FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 9700 A

Product name: RULER

Chemical active substance:

Fenazaquin, 200 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: May 2019

MS Finalisation date: 09/2020; 05/2021

Version history

When	What
September 2020	ZRMs Finalisation date
May 2021	Final Version

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

Fenazaquin residues in high acid and in high water content are stable for at least 12 months. TBPE is stable in grapes, raisins and orange pulp for at least 18 months, and in orange peel for at least 12 months under frozen conditions. 4-OHQ residues in fortified matrices of grapes, raisins, and citrus (orange peel and pulp) are stable under frozen conditions for at least 18 months.

Additional information on TBPE stability in the high water content matrix is required.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion of the active substance are sufficient to describe the behavior of the formulated product, and no further studies are required.

Plant residue definition for monitoring: Fenazaquin (Regulation No. 2019/50)

Plant residue definition for risk assessment (EFSAJournal2020;18(1):5955):

Fruits: 1) fenazaquin and 2) TBPE

Leafy vegetables(tentative): 1) fenazaquin and 2) TBPE

Magnitude of residues in plants

Melon, Tomato, Strawberry

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

Residue studies are on-going.

Uses are not accepted

Residue trials on melons, tomato and strawberry are required.

Ornamentals

Uses are accepted

Magnitude of residues in livestock

Uses on melon, ornamentals, tomato and strawberry are not edible for European livestock, therefore, dietary burden calculations are not necessary.

Processing studies

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

Additional information on processed commodities to cover proposed uses is required.

Magnitude of residues in representative succeeding crops

Not relevant as the intended uses consider only glasshouses.

Consumer risk assessment

Consumer risk assessment for fenazaquin and TBPE is required.

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 Fenazaquin 20% SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the EU for ornamentals, strawberry, melon and tomato. A list of all intended uses within the EU is given in Part B, Section 0.

Justification for the selection of the critical GAP

Overall conclusion

~~The data available are considered sufficient for risk assessment. An exceedance of the current MRL for fenazaquin as laid down in Reg. (EU) 396/2005 is not expected.~~
~~The chronic and the short-term intakes of Fenazaquin residues are unlikely to present a public health concern.~~
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use on ornamentals.

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).

Noticed data gaps are:

- Additional information on TBPE stability in the high water content matrix.
- Residue trials on melons, tomato and strawberry.
- Additional information on processed commodities to cover proposed uses.
- Consumer risk assessment for fenazaquin and TBPE.

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	**Melon**	CEU/SEU/NEU	Fenazaquin 20% SC	G	Spider mites	SC	200 g/L	Foliar spray	BBCH 70-79	1	NA	-	1000	0.2	7	N
2	**Ornamentals**	CEU/SEU/NEU	Fenazaquin 20% SC	G	Spider mites	SC	200 g/L	Foliar spray	BBCH 35-67	2	7	-	1000	0.2	-	A
3	**Tomato**	CEU/SEU/NEU	Fenazaquin 20% SC	G	Spider mites	SC	200 g/L	Foliar spray	BBCH 51-89	2	7	-	1000	0.2	3	N
4	**Strawberry**	CEU/SEU/NEU	Fenazaquin 20% SC	G	Spider mites	SC	200 g/L	Foliar spray	BBCH 15-91	2	7	-	1000	0.2	3	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 Fenazaquin 20% SC is composed of Fenazaquin.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fenazaquin					
ADI	EFSA	2013	0.005 mg/kg bw/d	2-year oral rat study	100
ARfD	EFSA	2013	0.1 mg/kg bw	Developmental rat study	100

7.1.2.1 Summary for Fenazaquin

Table 7.1-3: Summary for Fenazaquin

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	Melon	Yes	No	NR	No	No	No	No
2	Ornamentals	Yes	NR	NR	No	NR		No
3	Tomato	Yes	No	NR	No	No		No
4	Strawberry	Yes	No	NR	Yes	No		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 Fenazaquin 20% SC

Table 7.1-4: Information on Fenazaquin 20% SC (KCA 6.8)

Crop	PHI for Fenazaquin 20% SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Fenazaquin 20% SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fenazaquin		
Melon	NR	NR		
Ornamentals	NR	NR		
Tomato	NR	NR		
Strawberry	NR	NR		

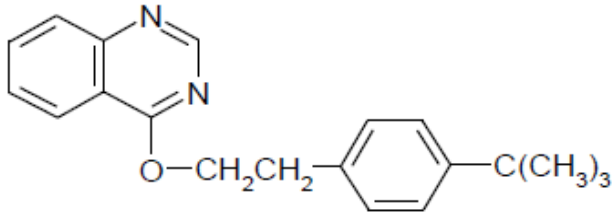
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Fenazaquin

General data on Fenazaquin are summarized in the table below (last updated 2019/03/20)

Table 7.2-1: General information on Fenazaquin

Active substance (ISO Common Name)	Fenazaquin
IUPAC	4-*tert*-butylphenethyl-quinazolin-4-yl ether
Chemical structure	
Molecular formula	$C_{20}H_{22}N_2O$
Molar mass	306.4 g/mol
Chemical group	It is a mitochondrial electron transport inhibitor acaricide
Mode of action (if available)	It is a mitochondrial electron transport inhibitor acaricide
Systemic	No
Company	Gowan Comércio Internacional e Serviços Limitada
Rapporteur Member State (RMS)	RMS: Germany Co-RMS: Poland
Approval status	Approved Date of (01/06/2011) and reference to decision (COM-MISSION DIRECTIVE 2011/39/EU - REGULATION (EU) No 2018/1266)
Restriction	Only uses as acaricide in greenhouse may be authorised.
Review Report	SANCO/10324/2011 – final 11/03/2011
Current MRL regulation	Regulation (EU) No 2019/50
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal: Conclusion on the peer review	Yes (EFSA Journal 2013;11(4)3166)
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2009-00048 Commodities Status: Evaluation ongoing

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			
Fenazaquin			
Plant products			
Orange	High acid content	12 months	Greece 2006, 2010, 2012 EFSA 2010, 2013 Gambie, Draper, 1993
Grapes	High acid content	12 months	Greece 2006, 2010, 2012 EFSA 2010, 2013 Gambie, Butcher, Laurie, 1994
Tomatoes, melon (peel and pulp), cucumber	High water content	12 months	Greece 2006, 2010, 2012 EFSA 2010, 2013 Buthcer, Laurie, 1993; Butcher, 1994
TBPE			
Grapes	High acid content	18 months	Greece 2006, 2010, 2012 EFSA 2010, 2013 June, 2009
Raisins	High acid content	18 months	
Orange pulp	High acid content	18 months	
Orange peel	High acid content	12 months	
4-OHQ			
Grapes	High acid content	18 months	Greece 2006, 2010, 2012 EFSA 2010, 2013 June, 2009
Raisins	High acid content	18 months	
Citrus (orange peel and pulp)	High acid content	18 months	

Conclusion on stability of residues during storage

Fenazaquin residues in high acid and in high water content are stable for for at least 12 months. TBPE is stable in grapes, raisins and orange pulp for at least 18 months, and in orange peel for at least 12 months under frozen conditions. 4-OHQ residues in fortified matrices of grapes, raisins, and citrus (orange peel and pulp) are stable under frozen conditions for at least 18 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data was submitted and required at EU level during the EU Review of Fenazaquin.

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	Grapes	^{14}C-fenazaquin , quinazoline ring (Q-fenazaquin) and phenyl ring (P-fenazaquin)	foliar treatment, F	0.015	1	0, 46, 76	-	Greece 2006, 2010, 2012 EFSA 2010, 2013 Haq, Worth, Francis, Mitsopoulos, 1994; Portwood, 1993
			foliar treatment, F	0.015 + 0.15	1	0, 28	-	
	Oranges	^{14}C-fenazaquin , quinazoline ring (Q-fenazaquin) and phenyl ring (P-fenazaquin)	foliar treatment, F		2	0, 28, 112 and 191 days after application 1. 0, 19 and 63 after second application.	-	Greece 2006, 2010, 2012 EFSA 2010, 2013 Berard, 1992
		^{14}C-fenazaquin , quinazoline ring (Q-fenazaquin)	foliar treatment, F		1	Leaves: 0, 2, 4, 8, 24, 48, 72 and 120 hours (0.5µL droplet size) 1, 3, 5, 8, 12, 18, 25 days (2 µL droplet size)	-	Greece 2006, 2010, 2012 EFSA 2010, 2013 Yackovich, 1991

						Fruits: 2, 6, 21 hours; 2, 5, 9 and 15 days after application.		

Summary of plant metabolism studies reported in the EU

Metabolism study in grapes is available covering the group of fruits. Furthermore, two metabolism studies in citrus fruits were submitted for additional data concerning the rate of penetration, degradation and distribution pattern of fenazaquin in citrus peel and pulp. In general, the degradation and metabolism of fenazaquin in fruits consist of the following steps:

- Hydroxylation of the tertiary butyl group to a hydroxyl- or a carboxyl function
- Oxidation of the quinazoline ring to carbonyl function or ring opening and deamination
- -cleavage of the ether bridge leading to quinazoline derivatives and tertiarybutylphenylethanol derivatives.

Conclusion on metabolism in primary crops

The residue definition for the crop group of fruits is:

- Fenazaquin for monitoring purposes
- Fenazaquin and TBPE for risk assessment.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

Metabolism data in rotational crops was not triggered during the peer review (representative uses on permanent crops only) and is not triggered by the current assessment (representative uses consider only glasshouses).

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Fenazaquin (35%), 4-OHQ (61%)	Greece 2006, 2010, 2012 EFSA 2010, 2013 Diehl, 2003
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Fenazaquin (62%), 4-OHQ (35.5%), unknown metabolite (<3%)	
Sterilisation (20 minutes, 120°C, pH 6)	Fenazaquin (71%), 4-OHQ (17.7%)	

Conclusion on nature of residues in processed commodities

Fenazaquin was shown to be hydrolytically unstable for all hydrolytic conditions: pasteurisation, baking/brewing/boiling and sterilisation. Up to two hydrolysis products were formed, one of which was characterised as 4-hydroxyquinazoline. 4-OHQ represented the major hydrolysis product (61% under pasteurisation conditions). The other hydrolysis product (M2) was shown to be more polar than the parent compound and did not exceed 3.7 of the applied radioactivity.

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	Fruits
Rotational crops covered	Not relevant for current assessment
Metabolism in rotational crops similar to metabolism in primary crops?	Not assessed, study not triggered.
Processed commodities	a.s. is highly degraded.
Residue pattern in processed commodities similar to pattern in raw commodities?	No Fenazaquin is significantly degraded to 4-OHQ [more than 60% AR at pH 4 and 90°C]. Fate of phenyl ring moiety not investigated.
Plant residue definition for monitoring	Fenazaquin (Regulation No. 2019/50)
Plant residue definition for risk assessment	Fenazaquin and TBPE
Conversion factor from enforcement to RA	Open

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-Fenazaquin	3 (2 + 1 control)	10 mg/kg diet/day	5	Milk	twice daily	Greece 2006, 2010, 2012 EFSA 2010, 2013 Portwood, 1992, 1993 1998; Dennis, 1998
						Urine and faeces	daily	
						Tissues	at sacrifice	

		^{14}C-Fenazaquin	3 (2 + 1 control)	0.84 mg/kg bw/d (quinazoline ring) 0.79 mg/kg bw/d (phenyl ring)	5	Milk	twice daily	Greece 2006, 2010, 2012 EFSA 2010, 2013 June, 2009
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

Portwood, 1992, 1993 1998; Dennis, 1998
The metabolism of ^{14}C-Fenazaquin was investigated in two lactating goats following oral administration of phenyl and quinazoline ring labelled Fenazaquin at a rate of 10 mg/kg diet per day for 5 consecutive days.
Over the dosing period and the 16 h depuration period 83-88% of the total applied dose was excreted: In the faeces 70-72% and in the urine 13-15% of the total applied radioactivity was found. A further 6-13% remained association with the GI tract and content at sacrifice. A smaller quantity, 0.03-0.28% of the total dose, was secreted in the milk over the sampling period of 120 h. At sacrifice the liver and kidneys accounted for 0.25-0.38% and 0.01-0.02% of the total dose, respectively. Between 0.32-1.37% was associated with the remaining carcass. The highest concentration of radioactivity was found in the liver (0.246-0.368 mg/kg). Lower concentrations were found in the kidney, perirenal fat, subcutaneous fat, muscle, whole blood and plasm. In liver, kidney and urine no Fenazaquin could be identified.
Characterisation of the radioactivity in the faeces showed 9-27% to be the parent Fenazaquin. The major part (~40%) was an unknown component (Unknown B).
In liver the radioactivity could be divided in parts: the major, very polar component had a retention time similar to Unknown B found in faeces and Metabolite B (2,2-dimethyl-2(4—2-((6-oxy-4-quinazolinyl) oxy) ethyl) phenyl)-ethane) a derivative which contains a carbonyl group in the quinazoline ring. Unknown B accounts for 24-25% of the TRR in liver but has not been identified in kidney. Unknown B seemed to consist of at least 2 components of which one could be detected as Tertiarybutylphenylethanol, that is considered as a toxicologically relevant metabolite. However, the percentage that Tertiarybutylphenylethanol accounts for within this Unknown B has not been further investigated. The fact that further investigation of the nature of the radioactivity of this Unknown B has not been performed.
In the kidney the Metabolite B (4-[2-(4-tert-butyl-phenyl)-ethoxy]-1h-quinazolin-2-one), Metabolite D (2,2-dimethyl-2-(4-((4-quinazolinyl) oxy) ethyl) phenyl) acetic acid) and Metabolite F (4-Hydroxyquinazoline) were found.

PD June 2009
The absorption, distribution, metabolism and excretion of ^{14}C-fenazaquin was studied in lactating goats. The chemical is rapidly absorbed, distributed and excreted, predominantly in faces and urine. The metabolism pathway consist of oxidation of the tertiarybutyl group and of the quinazoline ring followed by hydrolysis of the ether bridge.
Fenazaquin was the principal component of the radioactive residue in fat. Fenazaquin was also detected in milk. The phenyl labelled milk sample was separated into milk fat and skim milk before analysis, and essentially all of the fenazaquin in this milk sample was associated with the milk fat fraction. The concentrations of TRR in muscle samples were very small. Fenazaquin was not detected in the muscle sample that was analysed or in either liver or kidney samples. In addition, fenazaquin was not detected in phenyl and quinazoline labelled urine samples. This data indicated that fenazaquin accumulated to a small extent in fat tissue and milk fat, but not in skim milk, muscle, liver or kidney. The data also indicated that the portions of the fenazaquin dose adsorbed by the goats were extensively metabolised.
Small concentrations of 4-hydroxyquinazoline were found in milk, liver, and kidney from the quinazoline label. This metabolite was not found in fat.
Oxy-fenazaquin was not detected in any sample, except for a trace (0.001 mg/kg) in the fat samples. In addition, fenazaquin acid was also not found in any of the samples analysed.
M29, oxy-fenazaquin acid, was also a component of the residue in all samples analysed, except for fat

from the quinazoline label. M29 was also present as a major metabolite in both urine samples analysed, and was identified by mass spectroscopy. This chemical was formed by hydroxylation of the quinazoline and oxidation of the methyl groups to a carboxylic acid.
M34 was a significant metabolite in the phenyl label liver and kidney samples. The absence of this metabolite in the quinazoline label samples indicated that M34 lacked the quinazoline ring. M34 was not detected in the phenyl label milk, muscle or fat samples. It was also not present in the bile sample. M34 was partially purified from liver and shown to be the dicarboxylic acid.
In summary the parent fenazaquin could be detected in faeces, milk and composite fat, but was not found in liver and kidney. The major metabolites in liver and kidney were characterised as very polar.

Conclusion on metabolism in livestock

The residue definition for monitoring and assessment purposes is fenazaquin.

7.2.2.6 CConclusion 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
Time needed to reach a plateau concentration	4 days
Animal residue definition for monitoring	Fenazaquin (Regulation No. 2019/50)
Animal residue definition for risk assessment	Fenazaquin (EFSA Journal 2013;11(4):3166)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log P_{ow}= 5.51)

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of Fenazaquin 20% SC 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
Melon	New trials	EU	Study on-going	N/A				
	Overall supporting data for cGAP	EU						
Tomato	New trials	EU	Study on-going	N/A				
	Overall supporting data for cGAP	EU						
Strawberry	New trials	EU	Study on-going	N/A				
	Overall supporting data for cGAP	EU						

* Source of EU MRL: Regulation 2019/50

7.2.3.2 Conclusion on the magnitude of residues in plants

The use on ornamentals is not an edible crop. Therefore, no residues trials are needed.
Residue trials on melon, tomato and strawberry are on-going.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Uses on melon, ornamentals, tomato and strawberry are not edible for European livestock, therefore, dietary burden calculations are not necessary.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Conclusion on feeding studies

Uses on melon, ornamentals, tomato and strawberry are not edible for European livestock, therefore, feeding study is not necessary.

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

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-9: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Fenazaquin					
Citrus, Peel / pulp distribution	12	3.5 (peel) 0.07 (pulp)			EFSA Journal 2013;11(4):3166
Citrus, juice	4	0.07		-	EFSA Journal 2013;11(4):3166
Citrus, marmalade	4	0.48		-	EFSA Journal 2013;11(4):3166
Citrus, canned oranges	4	0.04			EFSA Journal 2013;11(4):3166
Citrus, wer pomace	1	2		-	EFSA Journal 2013;11(4):3166

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Citrus, dry pomace	1	8.4		-	EFSA Journal 2013;11(4):3166
Grapes, rasins	4	2.2			EFSA Journal 2013;11(4):3166
Grapes, wine	4	0.02		-	EFSA Journal 2013;11(4):3166
Grapes, juice	4	0.14		-	EFSA Journal 2013;11(4):3166

7.2.5.2 Conclusion on process.ing studies

No processing studies for the GAP uses were submitted in the framework of the EU review of Fenazaquin.

7.2.6 Magnitude of residues in representative succeeding crops

Not relevant as the intended uses consider only glasshouses.

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 Fenazaquin 20% SC. 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 7.2-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Fenazaquin		
Mandarins	0.17	STMR EFSA Journal 2013;11(4):3166
Oranges	0.09	STMR EFSA Journal 2013;11(4):3166
Apples	0.04	STMR EFSA Journal 2013;11(4):3166
Peaches	0.04	STMR EFSA Journal 2013;11(4):3166

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Table and wine grapes	0.04	STMR EFSA Journal 2013;11(4):3166
Other food commodities	MRL	Regulation (EU) No. 2019/50

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	**133%** (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	**91%** (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo	**Unprocessed commodities:** Results for children 29.07% Tomatoes 16.34% Strawberries 15.17% Melons Results for adults 9.33% Strawberries 7.93% Tomatoes 3.92% Melons **Processed commodities:** Results for children 9.5% Tomatoes / juice 4.8% Tomatoes / sauce/puree Results for adults 4.1% Tomatoes / sauce/puree

The proposed uses of Fenazaquin in the formulation Fenazaquin 20% SC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance Fenazaquin. EFSA Journal 2010;8(11):1892

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance Fenazaquin. EFSA Journal 2013;11(4):3166

Greece, 2006. Draft Assessment Report (DAR) Fenazaquin, Volume 3, Annex B, B.7

Greece, 2010. Additional report to the DAR Fenazaquin, Volume 3, Annex B, part 1, B.1- B.7

Greece, 2012. Addendum to the DAR (post Annex I inclusion), Annex B.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

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

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 Fenazaquin

A 2.1.1 Stability of residues

No new data have been submitted.

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

No new data have been submitted.

A 2.1.2.1 Nature of residues in livestock

No new data have been submitted.

A 2.1.3 Magnitude of residues in plants

Study on-going.

A 2.1.4 Magnitude of residues in livestock

No new data have been submitted.

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

No new data have been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data have been submitted.

A 2.1.7 Other/Special Studies

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fenazaquin

LOQs (mg/kg) range from: **0.01** to: **0.01**

Toxicological reference values

ADI (mg/kg bw/day):	**0.005**	ARfD (mg/kg bw):	**0.1**
Source of ADI:		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 : 2

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (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)
133%	NL toddler	6.63	22%	Oranges	22%	Apples	21%	Bananas	19%	17%
130%	DE child	6.49	40%	Oranges	25%	Apples	10%	Strawberries	7%	20%
95%	GEMS/Food G06	4.73	36%	Tomatoes	10%	Tea (dried leaves of Camellia sinensis)	10%	Oranges	5%	38%
86%	IE adult	4.30	26%	Tea (dried leaves of Camellia sinensis)	10%	Oranges	7%	Grapefruits	5%	9%
81%	NL child	4.06	14%	Oranges	12%	Apples	8%	Bananas	10%	12%
78%	FR child 3 15 yr	3.91	34%	Oranges	8%	Tomatoes	5%	Tea (dried leaves of Camellia sine	9%	14%
63%	GEMS/Food G07	3.16	14%	Oranges	11%	Tomatoes	10%	Tea (dried leaves of Camellia sine	6%	13%
61%	DE women 14-50 yr	3.07	19%	Oranges	7%	Tomatoes	6%	Tea (dried leaves of Camellia sine	5%	10%
61%	FR adult	3.05	28%	Tea (dried leaves of Camellia sinensis)	9%	Wine grapes	6%	Oranges	3%	7%
57%	GEMS/Food G10	2.87	14%	Tomatoes	11%	Oranges	6%	Tea (dried leaves of Camellia sine	6%	16%
57%	UK toddler	2.86	20%	Oranges	6%	Tomatoes	5%	Tea (dried leaves of Camellia sine	8%	10%
56%	UK infant	2.78	13%	Oranges	11%	Tea (dried leaves of Camellia sinensis)	8%	Milk: Cattle	11%	8%
55%	GEMS/Food G11	2.77	9%	Tomatoes	8%	Tea (dried leaves of Camellia sinensis)	7%	Oranges	7%	11%
55%	DE general	2.76	16%	Oranges	7%	Tomatoes	6%	Tea (dried leaves of Camellia sine	5%	9%
55%	FR toddler 2 3 yr	2.74	14%	Oranges	8%	Mandarins	6%	Apples	9%	8%
54%	RO general	2.70	19%	Tomatoes	7%	Wine grapes	4%	Sweet peppers/bell peppers	6%	20%
53%	ES child	2.67	22%	Oranges	10%	Tomatoes	4%	Bananas	6%	12%
53%	GEMS/Food G08	2.66	11%	Tomatoes	6%	Tea (dried leaves of Camellia sinensis)	5%	Oranges	6%	14%
53%	GEMS/Food G15	2.66	12%	Tomatoes	7%	Oranges	6%	Sweet peppers/bell peppers	6%	13%
48%	SE general	2.39	8%	Tomatoes	7%	Oranges	7%	Bananas	6%	11%
42%	PT general	2.08	10%	Wine grapes	9%	Tomatoes	6%	Oranges	3%	10%
41%	NL general	2.05	10%	Oranges	7%	Tea (dried leaves of Camellia sinensis)	4%	Tomatoes	5%	6%
40%	DK child	2.02	7%	Cucumbers	5%	Tomatoes	5%	Apples	7%	9%
39%	IT toddler	1.97	14%	Tomatoes	5%	Oranges	3%	Peaches	2%	17%
39%	UK vegetarian	1.96	10%	Tea (dried leaves of Camellia sinensis)	9%	Oranges	6%	Tomatoes	2%	8%
38%	ES adult	1.91	13%	Oranges	8%	Tomatoes	2%	Peaches	3%	9%
37%	FI 3 yr	1.84	7%	Strawberries	6%	Tomatoes	5%	Bananas	2%	13%
33%	UK adult	1.67	11%	Tea (dried leaves of Camellia sinensis)	6%	Oranges	4%	Tomatoes	2%	5%
32%	IT adult	1.62	12%	Tomatoes	4%	Peaches	4%	Oranges	1%	13%
28%	FI 6 yr	1.39	6%	Strawberries	4%	Tomatoes	3%	Mandarins	2%	10%
26%	DK adult	1.30	5%	Tomatoes	4%	Wine grapes	2%	Apples	2%	7%
22%	FI adult	1.12	6%	Tomatoes	4%	Oranges	3%	Strawberries	2%	8%
22%	FR infant	1.10	3%	Strawberries	3%	Milk: Cattle	3%	Apples	5%	4%
22%	PL general	1.09	9%	Tomatoes	4%	Apples	1%	Table grapes	1%	9%
17%	LT adult	0.87	6%	Tomatoes	4%	Apples	2%	Cucumbers	3%	7%
6%	IE child	0.30	0.8%	Oranges	0.8%	Bananas	0.7%	Milk: Cattle	1%	1%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 132.6 % of the ADI.
For 2 diet(s) the ADI is exceeded.

A 3.2 IEDI calculations

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI :	---					Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	91%	NL toddler	4.55	21%	Bananas	12%	Milk: Cattle	10%	Tomatoes	19%	
	77%	GEMS/Food G06	3.86	36%	Tomatoes	10%	Tea (dried leaves of Camellia sinensis)	5%	Sweet peppers/bell peppers	5%	
	72%	DE child	3.61	10%	Strawberries	10%	Apples	10%	Tomatoes	7%	
	65%	IE adult	3.27	26%	Tea (dried leaves of Camellia sinensis)	7%	Grapefruits	4%	Tomatoes	5%	
	53%	NL child	2.66	8%	Bananas	7%	Strawberries	6%	Tomatoes	10%	
	46%	FR adult	2.29	28%	Tea (dried leaves of Camellia sinensis)	5%	Tomatoes	2%	Strawberries	3%	
	44%	FR child 3 15 yr	2.18	8%	Tomatoes	6%	Oranges	5%	Tea (dried leaves of Camellia sine	9%	
	43%	RO general	2.14	19%	Tomatoes	4%	Sweet peppers/bell peppers	2%	Aubergines/egg plants	6%	
	42%	UK infant	2.12	11%	Tea (dried leaves of Camellia sinensis)	8%	Milk: Cattle	6%	Bananas	11%	
	42%	GEMS/Food G10	2.11	14%	Tomatoes	6%	Tea (dried leaves of Camellia sinensis)	2%	Strawberries	6%	
	42%	GEMS/Food G07	2.10	11%	Tomatoes	10%	Tea (dried leaves of Camellia sinensis)	3%	Oranges	6%	
	41%	GEMS/Food G11	2.07	9%	Tomatoes	8%	Tea (dried leaves of Camellia sinensis)	4%	Lemons	7%	
	40%	GEMS/Food G15	2.00	12%	Tomatoes	6%	Sweet peppers/bell peppers	3%	Tea (dried leaves of Camellia sine	6%	
	40%	GEMS/Food G08	2.00	11%	Tomatoes	6%	Tea (dried leaves of Camellia sinensis)	3%	Sweet peppers/bell peppers	6%	
	37%	DE women 14-50 yr	1.85	7%	Tomatoes	6%	Tea (dried leaves of Camellia sinensis)	3%	Oranges	5%	
	36%	SE general	1.81	8%	Tomatoes	7%	Bananas	3%	Strawberries	6%	
	36%	UK toddler	1.78	6%	Tomatoes	5%	Tea (dried leaves of Camellia sinensis)	4%	Bananas	8%	
	34%	DE general	1.72	7%	Tomatoes	6%	Tea (dried leaves of Camellia sinensis)	3%	Oranges	5%	
	34%	DK child	1.70	7%	Cucumbers	5%	Tomatoes	5%	Bananas	7%	
	33%	FR toddler 2 3 yr	1.66	6%	Milk: Cattle	5%	Tomatoes	3%	Strawberries	9%	
	31%	ES child	1.56	10%	Tomatoes	4%	Bananas	4%	Oranges	6%	
	30%	FI 3 yr	1.51	7%	Strawberries	6%	Tomatoes	5%	Bananas	2%	
	29%	IT toddler	1.47	14%	Tomatoes	2%	Strawberries	2%	Bananas	2%	
	28%	UK vegetarian	1.40	10%	Tea (dried leaves of Camellia sinensis)	6%	Tomatoes	2%	Oranges	2%	
	27%	NL general	1.33	7%	Tea (dried leaves of Camellia sinensis)	4%	Tomatoes	2%	Oranges	5%	
	24%	UK adult	1.20	11%	Tea (dried leaves of Camellia sinensis)	4%	Tomatoes	1%	Bananas	2%	
	23%	IT adult	1.17	12%	Tomatoes	1%	Aubergines/egg plants	1%	Strawberries	1%	
	23%	PT general	1.13	9%	Tomatoes	2%	Wine grapes	2%	Sweet peppers/bell peppers	3%	
	22%	FI 6 yr	1.12	6%	Strawberries	4%	Tomatoes	3%	Bananas	2%	
	22%	ES adult	1.11	8%	Tomatoes	2%	Oranges	2%	Sweet peppers/bell peppers	3%	
	19%	DK adult	0.93	5%	Tomatoes	2%	Tea (dried leaves of Camellia sinensis)	2%	Bananas	2%	
	17%	PL general	0.87	9%	Tomatoes	2%	Apples	1%	Plums	1%	
	17%	FR infant	0.83	3%	Strawberries	3%	Milk: Cattle	2%	Courgettes	5%	
	16%	FI adult	0.80	6%	Tomatoes	3%	Strawberries	1%	Cucumbers	2%	
	14%	LT adult	0.72	6%	Tomatoes	2%	Cucumbers	1%	Apples	3%	
	5%	IE child	0.23	0.8%	Bananas	0.7%	Milk: Cattle	0.5%	Tomatoes	1%	
	Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Fenazaquin is unlikely to present a public health concern.										

A 3.3 IESTI calculations - Raw commodities

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 of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Tomatoes	0.5 / 0.5	29
16%	Strawberries	1 / 1	16
15%	Melons	0.1 / 0.1	15

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
9%	Strawberries	1 / 1	9.3
8%	Tomatoes	0.5 / 0.5	7.9
4%	Melons	0.1 / 0.1	3.9

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Strawberries	1 / 1	16
15%	Tomatoes	0.5 / 0.5	15
9%	Melons	0.1 / 0.1	9.1

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Tomatoes	0.5 / 0.5	9.6
9%	Strawberries	1 / 1	9.3
2%	Melons	0.1 / 0.1	2.4

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Tomatoes / juice	0.5 / 0.5	9.5	4%	Tomatoes / sauce/puree	0.5 / 0.5	4.1	10%	Tomatoes / juice	0.5 / 0.5	9.5	4%	Tomatoes / sauce/puree	0.5 / 0.5	4.1
5%	Tomatoes / sauce/puree	0.5 / 0.5	4.8	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	5%	Tomatoes / sauce/puree	0.5 / 0.5	4.8	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short term intake of residues of Fenazaquin 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