	Yes
Companies	European Glyphosate Task Force, represented by Monsanto Europe S.A
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (01/07/2002) and reference to decision (REGULATION (EU) No 540/2011 and Reg (EU) 2016/1056) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1056&from=EN

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Restriction	Only uses as herbicide may be authorised
Review Report	SANTE/11051/2016 rev 0 11/07/2016
Current MRL regulation	Regulation (EC) No 293/2013
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2015;13(11):4302 43
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2012-00974 (EMS) Rape seed Status: Reasoned opinion available (EFSA Journal 2013;11(11):3456)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU				
Plant products				
Glyphosate	Oranges; tomatoes	High acid content	>14 to >31 months	RMS, 2013 EFSA, 2015
	Clover; maize forage, green plant and stover; soya bean forage; sorghum stover; sugar beet roots and leaves	High water content	>9 to 31 months	
	Linseed; rape seed; soya beans	High oil content	>18 to >24 months	
	Barley, maize, rye, sorghum and wheat grain	High starch content	18 to >48 months	
	Beans, dry	High protein content	>18 months	
	Barley, rye, soya bean and wheat straw; soya bean hay	Other plant matrices	18 to >45 months	
AMPA	Oranges; tomatoes	High acid content	>14 to >31 months	
	Clover; maize forage, green plant and stover; soya bean forage; sorghum stover; sugar beet roots and leaves	High water content	6 to 24 months	
	Soya beans	High oil content	>24 months	
	Barley, maize, rye, sorghum and wheat grain	High starch content	10 to >31 months	
	Barley, rye, soya bean and wheat straw; soya bean hay	Other plant matrices	6 to >24 months	

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Com- pound	Matrix	Characteristics of the matrix	Acceptable Maxi- mum Storage dura- tion	Reference
N-acetyl- glyphosate	Maize forage, green plant and stover; soya bean forage	High water content	6 to > 12 months	
	Soya beans	High oil content	> 12 months	
	Maize grain	High starch content	> 12 months	
	Soya bean hay	Other plant matrices	> 12 months	
N-acetyl- AMPA	maize forage, green plant and stover; soya bean forage	High water content	> 1 to > 12 months	
	soya beans	High oil content	> 1 month	
	maize grain	High starch content	> 12 months	
	soya bean hay	Other plant matrices	> 1 month	
Animal Products				
Glyphosate	Swine, cattle and poultry	Fat, muscle, liver and kidney, milk and eggs	14 to > 26 months	RMS, 2013
AMPA	Swine, cattle and poultry	Fat, muscle, liver and kidney, milk and eggs	14 to > 26 months	EFSA, 2015

Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU				
Plant products				
Glyphosate	Oranges	High acid content	24 months	RMS, 2013 EFSA, 2015 Mueth, M.G.; Allan, J.M., 2012
	tomatoes		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991
	Maize forage	High water content	12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Pasture grasses		12 months	RMS, 2013 EFSA, 2015 Hubbart, N. S. 1993
	Sugar beet leaves		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	soya bean forage, clover		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991

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Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
	Maize green plant, maize forage		9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya bean forage		12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Linseed, rape seed	High oil content	18 months	RMS, 2013 EFSA, 2015 Schulz H., 1997
	soya beans		6 months	RMS, 2013 EFSA, 2015 Hubbart, N. S. 1993
			24 months	RMS, 2013 EFSA, 2015 McKay, J.C. 1989
			12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Sorghum grain	High starch content / High protein content	48 months	RMS, 2013 EFSA, 2015 McKay, J.C. 1989
	Wheat grain		24 months	
	Barley grain, maize grain		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	Wheat grain, rye grain		45 months	RMS, 2013 EFSA, 2015 Morgenroth, U. 1995
	Maize grain		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991
			12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Beans, dry		18 months	RMS, 2013 EFSA, 2015 Schulz H., 1997
	Sugar beet roots			RMS, 2013

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Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
				EFSA, 2015 Weber, H., 2010
	Maize stover	Other plant matrices	12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
			9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya bean hay		12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Barley straw, maize straw		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	Wheat straw, rye straw		45 months	RMS, 2013 EFSA, 2015 Morgenroth, U. 1995
	Sorghum straw		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991
			13 months	RMS, 2013 EFSA, 2015 Hubbart, N. S. 1993
	Soya straw		24 months	RMS, 2013 EFSA, 2015 McKay, J.C. 1989
AMPA	Oranges	High acid content	24 months	RMS, 2013 EFSA, 2015 Mueth, M.G.; Allan, J.M., 2012
	tomatoes		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991
	Maize forage	High water content	12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Pasture grasses		12 months	RMS, 2013 EFSA, 2015 Hubbart, N. S. 1993
	Sugar beet leaves		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	soya bean forage, clover		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991

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Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
	Maize green plant, maize forage		9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya bean forage		12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya beans	High oil content	6 months	RMS, 2013 EFSA, 2015 Hubbart, N. S. 1993
			24 months	RMS, 2013 EFSA, 2015 McKay, J.C. 1989
			12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Sorghum grain	High starch content / High protein content	48 months	RMS, 2013 EFSA, 2015 McKay, J.C. 1989
	Wheat grain		24 months	
	Barley grain, maize grain		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	Maize grain		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991
			12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Wheat grain, rye grain		10 months	RMS, 2013 EFSA, 2015 Morgenroth, U. 1995
	Sugar beet roots		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	Maize stover	Other plant matrices	12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
			9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
			12 months	RMS, 2013 EFSA, 2015

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Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
				Schwartz, N.L. 2007
	Sorghum straw		31 months	RMS, 2013 EFSA, 2015 Mueth, M. G. 1991
	Wheat straw, rye straw		6 months	RMS, 2013 EFSA, 2015 Morgenroth, U. 1995
	Barley straw		18 months	RMS, 2013 EFSA, 2015 Weber, H., 2010
	Soya straw		13 months	RMS, 2013 EFSA, 2015 Hubbart, N. S. 1993
			24 months	RMS, 2013 EFSA, 2015 McKay, J.C. 1989
N-acetyl-glyphosate	Maize green plant, maize forage	High water content	9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Maize forage		12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya bean forage		12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya beans	High oil content	12 months	
	Maize grain	High starch content	12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Soya bean hay	Other plant matrices	12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Maize stover		12 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
			9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
N-acetyl-AMPA	soya bean forage	High water content	1 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Maize green plant, maize forage		9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007

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Compound	Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
	soya beans	High oil content	1 month	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	soya bean hay	Other plant matrices	1 month	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
	Maize stover		9 months	RMS, 2013 EFSA, 2015 Schwartz, N.L. 2007
Animal Products				
Glyphosate	Swine, cattle and poultry	Fat, muscle, liver and kidney, milk and eggs	14 to > 26 months	RMS, 2013 EFSA, 2015
AMPA	Swine, cattle and poultry	Fat, muscle, liver and kidney, milk and eggs	14 to > 26 months	xxxxxxxxxxxxxxxx1988

Conclusion on stability of residues during storage

EFSA conclusions drawn from EFSA Journal 2015;13(11):4302 are the following:

The residue data were supported by storage stability studies showing that glyphosate and AMPA residues are stable for at least 2 years to more than 3 years in the different matrix types. N-acetyl-glyphosate was stable for at least 1 year in high acid, high water and dry/starch matrices and N-acetyl-AMPA is stable for at least 1 year in high water and dry/starch matrices and 1 month in high oil matrices.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sam-pling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Citrus (mandarins)	¹⁴ C-glyphosate and ¹⁴ C-AMPA	Foliar treatment	2.24 (Glyphosate)	1	Each month (leaf) and at 4 months (soil, roots, stems, leaves, immature and		RMS, 2013 EFSA, 2015 Sutherland, M.L. 1975
			Soil treatment					

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						mature fruits)		
			Hydro-ponic treatment	Glyphosate: 4.4 x 10 ⁸ dmp or AMPA: 8.0 x 10 ⁸ dpm	1	1 or 2 weeks	Sampling on leaves, stem, roots and the rest of the plant	
			¹⁴ C-glyphosate	Foliar treatment	4 mg per citrus plant	1	1, 2, 3, 4, 6 and 8 weeks	Sampling on treated leaves, untreated leaves, stems and fruits
	Walnut, almond and pecan trees	¹⁴ C-glyphosate	Foliar treatment	100 µg*	1	2 or 5 weeks (14 or 35 DAT)	*applied to the surface of two trees per variety	RMS, 2013 EFSA, 2015 Nadeau, R.G., Cozad, S.J. 1976
			Soil treatment	12.9 mg*	1	16 weeks	*applied to the surface of pots (18 cm diameter for pecan and walnut, 26 cm diameter for almonds)	
	Apple trees	¹⁴ C-radiolabelled glyphosate and ¹⁴ C-AMPA	Foliar treatment	5.356 µg/ tree shoot with at least 4.5 leaves	1	7, 21, 28, 49 and 70 days	Sampling on treated leaves, new growth above treatment, other new growth, branches, trunk and roots	RMS, 2013 EFSA, 2015 Rueppel, M. L., Moran, S.J., 1974
			Trunk treatment	92.4 µg/tree	1	8 and 42 days	Sampling on leaves and	

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							stems, treated trunk, untreated trunk and branches and roots	
			Soil treatment	3.4 (Glyphosate) 1.7 (AMPA)	1	6 and 12 weeks	Sampling on leaves, stems, branches and trunk	
	Grape vines	¹⁴ C-radiolabelled either in the glyphosate- or in the trimethyl-sulfonium-ion	Ground treatment	8.0 (total target rate)	2	14		RMS, 2013 EFSA, 2015 Wilkinson, M.J.; Joseph, R.S.I. 1990
			Over spraying	14.3 mg/vine (¹⁴ C-glyphosate-label) 13.2 mg/vine (¹⁴ C-trimethyl-sulfonium-label)	1	14 and 365		RMS, 2013 EFSA, 2015 Parker, S.; Harris, M., 1991
		¹⁴ C-glyphosate and ¹⁴ C-AMPA	Soil treatment	3.4 kg ¹⁴ Cglyphosate per ha 1.7 kg ¹⁴ C-AMPA per ha	1	8 and 42 days		
			Trunk application	40 µg/tree	1	6 and 12 weeks		RMS, 2013 EFSA, 2015
			Hydroponic application	5, 10, 20 and 40 ppm ¹⁴ C-glyphosate		10, 21 and 42 days		Rueppel, M.L.; Suba, L. A.; Moran, S.J., 1973
			Foliar treatment	10, 60 µg or 120 µg ¹⁴ Cglyphosate on leaves	1 *	7, 14 and 28 days and 7, 14, 238, 42, 56 and 70 days for pulse treatment	*either as single treatment or as 7 days pulse	
	Avocado	¹⁴ C-radiolabelled glyphosate	Leaf painting	-	1	Up to 10 days	Study considered to be as	RMS, 2013 EFSA, 2015
			Filled	453000 cpm	1	10 days		

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			cavity into avocado fruit				addi- tional in- for- mation	Haseg- awa, L.S.; Kuma- moto, J.; Jordan, L.S. 1995
Root and tuber vegeta- bles	Potato	¹⁴ C-glyphosate ¹⁴ C-AMPA or ¹⁴ C- NaHCO ₃	Soil treat- ment	For soil treatment: 23.8 mg per pot (¹⁴ C-glyphosate) 23.4 mg per pot (¹⁴ C-AMPA) 8.23 x 10 ⁸ dpm per pot (¹⁴ C-NaHCO ₃) For weeds plough- ing simulation: 23.3 mg to the weeds, 3 weeks be- fore Incorporation (¹⁴ C- glyphosate)	1	9, 15 and 25 days for leaves and 128 days for tubers		RMS, 2013 EFSA, 2015 Nadeau, R.G., 1974
		¹⁴ C-glyphosate	Foliar treatment	100 µg to leaves	1	1, 3, 14 and 34 days	At har- vest, plants separated into the top part and the tubers	
	Sugar beets	¹⁴ Cglyphosate and ¹⁴ C-AMPA	Soil treat- ment	4.5 kg as/ha	1	4, 6 and 8 weeks	Sampling on leaves and roots	RMS, 2013 EFSA, 2015 Malik, J.M.; Brightwel l, B.B., 1976
	Pulses and oilseeds	¹⁴ C-glyphosate and ¹⁴ C-AMPA	Hydropop- nic appli- cation	2.24 kg as/ha	1	4, 10 and 18 days		RMS, 2013 EFSA, 2015 Rueppel, M.L.; Suba, L.A., 1973
			Soil treat- ment	4.5 kg as/ha 1.7 kg AMPA/ha	1	4, 6 and 8 weeks		
		¹⁴ C-glyphosate and ¹⁴ C-AMPA	Hydropop- nic appli- cation	2.24 kg as/ha	1	4, 10 and 18 days		
			Soil treat- ment	4.5 kg as/ha 1.7 kg AMPA/ha	1	4, 6 and 8 weeks		
Cereals	Maize	¹⁴ C-glyphosate and ¹⁴ C-AMPA	Hydropop- nic appli- cation	2.24 kg as/ha	1	4, 10 and 18 days		
			Soil treat- ment	4.5 kg as/ha 1.7 kg AMPA/ha	1	4, 6 and 8 weeks		

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	Wheat	¹⁴ C-glyphosate and ¹⁴ C-AMPA	Hydropop- nic appli- cation	2.24 kg as/ha	1	4, 10 and 18 days	RMS, 2013 EFSA, 2015 Stuart, C.; Parker, S.; Jo- seph, R. S. I., 1989
			Soil treat- ment	4.5 kg as/ha 1.7 kg AMPA/ha	1	4, 6 and 8 weeks	
		¹⁴ C-radiolabelled either in the glyphosate- or the trimethyl- sulfonium-moiety	Pre-harvest foliar treat- ment (des- sication)	6 kg as/ha	1	7 days	
	Sorghum	¹⁴ C-glyphosate	Soil treat- ment	4.5 kg as/ha	1	4, 6 and 8 weeks	RMS, 2013 EFSA, 2015 Suba, L.A.; Georgieff , M.K., 1974
			Hydropop- nic appli- cation	0.183 mg ¹⁴ C- glyphosate/mL	1	7, 14 and 28 days	
	Rice	¹⁴ C-glyphosate	Soil treat- ment	4.5 kg as/ha	1	4, 6 and 8 weeks	
			Hydropop- nic appli- cation	0.183 mg ¹⁴ C- glyphosate/mL	1	7, 14, 20 and 28 days	
	Oats	¹⁴ C-glyphosate	Soil treat- ment	4.5 kg as/ha	1	4, 6 and 8 weeks	
			Hydropop- nic appli- cation	0.183 mg ¹⁴ C- glyphosate/mL	1	7, 14 and 28 days	
	Barley	¹⁴ C-glyphosate	Soil treat- ment	4.5 kg as/ha	1	4, 6 and 8 weeks	
			Hydropop- nic appli- cation	0.183 mg ¹⁴ C- glyphosate/mL	1	7, 14 and 28 days	

Summary of plant metabolism studies reported in the EU

EFSA conclusions drawn from EFSA Journal 2015;13(11):4302 are the following:

In non-tolerant plants, metabolism was studied in the fruit, root, pulses/oilseeds, cereal and miscellaneous crop groups, using either soil, foliar, hydroponic or trunk application of ¹⁴C-glyphosate and in some experiments, with ¹⁴C-AMPA. Following soil application, the uptake of glyphosate was very low and amounted to mostly less than 1% of the applied radioactivity (AR) in plant matrices. Limited translocation was also observed after local foliar application, most of the applied radioactivity (80%) remaining in the treated parts of the plants. Hydroponic studies were therefore the key studies to identify the metabolic pattern of glyphosate in conventional plants. Globally without soil present as substrate, less than 5% AR was recovered in the aerial parts, up to 20% AR in the roots. No significant degradation was observed and unchanged glyphosate was observed as the major component of the residues in most of the samples (ca. 50% to 80% TRR) with low amounts of AMPA (4% to 10% TRR) and N-methyl-AMPA (0.3 to 5% TRR in root samples).

Conclusion on metabolism in primary crops

Cultivation of glyphosate tolerant GM crops is not authorised in most of the EU member states, but since an import of glyphosate tolerant commodities is possible, the two following residue definitions were proposed for monitoring:

- ‘sum glyphosate and N-acetyl glyphosate expressed as glyphosate’ for plants with glyphosate tolerant GM varieties available on the market (mostly maize, oilseed rape and soya bean) and considering that glyphosate alone is not an appropriate marker for some GAT-modified plants,
- ‘glyphosate’, for the other plant commodities.

For risk assessment the residue definition was proposed as:

- ‘sum glyphosate, N-acetyl glyphosate, AMPA and N-acetyl-AMPA expressed as glyphosate’ and considering that the N-acetyl glyphosate and N-acetyl-AMPA metabolites are relevant for the GM crops containing the GAT modification.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	¹⁴ C-glyphosate	Confined	4.16 kg a.s./ha (bare soil)	30, 120, 365	70, 90, 105, 147, 167, 181, 399, 425, 455	-	RMS, 2013 EFSA, 2015 Nicholls, R.G., 1990 McMulan, P.C.; Honnegger, J.L. Logusch E.W., 1990
				6.5 kg a.s./ha (bare soil)	30, 120, 365	55, 75, 145, 165, 390, 410	-	RMS, 2013 EFSA, 2015 Hatterman, D.R., 1998
	Cabbage	¹⁴ C-glyphosate	Confined	4.48 kg a.s./ha (bare soil, peas as primary crop)	4 weeks	14 weeks	Soil treatment before planting of primary crop. After harvest of primary crop, rotational crops	RMS, 2013 EFSA, 2015 Suba, L.A., 1976
				4.48 kg a.s./ha (bare soil, carrot)	7 weeks	24.5 weeks		

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				as primary crop)			grown in same soil	
			Confined	4.48 kg a.s./ha (bare soil, soybean as primary crop) plus additional 4.48 kg a.s./ha after 30 days for emergency	2-3, 30 days, 4 months, 1 year	90 days for emergency, 4 months, 1 year	Two rotations: 4 months (beets) and 1 year (cabbage) and beets as emergency crop	RMS, 2013 EFSA, 2015 Brightwell, B.; Cooper, B.J., 1978
			Confined	4.48 kg a.s./ha (bare soil, wheat as primary crop) plus additional 4.48 kg a.s./ha after 30 days for emergency with beets replanting	2-3, 30 days, 4 months, 1 year	90 days for emergency, 4 months, 1 year	Two rotations: 4 months (beets) and 1 year (cabbage) and wheat as emergency crop	
	Peas	¹⁴ C-glyphosate	Confined	4.48 kg a.s./ha (bare soil, cabbage as primary crop)	11 weeks	17.5 weeks	Soil treatment before planting of primary crop. After harvest of primary crop, rotational crops grown in same soil	RMS, 2013 EFSA, 2015 Suba, L.A., 1976
	String beans	¹⁴ C-glyphosate	Confined	4.48 kg a.s./ha (bare soil, carrot as primary crop)	7 weeks	13.5 weeks		
Root and tuber vegetables	Carrot	¹⁴ C-glyphosate	Confined	4.16 kg a.s./ha (bare soil)	30, 120, 365	154, 210, 482	-	RMS, 2013 EFSA, 2015 Nicholls, R.G., 1990
				4.48 kg a.s./ha (bare soil, peas as primary crop)	4 weeks	14 weeks	Soil treatment before planting of primary crop. After harvest of primary crop, rotational crops grown in same soil	RMS, 2013 EFSA, 2015 Suba, L.A., 1976
		¹⁴ C-glyphosate	Confined	4.48 kg a.s./ha (bare soil, cabbage as primary crop)	11 weeks	28.5 weeks		

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	Radish	¹⁴ C-glyphosate	Confined	6.5 kg a.s./ha (bare soil,)	30, 120, 365	55, 75, 145, 165, 390, 410	-	RMS, 2013 EFSA, 2015 Hatterman, D.R., 1998
	Beets	¹⁴ C-glyphosate	Confined	4.48 kg a.s./ha (bare soil, cabbage as primary crop) plus additional 4.48 kg a.s./ha after 30 days for emergency	2-3, 30 days, 4 months, 1 year	90 days for emergency, 4 months, 1 year	Two rotations: 4 months (wheat) and 1 year (beets) and cabbage as emergency crop	RMS, 2013 EFSA, 2015 Brightwell, B.; Cooper, B.J., 1978
Cereals	Barley	¹⁴ C-glyphosate	Confined	4.16 kg a.s./ha (bare soil)	30, 120, 365	125, 314, 412, 482	-	RMS, 2013 EFSA, 2015 Nicholls, R.G., 1990
	Wheat	¹⁴ C-glyphosate	Confined	6.5 kg a.s./ha (bare soil)	30, 120, 365	60, 120, 150, 210, 395, 455	-	RMS, 2013 EFSA, 2015 Hatterman, D.R., 1998
			Confined	4.48 kg a.s./ha (bare soil, beets as primary crop) plus additional 4.48 kg a.s./ha after 30 days for emergency	2-3, 30 days, 4 months, 1 year	90 days for emergency, 4 months, 1 year	Two rotations: 4 months (cabbage) and 1 year (wheat) and beets as emergency crop	RMS, 2013 EFSA, 2015 Brightwell, B.; Cooper, B.J., 1978
	Maize	¹⁴ C-glyphosate	Confined	4.48 kg a.s./ha (bare soil, string beans as primary crop)	6.5 weeks	16.5, 22 weeks	Soil treatment before planting of primary crop. After harvest of primary crop, rotational crops grown in same soil	RMS, 2013 EFSA, 2015 Suba, L.A., 1976

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Conclusion on metabolism in rotational crops

Plant metabolism in rotational crops was investigated on beets, carrots, radish, lettuce, cabbage, peas, soya beans, barley and wheat at different application rates, and using different application rates. Based on the EFSA conclusions drawn from EFSA Journal 2015;13(11):4302, significant residues of glyphosate or AMPA are not expected in rotational crops, and metabolism in rotational crops is similar to metabolism in primary crops. However, in rotational crops, higher relative amounts of AMPA are expected due to its formation in soil.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Marked compound	Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data			
¹⁴ C-glyphosate	Pasteurisation (20 minutes, 90°C, pH 4)	¹⁴ C-glyphosate (99.5%)	RMS, 2013 EFSA, 2015 Hiler, T., 2010
	Baking, boiling, brewing (60 minutes, 100°C, pH 5)	¹⁴ C-glyphosate (99.5%)	RMS, 2013 EFSA, 2015 Hiler, T., 2010
	Sterilisation (20 minutes, 120°C, pH 6)	¹⁴ C-glyphosate (98.5%)	RMS, 2013 EFSA, 2015 Hiler, T., 2010
¹⁴ C-N-acetyl-glyphosate	Pasteurisation (20 minutes, 90°C, pH 4)	N-acetyl-glyphosate (93.2%)	RMS, 2013 EFSA, 2015 Umstatter, S.; Peterson, B., 2006
	Baking, boiling, brewing (60 minutes, 100°C, pH 5)	N-acetyl-glyphosate (92.1%)	RMS, 2013 EFSA, 2015 Umstatter, S.; Peterson, B., 2006
	Sterilisation (20 minutes, 120°C, pH 6)	N-acetyl-glyphosate (93.9%)	RMS, 2013 EFSA, 2015 Umstatter, S.; Peterson, B., 2006

Conclusion on nature of residues in processed commodities

Based on the available data, no hydrolysis of neither glyphosate nor N-acetyl-glyphosate under simulated processing conditions was observed. Therefore, the active substance is considered as to be stable.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin

(KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	<p>Non-tolerant crops Fruits: Mandarins (soil, foliar, hydroponic), Almond, walnut and pecan (soil, foliar), Apples (soil, foliar, trunk), Grapes (soil, foliar, trunk, hydroponic), Avocado (foliar, direct fruit treatment) Root and tuber crops: Potato (soil, foliar), Sugar beets (soil) Pulses and oilseeds: Cotton (soil, hydroponic), Soya beans (soil, hydroponic) Cereal grains: Barley (soil, hydroponic), Maize (soil, hydroponic), Oats (soil, hydroponic), Rice (soil, hydroponic), Sorghum (soil, hydroponic), Wheat (soil, hydroponic, foliar - dessication) Miscellaneous crops: Coffee (soil, foliar, stem, hydroponic), Sugar cane (soil, foliar)</p> <p>Transgenic crops (all foliar sprayed) Oilseeds: Rape/canola (CP4-EPSPS & GOX, GAT), Soya beans (CP4-EPSPS, GAT), Cotton (CP4-EPSPS) Root and tubers: Sugarbeet (CP4-EPSPS) Cereal grains: Maize (CP4-EPSPS & GOX, GAT)</p>
Rotational crops covered	<p>Beets, carrots, radish Lettuce, cabbage Peas Soya beans Barley, wheat</p>
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, in rotational crops higher relative amounts of AMPA are expected due to its formation in soil
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	<p>Sweet corn, oilseed rape, soya beans and maize (non-tolerant and tolerant, all modifications): sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate</p> <p>Other plant commodities: glyphosate</p>
Plant residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate.
Conversion factor from enforcement to RA	For non-tolerant crops, the contribution of AMPA to the consumer exposure is minor, making a CF unnecessary. Residues in glyphosate tolerant GM crops and application type (pre-emergence/dessication) should be considered to derive CF for plant commodities. (EFSA, 2015)

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

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Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commod- ity	Time of samp- ling	
EU data								
Lactat- ing ru- minants (study 1)	Goat	¹⁴ C-glyphosate radiolabelled in the phosphonomethyl- moiety	2	Goat 1: 7.1	Goat 1: 5	Milk	Daily	RMS, 2013; EFSA, 2015 xxxxxx, 1994
				Goat 2: 8.0	Goat 2: 3	Urine and faeces	Daily	
						Tissues	At sacrifice	
Lactat- ing ru- minants (study 2)	Goat	¹⁴ C-radiolabelled substances in the phosphonomethyl- moiety	3	216 (Glyphosate) 24 (AMPA)	5 (with 5 days depuration for goat 3)	Milk	Twice daily	RMS, 2013; EFSA, 2015 xxxxxx, 1987 xxxxxxx, 1988
						Urine and faeces	Twice daily	
						Tissues	At sacrifice	
Lactat- ing ru- minants (study 3)	Goat	¹⁴ C-glyphosate- trimesium radiolabelled in the phosphonomethyl- glycine-anion	1 (and 1 control)	2.6	7	Milk	Daily	RMS, 2013; EFSA, 2015 xxxxxx, 1994
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Lactat- ing ru- minants (study 4)	Goat	¹⁴ C-N-acetyl- glyphosate	1 (and 1 control)	6.8	5	Milk	Daily	RMS, 2013; EFSA, 2015 xxxxxxx, 2007
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying hens (study 1)	Laying hen	¹⁴ C-glyphosate radiolabelled in the phosphonomethyl- moiety	2 groups of 5 animals	18.2	Group 1: 7	Eggs	Daily	RMS, 2013; EFSA, 2015 xxxxxxx, 1994
					Group 2: 5	Excreta	Daily	
						Tissues	At sacrifice	
Laying hens (study 2)	Laying hen	¹⁴ C-glyphosate and ¹⁴ C-AMPA	5 groups of 5 hens each (including 1 control)	Groups 1, 2 and 3: 9.7 (Glyphosate) 1.03 (AMPA) Group 4: 32.2 (Glyphosate) 3.4 (AMPA)	Groups 1, 2 and 4: 7 Group 3: 7 (with 10 days of depuration)	Eggs	Daily	RMS, 2013; EFSA, 2015 xxxxxx, 1988 xxxxxx, 1988
						Excreta	Daily	
						Tissues	At sacrifice	

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Laying hens (study 3)	Laying hen (Leghorn)	¹⁴ C-glyphosate-trimesium radiolabelled in the phosphonomethyl-glycine-anion	-	4.1	10	Eggs	Daily	RMS, 2013; EFSA, 2015 xxxxxx, 1994
						Excreta	Daily	
						Tissues	At sacrifice	
Laying hens (study 4)	Laying hen	¹⁴ C-N-acetyl-glyphosate	5	4.5	7	Eggs	Twice daily	RMS, 2013; EFSA, 2015 xxxxxx, 2007
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of animal metabolism studies reported in the EU

EFSA conclusions drawn from EFSA Journal 2015;13(11):4302 are the following:

Several livestock metabolism studies on goat and hen using ¹⁴C-glyphosate and ¹⁴C-AMPA labelled on the phosphonomethyl-moiety and conducted with glyphosate, glyphosate trimesium or a 9/1 glyphosate/AMPA mixture were submitted. Parent glyphosate was identified as the major component of the radioactive residues, accounting for 21% to 99% TRR in all animal matrices and AMPA was detected in significant proportions in liver (up to 36% TRR), muscle and fat (up to 19% TRR) and egg yolk (14% TRR). In addition, metabolism studies on goat and hen using ¹⁴C-N-acetyl-glyphosate were provided. In these studies, N-acetyl-glyphosate was identified as the major component of the radioactive residues, accounting for 17% to 77% TRR. Degradation to N-acetyl-AMPA was observed in fat (10% to 15% TRR), to glyphosate in liver (15% TRR), poultry fat (37% TRR) and egg white (11% TRR) and to AMPA in poultry muscle and fat (11% to 17% TRR).

Conclusion on metabolism in livestock

Based on these studies and considering that it cannot be excluded that livestock are exposed to feed items from genetically GAT-modified crops imported from third countries, the residue definition for monitoring was proposed as 'sum of glyphosate and N-acetyl-glyphosate expressed as glyphosate' for monitoring and as 'sum of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl-AMPA expressed as glyphosate' for risk assessment.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Goats
	Chicken
Time needed to reach a plateau concentration	< 7 days in milk
	14 days in eggs (based on 28 day feeding study, no plateau reached within 8 days in metabolism studies)
Animal residue definition for monitoring	Sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate
Animal residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate

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Conversion factor	Not proposed, since assessment based on conventional crops only while ratio of metabolites in animal matrices strongly depends on the ratio of metabolites in animal diet and therefore on the amount of GMO-feedstuff in diets. For non-tolerant feed crops, a conversion factor for animal commodities was considered unnecessary. (EFSA, 2015)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

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7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.2-9: Summary of EU reported ~~and new data~~ supporting the intended uses of Glyphosate 54% SL and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Grapes	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 3 x 0.72 kg as/ha, interval 28 days between application, at post emergence of weeds, no PHI, outdoor 6x <0.05, 0.07, 0.30**	N/A				
	Overall supporting data for cGAP	N-EU	6x <0.05, 0.07, 0.30	0.05	0.3	0.5	0.5	Yes
Pome fruit (apple and pear)	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 3 x 0.72 kg as/ha, interval 28 days between application, at post emergence of weeds, no PHI, outdoor <0.02, 3x <0.05	N/A				
	EFSA, 2015	S-EU	GAP on which EU a.s. assessment is based: 3 x 0.72 kg as/ha, interval 28 days between application, at post emergence of weeds, no PHI, outdoor 17x <0.05					
	Overall supporting data for cGAP	EU	<0.02, 20x <0.05***	0.05	0.05	0.05	0.1	Yes
Peaches	EFSA, 2015	S-EU	GAP on which EU a.s. assessment is based: 3 x 0.72 kg as/ha,	N/A				

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			interval 28 days between application, at post emergence of weeds, no PHI, outdoor 2x <0.05					
	Overall supporting data for cGAP	S-EU	2x <0.05***	0.05	0.05	0.05	0.1	Yes
Cherry	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 3 x 0.72 kg as/ha, interval 28 days between application, at post emergence of weeds, no PHI, outdoor 2x <0.05	N/A				
	Overall supporting data for cGAP	N-EU	2x <0.05***	0.05	0.05	0.05	0.1	Yes
Rape seed	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 14d, outdoor Mo: 1.4, 6.4, 9.0 RA: 1.7, 6.5, 9.0 ^(a)	N/A				
	Overall supporting data for cGAP	N-EU	Data not sufficient to derive an MRL proposal	-	-	-	10	-
Barley, oats (grain) <u>Dessication use</u>	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 1.2, 1.5, 2.0, 2.1, 2.1, 2.2, 2.4, 2.5, 2.6, 2.6, 2.8, 3.95; 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2, 5.2, 5.2, 5.3, 5.4, 5.5, 5.5, 5.7, 5.9, 5.9, 6.2, 6.5, 6.7, 7.4, 7.7, 7.8, 8.0, 8.1, 8.4, 9.8, 10, 10.3, 12.4, 12.5, 14, 15.5, 16.5, 17, 17.5, 18.4, 21, 21.4 RA: 1.3, 1.5 ^(a) , 2.1, 2.2, 2.2, 2.3, 2.5, 2.5, 2.7, 2.9, 3.2, 4.2, 4.4, 4.6, 4.9, 5.0, 5.1 ^(a) , 5.2, 5.3, 5.3, 5.3 ^(a) , 5.5, 5.5 ^(a) , 5.6, 5.8, 5.8, 5.9, 6.2, 6.2 ^(a) , 6.6, 6.9, 7.5, 7.9, 8.0, 8.2, 8.3, 8.4 ^(a) , 10, 10.3, 10.4, 12.4 ^(a) , 12.8, 14.4, 16, 16.6, 17.2, 17.8, 18.4 ^(a) , 21.4 ^(a) , 21.6	N/A				
	EFSA, 2015	S-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor					

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			Mo: 6.0, 7.8, 13.5, 19 RA: 6.0, 7.9, 13.7, 19.3					
	Overall supporting data for cGAP	EU	1.3, 2.1, 2.2, 2.2, 2.3, 2.5, 2.5, 2.7, 2.9, 3.2, 4.2, 4.4, 4.6, 4.9, 5.0, 5.2, 5.3, 5.3, 5.5, 5.6, 5.8, 5.8, 5.9, 6.0, 6.2, 6.6, 6.9, 7.5, 2x 7.9, 8.0, 8.2, 8.3, 10, 10.3, 10.4, 12.8, 13.7, 14.4, 16, 16.6, 17.2, 17.8, 19.3, 21.6	5.85	21.6	28.3	20	No
Barley, oats (straw) <u>Dessication use</u>	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 4.6, 6.9, 9.6, 10.5, 11, 11.5, 12.8, 12.8, 14.5, 16, 17, 18, 22, 24, 26, 26.3, 26.5, 27, 27.3, 28.4, 32.2, 33.3, 36.9, 37, 41.5, 44, 49.7, 54, 56, 60.5, 69.6, 80.5, 86, 90.2, 109, 115, 117, 136, 140 RA: 4.7, 6.9 ^(a) , 10, 10.6, 11.3, 12.1, 13.1, 13.2, 14.6, 16.3, 17.7, 18 ^(a) , 22 ^(a) , 24.5, 26.7, 27.1, 27.6, 28.6, 28.7, 29.3, 29.6, 32.7, 33.9, 37.8, 38, 42.1, 44.4, 51.3, 56 ^(a) , 60.8, 61.9, 70.7, 83.6, 89.8, 92, 109 ^(a) , 115 ^(a) , 119, 140, 142	N/A				
	EFSA, 2015	S-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 34, 49.5, 66, 102 RA: 34.9, 51, 68.1, 105					
	Overall supporting data for cGAP	EU	4.7, 10, 10.6, 11.3, 12.1, 13.1, 13.2, 14.6, 16.3, 17.7, 24.5, 26.7, 27.1, 27.6, 28.6, 28.7, 29.3, 29.6, 32.7, 33.9, 34.9, 37.8, 38, 42.1, 44.4, 51, 51.3, 60.8, 61.9, 68.1, 70.7, 83.6, 89.8, 92, 105, 119, 140, 142	29.45	142	-	-	-
Wheat, rye (grain) <u>Dessication use</u>	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 0.05, 0.11, 0.16, 0.19, 0.22, 0.23, 0.23, 0.26, 0.33, 0.5, 0.5, 0.6, 0.64, 0.67, 0.7, 0.7, 0.7(3), 0.71, 0.74, 0.75, 0.75, 0.77, 0.85, 1.3, 1.4, 1.5, 1.55, 1.6, 1.7, 1.7, 1.75, 2.2, 2.4, 2.9, 3.1, 3.45, 3.5, 3.7, 3.85, 4.7, 4.8, 4.85, 5.4, 9.5, 12.4, 17.5 RA: 0.125, 0.18, 0.24, 0.26, 0.27, 0.27, 0.28, 0.29, 0.36, 1.1, 0.58, 0.64 ^(a) , 0.7, 0.74, 0.74 ^(a) , 0.75, 0.77, 0.78, 0.78, 0.78, 0.78, 0.83, 0.83, 0.84, 0.93, 1.3 ^(a) , 1.5, 1.6, 1.6, 1.6 ^(a) , 1.7 ^(a) , 1.8, 1.9, 2.3, 2.4 ^(a) , 2.9 ^(a) , 3.1 ^(a) , 3.5, 3.6, 3.8, 3.9, 4.9, 5.0, 5.0, 5.4 ^(a) , 9.5 ^(a) , 13.3,	N/A				

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			18.1					
	EFSA, 2015	S-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 0.07, 0.38, 0.4, 0.4, 0.47, 0.6, 0.95, 1.2, 2.8 RA: 0.15, 0.45, 0.48, 0.48, 0.55, 0.68, 1.0, 1.3, 3.0					
	Overall supporting data for cGAP	EU	0.125, 0.15, 0.18, 0.24, 0.26, 0.27, 0.27, 0.28, 0.29, 0.36, 0.45, 2x 0.48, 0.55, 0.68, 1.0, 1.1, 1.3, 0.58, 0.7, 0.74, 0.75, 0.77, 0.78, 0.78, 0.78, 0.78, 0.83, 0.83, 0.84, 0.93, 1.5, 1.6, 1.6, 1.8, 1.9, 2.3, 3.0, 3.5, 3.6, 3.8, 3.9, 4.9, 5.0, 5.0, 13.3, 18.1	0.885	18.1	17.5	10	No
Wheat, rye (straw) <u>Dessication use</u>	EFSA, 2015	N-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 1.4, 5.3, 8.4, 9.5, 10.3, 10.6, 11.4, 14.7, 14.9, 17.3, 18.5, 19.1, 19.7, 21.5, 24.8, 26.9, 27.4, 27.5, 29.6, 31.4, 34.8, 42, 43.2, 43.8, 44.5, 46, 52.8, 63.3, 68, 70.5, 84.5, 85, 95.3, 95.5, 95.7, 96.5, 99, 175 RA: 1.5, 5.4, 9.3, 10.5, 10.9, 11, 12.6, 15.7, 15.7, 17.6, 19.2, 19.4, 19.9, 22.1, 25.5, 28, 28.2, 28.9, 29.6 ^(a) , 31.8, 35.9, 42.6, 43.2, 44.2, 45.4, 46 ^(a) , 52.8 ^(a) , 64.3, 68 ^(a) , 71.4, 87.5, 88.5, 96.5 ^(a) , 97.3, 97.6, 98, 103, 179	N/A				
	EFSA, 2015	S-EU	GAP on which EU a.s. assessment is based: 1 x 2.16 kg as/ha, at crop maturity (< 30% grain moisture), PHI 7d-14d, outdoor Mo: 3.4, 15.5, 16, 20, 22, 28, 28.5, 55.5, 98 RA: 3.5, 16.9, 18.6, 20.9, 23.2, 29.6, 29.7, 56.5, 99					
	Overall supporting data for cGAP	EU	1.5, 3.5, 5.4, 9.3, 10.5, 10.9, 11, 12.6, 15.7, 15.7, 16.9, 17.6, 18.6, 19.2, 19.4, 19.9, 20.9, 22.1, 23.2, 25.5, 28, 28.2, 28.9, 29.6, 29.7, 31.8, 35.9, 42.6, 43.2, 44.2, 45.4, 56.5, 64.3, 71.4, 87.5, 88.5, 97.3, 97.6, 98, 99, 103, 179	30.7	179	-	-	-

* Source of EU MRL: Reg. (EU) No 293/2013

** Residue of 0.07 and 0.30 mg/kg measured in low hanging fruits (following application at a lower rate of 2x 720 g/ha) were considered to derived a MRL of 0.5 mg/kg for grapes (EFSA, 2015)

*** Based on the trials conducted on apples, pears, cherries and peaches following soil application beneath trees, where residue levels were all <LOQ, a MRL of 0.05* mg/kg is proposed for the pome and stone fruits groups.

(a) AMPA not analysed for

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on grapes are considered acceptable, for outdoor use.
 According to the available data, the intended uses on pome fruits are considered acceptable, for outdoor use.
 According to the available data, the intended uses on stone fruits are considered acceptable, for outdoor use.
 According to the available data, the intended uses on Winter cereals and Spring barley as herbicide use are considered acceptable, for outdoor use.
 According to the available data, the intended uses on rape seed is considered acceptable, for outdoor use.
 According to the available data the intended use on sunflower is considered acceptable, for outdoor use.
 According to the available data the intended uses on maize is considered acceptable, for outdoor use.

To cover the uses of maize, sunflower, Winter cereals and Spring barley in applications before seeding, based on the EU guidance “SANCO 7525/VI/95 - rev.10.3, where it is stated that 2 trials are sufficient in case of a nil-residue situation, and considering that residues were all <LOQ in a wide range of crops, extrapolations to all other crops, as proposed by the RMS, are agreed (Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate - EFSA Journal 2015;13(11):4302)

According to the available data, the intended uses on Winter wheat (dessication use) is considered acceptable, for outdoor use.

To cover the use of Winter wheat as dessication use, based on information of Conclusion of Peer Review EFSA Journal 2015;13(11):4302; Pre-harvest uses in all crops include uses for weed control (higher doses) and harvest aid, sometimes referred to as desiccation (lower doses). The critical GAP is the high dose recommended used for weed control. On the other hand, In the RAR of Glyphosate, we can find residue trials carried out with a similar GAP to the one proposed by Sharda Cropchem (1,08 kg sa/ha) that justify that for this doses residue levels are enough to cover the use of Winter wheat as dessication use.

The data submitted show that no exceedance of the MRL will occur.

The uses on grapes, winter cereals, winter wheat (dessication use), spring barley, pome fruits, peaches, cherries, maize, sunflower and rape seed are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
sum of glyphosate and AMPA, expressed as glyphosate (dietary intake purposes)				
Green forage (all annual commodities)	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)
Grains, except maize	5.85	STMR barley (NEU) (DAR, 2015)	5.85	STMR barley (NEU) (DAR, 2015)

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Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize grain	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)
Bran, wheat and rye	1.494	STMR wheat (NEU) x PF 1.8 (DAR, 2015)	1.49	STMR wheat (NEU) x PF 1.8 (DAR, 2015)
Cereal straw	30.7	STMR wheat (NEU) (DAR, 2015)	179	HR wheat (NEU) (DAR, 2015)
Pulses	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)
Roots and tubers	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)
Oilseed meals	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)	0.05	pre-emergence application, LOQ of analytical method (DAR, 2015)
Glyphosate only (MRL setting purposes)				
Green forage (all annual commodities)	-	-	0.05	pre-emergence application, LOQ of analytical method
Grains, except maize	-	-	5.5	Median barley (NEU)
Maize grain	-	-	0.05	pre-emergence application, LOQ of analytical method
Bran, wheat and rye	-	-	1.458	Median wheat (NEU) x PF 1.8
Cereal straw	-	-	175	Highest residue wheat (NEU)
Pulses	-	-	0.05	pre-emergence application, LOQ of analytical method
Roots and tubers	-	-	0.05	pre-emergence application, LOQ of analytical method
Oilseed meals	-	-	0.05	pre-emergence application, LOQ of analytical method

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Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
sum of glyphosate and AMPA, expressed as glyphosate (dietary intake purposes)					
Beef cattle*	0.911	4.606	Cereal straw	107.471	Y
Dairy cattle*	0.365	1.619	Cereal straw	44.535	Y
Finishing swine*	0.222	0.222	Grains excepted maize	5.542	Y
Layer poultry*	0.308	0.306	Grains excepted maize	4.882	Y
Glyphosate only (MRL setting purposes)					
Beef cattle*	-	4.498	Cereal straw	104.942	Y
Dairy cattle*	-	1.58	Cereal straw	43.442	Y
Finishing swine*	-	0.209	Grains excepted maize	5.216	Y
Layer poultry*	-	0.29	Grains excepted maize	4.598	Y

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

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Table 7.2-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (RMS, 2015; EFSA, 2015)												
sum of glyphosate and AMPA, expressed as glyphosate (dietary intake purposes)												
ruminants												
1. xxxxxxxxxxx, 1987												
2. xxxxxxxxxxx, 1987												
3. xxxxxxxxxxx, 2007												
Poultry												
1. xxxxxxxxxxx, 1987												
2. xxxxxxxxxxx, 1987												
3. xxxxxxxxxxx, 2007												
Swine												
1. xxxxxxxxxxx, 1987												
Pig meat	0.222	0.222	1.08	4	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Pig fat	0.222	0.222	1.08	4	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Pig liver	0.222	0.222	1.08	4	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				

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Pig kidney	0.222	0.222	1.08	4	n.r.	n.r.	n.r.	n.r.	0.059	0.059	-	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Ruminant meat (study 1 / study 2), beef cattle	0.911	4.606	0.13	3	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Ruminant fat (study 1 / study 2), beef cattle	0.911	4.606	0.13	3	n.r.	n.r.	n.r.	n.r.	0.131	0.135	-	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Ruminant liver (study 1 / study 2), beef cattle	0.911	4.606	0.13	3	n.r.	n.r.	n.r.	n.r.	0.11	0.2	-	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Ruminant kidney (study 1 / study 2), beef cattle	0.911	4.606	0.13	3	n.r.	n.r.	n.r.	n.r.	0.31	1.82	-	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Poultry meat	0.308	0.306	0.025	10	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Poultry fat	0.308	0.306	0.025	10	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary

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			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Poultry liver	0.308	0.306	0.025	10	n.r.	n.r.	n.r.	n.r.	< 0.125	< 0.125	-	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Poultry kidney	0.308	0.306	0.025	10	n.r.	n.r.	n.r.	n.r.	0.155	0.155	-	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Milk	0.365	1.619	0.13	3	n.r.	N/A	n.r.	n.r.	< 0.05	-	-	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	N/A	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	N/A	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	N/A	n.r.	n.r.				
Eggs	0.308	0.306	0.025	10	n.r.	n.r.	n.r.	n.r.	< 0.04	< 0.04	-	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Glyphosate only (MRL setting purposes)												
Pig meat	-	0.209	1.08	4	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Pig fat	-	0.209	1.08	4	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Pig liver	-	0.209	1.08	4	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary

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			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Pig kidney	-	0.209	1.08	4	n.r.	n.r.	n.r.	n.r.	-	0.12	0.2	Unnecessary
			3.35	4	n.r.	n.r.	n.r.	n.r.				
			11.8	4	n.r.	n.r.	n.r.	n.r.				
Ruminant meat (study 1 / study 2), beef cattle	-	4.498	0.13	3	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Ruminant fat (study 1 / study 2), beef cattle	-	4.498	0.13	3	n.r.	n.r.	n.r.	n.r.	-	0.06	0.1	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Ruminant liver (study 1 / study 2), beef cattle	-	4.498	0.13	3	n.r.	n.r.	n.r.	n.r.	-	0.07	0.1	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Ruminant kidney (study 1 / study 2), beef cattle	-	4.498	0.13	3	n.r.	n.r.	n.r.	n.r.	-	1.6	2	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	n.r.	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	n.r.	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	n.r.	n.r.	n.r.				
Poultry meat	-	0.29	0.025	10	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				

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			2.2	10	n.r.	n.r.	n.r.	n.r.				
Poultry fat	-	0.29	0.025	10	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Poultry liver	-	0.29	0.025	10	n.r.	n.r.	n.r.	n.r.	-	< 0.05	0.05*	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Poultry kidney	-	0.29	0.025	10	n.r.	n.r.	n.r.	n.r.	-	0.078	0.1	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				
Milk	-	1.58	0.13	3	n.r.	N/A	n.r.	n.r.	-	< 0.02	0.05*	Unnecessary
			1.4 / 1.44	5 / 3	n.r.	N/A	n.r.	n.r.				
			4.0 / 7.38	5 / 3	n.r.	N/A	n.r.	n.r.				
			12.8 / 19.4	5 / 3	n.r.	N/A	n.r.	n.r.				
Eggs	-	0.29	0.025	10	n.r.	n.r.	n.r.	n.r.	-	< 0.01	0.05*	Unnecessary
			0.24	10	n.r.	n.r.	n.r.	n.r.				
			2.2	10	n.r.	n.r.	n.r.	n.r.				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

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Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, and regarding available feeding data, there is no risk for animal MRL to be exceeded, excepted for bovine fat and liver.

In this context, the following MRLs were estimated for animal commodities. MRLs estimated for bovine products based on cow feeding studies are extrapolated to goats and sheep commodities also. For swine and poultry (fat and liver), a higher MRL of 0.1* mg/kg was proposed based on the analytical methods for enforcement purposes available:

Swine, muscle, fat and liver	0.05* mg/kg
Swine, fat and liver	0.1* mg/kg
Swine, kidney	0.2 mg/kg
Bovine, goat and sheep, muscle	0.05* mg/kg
Bovine, goat and sheep, fat	0.1 mg/kg
Bovine, goat and sheep, liver	0.1 mg/kg
Bovine, goat and sheep, kidney	2 mg/kg
Milk	0.05* mg/kg
Poultry, muscle, fat and liver	0.05* mg/kg
Poultry, fat and liver	0.1* mg/kg
Poultry, kidney	0.1 mg/kg
Eggs	0.05* mg/kg

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *		Comments	Reference
		Glyphosate	AMPA		
EU data					
Citrus, juice	6	0.83	-		RMS, 2013; EFSA, 2015 Beasley, R.K., 1975 Cowell, J.E., 1986
Citrus, peel	6	3	-		
Citrus, feed meal	6	2.6	-		
Citrus, press liquor	6	2	-		
Potato, chips	3	-	1.3		RMS, 2013; EFSA, 2015 Mueth, M.G., 1988
Potato, flakes	3	-	1.5		
Potato, wet peel	3	-	0.31		
Potato, dry peel	3	-	1.5		
Potato, granules	3	-	2.3		
Olives, crude oil (vergin)	19	0.09	-		RMS, 2013; EFSA, 2015 Hontis, A.M. 1992, 1993, 1996
Olives, refined oil	6	0.22	-		
Linseed, oil	4	0.25	-		RMS, 2013; EFSA,

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Processed commodity	Number of studies	Median PF *		Comments	Reference
		Glyphosate	AMPA		
Linseed, press cake	4	1.6	-		2015 Mestdag, P., 1983
Rape seed, crude oil	4	0.14	-		RMS, 2013; EFSA, 2015 Mestdag, P., 1983
Rape seed, refined oil	4	0.13	-		
Rape seed, press cake	4	1.4	-		
Soya beans, fat free meal	2	0.98	0.95		RMS, 2013; EFSA, 2015 Kunstman, J.L.; Steinmetz, J.R.; Farmer, P.S.; Blount, L.M., 1983
Soya beans, hulls	2	4.8	2.45		
Soya beans, crude oil	2	0.01	0.055		
Soya beans, soapstock	2	0.045	0.29		
Maize, fat free meal	4 (2 AMPA)	1.1	0.64		RMS, 2013; EFSA, 2015 Kuntsman, J.L., 1987
Maize, crude oil	4 (2 AMPA)	0.1	0.5		
Maize, refined oil	4 (2 AMPA)	0.1	0.5		
Maize, soapstock	4 (0 AMPA)	0.1	-		
Maize, small grits	2 (0 AMPA)	0.9	-		RMS, 2013; EFSA, 2015 Kunda, U.S., 1990
Maize, medium grits	2 (0 AMPA)	0.75	-		
Maize, large grits	2 (0 AMPA)	0.75	-		
Maize, flour	2 (2 AMPA)	0.9	0.59		
Rye, bran	4	1.5	0.76		RMS, 2013; EFSA, 2015 Schulz, H., 1992
Rye, flour	4	0.44	1.3		
Rye, wholemeal flour	4	1	0.31		
Rye, wholemeal bread	4	0.63	0.61		
Rye, middlings	4	1.35	0.79		
Wheat, bran	13 (1 AMPA)	1.8	1.2		RMS, 2013; EFSA, 2015 Steinmetz, J.R., 1984 Steinmetz, J.R.; Cowell, J.E., 1984 Schulz, H., 1992 Mestdag, P., 1980 Zietz, E., 1993 Mestdag, P., 1982
Wheat, flour	13 (1 AMPA)	0.57	0.81		
Wheat, wholemeal flour	2	1.1	-		
Wheat, wholemeal bread	2	0.37	-		
Wheat, middlings	2	0.61	-		
Wheat, semolina	2	0.15	-		

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Processed commodity	Number of studies	Median PF *		Comments	Reference
		Glyphosate	AMPA		
Wheat, semolina bran	2	1.8	-		

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Confined rotational crop metabolism studies indicate a very minor uptake of residue from soil into plants. The active substance glyphosate is quickly degraded into AMPA and within few weeks into CO₂. The uptake of AMPA, as demonstrated in the confined rotational crop studies as well as in plant metabolism studies involving soil treatment, is also very low, not resulting in expected residues above 0.01 mg/kg event at exaggerated rates compared to the intended uses.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

In summary it can be concluded that neither glyphosate nor AMPA show a potential uptake into rotational crops. Further studies involving the uptake under field conditions are not considered necessary.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Glyphosate 54% SL. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

No STMR values are presented since no refinement of the chronic risk assessment is necessary.

Input values for the consumer risk assessment: MRL values Reg. (EU) No. 293/2013

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	78.1 % (based on UK toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	<p>Unprocessed commodities</p> <p>Barley: 29 % (based on Adults)</p> <p>Oats: 15.9 % (based on children)</p> <p>Processed commodities</p> <p>Wheat flour: 23.6 % (based on children)</p> <p>Bread/pizza: 8.8 % (based on adults)</p>

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Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	39 % (based on NL child)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Barley: 19 % (based on Adults) Wheat: 29 % (based on children) Processed commodities Wheat flour: 24 % (based on children) Barley/beer: % (based on adults)

The proposed uses of Glyphosate in the formulation Glyphosate 54% SL do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

Germany, October 2015. Final addendum to the Renewal Assessment Report. Risk assessment provided by the rapporteur Member State Germany and co-rapporteur Member State Slovakia for the active substance GLYPHOSATE according to the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC laid down in Commission Regulation (EU) No. 1141/2010.

Germany, 2013. Renewal assessment report of Glyphosate. Volume 3, annex B.7, residue data. 18 December 2013

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302.

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Mueth, M.G.; Allan, J.M.,	2012	Storage stability of Glyphosate and AMPA on citrus fruit Report No.: MSL0023608 GLP: yes not published ASB2012-12452	N	MOD
KCA 6.1	Mueth, M.G.	1991	Storage stability of Glyphosate residues in crop commodities Report No.: MSL-10843 GLP. yes not published RIP9501332	N	MOD
KCA 6.1	Morgenroth, U.	1995	Storage stability of Glyphosate and AMPA in wheat grain and straw and in rye grain and straw Report No.: 303614 GLP: yes not published ASB2010-14764	N	CHE
KCA 6.1	Schulz H.	1997	Determination of the storage stability of Glyphosate in beans, oilseed rape and linseed Report No.: IF-94/13882-00 GLP: yes not published ASB2010-14803	N	CHE

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Weber, H.	2010	Storage stability of residues of Glyphosate and AMPA in various plant materials Report No.: FSG-0707 GLP: yes not published ASB2012-12488	N	ADM
KCA 6.1	Hubbart, N. S.	1993	Determination of Glyphosate in soybean raw agricultural commodities (RAC) - Stability report Report No.: 91210 GLP: yes not published ASB2010-14765	N	CHE
KCA 6.1	McKay, J.C.	1989	Storage stability validation for ICIA0224 in raw agricultural commodities Report No.: WRC 89-22 GLP: yes not published RIP9500028	N	SYN
KCA 6.1	Schwartz, N.L.	2007	Stability of Glyphosate, N-Acetylglyphosate and Aminomethyl phosphonic acid in GAT corn forage, grain, and stover, stored frozen Report No.: DuPont-17379 GLP: yes not published ASB2008-2655	N	DPB
KCA 6.1	Schwartz, N.L.	2007	Stability of Glyphosate and metabolites in corn green plant, forage, grain, and stover containing the GAT and ZM-HRA genes during frozen	N	DPB

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			storage: Interim report Report No.: DuPont-20094 GLP: yes not published ASB2008-2656		
KCA 6.1	Schwartz, N.L.	2007	Stability of Glyphosate, N-Acetylglyphosate, Aminomethyl phosphonic acid and N-Acetyl AMPA in GAT soybean forage, seed, and hay stored frozen: Second interim report Report No.: DuPont-17573 GLP: yes not published ASB2008-2654	N	DPB
KCA 6.1	xxxxxxxxxxxxxxxx	1988	Storage stability of Glyphosate and AMPA in swine tissues, dairy cow tissues and milk laying hen tissues and eggs Report No.: MSL-7515 GLP: yes not published RIP9501253	Y	MOD
KCA 6.2.1	Sutherland, M.L.	1975	The metabolism of CP 67573 by citrus – February 1973 – October 1974. Report No. 328, RIP9501194 Non GLP Unpublished	N	MOD
KCA 6.2.1	Nadeu, R.G.; Cozad, S.J.	1976	Absorption, translocation and metabolism of Roundup herbicide in walnut, almond and pecan trees. April 1976, Report No. 403, RIP9501196. Non GLP Unpublished	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1	Rueppel, M.L.; Moran, S.J.	1974	CP 67573 residue and metabolism Part 23: The metabolism of CP 67573 in apple trees. Dec. 1974, report No. 342, RIP9501190 Non GLP Unpublished	N	MOD
KCA 6.2.1	Parker, S.; Harris, M.	1991	Glyphosate-trimesium: Uptake and metabolism in USA grape vines. 15.11.1991, RJ1002B GLP Unpublished	N	SYN
KCA 6.2.1	Wilkinson, M.J.; Joseph, R.S.I.	1990	Storage stability of residues of Glyphosate and AMPA in various plant materials Report No.: FSG-0707 GLP: yes not published ASB2012-12488	N	SYN
KCA 6.2.1	Rueppel, M.L.; Suba, L. A.; Moran, S.J.	1973	CP 67573 residue and emtabolism Part 20: The metabolism of CP 67573 in grape plants. March 1973, Report No. 355, RIP9501191. Non GLP Unpublished	N	MOD
KCA 6.2.1	Hasegawa, L.S.; Kumamoto, J.; Jordan, L.S.	1995	Degradation of glyphosate in avocado fruit. 10.04.1995, L365, ASB2011-13642. Non GLP Unpublished	N	LIT
KCA 6.2.1	Nadeau, R. G.	1974	CP 67573 residue and metabolism Part 26: The metabolism of CP 67573 in potato plants. March 1974, Report No. 376, RIP9501193. Non GLP Unpublished	N	MOD
KCA 6.2.1	Malik, J.M.; Brightwell, B.B.	1976	CP 67573 residue and metabolism Part 29: The metabolism of CP 67573 in sugar beets. March 1976, Report No. 394, RIP9501195 Non GLP	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.2.1	Rueppel, M.L.; Suba, L.A.	1973	CP 67573, Residue and metabolism Part 10: the metabolism of CP 67573 in soybeans, cotton, wheat and corn. 02.07.1973, Report No. 304, RIP9600099 GLP Unpublished	N	MOD
KCA 6.2.1	Stuart, C.; Parker, S.; Joseph, R. S.I.	1989	ICIA0224: Metabolism on wheat following a preharvest foliar spray. 06.12.1989, RJ0778B, RIP9500014. GLP Unpublished	N	SYN
KCA 6.2.1	Suba, L.A.; Georgieff, M.K.	1974	CP 67573 residue and metabolism Part 22: the metabolism of N-phosphonomethylglycine in barley, oats, rice and sorghum. Dec. 1974, Report No. 341, RIP9501189 Non GLP Unpublished	N	MOD
KCA 6.2.2	xxxxxxxxxxxxxxxx	1994	(14C-glyphosate): Absorption, distribution, metabolism and excretion following repeated oral administration to the dairy goat. 07.11.1994, Report No. 6769-1011, RIP9501207 GLP Unpublished	Y	MOD
KCA 6.2.2	xxxxxxxxxxxxxxxx	1987	Metabolism study of synthetic 13C/14C-labeled glyphosate and aminomethylphos-phonic acid in lactating goats. Part I. 30.12.1987, Report: MSL 7586, RIP9501203 GLP Unpublished	Y	MOD
KCA 6.2.2	xxxxxxxxxxxxxxxx	1988	Metabolism study of synthetic 13C/14C-labeled glyphosate and aminomethylphos-phonic acid in lactating goats. Part II. February 1988, Report: MSL 7458, RIP9501204 GLP	Y	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.2.2	xxxxxxxxxxxxxxxx	1994	The nature of residues of orally administered [phosphonomethylene-14C] glyphosate-trimesium in goat tissues and milk. 14.03.1994, Report No: RR 93-062B, RIP9500022 GLP Unpublished	Y	SYN
KCA 6.2.2	xxxxxxxxxxxxxxxx	2007	Metabolism of [14C]-N-Acetylglyphosate (IN-MCX20) in the lactating goat. 26.10.2007, Report No.: DuPont-19796, ASB2008-2660. GLP Unpublished	Y	DPB
KCA 6.2.3	xxxxxxxxxxxxxxxx	1994	(14C-glyphosate): Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen. 07.11.1994, Report No. 676/8-1011, RIP9501208 GLP Unpublished	Y	MOD
KCA 6.2.3	xxxxxxxxxxxxxxxx	1988	Metabolism study of synthetic 13C/14C-labeled glyphosate and aminomethylphosphonic acid in laying hens. Part I. 01.02.1998 Report No: MSL-7591, RIP9501205 GLP Unpublished	Y	SYN
KCA 6.2.3	xxxxxxxxxxxxxxxx	1988	Metabolism study of synthetic 13C/14C-labeled glyphosate and aminomethylphosphonic acid in laying hens. Part II. February 1988 Report No: MSL-7420, RIP9501206 GLP Unpublished	Y	MOD
KCA 6.2.3	xxxxxxxxxxxxxxxx	1994	[14C-PMG] glyphosate-trimesium nature of the residue in tissues and eggs of laying hens. 28.02.1994, Report No: RR-93-064, RIP9500020	Y	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.2.3	xxxxxxxxxxxxxxxxxx	2007	The metabolism of [14C]-N-acetylglyphosate (IN-MCX20) in laying hens. 08.11.2007, Report No.: DuPont-19795, ABS2008-2659 GLP Unpublished	Y	DPB
KCA 6.4.1	xxxxxxxxxxxxxxxxxx	1987	Residue determination of glyphosate and AMPA in dairy cow tissues and milk following a 28 day feeding study. September 1987, Report No.: MSL-6729, RIP9501250 GLP Unpublished	Y	MOD
KCA 6.4.1	xxxxxxxxxxxxxxxxxx	1987	Magnitude of SC-0224 residues in meat and milk. 31.07.1987, Report No.: RRC 87-44, RIP9500024 GLP Unpublished	Y	SYN
KCA 6.4.1	xxxxxxxxxxxxxxxxxx	2007	Magnitude of residues of N-acetylglyphosate and degradates in dairy cow tissues and milk. 15.11.2007, Report No.: DuPont-20087, ASB2008-2653 GLP Unpublished	Y	DPB
KCA 6.4.2	xxxxxxxxxxxxxxxxxx	1987	Residue determination of glyphosate and AMPA in laying hen tissues and eggs following a 28 day feeding study. November 1987, Report No.: MSL-6676, RIP9501252 GLP Unpublished	Y	MOD
KCA 6.4.2	xxxxxxxxxxxxxxxxxx	1987	Magnitude of SC-0224 residues in eggs and poultry. 31.07.1987, Report No.: RRC 87-43, RIP9500025. GLP	Y	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.4.2	xxxxxxxxxxxxxxxxxxxx	2007	Magnitude of residues of N-acetylglyphosate and degradates in laying hen tissues and eggs. 03.12.2007, Report No.: DuPont-20088, ASB2008-2652 GLP Unpublished	Y	DPB
KCA 6.4.3	xxxxxxxxxxxxxxxxxxxx	1987	Residue determination of glyphosate and AMPA in swine tissues following a 28-day feeding study. September 1987, Report-No.: MSL-6627, RIP9501251 GLP Unpublished	Y	MOD
KCA 6.5.1	Hiler, T.	2010	Nature of [14C]Glyphosate residues in processed commodities – high temperature hydrolysis. 07.10.2010, Report No.: MSL0023072, ASB2012-12432 GLP Unpublished	N	MOD
KCA 6.5.1	Umstatter, S.; Peterson, B.	2006	High temperature hydrolysis of [14C]IN-MCX20 in buffered aqueous solution at pH 4, 5 and 6. 10.08.2006, Report No.: DuPont-1979, ASB2008-2675 GLP Unpublished	N	DPB
KCA 6.5.2	Beasley, R.K.	1975	CP 57573, Residue and metabolism part 27: Determination of CP 67573 and CP 50435 residues in citrus process fractions 18.06.1975, Report No.: 377, RIP9501260 Non GLP Unpublished	N	MOD
KCA 6.5.2	Cowell, J.E.	1986	Determination of glyphosate and aminomethylphosphonic acid residues in citrus fruit and process fractions following post-directed treatment with Roundup herbicide. November 1986, Report No.: MSL-6194, RIP9501261 Non GLP	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.5.2	Mueth, M.G.	1988	Glyphosate residues in potatoes and processed fractions of potatoes after treatment with Roundup herbicide. July 1988, MSL-7877, RIP9501263 GLP Unpublished	N	MOD
KCA 6.5.2	Hontis, A.M.	1993	Residues of glyphosate/AMPA in olives and olive oil following a soil treatment with MON 65040 herbicide. Italian field trials 1993. Report No.: MLL 30319 GLP: yes Unpublished RIP9501290	N	MOD
KCA 6.5.2	Hontis, A.M.	1992	Residues of glyphosate/AMPA in olives and olive oil following use of Sting SE – Spanish field trials 1990/1992 Report No.: MLL 30297 GLP Unpublished RIP9501289		MOD
KCA 6.5.2	Hontis, A.M.	1996	Residues of glyphosate and AMPA in olives and olive oil, following a soil treatment with Roundup herbicide. Spanish field trials 1995. Report No.: MLL 30469 GLP Unpublished RIP9700184	N	MOD
KCA 6.5.2	Mestdagh, P.	1983	Residue analysis for glyphosate and AMPA in flax and processed fractions following preharvest Roundup herbicide treatments. UK and Ireland 1982 trials, 1983. MLL 30106, RIP9501266	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Non GLP Unpublished		
KCA 6.5.2	Mestdag, P.	1983	Residue analysis for glyphosate and AMPA in brassica seedcrops and processed fractions following preharvest Roundup herbicide treatments. UK and Scandinavian trials 1980-1982. 18.04.1983, MLL 30.103, RIP9501265 Non GLP Unpublished	N	MOD
KCA 6.5.2	Kuntsman, J.L.; Steinmetz, J.R.; Farmer, P.S.; Blount, L.M.	1983	Glyphosate residues in soybeans and soybean fractions following recirculating sprayer and preharvest topical treatment with Roundup herbicide. November 1983, MSL-3259, RIP9501259. Non GLP Unpublished	N	MOD
KCA 6.5.2	Kuntsman, J.L.	1987	Glyphosate residues in corn gran fractions following preharvest applications to corn with Roundup herbicide. September 1987, MSL-6917, RIP9501257 GLP Unpublished	N	MOD
KCA 6.5.2	Kunda, U.S.	1990	Glyphosate residues in or on corn frits and flour following preharvest applications of Roundup herbicide to corn. January 1990, MSL-9797, RIP9501258 GLP Unpublished	N	MOD
KCA 6.5.2	Schulz, H.	1992	Determination of residues of glyphosate and AMPA in cereals – (CHE 03690H). 10.11.1992, 275848, RIP9501327 GLP Unpublished	N	CHE

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5.2	Schulz, H.	1992	Determination of residues of glyphosate and AMPA in cereals – (SAG 539 00). 10.11.1992, 275837, RIP9501328 GLP Unpublished	N	CHE
KCA 6.5.2	Steinmetz, J.R.	1984	Glyphosate residues in wheat and wheat grain milling/fractionation products following pre-harvest applications with Roundup herbicide. July 1984, MSL-3677, RIP9501254 Non GLP Unpublished	N	MOD
KCA 6.5.2	Steinmetz, J.R.; Cowell, J.E.	1984	Addedendum to MSL-3612: glyphosate residues in wheat grain milling/fractionation products. October 1984, MSL-4005, RIP9501255 Non GLP Unpublished	N	MOD
KCA 6.5.2	Schulz, H.	1992	Determination of residues of glyphosate and AMPA in cereals – (CHE 03690H). 10.11.1992, 275848, RIP9501327 GLP Unpublished	N	CHE
KCA 6.5.2	Schulz, H.	1992	Determination of residues of glyphosate and AMPA in cereals – (SAG 539 00). 10.11.1992, 275837, RIP9501328 GLP Unpublished	N	CHE
KCA 6.5.2	Anon.	1992	Berichtsbogen für Rückstandsuntersuchungen mit Pflanzenschutzmitteln – Weizen. FRG-0065/R192-90 & FRG-0066/R-196-90, ASB2009-6582, ASB2009-6583 GLP Unpublished	N	CHE
KCA 6.5.2	Mestdagh, P.	1980	Glyphosate residues in cereals following preharvest application of Roundup in France. 25.01.1980, MLL 30046, RIP9501231	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Non GLP Unpublished		
KCA 6.5.2	Zietz, E.	1993	Determination of residues of glyphosate in cereals and processing products – treatment with GLYFOS – Germany season 1992. 06.04.1993, IF-92/11567-01, RIP95013329, RIP9500134, ASB2011-9181 GLP Unpublished	N	CHE
KCA 6.5.2	Mestdagh, P.	1982	Appendix D: Analytical residues methods glyphosate residues in cereal grain and straw following preharvest treatment with Roundup herbicide in the United Kingdom. 02.12.1982, MLL 30087, ASB2009-5491 Non GLP Unpublished	N	MOD
KCA 6.6.1	Nicholls, R.G.	1990	Confined rotational crops study of glyphosate – part I: In-field portion. 22.06.1990, Report No.: MSL 9810, RIP9501201. GLP Unpublished	N	MOD
KCA 6.6.1	McMullan, P.C.; Honegger, J.L.; Logush, E.W.	1990	Confined rotational crops study of glyphosate – part II: Quantitation, characterization and identification of glyphosate and its metabolites in rotational crops. 22.06.1990, Report No.: MSL 9811, RIP9501202. GLP Unpublished	N	MOD
KCA 6.6.1	Hatterman, D.R.	1998	LX1146-02 (glyphosate technical) confined rotational crop study on lettuce, radish and wheat in California. 20.04.1998, Report No.: 1651-91-146-01 GLP Unpublished	N	MOD
KCA 6.6.1	Suba, L.A.	1976	Metabolism of CP 67573 in representative vegetables and rotation. April 1976, Report No.: 406, RIP9501199.	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Non GLP Unpublished		
KCA 6.6.1	Brightwell, B.; Cooper, B.J.	1978	Uptake and metabolism of glyphosate in root, leaf and cereal type rotation crops. September 1978, Report No.: MSL 0882, RIP9501200. Non GLP Unpublished	N	MOD
KCP 8.3.1	Balluff, M.	1995	Determination of residues of Glistar in apples under field conditions at four locations in Germany Report No.: 94035 GLP: yes not published RIP9501344	N	ALK
KCP 8.3.1	Balluff, M.	1995	Determination of residues of Glistar in winter wheat under field conditions at four locations in Germany Report No.: 94035/01-FPWW GLP: yes not published RIP9501341	N	ALK
KCP 8.3.1	Grolleau, G.	2001	Magnitude of the Residue of Glyphosate in Cherry raw agricultural commodity; Germany - 2000; incl. Amendment Report No.: EA000181 GLP: yes not published	N	CHE MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1	Gustin, C.	1999	Glyphosate and AMPA residues in wheat and barley treated pre-harvest with Roundup herbicide and MON 14420. 1998 Field trials in Belgium and France Report No.: MLL 30815 GLP: yes not published RIP2000-1243	N	MOD
KCP 8.3.1	Gustin, C	2000	Glyphosate and AMPA residues in oil seed rape treated pre-harvest with Roundup (MON 2139) and MON 78294. 1999 Field trials in Belgium and France Report No.: MLL 31336 GLP: yes not published RIP2002-651	N	MOD
KCP 8.3.1	Hontis, A. M.	1989	Glyphosate and AMPA residues in oilseed rape following preharvest application of MON 14478 with Ammoniumsulfate and of Roundup herbicide. 1989 UK field trials Report No.: MLL 30235 GLP: no not published RIP9501286	N	MOD
KCP 8.3.1	Hontis, A. M.	1991	Glyphosate and AMPA residues in wheat and barley following application of MON 52276, MON 44068 and Roundup herbicide, one week before crop harvest. French trials 1991	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No.: MLL 30281 GLP: yes not published RIP9501287		
KCP 8.3.1	Hontis, A. M.	1992	Glyphosate and AMPA residues in barley following preharvest application of MON 44068 and Roundup herbicide. German field trials 1991 Report No.: MLL 30286 GLP: yes not published RIP9500162	N	MOD
KCP 8.3.1	Hontis, A. M.	1992	Glyphosate and AMPA residues in barley following preharvest application of MON 44068 and Roundup herbicide. German field trials 1991 Report No.: MLL 30286 GLP: yes not published RIP9501288	N	MOD
KCP 8.3.1	Hontis, A. M.	1993	Residues of Glyphosate/AMPA in winter oilseed rape following an application of MON 52276, MON 44068 and Roundup herbicide, two weeks before harvest. UK field trials 1992 Report No.: MLL 30321 GLP: yes not published RIP9501292	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1	Hontis, A. M.	1993	Residues of Glyphosate/AMPA in winter wheat following an application of MON 52276, MON 44068 and Roundup herbicide, one week before harvest. - U.K. field trials 1992. Report No.: MLL 30320 GLP: yes not published RIP9501291	N	MOD
KCP 8.3.1	Lemaire, P.	1999	Glyphosate and AMPA residues in oilseed rape treated pre-harvest with Roundup herbicide and MON 14420. 1998 Field trials in Belgium and France Report No.: MLL 30817 GLP: yes not published RIP2000-1244	N	MOD
KCP 8.3.1	Losseau, F.	1988	Glyphosate residues in cereals following preharvest applications of MON 14478, with and without Ammoniumsulfate (AS), in comparison to Roundup herbicide - 1987 France - Field trials Report No.: MLL 30205 GLP: no not published RIP9501280	N	MOD
KCP 8.3.1	Losseau, F.	1988	Glyphosate residues in cereals following preharvest applications of MON 14474, MON	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			8791, MON 8755, MON 14456, in comparison to Roundup herbicide - 1987 Fed. Rep. Germany - Field trials. Report No.: MLL 30209 GLP: no not published RIP9501282		
KCP 8.3.1	Losseau, F.	1988	Glyphosate residues in cereals following preharvest applications of MON 14474, MON 8791, MON 8755, MON 14456, in comparison to Roundup herbicide - 1987 Fed. Rep. Germany - Field trials. Report No.: MLL 30209 GLP: no not published RIP9501282	N	MOD
KCP 8.3.1	Losseau, F.	1989	Glyphosate and AMPA residues in grapes following MON 8755 (Arcade) herbicide applications in vineyards. German field trials 1988 Report No.: MLL 30227 GLP: yes not published RIP9501285	N	MOD
KCP 8.3.1	Losseau, F.	1989	Glyphosate and AMPA residues in oilseedrape (OSR), peas and beans following preharvest applications of MON 14478 with Ammoniumsulfate (AS) in comparison to	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Roundup or Roundup 480 herbicide applications. 1988 UK fieldtrials Report No.: MLL 30223 GLP: yes not published RIP9501284		
KCP 8.3.1	Mestdagh, P.	1979	Glyphosate residues in cereals following preharvest application of Roundup in the United Kingdom Report No.: MLL 30037 GLP: no not published RIP9501230	N	MOD
KCP 8.3.1	Mestdagh, P.	1980	Glyphosate residues in apples following Roundup application in Denmark Report No.: MLL 30053 GLP: no not published RIP9501235	N	MOD
KCP 8.3.1	Mestdagh, P.	1980	Glyphosate residues in cereals following preharvest application of Roundup in France Report No.: MLL 30046 GLP: no not published RIP9501231	N	MOD
KCP 8.3.1	Mestdagh, P.	1982	Glyphosate residues in cereal grain and straw following preharvest treatment with Roundup herbicide in the United Kingdom - 1982 trials -	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Part I. Report No.: MLL 30087 GLP: no not published RIP9501249		
KCP 8.3.1	Mestdag, P.	1983	Glyphosate residues in cereals following Roundup herbicide preharvest applications using low spray water volumes and/or additional surfactant/active ingredient ratios. UK 1982 trials Report No.: ML 30112 GLP: no not published RIP9501269	N	MOD
KCP 8.3.1	Mestdag, P.	1985	Glyphosate residues in rye and oat following Roundup herbicide preharvest applications. Denmark 1984 trials Report No.: MLL 30150 GLP: no not published RIP9501275	N	MOD
KCP 8.3.1	Mestdag, P.	1988	Glyphosate and AMPA residues in oilseed rape and peas following preharvest Roundup herbicide applications. 1986-1987 field trials Fed. Rep. of Germany Report No.: MLL 30204 GLP: no not published	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			RIP9501279		
KCP 8.3.1	Mestdagh, P.	1988	Glyphosate residues in cereals following preharvest applications of MON 14478, with and without Ammoniumsulfate (AS), in comparison to Roundup (MON 2139) and/or Roundup 480 (MON 8762) herbicide - 1987 UK field trials Report No.: MLL 30200 GLP: no not published RIP9501278	N	MOD
KCP 8.3.1	Michaux, M.	1975	CP 67573 :Determination of crop residues in grapes - Final Report Report No.: A2 GLP: no not published ASB2009-5294	N	MOD
KCP 8.3.1	Michaux, M.	1976	CP 67573 : Determination of crop residues in apples and pears - Final report Report No.: A9 GLP: no not published RIP9501211	N	MOD
KCP 8.3.1	Michaux, M.	1977	CP 67573: Determination of crop residues in grapes and apples Report No.: MON 2139 GLP: no not published	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			ASB2009-5276		
KCP 8.3.1	Perny, A.	2002	Glyphosate and AMPA residues in wheat and barley treated pre-harvest with Roundup(r) (MON 2139), MON 78273 and MON 78568. 2001 Field Trials in France, Germany and Italy. Report No.: RA1157 GLP: yes not published RIP2005-200	N	MOD
KCP 8.3.1	Puy, E.	1993	Détermination des résidus de glyphosate et de son métabolite l'AMPA dans des échantillons de pailles et de grains de céréales traitées avec Glistar en France en 1992 Report No.: RF 2052 GLP: yes not published RIP9501345	N	ALK
KCP 8.3.1	Reding, M. A.	1978	Determination of crop residues in apples Report No.: A22 GLP: no not published RIP9501218	N	MOD
KCP 8.3.1	Reding, M. A.	1986	Glyphosate and Aminomethylphosphonic acid residues in cereal grain and straw following preharvest treatment with Roundup herbicide in Europe Report No.: MLL 30177	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP: no not published RIP9501276		
KCP 8.3.1	Reding, M. A.	1987	Residual Glyphosate and AMPA in oilseed rape, beans and peas following application of MON 8762 - MON 8795 and Roundup herbicide. UK 1986 field trials Report No.: MLL 30180 GLP: no not published RIP9501277	N	MOD
KCP 8.3.1	Reding, M. A.	1988	Residue determination of Glyphosate and Aminomethylphosphonic acid in various crops following different Roundup, or Glyphosate based formulation, applications. 1978-1987 trial period Report No.: MLL 30206 GLP: no not published RIP9501281	N	MOD
KCP 8.3.1	Schulz, H.	1992	Determination of the residues of Glyphosate and AMPA in cereals (SAG 539 00) Report No.: 275837 GLP: yes not published RIP9501328	N	CHE
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter sown oilseed rape (seed and pods) -	N	CHE

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Treatment with CHE 3607 - UK Season 1992 - Agriseach UK Ltd. Study Plan AS/1908/CN Report No.: IF-93/13839-01 GLP: yes not published		
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter sown oilseed rape - Treatment with CHE 3607 - UK Season 1992, Agriseach UK Ltd. Study Plan AS/1899/CN Report No.: IF-93/13831-01 GLP: yes not published RIP9501322	N	CHE
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter barley (whole plant, grains and straws - Treatment with CHE 3607/Frigate - UK, Season 1992, Agriseach UK Ltd, Study Plan AS/1905/CN Report No.: IF-93/04573-01 GLP: yes not published RIP9501296	N	CHE
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter barley (grains and straws) - Treatment with CHE 3607/Frigate - UK, Season 1992, Agriseach UK Ltd, Study Plan AS/1896/CN Report No.: IF-93/04568-01 GLP: yes	N	CHE

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			not published RIP9501294		
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter oats (whole plant, grains and straw - Treatment with CHE 3607/Frigate - UK, Season 1992, Agrisearch UK Ltd, Study Plan AS/1907/CN Report No.: IF-93/04575-01 GLP: yes not published RIP9501300	N	CHE
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter oats (grains and straw) - Treatment with CHE 3607/Frigate - UK, Season 1992, Agrisearch UK Ltd, Study Plan AS/1897/CN Report No.: IF-93/04569-01 GLP: yes not published RIP9501298	N	CHE
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter wheat (grain and straw) - Treatment with CHE 3607/Frigate - UK, Season 1992, Agrisearch UK Ltd, Study Plan AS/1898/CN Report No.: IF-93/04570-01 GLP: yes not published RIP9501302	N	CHE

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1	Schulz, H.; Mirbach, M. J.	1994	Determination of residues of Glyphosate in winter wheat (whole plant, grains and straw - Treatment with CHE 3607/Frigate - UK, Season 1992, Agrisearch UK Ltd, Study Plan AS/1906/CN Report No.: IF-93/04574-01 GLP: yes not published RIP9501304	N	CHE
KCP 8.3.1	Vanbellingen, C.	2000	Glyphosate and AMPA residues in wheat and barley treated pre-harvest with Roundup herbicide (MON 2139) and MON 78294. 1999 Field trials in Belgium and France Report No.: MLL 31337 GLP: yes not published RIP2002-650	N	MOD
KCP 8.3.1	Zietz, E.	1993	Determination of residues of Glyphosate in cereals and processing products - Treatment with GLYFOS - Germany season 1992 Report No.: IF-92/11567-01 GLP: yes not published RIP9501329, RIP9500134 & ASB2011-9181	N	CHE
KCP 8.3.1	Mestdagh, P.	1981	Residual Glyphosate in processed oat grains following a preharvest application of Roundup herbicide in the United Kingdom Report No.: MLL 30.071	N	MOD

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP: no not published RIP9501239		
KCP 8.3.1	Schulz, H.	1992	Determination of residues of Glyphosate and AMPA in cereals - (CHE 03690H) Report No.: 275848 GLP: yes not published RIP9501327	N	CHE
KCP 8.3.1	Schulz, H.	1992	Determination of residues of Glyphosate and AMPA in cereals - (SAG 539 00) Report No.: 275837 GLP: yes not published RIP9501328	N	CHE

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Glyphosate

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new data were submitted in the framework of this application.

A 2.1.1.1.2 Storage stability of residues in animal products

No new data were submitted in the framework of this application.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new data were submitted in the framework of this application.

A 2.1.2.1.2 Nature of residue in rotational crops

No new data were submitted in the framework of this application.

A 2.1.2.1.3 Nature of residues in processed commodities

No new data were submitted in the framework of this application.

A 2.1.2.2 Nature of residues in livestock

No new data were submitted in the framework of this application.

A 2.1.3 Magnitude of residues in plants

No additional studies were necessary/provided

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new data were submitted in the framework of this application.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new data were submitted in the framework of this application.

A 2.1.5.2 Processing studies on a core set of representative processes

No new data were submitted in the framework of this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application.

A 2.1.7 Other/Special Studies

No new data were submitted in the framework of this application.

A 3.1 TMDI calculations

Chronic risk assessment										
				TMDI (range) in % of ADI minimum - maximum						
				1 78						
				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	pTMRs at LOQ (in % of ADI)
	78.1	UK Toddler		68.6	Sugar beet (root)	7.8	Wheat	0.3	Potatoes	
	38.0	UK Infant		30.2	Sugar beet (root)	5.2	Wheat	1.0	Oats	
	28.3	WHO Cluster diet B		17.1	Wheat	3.0	Sunflower seed	2.4	Soya bean	
	22.1	DK child		11.0	Wheat	8.8	Rye	1.6	Oats	
	19.6	WHO cluster diet D		13.0	Wheat	2.0	Sunflower seed	1.5	Soya bean	
	18.9	WHO cluster diet E		7.9	Wheat	3.2	Barley	2.3	Soya bean	
	16.5	UK vegetarian		11.3	Sugar beet (root)	4.1	Wheat	0.2	Oats	
	16.3	WHO Cluster diet F		7.2	Wheat	2.6	Soya bean	2.4	Barley	
	16.1	UK Adult		12.0	Sugar beet (root)	3.4	Wheat	0.1	Potatoes	
	14.1	IE adult		5.0	Barley	4.6	Wheat	0.8	Sunflower seed	
	14.0	IT kids/toddler		13.3	Wheat	0.1	Potatoes	0.1	Wild fungi	
	12.9	DE child		8.2	Wheat	1.6	Rye	0.8	Oats	
	12.5	NL child		9.5	Wheat	0.6	Potatoes	0.4	Oats	
	12.0	PT General population		7.8	Wheat	1.2	Soya bean	1.2	Sunflower seed	
	11.1	ES child		8.9	Wheat	0.5	Sunflower seed	0.5	Lentils	
	9.8	WHO regional European diet		5.9	Wheat	1.3	Barley	0.6	Sunflower seed	
	8.8	IT adult		8.3	Wheat	0.1	Wild fungi	0.1	Potatoes	
	8.7	FR all population		6.6	Wheat	1.3	Sunflower seed	0.4	Table and wine grapes	
	8.0	ES adult		4.7	Wheat	2.0	Barley	0.4	Sunflower seed	
	8.0	SE general population 90th percentile		6.4	Wheat	0.6	Rye	0.4	Potatoes	
	7.4	FR toddler		5.2	Wheat	0.6	Sunflower seed	0.5	Potatoes	
	6.9	NL general		4.1	Wheat	1.5	Barley	0.3	Potatoes	
	6.3	DK adult		4.0	Wheat	1.4	Rye	0.5	Oats	
	5.5	LT adult		2.2	Rye	2.1	Wheat	0.4	Oats	
	4.2	FI adult		2.0	Wheat	1.4	Rye	0.3	Oats	
	2.8	FR infant		1.7	Wheat	0.4	Potatoes	0.3	Milk and cream,	
	0.6	PL general population		0.3	Potatoes	0.0	Pome fruit	0.0	Peas	
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Gyphosate is unlikely to present a public health concern.										

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European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Glyphosate			
LOQs (mg/kg) range from:		0.05	to: 2.0
Toxicological reference values			
ADI (mg/kg bw/day):		0.5	ARID (mg/kg bw): 0.5
Source of ADI:		Reg. (EU)	Source of ARID: Reg. (EU) 2017/2324
Year of evaluation:			Year of evaluation:

Input values	
Details - chronic risk assessment	Supplementary results - chronic risk assessment
Details - acute risk assessment/children	Details - acute risk assessment/adults

Comments:	
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Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

				No of diets exceeding the ADI : -----						Exposure resulting from	
			Exposure	Highest contributor to		2nd contributor to MS		3rd contributor to MS		MRLs set at	commodities n
	Calculated exposure (% of ADI)	MS Diet	(µg/kg bw per day)	(in % of ADI)	Commodity / group of commodities	diet (in % of ADI)	Commodity / group of commodities	diet (in % of ADI)	Commodity / group of commodities	(in % of ADI)	under assessment (in % of ADI)
TMDI(NED)/IEDI calculation (based on average food consumption)	39%	NL child	193.83	25%	Sugar beet roots	8%	Wheat	1%	Sunflower seeds	0.6%	12%
	33%	NL toddler	166.62	16%	Sugar beet roots	8%	Wheat	2%	Rapeseeds/canola seeds	1%	15%
	28%	GEMS/Food G06	137.67	14%	Wheat	5%	Soyabeans	4%	Sugar beet roots	0.4%	16%
	27%	GEMS/Food G11	136.62	15%	Soyabeans	7%	Wheat	3%	Barley	0.4%	11%
	27%	GEMS/Food G10	134.57	13%	Soyabeans	8%	Wheat	2%	Barley	0.3%	12%
	25%	GEMS/Food G08	126.55	8%	Wheat	8%	Soyabeans	4%	Barley	0.3%	16%
	24%	GEMS/Food G15	118.93	9%	Wheat	7%	Soyabeans	3%	Barley	0.3%	16%
	23%	FR child 3-15 yr	116.75	11%	Sugar beet roots	9%	Wheat	0.9%	Sunflower seeds	0.5%	11%
	23%	GEMS/Food G07	115.21	8%	Wheat	7%	Soyabeans	2%	Barley	0.3%	14%
	22%	DK child	110.43	11%	Rye	9%	Wheat	2%	Oat	0.4%	21%
	21%	DE women 14-50 yr	107.31	14%	Sugar beet roots	4%	Wheat	1.0%	Rye	0.3%	7%
	21%	DE general	106.45	13%	Sugar beet roots	4%	Wheat	2%	Barley	0.3%	8%
	19%	UK toddler	95.60	10%	Sugar beet roots	8%	Wheat	0.3%	Potatoes	0.4%	8%
	18%	RO general	89.58	10%	Wheat	4%	Sugar beet roots	3%	Sunflower seeds	0.3%	13%
	17%	FR toddler 2-3 yr	84.79	9%	Sugar beet roots	6%	Wheat	0.5%	Sunflower seeds	0.5%	7%
	17%	NL general	83.05	9%	Sugar beet roots	4%	Wheat	1%	Barley	0.2%	7%
	14%	IT toddler	69.91	13%	Wheat	0.1%	Potatoes	0.1%	Wild fungi	0.2%	13%
	13%	DE child	66.43	8%	Wheat	2%	Rye	0.6%	Oat	0.7%	12%
	12%	UK infant	59.90	5%	Wheat	4%	Sugar beet roots	1%	Oat	0.6%	7%
	12%	PT general	59.84	8%	Wheat	1%	Soyabeans	1%	Sunflower seeds	0.1%	10%
	12%	ES child	58.02	9%	Wheat	0.5%	Sugar beet roots	0.5%	Sunflower seeds	0.3%	9%
	9%	IT adult	44.06	8%	Wheat	0.1%	Wild fungi	0.1%	Potatoes	0.1%	8%
	9%	IE adult	43.91	5%	Wheat	0.8%	Sunflower seeds	0.7%	Oat	0.4%	7%
	8%	ES adult	42.06	5%	Wheat	2%	Barley	0.4%	Sunflower seeds	0.2%	7%
	8%	FR adult	41.60	4%	Wheat	2%	Sugar beet roots	0.4%	Sunflower seeds	0.2%	5%
	8%	SE general	39.90	6%	Wheat	0.6%	Rye	0.4%	Potatoes	0.4%	7%
	7%	FI 3 yr	36.72	2%	Wheat	2%	Oat	1%	Rye	0.2%	7%
	7%	UK vegetarian	33.88	4%	Wheat	2%	Sugar beet roots	0.2%	Oat	0.1%	5%
	6%	FR infant	31.99	4%	Sugar beet roots	2%	Wheat	0.2%	Potatoes	0.3%	2%
	6%	UK adult	29.09	3%	Wheat	2%	Sugar beet roots	0.1%	Potatoes	0.1%	4%
	6%	FI 6 yr	26.02	2%	Wheat	1%	Oat	1%	Rye	0.1%	5%
	6%	LT adult	27.56	2%	Rye	2%	Wheat	0.4%	Oat	0.2%	5%
	4%	DK adult	18.69	2%	Wheat	1%	Rye	0.1%	Potatoes	0.2%	3%
	3%	FI adult	16.43	1%	Rye	0.6%	Wheat	0.5%	Oat	0.1%	3%
	3%	IE child	12.82	2%	Wheat	0.1%	Potatoes	0.0%	Oat	0.1%	2%
	0.6%	PL general	2.95	0.3%	Potatoes	0.0%	Peas	0.0%	Apples	0.1%	0.1%

Conclusion:
The estimated long-term dietary intake (TMDI(NED)/IEDI) was below the ADI.
The long-term intake of residues of Glyphosate is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

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A 3.2 IESTI calculations - Raw commodities

Acute risk assessment /children						Acute risk assessment / adults / general population						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 1	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2	*)	**) pTMRL/ threshold MRL (mg/kg)
	Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities	
	28.9	Wheat	10 / -	28.9	Wheat	10 / -	29.0	Barley	20 / -	29.0	Barley	20 / -
	15.9	Oats	20 / -	15.9	Oats	20 / -	15.6	Wheat	10 / -	15.6	Wheat	10 / -
	12.6	Rye	10 / -	12.6	Rye	10 / -	9.7	Rye	10 / -	9.7	Rye	10 / -
	12.3	Sunflower seed	20 / -	12.3	Sunflower seed	20 / -	5.7	Oats	20 / -	5.7	Oats	20 / -
	7.1	Barley	20 / -	7.1	Barley	20 / -	4.0	Sunflower seed	20 / -	4.0	Sunflower seed	20 / -
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
<p>The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>								<p>IESTI new calculations:</p> <p>The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</p> <p>Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</p>								
Show results of IESTI calculation only for crops with GAPs under assessment																
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI): ---				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new): ---				IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new): ---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (ug/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (ug/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (ug/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (ug/kg bw)
	29%	Wheat	10 / 10	144	19%	Barley	20 / 20	97	29%	Wheat	10 / 10	144	19%	Barley	20 / 20	97
	22%	Barley	20 / 20	112	17%	Wheat	10 / 10	84	22%	Barley	20 / 20	112	17%	Wheat	10 / 10	84
	13%	Sunflower seeds	20 / 20	64	10%	Rye	10 / 10	49	13%	Sunflower seeds	20 / 20	64	10%	Rye	10 / 10	49
13%	Rye	10 / 10	63	4%	Sunflower seeds	20 / 20	20	13%	Rye	10 / 10	63	4%	Sunflower seeds	20 / 20	20	
7%	Table grapes	0.5 / 0.5	36	3%	Table grapes	0.5 / 0.5	17	4%	Oat	20 / 20	22	3%	Oat	20 / 20	13	
4%	Oat	20 / 20	22	3%	Oat	20 / 20	13	4%	Table grapes	0.5 / 0.5	22	2%	Wine grapes	0.5 / 0.5	12	
3%	Pears	0.1 / 0.1	14	2%	Wine grapes	0.5 / 0.5	13	3%	Rapeseeds/canola seeds	10 / 10	14	2%	Table grapes	0.5 / 0.5	10	
3%	Rapeseeds/canola seeds	10 / 10	14	1%	Rapeseeds/canola seeds	10 / 10	5.3	1%	Maize/corn	1 / 1	6.7	1%	Rapeseeds/canola seeds	10 / 10	5.3	
2%	Apples	0.1 / 0.1	11	0.8%	Pears	0.1 / 0.1	3.1	1%	Apples	0.1 / 0.1	6.2	0.8%	Plums	0.1 / 0.1	3.9	
2%	Peaches	0.1 / 0.1	9.5	0.8%	Apples	0.1 / 0.1	2.8	1%	Pears	0.1 / 0.1	5.9	0.7%	Pears	0.1 / 0.1	3.6	
1%	Maize/corn	1 / 1	6.7	0.4%	Maize/corn	1 / 1	2.2	1%	Peaches	0.1 / 0.1	5.4	0.8%	Apples	0.1 / 0.1	3.0	
0.9%	Wine grapes	0.5 / 0.5	4.6	0.4%	Peaches	0.1 / 0.1	1.9	1.0%	Apricots	0.1 / 0.1	4.9	0.4%	Maize/corn	1 / 1	2.2	
0.8%	Plums	0.1 / 0.1	4.2	0.4%	Plums	0.1 / 0.1	1.8	0.9%	Wine grapes	0.5 / 0.5	4.6	0.4%	Peaches	0.1 / 0.1	2.0	
0.7%	Apricots	0.1 / 0.1	3.5	0.5%	Apricots	0.1 / 0.1	1.1	0.5%	Plums	0.1 / 0.1	2.8	0.3%	Apricots	0.1 / 0.1	1.3	
0.2%	Cherries (sweet)	0.1 / 0.1	1.2	0.2%	Cherries (sweet)	0.1 / 0.1	1.00	0.2%	Cherries (sweet)	0.1 / 0.1	1.2	0.2%	Cherries (sweet)	0.1 / 0.1	1.00	
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	23.6	Wheat flour	10 / -	8.8	Bread/pizza	10 / -
	3.3	Grape juice	0.5 / -	0.4	Wine	0.5 / -
	1.0	Apple juice	0.1 / -	0.1	Apple juice	0.1 / -
	0.9	Maize flour	1 / -	0.1	Maize flour	1 / -
	0.4	Peach juice	0.1 / -	0.0	Raisins	0.5 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
 **) pTMRL: provisional temporary MRL
 ***) pTMRL: provisional temporary MRL for unprocessed commodity

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Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI		IESTI		IESTI		IESTI new		IESTI new		IESTI new		IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Wheat / milling (flour)	10 / 10	121	29%	Barley / beer	20 / 4	144	24%	Wheat / milling (flour)	10 / 10	121	29%	Barley / beer	20 / 4	144	
15%	Oat / baked	20 / 20	73	9%	Wheat / bread/pizza	10 / 10	44	15%	Oat / baked	20 / 20	73	9%	Wheat / bread/pizza	10 / 10	44	
15%	Barley / cooked	20 / 20	73	8%	Wheat / pasta	10 / 10	38	15%	Barley / cooked	20 / 20	73	8%	Wheat / pasta	10 / 10	38	
12%	Oat / milling (flakes)	20 / 20	60	7%	Wheat / bread (wholemeal)	10 / 10	35	12%	Oat / milling (flakes)	20 / 20	60	7%	Wheat / bread (wholemeal)	10 / 10	35	
11%	Wheat / milling (wholemeal)-t	10 / 10	55	6%	Oat / baked	20 / 20	30	11%	Wheat / milling (wholemeal)-t	10 / 10	55	6%	Oat / baked	20 / 20	30	
9%	Sunflower seeds / oils	20 / 40	47	3%	Maize / oil	1 / 25	13	9%	Sunflower seeds / oils	20 / 40	47	3%	Maize / oil	1 / 25	13	
7%	Rye / baked	10 / 10	36	2%	Wine grapes / juice	0.5 / 0.5	10	7%	Rye / baked	10 / 10	36	2%	Wine grapes / juice	0.5 / 0.5	10	
7%	Barley / milling (flour)	20 / 20	36	0.9%	Wine grapes / wine	0.5 / 0.5	4.7	7%	Barley / milling (flour)	20 / 20	36	0.9%	Wine grapes / wine	0.5 / 0.5	4.7	
7%	Rye / milling (wholemeal)-ba	10 / 10	35	0.7%	Apples / juice	0.1 / 0.1	3.3	7%	Rye / milling (wholemeal)-ba	10 / 10	35	0.7%	Apples / juice	0.1 / 0.1	3.3	
5%	Maize / oil	1 / 25	23	0.6%	Table grapes / raisins	0.5 / 2.35	2.9	5%	Maize / oil	1 / 25	23	0.6%	Table grapes / raisins	0.5 / 2.35	2.9	
4%	Wine grapes / juice	0.5 / 0.5	22	0.2%	Peaches / canned	0.1 / 0.1	0.81	4%	Wine grapes / juice	0.5 / 0.5	22	0.2%	Peaches / canned	0.1 / 0.1	0.81	
1%	Rapeseeds / oils	10 / 20	5.9	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	1%	Rapeseeds / oils	10 / 20	5.9	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	
1%	Apples / juice	0.1 / 0.1	5.4	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	1%	Apples / juice	0.1 / 0.1	5.4	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	
0.7%	Pears / juice	0.1 / 0.1	3.3	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	0.7%	Pears / juice	0.1 / 0.1	3.3	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	
0.5%	Peaches / canned	0.1 / 0.1	2.6	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	0.4%	Maize / processed (not	1 / 1	2.1	#IUCZBAI	#IUCZBAI	#IUCZBAI	#IUCZBAI	
Expand/collapse list																
Conclusion:																
No exceedance of the toxicological reference value was identified for any unprocessed commodity.																
A short term intake of residues of Glyphosate is unlikely to present a public health risk.																
For processed commodities, no exceedance of the ARID/ADI was identified.																

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Appendix 4 Additional information provided by the applicant