FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ORKAN 350 SL

Product name(s): ORKAN 350 SL / SPRINTER 350 SL

Chemical active substance(s):

MCPA, 90 g/L

~~Glifosat~~ Glyphosate, 260 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

MS Finalisation date: 09.2020; 11.2021

Version history

When	What
04/2020	Dossier submission date
09/2020	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Stability of Residues

Glyphosate

During the peer review, residues of glyphosate and AMPA were found to be stable at -18/20°C for at least 24 months in matrices, including high water, high oil, high protein, high starch, high acid content commodities, other plant commodities and animal tissues.

Residues of N-acetyl-Glyphosate are stable for 6 to > 12 months in high water, high oil and high starch content matrices.

Residues of N-acetyl-AMPA are stable >1 to > 12 months in high water, high oil and high starch content matrices.

Sufficient stability has been demonstrated to support the residue data presented in the submission..

MCPA

Residues of MCPA in cereal plants, grain and straw are stable up to 18 months when stored in temperature below –18°C.

Metabolism in plants

Glyphosate

No new data submitted in the framework of this application.

Plant residue definition for monitoring	Sweet corn, oilseed rape, soya beans and mize (non-tolerant and tolerant, all modifications): sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate Other plant commodities: glyphosate (Regulation n°293/2013)
Plant residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and Nacetyl-AMPA, all expressed as glyphosate (EFSA, 2015).
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/desiccation) should be considered to derive CF for plant commodities (EFSA, 2015).

MCPA

No new data submitted in the framework of this application.

Plant residue definition for monitoring	MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (Reg. (EU) No 491/2014)
Plant residue definition for risk assessment	MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (EFSA, 2013)

Magnitude of residues in plants

Pome fruits (apple, pear, quince, medlar)

Glyphosate

Proposed GAP

1 application, 1.30 kg as./ha or 1.82-2.08 kg as./ha, Product used in period intensive growth weeds in dose needed to destruction occurring species weeds, PHI – n.a.

EU GAP: 0.72-2.88 kg as./ha, 1-3 application (interval 28 days), post emergence of weed, Stone & pome fruit, olives

Applications to avoid contact with tree branches. Maximum cumulative application rate 4.32 kg/ha glyphosate in any 12 month period.

MRL review (article 12) GAP: apple, pears; max 2 applications; 0.54 3.60 kg as./ha during the intensive growth of weeds; PHI: 7

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Three residue trials on apples were carried out in Poland in 2019. Product ORKAN 350 SL was applied once at a rate of 2080 g of glyphosate at the intensive growth of weeds. The apple trees was at the growth stage BBCH 69-71. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.

Results: 3 x<0.003 mg/kg – LOD (glyphosate, AMPA, N-acetyl-AMPA, N-acetyl-glyphosate)

LOQ: 0.01 mg/kg for each analyte

7 days of PHI is proposed by zRMS for apple and pears as is stated in EFSA Journal 2019;17(10):5862

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation from apple to whole group pome fruits is possible (major crop to group with minor and major crops (with residues lower than LOQs); available 7 trials).

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

The uses are considered acceptable.

MCPA

Proposed GAP

1 application, 0.45 kg as./ha or 0.63-0.72 kg as./ha, Product used in period intensive growth weeds in dose needed to destruction occurring species weeds, PHI – n.a.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Three residue trials on apples were carried out in Poland in 2019. Product ORKAN 350 SL was applied once at a rate of 720 g of MCPA at the intensive growth of weeds. The apple trees was at the growth stage BBCH 69-71. Apple samples were harvested during the commercial harvest. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.

Results: 3 x<0.003 mg/kg – LOD (MCPA, MCPB)

LOQ: 0.01 mg/kg for each analyte

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation from apple to whole group pome fruits is possible – 4 trials are required (with residues lower than LOQs). Three trials are available. One additional trial on apple is required.

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

The use on apple are considered acceptable. Extrapolation to whole group on pome fruit is not possible.

Stone fruits (cherries, sweet cherries, peaches, nectarines, plums, apricot)

Glyphosate

Proposed GAP

1 application, 1.30 kg as./ha or 1.82 kg as./ha, Product used in period intensive growth weeds in dose needed to destruction occurring species weeds, PHI – n.a.

EU GAP: 0.72-2.88 kg as./ha, 1-3 application (interval 28 days), post emergence of weed, Stone & pome fruit, olives

Applications to avoid contact with tree branches. Maximum cumulative application rate 4.32 kg/ha glyphosate in any 12 month period.

MRL review (article 12) GAP: cherry; max 2 applications; 0.54 3.60 kg as./ha during the intensive growth of weeds; PHI: 7

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Three residue trials on cherries were carried out in Poland in 2019. The field trials were established in three different locations Product ORKAN 350 SL was applied once at a rate of 2080 g of glyphosate at the intensive growth of weeds. The cherry trees was at the growth stage BBCH 72-73. Cherry samples were harvested during the commercial harvest (55 DALA in trial 19SGS22-01; 40 DALA in trial 19SGS22-02 and 53 DALA in trial 19SGS22-03). The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.

Results: 3 x<0.003 mg/kg – LOD (glyphosate, AMPA, N-acetyl-AMPA, N-acetyl-glyphosate)

LOQ: 0.01 mg/kg for each analyte

7 days of PHI is proposed by zRMS for apple and pears as is stated in EFSA Journal 2019;17(10):5862

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation to whole group stone fruits is possible (before forming of the edible part) with minimum 4 trials on apples + stone fruits, which is the case here.

The uses on peaches, nectarines, plums, apricot are considered acceptable before forming of the edible part.

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation from sour cherries to sweet cherries and from sweet cherries to sour cherries is possible.

Uses on cherries are accepted.

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

MCPA

Proposed GAP

1 application, 0.45 kg as./ha or 0.63 kg as./ha, Product used in period intensive growth weeds in dose needed to destruction occurring species weeds, PHI – n.a.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Three residue trials on cherries were carried out in Poland in 2019. The field trials were established in three different locations Product ORKAN 350 SL was applied once at a rate 720 g of MCPA at the intensive growth of weeds. The cherry trees was at the growth stage BBCH 72-73. Cherry samples were harvested during the commercial harvest (55 DALA in trial 19SGS22-01; 40 DALA in trial 19SGS22-02 and 53 DALA in trial 19SGS22-03). The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.

Results: 3 x<0.003 mg/kg – LOD (MCPA, MCPB)

LOQ: 0.01 mg/kg for each analyte

7 days of PHI is proposed by zRMS for apple and pears as is stated in EFSA Journal 2019;17(10):5862

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation to whole group Stone fruits is possible (before forming of the edible part) with minimum 4 trials on apples + stone fruits, which is not the case here. One additional trial on apple is required.

The uses on peaches, nectarines, plums, apricot are considered not acceptable.

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation from sour cherries to sweet cherries and from sweet cherries to sour cherries is possible.

Uses on cherries are accepted.

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

Hazelnuts, Walnuts

Glyphosate and MCPA

Proposed GAP is the same as GAP for stone fruits.

According to SANCO 7525/VI/95, rev 10.3 of 13 June 2017, extrapolation to tree nuts is possible (before forming of the edible part) with minimum 4 trials on apples + stone fruits, which is not the case here.

The uses are considered not acceptable.

Magnitude of residues in livestock

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

Magnitude of residues in processed commodities

Due to low residues at harvest, studies on residues in processed commodities are not required.

Magnitude of residues in representative succeeding crops

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

Estimation of exposure through diet and other means

The accepted uses of glyphosate and MCPA in the formulation ORKAN 350 SL do not represent unacceptable acute and chronic risks for the consumer.

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 ORKAN 350 SL are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for pome fruits, stone fruits and nuts. A list of all intended uses within the Central zone is given in Part B,

Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg for glyphosate and the current MRL of 0.05 mg/kg for MCPA as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of glyphosate and MCPA residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

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

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Residue section:

Noticed data gaps are:
MCPA
One additional trial on apple is required.

Uses on apples and cherries are accepted. Uses on pear, quince, medlar, peaches, nectarines, plums, apricot and nuts are not accepted.

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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	Pome fruits (Apple, ~~pear, quince, medlar~~)	PL	Orkan 350 SL	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Polygonum aviculare* *Malva neglecta* **susceptible weeds in dose 8,0 l/ha:** *Taraxacum officinale* *Epilobium ciliatum* *Lamium purpureum* *Elymus repens* *Equisetum arvense*	SL	MCPA: 90 g/L Glyphosate: 260 g/L	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-		300 L/ha	**In dose 5L/ha:** 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) **In dose 7-8L/ha:** 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	~~n.a.~~ 7 days	A apple N pear, quince, medlar

3	Stone fruits (cherries, sweet cherries, ~~peaches, nectarines, plums, apricot~~	PL	Orkan 350 SL	F	**sceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Poa annua* *Vicia cracca* *Chenopodium album* **susceptible weeds in dose 7,0 l/ha:** *Taraxacum officinale* *Epilobium ciliatum*	SL	MCPA: 90 g/L Glyphosate: 260 g/L	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-			**In dose 5L/ha:** 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) **In dose 7 L/ha:** 0,63 kg/ha (MCPA) 1,82 kg/ha (glyphosate)	~~n.a.~~ 7 days	cherries, sweet cherries, A peaches, nectarines, plums, apricot: N
4	Hazelnuts, Walnuts	PL	Orkan 350 SL	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis Polygonum aviculare* *Malva neglecta* **susceptible weeds in dose 8,0 l/ha:** *Taraxacum officinale* *Epilobium ciliatum* *Lamium purpureum* *Elymus repens* *Equisetum arvense*	SL	MCPA: 90 g/L Glyphosate: 260 g/L	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-		300 L/ha	**In dose 5L/ha:** 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) **In dose 7-8L/ha:** 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	~~n.a.~~ 7 days.	N

* 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

7.1.2 Summary of the evaluation

The preparation ORKAN 350 SL is composed of 260 g/L of glyphosate and 90 g/L of MCPA.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of glyphosate and MCPA

Reference value	Source	Year	Value	Study relied upon	Safety factor
Glyphosate					
ADI	EFSA	2015	0.5 mg/kg bw per day	Developmental toxicity study in rabbits	100
ARfD	EFSA	2015	0.5 mg/kg bw	Developmental toxicity study in rabbits	100
MCPA					
ADI	SANCO/4062/2001-final	2008	0.05 mg/kg bw per day	Rat, 2 years study	100
ARfD	SANCO/4062/2001-final	2008	0.15 mg/kg bw	Developmental toxicity study in rabbits	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	Pome fruits (Apple, pear, quinces. medlar)	Yes	Yes (7 trials)	Yes	Yes	Yes	No	No
2	Stone fruits (cherries, sweet cherries, peaches, nectarines, plums	Yes	Yes (5 trials)	Yes	Yes	Yes		No
3	Hazelnut, Walnut	Yes	Yes	Yes	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

7.1.2.2 Summary for MCPA

Table 7.1-4: Summary for MCPA

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	Pome fruits (Apple, ~~pear, quinces. medlar~~)	No	Yes (3 trials)	NR	Yes	Yes	No	No
2	Stone fruits (cherries, sweet cherries, ~~peaches, nectarines, plums~~	No	Yes (3 trials)	NR	Yes	Yes		No
3	Hazelnut, Walnut	Yes	~~Yes~~	~~Yes~~	Yes	Yes		~~No~~

7.1.2.3 Summary for ORKAN 350 SL

Table 7.1-5: Information on ORKAN 350 SL (KCA 6.8)

Crop	PHI for ORKAN 350 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for ORKAN 350 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate	MCPA		
Pome fruits (Apple~~, pear, quinces. medlar~~)	NR	NR	NR	7 days	As is stated in EFSA Journal 2019;17(10):5862
Stone fruits (cherries, sweet cherries, ~~peaches, nectarines, plums, apricot~~	NR	NR	NR	7 days	As is stated in EFSA Journal 2019;17(10):5862
Hazelnut, Walnut	NR	NR	~~NR~~		

NR: not relevant

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			**Overall waiting period proposed by zRMS for ORKAN 350 SL**
Crop group	**Led by glyphosate**	**Led by MCPA**	
Pome fruits (Apple, pear, quinces. medlar)	NR (Pome fruit trees are permanent crops)		
Stone fruits (cherries, sweet cherries, peaches, nectarines, plums, apricot	NR (Stone fruit trees are permanent crops)		
Hazelnut, Walnut	NR (Tree nuts are permanent crops)		

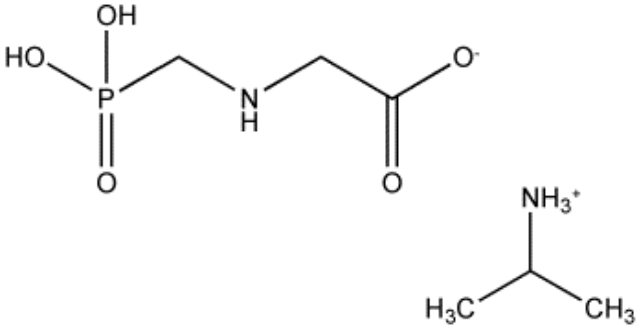
NR: not relevant

Assessment

7.2 Glyphosate

General data on glyphosate are summarized in the table below (last updated 2020/04)

Table 7.2-1: General information on glyphosate

Active substance (ISO Common Name)	Glyphosate, isopropylamine salt
IUPAC	*N*-(phosphonomethyl)glycine - isopropylamine (1:1)
Chemical structure	
Molecular formula	$C_6H_{17}N_2O_5P$
Molar mass	228,19 g/mol
Chemical group	Chemical class of glycine
Mode of action (if available)	Glyphosate kills the plant by blocking the shikimic acid pathway. Glyphosate binds to and blocks the activity of its target enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), an enzyme of the aromatic amino acid biosynthetic pathway. The inhibition of the enzyme prevents the plant from synthesising the essential aromatic amino acids needed for protein biosynthesis. Action at the shikimic acid pathway is unique to glyphosate and the absence of this pathway in animals is an important factor of its low vertebrate toxicity.
Systemic	Yes
Company (ies)	Monsanto, Cheminova, Syngenta and Helm *
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (16/12/2017) and reference to decision (COMMISSION IMPLEMENTING REGULATION (EU) No 2324/2017). https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1513679672002&uri=CELEX:32017R2324
Restriction	Only uses as herbicide may be authorised.
Review Report	SANTE/10441/2017 – rev. 2 09/11/2017
Current MRL regulation	Regulation (EC) No 293/2013
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (see reference list - EFSA Journal 2015)

EFSA Journal: conclusion on article 12	Yes (see reference list - EFSA Journal 2019)
Current MRL applications on intended uses	EFSA-Q-2019-00122 EFSA Journal 2019

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

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 ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Pome fruits	High water content	Glyphosate >9 to 31 months AMPA 6 to 24 months N-acetyl-glyphosate 6 to >12 months N-acetyl-AMPA >1 to >12 months	EFSA, 2015
Stone fruits	High water content	Glyphosate >9 to 31 months AMPA 6 to 24 months N-acetyl-glyphosate 6 to >12 months N-acetyl-AMPA >1 to >12 months	EFSA, 2015
Animal Products			
Ruminant (pig)	Muscle, kidney, liver, fat	Glyphosate 26 months AMPA 26 months	RMS, 2013
Ruminant (milk cattle)	Milk	Glyphosate 16 months AMPA 16 months	RMS, 2013
Ruminant (milk cattle)	Fat, muscle, liver and kidney	Glyphosate 24 months AMPA 24 months	RMS, 2013
Poultry	Eggs	Glyphosate >14 months AMPA 14 months	RMS, 2013
Poultry	Kidney	Glyphosate 13 months	RMS, 2013
Poultry	Fat, muscle, liver	Glyphosate 25 months AMPA 25 months	RMS, 2013

Conclusion on stability of residues during storage

The glyphosate and AMPA residues during the storage are stable for at least 2 years to more than 3 years in high water content matrix type. N-acetyl-glyphosate was stable for at least 1 year in high acid and high water matrices and N-acetyl-AMPA is stable for at least 1 year in a high water matrix type. Glyphosate and N-acetyl-glyphosate were stable under standard hydrolysis conditions.
The storage stability for glyphosate and AMPA in animal matrices was investigated in swine, cattle and chicken samples. For glyphosate no significant degradation during storage was observed for all matrices

investigated expect for chicken eggs. In eggs 14 months was the maximum storage period without a significant degradation of the residue. For all other matrices the maximum storage intervals were: 26 month for pig far, muscle, liver and kidney; 16 months for cattle milk, 24 months for cattle fat, muscle, liver and kidney; 13 months for chicken kidney and 25 months for chicken fat, muscle and liver.
For AMPA the fortification levels and the corresponding recoveries after storage were generally lower compared to glyphosate. For swine fat and liver, for cattle fat and muscle and for chicken fat and liver single recoveries below 70% were observed. However, either the low corresponding procedural recoveries or other samples stored for longer intervals suggest no true degradation of the residue. For chicken eggs, corresponding to the results for glyphosate, the degradation AMPA was significant during storage, indicating stable residues of AMPA after storage for only 14 months. Samples of chicken eggs stored for 25 and 28 months gave a significant decline of the AMPA residue. For all other animal commodities maximum storage intervals were: 26 month for pig fat, muscle, liver and kidney; 16 months for cattle milk, 24 months for cattle fat, muscle, liver and kidney; 13 months for chicken kidney and 25 months for chicken fat, muscle and liver.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data available.

Conclusion on stability of residues in sample extracts

No data available.

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	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Apple trees	^{14}C-radiolabelled glyphosate; ^{14}C-AMPA	soil treatment, F	3.4 kg glyphosate/ha; 1.7 kg AMPA/ha	1	6, 12 weeks		Germany, 2013
			trunk treatment, F	92.4 µg/tree	1	8, 24 days		
		^{14}C-radiolabelled	foliar treatment, F	5.356 µg/tree	1	4, 7 and 10 weeks		

		glyphosate						
Root and tuber vegetables	Sugar beets	^{14}C-radiolabelled glyphosate; ^{14}C-AMPA	soil treatment, F	4.5 kg a.s./ha	1	4, 6, 8 weeks		Germany, 2013
Pulses and oilseeds	Soya beans	^{14}C-radiolabelled glyphosate; ^{14}C-AMPA	soil treatment, F	4.5 kg a.s./ha; 1.7 kg AMPA/ha		4, 6, 8 weeks		Germany, 2013
Cereals	Wheat, corn	^{14}C-radiolabelled glyphosate; ^{14}C-AMPA	soil treatment, F	4.5 kg a.s./ha; 1.7 kg AMPA/ha		4, 6, 8 weeks		Germany, 2013

Summary of plant metabolism studies reported in the EU

In the study of metabolism of glyphosate and AMPA in apple trees, the uptake of this compounds via the roots was minimal. In addition application of glyphosate to the trunk or to leaves also gave very low rates of translocation into untreated plant parts. The composition of the extracted radioactivity mainly consisted of unchanged glyphosate, in treated leaves as well as untreated compartments.

Conclusion on metabolism in primary crops

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 ^{14}C-glyphosate and in the some experiments, with ^{14}C-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).

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Based on the supported uses, glyphosate and AMPA residues not expected in rotational crops. Pome fruit trees and stone fruit trees and Tree nuts are permanent crops.

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 7.2-4: Nature of the residues in processed commodities

Conclusion on nature of residues in processed commodities

Glyphosate and N-acetyl-glyphosate are stable under standard hydrolysis conditions. Processing studies were submitted and processing factors were proposed for several crop commodities (EFSA, 2015). Standard hydrolysis studies simulating the processing conditions representative of pasteurisation, baking, brewing, boiling and sterilisation were evaluated during the peer review for the renewal (Germany, 2015). Based on the results of these studies, it was possible to conclude that glyphosate and N-acetyl-glyphosate are hydrolytically stable under the standard conditions (EFSA, 2015). The effect of processing on the nature of AMPA was not investigated. However, considering the extremely simple structure of AMPA without structural elements capable of hydrolysis, AMPA is expected to be stable following processing and no additional studies are required.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	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) Transgenic crops (all foliar sprayed) **Oilseeds** - Rape/canola (CP4-EPSPS & GOX, GAT) - Soya beans (CP4-EPSPS, GAT) - Cotton (CP4-EPSPS) **Root and tubers** - Sugar beet (CP4-EPSPS) **Cereal grains** - Maize (CP4-EPSPS & GOX, GAT)
Rotational crops covered	-Beets, carrots, radish -Lettuce, cabbage

	-Peas -Soya beans -Barley, wheat
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	Stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Sweet corn, oilseed rape, soya beans and mize (non-tolerant and tolerant, all modifications): sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate Other plant commodities: glyphosate (Regulation n°293/2013)
Plant residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and Nacetyl-AMPA, all expressed as glyphosate (EFSA, 2015).
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/desiccation) 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.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	^{14}C-glyphosate	2	7.1 mg/kg bw; 8.0 mg/kg bw	5 days; 3 days	Milk	24 hour intervals	Germany, 2013
						Excreta	24 hour intervals	
						Tissues	23.5 hours after the final dose	
	Goat	^{14}C-glyphosate ^{14}C-AMPA	3	4.1 mg/kg bw/d – glyphosate 0.45 mg/kg bw/d - AMPA	5 days	Milk, urine, faeces	Twice daily	Germany, 2013
						Tissues	After sacrifice	

	Goat	^{14}C-N-acetyl-glyphosate	1	6.8 mg/kg bw/d	5 days	Tissues	After sacrifice	Germany, 2013
Laying poultry	Hens	^{14}C-glyphosate	2 groups with 5 hens each	18.2 mg/kg bw/d	5-7 days	Eggs, excreta	24 hour intervals	Germany, 2013
						Tissues	23.5 hours after the final dose	
	Hens	^{14}C-glyphosate and ^{14}C-AMPA	5 groups with 5 hens each	9.7 glyphosate and 1.03 AMPA mg/kg bw/d or 32.2 glyphosate and 3.4 AMPA mg/kg bw/d	7 days	Eggs	24 hour intervals	Germany, 2013
						Tissues	23 hours after the final dose	

Summary of plant metabolism studies reported in the EU

Several livestock metabolism studies on goat and hen using ^{14}C-glyphosate and ^{14}C-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 a 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 ^{14}C-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).

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

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats, Laying hens
Time needed to reach a plateau concentration	Milk: <7 days Eggs: 14 days (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 (Regulation n°293/2013)
Animal residue definition for risk assessment	Sum of glyphosate, AMPA, N-acetyl-glyphosate and Nacetyl-AMPA, all expressed as glyphosate (EFSA, 2015)
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

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of Orkan 350 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
Apple	Germany, 2013; EFSA, 2015	N-EU	GAP on which MRL/EU a.s. assessment is based: 2106 – 3600 g as/ha, BBCH 7 or later, outdoor E: <0.02, 3x <0.05 RA: <0.02, 3x <0.05	N/A				
	New trials Report 19SGS21	EU	Trials GAP: 2080 g as/ha, outdoor E: 3x <0.003 RA: 3x <0.003					
	Overall supporting data for cGAP	EU	E : <0.02, 3x <0.05, 3 x<0.003 RA: <0.02, 3x <0.05, 3 x<0.003	E: 0.02 RA: 0.02	E: 0.05 RA: 0.05	0.15	0.1	Yes
Cherries	Germany, 2013; EFSA, 2015	N-EU	GAP on which MRL/EU a.s. assessment is based: 2106 – 3600 g as/ha, BBCH 7 or later, outdoor E: <0.05, <0.05 RA: <0.05, <0.05	N/A				

	New trials Report 19SGS22	EU	Trials GAP: 2080 g as/ha, outdoor E: 3x <0.003 RA: 3x <0.003					
	Overall supporting data for cGAP	EU	E : <0.05, <0.05, 3x <0.003 RA: <0.05, <0.05, 3x <0.003	E: 0.01 RA: 0.01	E: 0.05 RA: 0.05	0.15	0.1	Yes
Apple (minimum 4 trials) + stone fruits extrapolated to whole Pome fruit group (pears, quinces, medlar); Stone fruit group (apricots, peaches, plums); Hazelnut, walnut	Overall supporting data for cGAP	EU	Trials GAP: 2080 g as/ha, outdoor E: <0.02, 3x <0.05, 3 x<0.003, <0.05, <0.05, 3x <0.003 RA: <0.02, 3x <0.05, 3 x<0.003, <0.05, <0.05, 3x <0.003	E: 0.01 RA: 0.01	E: 0.05 RA: 0.05	0.15	Pome fruits: 0.1 Stone fruits: 0.1 Tree nuts: 0.1	Yes

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

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on apple and cherry fruits are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to whole group pome fruits, stone fruits and tree nuts is possible with minimum 4 trials on apples + stone fruits, which is the case here.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure 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, AMPA, N-acetyl-glyphosate and Nacetyl-AMPA, all expressed as glyphosate				
Apple pomace, wet	0,05*	STMR x PF (EFSA, 2019)	0.05*	STMR x PF (EFSA, 2019)

Table 7.2-10: 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, AMPA, N-acetyl-glyphosate and Nacetyl-AMPA, all expressed as glyphosate					
Beef cattle*	0.003	0.003	Apple (pomace, wet)	0.13	No
Dairy cattle*	0.002	0.002	Apple (pomace, wet)	0.06	No
Lamb	0.003	0.003	Apple (pomace, wet)	0.06	No
Ram/Ewe	0.002	0.002	Apple (pomace, wet)	0.06	No

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burdens for all groups of livestock were not found to exceed the trigger value. Further investigation on residues is not required.

Conclusion on feeding studies

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

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.

7.2.5.2 Conclusion on processing studies

No studies investigating the effect of processing on the magnitude of the residues in the pome and stone fruits commodities under assessment were submitted (EFSA, 2015). In conclusion on pesticide peer review processing studies were submitted and processing factors were proposed for several crop commodities: citrus, potato, olives, linseed, rape seed, soya beans, maize, rye and wheat.
All results of glyphosate and metabolites residues in a new trials on apple and cherries fruit was below limit of detection, therefore, residues in processed commodities are not expected.

7.2.6 Magnitude of residues in representative succeeding crops

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

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 ORKAN 350 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

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate				
Hazelnuts	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Walnuts	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Apples	0.02	STMR (Report 19SGS21, 2020)	0.05	HR (Report 19SGS21, 2020)
Pears	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Quinces	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Medlars	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Apricots	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Cherries	0.01	STMR (Report 19SGS22, 2020))	0.05	STMR (Report 19SGS22, 2020)
Peaches	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)
Plums	0.05*	STMR x CF (1) (EFSA, 2019)	0.05*	HR x CF (1) (EFSA, 2019)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
Chronic and acute consumer exposure was calculated using revision 3 of the EFSA PRIMo rev.3.1.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.1 % (based on NL toddler)	
IESTI (% ARfD) according to EFSA PRIMo*	<u>Raw commodities- based on children diet:</u> 1% Pears 1% Apples 1% Peaches 0.4% Plums 0.3% Apricots 0.2% Quinces 0.1% Medlar	<u>Raw commodities - based on adult diet:</u> 0.3% Pears 0.3% Apples 0.2% Peaches 0.2% Plums 0.1% Apricots 0.2% Quinces 0.07% Medlar

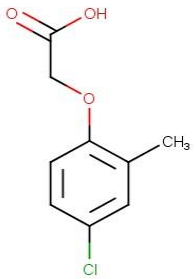
	0.1% Cherries (sweet) 0.03% Walnuts 0.03% Hazelnuts/cobnuts <u>Processed commodities- based on children diet:</u> 0.3% Pears/juice 0.3% Peaches/canned 0.2% Apples/juice 0.2% Peaches/juice 0.1% Plums/juice 0.0% Quinces/jam	0.1% Cherries (sweet) 0.02% Walnuts 0.01% Hazelnuts/cobnuts <u>Processed commodities- based on adult diet</u>: 0.1% Apples/juice 0.08% Peaches/canned 0.01% Quinces/jam
NTMDI (% ADI) **	Not required	
NEDI (% ADI)**	Not required	
NESTI (% ARfD) **	Not required	

The proposed uses of glyphosate in the formulation ORKAN 350 SL do not represent unacceptable acute and chronic risks for the consumer.

7.3 MCPA

General data on MCPA are summarized in the table below (last updated 2020/04)

Table 7.3-1: General information on MCPA

Active substance (ISO Common Name)	MCPA
IUPAC	(4-chloro- 2-methylphenoxy) acetic acid
Chemical structure	$C_9H_9ClO_3$
Molecular formula	
Molar mass	200.62 g/mol
Chemical group	Group of phenoxy acetic compounds
Mode of action (if available)	Synthetic auxins
Systemic	Yes
Company (ies)	Nufarm UK Limited and its affiliates Agrolinz and Akzo Chemicals, and AH Marks, BASF
Rapporteur Member State (RMS)	Italy
Approval status	Approved Date of (01/05/2006) and reference to decision (COM-MISSION DIRECTIVE 2005/57/EC. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005L0057

Restriction	Only uses as herbicide may be authorised.
Review Report	SANCO/4062/2001-final 11/07/2008
Current MRL regulation	Regulation (EU) No 491/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	No
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	Regulation (EU) No 491/2014

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cereal (grain, straw)	High protein content	12 months (> -18°C)	FAO, 2013
Animal Products			
Ruminant	Liver, milk	4 month	FAO, 2013
Ruminant	Kidney, fat	5 months	FAO, 2013

Conclusion on stability of residues during storage

There are no data in EU level of stability of MCPA residues in pome and stone fruits. The stability of MCPA residues in cereal was analysed. The results showed that residues of MCPA were stable for 12 month in wheat forage, straw and grain following storage ± 20°C. Storage stability studies on cereal green plants, grain and straw showed that MCPA are stable in samples for up to 18 months when stored frozen at -18º C. In animal commodities the storage stability studies, conducted concurrently with the cattle feeding study, confirmed that residues of MCPA are stable when stored frozen up to at least 4 months in liver and milk, 5 months in kidney and fat, and 3 months in muscle samples (FAO, 2013).

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No available data.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: 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	Sampling (DAT)	Remarks	
EU data								
Cereals	Winter wheat	(4-Chloro-2-methyl[ring-$U^{14}C$] phenoxy) acetic acid -	F (foliar spraying)	6.8 l/ha	1	1, 25 and 49, 102 DALA		Italy, 2001

Summary of plant metabolism studies reported in the EU

The metabolism studies in cereals are presented in Draft Assessment Report (Italy, 2001). The rate of degradation of MCPA in plant is high. The resulting metabolites were identified in wheat as parent MCPA acid, Hydroxy-MCPA, 2-carboxy-4-chlorophenoxyacetic acid, 2-hydroxymethyl-4-chlorophenoxyacetic acid and an unknown compound.
MCPA is hydroxylated at the methyl group with formation of 2-hydroxymethyl-4-chloro-phenoxyacetic acid. This metabolite, together with unchanged MCPA, constitutes approximately 75% of the residues extractable from straw with aqueous methanol at harvest.
2-Carboxy-4-chlorophenoxyacetic acid was identified as a further metabolite and constitutes nearly 10% of the residues extractable from straw with aqueous methanol at harvest. The hydroxylation of the aromatic ring observed to a slight extent is obviously a minor metabolic pathway in the plant.

Conclusion on metabolism in primary crops

Under EU evaluation the residue definition for plant commodities was set as MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA).

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Not necessary. Pome fruit trees, stone fruit trees and tree nuts are permanent crops.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

There are no available data for pome or stone fruits. Based on results from residue trials in cereals, no MCPA residues are expected at or above the limit of detection. It is therefore unlikely that MCPA residues will be detected in processed fractions. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of MCPA residues.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat) Cereal (Maize in a greenhouse conditions)
Rotational crops covered	Not applicable. The pome and stone fruit trees are permanent crops. In EU level rotational crops evaluated: Lettuce, turnip, barley
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	No data. Residues of MCPA are not expected.
Residue pattern in processed commodities similar to pattern in raw commodities?	NR
Plant residue definition for monitoring	MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (Reg. (EU) No 491/2014)
Plant residue definition for risk assessment	MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (EFSA, 2013)
Conversion factor from enforcement to RA	No data

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

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	^{14}C-MCPA	2	750 ppm	3 days	Milk	daily	Italy, 2001
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	^{14}C-MCPA	15	100 ppm	7 days	Eggs	daily	Italy, 2001
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

In studies with lactating goats the MCPA is rapidly excreted with 99.5% of the administered dose being excreted within 23 hr of the last dose. Milk and tissues collected in this study accounted for less than 0.1% of the dose. The small amount of MCPA that is not excreted is metabolized to the glycine conjugate of MCPA, which was only detected in milk.
In studies with laying hen approximately 99% of the administered radioactivity was eliminated in the excreta after 7 days. Eggs and tissues accounted for a mean of 0.04% of the dose; gastrointestinal tract and contents, 0.02%; cage rinse 0.10%; and excreta, 99.3%, giving a total recovery of 99.5%. MCPA or base-labile conjugates of MCPA were the principle labeled products found in eggs and tissues. Only egg yolk contained one of these metabolites at a concentration >0.01 ppm. No other single metabolite accounted for greater than 0.01 ppm (MCPA acid equivalents).
The daily recovery of ^{14}C in the excreta indicated that each daily dose is almost completely eliminated within 24 hr. Residue levels were very low.

Conclusion on metabolism in livestock

Considering the exposure of cattle to MCPA at dietary concentration of 250 mg/kg and the very low residues in tissues (mainly lower than the determination limit) and taking into account an interval of 7 days between treatment and slaughter, it is unlikely that appreciable residues of MCPA could occur in most feeds given to animals prior to slaughter and it is still more unlikely that enough animals could ingest sufficient MCPA immediately before slaughter to cause such a high incidence of residues in meat products. However from the two animal studies one in hen and one in goat, the MCPA administered to animals was completely excreted within 24 hours as parent compound.

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

Table 7.3-6: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	23 hr in milk
	7 days in eggs
Animal residue definition for monitoring	MCPA, MCPB and MCPA tioetyl expressed as MCPA (Reg. (EU) No 491/2014)
Animal residue definition for risk assessment	Sum of MCPA and its conjugates, expressed as MCPA (EFSA, 2013)
Conversion factor	No data
Metabolism in rat and ruminant similar	No data
Fat soluble residue	Yes (EFSA, 2013)

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.3-7: Summary of EU reported and new data supporting the intended uses of ORKAN 350 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)	Un-rounded OECD calcula-tor MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compli-ance
Apple	New trials Report 19SGS21	EU	GAP on which MRL a.s. assessment is based: 1 x 720 g as/ha, outdoor MCPA, MCPB E: 3x<0.003 RA: 3x<0.003	N/A				
	Overall supporting data for cGAP	EU	MCPA, MCPB E: 3x<0.003 RA: 3x<0.003	E: 0.003 RA: 0.003	E: 0.003 RA: 0.003	0.01	0.05	Yes
Cherry	New trials Report 19SGS22	EU	GAP on which MRL a.s. assessment is based: 1 x 720 g as/ha, outdoor MCPA, MCPB E: <0.01, 2x<0.003 R: <0.01, 2x<0.003	N/A				
	Overall supporting	EU	MCPA, MCPB E: <0.01, 2x<0.003	E: 0.005 RA: 0.005	E: 0.01 RA: 0.01	0.03	0.05	Yes

	data for cGAP		R: <0.01, 2x<0.003					
Apple (minimum 4 trials) + stone fruits extrapolated to whole Pome fruit group (pears, quinces, medlar); Stone fruit group (apricots, peaches, plums); Walnuts, Hazelnuts	New trials	N-EU	Trials GAP: GAP on which MRL a.s. assessment is based: 1 x 720 g as/ha, outdoor MCPA, MCPB E: 3x<0.003, <0.01, 2x<0.003 RA: 3x<0.003, <0.01, 2x<0.003	N/A				
	Overall supporting data for cGAP	N-EU	MCPA, MCPB E: 3x<0.003, <0.01, 2x<0.003 RA: 3x<0.003, <0.01, 2x<0.003	E: 0.004 RA: 0.004	E: 0.01 RA: 0.01	0.02	Pome fruits: 0.05 Stone fruits: 0.05 Tree nuts: 0.05	Yes/No

* Source of EU MRL: Reg. (EU) No 491/2014

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on apples and cherries are considered acceptable, for outdoor uses.
According to appendix D of EU guidelines, extrapolation to whole group pome fruits, stone fruits and tree nuts is possible with minimum 4 trials on apples + stone fruits. Three new trials on apples and three new trials on cherries are presented. All presented results of MCPA and MCPB residues was below the limit of detection and one trial on cherries showed result below the limit of quantification. When the residues of an active substance are foreseen to be below the limit of quantification (limit of determination) and at least two residue trials confirm this then no further trials are normally necessary. In addition, ORKAN 350 SL is not used directly on fruit trees.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

For active substance MCPA the Art. 12 evaluation was not presented yet. The plant protection product ORKAN 350 SL will be used to control weeds in fruit tree orchards. For weeds spraying, it is recommended to use a sprayer with covers, which effectively prevents the working liquid from getting on fruit trees. The occurrence of any residues of ORKAN 350 SL in fruit is therefore unlikely, as evidenced by the following 3 residue studies on apple and cherries. All results of MCPA and MCPB residues in a new trials on apple was below limit of detection, therefore, residues cannot be present in apple pomace. Therefore, no dietary burden calculations are needed.

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

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Not applicable.

Conclusion on feeding studies

There are no risk for animals during the feeding and there is no risk for animal MRL to be exceeded.

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

7.3.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.
No studies investigating the effect of processing on the magnitude of the residues in the pome and stone fruits commodities under EU level assessment were submitted.
All results of MCPA and MCPB residues in a new trials on apple and cherries fruit was below limit of detection, therefore, residues in processed commodities are not expected.

7.3.5.2 Conclusion on processing studies

There is no risk of MCPA and MCPB residues appearing in the processed commodities.

7.3.6 Magnitude of residues in representative succeeding crops

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

7.3.7 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 ORKAN 350 SL. Therefore, other special studies are not needed.

7.3.8 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).

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-8: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA)				
Apple	0.003	Median residue (Report 19SGS21, 2020)	0.003	Highest residue (Report 19SGS21, 2020)
Pome fruits (pears, quinces, medlar)	0.05	EU MRL	0.05	EU MRL

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cherry	0.004	Median residue (Report 19SGS22, 2020)	0.01	Highest residue (Report 19SGS22, 2020)
Stone fruit (apricots, sweet cherries, peaches, plums)	0.05	EU MRL	0.05	EU MRL
Tree nuts (Hazelnuts, walnuts)	0.05	EU MRL	0.05	EU MRL

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-9: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.6 % (based on NL toddler)	
IEDI (% ADI) according to EFSA PRIMo	See TMDI calculation.	
IESTI (% ARfD) according to EFSA PRIMo*	<u>Raw commodities:</u> Pears: 5% (based on children diet) Pears: 1% (based on adult diet) Peaches: 3% (based on children diet) Peaches: 0.6% (based on adult diet) Plums: 1% (based on children diet) Plums: 0.6% (based on adult diet) Apricots: 1% (based on children diet) Apricots: 0.4% (based on adult diet) Quinces: 0.8% (based on children diet) Quinces: 0.5% (based on adult diet) Medlar: 0.5% (based on children diet) Medlar: 0.2% (based on adult diet) Apples: 0.2% (based on children diet) Apples: 0.06% (based on adult diet) Walnuts: 0.1% (based on children diet) Walnuts: 0.07% (based on adult diet) Hazelnuts: 0.1% (based on children diet) Hazelnuts: 0.04% (based on adult diet) Cherries (sweet): 0.08% (based on children diet) Cherries (sweet): 0.07% (based on adult diet)	<u>Processed commodities:</u> Pears (juice): 1% (based on children diet) Peaches (canned): 0.9% (based on children diet) Peaches (canned): 0.3% (based on adult diet) Peaches (juice): 0.6% (based on children diet) Plums (juice): 0.3% (based on children diet) Apples (juice): 0.1% (based on children diet) Apples (juice): 0.07% (based on adult diet) Quinces (jam): 0.1% (based on children diet) Quinces (jam): 0.04% (based on adult diet)
NTMDI (% ADI) **	Not required	
NEDI (% ADI)**	Not required	
NESTI (% ARfD) **	Not required	

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of MCPA in the formulation ORKAN 350 SL do not represent unacceptable acute and chronic risks for the consumer.
Calculation was made according EFSA PRIMo revision 3.1.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.5 References

Germany, 2013. Renewal Assessment Report for Glyphosate. Volume 3, Annex B7. Residue data.

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.

EFSA (European Food Safety Authority), 2019. Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005 – revised version to take into account omitted data. EFSA Journal 2019;17(10):5862

EFSA (European Food Safety Authority), 2013. Scientific support for preparind an EU position for the 45th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2013;11(7):3312.

Italy, 2001. Draft Assesment Report. MCPA, MCPA thioethyl (phenothiol). Volume 3, Annex B.6. Residues.

FAO (Food and Agriculture Organization of the United Nations), 2013. MCPA (257) First draft prepared by Dr. Yibing He, Department of Science and Education, Ministry of Agriculture, Beijing, China. JMPR evaluation no. 257.

SANCO/4062/2001-final. Review report for the active substance MCPA Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 April 2005 in view of the inclusion of MCPA in Annex I of Directive 91/414/EEC

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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 6.3. 7.2.3. 7.3.3.	Peda T.	2020	Magnitude of the residue of MCPA, MCPB and glyphosate in apple (Raw Agricultural Commodity) after one application of Orkan 350 SL – three harvest trials in Poland – 2019. Company Report No 19SGS21 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3. 7.3.3.	Peda T.	2020	Magnitude of the residue of MCPA, MCPB and glyphosate in cherry (Raw Agricultural Commodity) after one application of Orkan 350 SL – three harvest trials in Poland – 2019. Company Report No 19SGS22 GLP Unpublished	N	Synthos Agro Sp. z o.o.

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.	Manning, M. J.;	1988	Storage stability of Glyphosate and AMPA in swine tissues, dairy cow tissues and milk laying hen	N	MOD

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
7.2.1.	Mueth, M. G		tissues and eggs Report No.: MSL-7515 GLP: yes, Not published RIP9501253		
KCA 6.1. 7.2.1.	Mueth, M. G.	1991	Storage stability of Glyphosate residues in crop commodities Report No.: MSL-10843 GLP: yes, Not published RIP9501332	N	MOD (owned by Glyphosate Task Force)
KCA 6.1. 7.2.1.	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	FSG
KCA 6.2.1.	George, Ch.	1995	Nature of Glyphosate residues in corn plants which are tolerant to Roundup herbicide Report MSL-14018 GLP: yes, Not published RIP970061	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 Report No. 394 GLP: no, Not published RIP9501195	N	MOD
KCA 6.2.1	Mehrsheikh, A.	1999	Protocol - Metabolism of Glyphosate in Roundup Ready(R) sugarbeet 99-63-M-7 GLP: yes, Not published RIP2003-1134	N	MOD
KCA 6.2.1	Mehrsheikh, A.	2000	Metabolism of Glyphosate in Roundup Ready Sugarbeet MSL-16247 GLP: yes, Not published RIP2001-906	N	MOD
KCA 6.2.1	Michaux, M.	1974	CP 67573: Determination of crop residues in winter wheat, spring wheat and spring barley Report A1 GLP: no, Not published RIP9501209	N	MOD
KCA 6.2.1	Rueppel, M. L.; Moran, S.	1974	CP 67573 residue and metabolism Part 23: The metabolism of CP 67573 in apple trees Report No. 342 GLP: no, Not published RIP9501190	N	MOD
KCA 6.2.1	Rueppel, M. L.;	1973	CP 67573, Residue and Metabolism Part 10: The Metabolism of CP 67573 in soybeans, cotton, wheat,	N	MOD

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
	Suba, L. A.		and corn Report No. 304 GLP: no, Not published RIP9600099		
KCA 6.2.1	Stuart, C.; Parker, S.; Joseph, R. S. I.	1989	ICIA0224: Metabolism on wheat following a preharvest foliar spray RJ 0778B GLP: yes, Not published RIP9500014	N	SYN
KCA 6.2.1	Tambling, D. R	1992	[^{14}C-Anion] ICIA0224: Nature of the residue: Soybeans RR 91-092B GLP: yes, Not published RIP9500015	N	SYN
KCA 6.2.2	xxxxxxxxxx	1988	Metabolism study of synthetic 13C/14C-labeled Glyphosate and Aminomethylphosphonic acid in laying hens. Part I Report No: MSL-7591 GLP: yes, Not published RIP9501205	Y	MOD
KCA 6.2.2	xxxxxxxxxx	1988	Metabolism study of synthetic 13C/14C-labeled Glyphosate and Aminomethylphosphonic acid in laying hens. Part II Report No: MSL-7420 GLP: yes, Not published RIP9501206	Y	MOD
KCA 6.2.2	xxxxxxxxxxx T.	1994	[^{14}C-PMG] Glyphosate-trimesium: Nature of the residue in tissues and eggs of laying hens Report No: RR-93-064B GLP: yes, not published RIP9500020	Y	SYN
KCA 6.2.2	xxxxxxxxxx	2007	The metabolism of [14C]-N-Acetylglyphosate (IN-MCX20) in laying hens Report No.: DuPont-19795 GLP: yes, not published ASB2008-2659	Y	DPB
KCA 6.2.2	xxxxxxxxxxx	1994	(14C-Glyphosate): Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen Report No. 676/8-1011 GLP: yes, not published RIP9501208	Y	MOD
KCA 6.2.2	xxxxxxxxxxxx	1988	Metabolism study of synthetic 13C/14C-labeled Glyphosate and Aminomethylphosphonic acid in	Y	MOD

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**
			lactating goats. Part I Report: MSL 7586 GLP: yes, not published RIP9501203		
KCA 6.2.2	xxxxxxxxxxxxxx	1988	Metabolism study of synthetic $^{13}C/1^{4}C$-labeled Glyphosate and Aminomethylphosphonic acid in lactating goats. Part II Report: MSL-7458 GLP: yes not published RIP9501204	Y	MOD
KCA 6.2.2	xxxxxxxxxxxxxxx	1994	(^{14}C-Glyphosate): Absorption, distribution, metabolism and excretion following repeated oral administration to the dairy goat Report No. 676/9-1011 GLP: yes not published RIP950120	Y	MOD
KCA 6.3. 7.2.3.	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
KCA 6.3. 7.2.3.	xxxxxxxxxxxxxxxx	1980	Glyphosate residues in apples following Roundup application in Denmark Report No.: MLL 30053 GLP: no, not published RIP9501235	Y	MOD
KCA 6.3. 7.2.3.	xxxxxxxxxxxxx	1978	Determination of crop residues in apples Report No.: A22 GLP: no, not published RIP9501218	Y	MOD
KCA 6.1 7.3.1.	Achhiereddy N. Kirkwood R. C. Fletcher W. W.	1984	The Uptake, Metabolsim and Phytotoxicity of MCPA in Plants Journal of Pesticide Science 9 Pp 617-622 IV Generated by: Published literature Submitted by: MCPA Dossier Preparation Working Group Report No: Not given GLP: no	N	-
KCA 6.2.1 MCPA	Fuchs		Summary and evaluation of MCPA residue behaviour in food and feed from plant origin. Residue situation in viticulture. Generated by: BASF Limburgerhof Submitted by: MCPA Dossier Preparation Working Group.	N	MCPA TASK FORCE

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: 88/10312 Annex 2, GLP: no		
KCA 6.2.1 MCPA	Fuchs	1988	Summary and evaluation of MCPA residue behaviour in food and feed from plant origin. Residue situation in cereals. Generated by: BASF Limburgerhof Submitted by: MCPA Dossier Preparation Working Group. Report no: 88/10312 Annex 3, GLP: no	N	MCPA TASK FORCE
KCA 6.2.1 MCPA	Keller W Otto S	1979	Investigations into the Metabolsim of MCPA in Winter Wheat. Generated by: BASF AG/TPH Submitted by: MCPA Dossier Preparation Working Group Report No: 1161a, GLP: no	N	MCPA TASK FORCE
KCA 6.2.1 MCPA	Leng M	1972	Residues in milk and meat and safety to livestock from the use of phenoxy herbicides in pasture and rangeland. Generated by: Published literature Submitted by: MCPA Dossier Preparation Working Group. Published in “Down t Earth”, vol 28(1) Pp 12-20 (1972) Report No: Not given, GLP: no	N	-

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

List of data relied on and not submitted by the applicant but necessary for evaluation

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Glyphosate

A 2.1.1 Stability of residues

Not required.

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

Not required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Apple

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, Germany, 2013)	1-3	720 – 2880 g as/ha	28 days	Post emergence of weeds	Not applicable
cGAP EU (Art. 12, EFSA, 2019)	1-2	540 – 3600 g as/ha	-	During the intensive growth of weeds	7
Intended cGAP (Raport number 19SGS21)	1	1300 – 2080 g as/ha	Not applicable	During the intensive growth of weeds	Not applicable

* Use number(s) in accordance with the list of all intended GAPs in Part

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS21
Report	Peda Tomasz, 2020. Magnitude of the residue of MCPA, MCPB and glyphosate in apple (Raw Agricultural Commodity) after one application of Orkan 350 SL – three harvest trials in Poland – 2019. Study number 19SGS21.
Guideline(s):	Yes (OECD 2009, Test No. 509; SANCO/3029/99 rev.4; SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Three residue trials on apples were carried out in Poland in 2019. Product ORKAN 350 SL was applied once at a rate of 2080 g of glyphosate at the intensive growth of weeds. The apple trees was at the growth stage BBCH 69-71. Apple samples were harvested during the commercial harvest (80 DALA in trial 19SGS21-01; 132 DALA in trial 19SGS21-02 and 110 DALA in trial 19SGS21-03).
Fruits were collected randomly from the inner part of each plot. Samples were taken from all parts of trees – from bottom, middle and top from all sides, especially from the heavily – laden parts. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of glyphosate (and its metabolites: AMPA, N-acetyl-AMPA, N-acetyl-glyphosate) were performed according to the QuPPe method.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day).
The method for determination of glyphosate in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1.

The range of linearity of the analytical graph of glyphosate, AMPA, N-acetyl AMPA and N-acetyl glyphosate varied from 0.001 to 0.5 mg/l, $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels in apple samples for glyphosate were: 82.3% and 78.2%, respectively; for AMPA: 91.6% and 81.4%; for N-Acetyl-AMPA 115.0% and 82.8% and for N-Acetyl-glyphosate 104.5 and 99.1%, respectively.
The precision was between 1.98% - 16.99% for glyphosate and metabolites. The limit of quantification (LOQ) for glyphosate and its metabolites was 0.01 mg/kg and the limit of detection was 0.003 mg/kg.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				glyphosate	AMPA	N-Acetyl-AMPA	N-acetyl-glyphosate		
	(a)	(b)				(c)							(d)	(e)
19SGS21-01	Apple/Gala Royal	Harvest: 03.09.2019	2080 g as/ha	300 l/ha	693.3 g a.s./hl	16.05.2019	BBCH 71	Fruits	<LOD	<LOD	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS21-02	Apple/Alwa	Harvest: 03.09.2019	2080 g as/ha	300 l/ha	693.3 g a.s./hl	11.05.2019	BBCH 67	Fruits	<LOD	<LOD	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS21-03	Apple/ Red Jonaprince	Harvest: 03.09.2019	2080 g as/ha	300 l/ha	693.3 g a.s./hl	10.05.2019	BBCH 69	Fruits	<LOD	<LOD	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds

Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.010 mg/k

A 2.1.3.2 Cherries

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, Germany, 2013)	1-3	720 – 2880 g as/ha	28 days	Post emergence of weeds	Not applicable
cGAP EU (Art. 12, EFSA, 2019)	1-2	540 – 3600 g as/ha	-	During the intensive growth of weeds	7
Intended cGAP (Raport number 19SGS22)	1	1300 – 2080 g as/ha	Not applicable	During the intensive growth of weeds	Not applicable

* Use number(s) in accordance with the list of all intended GAPs in Part

A 2.1.3.2.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS22
Report	Peda Tomasz, 2020. Magnitude of the residue of MCPA, MCPB and glyphosate in cherry (Raw Agricultural Commodity) after one application of Orkan 350 SL – three harvest trials in Poland – 2019. Study number 19SGS22.
Guideline(s):	Yes (OECD 2009, Test No. 509; SANCO/3029/99 rev.4; SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Three residue trials on cherries were carried out in Poland in 2019. The field trials were established in three different locations Product ORKAN 350 SL was applied once at a rate of 2080 g of glyphosate at the intensive growth of weeds. The cherry trees was at the growth stage BBCH 72-73. Cherry samples were harvested during the commercial harvest (55 DALA in trial 19SGS22-01; 40 DALA in trial 19SGS22-02 and 53 DALA in trial 19SGS22-03).
Fruits were collected randomly from the inner part of each plot. Samples were taken from all parts of trees – from bottom, middle and top from all sides, especially from the heavily – laden parts. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of glyphosate (and its metabolites: AMPA, N-acetyl-AMPA, N-acetyl-glyphosate) were performed according to the QuPPe method.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day).
The method for determination of glyphosate in cherries was the same as for apples according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and apples belongs to the same matrix group – commodities with high water content.

The range of linearity of the analytical graph of glyphosate, AMPA, N-acetyl AMPA and N-acetyl glyphosate varied from 0.001 to 0.5 mg/l, $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels in apple samples for glyphosate were: 82.3% and 78.2%, respectively; for AMPA: 91.6% and 81.4%; for N-Acetyl-AMPA 115.0% and 82.8% and for N-Acetyl-glyphosate 104.5 and 99.1%, respectively.
The precision was between 1.98% - 16.99% for glyphosate and metabolites. The limit of quantification (LOQ) for glyphosate and its metabolites was 0.01 mg/kg and the limit of detection was 0.003 mg/kg.

Table A 4: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				glyphosate	AMPA	N-Acetyl-AMPA	N-acetyl-glyphosate		
	(a)	(b)				(c)							(d)	(e)
19SGS22-01	Cherry/ Łutówka	Harvest: 10.07.2019	2080 g as/ha	300 l/ha	693.3 g a.s./hl	16.05.2019	BBCH 73	Fruits	<LOD	<LOD	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS22-02	Cherry/ Łutówka	Harvest: 02.07.2019	2080 g as/ha	300 l/ha	693.3 g a.s./hl	21.05.2019	BBCH 72	Fruits	<LOD	<LOD	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS22-03	Cherry/ Pandy	Harvest: 02.07.2019	2080 g as/ha	300 l/ha	693.3 g a.s./hl	10.05.2019	BBCH 72	Fruits	<LOD	<LOD	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds

Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

Not required.

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

Not required.

A 2.1.6 Magnitude of residues in representative succeeding crops

Not required.

A 2.1.7 Other/Special Studies

Not required.

A 2.2 MCPA

A 2.2.1 Stability of residues

Not required.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

Not required.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Apple

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (Raport number 19SGS21)	1	450 – 720 g a.s./ha	-	During the intensive growth of weeds	n.a.

* Use number(s) in accordance with the list of all intended GAPs in Part

A 2.2.3.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS21
Report	Peda Tomasz, 2020. Magnitude of the residue of MCPA, MCPB and glyphosate in apple (Raw Agricultural Commodity) after one application of Orkan 350 SL – three harvest trials in Poland – 2019. Study number 19SGS21.
Guideline(s):	Yes (OECD 2009, Test No. 59; SANCO/3029/99 rev.4; SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Three residue trials on apples were carried out in Poland in 2019. Product ORKAN 350 SL was applied once at a rate of 720 g of MCPA at the intensive growth of weeds. The apple trees was at the growth stage BBCH 69-71. Apple samples were harvested during the commercial harvest (80 DALA in trial 19SGS21-01; 132 DALA in trial 19SGS21-02 and 110 DALA in trial 19SGS21-03).
Fruits were collected randomly from the inner part of each plot. Samples were taken from all parts of trees – from bottom, middle and top from all sides, especially from the heavily – laden parts. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of MCPA and MCPB were performed according to the multi-residue QuEChERS method.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day).
The method for determination of MCPA and MCPB in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1.

The range of linearity of the analytical graph of MCPA and MCPB varied from 0.002 to 0.5 mg/l, $R^2 \geq$ 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels in apple samples for MCPA were: 104.0% and 109.4%, respectively; for MCPB: 99.4% and 94.5%, respectively.
The precision was between 1.58% - 3.61% for MCPA and between 2.76 – 0.70% for MCPB. The limit of quantification (LOQ) for MCPA and MCPB was 0.01 mg/kg and the limit of detection was 0.003 mg/kg.

Table A 6: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				MCPA	MCPB		
19SGS21-01	Apple/Gala Royal	Harvest: 03.09.2019	720 g as/ha	300 l/ha	240 g a.s./hl	16.05.2019	BBCH 71	Fruits	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS21-02	Apple/Alwa	Harvest: 03.09.2019	720 g as/ha	300 l/ha	240 g a.s./hl	11.05.2019	BBCH 67	Fruits	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS21-03	Apple/ Red Jonaprince	Harvest: 03.09.2019	720 g as/ha	300 l/ha	240 g a.s./hl	10.05.2019	BBCH 69	Fruits	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds

Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

A 2.2.3.2 Cherries

Table A 7: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (Raport number 19SGS22)	1	450 – 720 g as/ha	Not applicable	During the intensive growth of weeds	Not applicable

* Use number(s) in accordance with the list of all intended GAPs in Part

A 2.2.3.2.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS22
Report	Peda Tomasz, 2020. Magnitude of the residue of MCPA, MCPB and glyphosate in cherry (Raw Agricultural Commodity) after one application of Orkan 350 SL – three harvest trials in Poland – 2019. Study number 19SGS22.
Guideline(s):	Yes (OECD 2009, Test No. 59; SANCO/3029/99 rev.4; SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Three residue trials on cherries were carried out in Poland in 2019. The field trials were established in three different locations Product ORKAN 350 SL was applied once at a rate 720 g of MCPA at the intensive growth of weeds. The cherry trees was at the growth stage BBCH 72-73. Cherry samples were harvested during the commercial harvest (55 DALA in trial 19SGS22-01; 40 DALA in trial 19SGS22-02 and 53 DALA in trial 19SGS22-03).
Fruits were collected randomly from the inner part of each plot. Samples were taken from all parts of trees – from bottom, middle and top from all sides, especially from the heavily – laden parts. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of MCPA and MCPB were performed according to the multi-residue QuEChERS method.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day).
The method for determination of MCPA and MCPB in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and apples belongs to the same matrix group – commodities with high water content.
The range of linearity of the analytical graph of MCPA and MCPB varied from 0.002 to 0.5 mg/l, $R^2 \geq$ 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels in apple samples for MCPA were: 104.0% and 109.4%, respectively; for MCPB: 99.4% and 94.5%, respectively.
The precision was between 1.58% - 3.61% for MCPA and between 2.76 – 0.70% for MCPB. The limit of quantification (LOQ) for MCPA and MCPB was 0.01 mg/kg and the limit of detection was 0.003 mg/kg.

Table A 8: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				MCPA	MCPB		
	(a)	(b)				(c)					(d)	(e)
19SGS22-01	Cherry/ Łutówka	Harvest: 10.07.2019	720 g as/ha	300 l/ha	240 g a.a./hl	16.05.2019	BBCH 73	Fruits	<LOQ	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS22-02	Cherry/ Łutówka	Harvest: 02.07.2019	720 g as/ha	300 l/ha	240 g a.a./hl	21.05.2019	BBCH 72	Fruits	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds
19SGS22-03	Cherry/ Pandy	Harvest: 02.07.2019	720 g as/ha	300 l/ha	240 g a.a./hl	10.05.2019	BBCH 72	Fruits	<LOD	<LOD	n.a.	Application was done during the intensive growth of weeds

Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

Not required.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not required.

A 2.2.6 Magnitude of residues in representative succeeding crops

Not required.

A 2.2.7 Other/Special Studies

Not required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Glyphosate

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Glyphosate

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,5	ARfD (mg/kg bw):	0,5
Source of ADI:	2015	Source of ARfD:	2015
Year of evaluation:	EFSA	Year of evaluation:	EFSA

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0,1%	NL toddler	0,46	0,0%	Pears	0,0%	Apples	0,0%	Peaches		
	0,1%	DE child	0,33	0,0%	Apples	0,0%	Pears	0,0%	Apricots		
	0,0%	NL child	0,20	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	DK child	0,09	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	FR toddler 2 3 yr	0,08	0,0%	Apples	0,0%	Pears	0,0%	Apricots		
	0,0%	DE women 14-50 yr	0,08	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,0%	IE adult	0,07	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,0%	DE general	0,07	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,0%	PL general	0,07	0,0%	Apples	0,0%	Pears	0,0%	Plums		
	0,0%	FR child 3 15 yr	0,06	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	IT toddler	0,06	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,0%	ES child	0,06	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	GEMS/Food G15	0,06	0,0%	Apples	0,0%	Plums	0,0%	Pears		
	0,0%	PT general	0,06	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,0%	IT adult	0,06	0,0%	Peaches	0,0%	Apples	0,0%	Pears		
	0,0%	RO general	0,06	0,0%	Apples	0,0%	Plums	0,0%	Pears		
	0,0%	UK infant	0,05	0,0%	Apples	0,0%	Pears	0,0%	Apricots		
	0,0%	GEMS/Food G08	0,05	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,0%	GEMS/Food G06	0,05	0,0%	Apples	0,0%	Peaches	0,0%	Apricots		
	0,0%	UK toddler	0,05	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	SE general	0,05	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	GEMS/Food G11	0,05	0,0%	Apples	0,0%	Pears	0,0%	Plums		
	0,0%	ES adult	0,05	0,0%	Pears	0,0%	Apples	0,0%	Peaches		
	0,0%	LT adult	0,05	0,0%	Apples	0,0%	Pears	0,0%	Plums		
	0,0%	NL general	0,05	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	FR infant	0,05	0,0%	Apples	0,0%	Pears	0,0%	Quinces		
	0,0%	GEMS/Food G07	0,04	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	DK adult	0,04	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	FI 3 yr	0,04	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	GEMS/Food G10	0,04	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,0%	FR adult	0,03	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	FI 6 yr	0,03	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	UK vegetarian	0,02	0,0%	Apples	0,0%	Pears	0,0%	Plums		
	0,0%	FI adult	0,02	0,0%	Apples	0,0%	Pears	0,0%	Peaches		
	0,0%	UK adult	0,01	0,0%	Apples	0,0%	Pears	0,0%	Plums		
	0,0%	IE child	0,01	0,0%	Apples	0,0%	Pears	0,0%	Peaches		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Glyphosate is unlikely to present a public health concern.

MCPA

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

MCPA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,05	ARfD (mg/kg bw):	0,15
Source of ADI:	SANCO/4062/ 2008	Source of ARfD:	
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:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0,6%	NL toddler	0,28	0,4%	Pears	0,1%	Apples	0,0%	Peaches		
	0,2%	DE child	0,11	0,1%	Apples	0,1%	Pears	0,0%	Apricots		
	0,2%	NL child	0,10	0,1%	Pears	0,0%	Apples	0,0%	Peaches		
	0,1%	IE adult	0,06	0,0%	Pears	0,0%	Peaches	0,0%	Plums		
	0,1%	DK child	0,05	0,1%	Pears	0,0%	Apples	0,0%	Peaches		
	0,1%	IT toddler	0,05	0,0%	Peaches	0,0%	Pears	0,0%	Apricots		
	0,1%	IT adult	0,04	0,0%	Peaches	0,0%	Pears	0,0%	Apricots		
	0,1%	ES child	0,04	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,1%	PT general	0,04	0,0%	Peaches	0,0%	Pears	0,0%	Apples		
	0,1%	GEMS/Food G15	0,04	0,0%	Plums	0,0%	Pears	0,0%	Peaches		
	0,1%	FR child 3 15 yr	0,04	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,1%	GEMS/Food G06	0,04	0,0%	Peaches	0,0%	Apricots	0,0%	Pears		
	0,1%	ES adult	0,03	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,1%	PL general	0,03	0,0%	Pears	0,0%	Plums	0,0%	Apples		
	0,1%	DE women 14-50 yr	0,03	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,1%	SE general	0,03	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,1%	RO general	0,03	0,0%	Plums	0,0%	Pears	0,0%	Peaches		
	0,1%	GEMS/Food G08	0,03	0,0%	Peaches	0,0%	Pears	0,0%	Plums		
	0,1%	FR toddler 2 3 yr	0,03	0,0%	Pears	0,0%	Apples	0,0%	Apricots		
	0,1%	DE general	0,03	0,0%	Apples	0,0%	Peaches	0,0%	Pears		
	0,1%	GEMS/Food G10	0,03	0,0%	Peaches	0,0%	Pears	0,0%	Loquats/Japanese medlars		
	0,1%	GEMS/Food G07	0,03	0,0%	Pears	0,0%	Peaches	0,0%	Plums		
	0,1%	UK infant	0,03	0,0%	Pears	0,0%	Apricots	0,0%	Apples		
	0,0%	DK adult	0,02	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,0%	GEMS/Food G11	0,02	0,0%	Pears	0,0%	Apples	0,0%	Plums		
	0,0%	FI 3 yr	0,02	0,0%	Pears	0,0%	Peaches	0,0%	Plums		
	0,0%	NL general	0,02	0,0%	Pears	0,0%	Apples	0,0%	Peaches		
	0,0%	UK toddler	0,02	0,0%	Pears	0,0%	Apples	0,0%	Peaches		
	0,0%	FR adult	0,02	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,0%	FI 6 yr	0,02	0,0%	Pears	0,0%	Peaches	0,0%	Apples		
	0,0%	FR infant	0,02	0,0%	Pears	0,0%	Apples	0,0%	Quinces		
	0,0%	LT adult	0,02	0,0%	Pears	0,0%	Apples	0,0%	Plums		
	0,0%	UK vegetarian	0,01	0,0%	Pears	0,0%	Plums	0,0%	Apples		
	0,0%	UK adult	0,01	0,0%	Pears	0,0%	Plums	0,0%	Peaches		
	0,0%	FI adult	0,01	0,0%	Pears	0,0%	Apples	0,0%	Peaches		
	0,0%	IE child	0,00	0,0%	Pears	0,0%	Apples	0,0%	Peaches		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of MCPA is unlikely to present a public health concern.

A 3.2 IEDI calculations

Model is not required.

A 3.3 IESTI calculations - Raw commodities

Glyphosate

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
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.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Pears	0,1 / 0,05	6,9
1%	Apples	0,1 / 0,05	5,4
1,0%	Peaches	0,1 / 0,05	4,8
0,4%	Plums	0,1 / 0,05	2,1
0,3%	Apricots	0,1 / 0,05	1,7
0,2%	Quinces	0,1 / 0,05	1,2
0,1%	Medlar	0,1 / 0,05	0,69
0,1%	Cherries (sweet)	0,1 / 0,05	0,61
0,03%	Walnuts	0,1 / 0,05	0,17
0,03%	Hazelnuts/cobnuts	0,1 / 0,05	0,16

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Pears	0,1 / 0,05	1,5
0,3%	Apples	0,1 / 0,05	1,4
0,2%	Peaches	0,1 / 0,05	0,94
0,2%	Plums	0,1 / 0,05	0,89
0,2%	Quinces	0,1 / 0,05	0,76
0,1%	Apricots	0,1 / 0,05	0,54
0,1%	Cherries (sweet)	0,1 / 0,05	0,50
0,07%	Medlar	0,1 / 0,05	0,34
0,02%	Walnuts	0,1 / 0,05	0,11
0,01%	Hazelnuts/cobnuts	0,1 / 0,05	0,06

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Apples	0,1 / 0,1	6,2
1%	Pears	0,1 / 0,1	5,9
1%	Peaches	0,1 / 0,1	5,4
1,0%	Apricots	0,1 / 0,1	4,9
0,5%	Plums	0,1 / 0,1	2,6
0,3%	Quinces	0,1 / 0,1	1,5
0,2%	Cherries (sweet)	0,1 / 0,1	1,2
0,2%	Medlar	0,1 / 0,1	1,0
0,07%	Walnuts	0,1 / 0,1	0,34
0,07%	Hazelnuts/cobnuts	0,1 / 0,1	0,33

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Plums	0,1 / 0,1	3,9
0,7%	Pears	0,1 / 0,1	3,6
0,6%	Apples	0,1 / 0,1	3,0
0,4%	Peaches	0,1 / 0,1	2,0
0,3%	Apricots	0,1 / 0,1	1,3
0,2%	Cherries (sweet)	0,1 / 0,1	1,00
0,2%	Quinces	0,1 / 0,1	0,91
0,10%	Medlar	0,1 / 0,1	0,48
0,04%	Walnuts	0,1 / 0,1	0,22
0,02%	Hazelnuts/cobnuts	0,1 / 0,1	0,12

MCPA

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
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.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Pears	0,05 / 0,05	6,9
3%	Peaches	0,05 / 0,05	4,8
1%	Plums	0,05 / 0,05	2,1
1%	Apricots	0,05 / 0,05	1,7
0,8%	Quinces	0,05 / 0,05	1,2
0,5%	Medlar	0,05 / 0,05	0,69
0,2%	Apples	0 / 0	0,32
0,1%	Walnuts	0,05 / 0,05	0,17
0,1%	Hazelnuts/cobnuts	0,05 / 0,05	0,16
0,08%	Cherries (sweet)	0 / 0,01	0,12

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Pears	0,05 / 0,05	1,5
0,6%	Peaches	0,05 / 0,05	0,94
0,6%	Plums	0,05 / 0,05	0,89
0,5%	Quinces	0,05 / 0,05	0,76
0,4%	Apricots	0,05 / 0,05	0,54
0,2%	Medlar	0,05 / 0,05	0,34
0,07%	Walnuts	0,05 / 0,05	0,11
0,07%	Cherries (sweet)	0 / 0,01	0,10
0,06%	Apples	0 / 0	0,08
0,04%	Hazelnuts/cobnuts	0,05 / 0,05	0,06

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Pears	0,05 / 0,05	3,0
2%	Peaches	0,05 / 0,05	2,7
2%	Apricots	0,05 / 0,05	2,5
0,9%	Plums	0,05 / 0,05	1,3
0,5%	Quinces	0,05 / 0,05	0,74
0,3%	Medlar	0,05 / 0,05	0,51
0,1%	Walnuts	0,05 / 0,05	0,17
0,1%	Hazelnuts/cobnuts	0,05 / 0,05	0,16

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Plums	0,05 / 0,05	2,0
1%	Pears	0,05 / 0,05	1,8
0,7%	Peaches	0,05 / 0,05	1,0
0,4%	Apricots	0,05 / 0,05	0,64
0,3%	Quinces	0,05 / 0,05	0,46
0,2%	Medlar	0,05 / 0,05	0,24
0,07%	Walnuts	0,05 / 0,05	0,11
0,04%	Hazelnuts/cobnuts	0,05 / 0,05	0,06

A 3.4 IESTI calculations - Processed commodities

Glyphosate

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Pears / juice	0,1 / 0,05	1,6
0,3%	Peaches / canned	0,1 / 0,05	1,3
0,2%	Apples / juice	0,1 / 0,02	1,1
0,2%	Peaches / juice	0,1 / 0,05	0,83
0,1%	Plums / juice	0,1 / 0,05	0,47
0,0%	Quinces / jam	0,1 / 0,05	0,15
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Apples / juice	0,1 / 0,02	0,67
0,08%	Peaches / canned	0,1 / 0,05	0,41
0,01%	Quinces / jam	0,1 / 0,05	0,06
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Apples / juice	0,1 / 0,1	5,4
0,7%	Pears / juice	0,1 / 0,1	3,3
0,4%	Peaches / canned	0,1 / 0,1	1,9
0,3%	Peaches / juice	0,1 / 0,1	1,7
0,2%	Plums / juice	0,1 / 0,1	0,94
0,06%	Quinces / jam	0,1 / 0,1	0,30
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,7%	Apples / juice	0,1 / 0,1	3,3
0,2%	Peaches / canned	0,1 / 0,1	0,81
0,03%	Quinces / jam	0,1 / 0,1	0,13
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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 ARfD/ADI was identified.

MCPA

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Pears / juice	0,05 / 0,05	1,6
0,9%	Peaches / canned	0,05 / 0,05	1,3
0,6%	Peaches / juice	0,05 / 0,05	0,83
0,3%	Plums / juice	0,05 / 0,05	0,47
0,1%	Apples / juice	0 / 0	0,16
0,1%	Quinces / jam	0,05 / 0,05	0,15
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Peaches / canned	0,05 / 0,05	0,41
0,07%	Apples / juice	0 / 0	0,10
0,04%	Quinces / jam	0,05 / 0,05	0,06
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Pears / juice	0,05 / 0,05	1,6
0,6%	Peaches / canned	0,05 / 0,05	0,97
0,6%	Peaches / juice	0,05 / 0,05	0,83
0,3%	Plums / juice	0,05 / 0,05	0,47
0,1%	Quinces / jam	0,05 / 0,05	0,15
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Peaches / canned	0,05 / 0,05	0,41
0,04%	Quinces / jam	0,05 / 0,05	0,06
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of MCPA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not required.