FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 9700 B

Product name: RULER 10 EC

Chemical active substance:

Fenazaquin, 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: July 2019

Update date: July 2022

MS Finalisation date: 09/2020; 03/2023 03/2023

Version history

When	What
September 2020	ZRMs evaluated version of dRR.
July 2022	Applicant update
March 2023	Evaluation of the completed Section 7
March 2023	Correction of GAP table

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

February 2023 assessment of the document completed by the applicant

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, Reg. (EU) 2022/1324)

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

Fruits: 1) fenazaquin and 2) TBPE

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

All uses under consideration in the framework of this evaluation belong to the fruits and fruiting vegetable crop group and are covered by the metabolism studies assessed at European level.

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.

New data were submitted in the framework of this application

Melon (4 trials)

Trials GAP: 1 x 0.15 kg.a.s./ha, BBCH 79, PHI 7 days, indoor

Residues:

Fenazaquin:

4 x <0.01 mg/kg

TBPE

4 x <0.01 mg/kg

Application rate per treatment is too low to cover the proposed in GAP.

Acceptable application rate per treatment is 0.15 kg.a.s./ha.

Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Tomato (8 trials)

Trials GAP: 1 x 0.15 kg.a.s./ha, BBCH 85, PHI 3 days, indoor

Residues:

Fenazaquin:

4 x 0.01, 2 x 0.02, 0.03, 0.04 mg/kg

TBPE

8 x <0.01 mg/kg

Application rate per treatment is too low to cover the proposed in GAP.

Acceptable application rate per treatment is 0.15 kg.a.s./ha.

Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1.

Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Strawberry (8 trials)

Trials GAP: 1 x 0.2 kg.a.s./ha, BBCH 85, PHI 3 days, indoor

Residues:

Fenazaquin:

0.02, 0.04, 0.06, 0.07, 0.16, 0.22, 0.34, 0.37 mg/kg

TBPE

4 x <0.01, 0.01, 0.02, 0.17, 0.19 mg/kg

Sufficient acceptable trials are available to support the proposed uses. Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1.

The residues arising from the accepted use will not exceed the MRLs for strawberry (0.4 mg/kg ; Reg. (EU) 2022/1324).

Use is accepted with number of application: 1.

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 not 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~~.

New calculations were provided.

The accepted uses of Fenazaquin in the formulation RULER 10 EC 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 Fenazaquin 10% EC 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 and strawberries.

~~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~~.
- **Melon**: Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Acceptable application rate per treatment is 0.15 kg.a.s./ha. Additional information on TBPE stability in the high water content matrix is required.
- **Tomato**: Application rate per treatment in the residue is too low to cover the proposed in GAP. Acceptable application rate per treatment is 0.15 kg.a.s./ha. Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1. Additional information on TBPE stability in the high water content matrix is required.
- **Strawberry:** Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1.

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	SHA 9700 B	G	Spider mites	~~SC~~ EC	~~200 g/L~~ 100 g/L	Foliar spray	BBCH 70-79	1	NA	-	1000	0.2	7	N
2	**Ornamentals**	CEU/SEU/NEU	SHA 9700 B	G	Spider mites	~~SC~~ EC	~~200 g/L~~ 100 g/L	Foliar spray	BBCH 35-67	2	7	-	1000	0.2	-	A
3	**Tomato**	CEU/SEU/NEU	SHA 9700 B	G	Spider mites	~~SC~~ EC	~~200 g/L~~ 100 g/L	Foliar spray	BBCH 51-89	2	7	-	1000	0.2	3	N
4	**Strawberry**	CEU/SEU/NEU	SHA 9700 B	G	Spider mites	~~SC~~ EC	~~200 g/L~~ 100 g/L	Foliar spray	BBCH 15-91	~~2~~ 1	~~7~~	-	1000	0.2	3	A Acceptable number of applications is 1.

* 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 10% EC 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	~~No~~ C	~~No~~ Yes	~~No~~ Yes	No	~~No~~ Yes	No	No
2	Ornamentals	~~No~~ Yes	NR	NR	No	NR		No
3	Tomato	~~No~~ Yes	~~No~~ Yes	~~No~~ Yes	No	~~No~~ Yes		No
4	Strawberry	~~No~~ Yes	~~No~~ Yes	~~No~~ Yes	Yes	~~No~~ 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 Fenazaquin 10% EC

Table 7.1-4 : Information on Fenazaquin 10% EC (KCA 6.8)

Crop	PHI for Fenazaquin 10% EC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Fenazaquin 10% EC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fenazaquin		
Melon	~~NR~~ 7	~~NR~~ Yes		
Ornamentals	NR	NR		
Tomato	~~NR~~ 3	~~NR~~ Yes		
Strawberry	~~NR~~ 3	~~NR~~ Yes		

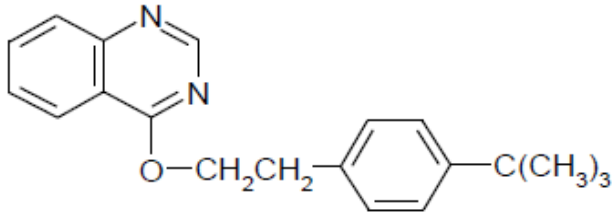
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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, Reg. (EU) 2022/1324)
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, Reg. (EU) 2022/1324)
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 pulp	~~New trials~~	~~EU~~	~~Study on going~~	N/A				
	New trials	NEU	Trials GAP: 1 x 0.15 kg.a.s./ha, BBCH 79, PHI 7 days, indoor Fenazaquin: 2 x n.d. (<0.003), 0.003 (<LOQ), 0.004 (<LOQ) TBPE: 4 x n.d. (<0.003)					
	Overall supporting data for cGAP	EU	Fenazaquin: 2 x n.d. (<0.003), 0.003 (<LOQ), 0.004 (<LOQ) TBPE 4 x n.d. (<0.003)	0.01 TBPE: 0.01	0.01 0.01		0.07	Yes
Tomato	~~New trials~~	~~EU~~	~~Study on going~~	N/A				
	New trials	NEU	Trials GAP: 1 x 0.15 kg.a.s./ha, BBCH 85, PHI 3 days, indoor Fenazaquin: 0.012, 2 x 0.013, 0.036 TBPE					

			4 x n.d. (<0.003)					
	New trials	SEU	Trials GAP: 1 x 0.15 kg.a.s./ha, BBCH 85, PHI 3 days, indoor Fenazaquin: 0.012, 0.016, 0.019, 0.027 TBPE 4 x n.d. (<0.003)					
	Overall supporting data for cGAP	EU	Fenazaquin: 2 x 0.012, 2 x 0.013, 0.016, 0.019, 0.027, 0.036 TBPE: 8 x n.d. (<0.003)	0.015 0.01	0.036 0.01		0.05	Yes
Strawberry	~~New trials~~	~~EU~~	~~Study on going~~	N/A				
	New trials	NEU	Trials GAP: 1 x 0.2 kg.a.s./ha, BBCH 85, PHI 3 days, indoor Fenazaquin: 0.024, 0.043, 0.062, 0.065 TBPE 2 x n.d. (<0.003), 2 x 0.003 (<LOQ)					
	New trials	SEU	Trials GAP: 1 x 0.2 kg.a.s./ha, BBCH 91, PHI 3 days, indoor Fenazaquin: 0.163, 0.223, 0.342, 0.367 TBPE 0.011, 0.015, 0.172, 0.188					
	Overall supporting data for cGAP	EU	Fenazaquin: 0.024, 0.043, 0.062, 0.065, 0.163, 0.223, 0.342, 0.367 TBPE 2 x n.d. (<0.003), 2 x 0.003 (<LOQ), 0.011, 0.015, 0.172, 0.188	0.114 0.011	0.367 0.188		0.4	Yes

* Source of EU MRL: ~~Regulation 2019/50~~ ~~2021/1110~~ Reg. (EU) 2022/1324

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.~~

According to the available data, the intended uses on ~~Melon, Tomato~~ and Strawberries are considered acceptable, for indoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

- **Melon**: Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Acceptable application rate per treatment is 0.15 kg.a.s./ha. Additional information on TBPE stability in the high water content matrix is required.
- **Tomato**: Application rate per treatment in the residue is too low to cover the proposed in GAP. Acceptable application rate per treatment is 0.15 kg.a.s./ha. Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1. Additional information on TBPE stability in the high water content matrix is required.
- **Strawberry:** Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1.

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
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
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.

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Fenazaquin				
Strawberries	0.114	STMR Sharda supervised residue trials	0.367	HR Sharda supervised residue trials
Tomato	0.015	STMR Sharda supervised residue trials	0.036	HR Sharda supervised residue trials
Melon	0.01	STMR Sharda supervised residue trials	0.01	HR Sharda supervised residue trials
TBPE				
Strawberries	0.01	STMR EFSA, 2020	0.01	STMR EFSA, 2020
Tomato	0.01	STMR EFSA, 2020	0.01	STMR EFSA, 2020
Melon	0.01	STMR EFSA, 2020	0.01	STMR EFSA, 2020

7.2.8.3 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	Fenazaquin 1 % (based on DE Child) TBPE 2% (GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	**Fenazaquin** **Raw commodities:** Based on children: Strawberries: 6% Tomatoes: 2% Melons: 2% Based on adults: Strawberries: 3% Tomatoes: 0.6% Melons: 0.4% **Processed commodities:** Based on children: Tomatoes/juice: 0.3% Tomatoes/sauce puree: 0.1% Based on adults: Tomatoes/sauce puree: 0.1%

	TBPE **Raw commodities:** Based on children: Melons: 76% Tomatoes: 29% Strawberries: 8% Based on adults: Melons: 20% Tomatoes: 8% Strawberries: 5% **Processed commodities:** Based on adults: Tomatoes/juice: 10% Tomatoes/sauce puree: 5% Based on children: Tomatoes/sauce puree: 4%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

The proposed uses of Fenazaquin in the formulation RULER 10 EC 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 dssReferences

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
KCP 8.3.1.1	G. Wagner	2021	Determination of the residues of Fenazaquin in/on indoor melon after one application of Fenazaquin 20% SC in Northern Europe. Hungary in 2020. G. Wagner, 2021, Report No. 065CPRHU20R01 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.1.2	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in Greenhouse Melon after one application of Fenazaquin 20% SC – one harvest and one decline trial in Hungary 2020. K. Wiktorowicz, 2021, Report No. PB-2021-22 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.1.3	R. Figurski	2021	Magnitude of the residue of fenazaquin in melon (Raw Agricultural Commodity – RAC) grown in a protected conditions after one application of formulated product Fenazaquin 20% SC – one harvest and one decline curve trial in Northern Europe – Poland, 2020. R. Figurski, 2021, Report No. D-2020-01 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.1.4	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in Greenhouse Melon after one application of Fenazaquin 20% SC – one harvest and one decline trial in Poland 2020. K. Wiktorowicz, 2021, Report No. PB-2021-21 GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.2.1	G. Wagner	2021	Determinaition of the residues of fenazaquin in/on indoor tomato after oone application of Fenazaquin 20% SC in Northern Europe – Hungary in 2020. G. Wagner, 2021, Report No. 065CPRHU20R02 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.2	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in/on indoor tomato after one application of Fenazaquin 20% SC – one harvest and one decline trial in Hungary 2020. K. Wiktorowicz, 2021, Report No. PB-2021-24 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.3	R. Figurski	2021	Magnitude of the residue of fenazaquin in tomato (Raw Agricultural Commodity – RAC) grown in protected conditions after one application of formulated product Fenazaquin 20% SC – one harvest and one decline curve trial in Northern Europe – Poland, 2020 GLP Unpbublished	N	Sharda Cropchem Limited
KCP 8.3.2.4	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in tomato grown in protected conditions after one application of FFenazaquin 20% SC – one harvest and one decline trial in Poland 2020. K. Wiktorowicz, 2021, Report No. PB-2021-23 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.5	G. Gotsis	2022	Generation of specimens for the determination of Magnitude of Residue of Fenazaquin in/on greenhouse tomato at fixed intervals and harvest, following one application of Fenazaquin 20% SC acaricide. Greece – 2020. G. Gotsis, 2022, Report No. S20-0002R GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.6	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in tomato grown in protected conditions after one application of Fenazaquin 20% SC – two harvest and two decline trials in Greece 2020. K. Wiktorowicz, 2021, Report No. PB-2021-15 GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.3.1	G. Wagner	2021	Determination of the residues of fenazaquin in/on indoor strawberry after one application of Fenazaquin 20% SC in Northern Europe- Hungary in 2020. G. Wagner, 2021, Report No. 065CPRHU20R03 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.3.2	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in/on indoor strawberry after one application of Fenazaquin 20% SC – one harvest and one decline trial in Hungary 2020. K. Wiktorowicz, 2021, Report No. PB-2021-26 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.3.3	R. Figurski	2021	Magnitude of the residue of fenazaquin in strawberry (Raw AgriculturalCommodity – RAC) grown in protected conditions after one application of formulated product Fenazaquin 20% SC – one harvest and one decline curve trial in Northern Europe – Poland, 2020. R. Figurski, 2021, Report No. D-2020-03 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.3.4	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in strawberry grown in protected conditions after one application of Fenazaquin 20% SC – one harvest and one decline trial in Poland 2020. K. Wiktorowicz, 2021, Report No. PB-2021-25 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.3.5	G. Gotsis	2022	Generation of specimens for the determination of magnitude of residue of fenazaquin in/on greenhouse strawberry at fixed intervals and harvest following one application of Fenazaquin 20% SC acaricide.G. Gotsis, 2022, Report No. S20-0003R GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.3.6	K. Wiktorowicz	2021	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in/on greenhouse strawberry after one application of Fenazaquin 20% SC – two harvest and two decline trials in Greece 2020. K. Wiktorowicz, 2021, Report No. PB-2021-16 GLP Un	N	Sharda Cropchem Limited

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 2.1.3.1 Melon

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 (Art. 12, EFSA, 2020)	1	150 g a.s/ha	-	BBCH 79	7
Intended cGAP (1)	1	200 g a.s./ha	-	BBCH 79	7

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Analytical method used is acceptable. Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Reference:	KCP 8.3.1.1
Report	Determination of the residues of Fenazaquin in/on indoor melon after one application of Fenazaquin 20% SC in Northern Europe. Hungary in 2020. G. Wagner, 2021, Report No. 065CPRHU20R01
Guideline(s):	Directive 91/414/EEC

Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

Fenazaquin 20% SC is an insecticide developed by Sharda Cropchem Ltd., for pest control in different crops. The objective of the study is to provide results from the magnitude of residues of fenazaquin in/on indoor melon to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).

Two trials were conducted in Hungary in 2020. The field phase was performed in Vép (CPRHU20-159-065IR), and in Kőszeg (CPRHU20-160-065IR).

One application (at BBCH 79, 7 days before harvest) of the formulated product Fenazaquin 20% SC (containing nominal concentration of 20 % fenazaquin) was applied at a target rate of 0.75 L formulated product/ha (150 g active ingredient/ha) onto the crop, to melon, using conventional sprayer equipment.

Specimens (fruits) were collected at 0, 3, and 7 (NCH) days after application (DAA) in decline trials and at 7 days after application (DAA) in harvest trial, frozen and shipped deep frozen to analytical facility.

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.1.2
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in Greenhouse Melon after one application of Fenazaquin 20% SC – one harvest and one decline trial in Hungary 2020. K. Wiktorowicz, 2021, Report No. PB-2021-22
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in melon fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.

Samples were homogenized inside knife mill with use of dry ice. Samples from harvest at 7 DAA were additionally divided into pulp and peel and weighed before homogenization. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.

Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	Feazaquin (whole fruit)	TBPE		
CPRHU20-159-065IR/NEU/Hungary/2020	Melon/Ananasz	28/05/2020 08/2020 09/2020	146	975	15	21/09/2020	BBCH 79	Pulp Peel	<0.003 (<LOD) 0.009 (<LOQ)	0.003 (<LOQ)	<0.003 (<LOD) <0.003 (<LOD)	7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
CPRHU20-160-065IR/NEU/Hungary/2020	Melon/Ananasz	28/05/2020 08/2020 09/2020	152	1013	15	21/09/2020	BBCH 79	fruit fruit Pulp Peel	<0.003 (<LOD) 0.011	0.027 0.029 0.003 (<LOQ)	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.1.3.1.2 Study 2

Comments of zRMS:	Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Analytical method used is acceptable. Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Reference:	KCP 8.3.1.3
Report	Magnitude of the residue of fenazaquin in melon (Raw Agricultural Commodity – RAC) grown in a protected conditions after one application of formulated product Fenazaquin 20% SC – one harvest and one decline curve trial in Northern Europe – Poland, 2020. R. Figurski, 2021, Report No. D-2020-01
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
One harvest trial and one decline curve trial were established in central Poland. Trials consisted of one untreated plot and one treated plot. Environmental conditions did not alter the normal growth. One foliar application of Fenazaquin 20% SC was performed with a boom sprayer on the treated plot at a target dose rate of 0.75 L/ha (equivalent to 150 g a.s./ha of fenazaquin).
The target spray volume was 1000 litres per hectare. An application was performed at BBCH 79.
In HS trial, RAC specimens for analyses were collected at 7 DALA. In decline curve trial, RAC specimens for analyses were collected at 0, 3 and 7 days.

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.1.4
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in Greenhouse Melon after one application of Fenazaquin 20% SC – one harvest and one decline trial in Poland 2020. K. Wiktorowicz, 2021, Report No. PB-2021-21
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in melon fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice. Samples from harvest at 7 DAA were additionally divided into pulp and peel and weighed before homogenization. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	Feazaquin (whole fruit)	TBPE		
D-2020-01-F01/NEU/Poland/2020	Melon/malaga	10/06/2020 01/07/2020 20/09/2020	156	996	15	25/08/2020	BBCH 79	Pulp Peel	0.004 (<LOQ) 0.009 (<LOQ)	0.004 (<LOQ)	<0.003 (<LOD) <0.003 (<LOD)	7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
D-2020-01-F02/NEU/Poland/2020	Melon/malaga	12/06/2020 01/07/2020 20/09/2020	150	962	15	25/08/2020	BBCH 79	fruit fruit Pulp Peel	0.003 (<LOQ) 0.029	0.036 0.020 0.007 (<LOQ)	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.1.3.2 Tomato

Table A 2: 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 (2)	1	200 g a.s./ha	-	BBCH 79	3

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

A 2.1.3.2.1 Study 1

Comments of zRMS:	Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Number of applications in the residue trials is too low to cover the proposed in GAP. Analytical method used is acceptable. Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Reference:	KCP 8.3.2.1
Report	Determinaition of the residues of fenazaquin in/on indoor tomato after oone application of Fenazaquin 20% SC in Northern Europe – Hungary in 2020. G. Wagner, 2021, Report No. 065CPRHU20R02
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of the Study was to provide results from the magnitude of residues of fenazaquin in/on tomato, grown in greenhouse conditions, in order to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).
Two trials were conducted in Hungary in 2020. The field phase was performed in Vép (CPRHU20-161-065IR) and in Kőszeg (CPRHU20-162-065IR).
One application of the formulated product Fenazaquin 20% SC was applied at a target rate of 0.75 L/ha to tomato, using conventional sprayer equipment, under greenhouse condition.
Specimens (fruit) were collected at 0, 1, 3 and 7 (corresponding to normal commercial harvest) days after last application (DALA) in decline trial, and at 3 and 7 (corresponding to normal commercial harvest) days after last application (DALA), frozen and shipped deep frozen to analytical facility of Fertico for residue analysis.

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.2.2
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in/on indoor tomato after one application of Fenazaquin 20% SC – one harvest and one decline trial in Hungary 2020. K. Wiktorowicz, 2021, Report No. PB-2021-24
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Coun-

	cil of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in tomato fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice.. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	TBPE		
CPRHU20-161-065IR/NEU/Hungary/2020	Tomato/Kecskemeti Jubileum	22/04/2020 06/2020 08/2020	145	1000	15	03/08/2020	BBCH 79	Fruit	0.013 0.012	<0.003 (<LOD) <0.003 (<LOD)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
CPRHU20-162-065IR/NEU/Hungary/2020	Tomato/Kecskemeti 549	20/04/2020 06/2020 08/2020	146	1000	a15	03/08/2020	BBCH 79	Fruit	0.032 0.021 0.013 0.009 (<LOQ)	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 1 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.1.3.2.2 Study 2

Comments of zRMS:	Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Number of applications in the residue trials is too low to cover the proposed in GAP. Analytical method used is acceptable. Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Reference:	KCP 8.3.2.3
Report	Magnitude of the residue of fenazaquin in tomato (Raw Agricultural Commodity – RAC) grown in protected conditions after one application of formulated product Fenazaquin 20% SC – one harvest and one decline curve trial in Northern Europe – Poland, 2020
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
One harvest trial and one decline curve trial were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth. One foliar application of Fenazaquin 20% SC was performed with a boom sprayer on the treated plot at a target dose rate of 0.75 L/ha (equivalent to 150 g a.s./ha of fenazaquin). The target spray volume was 1000 litres per hectare according to GAP. An application was performed at BBCH 79.
In HS trial, RAC specimens for analyses were collected at 3 and 7 DALA, In decline curve trial RAC specimens were collected at 0, 3 and 7 DALA.

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.2.4
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in tomato grown in protected conditions after one application of FFenazaquin 20% SC – one harvest and one decline trial in Poland 2020. K. Wiktorowicz, 2021, Report No. PB-2021-23
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in tomato fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice.. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	TBPE		
D-2020-02-F01/NEU/Poland/2020	Tomato/Boderine	15/06/2020 30/08/2020 30/09/2020	153	974	15	25/08/2020	BBCH 79	Fruit	0.020 0.013	<0.003 (<LOD) <0.003 (<LOD)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
D-2020-02-F02/NEU/Poland/2020	Tomato/Krakus	20/05/2020 28/08/2020 30/09/2020	161	1028	15	19/08/2020	BBCH 79	Fruit	0.047 0.039 0.036 0.023	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 1 3\ 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.1.3.2.3 Study 3

Comments of zRMS:	Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Number of applications in the residue trials is too low to cover the proposed in GAP. Analytical method used is acceptable. Data GAP (necessary to accept the trials): information on TBPE stability in the high water content matrix.

Reference:	KCP 8.3.2.5
Report	Generation of specimens for the determination of Magnitude of Residue of Fenazaquin in/on greenhouse tomato at fixed intervals and harvest, following one application of Fenazaquin 20% SC acaricide. Greece – 2020. G. Gotsis, 2022, Report No. S20-0002R
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of the study is to generate specimens of Tomato fruits Raw Agricultural Commodity following one application of Fenazaquin 20% SC to determine the magnitude of residues of Fenazaquin at fixed intervals and harvest.

Number of applications:	1 (A1)
Application timing:	One application (A1) was done at each trial site:
A1:	BBCH 89 and at 3 DB-H1 (Days Before First Harvest), and at 7 DB-H2 (Days Before Second Harvest).
Method of application:	Broadband Foliar spray.
Application equipment:	Plot sprayer with lance and hollow cone nozzles to simulate the local agricultural practice.
Target Spray Volume (L/ha):	1000

Trial code	Trial type	Timing of sampling (DALA)
S20-0002R-01	Harvest	3 DALA, 7 DALA
S20-0002R-02	Harvest	3 DALA, 7 DALA
S20-0002R-03	Decline	0, 1, 3, 7 DALA
S20-0002R-04	Decline	0, 1, 3, 7 DALA

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.2.6
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in tomato grown in protected conditions after one application of FFenazaquin 20% SC – two harvest and two decline trials in Greece 2020. K. Wiktorowicz, 2021, Report No. PB-2021-15
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the

	market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in tomato fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice.. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	TBPE		
S20-0002R-01/SEU/Greece/2020	Tomato/Primadona F1	12/03/2020 04/2020 06/2020	155	1033	15	26/05/2020	BBCH 89	Fruit	0.027 0.007 (<LOQ)	<0.003 (<LOD) <0.003 (<LOD)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
S20-0002R-02/SEU/Greece/2020	Tomato/Belladona F1	14/03/2020 04/2020 06/2020	155	1029	15	25/05/2020	BBCH 89	Fruit	0.016 0.013	<0.003 (<LOD) <0.003 (<LOD)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
S20-0002R-03/SEU/Greece/2020	Tomato/Ekstasis F1	11/03/2020 04/2020 06/2020	152	1011	15	26/05/2020	BBCH 89	Fruit	0.022 0.013 0.012 0.012	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 1 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
S20-0002R-04/SEU/Greece/2020	Tomato/Elpida F1	16/03/2020 04/2020 06/20204	155	1031	15	25/05/2020	BBCH 89	Fruit	0.019 0.019 0.019 0.011	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 1 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.1.3.3 Strawberry

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)
Intended cGAP (3)	1	200 g a.s./ha	-	BBCH 79	3

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

A 2.1.3.3.1 Study 1

Comments of zRMS:	Number of applications in the residue trials is too low to cover the proposed in GAP.

Reference:	KCP 8.3.3.1
Report	Determination of the residues of fenazaquin in/on indoor strawberry after one application of Fenazaquin 20% SC in Northern Europe- Hungary in 2020. G. Wagner, 2021, Report No. 065CPRHU20R03
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of this study is to provide results from the magnitude of residues of fenazaquin in/on strawberry in order to support the registration of the plant protection product applied according to Good Laboratory Practice (GLP).
Two trials were conducted in Hungary in 2020. The field phase was performed in Gelse (CPRHU20-163-065IR) and in Sé (CPRHU20-164-065IR). One application (at BBCH 85) of the formulated product Fenazaquin 20% SC were applied at a rate of 1.0 L formulated product/ha (200 g active ingredient of fenazaquin/ha) onto the crop, under open field condition.
Specimens (fruits) were collected at 0, 1, 3 and 7 (NCH) days after last application (DALA) in decline trial and at 3 cand 7 (NCH) days after last application

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.3.2
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in/on indoor strawberry after one application of Fenazaquin 20% SC – one harvest and one decline trial in Hungary 2020. K. Wiktorowicz, 2021, Report No. PB-2021-26
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4

	EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in strawberry fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice.. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	TBPE		
CPRHU20-164-065IR/NEU/Hungary/2020	Strawberry/Clery	10/09/2019 04/2020 06/2020	191	954	20	02/06/2020	BBCH 85	Fruit	0.065 0.048	0.003 (<LOQ) <0.003 (<LOD)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
CPRHU20-164-065IR/NEU/Hungary/2020	Strawberry/Elsanta	03/2018 04/2020 06/2020	190	951	20	02/06/2020	BBCH 85	Fruit	0.151 0.092 0.062 0.061	0.004 (<LOQ) 0.004 (<LOQ) 0.003 (<LOQ) 0.003 (<LOQ)	0 1 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.1.3.3.2 Study 2

Comments of zRMS:	Number of applications in the residue trials is too low to cover the proposed in GAP.

Reference:	KCP 8.3.3.3
Report	Magnitude of the residue of fenazaquin in strawberry (Raw Agricultural-Commodity – RAC) grown in protected conditions after one application of formulated product Fenazaquin 20% SC – one harvest and one decline curve trial in Northern Europe – Poland, 2020. R. Figurski, 2021, Report No. D-2020-03
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective oof the field phase was to provide an analytical laboratory with treated specimens resulting from application of Fenazaquin 20% SC. One harvest trial and one decline curve trial were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. One foliar application of Fenazaquin 20% SC was performed with a boom sprayer on the treated plot at a target dose rate of 1.0 L (equivalent to 200 g a.s./ha. The target spray volume was 1000 litres per hectare according to GAP. The application was performed at BBCH 91.
In HS trial, RAC specimens for analyses were collected at 3 and 7 DALA. In decline curve trials, RAC specimens for analyses were collected at 0, 3 and 7 DALA.

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.3.4
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in strawberry grown in protected conditions after one application of Fenazaquin 20% SC – one harvest and one decline trial in Poland 2020. K. Wiktorowicz, 2021, Report No. PB-2021-25
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in strawberry fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice.. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fenazaquin	TBPE	
D-2020-03-F01/NEU/Poland/2020	Strawberry/Aprica	08/2018 28/05/2020 22/06/2020	212	1015	20	05/06/2020	BBCH 91	Fruit	0.043 0.022	<0.003 (<LOD)	3 7
D-2020-03-F02/NEU/Poland/2020	Strawberry/Elsanta	09/2019 23/05/2020 07/06/2020	205	979	20	19/05/2020	BBCH 91	Fruit	0.024 0.014 0.024 0.020	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 1 3 7

A 2.1.3.3.3 Study 3

Comments of zRMS:	Number of applications in the residue trials is too low to cover the proposed in GAP.

Reference:	KCP 8.3.3.5
Report	Generation of specimens for the determination of magnitude of residue of fenazaquin in/on greenhouse strawberry at fixed intervals and harvest following one application of Fenazaquin 20% SC acaricide.G. Gotsis, 2022, Report No. S20-0003R
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of the study is to generate specimens of Strawberry fruits Raw Agricultural Commodity following one application of Fenazaquin 20% SC to determine the magnitude of residues of Fenazaquin at fixed intervals and at harvest.

Number of applications:		1 (A1)	
Application timing:		One application (A1) was done at each trial site: A1: 3 DB-H1 and 7 DB-H2 (3 Days Before First Harvest and 7 Days Before Second Harvest).	
Method of application:		Broadband Foliar spray.	
Application equipment:		Plot sprayer with lance and hollow cone nozzles to simulate the local agricultural practice.	
Target Spray Volume (L/ha):		1000.	
Trial Code:	**Trial Type:**	**Number of Sampling Events:**	**Timing of Sampling Events:**
S20-0003R-01	Harvest	2	3 DALA (Harvest 1), 7 DALA (Harvest 2)
S20-0003R-02	Harvest	2	3 DALA (Harvest 1), 7 DALA (Harvest 2)
S20-0003R-03	Decline	4	0, 1, 3, 7 DALA
S20-0003R-04	Decline	4	0, 1, 3, 7 DALA

Comments of zRMS:	Study is acceptable

Reference:	KCP 8.3.3.6
Report	Quantitative analysis of Fenazaquin and its metabolite TBPE residues in/on greenhouse strawberry after one application of Fenazaquin 20% SC – two harvest and two decline trials in Greece 2020. K. Wiktorowicz, 2021, Report No. PB-2021-16
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Coun-

	cil of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

The main goal of this study was to perform analysis of Fenazaquin and its TBPE metabolite residues in strawberry fruits grown indoor, collected at Fixed days and at harvest after application of Fenazaquin 20% SC.
Samples were homogenized inside knife mill with use of dry ice.. Grinded samples were transferred using separate laboratory spoons to separate glass beakers and mechanically remixed to create representative samples.
Samples were mixed and weighed into 50 mL PP falcones in a weighing room. To each sample 10 mL of acetonitrile was added using a dispenser. Fortified samples were prepared by addition of 100 µL of two standard solutions. To the spiked samples 9.8 mL of acetonitrile was added to receive the final volume of 10 mL. Falcones were closed and shaken by hand for 1 minute.

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking tube was centrifuged for 5 min at 5500 rpm.

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				Fenazaquin	TBPE		
S20-0003R-01/SEU/Greece/2020	Strawberry/Camarosa	10/08/2019 05/2020 06/2020	200	1017	20	05/05/2020	BBCH 91	Fruit	0.163 0.107	0.011 0.008 (<LOQ)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
S20-0003R-02/SEU/Greece/2020	Strawberry/Victory	10/08/2019 05/2020 06/2020	200	1000	20	05/05/2020	BBCH 91	Fruit	0.223 0.114	0.015 0.008 (<LOQ)	3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
S20-0003R-03/SEU/Greece/2020	Strawberry/Victory	10/08/2019 05/2020 06/2020	200	1000	20	05/05/2020	BBCH 91	Fruit	0.367 0.207 0.188 0.101	0.026 0.020 0.015 0.008 (<LOQ)	0 1 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
S20-0003R-04/SEU/Greece/2020	Strawberry/Camarosa	10/08/2019 05/2020 06/2020	200	1000	20	05/05/2020	BBCH 91		0.342 0.148 0.172 0.104	0.028 0.011 0.012 0.009 (<LOQ)	0 1 3 7	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

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
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)
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)

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)
9%	Strawberries	1 / 1	9.3
8%	Tomatoes	0.5 / 0.5	7.9
4%	Melons	0.1 / 0.1	3.9

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)
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
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)
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!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#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.

A 3.5 TMDI calculations – Fenazaquin

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fenazaquin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.005	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2020	Year of evaluation:	2020

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 : ---

TMD/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 re… MRLs set at the LOQ (in % of ADI)
1%	DE child	0.07	1%	Strawberries	0.3%	Tomatoes	0.0%	Melons	
1%	GEMS/Food G06	0.06	1%	Tomatoes	0.1%	Melons	0.1%	Strawberries	
1%	NL toddler	0.05	0.8%	Strawberries	0.3%	Tomatoes	0.0%	Melons	
1%	FI 3 yr	0.05	0.8%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.9%	NL child	0.05	0.7%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.8%	FR child 3 15 yr	0.04	0.5%	Strawberries	0.3%	Tomatoes	0.1%	Melons	
0.8%	FI 6 yr	0.04	0.6%	Strawberries	0.1%	Tomatoes	0.0%	Melons	
0.7%	IT toddler	0.04	0.4%	Tomatoes	0.3%	Strawberries	0.0%	Melons	
0.7%	RO general	0.04	0.6%	Tomatoes	0.1%	Strawberries	0.0%	Melons	
0.7%	GEMS/Food G10	0.03	0.4%	Tomatoes	0.3%	Strawberries	0.0%	Melons	
0.7%	IE adult	0.03	0.4%	Strawberries	0.2%	Melons	0.1%	Tomatoes	
0.6%	UK toddler	0.03	0.5%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.6%	SE general	0.03	0.4%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.6%	UK infant	0.03	0.5%	Strawberries	0.1%	Tomatoes	0.0%	Melons	
0.6%	GEMS/Food G08	0.03	0.3%	Tomatoes	0.2%	Strawberries	0.0%	Melons	
0.5%	DK child	0.03	0.3%	Strawberries	0.2%	Tomatoes	0.1%	Melons	
0.5%	FR toddler 2 3 yr	0.03	0.4%	Strawberries	0.1%	Tomatoes			
0.5%	GEMS/Food G07	0.03	0.3%	Tomatoes	0.2%	Strawberries	0.0%	Melons	
0.5%	GEMS/Food G11	0.03	0.3%	Tomatoes	0.2%	Strawberries	0.0%	Melons	
0.5%	GEMS/Food G15	0.03	0.4%	Tomatoes	0.1%	Strawberries	0.0%	Melons	
0.5%	DE women 14-50 yr	0.02	0.3%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.5%	IT adult	0.02	0.3%	Tomatoes	0.1%	Strawberries	0.0%	Melons	
0.5%	FI adult	0.02	0.3%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.5%	ES child	0.02	0.3%	Tomatoes	0.2%	Strawberries	0.0%	Melons	
0.4%	DE general	0.02	0.2%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.4%	FR adult	0.02	0.3%	Strawberries	0.1%	Tomatoes	0.0%	Melons	
0.4%	FR infant	0.02	0.4%	Strawberries	0.0%	Tomatoes			
0.4%	ES adult	0.02	0.2%	Tomatoes	0.1%	Strawberries	0.0%	Melons	
0.4%	PT general	0.02	0.3%	Tomatoes	0.1%	Strawberries	0.0%	Melons	
0.4%	UK vegetarian	0.02	0.2%	Tomatoes	0.2%	Strawberries	0.0%	Melons	
0.3%	DK adult	0.02	0.2%	Strawberries	0.2%	Tomatoes	0.0%	Melons	
0.3%	NL general	0.02	0.2%	Strawberries	0.1%	Tomatoes	0.0%	Melons	
0.3%	PL general	0.02	0.3%	Tomatoes	0.0%	Strawberries	0.0%	Melons	
0.3%	LT adult	0.01	0.2%	Tomatoes	0.1%	Strawberries			
0.2%	UK adult	0.01	0.1%	Tomatoes	0.1%	Strawberries	0.0%	Melons	
0.1%	IE child	0.00	0.1%	Strawberries	0.0%	Tomatoes	0.0%	Melons	

A 3.6 IESTI calculations - Fenazaquin Raw commodities

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)
6%	Strawberries	0 / 0.37	6.0
2%	Tomatoes	0 / 0.04	2.1
2%	Melons	0 / 0.01	1.5

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)
3%	Strawberries	0 / 0.37	3.4
0.6%	Tomatoes	0 / 0.04	0.57
0.4%	Melons	0 / 0.01	0.39

A 3.7 IESTI calculations – Fenazaquin Processed Commodities

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%	Tomatoes / juice	0 / 0.02	0.29
0.1%	Tomatoes / sauce/puree	0 / 0.02	0.14

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%	Tomatoes / sauce/puree	0 / 0.02	0.12
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

A 3.8 TMDI calculations – TBPE

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TBPE

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.002	ARfD (mg/kg bw):	0.002
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2020	Year of evaluation:	2020

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	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	MRLs set at the LOQ (in % of ADI)	Exposure re
TMD/NEDI/IEDI calculation (based on average food consumption)	2%	GEMS/Food G06	0.04	2%	Tomatoes	0.2%	Melons	0.0%	Strawberries		
	1%	RO general	0.02	1.0%	Tomatoes	0.0%	Strawberries	0.0%	Strawberries		
	0.8%	IT toddler	0.02	0.7%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.8%	GEMS/Food G10	0.02	0.7%	Tomatoes	0.1%	Melons	0.1%	Strawberries		
	0.8%	DE child	0.02	0.5%	Tomatoes	0.3%	Strawberries	0.0%	Melons		
	0.7%	GEMS/Food G08	0.01	0.6%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.7%	FR child 3 15 yr	0.01	0.4%	Tomatoes	0.2%	Melons	0.1%	Strawberries		
	0.7%	NL toddler	0.01	0.5%	Tomatoes	0.2%	Strawberries	0.0%	Melons		
	0.7%	IE adult	0.01	0.4%	Melons	0.2%	Tomatoes	0.1%	Strawberries		
	0.7%	IT adult	0.01	0.6%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.7%	GEMS/Food G15	0.01	0.6%	Tomatoes	0.0%	Melons	0.0%	Strawberries		
	0.7%	GEMS/Food G07	0.01	0.5%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.6%	ES child	0.01	0.5%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.6%	GEMS/Food G11	0.01	0.5%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.5%	ES adult	0.01	0.4%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.5%	PT general	0.01	0.4%	Tomatoes	0.0%	Melons	0.0%	Strawberries		
	0.5%	SE general	0.01	0.4%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.5%	NL child	0.01	0.3%	Tomatoes	0.2%	Strawberries	0.0%	Melons		
	0.5%	DK child	0.01	0.3%	Tomatoes	0.1%	Melons	0.1%	Strawberries		
	0.5%	FI 3 yr	0.01	0.3%	Tomatoes	0.2%	Strawberries	0.0%	Melons		
	0.5%	PL general	0.01	0.4%	Tomatoes	0.0%	Strawberries	0.0%	Melons		
	0.4%	DE women 14-50 yr	0.01	0.4%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.4%	UK toddler	0.01	0.3%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.4%	DE general	0.01	0.3%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.4%	UK vegetarian	0.01	0.3%	Tomatoes	0.0%	Strawberries	0.0%	Melons		
	0.4%	FI 6 yr	0.01	0.2%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.4%	FR adult	0.01	0.2%	Tomatoes	0.1%	Melons	0.1%	Strawberries		
	0.4%	DK adult	0.01	0.3%	Tomatoes	0.1%	Melons	0.0%	Strawberries		
	0.4%	FI adult	0.01	0.3%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.3%	LT adult	0.01	0.3%	Tomatoes	0.0%	Strawberries				
	0.3%	FR toddler 2 3 yr	0.01	0.2%	Tomatoes	0.1%	Strawberries				
	0.3%	UK infant	0.01	0.2%	Tomatoes	0.1%	Strawberries	0.0%	Melons		
	0.3%	NL general	0.01	0.2%	Tomatoes	0.0%	Strawberries	0.0%	Melons		
	0.3%	UK adult	0.01	0.2%	Tomatoes	0.0%	Strawberries	0.0%	Strawberries		
	0.1%	FR infant	0.00	0.1%	Strawberries	0.0%	Tomatoes				
	0.0%	IE child	0.00	0.0%	Tomatoes	0.0%	Strawberries	0.0%	Melons		

A 3.9 IESTI calculations – TBPE raw commodities

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
76%	Melons	0 / 0.01	1.5	20%	Melons	0 / 0.01	0.39
29%	Tomatoes	0 / 0.01	0.58	8%	Tomatoes	0 / 0.01	0.16
8%	Strawberries	0 / 0.01	0.16	5%	Strawberries	0 / 0.01	0.09
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.10 IESTI calculations – TBPE 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): ---			
IESTI				**IESTI**			
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 / 0.01	0.19	4%	Tomatoes / sauce/puree	0 / 0.01	0.08
5%	Tomatoes / sauce/puree	0 / 0.01	0.10	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Appendix 4 Additional information provided by the applicant